WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY: Health

TITLE-SERIES: 64-23

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: Radiological Health

CITE STATUTORY AUTHORITY: 16-1-4

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 08/05/2020 5:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME: April L. Robertson

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PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE: No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:

Definitions have been clarified and the rule has been updated to reflect national TENORM regulatory standards.

SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:

Amendments are designed to increase efficacy of the regulatory program, without which the state will shoulder the burden of radiological health effects from TENORM and may be left with legacy costs of site remediation.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

n/a

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

n/a

C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

n/a

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2020 Increase/Decrease (use "-")	2021 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			0
Personal Services			0
Current Expenses			0
Repairs and Alterations			0
Assets			0
Other			0
2. Estimated Total Revenues			0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

n/a

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 64
~~WEST VIRGINIA~~ LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 23
RADIOLOGICAL HEALTH ~~RULES~~

§64-23-1. General.

1.1. Scope. -- This legislative rule establishes the requirements that shall be applied to the use of sources of ionizing radiation to reduce, to an acceptable level, the risk that any person is likely to be injured by such radiation. This legislative rule is intended to be consistent with the recognized beneficial uses of sources of ionizing radiation. This legislative rule provides for the registration and applicable safety requirements of all sources of ionizing radiation including naturally occurring radioactive materials, accelerator produced radioactive material, and radiation producing equipment. This rule should be read in conjunction with the provisions of W. Va. Code §16-1-7 *et seq.*

1.2. Authority. -- ~~This legislative rule is issued under the authority of and are related to~~ W. Va. Code ~~§16-1-7 of 1931, as amended~~ §16-1-4.

1.3. Filing Date. -- ~~June 8, 2001.~~

1.4. Effective Date. -- ~~July 1, 2001.~~

1.5. ~~Repeal of Former Rule. -- This legislative rule repeals and replaces WV 64 CSR 23"Radiological Health Rule and Related Documents Filed in the Secretary of State's Office" filed January 12, 1979 and effective May 1, 1979.~~Sunset Provision -- This rule shall terminate and have no further force or effect upon the expiration of five years from its effective date.

~~1.6. Refiling Date. -- This legislative rule were refiled pursuant to W. Va. Code §29A-2-5 of 1931, as amended on the 30th day of December 1982, in the Secretary of State's office.~~

§64-23-2. Application, Enforcement.

2.1. Application -- Except as otherwise specifically provided, this rule applies to all persons in West Virginia who receive, possess, use, transfer, own or acquire any source of ionizing radiation, however, nothing in this rule shall apply, except the provision for registration, to any person to the extent such person is subject to regulation by the United States Nuclear Regulatory Commission. For the purpose of this rule, radiation machines and radioactive materials used by, or in the possession of, an employee within the scope of his duties shall be considered to be in the possession of the employer. The provisions of section 6 of this rule shall not be interpreted as limiting the intentional exposure of patients to radiation for the purpose of diagnosis or therapy by doctors of the healing arts, duly registered by the State of West Virginia and engaged in the lawful practice of their profession or administered by other professional persons acting under the direct supervision of a registered practitioner.

2.2. Enforcement -- The enforcement of this legislative rule is vested with the ~~Director~~Secretary of the West Virginia Department of Health and Human Resources or his lawful designee.

§64-23-3. Definitions.

As used in this rule, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

3.1. A_1 -- the maximum activity of special form radioactive material permitted in a Type A

package.

3.2. A_2 -- the maximum activity of radioactive material, other than special form radioactive material, permitted in a Type A package. These values are either listed in Table 64-23 Ee of this rule, Table 64-23 Ee ~~a~~A, or may be derived in accordance with the procedure prescribed in Table 64-23 Ee of this rule.

3.3. Absorbed Dose -- the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the Gray (Gy) and the Rad.

3.4. Accelerator -- any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV. For purposes of this definition, particle accelerator is an equivalent.

3.5. Accelerator Produced Material -- any material made radioactive by ~~exposing it in~~ a particle accelerator.

3.6. Activity -- the rate of disintegration or transformation or decay of radioactive material. The units of activity are the Becquerel (Bq) and the Curie (Ci).

3.7. Adult -- an individual 18 or more years of age.

3.8. Agency -- the West Virginia ~~division of health~~ Department of Health and Human Resources.

3.9. Airborne Radioactivity Area -- a room, enclosure, or area in which airborne radioactive materials exist in concentrations:

3.9.a. In excess of the derived air concentrations (DACS) specified in Table 64-23 F, Table i of this rule; or

3.9.b. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC hours.

3.10. Airborne Radioactive Material -- any airborne radioactive material dispersed in the air in the form of dusts, fumes, mists, vapors or gases.

3.11. As Low As Reasonably Achievable (ALARA) - making every reasonable effort to maintain exposures to radiation as far below the dose limits in this rule as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and registered sources of radiation in the public interest.

3.12. Background radiation -- radiation from cosmic sources; naturally occurring radioactive materials (which have not been technologically enchanced), including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices. Background radiation does not include sources of radiation from radioactive materials regulated by the agency.

3.13. Becquerel (Bq) -- the SI unit of activity. One Becquerel is equal to one disintegration or transformation per second (DPS or TPS).

3.14. Bioassay -- the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body. For purposes of this rule, "radiobioassay" is an equivalent term.

3.15. Brachytherapy - a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

3.16. Byproduct Material:

~~3.16.a~~3.16.1. Any radioactive material, except special nuclear material, yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material; and

~~3.16.b~~3.16.2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium or thorium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition.

3.17. Calibration - the determination of (a) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (b) the strength of a source of radiation relative to a standard.

3.18. Collective Dose -- the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

3.19. Committed Dose Equivalent ($H_{T,50}$) -- the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

3.20. Committed Effective Dose Equivalent ($H_{E,50}$) -- the sum of the products of the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues ($H_{E,50} = \Sigma\, w_T H_{T,50}$).

3.21. Calendar Quarter -- not less that 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No registrant shall change the method observed by him of determining calendar quarters for the purpose of this rule except at the beginning of the calendar year.

3.22. Curie -- a unit of quantity of activity. One Curie (Ci) is that quantity of radioactive material which decays at the rate of 3.7E+10 disintegrations or transformations per second (dps or tps).

3.23. Deep Dose Equivalent (H_d), which applies to external whole body exposure, is the dose equivalent at a tissue depth of one centimeter 1000 mg/cm^2).

3.24. Depleted Uranium -- the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

3.25. Dose -- as used in this rule shall mean absorbed dose or dose equivalent as appropriate.

3.25.a. Absorbed Dose -- is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The specific unit of absorbed dose is the rad.

3.25.b. Dose Equivalent -- the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

3.26. Dose Limits -- the permissible upper bounds of radiation doses established in accordance with this rule. For purposes of this rule, "limits" is an equivalent term.

3.27. Effective Dose Equivalent (H_E) -- the sum of the products of the dose equivalent to each organ or tissue (H_T) and the weighting factor (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma w_T H_T$).

3.28. Embryo or Fetus -- the developing human organism from conception until the time of birth.

3.29. Entrance or Access Point -- any opening through which an individual or extremity of an individual could gain access to radiation areas or to registered radioactive materials. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

3.30. Explosive Material -- any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

3.31. Exposure -- the quotient of the dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The SI unit of exposure is the Coulomb per kilogram (C/kg). (The special unit of exposure is the Roentgen [R].)

3.32. Exposure Rate -- the exposure per unit of time, such as R/min., mR/hr., etc.

3.33. Extremity -- hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

3.34. Eye Dose Equivalent -- the external dose equivalent to the lens of the eye at a tissue depth of 0.3 centimeter 300 mg/cm^2).

3.35. Former Atomic Energy Commission or Nuclear Regulatory Commission Licensed Facilities -- nuclear reactors, nuclear fuel reprocessing plants, uranium enrichment plants, or critical mass experimental facilities where Atomic Energy Commission or Nuclear Regulatory commission licenses have been terminated.

3.36. Generally Applicable Environmental Radiation Standards -- standards issued by the Environmental Protection Agency under the authority of the Atomic Energy act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

3.37. Gray (Gy) -- the SI unit of absorbed dose. One Gray is equal to an absorbed dose of one joule per kilogram (100 Rad).

3.38. Half Life -- the amount of time required for the activity of a specific radioactive material to reach one-half of its original activity.

3.39. Healing Arts -- diagnostic or healing treatment of human and animal maladies including but not limited to the following which are duly registered by the State of West Virginia for the lawful practice of: medicine and its associated specialties, dentistry, veterinary medicine, osteopathy, chiropractic, and podiatry.

3.40. High Radiation Area -- any area, accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of one mSv 0.1 rem in one hour at 30 centimeters from any source of radiation or from any surface that the radiation penetrates.

3.41. Human Use -- the internal or external administration of radiation or radioactive materials to human beings.

3.42. Individual -- any human being.

3.43. Individual Monitoring -- the assessment of:

~~3.43.a~~3.43.1. Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

~~3.43.b~~3.43.2. Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

3.44. Individual Monitoring Devices -- devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this rule, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDS), pocket ionization chambers, and personal air sampling devices.

3.45. Inspection -- an official examination or observation including but not limited to tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the agency.

3.46. Installation -- the location where one or more sources of ionizing radiation are used, operated or stored.

3.47. Instrument Traceability (for ionizing radiation measurements) -- the ability to show that an instrument has been calibrated at specified time intervals using a national standard or a transfer standard. If a transfer standard is used, the calibration must be at a laboratory accredited by a program which requires continuing participation in measurement quality assurance with the national institute of standards and technology or other equivalent national or international program.

3.48. Interlock -- a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

3.49. Internal Dose -- that portion of the dose equivalent received from radioactive material taken into the body.

3.50. Licensing State -- any state with regulations equivalent to the suggested state regulations for control of radiation relating to, and an effective program for, the regulatory control of ~~naturm~~natural occurring or accelerator produced radioactive material (NARM) and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

3.51. Limits -- the permissible upper bounds of radiation doses established in accordance with this rule.

3.52. Lost or Missing Source of Radiation -- registered source of radiation whose location is unknown. This definition includes, but is not limited to, radioactive material that has been shipped but has not reached its planned destination and whose location cannot be readily traced in the transportation system.

3.53. Major Processor -- a user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four times Type B quantities as sealed sources, but does not include nuclear medicine programs, universities, industrial radiographers, or small industrial programs. Type A and B quantities are defined in section 13.2. of this rule.

3.54. Member of the Public -- an individual except when that individual is receiving an occupational dose.

3.55. Minor -- an individual less than 18 years of age.

~~3.55~~3.56. Monitoring -- the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For purposes of this rule, "radiation monitoring" and "radiation protection monitoring" are equivalent terms.

~~3.56.~~3.57. NARM -- any naturally occurring or accelerator-produced radioactive material. It does not include byproduct, source, or special nuclear material.

~~3.57.~~3.58. Natural Radioactivity -- the radioactivity of naturally occurring nuclides.

~~3.58.~~3.59. Nuclear Regulatory Commission -- the Nuclear Regulatory Commission or its duly authorized representatives.

~~3.59.~~3.60. Occupational Dose -- the exposure of an individual to radiation (a) in a restricted area; or (b) in the course of employment in which the individual's duties involve exposure to radiation, provided, that occupational dose shall not be deemed to include any exposure of an individual to radiation for the purpose of diagnosis or therapy of such individual.

~~3.60.~~3.61. Package -- the packaging together with its radioactive contents as presented for transport.

~~3.61.~~3.62. Particle Accelerator -- any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one MeV. For purposes of this definition, particle accelerator is an equivalent.

~~3.62~~.3.63. Person -- any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of West Virginia, any other state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing, other than the United States Nuclear Regulatory Commission, or any successor thereto, or other federal government agencies.

~~3.63.~~3.64. Personnel Monitoring Equipment -- devices designed to be worn by a single individual for the assessment of dose equivalent. For purposes of this rule, "personnel dosimeter" and "dosimeter" are equivalent terms. Examples of individual monitoring devices are film badges, thermoluminescent dosimeters (TLDS), pocket ionization chambers, and personal air sampling devices.

~~3.64.~~3.65. Protective Apron -- an apron made of radiation-attenuating materials used to reduce exposure to radiation.

~~3.65.~~3.66. Public Dose -- the dose received by a member of the public from sources of radiation from registered operations. Public dose does not include occupational dose, or dose received from background radiation, or dose received as a patient from medical practices, or dose received from voluntary participation in medical research programs.

~~3.66.~~3.67. Pyrophoric Material -- any liquid that ignites spontaneously in dry or moist air at or below 130 °F (54.4 °C) or any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation, handling, or disposal hazard. Included are spontaneously combustible and water-reactive materials.

~~3.67.~~3.68. Qualified Expert -- an individual having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs, for example, individuals certified in the appropriate field by the American Board of Radiology, or the American Board of Health Physics, or the American Board of Medical Physics, or those having equivalent qualifications. With reference to the calibration of radiation therapy equipment, an individual having, in addition to the above qualifications, training and experience in the clinical applications of radiation physics to radiation therapy, for example, individuals certified in Therapeutic Radiological Physics or X-ray and Radium Physics by the American Board of Radiology, or those having equivalent qualifications.]

~~3.68.~~3.69. Quality Factor (Q) -- the modifying factor, listed in Tables 64-23 A and B, that is used to derive dose equivalent from absorbed dose.

~~3.69.~~3.70. Rad -- the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs per gram or 0.01 joule per kilogram (0.01 Gy).

~~3.70.~~3.71. Radiation -- ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, and other nuclear particles capable of producing ion pairs. For purposes of this rule, ionizing radiation is an equivalent term. Radiation, as used in this rule, does not include nonionizing radiation, such as microwaves, radio waves, visible, infrared, or ultraviolet light.

~~3.71.~~3.72. Radiation Area -- any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one hour a dose in excess of five millirems, or in any five consecutive days a dose of 100 millirems.

~~3.72.~~3.73. Radiation Machine -- any device capable of producing radiation except those which produce radiation only from radioactive material.

~~3.73.~~3.74. Radiation Safety Officer -- one who has the knowledge and responsibility to apply appropriate radiation protection rules.

~~3.74.~~3.75. Radioactive Material -- any material (solid, liquid, or gas) which emits ionizing radiation spontaneously.

~~3.75.~~3.76. Radioactivity -- the disintegration of unstable atomic nuclei by the emission of radiation.

~~3.76.~~3.77. Radiobioassay -- the determination of kinds, quantities or concentrations, and, in some cases, the locations of radioactive material in the human body, whether by direct measurement, in vivo counting, or by analysis and evaluation of materials excreted or removed from the human body.

~~3.77.~~3.78. Registered Material -- radioactive material received, possessed, used, transferred or disposed of under a registration issued by the agency.

~~3.78.~~3.79. Registrant -- any person who is registered with the agency and is legally obligated to register with the agency pursuant to this rule.

~~3.79.~~3.80. Registration -- the filling with the agency by a registrant of all registrable items in

accordance with this rule.

~~3.80.~~3.81. Rem -- the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (one rem = one 0.01 Sv).

~~3.81.~~3.82. Research and Development -- (a) theoretical analysis, exploration, or experimentation; or (b) the extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation or radioactive material to human beings.

~~3.82.~~3.83. Restricted Area (controlled area) -- any area access to which is controlled by the registrant for purposes of protection of individuals from exposure to radiation and radioactive material. Restricted areas shall not include any areas used for residential quarters, although a separate room or rooms in a residential building may be set apart as a restricted area.

~~3.83.~~3.84. Roentgen (R) -- the special unit of exposure. One Roentgen equals 2.58 E 10^{-4} Coulombs/kilogram of air.

~~3.84.~~3.85. Sealed Source -- radioactive material that is permanently bonded or fixed in a capsule or matrix designed to prevent release and dispersal of the radioactive material under the most severe conditions which are likely to be encountered in normal use and handling.

~~3.85.~~3.86. Shallow Dose Equivalent (H_s) -- which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter (seven mg/cm^2) averaged over an area of one square centimeter.

~~3.86.~~3.87. SI -- the abbreviation for the international system of units.

~~3.87.~~3.88. Sievert -- the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in Sievert is equal to the absorbed dose in gray multiplied by the quality factor (one Sv = 100 rem).

~~3.88.~~3.89. Source Material -- (a) uranium or thorium, or any combination thereof, in any physical or chemical form, or (b) ores which contain by weight $^1/_{20}$ of one percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material.

~~3.89.~~3.90. Source Material Milling -- any activity that results in the production of byproduct material as defined by definition (b) of byproduct material.

~~3.90.~~3.91. Source of Radiation -- any radioactive material, or any device or equipment emitting or capable of producing radiation.

~~3.91.~~3.92. Source Traceability -- the ability to show that a radioactive source has been calibrated either by the national standards laboratory of the national institute of standards and technology, or by a laboratory which participates in a continuing measurement quality assurance program with national institute of standards and technology or other equivalent national or international program.

~~3.92.~~3.93. Special Form Radioactive Material -- radioactive material that satisfies the following conditions:

~~3.92.a.~~3.93.a. It is either a single solid piece or is contained in a sealed capsule that can be

opened only by destroying the capsule;

~~3.92.b.~~3.93.b. The piece or capsule has at least one dimension not less than five millimeters (0.2 inches); and

~~3.92.c.~~3.93.c. It satisfies the test requirements specified by the Nuclear Regulatory Commission. A special form encapsulation designed in accordance with the Nuclear Regulatory Commission requirements in effect on June 30, 1983, and constructed prior to July 1, 1985, may continue to be used. A special form encapsulation either designed or constructed after June 30, 1985, must meet requirements of this definition applicable at the time of its design or construction.

~~3.93.~~3.94. Special Nuclear Materials:

~~3.93.a.~~3.94.a. Plutonium, Uranium-233, Uranium enriched in the isotope 233 or in the isotope 235, and any other material that the Nuclear Regulatory Commission, pursuant to the provisions of section 51 of the atomic energy act of 1954, as amended, determines to be special nuclear material, but does not include source material; or

~~3.93.b.~~3.94.b. Any material artificially enriched by any of the foregoing but does not include source material.

~~3.94.~~3.95. Special Nuclear Material in Quantities not Sufficient to Form a Critical Mass -- uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; Uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed one. For example, the following quantities in combination would not exceed the limitation and are within the formula:

~~FUNC{175~(grams~contained~U-235)}OVER~~
~~350~FUNC+~FUNC{50~(grams~U-233)}OVER~~

$$\frac{175\,(\text{grams contained U-235})}{350}+\frac{50\,(\text{grams U-233})}{200}+\frac{50\,(\text{grams Pu})}{200}=1$$

~~3.95.~~3.96. Survey -- the evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

~~3.96.~~3.97. Test -- the process of verifying compliance with an applicable regulation.

~~3.97. This rule - Sections 1., 2., 3., 4., 5., 6., 7., 8., 9., 10., 11., 12., 13., 14., 15. and 16. of the Radiological Health Rules and any subsequent changes or additions thereto.~~

3.98. Total Effective Dose Equivalent (TEDE) -- the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

3.99. Total Organ Dose Equivalent (TODE) -- the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in subdivision 6.46.a.6 of this rule.

3.100. Traceable to a National Standard -- the ability to show that an instrument or radioactive

source has been calibrated by a laboratory which participates in a continuing measurement quality assurance program with National Institute of Standards or other equivalent national or international program.

3.101. Units of Exposure and Dose.

3.101.a. As used in this rule, the unit of exposure is the Coulomb per kilogram (C/kg) of air. One Roentgen is equal to 2.58E-4 Coulomb per kilogram of air.

3.101.b. As used in this rule, the units of dose are:

3.101.b.1. Gray (Gy) is the SI unit of absorbed dose. One Gray is equal to an absorbed dose of one joule per kilogram (100 rad).

3.101.b.2. Rad is the special unit of absorbed dose. One Rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

3.101.b.3. Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in Rem is equal to the absorbed dose in rad multiplied by the quality factor (one Rem = 0.01 Sv).

3.101.b.4. Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in Sievert is equal to the absorbed dose in gray multiplied by the quality factor (one Sv = 100 Rem).

3.101.c. As used in this rule, the quality factors for converting absorbed dose to dose equivalent are shown in Table 64-23 A.

3.101.d. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in ~~Section 3.102.c.~~section 3.101.c., 0.01 Sv (one Rem) of neutron radiation of unknown energies may, for purposes of this rule, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the registrant may use the fluence rate per unit dose equivalent or the appropriate Q value from Table 64-23 B to convert a measured tissue dose in Gray or Rad to dose equivalent in Sievert or Rem.

3.102. Units of Activity. For purposes of this rule, activity is expressed in the SI unit of Becquerel (Bq) or in the special unit of Curie (Ci), or their multiples, or disintegrations or transformations per unit of time.

3.102.a. One Becquerel (Bq) = one disintegration or transformation per second (DPS or TPS).

3.102.b. One Curie (Ci) = 3.7E+10 disintegrations or transformations per second (DPS or TPS) = 3.7E+10 Becquerel (Bq) = 2.22E+12 disintegrations or transformations per minute (DPM or TPM).

3.103. Unrefined and Unprocessed Ore -- ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.

3.104. Unrestricted Area -- any area access to which is not controlled by the registrant for purposes of protection of individuals from exposure to radiation and radioactive material, and any area used for residential quarters.

~~3.105. Unrefined and Unprocessed Ore -- ore in its natural form prior to any processing, such as grinding, roasting, beneficiating, or refining.~~

~~3.106.~~3.105 Waste -- those low-level radioactive wastes that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level waste has the same meaning as in the Low-Level Radioactive Waste Policy Act, P.L. 96-573, as amended by P.L. 99-240, effective January 15, 1986; that is, radioactive waste (a) not classified as high-level radioactive waste, spent nuclear fuel, or byproduct material as defined in Section 11e.(2). of the Atomic Energy Act (uranium or thorium tailings and waste) and (b) classified as low-level radioactive waste consistent with existing law and in accordance with (c) by the Nuclear Regulatory Commission.

~~3.107.~~3.106 Waste Handling Registrant -- persons registered to receive and store radioactive wastes prior to disposal and persons registered to dispose of radioactive waste.

~~3.108.~~3.107. Week -- seven consecutive days starting on Sunday.

~~3.109.~~3.108. Whole Body -- the whole body, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

~~3.110.~~3.109. Worker -- an individual engaged in work under a registration issued by the agency and controlled by a registrant, but does not include the registrant.

~~3.111.~~3.110 Working Level (WL) -- any combination of short-lived radon daughters in one liter of air that will result in the ultimate emission of 1.3E+5 MeV of potential alpha particle energy. The short-lived radon daughters of Radon-222 are Polonium-218, Lead-214, Bismuth-214, and Polonium-214; and those of Radon-220 are Polonium-216, Lead-212, Bismuth-212, and Polonium-212.

~~3.112.~~3.111. Working Level Month (WLM) -- an exposure to one working level for 170 hours -- 2,000 working hours per year divided by 12 months per year is approximately equal to 170 hours per month.

~~3.113.~~3.112. Year -- the period of time beginning in January used to determine compliance with the provisions of this rule. The registrant may change the starting date of the year used to determine compliance by the registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

NOTE: Other terms not herein specifically defined shall be used in accordance with the definitions in the recommendations of the national council on radiation protection and measurements, or any successor thereto, as published in handbooks of the National Bureau of Standards or reports of the NCRP.

§64-23-4. Exemptions, Inspections, Tests, Violations, Impounding, Prohibitions and Communications.

4.1. Exemptions -- The agency may, upon application by any person or upon its own initiative, grant such exemptions or exceptions from the requirements of this rule as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

4.1.a. Department of Energy contractors or subcontractor and Nuclear Regulatory Commission contractors or sub-contractors of the following categories operating within this State are exempt from this rule to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers, or acquires sources of radiation:

4.1.b. Prime contractors performing work for the department of energy at U.S. government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

4.1.c. Prime contractors of the Department of Energy performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;

4.1.d. Prime contractors of the department of energy using or operating nuclear reactors or other nuclear devices in a United States government-owned vehicle or vessel; and

4.1.e. Any other prime contractor or subcontractor of the Department of Energy or of the Nuclear Regulatory Commission when the State and the Nuclear Regulatory Commission jointly determine:

4.1.e.1. That the exemption of the prime contractor or subcontractor is authorized by law; and

4.1.e.2. That, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

4.2. Records. Each registrant shall maintain records showing the receipt, transfer, and disposal of all sources of radiation. Additional record requirements are specified elsewhere in this rule.

4.3. Inspections

4.3.a. Each registrant shall afford the agency, at all reasonable times, opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

4.3.b. Each registrant shall make available to the agency for inspection, upon reasonable notice, records maintained pursuant to this rule.

4.4. Tests -- Each registrant shall perform, upon instructions from the agency, or shall permit the agency to perform such reasonable tests as the agency deems appropriate or necessary including, but not limited to, tests of:

4.4.a. Sources of ionizing radiation;

4.4.b. Facilities wherein sources of radiation are used or stored;

4.4.c. Radiation detection and monitoring instruments; and

4.4.d. Other equipment and devices used in connection with utilization or storage of registered sources of radiation.

4.5. Additional Requirements -- The agency may, by rule, regulation, or order, impose upon any registrant such requirements in addition to those established in this rule as it deems appropriate or necessary to minimize danger to public health and safety or property.

4.6. Violations -- The ~~Director~~Secretary shall, depending upon the severity of the violation and upon the degree of health hazard created, reprimand, or suspend or revoke the registration of any registerable facility, if the registrant:

4.6.a. Fraudulently or deceptively obtains or attempts to obtain a registration;

4.6.b. Fails at any time to comply with the requirements of ~~Chapter 16, Article 1, Ssection 7. of the West Virginia Code of 1931, as amended~~W. Va. Code §16-1-1 *et seq.*;

4.6.c. Fails to comply with fee for service;

4.6.d. Knowingly falsifies or attempts to falsify documents related to registration;

4.6.e. The ~~Director~~Secretary may impose a civil penalty of not less than $250.00 and not more than $5000.00 for each separate violation of this rule payable within 30 days of receipt of the penalty notification.

4.6.f. The ~~Director~~Secretary may, upon the finding of a violation, depending upon the severity of the violation and upon the degree of health hazard created, initiate an appropriate enforcement action which may include the issuance of a cease and desist order directing that all work be halted immediately. Posting the cease and desist order on work site constitutes notice of its contents to the owner and all persons working with radiation producing devices.

4.6.g. In any case where a person fails to halt work following the issuance of a cease and desist order by the Director, the violation is presumed to be willful and the person shall be assessed a civil penalty by the Director of not less than $10,000.00 nor more than $25,000.00 for an initial violation and not less than $25,000.00 nor more than $50,000.00 for each subsequent violation payable within 30 days of the receipt of the penalty notification.

4.7. Impounding -- In the event that an emergency exists affecting the public health and safety, the agency has the authority to impound or order the impounding of sources of radiation possessed by persons who are not equipped to observe or fail to observe the provisions of this rule.

4.8. Prohibitions

4.8.a. A hand-held fluoroscopic screen shall not be used with x-ray equipment unless it has been listed in the Registry of Sealed Source and Devices or accepted for certification by the Food and Drug Administration, Center for Devices and Radiological Health.

4.8.b. Shoe-fitting fluoroscopic devices shall not be used or displayed.

4.8.c. Operation of a diagnostic x-ray system shall not be permitted without a current diagnostic x-ray certificate issued by the West Virginia Bureau for Public Health.

4.9. Interpretations -- Except as specifically authorized by the agency in writing, no interpretation of this rule by an officer or employee of the agency other than a written interpretation by the legal counsel will be recognized to be binding upon the agency.

4.10. Communications -- All communications and reports concerning this rule, and applications filed thereunder, should be addressed to the West Virginia ~~Division of~~Bureau for Public Health, Radiological Health Program, ~~815 Quarrier Street~~350 Capitol Street, Charleston, WV 25301.

§64-23-5. Registration.

5.1. Purpose and Scope.

5.1.a. This section provides for the registration of sources of radiation and for the registration of persons providing radiation machine installation, servicing and/or services. The person having possession of any registrable item shall register such source of radiation with the agency in accordance with the requirements of this section.

5.1.b. For the purpose of section 5 of this rule, "facility" is the location at which one or more devices or sources of radiation are installed or located within one building, vehicle, or under one roof, and are under the same administrative control.

5.1.c. In addition to the requirements of this section, all registrants are subject to the applicable provisions of other parts of this rule.

5.1.d. For the purpose of this rule, "storage" is a condition in which a device or source is not being used for an extended period of time and has been made inoperable.

5.2. Exemptions.

5.2.a. The following sources of radiation do not require registration:

5.2.a.1. Less than 10 times the quantities of any radioactive material possessed simultaneously, listed in Table 64-23 Y of this rule.

5.2.a.2. Natural radioactive materials of an equivalent specific radioactivity not exceeding that of natural potassium, ~~(one one-hundred millionths [10^{-6}][$1E^{-8}$]~~ which is $1E^{-8}$ Curies/gm).

5.2.a.3. Time pieces, instruments, novelties, or devices containing self-luminous elements, except during manufacture or repair of the self-luminous elements themselves. Such time pieces, instruments, novelties, or devices shall not be exempt if they are stored, used, or handled in such quantity or fashion that an individual might receive a radiation dose exceeding the limits established in section 6.5.

5.2.a.4. Domestic television receivers.

5.2.a.5. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this part, providing dose equivalent rate averaged over an area of 10 square centimeters does not exceed five μSv (0.5 mrem) per hour at five cm from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

5.2.a.6. Radiation-producing machines while in transit or storage incident thereto. Radiation machines for mobile services are not exempt from registration.

5.2.b. Common and contract carriers operating within this state are exempt from registration requirements to the extent that they transport or store sources of radiation in the regular course of their carriage for another or storage incident thereto.

5.2.c. Inoperable radiation machines that cannot be energized to produce radiation when connected to a power supply without requiring repair or modification are exempt from the requirements of this section.

5.2.d. Financial institutions in possession of a radiation machine as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in this section as long as the equipment is possessed for the sole purpose of its sale, lease, or transfer of ownership, and only so long as the equipment is rendered unable to be energized to produce radiation.

5.2.d.1. The financial institution must notify the agency in writing within 10 days of the acquisition of the equipment pursuant to subsection 5.2.d, and provide at least quarterly updates regarding the location, status of the equipment, and any pending sales, leases or transfers of the equipment.

5.2.d.2. The financial institution must notify the agency in writing within 10 days of the sale, lease or transfer of the equipment, which shall include the name and contact information of the new owner, and the location of the machine.

5.2.e. Only facilities that have placed all radiation machines in storage, including on-site storage, and have notified the agency in writing, are exempt from the registration requirements of this section, which exemption becomes void if any radiation machine is installed and/or energized and could result in the production of radiation.

5.3. Application for Registration of Radiation Facilities.

5.3.a. The person possessing each registrable item which has not already been registered, shall:

5.3.a.1. Apply for registration of such facility with the agency within 30 days following the effective date of this rule or thereafter prior to the operation of a radiation facility.

5.3.a.2. Make application for registration on forms furnished by the agency and shall supply all the information required by the form and accompanying instructions, including, when applicable, shielding plans as described in section 7.4 of this rule.

5.3.a.3. Designate on the application form an individual to be responsible for radiation protection.

5.3.a.4. Prohibit any person from furnishing radiation machine servicing or services as described in subsection 5.5.d. to his radiation machine facility until such person provides evidence that he has been registered with the agency as a provider of services in accordance with section 5.5.

5.4. Vendor Obligation.

5.4.a. Each person who is engaged in the business of installing or offering to install radiation sources or is engaged in the business of furnishing or offering to furnish radiation source servicing or services in this state, shall apply for registration of such services with the agency within 30 days prior to furnishing or offering to furnish any such services.

5.4.b. Any person who sells, leases, transfers, disposes, assembles, installs or lends radiation sources in this state shall notify the agency within 15 days after the end of each calendar quarter of:

5.4.b.1. The name and address of persons who have received these sources;

5.4.b.2. The manufacturer, model and serial number of each source transferred;

5.4.b.3. The date of transfer of each radiation source.

5.4.c. No person shall make, sell, lease, transfer, lend or install x-ray equipment or radioactive material sources or auxiliaries and supplies necessary for the safe operation of such equipment unless such supplies and equipment, when placed in operation and use, will meet the requirements of this rule.

5.5. Application for Registration of Vendors ~~Servicing~~ and Physicist Providing Services.

5.5.a. Application for registration shall be completed on forms furnished by the agency and shall contain all information required by the agency as indicated on the forms and accompanying instructions.

5.5.b. Each person applying for registration under this section shall specify:

5.5.b.1. That he has read and understands the requirements of this and other applicable sections;

5.5.b.2. The services for which he is applying for registration;

5.5.b.3. The training and experience that qualify him to discharge the services for which he is applying for registration;

5.5.b.4. The type of measurement instruments to be used, frequency of calibration, and source of calibration; and

5.5.b.5. The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule.

5.5.c. For the purpose of section 5.5. services may include but shall not be limited to:

5.5.c.1. Installation or servicing of radiation machines and associated radiation machine components;

5.5.c.2. Calibration of radiation machines or radiation measurement instruments or devices;

5.5.c.3. Radiation protection or health physics consultations or surveys; and

5.5.c.4. Personnel dosimetry services.

5.5.d. No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the agency.

5.6. Issuance of Notice of Registration.

5.6.a. Upon a determination that an applicant meets the requirements of the rules, the agency shall issue a notice of registration.

5.6.b. The agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation producing devices as it deems appropriate or necessary.

5.7. Expiration of Notice of Registration. Except as provided by subsection 5.8.a, each notice of registration shall expire at the end of the specified day in the month and year stated therein.

5.8. Renewal of Registration

5.8.a. The person possessing each registrable item shall renew such registration with the agency at a date to be specified by the agency not later than within six months of the effective date of this rule and every three years thereafter.

5.9. Report of Changes

5.9.a. Except as provided in subsection 5.9.b, the registrant shall notify the agency in writing within 10 days after any change which renders the information on registration no longer accurate. In the case of disposition of radiation sources, such notification shall specify the recipient of these sources.

5.9.b. The registrant is not required to notify the agency of the use of radiation sources at a temporary location other than the designated storage location, provided the initial registration shows that their use at temporary locations is normal to the conduct of the registrant's operations.

5.10. Approval Not Implied

5.10.a. No person, in any advertisement, shall refer to the fact that a source of radiation is registered with the agency, and no person shall state or imply that any activity under such registration has been approved by the agency.

5.11. Reciprocal Recognition of Out-of-State Radiation Producing Devices.

5.11.a. Whenever any radiation producing device is to be brought into the state, for any temporary use, the person proposing to bring such device into the state shall give written notice to the agency at least two working days before such device is to be used in the state. The notice shall include:

5.11.a.1. The type of radiation device;

5.11.a.2. The nature, duration, and scope of use;

5.11.a.3. The exact location or locations where the radiation producing device is to be used; and

5.11.a.4. States in which this device is registered or licensed.

5.11.b. If, for a specific case, the two working-day period would impose an undue hardship on the person, upon application to the agency, permission to proceed sooner may be granted.

5.11.c. The person referred to in subsection 5.11.a shall:

5.11.c.1. Comply with all applicable rules of the agency;

5.11.c.2. Supply the agency with such other information as the agency may reasonably request; and

5.11.c.3. Not operate within the state on a temporary basis in excess of 180 calendar days per year.

5.12. Radiation Protection Requirements

5.12.a. Registrants and persons subject to section 5.11 shall comply with all applicable requirements of this rule, provided, however, that apart from registration, nothing in this rule shall apply to any person to the extent that such person is subject to regulation by the United States Nuclear Regulatory Commission and any legal successor thereof.

§64-23-6. Standards for Protection Against Radiation.

6.1. Purpose and Scope

6.1.a. Except as specifically provided in other sections of this rule, this section applies to persons registered by the agency to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this section do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

6.1.b. The requirements of this section are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by any registrant so the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this section. However, nothing in this section shall be construed as limiting actions that may be necessary to protect health and safety in an emergency.

6.2. Definitions -- As used in this section, the following definitions apply:

6.2.a. Annual Limit On Intake (ALI) -- the derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 0.05 Sv (five rem) or a committed dose equivalent of 0.5 Sv (50 rem) to any individual organ or tissue. ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table 64-23 F, Columns 1 and 2.

6.2.b. Class -- a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, days, of less than 10 days, for Class W, weeks, from 10 to 100 days , and for Class Y, years, of greater than 100 days. For purposes of this rule, "lung class" and "inhalation class" are equivalent terms.

6.2.c. Declared Pregnant Woman -- a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

6.2.d. Derived Air Concentration (DAC) -- the concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work, results in an intake of one ALI. For purposes of this rule, the condition of light work is an inhalation rate of 1.2 cubic meters of air per hour for 2,000 hours in a year. DAC values are given in Table 64-23 F, Table I, Column 3.

6.2.e. Derived Air Concentration-hour (DAC-hour) -- the product of the concentration of radioactive material in air, expressed as a fraction or multiple of the derived air concentration for each radionuclide, and the time of exposure to that radionuclide, in hours. A registrant may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 0.05 Sv (five rem).

6.2.f. Dosimetry Processor -- an individual or an organization that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

6.2.g. Inhalation Class -- a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, days, of less than 10 days, for Class W, weeks, from 10 to 100 days , and for Class Y, years, of greater than 100 days.

6.2.h. Lung Class -- a classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D, days, of less than 10 days, for Class W, weeks, from 10 to 100 days , and for Class Y, years, of greater than 100 days.

6.2.i. Nonstochastic Effect -- a health effect, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect. For purposes of this rule, "deterministic effect" is an equivalent term.

6.2.j. Planned Special Exposure -- an infrequent exposure to radiation, separate from and in addition to the annual occupational dose limits.

6.2.k. Quarter -- a period of time equal to one-fourth of the year observed by the registrant, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

6.2.l. Reference Man -- a hypothetical aggregation of human physical and physiological characteristics determined by international consensus. These characteristics may be used by researchers and public health employees to standardize results of experiments and to relate biological insult to a common base. A description of the reference man is contained in the International Commission on Radiological Protection Report, ICRP publication 23, "Report of the Task Group on Reference Man."

6.2.m. Respiratory Protective Equipment -- an apparatus, such as a respirator, used to reduce an individual's intake of airborne radioactive materials.

6.2.n. Sanitary Sewerage -- a system of public sewers for carrying off wastewater and refuse, but excluding sewage treatment facilities, septic tanks, and leach fields owned or operated by the registrant.

6.2.o. Stochastic Effect -- a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects. For purposes of this rule, "probabilistic effect" is an equivalent term.

6.2.p. Very High Radiation Area -- an area, accessible to individuals, in which radiation levels could result in an individual receiving an absorbed dose in excess of five Gy (500 Rad) in one hour at one meter from a source of radiation or from any surface that the radiation penetrates.[1]

6.2.q. Weighting Factor w_T for An Organ or Tissue (T) -- the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of w_T are listed in Table 64-23 C.

6.3. Implementation

6.3.a. Any existing registration condition that is more restrictive than section 6 remains in force until there is an amendment or renewal of the registration.

6.3.b. If a registration condition exempts a registrant from a provision of section 6 in effect on or before July 1, 2001, it also exempts the registrant from the corresponding provision of section 6.

6.3.c. If a registration condition cites provisions of section 6 in effect prior to July 1, 2001, which do not correspond to any provisions of section 6, the registration condition remains in force until there is an amendment or renewal of the registration that modifies or removes this condition.

6.4. Radiation Protection Programs.

6.4.a. Each registrant shall develop, document, and implement a radiation protection program sufficient to ensure compliance with the provisions of section 6. See section 6.41 for record keeping requirements relating to these programs.

6.4.b. The registrant shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are as low as is reasonably achievable (ALARA).

[1] At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, Sievert and Rem.

6.4.c. The registrant shall, at intervals not to exceed 12 months, review the radiation protection program content and implementation.

6.5. Occupational Dose Limits for Adults.

6.5.a. The registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to section 6.10 to the following dose limits:

6.5.a.1. An annual limit, which is the more limiting of:

6.5.a.1.A. The total effective dose equivalent being equal to 0.05 Sv (five rem); or

6.5.a.1.B. The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 0.5 Sv (50 rem).

6.5.a.2. The annual limits to the lens of the eye, to the skin, and to the extremities which are listed in Table 64-23 D.

6.5.a.2.A. An eye dose equivalent of 0.15 Sv; and

6.5.a.2.B. A shallow dose equivalent of 0.5 Sv (50 rem) to the skin or to any extremity.

6.5.b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. See subdivisions 6.10.f.1 and 6.10.f.2.

6.5.c. The assigned deep dose equivalent and shallow dose equivalent shall be for the portion of the body receiving the highest exposure:

6.5.c.1. The deep dose equivalent, eye dose equivalent and shallow dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable; or

6.5.c.2. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in subdivision 6.17.a.5, the effective dose equivalent for external radiation shall be determined as follows:

6.5.c.2.A. When only one individual monitoring device is used and it is located at the neck outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

6.5.c.2.B. When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in subsection 6.5.a, the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

6.5.c.2.C. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

6.5.d. Derived air concentration (DAC) and annual limit on intake (ALI) values are specified in Table 64-23 F Table I and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. See section 6.46.

6.5.e. Notwithstanding the annual dose limits, the or registrant shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (footnote [c] of Table 64-23 F).

6.5.f. The registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year (section 6.9).

6.6. Compliance with Requirements for Summation of External and Internal Doses.

6.6.a. If the registrant is required to monitor pursuant to both subsections 6.17.a and 6.17.b, the registrant shall demonstrate compliance with the dose limits by summing external and internal doses. If the registrant is required to monitor only pursuant to subsection 6.17.a or only pursuant to subsection 6.17.b, then summation is not required to demonstrate compliance with the dose limits. The registrant may demonstrate compliance with the requirements for summation of external and internal doses pursuant to subsections 6.6.b – 6.6.d. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

6.6.b. Intake by Inhalation. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

6.6.b.1. The sum of the fractions of the inhalation ALI or each radionuclide; or

6.6.b.2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

6.6.b.3. The sum of the calculated committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. For purposes of this requirement, an organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

6.6.c. Intake by Oral Ingestion. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the registrant shall account for this intake and include it in demonstrating compliance with the limits.

6.6.d. Intake through Wounds or Absorption through Skin. The registrant shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin has been included in the calculation of DAC for Hydrogen-3 and does not need to be evaluated or accounted for pursuant to subsection 6.6.d.

6.6.e. Orders Requiring Furnishing of Bioassay Services -- Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the agency may incorporate registration provisions or issue an order requiring a registrant to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the agency.

6.7. Determination of External Dose from Airborne Radioactive Material.

6.7.a. Registrants shall, when determining the dose from airborne radioactive material, include the contribution to the deep dose equivalent, eye dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud. See Table 64-23 F, footnotes [a] and [b].

6.7.b. Airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep dose equivalent to an individual shall be based upon measurements using instruments or individual monitoring devices.

6.8. Determination of Internal Exposure.

6.8.a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the registrant shall, when required pursuant to section 6.17, take suitable and timely measurements of:

6.8.a.1. Concentrations of radioactive materials in air in work areas; or

6.8.a.2. Quantities of radionuclides in the body; or

6.8.a.3. Quantities of radionuclides excreted from the body; or

6.8.a.4. Combinations of these measurements.

6.8.b. Unless respiratory protective equipment is used, as provided in section 6.24, or the assessment of intake is based on bioassays, the registrant shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

6.8.c. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual is known, the registrant may:

6.8.c.1. Use that information to calculate the committed effective dose equivalent, and, if used, the registrant shall document that information in the individual's record; and

6.8.c.2. Upon prior approval of the agency, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size distribution or density; and

6.8.c.3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. See Table 64-23 F.

6.8.d. If the registrant chooses to assess intakes of class y material using the measurements given in subdivision 6.8.a.2 or 6.8.a.3, the registrant may delay the recording and reporting of the assessments for periods up to seven months, unless otherwise required by sections 6.42 or 6.43. This delay permits the registrant to make additional measurements basic to the assessments.

6.8.e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

6.8.e.1. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Table 64-23 F for each radionuclide in the mixture; or

6.8.e.2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

6.8.f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

6.8.g. When a mixture of radionuclides in air exists, a registrant may disregard certain radionuclides in the mixture if:

6.8.g.1. The registrant uses the total activity of the mixture in demonstrating compliance with the dose limits in section 6.5. and in complying with the monitoring requirements in subsection 6.17.b; and

6.8.g.2. The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

6.8.g.3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

6.8.h. When determining the committed effective dose equivalent, the following information may be considered:

6.8.h.1. In order to calculate the committed effective dose equivalent, the registrant may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sv (five rem) for radionuclides that have their ALIs or DACS based on the committed effective dose equivalent;

6.8.h.2. For an ALI and the associated DAC determined by the nonstochastic organ dose limit of 0.5 Sv (50 rem), the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sv (five rem), that is, the stochastic ALI, is listed in parentheses in Table I of Table 64-23 F. The registrant may, as a simplifying assumption, use the stochastic ALI to determine committed effective dose equivalent. However, if the registrant uses the stochastic ALI, the registrant shall also demonstrate that the limit in paragraph 6.5.a.1.B is met.

6.9. Determination of Prior Occupational Dose.

6.9.a. For each individual who may enter the registrant's restricted area and is likely to receive, in a year, an occupational dose requiring monitoring pursuant to section 6.17, the registrant shall:

6.9.a.1. Determine the occupational radiation dose received during the current year; and

6.9.a.2. Attempt to obtain the records of lifetime cumulative occupational radiation dose.

6.9.b. Prior to permitting an individual to participate in a planned special exposure, the registrant shall determine:

6.9.b.1. The internal and external doses from all previous planned special exposures; and

6.9.b.2. All doses in excess of the limits, including doses received during accidents and emergencies, received during the lifetime of the individual.

6.9.c. In complying with the requirements of subsection 6.9.a, a registrant may:

6.9.c.1. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual received during the current year; and

6.9.c.2. Accept, as the record of lifetime cumulative radiation dose, an up-to-date Agency Form Y or equivalent, signed by the individual and countersigned by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant; and

6.9.c.3. Obtain reports of the individual's dose equivalent from the most recent employer for work involving radiation exposure, or the individual's current employer, if the individual is not employed by the registrant, by telephone, telegram, facsimile, or letter. The registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

6.9.d. The registrant shall record the exposure history, as required by subsection 6.9.a, on Agency Form Y, or other clear and legible record, of all the information required on that form. The form or record shall show each period in which the individual received occupational exposure to radiation or radioactive material and shall be signed by the individual who received the exposure. For each period for which the registrant obtains reports, the registrant shall use the dose shown in the report in preparing Agency Form Y or equivalent. For any period in which the registrant does not obtain a report, the registrant shall place a notation on Agency Form Y or equivalent indicating the periods of time for which data are not available.

6.9.e. Registrants are not required to partition historical dose between external dose equivalent and internal committed dose equivalent. Further, occupational exposure histories obtained and recorded on Agency Form Y or equivalent before July 1, 2001, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

6.9.f. If the registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the registrant shall assume:

6.9.f.1. In establishing administrative controls pursuant to subsection 6.5.f for the current year, that the allowable dose limit for the individual is reduced by 12.5 mSv (1.25 rem) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

6.9.f.2. That the individual is not available for planned special exposures.

6.9.g. The registrant shall retain the records on Agency Form Y or equivalent until the agency terminates each pertinent registration requiring this record. The registrant shall retain records used in preparing Agency Form Y or equivalent for three years after the record is made.

6.10. Planned Special Exposures.

6.10.a. A registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in section 6.5, provided that each of the following conditions is satisfied:

6.10.b. The registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the higher exposure are unavailable or impractical;

6.10.c. The registrant, and employer if the employer is not the registrant, specifically authorizes the planned special exposure, in writing, before the exposure occurs;

6.10.d. Before a planned special exposure, the registrant ensures that each individual involved is:

6.10.d.1. Informed of the purpose of the planned operation; and

6.10.d.2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

6.10.d.3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present;

6.10.e. Prior to permitting an individual to participate in a planned special exposure, the registrant ascertains prior doses as required by subsection 6.9.b during the lifetime of the individual for each individual involved;

6.10.f. Subject to subsection 6.5.b, the registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

6.10.f.1. The numerical values of any of the dose limits in subsection 6.5.a in any year; and

6.10.f.2. Five (5) times the annual dose limits in subsection 6.5.a during the individual's lifetime;

6.10.g. The registrant maintains records of the conduct of a planned special exposure in accordance with section 6.45 and submits a written report in accordance with section 6.55;

6.10.h. The registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days from the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling future occupational dose of the individual pursuant to subsection 6.5.a but shall be included in evaluations required by subsections 6.10.d and 6.10.e.

6.11. Occupational Dose Limits for Minors. The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for adult workers in section 6.5.

6.12. Dose to an Embryo or Fetus.

6.12.a. The registrant shall ensure that the dose to an embryo or fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed five mSv (0.5 rem). See section 6.46 for record keeping requirements.

6.12.b. The registrant shall make efforts to avoid substantial variation [2]above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in subsection 6.12.a.

6.12.c. The dose to an embryo or fetus shall be taken as the sum of:

6.12.c.1. The dose to the embryo or fetus from radionuclides in the embryo or fetus and radionuclides in the declared pregnant woman; and

[2] Labeled means labeled with a Radioactive White I, Yellow II or Yellow III label as specified in Department of Transportation Regulations 49 CFR .403 and 172.436-440.

6.12.c.2. The dose that is most representative of the dose to the embryo or fetus from external radiation, that is, in the mother's lower torso region.

6.12.c.2.A. If multiple measurements have not been made, assignment of the highest deep dose equivalent for the declared pregnant woman shall be the dose to the embryo or fetus, in accordance with subsection 6.9.c; or

6.12.c.2.B. If multiple measurements have been made, assignment of the deep dose equivalent for the declared pregnant woman from the individual monitoring device which is most representative of the dose to the embryo or fetus shall be the dose to the embryo or fetus. Assignment of the highest deep dose equivalent for the declared pregnant woman to the embryo or fetus is not required unless that dose is also the most representative deep dose equivalent for the region of the embryo or fetus.

6.12.d. If by the time the woman declares pregnancy to the registrant, the dose to the embryo or fetus has exceeded 4.5 mSv (0.45 rem), the or registrant shall be deemed to be in compliance with section 6.12.a if the additional dose to the embryo or fetus does not exceed 0.5 mSv (0.05 rem) during the remainder of the pregnancy.

6.13. Dose Limits for Individual Members of the Public.

6.13.a. Each registrant shall conduct operations so that:

6.13.a.1. Except as provided in subdivision 6.13.a.3, the total effective dose equivalent to individual members of the public from the registered operation does not exceed one mSv (0.1 rem) in a year, exclusive of the dose contribution from the registrant's disposal of radioactive material into sanitary sewerage in accordance with section 6.35; and

6.13.a.2. The dose in any unrestricted area from external sources does not exceed 0.02 mSv (0.002 rem) in any one hour; and

6.13.a.3. The total effective dose equivalent to individual members of the public from infrequent exposure to radiation from radiation machines does not exceed five mSv (0.5 rem).

6.13.b. If the registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

6.13.c. A registrant or an applicant for registration may apply for prior agency authorization to operate up to an annual dose limit for an individual member of the public of five mSv (0.5 rem). This application shall include the following information:

6.13.c.1. Demonstration of the need for and the expected duration of operations in excess of the limit in 6.13.a.; and

6.13.c.2. The registrant's program to assess and control dose within the five mSv (0.5 rem) annual limit; and

6.13.c.3. The procedures to be followed to maintain the dose ALARA.

6.13.d. In addition to the requirements of section 6, a registrant subject to the provisions of the United States Environmental Protection Agency's generally applicable Environmental Radiation Standards in 40 CFR 190 shall comply with those standards.

6.13.e. The agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a registrant may release in effluents in order to restrict the

collective dose.

6.14. Compliance with Dose Limits for Individual Members of the Public.

6.14.a. The registrant shall make or cause to be made surveys of radiation levels in unrestricted areas and radioactive materials in effluents released to unrestricted areas to demonstrate compliance with the dose limits for individual members of the public in section 6.13.

6.14.b. A registrant shall show compliance with the annual dose limit in section 6.13 by:

6.14.b.1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the registered operation does not exceed the annual dose limit; or

6.14.b.2. Demonstrating that:

6.14.b.2.A. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Table 64-23 F; and

6.14.b.2.B. If an individual were continuously present in an unrestricted area, the dose from external sources would not exceed 0.02 mSv (0.002 rem) in an hour and 0.5 mSv (0.05 rem) in a year.

6.14.c. Upon approval from the agency, the registrant may adjust the effluent concentration values in Table 64-23 F, or members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

6.15. Testing for Leakage or Contamination of Sealed Sources.

6.15.a. The registrant in possession of any sealed source shall assure that:

6.15.a.1. Each sealed source, except as specified in subsection 6.15.b, is tested for leakage or contamination and the test results are received before the sealed source is put into use unless the registrant has a certificate from the transferor indicating that the sealed source was tested within six months before transfer to the registrant monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

6.15.a.2. Each sealed source that is not designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed six months or at alternative intervals approved by the agency, after evaluation of information specified by of this rule, an agreement state, a licensing state, or the Nuclear Regulatory Commission;

6.15.a.3. Each sealed source that is designed to emit alpha particles is tested for leakage or contamination at intervals not to exceed three months or at alternative intervals approved by the agency, after evaluation of information specified by this rule, an agreement state, a licensing state, or the Nuclear Regulatory Commission;

6.15.a.4. For each sealed source that is required to be tested for leakage or contamination, at any other time there is reason to suspect that the sealed source might have been damaged or might be leaking, the registrant shall assure that the sealed source is tested for leakage or contamination before further use;

6.15.a.5. Tests for leakage for all sealed sources, except brachytherapy sources manufactured to contain radium, shall be capable of detecting the presence of 185 Bq (0.005 μCi) of radioactive material on a test sample. Test samples shall be taken from the sealed source or from the surfaces of the container in which the sealed source is stored or mounted on which one might expect contamination to accumulate. For a sealed source contained in a device, test samples are obtained when the source is in the "off" position;

6.15.a.6. The test for leakage for brachytherapy sources manufactured to contain radium shall be capable of detecting an absolute leakage rate of 37 Bq (0.001 μCi) of Radon-222 in a 24 hour period when the collection efficiency for Radon-222 and its daughters has been determined with respect to collection method, volume and time;

6.15.a.7. Tests for contamination from radium daughters shall be taken on the interior surface of brachytherapy source storage containers and shall be capable of detecting the presence of 185 Bq (0.005 μCi) of a radium daughter which has a half-life greater than four days.

6.15.b. A registrant need not perform test for leakage or contamination on the following sealed sources:

6.15.b.1. Sealed sources containing only radioactive material with a half-life of less than 30 days;

6.15.b.2. Sealed sources containing only radioactive material as a gas;

6.15.b.3. Sealed sources containing 3.7 MBq (100 μCi) or less of beta or photon-emitting material or 370 kBq (10 μCi) or less of alpha-emitting material;

6.15.b.4. Sealed sources containing only hydrogen-3;

6.15.b.5. Seeds of Iridium-192 encased in nylon ribbon; and

6.15.b.6. Sealed sources, except teletherapy and brachytherapy sources, which are stored, not being used and identified as in storage. The registrant shall, however, test each such sealed source for leakage or contamination and receive the test results before any use or transfer unless it has been tested for leakage or contamination within six months before the date of use or transfer.

6.15.c. Tests for leakage or contamination from sealed sources shall be performed by persons specifically authorized by the agency, an agreement state, a licensing state, or the Nuclear Regulatory Commission to perform such services.

6.15.d. Test results shall be kept in units of becquerel or microcurie and maintained for inspection by the agency. Records of test results for sealed sources shall be made pursuant to section 6.43.

6.15.e. The following shall be considered evidence that a sealed source is leaking:

6.15.e.1. The presence of 185 Bq (0.005 μCi) or more of removable contamination on any test sample;

6.15.e.2. Leakage of 37 Bq (0.001μCi) of Radon-222 per 24 hours for brachytherapy sources manufactured to contain radium;

6.15.e.3. The presence of removable contamination resulting from the decay of 185 Bq

(0.005 μCi) or more of radium.

6.15.f. The registrant shall immediately withdraw a leaking sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with this section.

6.15.g. Reports of test results for leaking or contaminated sealed sources shall be made pursuant to section 6.58.

6.16. Surveys and Monitoring

6.16.a. Each registrant shall make, or cause to be made, surveys that:

6.16.a.1. Are necessary for the registrant to comply with section 6.; and

6.16.a.2. Are necessary under the circumstances to evaluate:

6.16.a.2.A. Radiation levels; and

6.16.a.2.B. Concentrations or quantities of radioactive material; and

6.16.a.2.C. The potential radiological hazards that could be present.

6.16.b. The registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated at intervals not to exceed 12 months for the radiation measured, except when a more frequent interval is specified in another applicable section of this rule.

6.16.c. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by registrants to comply with subsection 6.5, with other applicable provisions of this rule, or with conditions specified in a registration shall be processed and evaluated by a dosimetry processor:

6.16.c.1. Holding current personnel dosimetry accreditation from the national voluntary laboratory accreditation program of the national institute of standards and technology; and

6.16.c.2. Approved in this accreditation process for the type of radiation or radiations included in the national voluntary laboratory accreditation program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

6.16.d. The registrant shall ensure that adequate precautions are taken to prevent a deceptive exposure of an individual monitoring device.

6.17. Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

6.17.a. Each registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of section 6. As a minimum:

6.17.a.1. Each registrant shall monitor occupational exposure to radiation and shall supply and require the use of individual monitoring devices by:

6.17.a.2. Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in subsection 6.5.a;

6.17.a.3. Minors and declared pregnant women likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of any of the applicable limits in sections 6.11 or 6.12;

6.17.a.4. Individuals entering a high or very high radiation area; and

6.17.a.5. Individuals working with medical fluoroscopic equipment;

6.17.a.5.A. An individual monitoring device used for the dose to an embryo or fetus of a declared pregnant woman, pursuant to subsection 6.12.a, shall be located under the protective apron at the waist;

6.17.a.5.B. An individual monitoring device used for eye dose equivalent shall be located at the neck, or an unshielded location closer to the eye, outside the protective apron; and

6.17.a.5.C. When only 1 individual monitoring device is used to determine the effective dose equivalent for external radiation pursuant to subdivision 6.5.c.2, it shall be located at the neck outside the protective apron. When a second individual monitoring device is used, for the same purpose, it shall be located under the protective apron at the waist. The second individual monitoring device is required for a declared pregnant woman.

6.17.b. Each registrant shall monitor, to determine compliance with section 6.8, the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

6.17.b.1. Adults likely to receive, in one year, an intake in excess of 10 percent of the applicable ALI in Table I, Columns 1 and 2, of Table 64-23 F; and

6.17.b.2. Minors and declared pregnant women likely to receive, in one year, a committed effective dose equivalent in excess of 0.5 mSv (0.05 rem).

6.18. Location of Individual Monitoring Devices.

6.18.a. Each registrant shall ensure that individuals who are required to monitor occupational doses in accordance with subsection 6.17.a wear individual monitoring devices as follows:

6.18.a.1. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

6.18.a.2. An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman, pursuant to subsection 6.12.a, shall be located at the waist under any protective apron being worn by the woman;

6.18.a.3. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with paragraph 6.5.a.2.A, shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

6.18.a.4. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with subdivision 6.5.a.2, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored;

6.18.a.5. An individual monitoring device used for monitoring the dose to an embryo or fetus of a declared pregnant woman, pursuant to subsection 6.12.a, shall be located at the waist under any

protective apron being worn by the woman;

6.18.a.6. An individual monitoring device used for monitoring the eye dose equivalent, to demonstrate compliance with paragraph 6.5.a.2.A, shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

6.18.a.7. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with paragraph 6.5.a.2.B, shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

6.19. Control of Access to High Radiation Areas.

6.19.a. The registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

6.19.a.1. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep dose equivalent of one mSv (0.1 rem) in one hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

6.19.a.2. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

6.19.a.3. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

6.19.b. In place of the controls required by subsection 6.19.a for a high radiation area, the registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

6.19.c. The registrant may apply to the agency for approval of alternative methods for controlling access to high radiation areas.

6.19.d. The registrant shall establish the controls required by subsections 6.19.a and 6.19.c in a way that does not prevent individuals from leaving a high radiation area.

6.19.e. The registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the rules of the Department of Transportation provided that:

6.19.e.1. The packages do not remain in the area longer than three days; and

6.19.e.2. The dose rate at 1 meter from the external surface of any package does not exceed 0.1 mSv (0.01 rem) per hour.

6.19.f. The registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who are taking the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the established limits in section 6 and to operate within the ALARA provisions of the registrant's radiation protection program.

6.19.g. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in section 6.19 if the registrant has met all the specific requirements for access and control specified in other applicable sections of this rule, such as, section 7 for x-rays in the healing arts, section 9 for industrial radiography, and section 10 for particle accelerators.

6.20. Control of Access to Very High Radiation Areas.

6.20.a. In addition to the requirements in section 6.19, the registrant shall institute measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at five Gy (500 Rad) or more in one hour at one meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic x-ray systems are the only source of radiation, or to non-self-shielded irradiators.

6.20.b. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in subsection 6.20.a if the registrant has met all the specific requirements for access and control specified in other applicable sections of this rule, such as, section 7 for x- rays in the healing arts, section 9 for industrial radiography, and section 10 for particle accelerators.

6.21. Control of Access to Very High Radiation Areas -- Irradiators.

6.21.a. Section 6.21 applies to registrants with sources of radiation in non-self-shielded irradiators. section 6.21 does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

6.21.b. Each area in which there may exist radiation levels in excess of five Gy (500 Rad) in one hour at one meter from a source of radiation that is used to irradiate materials shall meet the following requirements:

6.21.b.1. Each entrance or access point shall be equipped with entry control devices which:

6.21.b.1.A. Function automatically to prevent any individual from inadvertently entering a very high radiation area; and

6.21.b.1.B. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

6.21.b.1.C. Prevent operation of the source of radiation if it would produce radiation levels in the area that could result in a deep dose equivalent to an individual in excess of one mSv (0.1 rem) in one hour.

6.21.b.2. Additional control devices shall be provided so that, upon failure of the entry control devices to function as required by subdivision 6.21.b.1:

6.21.b.2.A. The radiation level within the area, from the source of radiation, is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

6.21.b.2.B. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity, and prepared to render or summon assistance, aware of the failure of the entry control devices.

6.21.b.3. The registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

6.21.b.3.A. The radiation level from the source of radiation is reduced below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour; and

6.21.b.3.B. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

6.21.b.4. When the shield for stored sealed sources is a liquid, the registrant shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

6.21.b.5. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances need not meet the requirements of subdivisions 6.21.b.3 and 6.21.b.4.

6.21.b.6. Each area shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source of radiation from being put into operation.

6.21.b.7. Each area shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

6.21.b.8. Each area shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source of radiation in the area is below that at which it would be possible for an individual to receive a deep dose equivalent in excess of one mSv (0.1 rem) in one hour.

6.21.b.9. The entry control devices required in subdivision 6.21.b.1 shall be tested for proper functioning. See section 6.42 for recordkeeping requirements.

6.21.b.9.A. Testing shall be conducted prior to initial operation with the source of radiation on any day, unless operations were continued uninterrupted from the previous day; and

6.21.b.9.B. Testing shall be conducted prior to resumption of operation of the source of radiation after any unintentional interruption; and

6.21.b.9.C. The registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

6.21.b.10. The registrant shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning

properly.

6.21.b.11. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. Exit portals for irradiated materials shall be equipped to detect and signal the presence of any loose radioactive material that is carried toward such an exit and automatically to prevent loose radioactive material from being carried out of the area.

6.21.c. Registrants, or applicants for registrations for sources of radiation within the purview of subsection 6.21.b which will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of subsection 6.21.b, such as those for the automatic control of radiation levels, may apply to the agency for approval of alternative safety measures. Alternative safety measures shall provide personnel protection at least equivalent to those specified in subsection 6.21.b At least one of the alternative measures shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation are used.

6.21.d. The entry control devices required by subsections 6.21.b and 6.21.c shall be established in such a way that no individual will be prevented from leaving the area.

6.22. Use of Process or Other Engineering Controls. The registrant shall use, to the extent practicable, process or other engineering controls, such as, containment or ventilation, to control the concentrations of radioactive material in air.

6.23. Use of Other Controls. When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the registrant shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

6.23.a. Control of access; or

6.23.b. Limitation of exposure times; or

6.23.c. Use of respiratory protection equipment; or

6.23.d. Other controls.

6.24. Use of Individual Respiratory Protection Equipment.

6.24.a. If the registrant uses respiratory protection equipment to limit intakes pursuant to section 6.23:

6.24.a.1. Except as provided in subdivision 6.24.a.2, the registrant shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration;

6.24.a.2. The registrant may use equipment that has not been tested or certified by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration has not had certification extended by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration, or for which there is no schedule for testing or certification, provided the registrant has submitted to the agency and the agency has approved an application for authorized use of that equipment, including a demonstration by testing, or a demonstration on the basis of test information, that the material and performance characteristics of the equipment are capable of providing

the proposed degree of protection under anticipated conditions of use;

6.24.a.3. The registrant shall implement and maintain a respiratory protection program that includes:

6.24.a.3.A. Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate exposures; and

6.24.a.3.B. Surveys and bioassays, as appropriate, to evaluate actual intakes; and

6.24.a.3.C. Testing of respirators for operability immediately prior to each use; and

6.24.a.3.D. Written procedures regarding selection, fitting, issuance, maintenance, and testing of respirators, including testing for operability immediately prior to each use; supervision and training of personnel; monitoring, including air sampling and bioassays; and record keeping; and

6.24.a.3.E. Determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment;

6.24.a.4. The registrant shall issue a written policy statement on respirator usage covering:

6.24.a.4.A. The use of process or other engineering controls, instead of respirators; and

6.24.a.4.B. The routine, nonroutine, and emergency use of respirators; and

6.24.a.4.C. The length of periods of respirator use and relief from respirator use;

6.24.a.5. The registrant shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief;

6.24.a.6. The registrant shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for Type and mode of use and shall provide proper visual, communication, and other special capabilities, such as adequate skin protection, when needed.

6.24.b. When estimating exposure of individuals to airborne radioactive materials, the registrant may make allowance for respiratory protection equipment used to limit intakes pursuant to section 6.23, provided that the following conditions, in addition to those in subsection 6.24.a, are satisfied:

6.24.b.1. The registrant selects respiratory protection equipment that provides a protection factor, specified in Table 64-23 E, greater than the multiple by which peak concentrations of airborne radioactive materials in the working area are expected to exceed the values specified in Table 64-23 F, Table I, column 3. However, if the selection of respiratory protection equipment with a protection factor greater than the peak concentration is inconsistent with the goal specified in section 6.23 of keeping the total effective dose equivalent ALARA, the registrant may select respiratory protection equipment with a lower protection factor provided that such a selection would result in a total effective dose equivalent that is ALARA. The concentration of radioactive material in the air that is inhaled when respirators are worn may be initially estimated by dividing the average concentration in air, during each period of uninterrupted use, by the protection factor. If the exposure is later found to be greater than initially estimated, the corrected value shall be used; if the exposure is later found to be less than initially estimated, the corrected value may be used;

6.24.b.2. The registrant shall obtain authorization from the agency before assigning respiratory protection factors in excess of those specified in Table 64-23 E. The agency may authorize a registrant to use higher protection factors on receipt of an application that:

6.24.b.2.A. Describes the situation for which a need exists for higher protection factors; and

6.24.b.2.B. Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

6.24.c. In an emergency, the registrant shall use as emergency equipment only respiratory protection equipment that has been specifically certified or had certification extended for emergency use by the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration.

6.24.d. The registrant shall notify the agency in writing at least 30 days before the date that respiratory protection equipment is first used pursuant to either subsections 6.24.a or 6.24.b.

6.25. Storage and Control of Registered Sources of Radiation.

6.25.a. The registrant shall secure registered radioactive material from unauthorized removal or access.

6.25.b. The registrant shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of registered radioactive material that is in an unrestricted area and that is not in storage.

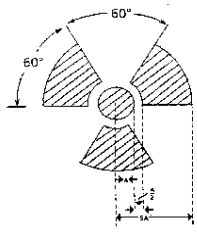
6.25.c. The registrant shall secure registered radiation machines from unauthorized removal.

6.25.d. The registrant shall use devices or administrative procedures to prevent unauthorized use of registered radiation machines.

6.25.e. Sources of radiation shall be secured against unauthorized removal from the place of storage and shall be provided with reasonable protection against loss, leakage, or dispersion be the effects of fire or water.

6.26. Caution Signs.

6.26.a. Standard Radiation Symbol. Unless otherwise authorized by the agency, the symbol prescribed by section 6.26 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:



1. Cross-hatched area is to be magenta, or purple, or black, and

2. The background is to be yellow.

Radiation Symbol

6.26.b. Exception to Color Requirements for Standard Radiation Symbol. Notwithstanding the requirements of subsection 6.26.a, registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

6.26.c. Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in section 6, the registrant may provide, on or near the required signs and labels, additional information, as appropriate, to make individuals aware of potential radiation exposures and to minimize the exposures.

6.27. Posting Requirements.

6.27.a. Posting of Radiation Areas. The registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

6.27.b. Posting of High Radiation Areas. The registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

6.27.c. Posting of Very High Radiation Areas. The registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and words "GRAVE DANGER, VERY HIGH RADIATION AREA."

6.27.c.1. Each entrance or access point to a high radiation area shall be:

6.27.c.1.A. Equipped with a control device which shall cause the level of radiation to be reduced below that at which an individual might receive a dose of 100 millirems in one hour upon entry into the area; or

6.27.c.1.B. Equipped with a control device which shall energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the registrant or a supervisor of the activity are made aware of the entry; or

6.27.c.1.C. Maintained locked except during periods when access to the area is required, with positive control over each individual entry.

6.27.c.1.D. The controls required by subdivision 6.27.c.1 shall be established in such a way that no individual will be prevented from leaving a high radiation area.

6.27.c.2. In the case of a high radiation area established for a period of 30 days or less, direct surveillance to prevent unauthorized entry may be substituted for the controls required by subdivision 6.21.b.1.

6.27.c.3. Any registrant may apply to the agency for approval of methods not included in subsection 6.21.b and 6.21.c for controlling access to high radiation areas. The agency will approve the proposed alternatives if the registrant demonstrates that the alternative methods of control will prevent unauthorized entry into a high radiation area, and that the requirement of subsection 6.21.b is met.

6.27.d. Posting of Airborne Radioactivity Areas. The registrant shall post each airborne

radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

6.27.e. Posting of Areas or Rooms in Which Registered Material is Used or Stored. The registrant shall post each area or room in which there is used or stored an amount of registered material exceeding 10 times the quantity of such material specified in Table 64-23 G with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIALS" or "DANGER, RADIOACTIVE MATERIALS."

6.28. Exceptions to Posting Requirements.

6.28.a. A registrant is not required to post caution signs in areas or rooms containing sources of radiation for periods of less than eight hours, if each of the following conditions is met:

6.28.a.1. The sources of radiation are constantly attended during these periods by an individual who takes the precautions necessary to prevent the exposure of individuals to sources of radiation in excess of the limits established in section 6; and

6.28.a.2. The area or room is subject to the registrant's control.

6.28.b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs pursuant to section 6.27, provided that the requirements of subdivisions 11.38.b.2 or 11.44.b.3 of this rule are met.

6.28.c. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs, provided that:

6.28.c.1. A patient being treated with a permanent implant could be released from confinement pursuant to section 11.26 of this rule; or

6.28.c.2. A patient being treated with a therapeutic radiopharmaceutical could be released from confinement pursuant to subsection 11.38.c of this rule.

6.28.d. A room or area is not required to be posted with a caution sign because of the presence of a sealed source provided the radiation level at 30 centimeters from the surface of the sealed source container or housing does not exceed 0.05 mSv (0.005 rem) per hour.

6.28.e. A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts.

6.29. Labeling Containers and Radiation Machines.

6.29.a. The registrant shall ensure that each container of registered material bears a durable, clearly visible label bearing the radiation symbol and the words "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL." The label shall also provide information, such as the radionuclides present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment, to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

6.29.b. Each registrant shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

6.29.c. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner which cautions individuals that radiation is produced when it is energized.

6.30. Exemptions to Labeling Requirements.

6.30.a. A registrant is not required to label:

6.30.a.1. Containers holding registered material in quantities less than the quantities listed in Table 64-23 G; or

6.30.a.2. Containers holding registered material in concentrations less than those specified in Table III of Table 64-23 F; or

6.30.a.3. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by section 6; or

6.30.a.4. Containers when they are in transport and packaged and labeled in accordance with the rules of the Department of Transportation[3]; or

6.30.a.5. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record. Examples of containers of this Type Are containers in locations such as water-filled canals, storage vaults, or hot cells. The record shall be retained as long as the containers are in use for the purpose indicated on the record; or

6.30.a.6. Installed manufacturing or process equipment, such as piping and tanks.

6.31. Procedures for Receiving and Opening Packages.

6.31.a. Each registrant who expects to receive a package containing quantities of radioactive material in excess of a Type A quantity, as defined in section 14 and Table 64-23 Ee of this rule, shall make arrangements to receive:

6.31.a.1. The package when the carrier offers it for delivery; or

6.31.a.2. The notification of the arrival of the package at the carrier's terminal and to take possession of the package expeditiously.

6.31.b. Each registrant shall:

6.31.b.1. Monitor the external surfaces of a labeled[4] package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in section 3 of this rule; and

6.31.b.2. Monitor the external surfaces of a labeled package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in section 3 and Table Ee of this rule; and

[3] Labeling of packages containing radioactive materials is required by the Department of Transportation if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by Department of Transportation regulations 49 CFR 173.403 (m) (w) and 173.421 - 424.

[4] Labeled means labeled with a radioactive white I, yellow II or yellow III label as specified in Department of Transportation regulations 49 CFR 173.403 and 172.436 - 440.

6.31.b.3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

6.31.c. The registrant shall perform the monitoring required by subsection 6.31.b as soon as practicable after receipt of the package, but not later than three hours after the package is received at the registrant's facility if it is received during the registrant's normal working hours or if there is evidence of degradation of package integrity, such as a package that is crushed, wet, or damaged. If a package is received after working hours, and has no evidence of degradation of package integrity, the package shall be monitored no later than three hours from the beginning of the next working day.

6.31.d. The registrant shall immediately notify the final delivery carrier and, by telephone and either telegram, or facsimile, the agency when:

6.31.d.1. Removable radioactive surface contamination exceeds the limits of subsection 14.14.h of this rule; or

6.31.d.2. External radiation levels exceed the limits of subsection 14.14.j and 14.14.k of this rule.

6.31.e. Each registrant shall:

6.31.e.1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

6.31.e.2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

6.31.f. Registrants transferring special form sources in vehicles owned or operated by the registrant to and from a work site are exempt from the contamination monitoring requirements of subsection 6.31.b, but are not exempt from the monitoring requirement in subsection 6.31.b for measuring radiation levels that ensures that the source is still properly lodged in its shield.

6.32. Waste Disposal

6.32.a. General Requirements -- No registrant shall dispose of any registered radioactive material except:

6.32.a.1. By transfer to an authorized recipient as provided in section 6.39 or in section 11 of this rule or to the Department of Energy; or

6.32.a.2. By release in effluents within limits of section 6.13; or

6.32.a.3. As authorized pursuant to sections 6.33, 6.34, 6.35, or 6.36; or

6.32.a.4. By decay in storage.

6.32.b. A person shall be specifically registered to receive waste containing registered material from other persons for:

6.32.b.1. Treatment prior to disposal; or

6.32.b.2. Treatment or disposal by incineration; or

6.32.b.3. Decay in storage; or

6.32.b.4. Disposal at a land disposal facility; or

6.32.b.5. Storage until transferred to a storage or disposal facility authorized to receive the waste.

6.33. Methods of Obtaining Approval of Proposed Disposal Procedures

6.33.a. Any registrant or applicant for registration may apply to the agency for approval of proposed procedures to dispose of radioactive material in a manner not otherwise authorized in this section.

6.33.b. Each application shall include a description of the radioactive material, including the quantities and kinds of radioactive material and levels of radioactivity involved, and the proposed manner and conditions of disposal.

6.33.c. The application, where appropriate should also include an analysis and evaluation of pertinent information as to the nature of the environment, including topographical, geological, meteorological and hydrological characteristics; usage of ground and surface waters in the general area; the nature and location of other potentially affected facilities; and procedures to be observed to minimize the risk of unexpected or hazardous exposures.

6.33.d. The agency will not approve any application for a registration to receive radioactive material from other persons for disposal on land not owned by a state or the federal government.

6.34. Disposal by Release Into Sanitary Sewerage Systems

6.34.a. No registrant shall dispose of radioactive material into a sanitary sewerage system unless:

6.34.a.1. It is readily soluble or dispersible in water;

6.34.a.2. The quantity of any registered radioactive material released into the system by the registrant in any one day does not exceed the larger of the following:

6.34.a.3. The quantity of registered radioactive material that the registrant releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the registrant does not exceed the concentration listed in Table III of Table 64-23 F; and

6.34.a.4. If more than one radionuclide is released, the following conditions must also be satisfied:

6.34.a.4.A. The registrant shall determine the fraction of the limit in Table III of Table 64-23 F represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the registrant into the sewer by the concentration of that radionuclide listed in Table III of Table 64-23 F; and

6.34.a.4.B. The sum of the fractions for each radionuclide required by section 6.34.a.iii does not exceed unity; and

6.34.a.4.C. The total quantity of registered radioactive material that the registrant releases into the sanitary sewerage in a year does not exceed 185 GBq (five Ci) of Hydrogen-3, 37 GBq (one Ci) of Carbon-14, and 37 GBq (one Ci) of all other radioactive materials combined.

6.34.b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material are not subject to the limitations contained in subsection 6.34.a.

6.35. Treatment or Disposal by Incineration. A registrant may treat or dispose of registered material by incineration only in the form and concentration specified in section 6.36 or as specifically approved by the agency pursuant to section 6.33.

6.36. Disposal of Specific Wastes.

6.36.a. A registrant may dispose of the following registered material as if it were not radioactive:

6.36.a.1. 1.85 kBq (0.05 FCi), or less, of Hydrogen-3 or Carbon-14 per gram of medium used for liquid scintillation counting; and

6.36.a.2. 1.85 kBq (0.05 FCi), or less, of Hydrogen-3 or Carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

6.36.b. A registrant shall not dispose of tissue pursuant to subdivision 6.36.a.2 in a manner that would permit its use either as food for humans or as animal feed.

6.36.c. The registrant shall maintain records in accordance with section 6.48.

6.37. Transfer of Material

6.37.a. No registrant shall transfer radioactive material except as authorized pursuant to this section.

6.37.b. Any registrant may transfer radioactive material:

6.37.b.1. To the U.S. Nuclear Regulatory Commission;

6.37.b.2. To any person authorized to receive such material under terms of a general license or its equivalent, or a specific license or equivalent licensing document, issued by the U.S. Nuclear Regulatory Commission, or any agreement state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, or any agreement state; or,

6.37.b.3. As otherwise authorized by the agency in writing.

6.38. Transfer for Disposal and Manifests.

6.38.a. The requirements of section 6.38 and Table 64-23 H are designed to control transfers of low-level radioactive waste intended for disposal at a licensed low-level radioactive waste disposal facility, establish a manifest tracking system, and supplement existing requirements concerning transfers and recordkeeping for those wastes.

6.38.b. Each shipment of radioactive waste designated for disposal at a licensed low-level radioactive waste disposal facility shall be accompanied by a shipment manifest as specified in Table 64-23 H i.

6.38.c. Each shipment manifest shall include a certification by the waste generator as specified in Table 64-23 H ii.

6.38.d. Each person involved in the transfer of waste for disposal or in the disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall

comply with the requirements specified in Table 64-23 H iii.

6.39. Compliance with Environmental and Health Protection Rules.

6.39.a. Nothing in sections 6.32 - 6.37 relieves the registrant from complying with other applicable federal, state and local rules governing any other toxic or hazardous properties of materials that may be disposed.

6.40. Intrastate Transportation of Radioactive Material

6.40.a. The provisions of this section apply to transportation of radioactive material, or the delivery of radioactive material to a carrier for transportation, which is not subject to the rules and rules of the U.S. Department of Transportation, the U.S. Postal Service and other federal agencies.

6.40.b. No registrant shall transport any radioactive material outside of the confines of his plant or other authorized location of use, or deliver any radioactive material to a carrier for transportation, unless the registrant complies with all requirements, appropriate to the mode of transportation, relating to the packaging of the radioactive material, and to the marking and labeling of the package and transporting vehicle, of the rules and regulations, as amended of the U.S. Department of Transportation and other federal agencies regulating the transportation of radioactive material.

6.41. Records

6.41.a. Each registrant shall use SI units Becquerel, Gray, Sievert and Coulomb per kilogram, or the special units Curie, Rad, rem and Roentgen, including multiples and subsection, and shall clearly indicate the units of all quantities on records required by section 6.

6.41.b. The registrant shall make a clear distinction among the quantities entered on the records required by section 6, such as, total effective dose equivalent, total organ dose equivalent, shallow dose equivalent, eye dose equivalent or committed effective dose equivalent.

6.41.c. Upon termination of employment of an individual, the individual or agency shall, upon request, be supplied with a summary statement of that individual's radiation dose. This record shall include statements of any circumstances wherein the dose to the employee from any source of radiation, exceeded those specified in this rule. Employee records must be kept available for inspection by the agency during the tenure of employment of an employee and for a period of five years thereafter.

6.41.d. Each registrant shall maintain records in the same units used in this rule, showing the results of surveys and calibrations required to comply with this rule and disposals made under section 6.32. - 6.36. The registrant shall retain these records for three years after the record is made.

6.41.e. Records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of section 6.46 and records of bioassays, including results of whole body counting examinations, made pursuant to subsection 6.6.e shall be preserved indefinitely or until the agency authorizes their disposal. (Records which must be maintained pursuant to this part may be maintained in the form of microfilms.)

6.41.f. An accurate accounting for all radioactive materials shall be maintained for a radiation installation. Such records shall show radioactive materials received, produced, transferred and disposed, the amounts and form of the radioactive materials, and such information as may be necessary to account for the difference between the amount of radioactive materials, received or produced and the amount on hand. Such records shall be retained for at least five years after the final disposition of any radioactive material.

6.41.g. Copies of all records required under this rule shall be transferred to the agency in the event of termination of the registrant's business operations and at such other times as the agency may direct.

6.42. Records of Surveys.

6.42.a. Each registrant shall maintain records showing the results of surveys and calibrations required by section 6.16 and subsection 6.31.b The registrant shall retain these records for three years after the record is made.

6.42.b. The registrant shall retain each of the following records until the agency terminates each pertinent registration requiring the record:

6.42.b.1. Records of the results of surveys to determine the dose from external sources of radiation used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents; and

6.42.b.2. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose; and

6.42.b.3. Records showing the results of air sampling, surveys, and bioassays required pursuant to paragraphs 6.24.a.3.A and 6.24.a.3.B; and

6.42.b.4. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

6.42.c. Upon termination of the registration, the registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the agency for transfer to the agency.

6.43. Records of Tests for Leakage or Contamination of Sealed Sources. Records of tests for leakage or contamination of sealed sources as required by section 6.15 shall be kept in units of becquerel or microcurie and maintained for inspection by the agency for five years after the records are made.

6.44. Records of Prior Occupational Dose.

6.44.a. The registrant shall retain the records of prior occupational dose and exposure history as specified in section 6.9 on agency form y or equivalent until the agency terminates each pertinent registration requiring this record. The registrant shall retain records used in preparing Agency Form Y or equivalent for three years after the record is made.

6.44.b. Upon termination of the registration, the registrant shall permanently store records on Agency Form Y or equivalent, or shall make provision with the agency for transfer to the agency.

6.45. Records of Planned Special Exposures.

6.45.a. For each use of the provisions of section 6.10 for planned special exposures, the registrant shall maintain records that describe:

6.45.a.1. The exceptional circumstances requiring the use of a planned special exposure;

6.45.a.2. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

6.45.a.3. What actions were necessary;

6.45.a.4. Why the actions were necessary;

6.45.a.5. What precautions were taken to assure that doses were maintained ALARA;

6.45.a.6. What individual and collective doses were expected to result; and

6.45.a.7. The doses actually received in the planned special exposure.

6.45.b. The registrant shall retain the records until the agency terminates each pertinent registration requiring these records.

6.46. Records of Individual Monitoring Results.

6.46.a. Recordkeeping Requirement. Each registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to section 6.17, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before July 1, 2001 need not be changed. These records shall include, when applicable:

6.46.a.1. The deep dose equivalent to the whole body, eye dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities; and

6.46.a.2. The estimated intake of radionuclides, see section 6.6;

6.46.a.3. The committed effective dose equivalent assigned to the intake of radionuclides;

6.46.a.4. The specific information used to calculate the committed effective dose equivalent pursuant to subsection 6.8.c;

6.46.a.5. The total effective dose equivalent when required by section 6.6; and

6.46.a.6. The total of the deep dose equivalent and the committed dose to the organ receiving the highest total dose.

6.46.b. Recordkeeping Frequency. The registrant shall make entries of the records specified in subsection 6.46.a at intervals not to exceed one year.

6.46.c. Recordkeeping Format. The registrant shall maintain the records specified in subsection 6.46.a on Agency Form Z, in accordance with the instructions for Agency Form Z, or in clear and legible records containing all the information required by Agency Form Z.

6.46.d. The registrant shall maintain the records of dose to an embryo or fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

6.46.e. The registrant shall retain each required form or record until the agency terminates each pertinent registration requiring the record.

6.47. Records of Dose to Individual Members of the Public.

6.47.a. Each registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public. See section 6.13.

6.47.b. The registrant shall retain the records required by section 6.47.a until the agency terminates each pertinent registration requiring the record.

6.48. Records of Waste Disposal.

6.48.a. Each registrant shall maintain records of the disposal of registered materials made pursuant to sections 6.33, 6.34, 6.35 and 6.36, of this rule.

6.48.b. The registrant shall retain the records required by subsection 6.48.a until the agency terminates each pertinent registration requiring the record.

6.49. Records of Testing Entry Control Devices for Very High Radiation Areas.

6.49.a. Each registrant shall maintain records of tests made pursuant to subdivision 6.21.b.9 on entry control devices for very high radiation areas. These records must include the date, time, and results of each such test of function.

6.49.b. The registrant shall retain the records required by subsection 6.49.a for three years after the record is made.

6.50. Form of Records. Each record required by section 6 shall be legible throughout the specified retention period. The record shall be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period or the record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, shall include all pertinent information, such as stamps, initials, and signatures. The registrant shall maintain adequate safeguards against tampering with and loss of records.

6.51. Reports

6.51.a. Report to Employees and Others of Radiation Dosage. Each registrant, at the request of any individual employed or associated with him, shall advise such individual annually of the individual's exposure to radiation as shown in records maintained by the registrant pursuant to section 6.46.

6.51.b. Report to Former Employees and Others of Exposure to Radiation.

6.51.b.1. A registrant, at the request of any individual formerly employed or associated with him (i.e., student, craftsman, etc.) shall furnish to such individual a report of his exposure to radiation as shown in records maintained pursuant to section 6.46. Such report shall be furnished within 30 days from the time the request is made and shall cover each calendar quarter of the individual's employment or association involving exposure to radiation, or such lesser period as may be requested by the individual. The report shall also include the results of any calculations and analysis of radioactive material deposited in the body of the individual and made pursuant to the provisions of subsection 6.6.e. The report shall be in writing and contain the following statement:

"This report is furnished to you under the provisions of the West Virginia Bureau for Public Health's rule entitled, Radiological Health Rules. You should preserve this report for future reference."

6.51.b.2. The individual's request should include appropriate identifying data, such as social security number and dates and locations of employment of association.

6.52. Reports of Stolen, Lost, or Missing Registered Sources of Radiation.

6.52.a. Telephone Reports. Each registrant shall report to the agency by telephone as follows:

6.52.a.1. Immediately after its occurrence becomes known to the registrant, stolen, lost, or missing registered radioactive material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix C under such circumstances that it appears to the registrant that an exposure could result to individuals in unrestricted areas; or

6.52.a.2. Within 30 days after its occurrence becomes known to the registrant, lost, stolen, or missing registered radioactive material in an aggregate quantity greater than 10 times the quantity specified in Table 64-23 G that is still missing;

6.52.a.3. Immediately after its occurrence becomes known to the registrant, a stolen, lost, or missing radiation machine.

6.52.b. Written Reports. Each registrant required to make a report pursuant to subsection 6.51.a shall, within 30 days after making the telephone report, make a written report to the agency setting forth the following information:

6.52.b.1. A description of the registered source of radiation involved, including, for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model and serial number, type and maximum energy of radiation emitted;

6.52.b.2. A description of the circumstances under which the loss or theft occurred;

6.52.b.3. A statement of disposition, or probable disposition, of the registered source of radiation involved;

6.52.b.4. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

6.52.b.5. Actions that have been taken, or will be taken, to recover the source of radiation; and

6.52.b.6. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of registered sources of radiation.

6.52.c. Subsequent to filing the written report, the registrant shall also report additional substantive information on the loss or theft within 30 days after the registrant learns of such information.

6.52.d. The registrant shall prepare any report filed with the agency pursuant to section 6.51, so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

6.53. Notification of Incidents

6.53.a. Immediate Notification. Each registrant shall immediately notify the agency by telephone or facsimile of any incident involving any sources of radiation possessed by him and which may have caused or threatens to cause an individual to receive:

6.53.a.1. A total effective dose equivalent exceeding 0.25 Sv (25 rem) or more; or

6.53.a.2. An eye dose equivalent exceeding 0.75 Sv (75 rem) or more; or

6.53.a.3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent

of 2.5 Gy (250 Rad) or more; or

6.53.a.4. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot cells or process enclosures.

6.53.a.5. A loss of one working week or more of the operation of any facilities affected; or

6.53.a.6. Damage to property to property in excess of $100,000.00.

6.53.b. 24 Hour Notification. Each registrant shall, within 24 hours of discovery of the event, notify the agency by telephone or facsimile of any incident involving any sources of radiation possessed by him and which may have caused or threatens to cause an individual to receive, in a period of 24 hours:

6.53.b.1. A total dose equivalent exceeding 0.05 Sv (five rem); or

6.53.b.2. An eye dose equivalent exceeding 0.15 Sv (15 rem); or

6.53.b.3. A shallow dose equivalent to the skin or extremities or a total organ dose equivalent exceeding 0.5 Sv (50 rem); or

6.53.c. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the occupational ALI. This provision does not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures; or

6.53.d. A loss of one day or more on the operation of any facilities affected; or

6.53.e. Damage to property in excess of $1,000.00.

6.53.f. Any report filed with the agency pursuant to this part shall be prepared in such a manner that names of individuals who have received exposure to radiation will be stated in a separate part of the report.

6.53.g. Registrants shall make the reports required by subsections 6.52.a and 6.52.b by initial contact by telephone to the agency and shall confirm the initial facsimile to the agency.

6.53.h. The registrant shall prepare each report filed with the agency pursuant to section 6.52, so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable portion of the report.

6.53.i. The provisions of section 6.52 do not apply to doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported pursuant to section 6.54.

6.54. Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding Limits.

6.54.a. In addition to any notification required by section 6.52, each registrant shall make a report in writing within 30 days to the agency after learning of any of the following occurrences:

6.54.a.1. Incidents for which notification is required by section 6.52;

6.54.a.2. Doses in excess of any of the following:

6.54.a.2.A. The occupational dose limits for adults in section 6.5;

6.54.a.2.B. The occupational dose limits for a minor in section 6.11;

6.54.a.2.C. The limits for an embryo or fetus of a declared pregnant woman in section 6.12;

6.54.a.2.D. The limits for an individual member of the public in section 6.13, or

6.54.a.2.E. Any applicable limit in the registration;

6.54.a.3. Levels of radiation or concentrations of radioactive material in:

6.54.a.3.A. A restricted area in excess of applicable limits in the registration;

6.54.a.3.B. An unrestricted area in excess of 10 times the applicable limit set forth in section 6 or in the registration, whether or not involving exposure of any individual in excess of the limits in section 6.13; or

6.54.a.3.C. For registrants subject to the provisions of the Environmental Protection Agency's generally applicable Environmental Radiation Standards in 40 CFR 190, levels of radiation or releases of radioactive material in excess of those standards, or of registration conditions related to those standards.

6.54.b. In any case where a registrant is required pursuant to the provisions of this section to report to the agency any exposure of an individual to radiation or concentrations of radioactive material, the registrant shall no later than the making of such report to the agency also notify such individual of the nature and extent of exposure. Such notice shall be in writing and shall contain the following statement:

"This report is furnished to you under the provisions of the West Virginia Bureau for Public Health rule entitled, Radiological Health Rules. You should preserve this report for future reference."

6.54.c. Contents of Reports.

6.54.c.1. Each report required by subsection 6.53.a shall describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

6.54.c.1.A. Estimates of each individual's dose;

6.54.c.1.B. The levels of radiation and concentrations of radioactive material involved;

6.54.c.1.C. The cause of the elevated exposures, dose rates, or concentrations; and

6.54.c.1.E. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, generally applicable environmental standards, and associated registration conditions.

6.54.d. Each report filed pursuant to subsection 6.53.a shall include for each individual exposed the name, social security account number, and date of birth. With respect to the limit for the embryo or fetus in section 6.12, the identifiers should be those of the declared pregnant woman. The report shall be prepared so that this information is stated in a separate and detachable portion of the report.

6.54.e. All registrants who make reports pursuant to subsection 6.53.a shall submit the report in writing to the agency.

6.55. Reports of Planned Special Exposures. The registrant shall submit a written report to the agency within 30 days following any planned special exposure conducted in accordance with section 6.10, informing the agency that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by section 6.38.

6.56. Reports of Individual Monitoring.

6.56.a. This section applies to each person registered by the agency to:

6.56.a.1. Possess or use sources of radiation for purposes of industrial radiography pursuant to sections 9 and 11 of this rule; or

6.56.a.2. Possess or use at any time, for processing or manufacturing for distribution pursuant to sections 11 or 12 of this rule, radioactive material in quantities exceeding any one of the quantities listed in Table 64-23 D.

6.56.b Each registrant in a category listed in subsection 6.55.a shall submit an annual report of the results of individual monitoring carried out by the registrant for each individual for whom monitoring was required by section 6.17 during that year. The registrant may include additional data for individuals for whom monitoring was provided but not required. The registrant shall use Agency Form Z or equivalent or electronic media containing all the information required by Agency Form Z.

6.56.c. The registrant shall file the report required by section 6.55, covering the preceding year, on or before April 30 of each year. The registrant shall submit the report to the agency.

6.57. Notifications and Reports to Individuals.

6.57.a. Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in section 13.4 of this rule.

6.57.b. When a registrant is required pursuant to section 6.53 to report to the agency any exposure of an individual to radiation or radioactive material, the registrant shall also notify the individual. Such notice shall be transmitted at a time not later than the transmittal to the agency, and shall comply with the provisions of subsection 13.4.a of this rule.

6.58. Reports of Leaking or Contaminated Sealed Sources. The registrant shall file a report within five days with the agency if the test for leakage or contamination as required pursuant to section 6.15, indicates a sealed source is leaking or contaminated. The report shall include the equipment involved, the test results and the corrective action taken.

6.59. Vacating Premises

6.59.a. Each registrant shall, no less than 30 days before vacating or relinquishing possession or control of premises in which radioactive material has been stored or used, notify the agency in writing of intent to vacate and afford the agency the opportunity to survey the premises for contamination. When deemed necessary by the agency the registrant shall decontaminate said premises in such a manner as the agency may authorize and shall not vacate or relinquish possession or control of said premises without written consent of the agency. Quantities to be used in decommissioning are listed in Table 64-23 L.

6.60. Portable and mobile radiographic equipment must be locked in a secure location, be accessible by password, or have keys removed to prevent unauthorized operation.

§64-23-7. Requirements for Radiation Usage in the Healing Arts.

7.1. Scope -- This section establishes requirements for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and registered in accordance with West Virginia statutes to engage in the healing arts or veterinary medicine. The provisions of this section are in addition to, and not in substitution for, other applicable provisions of this rule.

7.2. Definitions -- As used in this section, the following definitions apply:

7.2.1. Accessible Surface -- the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

7.2.2. Added Filtration -- any filtration which is in addition to the inherent filtration.

7.2.3. Aluminum Equivalent -- the thickness of aluminum (type 1100 alloy) affording the same attenuation, under specified conditions, as the material in question. (The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.)

7.2.4. Assembler -- any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

7.2.5. Attenuation Block -- a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

7.2.6. Automatic Exposure Control (AEC) -- a device which automatically controls one or more technique factors in order to obtain at a preselected locations a required quantity of radiation (Includes devices such as phototimers and ion chambers).

7.2.7. Barrier -- the material, excluding filters, placed in the useful and scattered beam, for protection purposes, to reduce the radiation exposure.

7.2.8. Beam Axis -- a line from the source through the centers of the x-ray fields.

7.2.9. Beam-limiting device -- a device which provides a means to restrict the dimensions of the x-ray field.

7.2.10. C-arm X-ray System -- an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

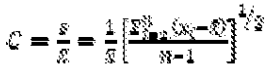
7.2.11. Cephalometric Device -- a device intended for the radiographic visualization and measurement of the dimensions of the human head.

7.2.12. Certified Components -- components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968, the Food and Drug Administration.

7.2.13. Certified System -- any x-ray system which has one or more certified components.

7.2.14. Changeable Filters -- any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

7.2.15. Coefficient of Variation -- the ratio of the standard deviation to the mean value of a set of observations. It is estimated using the following equation:



where:

~~{FUNC s} = Standard deviation of the observed values;~~

~~{OVERLINE FUNC ALIGNC x} = Mean value of observations in sample;~~

~~{FUNC x SUB i} = i_{th} observation in sample;~~

~~{FUNC n} = Number of observations in sample.~~

s = Standard deviation of the observed values;

$\bar{x}$ = Mean value of observations in sample;

x_i = i_{th} observation in sample;

n = Number of observations in sample.

7.2.16. Collimator -- a device or mechanism by which the x-ray beam is restricted in size.

7.2.17. Computed Tomography (CT) -- the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

7.2.18. Control Panel -- that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

7.2.19. Cooling Curve -- the graphical relationship between heat units stored and cooling time.

7.2.20. Dead-man Switch -- a switch so constructed that circuit-closing contact can be maintained only be continuous pressure on the switch by the operator.

7.2.21. Detector -- a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

7.2.22. Diagnostic-type Protective Tube Housing -- an x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the target cannot exceed 100 milliroentgens in one hour when the tube is operated at its maximum continuous rated current for the maximum rated tube potential.

7.2.23. Diagnostic Source Assembly -- the tube housing assembly with a beam-limiting device attached.

7.2.24. Diagnostic X-ray System -- an x-ray system designed for irradiation of any part of the human or animal body for the purpose of diagnosis or visualization.

7.2.25. Diagnostic X-ray Imaging System -- an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

7.2.26. Diaphragm -- a device or mechanism by which the x-ray beam is restricted in size.

7.2.27. Direct Scattered Radiation -- that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam (See "Scattered Radiation").

7.2.28. Entrance Exposure Rate -- the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

7.2.29. Field Emission Equipment -- equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

7.2.30. Filter -- the material placed in the useful beam to absorb preferentially selected radiations.

7.2.31. Fluoroscopic Imaging Assembly -- a subsystem in which x-ray photons produce a visible image. It includes the image receptor or receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

7.2.32. Focal Spot (Actual) -- the area projected on the anode on the x-ray tube bombarded by electrons accelerated from the cathode and from which the useful beam originates.

7.2.33. General Purpose Radiographic X-ray System -- any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

7.2.34. Gonadal Shield -- a protective barrier for the testes or ovaries.

7.2.35. Half-value Layer (HVL) -- the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

7.2.36. Healing Arts Screening -- the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

7.2.37. Heat Unit -- a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

7.2.38. Image Intensifier -- a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

7.2.39. Image Receptor -- any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

7.2.40. Image Receptor Support -- for mammographic systems, that part of the system designed to support the image receptor during mammography.

7.2.41. Inherent Filtration -- the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

7.2.42. Interlock -- a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

7.2.43. Irradiation -- the exposure of matter to ionizing radiation.

7.2.44. kV -- kilovolts.

7.2.45. kVp -- the maximum value of the potential difference across the x-ray tube during an exposure.

7.2.46. kWs -- kilowatt second.

7.2.47. Lead Equivalent -- the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

7.2.48. Leakage Technique Factors -- the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:

7.2.48.a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds, or the minimum obtainable from the unit, whichever is larger;

7.2.48.b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential;

7.2.48.c. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

7.2.49. Light Field - that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is $^1/_4$ of the maximum in the intersection.

7.2.50. Line-voltage Regulation -- the difference between the no-load and the load line potentials expressed as a percent of the load line potential. It is calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100\ (V_n - V_l)/V_l$$

where:

V_n = No-load line potential; and

V_l = Load line potential.

7.2.51. mA - milliampere.

7.2.52. mAs - milliampere second.

7.2.53. Maximum Line Current -- the root-mean-square current in the supply line of an x-ray

machine operating at its maximum rating.

7.2.54. Mobile X-ray Equipment -- x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

7.2.55. Patient -- an individual or animal subjected to healing arts examination, diagnosis, or treatment.

7.2.56. PBL -- See Positive Beam Limitation.

7.2.57. Peak Tube Potential -- the maximum value of the potential difference across the x-ray tube during an exposure.

7.2.58. Phantom -- a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

7.2.59. PID -- a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

7.2.60. Portable X-ray Equipment -- x-ray equipment designed to be hand-carried.

7.2.61. Position Indicating Device -- a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

7.2.62. Positive Beam Limitation -- the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

7.2.63. Primary Protective Barrier -- the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

7.2.64. Protective Apron -- an apron made of radiation absorbing materials used to reduce radiation exposure.

7.2.65. Protective Glove -- a glove made of radiation absorbing materials used to reduce radiation exposure.

7.2.66. Qualified Expert -- an individual who has demonstrated to the satisfaction of the agency that he possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protective needs.

7.2.67. Radiation Detector -- a device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

7.2.68. Radiation Therapy Simulation System -- a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

7.2.69. Radiograph -- an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

7.2.70. Radiographic Imaging System -- any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

7.2.71. Rating -- the operating limits as specified by the component manufacturer.

7.2.72. Recording -- producing a permanent form of an image resulting from x-ray photons.

7.2.73. Registrant as used in this section -- any person who owns or possesses and administratively controls and x-ray system which is used to deliberately expose humans or animals to the useful beam of the system and is required by the provisions of sections 4 and 5 of this rule to register with this agency.

7.2.74. Scattered Radiation -- radiation that, during passage through matter, has been deviated in direction.

7.2.75. Secondary Protective Barrier -- a barrier sufficient to attenuate the stray radiation to the required degree.

7.2.76. Shutter -- a device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

7.2.77. Source-image Distance (SID) -- the distance from the source to the center of the input surface of the image receptor.

7.2.78. Source -- the focal spot of the x-ray tube.

7.2.79. Spot Film -- a radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

7.2.80. Spot-film Device -- a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

7.2.81. SSD -- the distance between the source and the skin entrance plane of the patient.

7.2.82. Stationary X-ray Equipment -- x-ray equipment which is installed in a fixed location.

7.2.83. Stray Radiation -- the sum of leakage and scattered radiation.

7.2.84. Technique Factors -- the following conditions of operation:

7.2.84.a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

7.2.84.b. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;

7.2.84.c. For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

7.2.84.d. For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time

in mAs and the scan time when the scan time and exposure time are equivalent; and

7.2.84.e. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

7.2.85. Termination of Irradiation -- the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

7.2.86. Therapeutic-type Tube Housing:

7.2.86.a. For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm^2 area at a distance of one meter from the source does not exceed one Roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.

7.2.86.b. For x-ray therapy equipment capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm^2 area at a distance of one meter from the source does not exceed 0.1 percent of useful beam dose rate at one meter from the source for any of its operating conditions.

7.2.87. Tomogram -- the depiction of the x-ray attenuation properties of a section through the body.

7.2.88. Tube Housing Assembly -- the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

7.2.89. Tube Rating Chart -- the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

7.2.90. Useful Beam -- the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

7.2.91. Variable-aperture Beam-limiting Device -- a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

7.2.92. Visible Area -- that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

7.2.93. X-ray Exposure Control -- a device, switch, button or other similar means by which an operator initiates or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

7.2.94. X-ray Equipment -- an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

7.2.94.a. Mobile X-ray Equipment -- x-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

7.2.94.b. Portable X-ray Equipment -- x-ray equipment designed to be hand-carried.

7.2.94.c. Stationary X-ray Equipment -- x-ray equipment which is installed in a fixed location.

7.2.95. X-ray Field -- that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

7.2.96. X-ray High-voltage Generator -- a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tubes, high-voltage switches, electrical protective devices, and other appropriate elements.

7.2.97. X-ray System -- an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

7.2.98 . X-ray Table -- a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any Table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the Tabletop.

7.2.99. X-ray Tube -- any electron tube which is designed for the conversion of electrical energy into x-ray energy.

7.3. Use of X-Ray Equipment in the Healing Arts and Administrative Requirements

7.3.a. Radiation Safety Requirements The registrant shall be responsible for directing the operation of the x-ray systems under his administrative control. The registrant or the registrant's agent shall assure that the requirements of this rule are met in the operation of the x-ray systems.

7.3.a.1. An x-ray system which does not meet the provisions of this rule shall not be operated for diagnostic purposes.

7.3.a.2. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. See Table 64-23 P for a list of subject matters pertinent to this requirement. The agency may use interview, observation or testing to determine compliance.

7.3.a.3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

7.3.a.3.A. Patient's body part and anatomical size, or body part thickness, or age (for pediatrics), versus technique factors to be utilized;

7.3.a.3.B. Type and size of the film or film-screen combination to be used;

7.3.a.3.C. Type and focal distance of the grid to be used, if any;

7.3.a.3.D. Source to image receptor distance to be used (except for dental intra-oral radiography);

7.3.a.3.E. Type and location of placement of patient shielding (e.g., gonad, etc.) to be used; and

7.3.a.3.F. For mammography, indication of kVp or target or filter combination.

7.3.a.4. The registrant shall create and make available to x-ray operators written safety policies, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

7.3.a.5. Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

7.3.a.5.A. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

7.3.a.5.B. The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material;

7.3.a.5.C. Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

7.3.a.6. Gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

7.3.a.7. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

7.3.a.7.A. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

7.3.a.7.B. Exposure of an individual for the purpose of healing arts screening except as authorized by subdivision 7.3.a.11.

7.3.a.8. When a patient or film must be provided with auxiliary support during a radiation exposure:

7.3.a.8.A. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by subdivision 7.3.a.5, shall list individual projections where holding devices cannot be utilized;

7.3.a.8.B. Written safety procedures, as required by subdivision 7.3.a.5, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

7.3.a.8.C. The human holder shall be instructed in personal radiation safety and protected as required by subdivision 7.3.a.5;

7.3.a.8.D. No individual shall be used routinely to hold film or patients;

7.3.a.8.E. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

7.3.a.8.F. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

7.3.a.9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized.

7.3.a.9.A. The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography and standard film packets for intra-oral use in dental radiography.

7.3.a.9.B. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

7.3.a.9.C. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patients to a stationary x-ray installation.

7.3.a.9.D. X-ray systems subject to section 7.8 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems.

7.3.a.9.E. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

7.3.a.9.E.1. Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;

7.3.a.9.E.2. If of the focused type, be of the proper focal distance for the SIDs being used.

7.3.a.10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of sections 6.5, 6.9, 6.11 and 6.12 of this rule.

7.3.a.11. Healing Arts Screening. Any person proposing to conduct a healing arts program shall not initiate such a program without prior approval of the agency. When requesting such approval, that person shall submit the information outlined in Table 64-23 T. If any information submitted to the agency becomes invalid or outdated, the agency shall be immediately notified.

7.3.a.12. Information and Maintenance Record and Associated Information. The registrant shall maintain the following information for each x-ray system for inspection by the agency:

7.3.a.12.A. Model and serial numbers of all major components, and user's manuals for those components;

7.3.a.12.B. Tube rating charts and cooling curves;

7.3.a.12.C. Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system or systems; and

7.3.a.12.D. A copy of all correspondence with this agency regarding that x-ray system.

7.3.a.13. X-Ray Utilization Log. Except for veterinary facilities, each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were

performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

7.3.b. X-Ray Film Processing Facilities and Practices.

7.3.b.1. Each installation using a radiographic x-ray system and using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

7.3.b.1.A. Manually developed film:

7.3.b.1.A.1. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material; and

7.3.b.1.A.2. The temperature of solutions in the tanks shall be maintained within the range of 60 °F to 80 °F (16 °C to 27 °C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the time-temperature chart in Table 64-23 M.

7.3.b.1.A.3. Devices shall be utilized which will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

7.3.b.1.B. Automatic processors and other closed processing systems:

7.3.b.1.B.1. Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using Table 64-23 N.

7.3.b.1.B.2. The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor.

7.3.b.1.B.3. Processing deviations from the requirements of subdivision 7.3.b.1 shall be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry).

7.3.b.2. Other Requirements.

7.3.b.2.A. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

7.3.b.2.B. The darkroom shall be light tight and use proper safe-lighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 (0.05 for mammography) when exposed in the darkroom for two minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

7.3.b.2.C. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

7.3.b.2.D. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

7.3.b.2.E. Film cassettes and intensifying screens shall be inspected periodically and

shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

7.3.b.2.F. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a senstometric test for normal ranges of base plus fog and speed.

7.3.b.2.G. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

7.4. Shielding Plan Review.

7.4.a. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be submitted to the agency for review and approval. The required information is denoted in Tables 64-23 Q and R.

7.4.b. The agency may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

7.4.c. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in sections 6.5, 6.9 - 6.14 of this rule.

7.4.d. After installation of a radiation machine, the registrant shall maintain for inspection by the agency:

7.4.d.1. The maximum rated technique factors of each machine;

7.4.d.2. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

7.4.d.2.A. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

7.4.d.2.B. The Type And thickness of materials, or lead equivalency, of each protective barrier.

7.5. Prohibited Use -- No registrant shall operate or permit the operation of x-ray equipment unless the equipment and installation meet the applicable requirements of this rule.

7.6. General Requirements for All Diagnostic X-Ray Systems. In addition to other requirements of this section, all diagnostic x-ray systems shall meet the following requirements:

7.6.a. Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

7.6.b. Battery Charge Indicator. On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

7.6.c. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not

exceed 25.8 μC/kg (100 milliroentgens in one hour when the x-ray tube is operated at its leakage technique factors). Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

7.6.d. Radiation from Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 μC/kg (two milliroentgens) in one hour at five centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

7.6.e. Beam Quality.

7.6.e.1. Half-Value Layer.

7.6.e.1.A. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 64-23 O. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

7.6.e.1.B. For capacitor energy storage equipment, compliance with the requirements of subdivision 7.6.e.1 shall be determined with the system fully charged and a setting of 10 mAs for each exposure.

7.6.e.1.C. The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials which are permanently between the source and the patient.

7.6.e.2. Filtration Controls. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter or filters and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by subdivision 7.6.e.1 is in the useful beam for the given kVp which has been selected.

7.6.f. Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

7.6.g. Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

7.6.h. Technique Indicators.

7.6.h.1. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

7.6.h.2. The requirement of subdivision 7.6.h.1 may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

7.6.i. Maintaining Compliance. Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the federal x-ray equipment performance standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

7.6.j. Locks. All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

7.7. Fluoroscopic X-Ray Systems. All fluoroscopic x-ray systems used shall be image intensified and meet the following requirements:

7.7.a. Limitation of Useful Beam.

7.7.a.1. Primary Barrier.

7.7.a.1.A. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID.

7.7.a.1.B. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

7.7.a.2. Fluoroscopic Beam Limitation.

7.7.a.2.A. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent of the SID. The sum of the excess length and the excess width shall be no greater than four percent of the SID.

7.7.a.2.B. For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the minimum SID available but at no less than 20 centimeters tabletop to the film plane distance.

7.7.a.2.C. For uncertified fluoroscopic systems without a spot film device, the requirements of paragraph 7.7.a.2.A apply.

7.7.a.2.D. Other Requirements for Fluoroscopic Beam Limitation:

7.7.a.2.D.1. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

7.7.a.2.D.2. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;

7.7.a.2.D.3. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five centimeters by five centimeters or less;

7.7.a.2.D.4. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

7.7.a.2.D.5. For non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

7.7.a.3. Spot-film Beam Limitation. Spot-film devices shall meet the following requirements:

7.7.a.3.A. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

7.7.a.3.B. Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent of the SID;

7.7.a.3.C. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters by five centimeters;

7.7.a.3.D. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent of the SID; and

7.7.a.3.E. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

7.7.a.4. Override. If a means exists to override any of the automatic x-ray field size adjustments required in subdivisions 7.7.a.2 and 7.7.a.3, that means:

7.7.a.4.A. Shall be designed for use only in the event of system failure;

7.7.a.4.B. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and

7.7.a.4.C. Shall be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

7.7.b. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposures at any time, but means may be provided to permit completion of any single exposure of the series in process.

7.7.c. Exposure Rate Limits.

7.7.c.1. Entrance Exposure Allowable Limits.

7.7.c.1.A. Fluoroscopic equipment which is provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 2.6 mC/kg (10 Roentgens) per minute at the point where the center of the

useful beam enters the patient, except:

7.7.c.1.A.1. During recording of fluoroscopic images; or

7.7.c.1.A.2. When an optional high level control is provided. ~~When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of one and three-tenths (1.3) mC/kg (five [5] Roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.~~

7.7.c.1.A.2.1. Equipment provided with an AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.6 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

7.7.c.1.A.2.2. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.6 mC/kg (ten roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

7.7.c.1.B. Fluoroscopic equipment which is not provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 1.3 mC/kg (five Roentgens) per minute at the point where the center of the useful beam enters the patient, except:

7.7.c.1.B.1. During recording of fluoroscopic images; or

7.7.c.1.B.2. When an optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

7.7.c.1.C. Compliance with the requirements of subsection 7.7.c shall be determined as follows:

7.7.c.1.C.1. If the source is below the x-ray Table, the exposure rate shall be measured one (1) centimeter above the Tabletop or cradle;

7.7.c.1.C.2. If the source is above the x-ray Table, the exposure rate shall be measured at 30 centimeters above the Tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

7.7.c.1.C.3. For a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly;

7.7.c.1.C.4. For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

7.7.c.2. Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows: [5]

7.7.c.2.A. Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate;

7.7.c.2.B. Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in subdivision 7.3.a.12. The measurement results shall be stated in coulombs per kilogram (Roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results;

7.7.c.2.C. Conditions of periodic measurement of typical entrance exposure rate are as follows:

7.7.c.2.C.1. The measurement shall be made under the conditions that satisfy the requirements of 7.7.c.2.C.2.;

7.7.c.2.C.2. The kVp, mA, and other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

7.7.c.2.C.3. The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage or kilovoltage to satisfy the conditions of subparagraph 7.7.c.2.C.2;

7.7.c.2.D. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

7.7.c.2.D.1. The measurement shall be made under the conditions that satisfy the requirements of subparagraph 7.7.c.2.C.2.;

7.7.c.2.D.2. The kVp, mA or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

7.7.c.2.D.3. The x-ray systems that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

7.7.d. Barrier Transmitted Radiation Rate Limits.

7.7.d.1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 μC/kg (two milliroentgens) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (Roentgen)

[5] Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.

per minute of entrance exposure rate.

7.7.d.2. Measuring Compliance of Barrier Transmission.

7.7.d.2.A. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

7.7.d.2.B. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

7.7.d.2.C. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

7.7.d.2.E. Movable grids and compression devices shall be removed from the useful beam during the measurement.

7.7.e. Indication of Potential and Current. During fluoroscopy and cine-fluorography the kV and the mA shall be continuously indicated.

7.7.f. Source-to-Skin Distance. The SSD shall not be less than:

7.7.f.1. 38 centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

7.7.f.2. 35.5 centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

7.7.f.3. 30 centimeters on all mobile fluoroscopes; or

7.7.f.4. 20 centimeters for all mobile fluoroscopes when used for specific surgical applications.

7.7.g. Fluoroscopic Timer.

7.7.g.1. Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting.

7.7.g.2. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

7.7.h. Control of Scattered Radiation.

7.7.h.1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.

7.7.h.2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

7.7.h.2.A. Is at least 120 centimeters from the center of the useful beam; or

7.7.h.2.B. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in subdivision 7.3.a.5.

7.7.h.3. The agency may grant exemptions to subdivision 7.7.h.2 where a sterile field will not permit the use of the normal protective barriers. Where the use of pre-fitted sterilized covers for the barriers is practical, the agency shall not permit such exemption. See Table 64-23 S for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted.

7.7.i. Spot Film Exposure Reproducibility. Fluoroscopic systems equipped with spot film (radiographic) mode shall meet the exposure reproducibility requirements of subsection 7.8.d when operating in the spot film mode.

7.7.j. Radiation Therapy Simulation Systems. Radiation therapy simulation systems shall be exempt from all the requirements of subsection 7.7.c In addition, these systems shall be exempt from:

7.7.j.1. The requirements of subsections 7.7.a and 7.7.d, provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

7.7.j.2. The requirements of subsection 7.7.g if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

7.8. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, or Computed Tomography X-Ray Systems.

7.8.a. Beam Limitation, Except Mammographic Systems. The useful beam shall be limited to the area of clinical interest. This shall be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of subdivision 7.8.h.2 has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

7.8.a.1. General Purpose Stationary and Mobile X-Ray Systems, Including Veterinary Systems (Other than Portable) Installed After the Effective Date of This rule.

7.8.a.1.A. Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used.

7.8.a.1.B. A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

7.8.a.1.C. The agency may grant an exemption on non-certified x-ray systems to paragraphs 7.8.a.1.A and 7.8.a.1.B., provided the registrant makes a written application for such exemption and in that application:

7.8.a.1.C.1. Demonstrates it is impractical to comply with paragraphs 7.8.a.1.A and 7.8.a.1.B; and

7.8.a.1.C.2. The purpose of paragraphs 7.8.a.1.A and 7.8.a.1.B will be met by other methods.

7.8.a.2. Additional Requirements for Stationary General-Purpose X-Ray Systems. In addition to the requirements of subdivision 7.8.a.1, stationary general-purpose x-ray systems, both certified and noncertified, shall meet the following requirements:

7.8.a.2.A. A method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent;

7.8.a.2.B. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

7.8.a.2.C. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

7.8.a.3. X-Ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

7.8.a.4. X-Ray Systems Other Than Those Described in paragraphs 7.8.a.1.A – 7.8.a.1.C and veterinary systems installed prior to the effective date of this rule and all portable veterinary x-ray systems.

7.8.a.4.A. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

7.8.a.4.B. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

7.8.a.4.C. Paragraphs 7.8.a.4.A and 7.8.a.4.B may be met with a system that meets the requirements for a general purpose x-ray system as specified in subdivision 7.8.a.1 or, when alignment means are also provided, may be met with either:

7.8.a.4.C.1. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

7.8.a.4.C.2. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

7.8.b. Radiation Exposure Control.

7.8.b.1. Exposure Initiation. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a "zero" or "off" position if either position is provided.

7.8.b.2. Exposure Indication. Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

7.8.b.3. Exposure Termination. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

7.8.b.3.A. Manual Exposure Control. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for:

7.8.b.3.A.1. Exposure of 0.5 seconds or less; or

7.8.b.3.A.2. During serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

7.8.b.3.B. Automatic Exposure Controls. When an automatic exposure control is provided:

7.8.b.3.B.1. Indication shall be made on the control panel when this mode of operation is selected;

7.8.b.3.B.2. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses;

7.8.b.3.B.3. The minimum exposure time for all equipment other than that specified in subparagraph 7.8.b.3.B.2 shall be equal to or less than 1/60 second or a time interval required to deliver five mAs, whichever is greater;

7.8.b.3.B.4. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

7.8.b.3.B.5. A visible signal shall indicate when an exposure has been terminated at the limits required by subparagraph 7.8.b.3.B.4., and manual resetting shall be required before further automatically timed exposures can be made.

7.8.b.4. Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than one-tenth (0.10) times their sum. This is written as:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

7.8.b.5. Exposure Control Location. The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure.

7.8.b.6. Operator Protection, Except Veterinary Systems.

7.8.b.6.A. Stationary Systems. Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

7.8.b.6.B. Mobile and Portable Systems. Mobile and portable x-ray systems which are:

7.8.b.6.B.1. Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph 7.8.b.6.A;

7.8.b.6.B.2. Used for less than one week at the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection during exposures, or means shall be provided to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly during the exposure.

7.8.b.7. Operator Protection for Veterinary Systems. All stationary, mobile or portable x-ray systems used for veterinary work shall be provided with either a two meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least two and 2.7 meters (nine feet) from the tube housing assembly during exposures.

7.8.c. Source-to-Skin Distance. All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than 30 centimeters, except for veterinary systems.

7.8.d. Exposure Reproducibility. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

7.8.e. Radiation from Capacitor Energy Storage Equipment in Standby Status. Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of 0.5 μC/kg (two milliroentgens) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

7.8.f. Accuracy. Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

7.8.g. mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated:

7.8.g.1. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product C kg^{-1} mAs^{-1} (or mR/mAs)

obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

7.8.g.2. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

7.8.g.3. Measuring Compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

7.8.h. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component or components shall be required to comply with the following additional require mentor requirements which relate to that certified component or components.

7.8.h.1. Beam Limitation for Stationary and Mobile General-Purpose X-Ray Systems.

7.8.h.1.A. There shall be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of one 100 centimeters shall be equal to or less than five centimeters by five centimeters.

7.8.h.1.B. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

7.8.h.1.C. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination three millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter.

7.8.h.2. Beam Limitation and Alignment on Stationary General-Purpose X-Ray Systems Equipped with PBL. If PBL is being used, the following requirements shall be met:

7.8.h.2.A. PBL shall prevent the production of x-rays when:

7.8.h.2.A.1. Either the length or width of the x-ray field in the plane of the image

receptor differs, except as permitted by paragraph 7.8.h.2.C, from the corresponding image receptor dimensions by more than three percent of the SID; or

7.8.h.2.A.2. The sum of the length and width differences as stated in division 7.8.h.2.A.1. without regard to sign exceeds four percent of the SID;

7.8.h.2.B. Compliance with paragraph 7.8.h.2.A shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor;

7.8.h.2.C. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at an SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters;

7.8.h.2.D. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in paragraph 7.8.h.2.A, then any change of image receptor size or SID must cause the automatic return.

7.8.h.3. Beam Limitation for Portable X-Ray Systems. Beam limitation for portable x-ray systems shall meet the beam limitation requirements of subdivisions 7.8.a.1 or 7.8.h.2.

7.8.i. Tube Stands for Portable X-Ray Systems. A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

7.9. Intraoral Dental Radiographic Systems. In addition to the provisions of sections 7.3 and 7.4, the requirements of section 7.9 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in section 7.8. Only systems meeting the requirements of section 7.9 shall be used.

7.9.a. Source-to-Skin Distance (SSD). X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit SSD, to not less than:

7.9.a.1. 18 centimeters if operable above 50 kVp; or

7.9.a.2. 10 centimeters if operable at 50 kVp only.

7.9.b. Beam Limitation. Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that the beam at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters.

7.9.c. Radiation Exposure Control.

7.9.c.1. Exposure Initiation.

7.9.c.1.A. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

7.9.c.1.B. It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

7.9.c.2. Exposure Indication. Means shall be provided for visual indication observable at or

from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

7.9.c.3. Exposure Termination.

7.9.c.3.A. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

7.9.c.3.B. An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 0.5 second or less.

7.9.c.3.C. Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

7.9.c.4. Exposure Duration (Timer) Linearity. For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C kg^{-1} s^{-1} (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

~~$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$~~ $(X_1 - X_2) < 0.1 (X_1 + X_2)$

where X_1 and X_2 are the average values.

7.9.c.5. Exposure Control Location and Operator Protection.

7.9.c.5.A. Stationary x-ray systems installed after the effective date of this rule shall be required to have the x-ray exposure control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

7.9.c.5.B. Mobile and portable x-ray systems which are:

7.9.c.5.B.1. Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph 7.9.c.5.a;

7.9.c.5.B.2. Used for less than one week in the same location shall be provided with either a protective barrier at least two meters (6.5 feet) high for operator protection, or means to allow the operator to be at least 2.7 meters (nine feet) from the tube housing assembly while making exposures.

7.9.d. Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

7.9.e. mA/mAs Linearity. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

7.9.e.1. Equipment Having Independent Selection of X-Ray Tube Current (mA). The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1+X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous.

7.9.e.2. Equipment Having a Combined X-Ray Tube Current-Exposure Time Product (mAs) Selector, But Not a Separate Tube Current (mA) Selector. The average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection.

7.9.e.3. Measuring Compliance. Determination of compliance shall be based on 10 exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

7.9.f. Accuracy. Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications the deviation shall not exceed 10 percent of the indicated value for kVp and 20 percent for time.

7.9.g. kVp Limitations. Dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

7.9.h. Administrative Controls.

7.9.h.1. Patient and film holding devices shall be used when the techniques permit.

7.9.h.2. The tube housing and PID shall not be hand-held during an exposure.

7.9.h.3. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of subsection 7.9.2.

7.9.h.4. Fluoroscopy without image intensification shall not be used in dental examinations.

7.9.h.5. The tube head shall remain stationary when placed in the exposure position.

7.10. Computed Tomography X-Ray Systems.

7.10.a. Definitions. In addition to the definitions provided in section 3 and section 7.2 of this rule, the following definitions shall be applicable to section 7.10:

7.10.a.1. Computed Tomography Dose Index - the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan, that is:

$$\overline{CTDI} = \frac{1}{n\,T} \int_{-7T}^{+7T} D(z)\,dz$$

~~OVERLINE FUNC {CTDI}~~=~~1 OVER {FUNC n~FUNC T}~ INT_{ 7 FUNC T} SUP {+7 FUNC T} FUNC D(FUNC z)~ FUNC dz~~

where:

z = Position along a line perpendicular to the tomographic plane;

D(z) = Dose at position z;

T = Nominal tomographic section thickness;

n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

7.10.a.2. Contrast Scale - the change in the linear attenuation coefficient per ctn relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water;

$\overline{CTN}_x$ = of the material of interest;

$\overline{CTN}_w$ = of water.

~~{OVERLINE FUNC CS}~~=~~{FUnc mu SUB x~\ ~ FUNC mu SUB w} OVER {{OVERLINE FUNC CTN}_FUNC x ~\ ~ {OVERLINE FUNC CTN}_FUNC w}~~

~~where:~~

~~mu SUB FUNC x = Linear attenuation coefficient of the material of interest;~~

~~mu SUB FUNC w = Linear attenuation coefficient of water;~~

~~{ FUNC OVERLINE CTN } SUB FUNC x = of the material of interest;~~

~~{ FUNC OVERLINE CTN } SUB FUNC w = of water.~~

7.10.a.3. CS - Contrast Scale.

7.10.a.4. CT Conditions of Operation - all selectable parameters governing the operation of a

CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in section 7.2.

7.10.a.5. CTDI - Computed Tomography Dose ID Index.

7.10.a.6. CT Gantry - the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

7.10.a.7. CTN - CT Number.

7.10.a.8. CT Number - the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

~~{OVERLINE FUNC CTN}~~=~~{FUNC k~(FUnc mu SUB x~\ ~ FUNC mu SUB w)} OVER { mu_func w}~~

$$\overline{\text{CTN}} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of one thousand (1,000) when the Hounsfield scale of CTN is used;

μ_x = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water.

~~where:~~

~~FUNC k= A constant, a normal value of one thousand (1,000) when the Hounsfield scale of ctn is used;~~

~~mu SUB FUNC x = Linear attenuation coefficient of the material of interest;~~
~~mu SUB FUNC w = Linear attenuation coefficient of water.~~

7.10.a.9. Dose Profile - the dose as a function of position along a line.

7.10.a.10. Elemental Area - he smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

7.10.a.11. Multiple Tomogram System - a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

7.10.a.12. Noise - the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \bullet \overline{CS} \bullet s}{\mu_w}$$

~~where:~~

~~$\overline{CS}$ = Linear attenuation coefficient of the material of interest.~~
~~μ_w = Linear attenuation coefficient of water.~~
~~s = Standard deviation of the CTN of picture elements in a specified area of the CT image.~~

~~FUNC S_FUNC n~~=~~{100 ~ CDOT ~ {OVERLINE FUNC CS} ~ CDOT ~ FUNC s} OVER { mu_func w}~~

~~where:~~

~~FUNC OVERLINE { CS } = Linear attenuation coefficient of the material of interest.~~
~~mu SUB FUNC w = Linear attenuation coefficient of water.~~
~~FUNC s = Standard deviation of the CTN of picture elements in a specified area of the CT image.~~

7.10.a.13. Nominal Tomographic Section Thickness - the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

7.10.a.14. Picture Element - an elemental area of a tomogram.

7.10.a.15. Reference Plane - a plane which is displaced from and parallel to the tomographic plane.

7.10.a.16. Scan - the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

7.10.a.17. Scan Increment - the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

7.10.a.18. Scan Sequence - a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

7.10.a.19. Scan Time - the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

7.10.a.20. Single Tomogram System - a CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram..

7.10.a.21. Tomographic Plane - that geometric plane which is identified as corresponding to

the output tomogram.

7.10.a.22. Tomographic ~~S~~section - the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

7.10.b. Requirements for Equipment.

7.10.b.1. Termination of Exposure.

7.10.b.1.A. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices which monitor equipment function.

7.10.b.1.B. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by paragraph 7.10.b.1.A.

7.10.b.1.C. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than 0.5 second duration.

7.10.b.2. Tomographic Plane Indication and Alignment.

7.10.b.2.A. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

7.10.b.2.B. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

7.10.b.2.C. If a device using a light source is used to satisfy the requirements of paragraphs 7.10.b.2.A or 7.10.b.2.B, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

7.10.b.3. Beam-On and Shutter Status Indicators and Control Switches.

7.10.b.3.A. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

7.10.b.3.B. Each emergency button or switch shall be clearly labeled as to its function.

7.10.b.4. Indication of CT Conditions of Operation. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

7.10.b.5. Extraneous Radiation. When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subsection 7.6.c.

7.10.b.6. Maximum Surface CTDI Identification. The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

7.10.b.7. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985.

7.10.b.7.A. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters.

7.10.b.7.B. If the x-ray production period is less than one-half second, the indication of x-ray production shall be accurate for at least 0.5 second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of the human body into the primary beam is possible.

7.10.b.7.C. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from zero to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

7.10.b.7.D. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

7.10.c. Facility Design Requirements.

7.10.c.1. Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

7.10.c.2. Viewing Systems.

7.10.c.2.A. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

7.10.c.2.B. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

7.10.d. Surveys, Calibrations, Spot Checks, and Operating Procedures.

7.10.d.1. Surveys.

7.10.d.1.A. All CT x-ray systems installed after July 1, 2000 and those systems not previously surveyed shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

7.10.d.1.B. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the agency upon request.

7.10.d.2. Radiation Calibrations.

7.10.d.2.A. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

7.10.d.2.B. The calibration of a CT x-ray system shall be performed at intervals specified

by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

7.10.d.2.C. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years.

7.10.d.2.D. CT dosimetry phantoms shall be used in determining the radiation output of a CT x-ray system. Such phantoms shall meet the following specifications and conditions of use:

7.10.d.2.D.1. CT dosimetry phantoms shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantoms shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

7.10.d.2.D.2. CT dosimetry phantoms shall provide means for the placement of a dosimeter or dosimeters along the axis of rotation and along a line parallel to the axis of rotation one centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

7.10.d.2.D.3. Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom;

7.10.d.2.D.4. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

7.10.d.2.E. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

7.10.d.2.F. Calibration shall meet the following requirements:

7.10.d.2.F.1. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

7.10.d.2.F.2. The CTDI[6] along the two axes specified in subparagraph 7.10.d.2.D.2 shall be measured. The CT dosimetry phantom shall be oriented so that the measurement point is one centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant;

7.10.d.2.F.3. The spot checks specified in subdivision 7.10.d.3 shall be made.

7.10.d.2.G. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the agency.

[6] For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic ~~S~~section thickness for that particular system may be utilized.

7.10.d.3. Spot Checks.

7.10.d.3.A. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

7.10.d.3.B. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

7.10.d.3.C. All spot checks shall be included in the calibration required by paragraph 7.10.d.2. and at time intervals and under system conditions specified by a qualified expert.

7.10.d.3.D. Spot checks shall include acquisition of images obtained with the CT dosimetry phantoms using the same processing mode and CT conditions of operation as are used to perform calibrations required by subdivision 7.11.d.2. The images shall be retained, until a new calibration is performed, in two forms as follows:

7.10.d.3.D.1. Photographic copies of the images obtained from the image display device; and

7.10.d.3.D.2. Images stored in digital form on a storage medium compatible with the CT x-ray system.

7.10.d.3.E. Written records of the spot checks performed shall be maintained for inspection by the agency.

7.10.d.4. Operating Procedures.

7.10.d.4.A. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

7.10.d.4.B. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

7.10.d.4.B.1. Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

7.10.d.4.B.2. Instructions on the use of the CT dosimetry phantoms including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

7.10.d.4.B.3. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

7.10.d.4.B.4. A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.

7.10.d.4.C. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

7.11. Mammography.

7.11.a. Equipment Standards. Only x-ray systems meeting the following standards shall be used.

7.11.a.1. System Design. The x-ray system shall be specifically designed for mammography.

7.11.a.2. Image Receptor. The image receptor systems and their individual components shall be specifically designed for or appropriate for mammography. Each screen-film mammography system must have, at a minimum, both an 18 by 24 cm and 24 by 30 cm image receptor and moving grids matched to each image receptor size provided with the system.

7.11.a.3. kVp/Target/Filter. The x-ray system shall have the capability of providing kVp/target/filter combinations compatible with the selected image receptor system.

7.11.a.4. Beam Quality.

7.11.a.4.A. When used with screen-film image receptors, and when the contribution to filtration made by the compression device is included, the useful beam shall have a half-value layer (HVL):

7.11.a.4.A.1. Between the values of: [(measured kVp)/100] and [(measured kVp)/100 + 0.1] millimeters aluminum for molybdenum targets;

7.11.a.4.A.2. At least the value of [(measured kVp)/100] millimeters aluminum for rhodium alloy targets.

7.11.a.4.B. For xeroradiography, the HVL of the useful beam with the compression device in place shall be at least one and not greater than 1.6 mm aluminum, measured at 49 kVp with a tungsten target tube.

7.11.a.5. Resolution. The combination of focal spot size, source-to-image receptor distance and magnification shall result in a resolution of at least 12 line pairs per millimeter (cycles/mm) measured when a resolution pattern is positioned 4.2 cm above all breast supports and when the resolution pattern is either perpendicular to or parallel with the chest wall edge of the image receptor support. The measurement shall be made with the kVp in the range of 25-30 and the mA shall be the highest available for the focal spot size selected.

7.11.a.6. Compression.

7.11.a.6.A. The x-ray system shall be capable of compressing the breast with a force of at least 25 pounds and shall be capable of maintaining this compression for at least three minutes. The maximum force shall be no greater than 40 pounds.

7.11.a.6.B. The chest wall edge of the compression paddle shall extend beyond the chest wall edge of the image receptor by no more than two percent of the source-to-image receptor distance with the compression paddle placed 4.2 cm above the breast support device. With the compression paddle in this position, the chest wall edge of the compression paddle shall not be visible in the acquired image.

7.11.a.7. System capabilities. A mammographic x-ray system utilizing screen-film image receptors shall have:

7.11.a.7.A. The capability of using anti-scatter grids which are:

7.11.a.7.A.1. Integral to the x-ray system;

7.11.a.7.A.2. Available for all image receptor sizes used;

7.11.a.7.B. The capability of automatic exposure control, for systems installed after the effective date of this rule; and

7.11.a.7.C. The capability of displaying post-exposure mAs after an exposure made using an automatic exposure control device, for systems installed after the effective date of this rule.

7.11.a.8. Milliampere-Second Read-Out Accuracy. For those mammographic x-ray systems equipped with automatic exposure control and post-exposure mAs read-out, the indicated mAs read-out shall be within ± 10 percent of the actual mAs delivered.

7.11.a.9. Transmission. For x-ray systems manufactured after September 5, 1978, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure five centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 25.8 nC/kg (0.1 milliroentgen) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

7.11.a.10. Collimation.

7.11.a10.A. The mammographic system shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than two percent of the SID.

7.11.a.10.B. Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

7.11.a.11. Accuracy of kVp. Deviation of actual kVp from the indicated kVp shall not exceed the limits specified by the manufacturer of the x-ray system, or, the actual kVp shall be within ± two kVp of the indicated kVp, whichever limit is more restrictive.

7.11.a.12. Automatic Exposure Control Performance. In addition to subsection 7.8.d, mammographic systems in the AEC mode shall be able to maintain constant film density to within an optical density of ± 0.3 of the average optical density over the kVp range used clinically, using phantoms of BR-12 or other breast equivalent material thicknesses of two centimeters to six centimeters. If the facility has established a technique chart that utilizes varying technical factors for different breast thicknesses, those adjustments in technique may be used when performing this test.

7.11.a.13. Radiation Output Minimum. At 28 kVp, with a focal spot meeting the requirements of paragraph 7.11.a.5, the mammographic system shall be capable of sustaining a minimum output rate of 130 μC/kg/sec (500 mR/sec) for at least three seconds. This output shall be measured at a point 4.2 centimeters from the surface of the breast support device when the SID is at its maximum and the effect of compression paddle attenuation is included.

7.11.a.14. Screen-film Contact. Cassettes shall not be used for mammography if poor contact

of two or more large areas (> one cm in diameter) or a section longer than one cm and >two mm in width along the chest wall edge can be seen in a 40 mesh test.

7.11.a.15. Image quality. The mammographic x-ray imaging system shall be capable of providing an image of a 0.75 mm fiber, 0.32 mm speck group, and a 0.75 mm mass from the conference of Radiation Control Program directors next '92 phantom (or equivalent) on the standard mammographic image receptor system in use at a facility. Mammograms shall not be taken on patients if this minimum is not met. Any fibers, speck groups and masses larger than those specified shall also be imaged.

7.11.a.16. Dose. The mean glandular dose for one craniocaudal view, measured with the phantom referenced in paragraph 7.11.a.15, based on exposure measured at the breast entrance location, and using dose conversion factors specified by the health care financing administration in their medicare mammography survey protocols, shall not exceed the following values:

7.11.a.16.A. 1.5 mGy (150 millirads) for non-grid screen film systems;

7.11.a.16.B. 2.5 mGy (250 millirads) for screen-film systems with grid;

7.11.a.16.C. Four mGy (400 millirads) for xerography systems.

7.11.a.17. Technique Settings. The technique settings used for paragraphs 7.11.a.15 and 7.11.a.16 shall be those used by the facility for its clinical images of a 50 percent adipose, 50 percent glandular, 4.2 cm compressed breast.

7.11.b. Quality Assurance.

7.11.b.1. Quality Assurance Program Required. The registrant shall have a written, on-going equipment quality assurance program specific to mammographic imaging, covering all components of the diagnostic x-ray imaging system, to ensure consistently high-quality images with minimum patient exposure. Responsibilities under this requirement include providing qualified individuals who are to:

7.11.b.1.A. Conduct equipment performance monitoring functions;

7.11.b.1.B. Analyze the monitoring results to determine if there are problems requiring correction;

7.11.b.1.C. Carry out or arrange for the necessary corrective actions when results of quality control tests including those specified in paragraph 7.11.b.3 indicate the need; and

7.11.b.1.D. Maintain records for a minimum of two years documenting that actions required under paragraphs 7.11.b.1.A – 7.11.b.1.C have been completed.

7.11.b.2. Quality Assurance Program Review. At intervals not to exceed 12 months, the registrant shall:

7.11.b.2.A. Have the annual quality control tests specified in paragraph 7.11.b.3 performed by a qualified individual (table 64-23 P) and obtain the results of those tests, incorporating them into the records specified in paragraph 7.11.b.1.D; and

7.11.b.2.B. Conduct a review of the effectiveness of the quality assurance program required in paragraph 7.11.b.1 and maintain a written report of such review. Records of annual reviews shall be maintained for a minimum of two years and shall be available for agency review.

7.11.b.3. Equipment Quality Control Tests. The registrant shall ensure that the following

quality control tests are performed when applicable equipment or components are initially installed, or replaced or serviced (if such servicing affects test results), and performed thereafter at least as often as the frequency specified. If such tests indicate the need for corrective action, based on limits defined here, or in subsection 7.11.a., patient mammography may not be performed until correction is accomplished.

7.11.b.3.A. Processor performance by sensitometric - daily, or day of use, prior to the first patient exposure. For any mammography registrant using film processors at multiple locations, such as a mobile service, each processor shall be subject to this requirement. Corrective action shall be taken when:

7.11.b.3.A.1. Deviations of ± 0.15 or more in optical density from established operating levels occur for readings of mid-density (MD) and density difference (DD) on the sensitometric control charts;

7.11.b.3.A.2. Base plus fog (B+F) exceeds the established operating level by more than 0.03 in optical density.

7.11.b.3.B. Resolution - upon tube installation or replacement and every 12 months.

7.11.b.3.C. Focal spot size - upon tube installation or tube replacement only.

7.11.b.3.D. Half-value layer - 12 months.

7.11.b.3.E. kVp accuracy and reproducibility - 12 months.

7.11.b.3.F. Output reproducibility, mA linearity, and mR/mAs - 12 months.

7.11.b.3.G. Automatic exposure control reproducibility and performance (response to kVp and phantom thickness variations): 12 months.

7.11.b.3.H. Screen-film contact and screen artifact detection: Six months.

7.11.b.3.I. Compression device performance (releases, level of force, etc): Six months.

7.11.b.3.J. Collimator alignment: 12 months.

7.11.b.3.K. Primary or secondary barrier transmission - upon initial x-ray system installation and significant modification of the system or the facility.

7.11.b.3.L. Image quality (using a test "phantom," which simulates the composition of the breast and includes simulations of breast structures) - monthly for stationary systems, on each day of use for mobile systems, and upon significant service or modification of any mammographic system.

7.11.b.3.M. Densitometer accuracy check: Every six months.

7.11.b.3.N. If xeroradiography is used, the quality assurance procedures and frequencies recommended by the manufacturer shall be followed.

7.11.b.4. Additional Quality Control Requirements. The registrant shall perform the following observations and procedures according to the frequency noted and record the results. Corrections of problems noted shall be made and recorded. Records shall be maintained over the most recent two year period.

7.11.b.4.A. Retake Analysis: The earlier of three months, or 250 patients.

7.11.b.4.B. Viewbox uniformity: Six months.

7.11.b.4.C. Darkroom integrity (safelight condition, light leaks, etc.): Six months.

7.11.b.4.D. Screen cleaning: Weekly.

7.11.c. Additional Facility Requirements.

7.11.c.1. Masks. Masks shall be provided on the viewboxes to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the exposed area of the film.

7.11.c.2. Film Processing.

7.11.c.2.A. Film processors utilized for mammography shall be adjusted to and operated at the specifications recommended by the mammographic film manufacturer, or at other settings such that the sensitometric performance is at least equivalent.

7.11.c.2.B. Clinical films and phantom image quality films shall be processed within 10 hours of exposure.

7.11.c.3. Instruments and Devices. An image quality phantom, sensitometer, and a calibrated densitometer shall be available to each facility in order to comply with the quality control test frequencies specified in paragraph 7.11.b.3.

7.11.c.4. Operator Qualifications. The operator of the x-ray machine shall be certified by the American Registry of Radiologic Technologists or an equivalent state licensing body and shall have had specialized training in mammography.

7.11.c.5. Physician Qualifications. The physician interpreting the mammograms shall be certified by the American Board of Radiology, the American Osteopathic Board of Radiology, or board eligible, or equivalent, and shall have had specialized training in mammography and image interpretation.

7.11.c.6. Physicist Qualifications. The person performing evaluation of mammographic system performance in accordance with this rule shall be certified by the American Board of Radiology, the American Board of Medical Physics, or with academic and experience required for board certification, or equivalent, or recognized as competent by an appropriate state agency.

7.11.c.7. Image Retention. Clinical images shall be retained for a minimum of five years.

7.11.c.8. Retake Rate. Corrective action shall be taken if the retake rate exceeds five percent. The retake rate shall be calculated as [repeated + rejected films]/ total number of clinical films.

7.11.c.9. Darkroom Fog. Darkroom fog levels shall not exceed 0.05 in optical density when sensitized mammographic film of the type used in the facility is exposed to darkroom conditions with safelight on for two minutes. Film shall be sensitized by exposing it to sufficient light from an appropriate intensifying screen or sensitometer so that after processing an optical density of 1.2 - 1.5 is achieved.

7.12. Therapeutic Radiation Machines.

7.12.a. Purpose and Scope.

7.12.a.1. This section establishes requirements, for which the registrant is responsible, for use of therapeutic radiation machines. The provisions of this section are in addition to, and not in

substitution for, other applicable provisions of this rule.

7.12.a.2. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria established by subsection 12.3.c.

7.12.b. Definitions. As used in this section, the following definitions apply:

7.12.b.1. Absorbed Dose (D) -- the mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM.. The SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the Gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

7.12.b.2. Absorbed Dose Rate -- absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

7.12.b.3. Accessible Surface -- surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

7.12.b.4. Added Filtration -- any filtration which is in addition to the inherent filtration.

7.12.b.5. Air Kerma (K) -- the kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM.. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

7.12.b.6. Barrier -- a barrier of radiation absorbing materials used to reduce radiation exposure.

7.12.b.7. Beam Axis -- the axis of rotation of the beam limiting device.

7.12.b.8. Beam-limiting Device -- a field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

7.12.b.9 Beam Monitoring System -- a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

7.12.b.10. Beam Scattering Foil -- a thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

7.12.b.11. Bent Beam Linear Accelerator -- a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

7.12.b.12. Changeable Filters -- any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

7.12.b.13. Contact Therapy System -- a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five (5) centimeters.

7.12.b.14. Detector -- a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

7.12.b.15. Dose Monitor Unit (DMU) -- a unit response from the beam monitoring system from which the absorbed dose can be calculated.

7.12.b.16. External Beam Radiation Therapy -- therapeutic irradiation in which the source of radiation is at a distance from the body.

7.12.b.17. Field-flattening Filter -- a filter used to homogenize the absorbed dose rate over the radiation field.

7.12.b.18. Filter -- material placed in the useful beam to change beam quality in therapeutic radiation machines subject to subsection 7.12.f.

7.12.b.19. Gantry -- that part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

7.12.b.20. Gray (Gy) -- the SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the Gray. (one Gy=100 rad).

7.12.b.21. Half-value Layer (HVL) -- the thickness of a specified material which attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate or absorbed dose rate is reduced to one-half of the value measured without the material at the same point.

7.12.b.22. Interlock -- a device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

7.12.b.23. Interruption of Irradiation -- the stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

7.12.b.24. Irradiation -- the exposure of a living being or matter to ionizing radiation.

7.12.b.25. Isocenter -- the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

7.12.b.26. Kilovolt (kV) [kilo electron volt (keV)] -- the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. [Note: current convention is to use kV for photons and keV for electrons.]

7.12.b.27. Lead Equivalent -- the thickness of the material in question affording the same attenuation, under specified conditions, as lead.

7.12.b.28. Leakage Radiation -- radiation emanating from the radiation therapy system except for the useful beam.

7.12.b.29. Light Field -- the area illuminated by light, simulating the radiation field.

7.12.b.30. mA -- milliampere.

7.12.b.31. Megavolt (MV) [mega electron volt (MeV)] -- the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1,000,000 volts in a vacuum. [Note: current convention is to use MV for photons and MeV for electrons.]

7.12.b.32. Monitor Unit (MU) -- a unit response from the beam monitoring system from

which the absorbed dose can be calculated.

~~7.12.b.31~~7.12.b.33. Moving Beam Radiation Therapy -- radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation and rotational therapy.

~~7.12.b.32~~7.12.b.34. Nominal Treatment Distance:

~~7.12.b.32.A~~7.12.b.34.A. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

~~7.12.b.32.B~~7.12.b.34.B. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

~~7.12.b.33~~7.12.b.35. Patient -- an individual subjected to machine produced external beam radiation for the purposes of medical therapy.

~~7.12.b.34~~7.12.b.36. Peak Tube Potential -- the maximum value of the potential difference across the x-ray tube during an exposure.

~~7.12.b.35~~7.12.b.37. Periodic Quality Assurance Check -- a procedure which is performed to ensure that a previous calibration continues to be valid.

~~7.12.b.36~~7.12.b.38. Phantom -- an object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

~~7.12.b.37~~7.12.b.39. Practical Range of Electrons -- corresponds to classical electron range where the only remaining contribution to dose is from Bremsstrahlung X-rays. A further explanation may be found in "Clinical Electron Beam Dosimetry: Report of AAPM Radiation Therapy Committee Task Group 25" [Medical Physics 18(1): 73-109, Jan/Feb. 1991] and ICRU Report 35, "Radiation Dosimetry: Electron Beams with Energies Between 1 and 50 MeV", International Commission on Radiation Units and Measurements, September 15, 1984.

~~7.12.b.38~~7.12.b.40. Primary Dose Monitoring System -- a system which will monitor the useful beam during irradiation and which will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

~~7.12.b.39~~7.12.b.41. Primary Protective Barrier -- the material, excluding filters, placed in the useful beam.

~~7.12.b.40~~7.12.b.42. Protective Barrier -- a barrier of radiation absorbing materials used to reduce radiation exposure.

~~7.12.b.41~~7.12.b.43. Radiation Detector -- a device which, in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

~~7.12.b.42~~7.12.b.44. Radiation Field -- the material which attenuates stray radiation.

~~7.12.b.43~~7.12.b.45. Radiation Head -- the structure from which the useful beam emerges.

~~7.12.b.44~~7.12.b.46. Radiation Therapy Physicist -- an individual qualified in accordance

with Paragraph 7.12.c.4.

~~7.12.b.45~~7.12.b.47. Redundant Beam Monitoring System -- a combination of two dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

~~7.12.b.46~~7.12.b.48. Scattered Radiation -- ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

~~7.12.b.47~~7.12.b.49. Secondary Dose Monitoring System -- a system which will terminate irradiation in the event of failure of the primary dose monitoring system.

~~7.12.b.48~~7.12.b.50. Secondary Protective Barrier -- the material which attenuates stray radiation.

~~7.12.b.49~~7.12.b.51. Shadow Tray -- a device attached to the radiation head to support auxiliary beam blocking material.

~~7.12.b.50~~7.12.b.52. Shutter -- a device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

~~7.12.b.51~~7.12.b.53. Sievert (Sv) -- the SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the Sievert. (One Sv=100 rem).

~~7.12.b.52~~7.12.b.54. Simulator (Radiation Therapy Simulation System) -- any x-ray system intended for localizing the volume to be exposed during radiation therapy and reproducing the position and size of the therapeutic irradiation field.

~~7.12.b.53~~7.12.b.55. Source -- the region or material from which the radiation emanates.

~~7.12.b.54~~7.12.b.56. Source-skin Distance (SSD) -- the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source to the surface of the irradiated object or patient.

~~7.12.b.55~~7.12.b.57. Stationary beam radiation therapy -- radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

~~7.12.b.56~~7.12.b.58. Stray Radiation -- the sum of leakage and scattered radiation.

~~7.12.b.57~~7.12.b.59. Target -- that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

~~7.12.b.58~~7.12.b.60. Target-skin Distance (TSD) -- the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source to the surface of the irradiated object or patient.

~~7.12.b.59~~7.12.b.61. Tenth-value Layer (TVL) -- ~~s~~ the thickness of a specified material which attenuates x-radiation or gamma radiation to an extent such that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point.

~~7.12.b.60~~7.12.b.62. Termination of Irradiation -- the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

~~7.12.b.61~~7.12.b.63. Therapeutic Radiation Machine -- x-ray or electron-producing equipment designed and used for external beam radiation therapy.

~~7.12.b.62~~7.12.b.64. Tube -- an x-ray tube, unless otherwise specified.

~~7.12.b.63~~7.12.b.65. Tube Housing Assembly -- the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

~~7.12.b.64~~7.12.b.66. Useful Beam -- the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

~~7.12.b.65~~7.12.b.67. Virtual Source -- a point from which radiation appears to originate.

~~7.12.b.66~~7.12.b.68. Wedge Filter -- a filter which effects continuous change in transmission over all or a part of the useful beam.

~~7.12.b.67~~7.12.b.69. X-ray Tube -- any electron tube which is designed to be used primarily for the production of x-rays.

7.12.c. General Administrative Requirements for Facilities Using Therapeutic Radiation Machines.

7.12.c.1. The registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been registered with the agency. The registrant or the registrant's agent shall ensure that the requirements of section 7.12 are met in the operation of the therapeutic radiation machines.

7.12.c.2. A therapeutic radiation machine that does not meet the provisions of this rule shall not be used for irradiation of patients.

7.12.c.3. The registrant for any therapeutic radiation machine subject to subsection 7.12.f or 7.12.g shall require the radiation therapy physicist to:

7.12.c.3.A. Be registered with the agency, under the provisions of section 2 of this rule, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units; and

7.12.c.3.B. Be certified by the American Board of Radiology in:

7.12.c.3.B.1. Therapeutic Radiological Physics;

7.12.c.3.B.2. Roentgen-ray and Gamma-ray Physics;

7.12.c.3.B.3. X-ray and Radium Physics;

7.12.c.3.B.4. Radiological Physics;

7.12.c.3.C. Be certified by the American Board of Medical Physics in Radiation

Oncology Physics; or

7.12.c.3.D. Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed one year of full time training in therapeutic radiological physics and also one year of full time work experience under the supervision of a radiation therapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in subdivisions 7.12.d.1, 7.12.f.16 or 7.12.g.20, and 7.12.f.17 or 7.12.g.21 under the supervision of a radiation therapy physicist during the year of work experience.

7.12.c.3.E. Notwithstanding the provisions of paragraph 7.12.c.3.C., certification pursuant paragraphs 7.12.c.3.B. and 7.12.c.3.C. shall be required on or before December 31, 1999, for all persons currently qualifying as a radiation therapy physicist pursuant to paragraph 7.12.c.3.D.

7.12.c.4. Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with this rule.

7.12.c.5. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a licensed practitioner of the healing arts who is specifically identified on the registration. This provision specifically prohibits deliberate exposure of an individual for training, demonstration or other non-healing-arts purposes.

7.12.c.6. Visiting Authorized User.

7.12.c.6.A. Notwithstanding the provisions of subdivision 7.12.c.5, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's registration for up to 60 days per calendar year under the following conditions:

7.12.c.6.A.1. The visiting authorized user has the prior written permission of the registrant's management and, if the use occurs on behalf of an institution, the institution's radiation safety committee; and

7.12.c.6.A.2. The visiting authorized user meets the requirements established for authorized users in paragraph 7.12.c.3.B; and

7.12.c.6.a.3. The registrant maintains copies of all records specified by subdivision 7.12.c.6 for five years from the date of the last visit.

7.12.c.6.B. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the registrant's quality management program. In addition to the requirements of section 7.12, these individuals are also subject to the requirements of sections 6.5, 6.9 and 6.17 of this rule.

7.12.c.7. Information and Maintenance Record and Associated Information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the agency:

7.12.c.7.A. Report of acceptance testing;

7.12.c.7.B. Records of all surveys, calibrations, and periodic quality assurance checks of the therapeutic radiation machine required by section 7.12, as well as the names of persons who performed such activities;

7.12.c.7.C. Records of maintenance and modifications performed on the therapeutic radiation machine after July 1, 2001, as well as the names of persons who performed such services;

7.12.c.7.D. Signature of person authorizing the return of therapeutic radiation machine to clinical use after service, repair, or upgrade.

7.12.c.8. Records Retention. All records required by section 7.12. shall be retained until disposal is authorized by the agency unless another retention period is specifically authorized in section 7.12. All required records shall be retained in an active file from at least the time of generation until the next agency inspection. Any required record generated prior to the last agency inspection may be microfilmed or otherwise archived as long as a complete copy of said record can be retrieved until such time as the agency authorizes final disposal.

7.12.d. General Technical Requirements for Facilities Using Therapeutic Radiation Machines.

7.12.d.1. Protection Surveys.

7.12.d.1.A. The registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with subsection 7.12.h. The radiation protection survey shall be performed by, or under the direction of, a radiation therapy physicist or a qualified expert and shall verify that, with the therapeutic radiation machine in a "BEAM-ON" condition, with the largest clinically available treatment field and with a scattering phantom in the useful beam of radiation:

7.12.d.1.A.1. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in subsection 6.5.a of this rule.; and

7.12.d.1.A.2. Radiation levels in unrestricted areas do not exceed the limits specified in subsections 6.13.a and 6.13.b of this rule.

7.12.d.1.B. In addition to the requirements of paragraph 7.12.d.1.A, a radiation protection survey shall also be performed prior to any subsequent medical use and:

7.12.d.1.B.1. After making any change in the treatment room shielding;

7.12.d.1.B.2. After making any change in the location of the therapeutic radiation machine within the treatment room;

7.12.d.1.B.3. After relocating the therapeutic radiation machine; or

7.12.d.1.B.4. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room.

7.12.d.1.C. The survey record shall indicate all instances where the facility, in the opinion of the radiation therapy physicist or a qualified expert, is in violation of applicable rules. The survey record shall also include: the date of the measurements; the reason the survey is required; the manufacturer's name; model number and serial number of the therapeutic radiation machine; the instruments used to measure radiation levels; a plan of the areas surrounding the treatment room that were surveyed; the measured dose rate at several points in each area expressed in microsieverts or millirems per hour; the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area; and the signature of the individual responsible for conducting the survey;

7.12.d.1.D. If the results of the surveys required by paragraphs 7.12.d.1.A or 7.12.d.1.B indicate any radiation levels in excess of the respective limit specified in paragraph 7.12.d.1.A, the

registrant shall lock the control in the "OFF" position and not use the unit:

7.12.d.1.D.1. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

7.12.d.1.D.2. Until the registrant has received a specific exemption from the agency.

7.12.d.2. Modification of radiation therapy unit or room before beginning a treatment program. If the survey required by Paragraph 7.12.d.1. indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by subsections 6.13.a and 6.13.b of this rule, before beginning the treatment program the registrant shall:

7.12.d.2.A. Either equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with subsections 6.13.a and 6.13.b of this rule;

7.12.d.2.B. Perform the survey required by subdivision 7.12.d.1 again; and

7.12.d.2.C. Include in the report required by subdivision 7.12.d.4, the results of the initial survey, a description of the modification made to comply with paragraph 7.12.d.2.A, and the results of the second survey; or

7.12.d.2.D. Request and receive a registration amendment under subsection 6.13.c of this rule that authorizes radiation levels in unrestricted areas greater than those permitted by subsections 6.13.a and 6.13.b of this rule.

7.12.d.3. Dosimetry Equipment.

7.12.d.3.A. The registrant shall have a calibrated dosimetry system available for use. The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) accredited dosimetry calibration laboratory (ADCL). The calibration shall have been performed within the previous 24 months and after any servicing that may have affected system calibration. An independent survey shall be conducted by a qualified expert or radiation therapy physicist other that the person performing the original survey prior to the equipment being used except as described in paragraph 7.12.d.1.D.

7.12.d.3.A.1. For beams with energies greater than one MV (one MeV), the dosimetry system shall have been calibrated for Cobalt-60;

7.12.d.3.A.2. For beams with energies equal to or less than one MV (one MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

7.12.d.3.B. The registrant shall have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph 7.12.d.3.A. This comparison shall have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirement in paragraph 7.12.d.3.1;

7.12.d.3.C. The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record shall include: the date; the model numbers and serial numbers of the instruments that were calibrated, inter-compared, or compared as required by paragraphs 7.12.d.3.A and 7.12.d.3.B; the correction factors that were determined; the names of the individuals who performed

the calibration, intercomparison, or comparison; and evidence that the intercomparison was performed by, or under the direct supervision and in the physical presence of, a radiation therapy physicist.

7.12.d.4. Reports of external beam radiation therapy surveys and measurements. The registrant for any therapeutic radiation machine subject to subsections 7.12.f or 7.12.g shall furnish a copy of the records required in subdivisions 7.12.d.1 and 7.12.d.2 to the agency within 30 days following completion of the action that initiated the record requirement.

7.12.e. Quality Management Program. The facility shall implement a quality management program. The facility may use the quality management programs found in either Table 64-23 V or Table 64-23 W.

7.12.f. Therapeutic Radiation Machines of Less Than 500 kV.

7.12.f.1. Leakage Radiation. When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

7.12.f.1.A. Five to 50 kV Systems. The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed one mGy (100 mRad) in any one hour.

7.12.f.1.B. Greater than 50 and less than 500 kV Systems. The leakage air kerma rate measured at a distance of one meter from the target in any direction shall not exceed one cGy (one Rad) in any one hour. This air kerma rate measurement may be averaged over areas no larger than 100 square centimeters. In addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly shall not exceed 30 cGy (30 rad) per hour.

7.12.f.1.C. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs 7.12.f.1.A and 7.12.f.1.B for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the agency.

7.12.f.2. Permanent beam limiting devices. Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

7.12.f.3. Adjustable or Removable Beam Limiting Devices.

7.12.f.3.A. All adjustable or removable beam limiting devices, diaphragms, cones or blocks shall not transmit more than five percent of the useful beam for the most penetrating beam used;

7.12.f.3.B. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

7.12.f.4. Filter System. The filter system shall be so designed that:

7.12.f.4.A. Filters cannot be accidentally displaced at any possible tube orientation;

7.12.f.4.B. For equipment installed after July 1, 2001, an interlock system prevents irradiation if the proper filter is not in place;

7.12.f.4.C. The air kerma rate escaping from the filter slot shall not exceed one cGy (one Rad) per hour at one meter under any operating conditions; and

7.12.f.4.D. Each filter shall be marked as to its material of construction and its thickness.

7.12.f.5. Tube Immobilization.

7.12.f.5.A. The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

7.12.f.5.B. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

7.12.f.6. Source Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five millimeters, and such marking shall be readily accessible for use during calibration procedures.

7.12.f.7. Beam Block. Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, which can be positioned over the entire useful beam exit port during periods when the beam is not in use.

7.12.f.8. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

7.12.f.8.A. A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

7.12.f.8.B. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

7.12.f.8.C. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

7.12.f.8.D. The timer shall permit accurate pre-setting and determination of exposure times as short as one second;

7.12.f.8.E. The timer shall not permit an exposure if set at zero;

7.12.f.8.F. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7.12.f.8.G. Timer shall be accurate to within one percent of the selected value or one second, whichever is greater.

7.12.f.9. Control Panel Functions. The control panel, in addition to the displays required by other provisions in subsection 7.12.f, shall have:

7.12.f.9.A. An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

7.12.f.9.B. An indication of whether x-rays are being produced;

7.12.f.9.C. A means for indicating x-ray tube potential and current;

7.12.f.9.D. The means for terminating an exposure at any time;

7.12.f.9.E. A locking device which will prevent unauthorized use of the therapeutic radiation machine; and

7.12.f.9.F. For therapeutic radiation machines manufactured after July 1, 2001, a positive display of specific filter or filters in the beam.

7.12.f.10. Multiple Tubes. When a control panel may energize more than one x-ray tube:

7.12.f.10.A. It shall be possible to activate only one x-ray tube at any time;

7.12.f.10.B. There shall be an indication at the control panel identifying which x-ray tube is activated; and

7.12.f.10.C. There shall be an indication at the tube housing assembly when that tube is energized.

7.12.f.11. Target-to-Skin Distance (TSD). There shall be a means of determining the central axis TSD to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

7.12.f.12. Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

7.12.f.13. Low Filtration X-ray Tubes. Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

7.12.f.14. Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV. In addition to shielding adequate to meet requirements of subsection 7.12.i, the treatment room shall meet the following design requirements:

7.12.f.14.A. Aural Communication. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel;

7.12.f.14.B. Viewing Systems. Provision shall be made to permit continuous observation of the patient during irradiation and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational.

7.12.f.15. Additional Requirements. Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

7.12.f.15.A. All protective barriers shall be fixed except for entrance doors or beam interceptors;

7.12.f.15.B. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

7.12.f.15.C. Interlocks shall be provided such that all entrance doors, including doors to

any interior booths, shall be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

7.12.f.15.D. When any door referred to in paragraph 7.12.f.15.C is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source shall be reduced to less than one mGy (100 mRad) per hour.

7.12.f.16. Full Calibration Measurements.

7.12.f.16.A. Full calibration of a therapeutic radiation machine subject to subsection 7.12.f shall be performed by, or under the direct supervision of, a radiation therapy physicist:

7.12.f.16.A.1. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

7.12.f.16.A.2. At intervals not exceeding one year; and

7.12.f.16.A.3. Before medical use under the following conditions:

7.12.f.16.A.3(a). Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

7.12.f.16.A.3(b). Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

7.12.f.16.A.4. Notwithstanding the requirements of subparagraph 7.12.f.16.A.3:

7.12.f.16.A.4(a). Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes or energies that are not within their acceptable range; and

7.12.f.16.A.4(b). If the repair, replacement or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. The remaining energies may be validated with quality assurance check procedures against the criteria in part 7.12.f.16.A.3(a).

7.12.f.16.B. To satisfy the requirement of paragraph 7.12.f.16.A, full calibration shall include all measurements recommended for annual calibration by NCRP Report 69, "Dosimetry of X-ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV" (1981).

7.12.f.16.C. The registrant shall maintain a record of each calibration for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray tube; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.

7.12.f.17. Periodic Quality Assurance Checks.

7.12.f.17.A. Periodic quality assurance checks shall be performed on therapeutic radiation machines subject to subsection 7.12.f, which are capable of operation at greater than or equal to 50 kV.

7.12.f.17.B. To satisfy the requirement of paragraph 7.12.f.17.A, quality assurance checks shall meet the following requirements:

7.12.f.17.B.1. The registrant shall perform quality assurance checks in accordance with written procedures established by the radiation therapy physicist; and

7.12.f.17.B.2. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed. The quality assurance check procedures shall specify that the quality assurance check shall be performed during the calibration specified in paragraph 7.12.f.16.A. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in paragraph 7.12.f.16.A, shall be stated.

7.12.f.17.C. The cause for a parameter exceeding a tolerance set by the radiation therapy physicist shall be investigated and corrected before the system is used for patient irradiation;

7.12.f.17.D. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the radiation therapy physicist's quality assurance check procedures, the system shall be recalibrated as required in paragraph 7.12.f.16.A;

7.12.f.17.E. The registrant shall use the dosimetry system described in paragraph 7.12.d.3.B to make the quality assurance check required in paragraph 7.12.f.17.A;

7.12.f.17.F. The registrant shall have the radiation therapy physicist review and sign the results of each radiation output quality assurance check within one month of the date that the check was performed;

7.12.f.17.G. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to subsection 7.12.f are performed at intervals not to exceed one month;

7.12.f.17.H. Notwithstanding the requirements of paragraphs 7.12.f.17.F and 7.12.f.17.G, the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by paragraphs 7.12.f.17.F and 7.12.f.17.G have been performed within the 30 day period immediately prior to said administration;

7.12.f.17.I. To satisfy the requirement of paragraph 7.12.f.17.G, safety quality assurance checks shall ensure proper operation of:

7.12.f.17.I.1. Electrical interlocks at each external beam radiation therapy room entrance;

7.12.f.17.I.2. The "BEAM-ON" and termination switches;

7.12.f.17.I.3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

7.12.f.17.I.4. Viewing systems;

7.12.f.17.I.5. If applicable, electrically operated treatment room doors from inside and outside the treatment room.

7.12.f.17.J. The registrant shall maintain a record of each quality assurance check required by paragraphs 7.12.f.17.A and 7.12.f.17.G for three years. The record shall include: the date of

the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name; model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

7.12.f.18. Operating Procedures.

7.12.f.18.A. The therapeutic radiation machine shall not be used for irradiation of patients unless the requirements of subdivisions 7.12.f.16 and 7.12.f.17 have been met;

7.12.f.18.B. Therapeutic radiation machines shall not be left unattended unless secured pursuant to paragraph 7.12.f.1.E;

7.12.f.18.C. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

7.12.f.18.D. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at one 100 kV;

7.12.f.18.E. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console; and

7.12.f.18.F. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room shall be protected by a barrier sufficient to meet the requirements of section 6.5 of this rule.

7.12.f.19. Possession of Survey Instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with subsection 7.12.f shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 □Sv (one mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with subsection 7.12.h.

7.12.g. Therapeutic Radiation Machines -- photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above).

7.12.g.1. Possession of Survey Instruments. Each facility location authorized to use a therapeutic radiation machine in accordance with subsection 7.12.g shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range ten □Sv (one mrem) per hour to 10 mSv (1000 mrem) per hour. The survey instruments shall be operable and calibrated in accordance with subsection 7.12.h.

7.12.g.2. Leakage Radiation Outside the Maximum Useful Beam in Photon and Electron Modes.

7.12.g.2.A. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e. patient plane), shall not exceed a maximum of two-tenths percent and an average of one-tenth percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall

be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane;

7.12.g.2.B. Except for the area defined in paragraph 7.12.g.2.A, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window shall not exceed five-tenths percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding 100 square centimeters;

7.12.g.2.C. For equipment manufactured after July 1, 2001, the neutron absorbed dose outside the useful beam shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1; and

7.12.g.2.D. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in paragraphs 7.12.g.2.A - 7.12.g.2.C for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the agency.

7.12.g.3. Leakage Radiation Through Beam Limiting Devices.

7.12.g.3.A. Photon Radiation. All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting devices shall not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a 10 centimeter by 10 centimeter radiation field;

7.12.g.3.B. Electron Radiation. All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

7.12.g.3.B.1. A maximum of two percent and average of five-tenths percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven centimeters outside the periphery of the useful beam; and

7.12.g.3.B.2. A maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two centimeters outside the periphery of the useful beam.

7.12.g.3.C. Measurement of Leakage Radiation.

7.12.g.3.C.1. Photon Radiation. Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding 10 square centimeters;

7.12.g.3.C.2. Electron Radiation. Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one centimeter of water equivalent build up material.

7.12.g.4. Filters or Wedges.

7.12.g.4.A. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined;

7.12.g.4.B. If the absorbed dose rate information required by subdivision 7.12.g.1 relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools;

7.12.g.4.C. For equipment manufactured after July 1, 2001 which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

7.12.g.4.C.1. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

7.12.g.4.C.2. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

7.12.g.4.C.3. A display shall be provided at the treatment control panel showing the wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils in use; and

7.12.g.4.C.4. An interlock shall be provided to prevent irradiation if any filter or beam scattering foil selection operation carried out in the treatment room does not agree with the filter or beam scattering foil selection operation carried out at the treatment control panel.

7.12.g.5. Stray radiation in the useful beam. For equipment manufactured after July 1, 2001, the registrant shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation and stray neutron radiation in the useful x-ray beam are in compliance with International Electrotechnical Commission (IEC) Document 601-2-1 (most current revision).

7.12.g.6. Beam Monitors. All therapeutic radiation machines subject to subsection 7.12.g shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

7.12.g.6.A. Equipment manufactured after July 1, 2001 shall be provided with at least two independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

7.12.g.6.B. Equipment manufactured on or before July 1, 2001 shall be provided with at least one radiation detector. This detector shall be incorporated into a useful beam monitoring system;

7.12.g.6.C. The detector and the system into which that detector is incorporated shall meet the following requirements:

7.12.g.6.C.1. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

7.12.g.6.C.2. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

7.12.g.6.C.3. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation; and

7.12.g.6.C.4. For equipment manufactured after July 1, 2001, the design of the beam monitoring systems shall ensure that the:

7.12.g.6.C.4(a). Malfunctioning of one system shall not affect the correct functioning of the other systems; and

7.12.g.6.C.4(b). Failure of either system shall terminate irradiation or prevent the initiation of radiation.

7.12.g.6.C.5. Each beam monitoring system shall have a legible display at the treatment control panel. For equipment manufactured after July 1, 2001, each display shall:

7.12.g.6.C.5.(a). Maintain a reading until intentionally reset;

7.12.g.6.C.5.(b). Have only one scale and no electrical or mechanical scale multiplying factors;

7.12.g.6.C.5(c). Utilize a design such that increasing dose is displayed by increasing numbers; and

7.12.g.6.C.5(d). In the event of power failure, the beam monitoring information required in subparagraph 7.12.g.5.E.3 displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

7.12.g.7. Beam Symmetry.

7.12.g.7.A. Bent-beam linear accelerators subject to subsection 7.12.g shall be provided with auxiliary devices to monitor beam symmetry;

7.12.g.7.B. The devices referenced in paragraph 7.12.g.7.A shall be able to detect field asymmetry greater than 10 percent; and

7.12.g.7.C. The devices referenced in paragraph 7.12.g.7.A shall be configured to terminate irradiation if the specifications in paragraph 7.12.g.7.B cannot be maintained.

7.12.g.8. Selection and Display of Dose Monitor Units.

7.12.g.8.A. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

7.12.g.8.B. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

7.12.g.8.C. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

7.12.g.8.D. For equipment manufactured after July 1, 2001, after termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

7.12.g.9. Air Kerma Rate or Absorbed Dose Rate. For equipment manufactured after July 1,

2001, a system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. In addition:.

7.12.g.9.A. The dose monitor unit rate shall be displayed at the treatment control panel;

7.12.g.9.B. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be a record maintained by the registrant;

7.12.g.9.C. If the equipment can deliver under any fault condition or conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds four Gy (400 Rad); and

7.12.g.9.D. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum values specified in paragraphs 7.12.g.9.B and 7.12.g.9.C for the specified operating conditions. Records of these maximum values shall be maintained at the installation for inspection by the agency.

7.12.g.10. Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy.

7.12.g.10.A. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system;

7.12.g.10.B. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

7.12.g.10.C. For equipment manufactured after July 1, 2001, an indicator on the control panel shall show which monitoring system has terminated irradiation.

7.12.g.11. Termination of Irradiation. It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

7.12.g.12. Interruption of Irradiation. If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Following an interruption it shall be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

7.12.g.13. Timer. A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

7.12.g.13.A. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

7.12.g.13.B. The timer shall be a cumulative timer that activates with an indication of

"BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

7.12.g.13.C. The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

7.12.g.14. Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

7.12.g.14.A. Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

7.12.g.14.B. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

7.12.g.14.C. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

7.12.g.14.D. An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

7.12.g.14.E. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

7.12.g.14.F. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

7.12.g.15. Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

7.12.g.15.A. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

7.12.g.15.B. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

7.12.g.15.C. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

7.12.g.15.D. For equipment manufactured after July 1, 2001, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 601-2-1.

7.12.g.16. Selection of Stationary Beam Radiation Therapy or Moving Beam Radiation Therapy. Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

7.12.g.16.A. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

7.12.g.16.B. The mode of operation shall be displayed at the treatment control panel;

7.12.g.16.C. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

7.12.g.16.D. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

7.12.g.16.E. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For equipment manufactured after July 1, 2001:

7.12.g.16.E.1. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or one cm of linear motion differs by more than 20 percent from the selected value;

7.12.g.16.E.2. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent from the dose monitor unit value selected;

7.12.g.16.E.3. An interlock shall be provided to prevent motion of more than five degrees or one cm beyond the selected limits during moving beam radiation therapy;

7.12.g.16.E.4. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counterclockwise moving beam radiation therapy.

7.12.g.16.E.5. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement.

7.12.g.16.E.6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by subdivision 7.12.g.10; and

7.12.g.16.E.7. For equipment manufactured after July 1, 2001, an interlock system shall be provided to terminate irradiation if movement:

7.12.g.16.E.7.(a). Occurs during stationary beam radiation therapy; or

7.12.g.16.E.7.(b). Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

7.12.g.17. Facility Design Requirements for Therapeutic Radiation Machines Operating Above 500 kV. In addition to shielding adequate to meet requirements of subsection 1.12.i, the following design requirements are made:

7.12.g.17.A. Protective Barriers. All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

7.12.g.17.B. Control Panel. In addition to other requirements specified in section 7.12, the control panel shall also:

7.12.g.17.B.1. Be located outside the treatment room;

7.12.g.17.B.2. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

7.12.g.17.B.3. Provide an indication of whether radiation is being produced; and

7.12.g.17.B.4. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine.

7.12.g.17.C. Viewing Systems. Windows, mirrors, closed-circuit television or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for patient irradiation unless at least one viewing system is operational;

7.12.g.17.D. Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

7.12.g.17.E. Room Entrances. Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "ON" and when it is "OFF";

7.12.g.17.F. Entrance Interlocks. Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

7.12.g.17.G. Beam Interceptor Interlocks. If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with subsections 6.13.a and 6.13.b of this rule, interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barriers;

7.12.g.17.H. Emergency Cutoff Switches. At least 1 emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by subdivision 7.12.g.11. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

7.12.g.17.I. Safety Interlocks. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

7.12.g.17.J. Surveys for Residual Radiation. Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production.

7.12.g.18. Radiation Therapy Physicist Support.

7.12.g.18.A. The services of a radiation therapy physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The radiation therapy physicist shall be responsible for:

7.12.g.18.A.1. Full calibrations required by subdivision 7.12.g.20 and protection

surveys required by subdivision 7.12.d.1;

7.12.g.18.A.2. Supervision and review of dosimetry;

7.12.g.18.A.3. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

7.12.g.18.A.4. Quality assurance, including quality assurance check review required by paragraph 7.12.g.21.E.

7.12.g.18.A.5. Consultation with the authorized user in treatment planning, as needed; and

7.12.g.18.A.6. Perform calculations/assessments regarding misadministrations.

7.12.g.18.B. If the radiation therapy physicist is not a full-time employee of the registrant, the operating procedures required by paragraph 7.12.g.24 shall also specifically address how the radiation therapy physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the radiation therapy physicist can be contacted.

7.12.g.19. Operating Procedures.

7.12.g.19.A. No individual, other than the patient, shall be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

7.12.g.19.B. Therapeutic radiation machines shall not be made available for medical use unless the requirements of subdivisions 7.12.a.1, 7.12.g.20 and subsection 7.12.21 have been met;

7.12.g.19.C. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

7.12.g.19.D. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.

7.12.g.19.E. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used; and

7.12.g.19.F. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

7.12.g.20. Acceptance testing, commissioning and full calibration measurements.

7.12.g.20.A. Acceptance testing, commissioning and full calibration of a therapeutic radiation machine subject to section 7.12. shall be performed by, or under the direct supervision of, a radiation therapy physicist.

7.12.g.20.B. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: Report of AAPM Radiation Therapy Task Group 45" and shall be conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

7.12.g.20.C. Full calibration shall include measurement of all parameters required by Table II of "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" and shall be performed in accordance with "AAPM Code of Practice for Radiotherapy

Accelerators: Report of AAPM Radiation Therapy Task Group 45". Although it shall not be necessary to complete all elements of a full calibration at the same time, all parameters (for all energies) shall be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table ii.

7.12.g.20.D. The radiation therapy physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

7.12.g.20.D.1. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy or multi-mode capabilities shall only require measurements for those modes or energies that are not within their acceptable range; and

7.12.g.20.D.2. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement or modification does not affect all modes or energies, measurements shall be performed on the effected mode or energy that is in most frequent clinical use at the facility. The remaining energies or modes may be validated with quality assurance check procedures against the criteria in subparagraph 7.12.g.20.D.1.

7.12.g.20.E. The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record shall include: the date of the calibration; the manufacturer's name, model number and serial number for the therapeutic radiation machine; the model numbers and serial numbers of the instruments used to calibrate the therapeutic radiation machine; and the signature of the radiation therapy physicist responsible for performing the calibration.

7.12.g.21. Periodic Quality Assurance Checks.

7.12.g.21.A. Periodic quality assurance (QA) checks shall be performed on all therapeutic radiation machines subject to section 7.12 at intervals not to exceed those specified in "comprehensive QA for radiation oncology: report of AAPM radiation therapy committee task group 40";

7.12.g.21.B. To satisfy the requirement of paragraph 7.12.g.21.A, quality assurance checks shall include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in "comprehensive QA for radiation oncology: report of AAPM radiation therapy committee task group 40". Representative sampling shall include all referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months;

7.12.g.21.C. The registrant shall use a dosimetry system that has been inter-compared within the previous 12 months with the dosimetry system described in paragraph 7.12.d.3.A to make the periodic quality assurance checks required in paragraph 7.12.g.21.B;

7.12.g.21.D. The registrant shall perform periodic quality assurance checks required by paragraph 7.12.g.21.A in accordance with procedures established by the radiation therapy physicist;

7.12.g.21.E. The registrant shall review the results of each periodic radiation output check according to the following procedures:

7.12.g.21.E.1. The authorized user and radiation therapy physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the radiation therapy physicist has determined that all parameters are within their acceptable tolerances;

7.12.g.21.E.2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within three treatment days; and

7.12.g.21.E.3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

7.12.g.21.F. Therapeutic radiation machines subject to section 7.12. shall have safety quality assurance checks listed in "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40" performed at intervals not to exceed one week;

7.12.g.21.G. To satisfy the requirement of paragraph 7.12.g.21.F, safety quality assurance checks shall ensure proper operation of:

7.12.g.21.G.1. Electrical interlocks at each external beam radiation therapy room entrance;

7.12.g.21.G.2. Proper operation of the "BEAM-ON", interrupt and termination switches;

7.12.g.21.G.3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

7.12.g.21.G.4. Viewing systems;

7.12.g.21.G.5. Electrically operated treatment room doors from inside and outside the treatment room;

7.12.g.21.G.6. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

7.12.g.21.H. The registrant shall promptly repair any system identified in paragraph 7.12.g.21.G that is not operating properly; and

7.12.g.21.I. The registrant shall maintain a record of each quality assurance check required by paragraphs 7.12.g.21.A and 7.21.g.21.G for three years. The record shall include: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model number and serial number for the instruments used to measure the radiation output of the therapeutic radiation machine; and the signature of the individual who performed the periodic quality assurance check.

7.12.h. Calibration of Survey Instruments.

7.12.h.1. The registrant shall ensure that the survey instruments used to show compliance with section 7.12 have been calibrated before first use, at intervals not to exceed 12 months, and following repair.

7.12.h.2. To satisfy the requirements of subdivision 7.12.h.1, the registrant shall:

7.12.h.2.A. Calibrate all required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and

Technology (NIST);

7.12.h.2.B. Calibrate at least two points on each scale to be calibrated. These points should be at approximately one-third and two-thirds of full-scale; and

7.12.h.3. To satisfy the requirements of subdivision 7.12.h.2, the registrant shall:

7.12.h.3.B. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent; and

7.12.h.3.C. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent if a correction factor or graph is conspicuously attached to the instrument.

7.12.h..3.D. The registrant shall retain a record of each calibration required in subdivision 7.12.h.1 for three years. The record shall include:

7.12.h.3.D.1. A description of the calibration procedure; and

7.12.h.3.D.2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

7.12.h.3.E. The registrant may obtain the services of individuals registered by the agency, the US Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations that contain information required by Paragraph 7.12.h.4. shall be maintained by the registrant.

7.12.i. Shielding and Safety Design Requirements.

7.12.i.1. Each therapeutic radiation machine subject to subsections 7.12.g or 7.12.h shall be provided with such primary or secondary barriers as are necessary to ensure compliance with sections 6.5 and 6.13 of this rule.

7.12.i.2. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for agency approval prior to actual installation of the therapeutic radiation machine. The minimum facility design information that must be submitted is contained in Table 64-23 U.

§64-23-8. Radiation Safety Requirements for Industrial Radiographic Operations.

8.1. Purpose. The rules in this section establish radiation safety requirements for using sources of radiation for industrial radiography. The requirements of this section are in addition to, and not in substitution for, other applicable requirements of this rule.

8.2. Scope. The rules in this section apply to all registrants who use sources of radiation for industrial radiography. Except for those rules of this section clearly applicable only to sealed radioactive sources, both radiation machines and sealed radioactive sources are covered by this section.

8.3 Definitions. As used in this section, the following definitions apply:

8.3.1. Cabinet Radiography -- industrial radiography conducted in an enclosure or cabinet shielded so that radiation levels at every location on the exterior meet the limitations specified in section

6.5 of this rule.

8.3.2. Cabinet X-ray System -- an x-ray system with the x-ray tube installed in an enclosure independent of existing architectural structures except the floor on which it may be placed. The cabinet x-ray system is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not considered a cabinet x-ray system.

8.3.3. Certified Cabinet X-ray System -- an x-ray system which has been certified in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of 21 CFR 1020.40.

8.3.4. Collimator -- a device used to limit the size, shape, and direction of the primary radiation beam.

8.3.5. Field Radiography -- all industrial radiography other than cabinet radiography and shielded room radiography.

8.3.5.a Mobile industrial radiographic equipment -- radiographic equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

8.3.5.b Portable industrial portable radiographic equipment -- radiographic equipment designed to be hand-carried.

8.3.6. Industrial Radiography -- the examination of the macroscopic structure of materials by nondestructive methods using sources of ionizing radiation to produce radiographic images.

8.3.7. Lixiscope -- a portable light-intensified imaging device using a sealed source.

8.3.8. Permanent Radiographic Installation -- an installation or structure designed or intended for radiography and in which radiography is regularly performed.

8.3.9 Personal Supervision -- guidance and instruction provided to a radiographer trainee by a radiographer instructor who is present at the site, in visual contact with the trainee while the trainee is using sources of radiation, and in such proximity that immediate assistance can be given if required.

8.3.10. Radiographer -- any individual who performs or personally supervises industrial radiographic operations and who is responsible to the registrant for assuring compliance with the requirements of this rule and all certificate of registration conditions.

8.3.11. Radiographer Instructor -- any radiographer who has been authorized by the agency to provide on-the-job training to radiographer trainees in accordance with subdivision 8.14.b.2.

8.3.12. Radiographer Trainee -- any individual who, under the personal supervision of a radiographer instructor, uses sources of radiation, related handling tools, or radiation survey instruments during the course of his instruction.

8.3.13. Radiographic Exposure Device -- any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved, or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

8.3.14. Radiographic Personnel -- any radiographer, radiographer instructor, or radiographer trainee.

8.3.15. Residential Location -- any area where structures in which people lodge or live are located, and the grounds on which such structures are located including, but not limited to, houses, apartments, condominiums, and garages.

8.3.16. Shielded Position -- the location within the radiographic exposure device or storage container which, by manufacturer's design, is the proper location for storage of the sealed source.

8.3.17. Shielded Room Radiography -- industrial radiography which is conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets the limitations specified in section 6.5 of this rule and the only access to which is through openings which are interlocked so that the radiation machine will not operate unless all openings are securely closed.

8.3.18. Source Changer -- a device designed and used for replacement of sealed sources in radiographic exposure devices, including those source changers also used for transporting and storage of sealed sources.

8.3.19. Storage Area -- any location, facility, or vehicle which is used to store, to transport, or to secure a radiographic exposure device, a storage container, or a sealed source when it is not in use and which is locked or has a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, container, or source.

8.3.20. Storage Container -- a device in which sealed sources are transported or stored.

8.3.21. Temporary Job Site -- any location where industrial radiography is performed other than the location or locations listed in a specific registration or certificate of registration.

8.3.22. Transport Container -- a package that is designed to provide radiation safety and security when sealed sources are transported and which meets all applicable requirements of the U.S. Department of Transportation.

8.4. Exemptions

8.4.a. Except for the requirements of subsections 8.22.b and 8.22.c, certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this section.

8.4.b. Industrial uses of lixiscopes are exempt from the requirements in this section.

8.5. Limits on Radiation Levels for Radiography Exposure Devices and Storage Containers

8.5.a. Radiographic exposure devices measuring less than four inches 10 cm from the sealed source storage position to any exterior surface of the device shall have no radiation level in excess of 50 milliroentgens 1.29×10^{-5} C/kg per hour at six inches (15cm) from any exterior surface of the device. Radiographic exposure devices measuring a minimum of four inches from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of 200 milliroentgens per hour at any exterior surface, The radiation levels specified are with the sealed source in the shielded position.

8.5.b. Radiographic exposure devices measuring a minimum of four inches 10 cm from the sealed source storage position to any exterior surface of the device, and all storage containers for sealed sources or outer containers for radiographic exposure devices, shall have no radiation level in excess of

200 milliroentgens (5.16×10^{-5} C/kg) per hour at any exterior surface, and 10 milliroentgens (2.58×10^{-6} C/kg) per hour at 39.4 inches (one m) from any exterior surface. The radiation levels specified are with the sealed source in the shielded (i.e., "off") position.

8.6. Locking of Sources of Radiation -- Each source of radiation shall be provided with a lock or outer lockable container designed to prevent unauthorized or accidental production of radiation or removal or exposure of a sealed source and shall be kept locked at all times except when under the direct surveillance of a radiographer or radiographer's assistant, or as may be otherwise authorized pursuant to subsection 8.18.a. Each storage container likewise shall be provided with a lock and kept locked when containing sealed sources except when the container is under the direct surveillance of a radiographer or radiographer's trainee.

8.6.a. Radiographic exposure devices, source changers, and storage containers, prior to being moved from one location to another and also prior to being secured at a given location, shall be locked and surveyed to assure that the sealed source is in the shielded position.

8.6.b. The sealed source shall be secured in its shielded position by locking the exposure device or securing the remote control each time the sealed source is returned to its shielded position. Then a survey shall be performed to determine that the sealed source is in the shielded position pursuant to subsection 8.19.b.

8.7. Storage Precautions

8.7.a. Locked radiographic exposure devices source changers, storage containers, and radiation machines shall be physically secured to prevent tampering or removal by unauthorized personnel.

8.7.b. Radiographic exposure devices, source changers, or transport containers that contain radioactive material shall not be stored in residential locations. This requirement does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the registrant complies with subsection 8.7.c, and if the vehicle does not constitute a permanent storage location as described in subsection 8.7.d.

8.7.c. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in section 6.5 of this rule at the exterior surface of the vehicle.

8.7.d. A storage or use location is permanent if radioactive material is stored at the location for more than 90 days and any one or more of the following applies to the location:

8.7.d.1. Telephone service is established by the registrant;

8.7.d.2. Industrial radiographic services are advertised for or from the location;

8.7.d.3. Industrial radiographic operations are conducted at other sites due to arrangements made from the location.

8.8. Radiation Survey Instruments -- The registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this section and section 12 of this rule. Instrumentation required by this section shall have a range such that two milliroentgens (5.16×10^{-7} C/kg) per hour through one Roentgen (2.58×10^{-4} C/kg) per hour can be measured.

8.8.a. The registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this section and section 6.5 of this rule. Instrumentation required by this section shall have a range such that two milliroentgens (5.16×10^{-7} C/kg)

per hour through one Roentgen (2.58×10^{-4} C/kg) per hour can be measured.

8.8.b. Each radiation survey instrument shall be calibrated:

8.8.b.1. At energies appropriate for use and at intervals not to exceed three months and after each instrument servicing;

8.8.b.2. Such that accuracy within plus or minus 20 percent can be demonstrated; and

8.8.b.3. At two points located approximately one-third (⅓) and two-thirds (⅔) of full-scale on each scale for linear scale instruments; at midrange of each decade, and at two points of at least one decade for logarithmic scale instruments; and at appropriate points for digital instruments.

8.8.c. Records of these calibrations shall be maintained for two years after the calibration date for inspection by the agency.

8.8.d. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

8.9. Leak Testing, Repair, Tagging, Opening, Modification, and Replacement of Sealed Sources

8.9.a. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing, repair, tagging, opening, or any other modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the U.S. Nuclear Regulatory Commission, or any agreement state.

8.9.b. Each sealed source shall be tested for leakage at intervals not to exceed six months. In the absence of a certificate from a transferor that a test has been made within the six-month period prior to the transfer, the sealed source shall not be put into use until tested.

8.9.c. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of removable contamination on the sealed source. An acceptable leak test for sealed sources in the possession of a radiography registrant would be to test at the nearest accessible point to the sealed source storage position or other appropriate measuring point by a procedure to be approved by the agency. The applicant who desires to conduct his own leak test shall establish adequate procedures to be followed in leak testing sealed sources for possible leakage and contamination and shall submit to the agency a description of such procedures including:

8.9.c.1. Instrumentation to be used;

8.9.c.2. Method of performing tests, e.g., points on equipment to be smeared and methods of taking smear; and

8.9.c.3. Pertinent experience of the person who will perform the test.

8.9.d. Records of leak test results shall be kept in units of microcuries (Becquerels) and maintained for inspection by the agency.

8.9.e. Any test conducted pursuant to subsections 8.9.b and 8.9.c of this section which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material shall be considered evidence that the sealed source is leaking. The registrant shall immediately withdraw such defective equipment from use and shall cause it to be decontaminated and repaired or to be disposed of, in accordance with rules of the agency. Within five days after obtaining results of the test, the registrant shall file a report with the agency describing the equipment involved, the test results, and the corrective

action taken.

8.9.f. Each radiographic exposure device shall have permanently attached to it a durable tag at least one inch square bearing the prescribed radiation caution symbol in conventional colors, magenta or purple on a yellow background, and at least the instructions: "Danger--Radioactive Material--Do Not Handle-Notify Civil Authorities if Found."

8.10. Quarterly Inventory -- Each registrant shall conduct a quarterly physical inventory to account for all sources of radiation received or possessed by him. The records of the inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of radioactive material, the location of all sources of radiation, the date of the inventory, the name of the individual making the inventory, the manufacturer, the model and the serial number.

8.11. Utilization Logs -- Each registrant shall maintain current logs, which shall be kept available for inspection by the agency for twoyears from the date of the recorded event, showing for each source of radiation the following information:

8.11.a. A unique identification, such as a serial number, of each radiation machine, each radiographic exposure device in which a sealed source is located and each sealed source;

8.11.b. The identity of the radiographer to whom assigned;

8.11.c. Locations where used and date or dates each source of radiation was removed from storage and returned to storage; and

8.11.d. The voltage, current, and exposure time for each radiographic exposure employing a radiation machine.

8.12. Inspection and Maintenance

8.12.a. Each registrant shall ensure that checks for obvious defects in radiation machines, radiographic exposure devices, storage containers, and source changers are performed prior to each day or shift of use.

8.12.b. Each registrant shall conduct a program of at least quarterly inspection and maintenance of radiation machines, radiographic exposure devices, storage containers, and source changers to assure proper functioning of components important to safety. All appropriate parts shall be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance shall be maintained for inspection by the agency for two years from the date of the recorded event.

8.12.c. If any inspection conducted pursuant to subsections 8.12.a or 8.12.b reveals damage to components critical to radiation safety, the device shall be removed from service and labeled as defective until repairs have been made.

8.13. Permanent Radiographic Installations. Permanent radiographic installations having high radiation area entrance controls of the type described in section 6.19 of this rule shall also meet the following requirements:

8.13.a. Each entrance that is used for personnel access to the high radiation area shall have both visible and audible warning signals to warn of the presence of radiation. The visible signal shall be activated by radiation. The audible signal shall be activated when an attempt is made to enter the installation while the source is exposed.

8.13.b. The control device or alarm system shall be tested for proper operation at the beginning of each day of equipment use. If a control device or alarm system is operating improperly, it shall be immediately labeled as defective and repaired before industrial radiographic operations are resumed. Records of these tests shall be maintained for inspection by the agency for two years from the date of the event.

8.14. Personal Radiation Safety Requirements for Radiographic Personnel

8.14.a. Training and Testing

8.14.a.1. No registrant shall permit any individual to act as a radiographer trainee unless such individual has received copies of, instructions in, and has demonstrated an understanding of:

8.14.a.1.A. The subjects outlined in Table 64-23 X;

8.14.a.1.B. The rules contained in this section and the applicable provisions of sections 6, 13 and 14 of this rule;

8.14.a.1.C. The appropriate registration or certificate of registration; and

8.14.a.1.D. The registrant's operating and emergency procedures.

8.14.b. No registrant shall permit any individual to act as a radiographer, as defined in this subsection, until such individual:

8.14.b.1. Has met the requirements of subdivision 8.14.a.1;

8.14.b.2. Has provided the agency with documentation on agency form r or equivalent showing completion of at least 30 days of on-the-job training by a radiographer instructor as a radiographer trainee following completion of the requirements of subdivision 8.14.a.1;

8.14.b.3. Has demonstrated competence in the use of sources of radiation, radiographic exposure devices, related handling tools, and radiation survey instruments which may be employed in industrial radiographic assignments;

8.14.b.4. Has demonstrated an understanding of the instructions in subdivision 8.14.a.1 by successful completion of a written test and a field examination on the subjects covered; and

8.14.b.5. Has successfully completed an examination administered by the agency or its agent.

8.14.c. Records of the above training, including copies of written tests and dates of oral tests and field examinations, shall be maintained by the registrant for inspection by the agency for three years following termination of employment.

8.14.d. Each registrant shall conduct an internal audit program to ensure that the agency's radioactive material registration conditions and the registrant's operating and emergency procedures are followed by each radiographer. These internal audits shall be performed at least quarterly, and each radiographer shall be audited at least quarterly. Records of internal audits shall be maintained for inspection by the agency for two years from the date of the audit.

8.15. Operating and Emergency Procedures -- The registrant's operating and emergency procedures shall include instructions in at least the following:

8.15.a. The handling and use of sources of radiation to be employed such that no person is likely to be exposed to radiation doses in excess of the limits established in section 6.;

8.15.b. Methods for controlling access to radiographic areas;

8.15.c. Methods and occasions for conducting radiation surveys;

8.15.d. Methods and occasions for locking and securing sources of radiation;

8.15.e. Personnel monitoring and the use of personnel monitoring equipment, including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale;

8.15.f. Transportation to field locations, including packing of sources of radiation in the vehicles, posting of vehicles, and control of sources of radiation during transportation;

8.15.g. Minimizing exposure of persons in the event of an accident;

8.15.h. The procedure for notifying proper persons in the event of an accident; and

8.15.i. Maintenance of records.

8.15.j. The inspection and maintenance of radiographic exposure devices, source changers, storage containers, and radiation machines.

8.16. Personnel Monitoring Control.

8.16.a. No registrant shall permit any person to act as a radiographer or as a radiographer's trainee unless, at all times during radiographic operations, each such person shall wear a film badge or thermoluminescent dosimeter (TLD) and a direct reading pocket dosimeter. Pocket dosimeters shall be capable of measuring exposures from zero to at least 200 milliroentgens (5.16×10^{-5} C/kg) and shall be recharged daily or at the start of each shift. Each film badge or TLD shall be assigned to and worn by only one person.

8.16.b. Pocket dosimeters shall be read and exposures recorded daily. A film badge or TLD shall be immediately processed if a pocket chamber or pocket dosimeter is discharged beyond its range.

8.16.c. Pocket dosimeters shall be checked for correct response to radiation at periods not to exceed one year. Acceptable dosimeters shall read within plus or minus 30 percent of the true radiation exposure. Records of this check shall be maintained for inspection by the agency for two years from the date of the event.

8.16.d. If an individual's pocket dosimeter is discharged beyond its range, industrial radiographic operations by that individual shall cease and the individual's film badge or TLD shall be processed immediately. The individual shall not return to work with sources of radiation until a determination of the radiation exposure has been made.

8.16.e. Reports received from the film badge or TLD processor and records of daily pocket dosimeter readings shall be kept for inspection by the agency until the agency authorizes disposition.

8.16.f. If a film badge or TLD is lost or damaged, the worker shall cease work immediately until a replacement film badge or TLD is provided and the exposure is calculated for the time period from issuance to loss or damage of the film badge or TLD.

8.17. Supervision of Radiographer Trainee. Whenever a radiographer trainee uses radiographic exposure devices, sealed sources or related source handling tools, or conducts radiation surveys required by subsections 8.19.b and 8.19.c to determine that the sealed source has returned to the shielded position after an exposure, the radiographer trainee shall be under the personal supervision of a radiographer instructor.

8.18. Precautionary Procedures in Radiographic Operations.

8.18.a. Security. During each radiographic operation, the radiographer, radiographer instructor or radiographer trainee shall maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in section 6. of this rule, except:

8.18.a.1. Where the high radiation area is equipped with a control device or alarm system as described in section 6.19.

8.18.a.2. Where the high radiation area is locked to protect against unauthorized or accidental entry.

8.18.b. Posting. Areas in which radiography is being performed shall be conspicuously posted as required by section 6.2 of this rule.

8.19. Radiation Surveys and Survey Records.

8.19.a. No radiographic operation shall be conducted unless calibrated and operable radiation survey instrumentation, as described in section 8.8, is available and used at each site where radiographic exposures are made.

8.19.b. A survey with a radiation survey instrument shall be made after each radiographic exposure to determine that the sealed source has been returned to its shielded position. The entire circumference of the radiographic exposure device shall be surveyed. If the radiographic exposure device has a source guide tube, the survey shall also include the entire length of the guide tube.

8.19.c. A survey shall be made of the storage area as defined in subsection 8.5.a whenever a radiographic exposure device is being placed in storage.

8.19.d. A physical radiation survey, as specified in section 8.6, shall be made to determine that each sealed source is in its shielded position prior to securing the radiographic exposure device, storage container, or source changer in a storage area as defined in subsection 8.5.a.

8.19.e. A physical radiation survey shall be made after each radiographic exposure using radiation machines to determine that the machine is "off".

8.19.f. Records shall be kept of the surveys required by subsections 8.19.c and 8.19.d. Such records shall be maintained for inspection by the agency for two years after completion of the survey. If the survey was used to determine an individual's exposure, however, the records of the survey shall be maintained until the agency authorizes their disposition.

8.20. Documents and Records Required at Temporary Job sites. Each registrant conducting industrial radiography at a temporary jobsite shall have the following records available at that site for inspection by the agency:

8.20.a. Appropriate registration or certificate of registration or equivalent document;

8.20.b. Operating and emergency procedures;

8.20.c. Applicable rules;

8.20.d. Survey records required pursuant to section 8.19 and area survey records required pursuant to subsection 6.15.a of this rule for the period of operation at the site;

8.20.e. Daily pocket dosimeter records for the period of operation at the site; and

8.20.f. The latest instrument calibration and leak test records for specific devices and sealed sources in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter.

8.21. Specific Requirements for Radiographic Personnel Performing Industrial Radiography

8.21.a. At a jobsite, the following shall be supplied by the registrant:

8.21.a.1. At least one operable, calibrated survey instrument;

8.21.a.2. A current whole body personnel monitor (TLD or film badge) for each individual;

8.21.a.3. An operable, calibrated pocket dosimeter with a range of zero to 200 milliroentgens (5.16×10^{-5} C/kg) for each worker; and

8.21.a.4. The appropriate barrier ropes and signs.

8.21.b. Industrial radiographic operations shall not be performed if any of the items in subsection 8.20.a are not available at the jobsite or are inoperable.

8.21.c. Each registrant shall provide as a minimum two radiographic personnel when sources of radiation are used at temporary job sites. If one of the personnel is a radiographer trainee, the other shall be a radiographer instructor.

8.21.d. No individual other than a radiographer or a radiographer trainee who is under the personal supervision of a radiographer instructor shall manipulate controls or operate equipment used in industrial radiographic operations.

8.21.e. No individual shall act as a radiographer instructor unless such individual:

8.21.e.1. Has met the requirements of subsection 8.14.a;

8.21.e.2. Has 1 year of documented experience as a radiographer; and

8.21.e.3. Has been named as a radiographer instructor on the registration or registration certificate issued by the agency.

8.21.f. During an inspection by the agency, the agency inspector may terminate an operation if any of the items in subsection 8.21.a are not available and operable or if the required number of radiographic personnel are not present. Operations shall not be resumed until such conditions are met.

8.22. Special Requirements and Exemptions for Cabinet Radiography.

8.22.a. Systems for cabinet radiography designed to allow admittance of individuals shall:

8.22.a.1. Comply with all applicable requirements of this section and section 6.5 of this rule.

If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this section and 21 CFR 1020.40.

8.22.a.2. Be evaluated at intervals not to exceed one year to assure compliance with the applicable requirements as specified in subdivision 8.21.a.1. Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

8.22.b. Certified cabinet x-ray systems designed to exclude individuals from the interior of the cabinet are exempt from the requirements of this section except that:

8.22.b.1. Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter, and reports of the results shall be maintained for inspection by the agency.

8.22.b.2. No registrant shall permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this subdivision shall be maintained for inspection by the agency until disposition is authorized by the agency.

8.22.b.3. Tests for proper operation of high radiation area control devices or alarm systems, where applicable, shall be conducted, recorded, and maintained in accordance with section 8.13.

8.22.b.4. The registrant shall perform an evaluation, at intervals not to exceed one year, to determine conformance with section 6.5 of this rule. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed one year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the agency for a period of two years after the evaluation.

8.22.c. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the agency pursuant to section 4.1. of this rule.

8.23. Prohibitions. Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device, known as fishpole radiography, is prohibited unless specifically authorized in a registration issued by the agency.

§64-23-9. Radiation Safety Requirements for Analytical X-Ray Equipment.

9.1. Scope -- This section provides special requirements for analytical x-ray equipment. The requirements of this section are in addition to, and not in substitution for applicable requirements in other sections of this rule.

9.2. Definitions.

9.2.1. Analytical X-ray Equipment -- equipment used for x-ray diffraction of fluorescence analysis.

9.2.2. Analytical X-ray System -- a group of components utilizing x-ray to determine the elemental composition or to examine the microstructure of materials.

9.2.2.a. Mobile analytical radiographic equipment -- radiographic equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

9.2.2.b. Portable analytical radiographic equipment -- radiographic equipment designed to be hand-carried.

9.2.3. Fail-safe Characteristics -- a design feature which causes beam port shutters to close, or otherwise prevents emergency of the primary beam, upon the failure of a safety or warning device.

9.2.4. Local Components -- part of an analytical x-ray system and includes areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but do not include power supplies, transformers, amplifiers, readout devices, and control panels.

9.2.5. Normal Operating Procedures -- step-by-step instructions necessary to accomplish the analysis. These procedures shall include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures which are related to radiation safety.

9.2.6. Open-beam Configuration -- an analytical x-ray system in which an individual could accidently place some part of his body in the primary beam path during normal operation.

9.2.7. Primary Beam -- radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing.

9.3. General Regulatory Provisions and Specific Requirements

9.3.a. Equipment Requirements.

9.3.a.1. Safety Device -- A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the agency for an exemption from the requirement of a safety device. Such application shall include:

9.3.a.1.A. A description of the various safety devices that have been evaluated;

9.3.a.1.B. The reason each of these devices cannot be used; and

9.3.a.1.C. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

9.3.b. Warning Devices.

9.3.b.1. Open-beam configurations shall be provided with a readily discernible indication of:

9.3.b.1.A. X-ray tube status (ON-OFF) located near the radiation source housing, if the primary beam is controlled in this manner; or

9.3.b.1.B. Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

9.3.b.2. Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after the effective date of this rule, warning devices shall have fail-safe characteristics.

9.3.c. Ports -- Unused ports on radiation source housings shall be identified in the closed position in a manner which will prevent casual opening.

9.3.d. Labeling -- All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

9.3.d.1. "CAUTION - HIGH INTENSITY X-RAY BEAM," or words having a similar intent, on the x-ray housing; and

9.3.d.2. "CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED," or words having a similar intent, near any switch that energizes an x-ray tube if the radiation source is an x-ray tube; or "CAUTION - RADIOACTIVE MATERIAL," or words having a similar intent, on the source housing if the radiation source is a radionuclide.

9.3.e. Shutters -- On open-beam configurations installed after the effective date of this rule, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

9.3.f. Warning Lights.

9.3.f.1. An easily visible warning light labeled with the words "X-RAY ON", or words having a similar intent, shall be located:

9.3.f.1.A. Near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized; or

9.3.f.1.B. In the case of a radioactive source, near any switch that opens a housing shutter, and shall be illuminated only when the shutter is open.

9.3.f.2. On equipment installed after the effective date of this rule, warning lights shall have fail-safe characteristics.

9.3.g. Radiation Source Housing -- Each x-ray tube housing shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of five cm from its surface is not capable of producing a dose in excess of 2.5 mrem in one hour at any specified tube rating.

9.3.h. Generator Cabinet -- Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five cm from its surface such that it is not capable of producing a dose in excess of 0.25 mrem in one hour.

9.4. Area Requirements.

9.4.a. Radiation Levels -- The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in section 6.5 of this rule. For systems utilizing x-ray tubes, these levels shall be met at any specified tube rating.

9.4.b. Surveys

9.4.b.1. Radiation surveys, as required by section 6.5 of this rule, of all analytical x-ray systems sufficient to show compliance with subsection 9.4.a shall be performed:

9.4.b.1.A. Upon installation of the equipment and at least once every 12 months thereafter;

9.4.b.1.B. Following any change in the initial arrangement, number, or type of local components in the system;

9.4.b.1.C. Following any maintenance requiring the disassembly or removal of a local

component in the system;

9.4.b.1.D. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

9.4.b.1.E. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

9.4.b.1.F. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in section 6.4 of this rule.

9.4.b.2. Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the agency with subsection 9.4.a in some other manner.

9.4.c. Posting -- Each area or room containing analytical x-ray equipment shall conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT" or words having a similar intent.

9.5. Operating Requirements.

9.5.a. Procedures -- Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the radiation safety officer.

9.5.b. Bypassing -- No person shall bypass a safety device unless such person has obtained the approval of the radiation safety officer. Such approval shall be for a specified period of time. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.

9.5.c. Repair or Modification of X-Ray Tube Systems. Except as specified in subsection 9.5.b, no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

9.5.d. Radioactive Source Replacement, Testing, or Repair. Radioactive source housings shall be opened for source replacement, leak testing, or other maintenance or repair procedures only by individuals authorized to specifically conduct such procedures under a registration issued by the U.S. Nuclear Regulatory Commission (NRC), an agreement state, or a licensing state.

9.6. Personnel Requirements.

9.6.a. Instruction -- No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:

9.6.a.1. Identification of radiation hazards associated with the use of the equipment;

9.6.a.2. Significance of the various radiation warning and safety devices incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

9.6.a.3. Proper operating procedures for the equipment;

9.6.a.4. Symptoms of an acute localized exposure; and

9.6.a.5. Proper procedures for reporting an actual or suspected exposure.

9.6.b. Personnel Monitoring

9.6.b.1. Finger or wrist dosimetric devices shall be provided to and shall be used by:

9.6.b.1.A. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and

9.6.b.1.B. Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.

9.6.b.2. Reported dose values shall not be used for the purpose of determining compliance with section 6.4 of this rule unless evaluated by a qualified expert.

§64-23-10 Radiation Safety Requirements for Particle Accelerators.

10.1. Purpose and Scope.

10.1.a. This section establishes procedures for the registration and use of particle accelerators.

10.1.b. In addition to the requirements of this section, all registrants are subject to the requirements of sections 1, 5, 6, 11, 13, 13.5., 13.6 and 13.7 of this rule. Registrants engaged in industrial radiographic operations are subject to the requirements of section 8.16. of this rule, and registrants engaged in the healing arts are subject to the requirements of sections 7 and 12, 11.7 and 11.8 of this rule. Registrants whose operations result in the production of radioactive material are subject to the requirements of section 11 of this rule.

10.2. Registration Procedure.

10.2.a. Registration Requirements -- No person shall receive, possess, use, transfer, own or acquire a particle accelerator unless such is in compliance with the registration requirements in section 5 of this rule.

10.3. General Requirements for the Use of Particle Accelerators. In addition to the requirements set forth in sections 5 or 11 of this rule ~~Subsection 3~~, a registration for the use of a particle accelerator will not be issued unless the agency determines that:

10.3.a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose intended in accordance with this section and sections 6 and 13 of this rule in such a manner as to minimize danger to public health and safety or property;

10.3.b. The applicant's proposed equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

10.3.c. The issuance of the registration will not be inimical to the health and safety of the public, and the applicant satisfies any applicable special requirement in section 11.4 of this rule;

10.3.d. The applicant has appointed a radiation safety officer;

10.3.e. The applicant or his staff has substantial experience in the use of particle accelerators for

the intended use;

10.3.f. The applicant has established a radiation safety committee to approve, in advance, proposals for use of particle accelerators, whenever deemed necessary by the agency; and

10.3.g. The applicant has an adequate training program for particle accelerator operators.

10.4. Human Use of Particle Accelerators. In addition to the requirements set forth in section 5, a registration for use of a particle accelerator in the healing arts will be issued only if:

10.4.a. Whenever deemed necessary by the agency, the registrant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. Membership of the committee shall include physicians expert in internal medicine, hematology, therapeutic radiology and a person experienced in depth dose calculations and protection against radiation;

10.4.b. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and

10.4.c. The individual designated on the application as the user must be a physician.

10.5. Radiation Safety Requirements for the Use of Particle Accelerators

10.5.a. General Provisions.

10.5.a.1. This subdivision establishes radiation safety requirements for the use of particle accelerators which are in addition to, and not in substitution for, other applicable provisions of this rule.

10.5.a.2. The registrant shall be responsible for assuring that all requirements of this subdivision are met.

10.6. Limitations.

10.6.a. No registrant shall permit any person to act as a particle accelerator operator until such person:

10.6.a.1. Has been instructed in radiation safety and shall have demonstrated an understanding thereof:

10.6.a.2. Has received copies of and instruction in this section and the applicable requirements of sections 6 and 13, pertinent registration conditions and the registrant's operating and emergency procedures, and

10.6.a.3. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in his assignment.

10.6.b. Either the radiation safety committee or the radiation safety officer shall have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and minimize danger to public health and safety or property.

10.7. Shielding and Safety Design Requirements.

10.7.a. A qualified expert specifically accepted by the agency shall be consulted in the design of the particle accelerator installation and called upon to perform a radiation survey when the accelerator is

first capable of producing radiation.

10.7.b. Each particle accelerator installation shall be provided with such primary and or secondary barriers as are necessary to assure compliance with sections 6.2 and 6.3.

10.8. Particle Accelerator Controls and Interlock Systems.

10.8.a. Instrumentation, readouts, and controls on the particle accelerator control console shall be clearly identified and easily discernible.

10.8.b. All entrances into a target room or other high radiation area shall be provided with interlocks that shut down the machine under conditions of barrier penetration.

10.8.c. When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and lastly at the main control console.

10.8.d. Each safety interlock shall be on a circuit which shall allow its operation independently of all other safety interlocks.

10.8.e. All safety interlocks shall be failsafe, i.e., designed so that any defect or component failure in the interlock system prevents operation of the accelerator.

10.8.f. A scram button or other emergency power cutoff switch shall be located and easily identifiable in all high radiation areas. Such a cutoff switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch.

10.9. Warning Devices.

10.9.a. All locations designated as high radiation areas, and entrances to such locations shall be equipped with easily observable flashing or rotating warning lights that operate when, and only when, radiation is being produced.

10.9.b. Except in facilities designed for human exposure, each high radiation area shall have any audible warning device which shall be activated for 15 seconds prior to the possible creation of such high radiation area. Such warning device shall be clearly discernible in all high radiation areas and all radiation areas.

10.9.c. Barriers, temporary or otherwise, and pathways leading to high radiation areas shall be identified in accordance with section 6.6.

10.10. Operating Procedures.

10.10.a. Particle accelerators, when not in use, shall be secured to prevent unauthorized use.

10.10.b. Only a switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency.

10.10.c. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three months. Results of such test shall be maintained for inspection by the agency at the accelerator facility.

10.10.d. Electrical circuit diagrams of the accelerator, and the associated interlock systems, shall

be kept current and maintained for inspection by the agency and available to the operator at each accelerator facility.

10.10.e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

10.10.e.1. Authorized by the radiation safety committee and/or the radiation safety officer;

10.10.e.2. Recorded in a permanent log and a notice posted at the accelerator control console; and

10.10.e.3. Terminated as soon as possible.

10.10.f. A copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

10.11. Radiation Monitoring Requirements.

10.11.a. There shall be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and has been calibrated for the appropriate radiations being produced at the facility. Such equipment shall be tested for proper operation daily and calibrated at intervals not to exceed one year, and after servicing and repair.

10.11.b. A radiation protection survey shall be performed and documented by a qualified expert specifically approved by the agency when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas.

10.11.c. Radiation levels in all high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and interlock systems and capable of providing a remote and local readout with visual and/or audible alarms at both the control panel and at the entrance to high radiation areas, and other appropriate locations so that people entering or present become aware of the existence of the hazard.

10.11.d. All area monitors shall be calibrated quarterly.

10.11.e. Whenever applicable, periodic surveys shall be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards.

10.11.f. Whenever applicable, periodic smear surveys shall be made to determine the degree of contamination in target and other pertinent areas.

10.11.g. All area surveys shall be made in accordance with the written procedures established by a qualified expert or the radiation safety officer of the particulate accelerator facility.

10.11.h. Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results shall be kept current and on file at each accelerator facility.

10.12. Ventilation Systems.

10.12.a. Adequate ventilation shall be provided in areas where airborne radioactivity may be produced.

10.12.b. A registrant, as required by section 6.6, shall not vent, release or otherwise discharge airborne radioactive material to an unrestricted area which exceeds the limits in section 6, Table 64-23 E,

Table II, except as authorized pursuant to section 6.14 or subsection 6.6.b. For purposes of this subsection, concentrations may be averaged over a period not greater than one year. Every reasonable effort should be made to maintain releases of radioactive material to unrestricted areas as far below these limits as practicable.

§64-23-11. Registration of Radioactive Materials.

11.1. Purpose and Scope.

11.1.a. This section, and sections 13 and 15 of this rule provide for the registration of radioactive material. No person shall receive, possess, use, transfer, own, or acquire radioactive material except as authorized pursuant to this section and sections 13 and 15 of this rule, or as otherwise provided in these sections.

11.1.b. In addition to the requirements of this section, all registrants are subject to the requirements of sections 1, 6, 13, and 15 of this rule. Furthermore, registrants engaged in industrial radiographic operations are subject to the requirements of section 8 of this rule, registrants using radionuclides in the healing arts are subject to the requirements of section 12 of this rule, and registrants engaged in wireline and subsurface tracer studies are subject to the requirements of section 15 of this rule.

11.2. Source Material.

11.2.a. Any person is exempt from this section to the extent that such person receives, possesses, uses, owns, or transfers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of one percent (0.05 percent) of the mixture, compound, solution, or alloy.

11.2.b. Any person is exempt from this section to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific registration, such person shall not refine or process such ore.

11.2.c. Any person is exempt from this section to the extent that such person receives, possesses, uses, or transfers:

11.2.c.1. Any quantities of thorium contained in:

11.2.c.1.A. Incandescent gas mantles,

11.2.c.1.B. Vacuum tubes,

11.2.c.1.C. Welding rods,

11.2.c.1.D. Electric lamps for illuminating purposes provided that each lamp does not contain more than 50 milligrams of thorium,

11.2.c.1.E. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting provided that each lamp does not contain more than two grams of thorium,

11.2.c.1.F. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these, or

11.2.c.1.G. Personnel neutron dosimeters, provided that each dosimeter does not contain more than 50 milligrams of thorium;

11.2.c.2. Source material contained in the following products:

11.2.c.2.A. glazed ceramic Tableware, provided that the glaze contains not more than 20 percent by weight source material,

11.2.c.2.B. Glassware containing not more than 10 percent by weight source material, but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction,

11.2.c.2.C. Glass enamel or glass enamel frit containing not more than 10 percent by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983, or

11.2.c.2.D. Piezoelectric ceramic containing not more than two percent by weight source material;

11.2.c.3. Photographic film, negatives, and prints containing uranium or thorium;

11.2.c.4. Any finished product or part fabricated of, or containing, tungsten-thorium or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent by weight and that this exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

11.2.c.5. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles, or stored or handled in connection with installation or removal of such counterweights, provided that:

11.2.c.5.A. The counterweights are manufactured in accordance with a specific registration issued by the U.S. Nuclear Regulatory Commission (NRC), authorizing distribution by the registrant pursuant to 10 CFR Part 40;

11.2.c.5.B. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: "DEPLETED URANIUM";[2]

11.2.c.5.C. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement: "UNAUTHORIZED ALTERATIONS PROHIBITED";[1/] and

11.2.c.5.D. This exemption shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering.

11.2.c.6. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

11.2.c.6.A. The shipping container is conspicuously and legibly impressed with the legend "CAUTION - RADIOACTIVE SHIELDING - URANIUM", and

11.2.c.6.B. The uranium metal is encased in mild steel or equally fire resistant metal of

[2] The requirements specified in ~~S~~subdivisions 11.2.c.2. and 3. need not be met by counterweights manufactured prior to December 31, 1969; provided, that such counterweights are impressed with the legend, "CAUTION - RADIOACTIVE MATERIAL - URANIUM", as previously required by the rules.

minimum wall thickness of one-eighth (⅛) inch (3.2 mm);

11.2.c.7. Thorium contained in finished optical lenses, provided that each lens does not contain more than 30 percent by weight of thorium, and that this exemption shall not be deemed to authorize either:

11.2.c.7.A. The shaping, grinding, or polishing of such lens or manufacturing processes other than the assembly of such lens into optical systems and devices without any alteration of the lens, or

11.2.c.7.B. The receipt, possession, use, or transfer of thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

11.2.c.8. Uranium contained in detector heads for use in fire detection units, provided that each detector head contains not more than 0.005 microcurie of uranium; or

11.2.c.9. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

11.2.c.9.A. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide), and

11.2.c.9.B. The thorium content in the nickel-thoria alloy does not exceed 4 percent by weight.

11.2.d. The exemptions in subsection 11.2.b do not authorize the manufacture of any of the products described.

11.3. Radioactive Material Other Than Source Material.

11.3.a. Exempt Concentrations.

11.3.a.1. Except as provided in subdivision 11.3.a.2, any person is exempt from this section to the extent that such person receives, possesses, uses, transfers, owns or acquires products containing radioactive material introduced in concentrations not in excess of those listed in Table 64-23 Y.

11.3.a.2. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under subdivision 11.3.a.1 or equivalent rules of the NRC, any agreement state or licensing state, except in accordance with a specific registration issued pursuant to subsection 11.17.a or the general registrant provided in section 11.28.

11.3.b. Exempt Quantities.

11.3.b.1. Except as provided in subdivisions 11.3.b.3 and 11.3.b.4, any person is exempt from this rule to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in Table 64-23 Z.

11.3.b.2. Any person who possesses radioactive material received or acquired under the general registrant formerly provided in section 11.7 is exempt from the requirements for a registrant set forth in this section to the extent that such person possesses, uses, transfers or owns such radioactive material. Such exemption does not apply for Radium-226.

11.3.b.3. This subdivision does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution, or the incorporation of radioactive material

into products intended for commercial distribution.

11.3.b.4. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Table 64-3 Z, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under subsection 11.3.b or equivalent rules of the NRC, any agreement state or licensing state, except in accordance with a specific registrant issued by the NRC pursuant to Section 32.18 of 10 CFR Part 32 or by the agency pursuant to subsection 11.17.b which registrant states that the radioactive material may be transferred by the registrant to persons exempt under subsection 11.3.b or the equivalent rules of the NRC, an agreement state, or licensing state.[8]

11.3.c. Exempt Items.

11.3.c.1. Certain Items Containing Radioactive Material. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into the following products, any person is exempt from this rule to the extent that he receives, possesses, uses, transfers, owns, or acquires the following products:[8]

11.3.c.1.A. Timepieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified radiation dose rate:

11.3.c.1.A.1. 25 millicuries (925 MBq) of tritium per timepiece.

11.3.c.1.A.2. Five millicuries (185 MBq) of tritium per hand.

11.3.c.1.A.3. 15 millicuries (555 MBq) of tritium per dial (bezels when used shall be considered as part of the dial).

11.3.c.1.A.4. 100 microcuries (3.7 MBq) of promethium-147 per watch or 200 microcuries (7.4 MBq) of promethium-147 per any other timepiece.

11.3.c.1.A.5. 20 microcuries (0.74 MBq) of promethium-147 per watch hand or 40 microcuries (1.48 MBq) of Promethium-147 per other timepiece hand.

11.3.c.1.A.6. 60 microcuries (2.22 MBq) of promethium-147 per watch dial or 120 microcuries (4.44 MBq) of Promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial).

11.3.c.1.A.7. The radiation dose rate from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

11.3.c.1.A.7.(a) For wrist watches, one-tenth millirad (one μGy) per hour at 10 centimeters from any surface.

11.3.c.1.A.7.(b) For pocket watches, one-tenth millirad (one μGy) per hour at one centimeter from any surface.

11.3.c.1.A.7.(c) For any other timepiece, two-tenth millirad (two μGy) per hour at 10 centimeters from any surface.

[8] Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555

11.3.c.1.A.8. One microcurie (37 kBq) of Radium-226 per timepiece in timepieces acquired prior to July 1, 2001..

11.3.c.1.A.9. Lock illuminators containing not more than 15 millicuries (555 MBq) of tritium or not more than two millicuries (74 MBq) of Promethium-147 installed in automobile locks. The radiation dose rate from each lock illuminator containing Promethium-147 will not exceed one millirad (10 μGy) per hour at one centimeter from any surface when measured through 50 milligrams per square centimeter of absorber.

11.3.c.1.B. Precision balances containing not more than one millicurie (37 MBq) of tritium per balance or not more than five-tenths millicurie (18.5 MBq) of tritium per balance part.

11.3.c.1.C. Automobile shift quadrants containing not more than 25 millicuries (925 MBq) of tritium.

11.3.c.1.D. Marine compasses containing not more than 750 millicuries (27.8 GBq) of tritium gas and other marine navigational instruments containing not more than 250 millicuries (9.25 GBq) of tritium gas.

11.3.c.1.E. Thermostat dials and pointers containing not more than 25 millicuries (925 MBq) of tritium per thermostat.

11.3.c.1.F. Electron tubes; provided, that each tube does not contain more than one of the following specified quantities of radioactive material:

11.3.c.1.F.1. 150 millicuries (5.55 GBq) of tritium per microwave receiver protector tube or 10 millicuries (370 mBq) of tritium per any other electron tube.

11.3.c.1.F.2. One microcurie (37 kBq) of Cobalt-60.

11.3.c.1.F.3. Five microcuries (185 kBq) of nickel-63.

11.3.c.1.F.4. 30 microcuries (1.11 MBq) of krypton-85.

11.3.c.1.F.5. Five microcuries (185 kBq) of cesium-137.

11.3.c.1.F.6. 30 microcuries (1.11 MBq) of promethium-147.

11.3.c.1.G. And provided further, that the radiation dose rate from each electron tube containing radioactive material will not exceed one millirad (10 μGy) per hour at one centimeter from any surface when measured through seven milligrams per square centimeter of absorber.

11.3.c.1.H. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material, provided that:

11.3.c.1.H.1. Each source contains no more than one exempt quantity set forth in Table 64-23 Z, and

11.3.c.1.H.2. Each instrument contains no more than 10 exempt quantities. For purposes of this requirement, an instrument's sources may contain either one or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in Table 64-23 Z, provided that the sum of such fractions shall not exceed unity.

11.3.c.1.H.3. For Americium-241, 0.05 microcurie (1.85 kBq) is considered an exempt quantity under paragraph ~~C.4.c.i.(8)~~11.3.b.

11.3.c.1.I. Spark gap irradiators containing not more than 1 microcurie (37 kBq) of Cobalt-60 per spark gap irradiator for use in electrically ignited fuel oil burners having a firing rate of at least three gallons ~~(eleven and four-tenths [11.4] l)~~ per hour.

11.3.c.2. Self-Luminous Products Containing Radioactive Material

11.3.c.2.A. Tritium, Krypton-85, or Promethium-147. Except for persons who manufacture, process, or produce self-luminous products containing tritium, Krypton-85, or Promethium-147, any person is exempt from this rule to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, Krypton-85 or Promethium-147 in self-luminous products manufactured, processed, produced, imported, or transferred in accordance with a specific registrant issued by the NRC pursuant to Section 32.22 of 10 CFR Part 32, which registrant authorizes the transfer of the product to persons who are exempt from regulatory requirements. The exemption in subdivision 11.3.c.2 does not apply to tritium, Krypton-85, or Promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

11.3.c.2.B. Radium-226. Any person is exempt from this rule to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than one-tenth microcurie (3.7 kBq) of Radium-226 which were acquired prior to July 1, 2001.

11.3.c.3. Gas and Aerosol Detectors Containing Radioactive Material

11.3.c.3.A. Except for persons who manufacture, process, or produce gas and aerosol detectors containing radioactive material, any person is exempt from this rule to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards provided that detectors containing radioactive material shall have been manufactured, imported, or transferred in accordance with a specific registrant issued by the NRC[9]equipment, device, commodity, or other product containing byproduct material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements may be obtained only from the NRC, Washington, D.C. 20555 pursuant to Section 32.26 of 10 CFR Part 32; or a licensing state pursuant to paragraph 11.3.a.3.A, which authorizes the transfer of the detectors to persons who are exempt from regulatory requirements.

11.3.c.3.B. Gas and aerosol detectors previously manufactured and distributed to general registrants in accordance with a specific registrant issued by an agreement state shall be considered exempt under paragraph 11.3.c.3.A, provided that the device is labeled in accordance with the specific registrant authorizing distribution of the generally registered device, and provided further that they meet the requirements of subsection 11.17.c.

11.3.c.3.C. Gas and aerosol detectors containing NARM previously manufactured and distributed in accordance with a specific registrant issued by a licensing state shall be considered exempt under paragraph 11.3.c.3.A., provided that the device is labeled in accordance with the specific registrant authorizing distribution, and provided further that they meet the requirements of subsection 11.17.c.

11.3.c.4. Resins Containing Scandium-46 and Designed for Sand Consolidation in Oil Wells. Any person is exempt from this rule to the extent that such person receives, possesses, uses, transfers, owns or acquires synthetic plastic resins containing scandium-46 which are designed for sand

[9] Authority to transfer possession or control by the manufacturer, processor, or producer of any

consolidation in oil wells. Such resins shall have been manufactured or imported in accordance with a specific registrant issued by the NRC, or shall have been manufactured in accordance with the specifications contained in a specific registrant issued by the agency or any agreement state to the manufacturer of such resins pursuant to registration requirements equivalent to those in Sections 32.16 and 32.17 of 10 CFR Part 32 of the rules of the NRC. This exemption does not authorize the manufacture of any resins containing scandium-46.

11.4. Types of Registrants. Registrants for radioactive materials are of two types: general and specific.

11.4.a. General registrants provided in this section are effective without the filing of applications with the agency or the issuance of registration documents to the particular persons, although the filing of a certificate with the agency may be required by the particular general registrant. The general registrant is subject to all other applicable portions of this rule and any limitations of the general registrant.

11.4.b. Specific registrants require the submission of an application to the agency and the issuance of a registration document by the agency. The registrant is subject to all applicable portions of this rule as well as any limitations specified in the registration document.

11.5. General Registrants -- Source Material.

11.5.a. A general registrant is hereby issued authorizing commercial and industrial firms, research, educational and medical institutions, and state and local government agencies to use and transfer not more than 15 pounds (6.82 kg) of source material at any one time for research, development, educational, commercial, or operational purposes. A person authorized to use or transfer source material, pursuant to this general registrant, may not receive more than a total of one 150 pounds (68.2 kg) of source material in any one calendar year.

11.5.b. Persons who receive, possess, use, or transfer source material pursuant to the general registrant issued in subsection 11.15.a are exempt from the provisions of sections 6 and 14 of this rule to the extent that such receipt, possession, use, or transfer is within the terms of such general registrant; provided, however, that this exemption shall not be deemed to apply to any such person who is also in possession of source material under a specific registrant issued pursuant to this section.

11.5.c. Persons who receive, possess, use, or transfer source material pursuant to the general registrant in 11.5.a are prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the agency in a specific registrant.

11.5.d. A general registrant is hereby issued authorizing the receipt of title to source material without regard to quantity. This general registrant does not authorize any person to receive, possess, use, or transfer source material.

11.6. Depleted Uranium in Industrial Products and Devices.

11.6.a. A general registrant is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of subsections 11.6.b – 11.6.e., depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

11.6.b. The general registrant in subsection 11.6.a applies only to industrial products or devices which have been manufactured either in accordance with a specific registrant issued to the manufacturer of the products or devices pursuant to subsection 11.17.1 or in accordance with a specific registration issued to the manufacturer by the NRC or an agreement state which authorizes manufacture of the

products or devices for distribution to persons generally licensed by the NRC or an agreement state.

11.6.c. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general registrant established by subsection 11.6.a shall file Agency Form W "certificate - use of depleted uranium under general registrant", with the agency. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. The general registrant shall furnish on Agency Form W the following information and such other information as may be required by that form:

11.6.c.1. Name and address of the general registrant;

11.6.c.2. A statement that the general registrant has developed and will maintain procedures designed to establish physical control over the depleted uranium described in subsection 11.6.a and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

11.6.c.2.A. Name and title, address, and telephone number of the individual duly authorized to act for and on behalf of the general registrant in supervising the procedures identified in subdivision 11.6.c.2.

11.6.c.2.B. The general registrant possessing or using depleted uranium under the general registration established by subsection 11.6.a shall report in writing to the agency any changes in information furnished by him in Agency Form W "Certificate - Use of Depleted Uranium Under General Registration". The report shall be submitted within 30 days after the effective date of such change.

11.6.d. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general registration established by subsection 11.6.a:

11.6.d.1. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

11.6.d.2. Shall not abandon such depleted uranium;

11.6.d.3. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of section 11.26. In the case where the transferee receives the depleted uranium pursuant to the general registration established by subsection 11.6.a, the transferor shall furnish the transferee a copy of this rule and a copy of Agency Form W. In the case where the transferee receives the depleted uranium pursuant to a general registration contained in the NRC's or agreement state's rule equivalent to subsection 11.6.a, the transferor shall furnish the transferee a copy of this rule and a copy of Agency Form W accompanied by a note explaining that use of the product or device is regulated by the NRC or agreement state under requirements substantially the same as those in this rule;

11.6.d.4. Within 30 days of any transfer, shall report in writing to the agency the name and address of the person receiving the depleted uranium pursuant to such transfer; and

11.6.d.5. Shall not export such depleted uranium except in accordance with a license issued by the NRC pursuant to 10 CFR Part 110.

11.6.e. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general registration established by subsection 11.6.a is exempt from the requirements of sections 6 and 14 of this rule with respect to the depleted uranium covered by that general registration.

11.7. General Registrations -- Radioactive Material Other Than Source Material.

11.7.a. Certain Devices and Equipment. A general registration is hereby issued to transfer, receive, acquire, own, possess, and use radioactive material incorporated in the following devices or equipment which have been manufactured, tested and labeled by the manufacturer in accordance with a specific registration issued to the manufacturer by the NRC for use pursuant to Section 31.3 of 10 CFR Part 31. This general registration is subject to the provisions of sections 4.3 through 4.7, 11.3.a.2, sections 11.19, 11.26, 11.27, and sections 6, 14 and 15 of this rule.

11.7.a.1. Static Elimination Device. Devices designed for use as static eliminators which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of Polonium-210 per device.

11.7.a.2. Ion Generating Tube. Devices designed for ionization of air which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 microcuries (18.5 MBq) of Polonium-210 per device or a total of not more than 50 millicuries (1.85 GBq) of hydrogen-3 (tritium) per device.

11.7.b. Certain Measuring, Gauging or Controlling Devices.

11.7.b.1. A general registration is hereby issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business, and state or local government agencies to own, receive, acquire, possess, use or transfer in accordance with the provisions of subdivisions 11.7.b.2 – 11.7.b. 4, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

11.7.b.2. The general registration in subdivision 11.7.b.1 applies only to radioactive material contained in devices which have been manufactured and labeled in accordance with the specifications contained in a specific registration issued by the agency pursuant to subsection 11.17.d or in accordance with the specifications contained in a specific registration issued by the NRC, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the NRC, an agreement state or a licensing state.

11.7.b.3. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general registration in subdivision 11.7.a.1 or paragraph 11.7.b.3.A shall assure that all labels affixed to the device at the time of receipt, and bearing a statement that removal of the label is prohibited, are maintained thereon and shall comply with all instructions and precautions provided by such labels;

11.7.b.3.A. Shall assure that the device is tested for leakage of radioactive material and proper operation of the "on-off" mechanism and indicator, if any, at no longer than six month intervals or at such other intervals as are specified in the label, however,

11.7.b.3.A.1. Devices containing only krypton need not be tested for leakage of radioactive material, and

11.7.b.3.A.2. Devices containing only tritium or not more than 100 microcuries (3.7 MBq) of other beta or beta-gamma-emitting material or 10 microcuries (0.37 MBq) of alpha-emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

11.7.b.3.B. Shall assure that other testing, installation, servicing, and removal from installation involving the radioactive material, its shielding or containment, are performed:

11.7.b.3.B.1. In accordance with the instructions provided by the labels, or

11.7.b.3.B.2. By a person holding an applicable specific registration from the agency, the NRC, an agreement state or a licensing state to perform such activities;

11.7.b.3.C. Shall maintain records showing compliance with the requirements of paragraphs 11.7.b.3.A and 11.7.b.3.B. The records shall show the results of tests. The records also shall show the dates of performance of, and the names of persons performing, testing, installation, servicing, and removal from installation concerning the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by paragraph 11.7.b.3.A shall be maintained for one year after the next required leak test is performed or until the sealed source is transferred or disposed of. Records of tests of the "on-off" mechanism and indicator required by paragraph 11.7.b.3.A shall be maintained for one year after the next required test of the "on-off" mechanism and indicator is performed or until the sealed source is transferred or disposed of. Records which are required by paragraph 11.7.b.3.A shall be maintained for a period of two years from the date of the recorded event or until the device is transferred or disposed of;

11.7.b.3.D. Upon the occurrence of a failure of or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the "on-off" mechanism or indicator, or upon the detection of 0.005 microcurie (185 Bq) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific registration from the agency, the NRC, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific registration to receive the radioactive material contained in the device and, within 30 days, furnish to the agency a report containing a brief description of the event and the remedial action taken;

11.7.b.3.E. Shall not abandon the device containing radioactive material;

11.7.b.3.F. Except as provided in paragraph 11.7.b.3.G, shall transfer or dispose of the device containing radioactive material only by transfer to a specific registrant of the agency, the NRC, an agreement state or a licensing state whose specific registration authorizes him to receive the device and within 30 days after transfer of a device to a specific registrant shall furnish to the agency a report containing identification of the device by manufacturer's name and model number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific registrant in order to obtain a replacement device;

11.7.b.3.G. Shall transfer the device to another general registrant only:

11.7.b.3.G.1. Where the device remains in use at a particular location. In such case the transferor shall give the transferee a copy of this rule and any safety documents identified in the label on the device and within 30 days of the transfer, report to the agency the manufacturer's name and model number of device transferred, the name and address of the transferee, and the name and position of an individual who may constitute a point of contact between the agency and the transferee; or

11.7.b.3.G.2. Where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general registration; and

11.7.b.3.H. Shall comply with the provisions of sections 6.53 and 6.54 of this rule for reporting radiation incidents, theft, or loss of registered material, but shall be exempt from the other requirements of sections 6 and 14 of this rule.

11.7.b.4. The general registration in subdivision 11.7.b.1 does not authorize the manufacture of devices containing radioactive material.

11.7.b.5. The general registration provided in subdivision 11.7.b.1 is subject to the provisions of sections 4.2 - 4.7, 11.19, 11.26, 11.27 and 15 of this rule.

11.8. Luminous Safety Devices for Aircraft.

11.8.a. A general registration is hereby issued to own, receive, acquire, possess, and use tritium or Promethium-147 contained in luminous safety devices for use in aircraft, provided:

11.8.a.1. Each device contains not more than 10 curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147; and

11.8.a.2. Each device has been manufactured, assembled or imported in accordance with a specific license issued by the NRC, or each device has been manufactured or assembled in accordance with the specifications contained in a specific registration issued by the agency or any agreement state to the manufacturer or assembler of such device pursuant to registration requirements equivalent to those in Section 32.53 of 10 CFR Part 32.

11.8.b. Persons who own, receive, acquire, possess, or use luminous safety devices pursuant to the general registration in subsection 11.8.a are exempt from the requirements of sections 6 and 14 of this rule, except that they shall comply with the provisions of sections 6.53 and 6.54.

11.8.c. This general registration does not authorize the manufacture, assembly, or repair of luminous safety devices containing tritium or Promethium-147.

11.8.d. This general registration does not authorize the ownership, receipt, acquisition, possession or use of Promethium-147 contained in instrument dials.

11.8.e. This general registration is subject to the provisions of sections 4.3 - 4.7, 11.19, 11.26, 11.27, and section 15 of this rule.

11.9. Ownership of Radioactive Material. A general registration is hereby issued to own radioactive material without regard to quantity. Notwithstanding any other provisions of this section, this general registration does not authorize the manufacture, production, transfer, receipt, possession or use of radioactive material.

11.10. Calibration and Reference Sources.

11.10.a. A general registration is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of subsections 11.10.d and 11.10.e and Americium-241 in the form of calibration or reference sources:

11.10.a.1. Any person who holds a specific registration issued by the agency which authorizes him to receive, possess, use, and transfer radioactive material; and

11.10.a.2. Any person who holds a specific registration issued by the NRC which authorizes him to receive, possess, use, and transfer special nuclear material.

11.10.b. A general registration is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of subsections 11.10.d and 11.10.e to any person who holds a specific registration issued by the agency which authorizes him to receive, possess, use, and transfer radioactive material.

11.10.c. A general registration is hereby issued to own, receive, possess, use, and transfer Radium-226 in the form of calibration or reference sources in accordance with the provisions of

subsections 11.10.d and 11.10.e to any person who holds a specific registration issued by the agency which authorizes him to receive, possess, use, and transfer radioactive material.

11.10.d. The general registrations in subsections 11.10.a - 11.10.c apply only to calibration or reference sources which have been manufactured in accordance with the specifications contained in a specific registration issued to the manufacturer or importer of the sources by the NRC pursuant to Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70 or which have been manufactured in accordance with the specifications contained in a specific registration issued to the manufacturer by the agency, any agreement state or licensing state pursuant to registration requirements equivalent to those contained in Section 32.57 of 10 CFR Part 32 or Section 70.39 of 10 CFR Part 70.

11.10.e. The general registrations provided in subsections 11.10.a - 11.10.c are subject to the provisions of sections 4.3 through 4.7, 6, 11.19, 11.26, 11.27, 14, and 15 of this rule. In addition, persons who own, receive, acquire, possess, use, or transfer one or more calibration or reference sources pursuant to these general registrations:

11.10.e.1. Shall not possess at any one time, at any one location of storage or use, more than five microcuries (185 kBq) of Americium-241, five microcuries (185 kBq) of plutonium, five microcuries (185 kBq) of Radium-226 in such sources;

11.10.e.2. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, as appropriate:

11.10.e.2.A. The receipt, possession, use and transfer of this source, Model _____, Serial No._____, are subject to a general registration and the rules of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS (AMERICIUM-241).
(PLUTONIUM) DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

11.10.e.2.B. The receipt, possession, use and transfer of this source, Mode _____, Serial No. _____ , are subject to a general registration and the rules of a Licensing State. Do not remove this label.

CAUTION - RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS RADIUM-226.
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or importer

11.10.e.3. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a registration from the agency, the NRC, an agreement state or a licensing state to receive the source;

11.10.e.4. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain Americium-241, Plutonium, or Radium-226 which might otherwise escape during storage; and

11.10.e.5. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

11.10.f. These general registrations do not authorize the manufacture of calibration or reference sources containing Americium-241, Plutonium, or Radium-226.

11.11. General Registration for Use of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing.

11.11.a. A general registration is hereby issued to any physician, veterinarian, clinical laboratory or hospital to receive, acquire, possess, transfer or use, for any of the following stated tests, in accordance with the provisions of subsections 11.11.b - 11.11.f, the following radioactive materials in prepackaged units for use in vitro clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals:

11.11.a.1. Carbon-14, in units not exceeding 10 microcuries (370 kBq) each.

11.11.a.2. Cobalt-57, in units not exceeding 10 microcuries (370 kBq) each.

11.11.a.3. Hydrogen-3 (tritium), in units not exceeding 50 microcuries (1.85 MBq) each.

11.11.a.4. Iodine-125, in units not exceeding 10 microcuries (370 kBq) each.

11.11.a.5. Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (1.85 Bq) of Americium-241 each.

11.11.a.6. Iodine-131, in units not exceeding 10 microcuries (370 kBq) each.

11.11.a.7. Iron-59, in units not exceeding 20 microcuries (740 kBq) each.

11.11.a.8. Selenium-75, in units not exceeding 10 microcuries (370 kBq) each.

11.11.b. No person shall receive, acquire, possess, use or transfer radioactive material pursuant to the general registration established by subsection 11.11.a until he has filed Agency Form F, "certificate - in vitro testing with radioactive material under general registration", with the agency and received from the agency a validated copy of Agency Form V with certification number assigned. The physician, veterinarian, clinical laboratory or hospital shall furnish on agency form v the following information and such other information as may be required by that form:

11.11.b.1. Name and address of the physician, veterinarian, clinical laboratory or hospital;

11.11.b.2. The location of use; and

11.11.b.3. A statement that the physician, veterinarian, clinical laboratory or hospital has appropriate radiation measuring instruments to carry out in vitro clinical or laboratory tests with radioactive material as authorized under the general registration in subsection 11.11.a and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive material.

11.11.c. A person who receives, acquires, possesses or uses radioactive material pursuant to the general registration established by subsection 11.11.a shall comply with the following:

11.11.c.1. The general registrant shall not possess at any one time, pursuant to the general

registration in subsection 11.11.a, at any one location of storage or use, a total amount of Iodine-125, Iodine-131, Selenium-75, Iron-59, or Cobalt-57 in excess of 200 microcuries (7.4 MBq).

11.11.c.2. The general registrant shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

11.11.c.3. The general registrant shall use the radioactive material only for the uses authorized by subsection 11.11.a.

11.11.c.4. The general registrant shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a registration issued by the agency, the NRC, any agreement state or licensing state, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

11.11.c.5. The general registrant shall dispose of the mock Iodine-125 reference or calibration sources described in subdivision 11.11.a.7 as required by section 6.13 of this rule.

11.11.d. The general registrant shall not receive, acquire, possess, or use radioactive material pursuant to subsection 11.11.a:

11.11.d.1. Except as prepackaged units which are labeled in accordance with the provisions of an applicable specific registration issued pursuant to subsection 11.17.g or in accordance with the provisions of a specific registration issued by the NRC, any agreement state or licensing state which authorizes the manufacture and distribution of Iodine-125, Iodine-131, Carbon-14, Hydrogen-3 (tritium), Iron-59, Selenium-75, Cobalt-57, or mock Iodine-125 to persons generally registered under paragraph 11.3.3.c.A or its equivalent, and

11.11.d.2. Unless one of the following statements, as appropriate, or a substantially similar statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

11.11.d.2.A. This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules and a general registration of the NRC or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

11.11.d.2.B. This radioactive material shall be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the rules and a general registration of a licensing state.

_____
Name of manufacturer

11.11.e. The physician, veterinarian, clinical laboratory or hospital possessing or using radioactive material under the general registration of subsection 11.11.a shall report in writing to the agency, any changes in the information furnished by him in the "Certificate - In Vitro Testing With Radioactive Material Under General Registration", Agency Form V. The report shall be furnished within

30 days after the effective date of such change.

11.11.f. Any person using radioactive material pursuant to the general registration of subsection 11.11.a is exempt from the requirements of sections 6 and 14 of this rule with respect to radioactive material covered by that general registration, except that such persons using the mock Iodine-125 described in subdivision 11.11.a.7 shall comply with the provisions of sections 6.13, 6.53 and 6.54 of this rule.

11.12. Ice Detection Devices.

11.12.a. A general registration is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and each device has been manufactured or imported in accordance with a specific registration issued by the NRC or each device has been manufactured in accordance with the specifications contained in a specific registration issued by the agency or an agreement state to the manufacturer of such device pursuant to registration requirements equivalent to those in Sections 32.61 of 10 CFR 32.

11.12.b. Persons who own, receive, acquire, possess, use, or transfer Strontium-90 contained in ice detection devices pursuant to the general registration in subsection 11.12.a, and

11.12.b.1. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating to the device, discontinue use of the device until it has been inspected, tested for leakage and repaired by a person holding a specific registration from the NRC or an agreement state to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of section 6.13. of this rule;

11.12.b.2. Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon; and

11.12.b.3. Are exempt from the requirements of sections 6 and 14 of this rule except that such persons shall comply with the provisions of sections 6.13, 6.53 and 6.54.

11.12.c. This general registration does not authorize the manufacture, assembly, disassembly or repair of strontium-90 in ice detection devices.

11.12.d. This general registration is subject to the provisions of sections 4.3 through 4.7, 11.19, 11.26, 11.27 and section 15 of this rule.

11.13. Filing Application for Specific Registrations.

11.13.a. Applications for specific registrations shall be filed on a form prescribed by the agency.

11.13.b. The agency may at any time after the filing of the original application, and before the expiration of the registration, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a registration should be modified or revoked.

11.13.c. Each application shall be signed by the applicant or registrant or a person duly authorized to act for and on his behalf.

11.13.d. An application for a registration may include a request for a registration authorizing one or more activities.

11.13.e. In his application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency provided such references are clear and specific.

11.13.f. Applications and documents submitted to the agency may be made available for public inspection except that the agency may withhold any document or part thereof from public inspection if disclosure of its content is not required in the public interest and would adversely affect the interest of a person concerned.

11.14. General Requirements for the Issuance of Specific Registrations. A registration application will be approved if the agency determines that:

11.14.a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with this rule in such a manner as to minimize danger to public health and safety or property;

11.14.b. The applicant's proposed equipment, facilities, and procedures are adequate to minimize danger to public health and safety or property;

11.14.c. The issuance of the registration will not be inimical to the health and safety of the public; and

11.14.d. The applicant satisfies any applicable special requirements in sections 11.15, 11.17, sections 8, 13 or 15 of this rule.

11.14.e. Environmental Report, Commencement of Construction. In the case of an application for a registration to receive and possess radioactive material for commercial waste disposal by land burial, or for the conduct of any other activity which the agency determines will significantly affect the quality of the environment, the agency, before commencement of construction of the plant or facility in which the activity will be conducted, has concluded, after weighing the environmental, economic, technical and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed registration, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a registration to receive and possess radioactive material in such plant or facility. As used in this subsection the term "commencement of construction" is any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, necessary roads for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

11.14.f. Financial Surety Arrangements for Site Reclamation.

11.14.f.1. Financial surety arrangements for site reclamation which may consist of surety bonds, cash deposits, certificates of deposit, deposits of government securities, letters or lines of credit, or any combination of the above for the categories of registrations listed in subdivision 11.14.f.4 shall be established to ensure the protection of the public health and safety in the event of abandonment, default, or other inability of the registrant to meet the requirements of the act and this rule.

11.14.f.1.A. The amount of funds to be ensured by such surety arrangements shall be based on agency-approved cost estimates.

11.14.f.1.B. Self insurance, or any arrangement which essentially constitutes self insurance, will not satisfy the surety requirement since this provides no additional assurance other than that which already exists through registration requirements.

11.14.f.2. The arrangements required in paragraph 11.14.f.1. shall be established prior to issuance of the registration to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility.

11.14.f.3. Amendments to registrations in effect on July 1, 2001. may be issued providing that the required surety arrangements are established within 90 days.

11.14.f.4. The following specific registrations are required to make financial surety arrangements:

11.14.f.4.A. Major processors;

11.14.f.4.B. Waste handling registrants;

11.14.f.4.C. Former U.S. Atomic Energy Commission or NRC licensed facilities; and

11.14.f.4.D. All others except persons exempt pursuant to subdivision 11.14.f.5.

11.14.f.5. The following persons are exempt from the requirements of subdivision 11.14.f.1:

11.14.f.5.A. All state, local, or other government agencies, unless they are subject to paragraph 11.14.f.4.B;

11.14.f.5.B. Persons authorized to possess no more than 1,000 times the quantity specified in Table 64-23 Z or combination of radioactive material listed therein as given in Table 64-23 Z, note 1;

11.14.f.5.C. Persons authorized to possess Hydrogen-3 contained as hydrogen gas in a sealed source; or

11.14.f.5.D. Persons authorized to possess radioactive noble gases in sealed sources with no radioactive daughter product with half-life greater than thirty (30) days.

11.15. Special Requirements for Issuance of Certain Specific Registrations for Radioactive Material

11.15.a. Use of Sealed Sources in Industrial Radiography. In addition to the requirements set forth in section 11.14, a specific registration for use of sealed sources in industrial radiography will be issued if:

11.15.a.1. The applicant will have an adequate program for training radiographic personnel and submits to the agency a schedule or description of such program which specifies the:

11.15.a.1.A. Initial training,

11.15.a.1.B. Periodic training,

11.15.a.1.C. On-the-job training, and

11.15.a.1.D. Means to be used by the registrant to determine the radiographic personnel's knowledge and understanding of and ability to comply with agency rules and registration requirements, and the operating and emergency procedures of the applicant.

11.15.b. The applicant has established and submits to the agency satisfactory written operating

and emergency procedures described in section 8.15 of this rule;

11.15.c. The applicant will have an internal inspection system adequate to assure that this rule, registration provisions, and the applicant's operating and emergency procedures are followed by radiographic personnel; the inspection system shall include the performance of internal inspections at intervals not to exceed three months and the retention of records of such inspections for two years;

11.15.d. The applicant submits to the agency a description of the overall organizational structure pertaining to the industrial radiography program, including specified delegations of authority and responsibility for operation of the program;

11.15.e. The applicant who desires to conduct his own leak tests has established adequate procedures to be followed in testing sealed sources for possible leakage and contamination and submits to the agency a description of such procedures including:

11.15.e.1. Instrumentation to be used,

11.15.e.2. Method of performing tests, and

11.15.e.3. Pertinent experience of the individual who will perform the test; and

11.15.f. The registrant shall conduct a program for inspection and maintenance of radiographic exposure devices and storage containers to assure proper functioning of components important to safety.

11.16. Special Requirements for Specific Registrations of Broad Scope. This section prescribes requirements for the issuance of specific registrations of broad scope for radioactive material and certain rules governing holders of such registrations.

11.16.a. The different types of broad scope registrations are set forth below:

11.16.a.1. A "Type A specific registration of broad scope" is a specific registration authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the registration, but not exceeding quantities specified in the registration, for any authorized purpose. The quantities specified are usually in the multicurie range.

11.16.a.2. A "Type B specific registration of broad scope" is a specific registration authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in Table 64-23 Aa, for any authorized purpose. The possession limit for a Type B registration of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Table 64-23 Aa, column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Table 64-23 Aa, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the registration shall not exceed unity.

11.16.a.3. A "Type C specific registration of broad scope" is a specific registration authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of radioactive material specified in Table 64-23 Aa, for any authorized purpose. The possession limit for a Type C registration of broad scope, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Table 64-23 Aa, column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Table 64-23 Aa, column ii, for that radionuclide. The sum of the ratios for all radionuclides possessed under the registration shall not exceed unity.

11.16.b. An application for a Type A specific registration of broad scope will be approved if:

11.16.b.1. The applicant satisfies the general requirements specified in section 11.14;

11.16.b.2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

11.16.b.3. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

11.16.b.3.A. The establishment of a radiation safety committee composed of such persons as a radiation safety officer, a representative of management, and persons trained and experienced in the safe use of radioactive material;

11.16.b.3.B. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters; and

11.16.b.3.C. The establishment of appropriate administrative procedures to assure:

11.16.b.3.C.1. Control of procurement and use of radioactive material;

11.16.b.3.C.2. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

11.16.b.3.C.3. Review, approval, and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with subparagraph 11.16.b.3.C.2 prior to use of the radioactive material.

11.16.c. An application for a Type B specific registration of broad scope will be approved if:

11.16.c.1. The applicant satisfies the general requirements specified in section 11.14; and

11.16.c.2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

11.16.c.2.A. The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiation safety matters, and

11.16.c.2.B. The establishment of appropriate administrative procedures to assure,

11.16.c.2.B.1. Control of procurement and use of radioactive material,

11.16.c.2.B.2. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures, and

11.16.c.2.B.3. Review, approval, and recording by the radiation safety officer of

safety evaluations of proposed uses prepared in accordance with subparagraph 11.16.c.2.B.2 prior to use of the radioactive material.

11.16.d. An application for a type c specific registration of broad scope will be approved if:

11.16.d.1. The applicant satisfies the general requirements specified in section 11.14;

11.16.d.2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

11.16.d.2.A. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or in engineering, and

11.16.d.2.B. At least 40 hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

11.16.d.3. The applicant has established administrative controls and provisions relating to procurement of radioactive material, procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

11.16.e. Specific registrations of broad scope are subject to the following conditions:

11.16.e.1. Unless specifically authorized, persons registered pursuant to section 11.16 shall not:

11.16.e.1.A. Conduct tracer studies in the environment involving direct release of radioactive material;

11.16.e.1.B. Receive, acquire, own, possess, use, or transfer devices containing 100,000 curies (3.7 PBq) or more of radioactive material in sealed sources used for irradiation of materials;

11.16.e.1.C. Conduct activities for which a specific registration issued by the agency under sections 11.15, 11.17, or section 12 of this rule is required; or

11.16.e.1.D. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug, or other product designed for ingestion or inhalation by, or application to, a human being.

11.16.e.2. Each Type A specific registration of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the registration may only be used by, or under the direct supervision of, individuals approved by the registrant's radiation safety committee.

11.16.e.3. Each Type B specific registration of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the registration may only be used by, or under the direct supervision of, individuals approved by the registrant's radiation safety officer.

11.16.e.4. Each type c specific registration of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the registration may only be used by, or under the direct supervision of, individuals who satisfy the requirements of subsection 11.16.d.

11.17. Special Requirements for a Specific Registration to Manufacture, Assemble, Repair, or Distribute Commodities, Products, or Devices Which Contain Radioactive Material

11.17.a. Registration of the Introduction of Radioactive Material into Products in Exempt Concentrations

11.17.a.1. In addition to the requirements set forth in section 11.14, a specific registration authorizing the introduction of radioactive material into a product or material owned by or in the possession of the registrant or another to be transferred to persons exempt under subsection 11.3.a.1 will be issued if:

11.17.a.1.A. The applicant submits a description of the product or material into which the radioactive material will be introduced, intended use of the radioactive material and the product or material into which it is introduced, method of introduction, initial concentration of the radioactive material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioactive material in the product or material at the time of transfer; and

11.17.a.1.B. The applicant provides reasonable assurance that the concentrations of radioactive material at the time of transfer will not exceed the concentrations in Table 64-23 Y, that reconcentration of the radioactive material in concentrations exceeding those in Table 64-23 Y is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

11.17.a.1.C. Each person registered under subsection 11.17.a shall file an annual report with the agency which shall identify the type and quantity of each product or material into which radioactive material has been introduced during the reporting period; name and address of the person who owned or possessed the product or material, into which radioactive material has been introduced, at the time of introduction; the type and quantity of radionuclide introduced into each such product or material; and the initial concentrations of the radionuclide in the product or material at time of transfer of the radioactive material by the registrant. If no transfers of radioactive material have been made pursuant to subsection 11.17.a during the reporting period, the report shall so indicate. The report shall cover the year ending June 30, and shall be filed within 30 days thereafter.

11.17.b. Registration of the Distribution of Radioactive Material in Exempt Quantities.

11.17.b.1. An application for a specific registration to distribute NARM to persons exempted from this rule pursuant to subsection 11.3.b will be approved if:

11.17.b.1.A. The radioactive material is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being;

11.17.b.1.B. The radioactive material is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples, counting standards, plated or encapsulated sources, or similar substances, identified as radioactive and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

11.17.b.1.C. The applicant submits copies of prototype labels and brochures and the agency approves such labels and brochures.

11.17.b.2. The registration issued under subdivision 11.17.b.1 is subject to the following conditions:

11.17.b.2.A. No more than 10 exempt quantities shall be sold or transferred in any single

transaction. However, an exempt quantity may be composed of fractional parts of one or more of the exempt quantity provided the sum of the fractions shall not exceed unity.

11.17.b.2.B. Each exempt quantity shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to subsection 11.3.b The outer package shall be such that the dose rate at the external surface of the package does not exceed 0.5 millirem (five μSv) per hour.

11.17.b.2.C. The immediate container of each quantity or separately packaged fractional quantity of radioactive material shall bear a durable, legible label which:

11.17.b.2.C.1. Identifies the radionuclide and the quantity of radioactivity, and

11.17.b.2.C.2. Bears the words "radioactive material".

11.17.b.2.D. In addition to the labeling information required by paragraph 11.17.b.2.C, the label affixed to the immediate container, or an accompanying brochure, shall:

11.17.b.2.D.1. State that the contents are exempt from registration requirements,

11.17.b.2.D.2. Bear the words "radioactive material - not for human use - introduction into foods, beverages, cosmetics, drugs, or medicinals, or into products manufactured for commercial distribution is prohibited--exempt quantities should not be combined", and

11.17.b.2.D.3. Set forth appropriate additional radiation safety precautions and instructions relating to the handling, use, storage, and disposal of the radioactive material.

11.17.b.3. Each person registered under subsection 11.17.b shall maintain records identifying, by name and address, each person to whom radioactive material is transferred for use under subsection 11.17.b or the equivalent rules of a licensing state, and stating the kinds and quantities of radioactive material transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific registration shall be filed with the agency. Each report shall cover the year ending June 30, and shall be filed within 30 days thereafter. If no transfers of radioactive material have been made pursuant to subsection 11.17.b during the reporting period, the report shall so indicate.

11.17.c. Registration of the Incorporation of Naturally Occurring and Accelerator-Produced Radioactive Material into Gas and Aerosol Detectors. An application for a specific registration authorizing the incorporation of NARM into gas and aerosol detectors to be distributed to persons exempt under subdivision 11.3.c.3 will be approved if the application satisfies requirements equivalent to those contained in Section 32.26 of 10 CFR Part 32. The maximum quantity of radium-226 in each device shall not exceed 0.1 microcurie (3.7 kBq).

11.17.d. Registration of the Manufacture and Distribution of Devices to Persons Generally Registered Under Subsection 11.7.b.

11.17.d.1. An application for a specific registration to manufacture or distribute devices containing radioactive material, excluding special nuclear material, to persons generally registered under subsection 11.7.b or equivalent rules of the NRC, an agreement state, or a licensing state will be approved if:

11.17.d.1.A. The applicant satisfies the general requirements of section 11.14;

11.17.d.1.B. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing,

operating and safety instructions, and potential hazards of the device to provide reasonable assurance that:

11.17.d.1.B.1. The device can be safely operated by persons not having training in radiological protection,

11.17.d.1.B.2. Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in section 6.4.a of this rule, and

11.17.d.1.B.3. Under accident conditions such as fire and explosion associated with handling, storage, and use of the device, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the organ doses listed in Table 64-23 Ll column III: and

11.17.d.1.C. Each device bears a durable, legible, clearly visible label or labels approved by the agency, which contain in a clearly identified and separate statement:

11.17.d.1.C.1. Instructions and precautions necessary to assure safe installation, operation, and servicing of the device; documents such as operating and service manuals may be identified in the label and used to provide this information,

11.17.d.1.C.2. The requirement, or lack of requirement, for leak testing, or for testing any "on-off" mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity, and

11.17.d.1.C.3. The information called for in one of the following statements, as appropriate, in the same or substantially similar form:

11.17.d.1.C.3.(a) The receipt, possession, use, and transfer of this device, Model_____, Serial No._____[10], are subject to a general registration or the equivalent and the rules of the NRC or a state with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

11.17.d.1.C.3.(b) The receipt, possession, use, and transfer of this device, Model_____, Serial No._____[4/], are subject to a general registration or the equivalent, and the rules of a licensing state. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

CAUTION - RADIOACTIVE MATERIAL

Name of manufacturer or distributor

[10] The model, serial number and name of the manufacturer or distributor may be omitted from this label provided the information is elsewhere specified in labeling affixed to the device.

11.17.d.2. In the event the applicant desires that the device be required to be tested at intervals longer than 6 months, either for proper operation of the "on-off" mechanism and indicator, if any, or for leakage of radioactive material or for both, the applicant shall include in the application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the "on-off" mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the agency will consider information which includes, but is not limited to:

11.17.d.2.A. Primary containment or source capsule;

11.17.d.2.B. Protection of primary containment;

11.17.d.2.C. Method of sealing containment;

11.17.d.2.D. Containment construction materials;

11.17.d.2.E. Form of contained radioactive material;

11.17.d.2.F. Maximum temperature withstood during prototype tests;

11.17.d.2.G. Maximum pressure withstood during prototype tests;

11.17.d.2.H. Maximum quantity of contained radioactive material;

11.17.d.2.I. Radiotoxicity of contained radioactive material; and

11.17.d.2.J. Operating experience with identical devices or similarly designed and constructed devices.

11.17.d.3. In the event the applicant desires that the general registration under subsection 11.7.b, or under equivalent rules of the NRC, an agreement state, or a licensing state be authorized to install the device, collect the sample to be analyzed by a specific registration for leakage of radioactive material, service the device, test the "on-off" mechanism and indicator, or remove the device from installation, the applicant shall include in the application written instructions to be followed by the general registration, estimated calendar quarter doses associated with such activity or activities, and basis for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage, and use of devices under the general registration, is unlikely to cause that individual to receive a calendar quarter dose in excess of 10 percent of the limits specified in section 6.4 of this rule.

11.17.d.4. Each person registered under subsection 11.17.d to distribute devices to generally registered persons shall:

11.17.d.4.A. Furnish a copy of the general registration contained in subsection 11.7.d to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general registration contained in subsection 11.7.d;

11.17.d.4.B. Furnish a copy of the general registration contained in the NRC's, agreement state's, or licensing state's rule equivalent to subsection 11.7.d, or alternatively, furnish a copy of the general registration contained in subsection 11.7.d to each person to whom he directly or through an intermediate person transfers radioactive material in a device for use pursuant to the general registration of the NRC, the agreement state, or the licensing state. If a copy of the general registration in

use of the device is regulated by the NRC, agreement state, or licensing state under requirements subsection 11.7.d is furnished to such a person, it shall be accompanied by a note explaining that the substantially the same as those in subsection 11.7.d;

11.17.d.4.C. Report to the agency all transfers of such devices to persons for use under the general registration in subsection 11.7.d. Such report shall identify each general registration by name and address, an individual by name and position who may constitute a point of contact between the agency and the general registration, the type and model number of device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. If no transfers have been made to persons generally registered under subsection 11.7.d during the reporting period, the report shall so indicate. The report shall cover each calendar quarter and shall be filed within 30 days thereafter;

11.17.d.4.D. Furnish reports to other agencies.

11.17.d.4.D.1. Report to the NRC all transfers of such devices to persons for use under the NRC general registration in Section 31.5 of 10 CFR Part 31.

11.17.d.4.D.2. Report to the responsible State agency all transfers of devices manufactured and distributed pursuant to subsection 11.17.d for use under a general registration in that state's rules equivalent to subsection 11.7.d.

11.17.d.4.D.3. Such reports shall identify each general registration by name and address, an individual by name and position who may constitute a point of contact between the agency and the general registration, the type and model of the device transferred, and the quantity and type of radioactive material contained in the device. If one or more intermediate persons will temporarily possess the device at the intended place of use prior to its possession by the user, the report shall include identification of each intermediate person by name, address, contact, and relationship to the intended user. The report shall be submitted within 30 days after the end of each calendar quarter in which such a device is transferred to the generally registered person.

11.17.d.4.D.4. If no transfers have been made to NRC registrants during the reporting period, this information shall be reported to the NRC.

11.17.d.4.D.5. If no transfers have been made to general registrations within a particular state during the reporting period, this information shall be reported to the responsible state agency upon request of that agency; and

11.17.d.4.E. Keep records showing the name, address, and the point of contact for each general registration to whom he directly or through an intermediate person transfers radioactive material in devices for use pursuant to the general registration provided in subsection 11.7.b, or equivalent rules of the NRC, an agreement state, or a licensing state. The records shall show the date of each transfer, the radionuclide and the quantity of radioactivity in each device transferred, the identity of any intermediate person, and compliance with the report requirements of paragraph 11.17.d.1.C.

11.17.e. Special Requirements for the Manufacture, Assembly, or Repair of Luminous Safety Devices for Use in Aircraft. An application for a specific registration to manufacture, assemble, or repair luminous safety devices containing tritium or Promethium-147 for use in aircraft, for distribution to persons generally registered under section 11.8. will be approved if:

11.17.e.1. The applicant satisfies the general requirements specified in section 11.14; and

11.17.e.2. The applicant satisfies the requirements of Sections 32.53, 32.54, 32.55, 32.56, and 32.101 of 10 CFR Part 32, or their equivalent.

11.17.f. Special Requirements for Registration to Manufacture Calibration Sources Containing Americium-241, Plutonium or Radium-226 for Distribution to Persons Generally Registered Under section 11.10. An application for a specific registration to manufacture calibration and reference sources containing Americium-241, plutonium or Radium-226 to persons generally registered under section 11.10. will be approved if:

11.17.f.1. The applicant satisfies the general requirement of section 11.14.; and

11.17.f.2. The applicant satisfies the requirements of sections 32.57, 32.58, 32.59, and 32.102 of 10 CFR Part 32 and Section 70.39 of 10 CFR Part 70 or their equivalent.

11.17.g. Manufacture and Distribution of Radioactive Material for Certain In Vitro Clinical or Laboratory Testing Under General Registration. An application for a specific registration to manufacture or distribute radioactive material for use under the general registration of section 11.11. will be approved if:

11.17.g.1. The applicant satisfies the general requirements specified in section 11.14.

11.17.g.2. The radioactive material is to be prepared for distribution in prepackaged units of:

11.17.g.2.A. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

11.17.g.2.B. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

11.17.g.2.C. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

11.17.g.2.D. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

11.17.g.2.E. Mock iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of iodine-129 and 0.005 microcurie (185 Bq) of americium-241 each.

11.17.g.2.F. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

11.17.g.2.G. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

11.17.g.2.H. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

11.17.g.3. Each prepackaged unit bears a durable, clearly visible label:

11.17.g.3.A. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of Iodine-125, Iodine-131, Carbon-14, Cobalt-57, or Selenium-75; 50 microcuries (1.85 MBq) of Hydrogen-3 (tritium); 20 microcuries (740 kBq) of Iron-59; or mock Iodine-125 in units not exceeding 0.05 microcurie (1.85 kBq) of Iodine-129 and 0.005 microcurie (185 Bq) of Americium-241 each; and

11.17.g.3.B. Displaying the radiation caution symbol described in section 6.7 and the words, "CAUTION, RADIOACTIVE MATERIAL", and "Not for Internal or External Use in Humans or Animals".

11.17.g.4. One of the following statements, as appropriate, or a substantially similar

statement which contains the information called for in one of the following statements, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

11.17.g.4.A. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules and a general registration of the NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.

_____
Name of manufacturer

11.17.g.4.B. This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the rules and a general registration of a licensing state.

_____
Name of manufacturer

11.17.g.5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the registrant regarding the waste disposal requirements set out in section 6.7 of this rule.

11.17.h. Registration of the Manufacture and Distribution of Ice Detection Devices. An application for a specific registration to manufacture and distribute ice detection devices to persons generally registered under section 11.12 will be approved if:

11.17.h.1. The applicant satisfies the general requirements of section 11.14; and

11.17.h.2. The criteria of Sections 32.61, 32.62, and 32.103 of 10 CFR Part 32 are met.

11.17.i. Manufacture and Distribution of Radiopharmaceuticals Containing Radioactive Material for Medical Use Under Group Registrants. An application for a specific registration to manufacture and distribute radiopharmaceuticals containing radioactive material for use by persons registered pursuant to this section for the uses listed in sections 11.30, 11.32, and 11.36 of this rule will be approved if:

11.17.i.1. The applicant satisfies the general requirements specified in section 11.14 of this rule;

11.17.i.2. The applicant submits evidence that:

11.17.i.2.A. The radiopharmaceutical containing radioactive material will be manufactured, labeled, and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "notice of claimed investigational exemption for a new drug" (IND) that has been accepted by the FDA, or

11.17.i.2.B. The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the Federal Food, Drug and Cosmetic Act and the Public Health

Service Act;

11.17.i.3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material which is appropriate for safe handling and storage of radiopharmaceuticals by group registrations; and

11.17.i.3.A. The label affixed to each package of the radiopharmaceutical contains information on the radionuclide, quantity, and date of assay and the label affixed to each package, or the leaflet or brochure which accompanies each package, contains a statement that the radiopharmaceutical is registered by the agency for distribution to persons registered pursuant to this section for the uses listed in 11.17.i.

11.17.i.3.B. The labels, leaflets, or brochures required by paragraph 11.17.i.3.A are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

11.17.j. Manufacture and Distribution of Generators or Reagent Kits for Preparation of Radiopharmaceuticals Containing Radioactive Material.[11] An application for a specific registration to manufacture and distribute generators or reagent kits containing radioactive material for preparation of radiopharmaceuticals by persons registered pursuant to this subection for the uses listed in section 11.32 of this rule will be approved if:

11.17.j.1. The applicant satisfies the general requirements specified in section 11.25;

11.17.j.2. The applicant submits evidence that:

11.17.j.2.a. The generator or reagent kit is to be manufactured, labeled and packaged in accordance with the Federal Food, Drug and Cosmetic Act or the Public Health Service Act, such as a new drug application (NDA) approved by the Food and Drug Administration (FDA), or a "notice of claimed investigational exemption for a new drug" (IND) that has been accepted by the FDA, or

11.17.j.2.B. The manufacture and distribution of the generator or reagent kit are not subject to the Federal Food, Drug and Cosmetic Act and the Public Health Service Act;

11.17.j.3. The applicant submits information on the radionuclide, chemical and physical form, packaging including maximum activity per package, and shielding provided by the packaging of the radioactive material contained in the generator or reagent kit;

11.17.j.4. The label affixed to the generator or reagent kit contains information on the radionuclide, quantity, and date of assay; and

11.17.j.5. The label affixed to the generator or reagent kit, or the leaflet or brochure which accompanies the generator or reagent kit, contains:

11.17.j.5.A. Adequate information, from a radiation safety standpoint, on the procedures to be followed and the equipment and shielding to be used in eluting the generator or processing radioactive material with the reagent kit, and

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[11] Although the agency does not regulate the manufacture and distribution of reagent kits that do not contain radioactive material, it does regulate the use of such reagent kits for the preparation of radiopharmaceuticals containing radioactive material as part of its registration and rule of the users of radioactive material. Any manufacturer of reagent kits that do not contain radioactive material who desires to have his reagent kits approved by the agency for use by persons registered pursuant to ~~S~~subsection 11.32. of this rule may submit the pertinent information specified in ~~S~~subdivision 11.17.j.

11.17.j.5.B. A statement that this generator or reagent kit, as appropriate, is approved for use by persons registered by the agency pursuant to section 11.32 of this rule or under equivalent licenses of the NRC, an agreement state, or a licensing state. The labels, leaflets, or brochures required by subsection 11.17.j are in addition to the labeling required by the Food and Drug Administration (FDA) and they may be separate from or, with the approval of FDA, may be combined with the labeling required by FDA.

11.17.k. Manufacture and Distribution of Sources or Devices Containing Radioactive Material for Medical Use. An application for a specific registration to manufacture and distribute sources and devices containing radioactive material to persons registered pursuant to section 12 for use as a calibration or reference source or for the uses listed in sections 12.40 and 12.42 of this rule will be approved if:

11.17.k.1. The applicant satisfies the general requirements in section 11.14 of this subdivision;

11.17.k.2. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

11.17.k.2.A. The radioactive material contained, its chemical and physical form, and amount,

11.17.k.2.B. Details of design and construction of the source or device,

11.17.k.2.C. Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents,

11.17.k.2.D. For devices containing radioactive material, the radiation profile of a prototype device,

11.17.k.2.E. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests,

11.17.k.2.F. Procedures and standards for calibrating sources and devices,

11.17.k.2.G. Legend and methods for labeling sources and devices as to their radioactive content, and

11.17.k.2.H. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

11.17.k.3. The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity, and date of assay, and a statement that the source or device is registered by the agency for distribution to persons registered pursuant to section 12 and sections 12.40 and 12.42 of this rule or under equivalent licenses of the NRC, an agreement state, or a licensing state, provided that such labeling for sources which do not require long term storage may be on a leaflet or brochure which accompanies the source;

11.17.k.4. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics

of the source or device or similar sources or devices and by design features that have a significant bearing on the probability or consequences of leakage of radioactive material from the source; and

11.17.k.5. In determining the acceptable interval for test of leakage of radioactive material, the agency will consider information that includes, but is not limited to:

11.17.k.5.A. Primary containment or source capsule,

11.17.k.5.B. Protection of primary containment,

11.17.k.5.C. Method of sealing containment,

11.17.k.5.D. Containment construction materials,

11.17.k.5.E. Form of contained radioactive material,

11.17.k.5.F. Maximum temperature withstood during prototype tests,

11.17.k.5.G. Maximum pressure withstood during prototype tests,

11.17.k.5.H. Maximum quantity of contained radioactive material,

11.17.k.5.I. Radiotoxicity of contained radioactive material, and

11.17.k.5.J. Operating experience with identical sources or devices or similarly designed and constructed sources or devices.

11.17.l. Requirements for Registration to Manufacture and Distribute Industrial Products Containing Depleted Uranium for Mass-Volume Applications

11.17.l.1. An application for a specific registration to manufacture industrial products and devices containing depleted uranium for use pursuant to subsection 11.5.d equivalent rules of the NRC or an agreement state will be approved if:

11.17.l.1.A. The applicant satisfies the general requirements specified in section 11.14;

11.17.l.1.B. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in any period of one calendar quarter a radiation dose in excess of 10 percent of the limits specified in section 6.4 of this rule; and

11.17.l.1.C. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

11.17.l.2. In the case of an industrial product or device whose unique benefits are questionable, the agency will approve an application for a specific registration under subsection 11.17.l only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

11.17.l.3. The agency may deny any application for a specific registration under subsection

11.17.l if the end uses of the industrial product or device cannot be reasonably foreseen.

11.17.l.4. Each person registered pursuant to subsection 11.17.l shall:

11.17.l.4.A. Maintain the level of quality control required by the registration in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

11.17.l.4.B. Label or mark each unit to:

11.17.l.4.B.1. Identify the manufacturer of the product or device and the number of the registration under which the product or device was manufactured, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

11.17.l.4.B.2. State that the receipt, possession, use, and transfer of the product or device are subject to a general registration or the equivalent and the rules of the NRC or an agreement state;

11.17.l.4.C. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "depleted uranium";

11.17.l.4.C.1. Furnish a copy of the general registration contained in subsection 11.5.d and a copy of Agency Form W to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general registration contained in subsection 11.5.d, or

11.17.l.4.C.2. Furnish a copy of the general registration contained in the NRC's or agreement state's rule equivalent to subsection 11.5.d and a copy of the NRC's or agreement state's certificate, or alternatively, furnish a copy of the general registration contained in subsection 11.5.d and a copy of Agency Form W to each person to whom he transfers depleted uranium in a product or device for use pursuant to the general registration of the NRC or an agreement state, with a note explaining that use of the product or device is regulated by the NRC or an agreement state under requirements substantially the same as those in subsection 11.5.d;

11.17.l.4.D. Report to the agency all transfers of industrial products or devices to persons for use under the general registration in subsection 11.5.d Such report shall identify each general registration by name and address, an individual by name and position who may constitute a point of contact between the agency and the general registration, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally registered person. If no transfers have been made to persons generally registered under subsection 11.5.d during the reporting period, the report shall so indicate;

11.17.l.4.D.1. Report to the NRC all transfers of industrial products or devices to persons for use under the NRC general registration in Section 40.25 of 10 CFR Part 40,

11.17.l.4.D.2. Report to the responsible state agency all transfers of devices manufactured and distributed pursuant to subsection 11.17.l for use under a general registration in that state's rules equivalent to subsection 11.5.d,

11.17.l.4.D.3. Such report shall identify each general registration by name and address, an individual by name and position who may constitute a point of contact between the agency and the general registration, the type and model number of the device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after

the end of each calendar quarter in which such product or device is transferred to the generally registered person,

11.17.l.4.D.4. If no transfers have been made to NRC registrants during the reporting period, this information shall be reported to the NRC, and

11.17.l.4.D.5. If no transfers have been made to general registrations within a particular agreement state during the reporting period, this information shall be reported to the responsible agreement state agency upon the request of that agency; and

11.17.l.4.D.6. Keep records showing the name, address, and point of contact for each general registration to whom he transfers depleted uranium in industrial products or devices for use pursuant to the general registration provided in subsection 11.5.d or equivalent rules of the NRC or an agreement state. The records shall be maintained for a period of two years and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this subparagraph.

11.18. Issuance of Specific Registrations.

11.18.a. Upon a determination that an application meets the requirements of this rule and the rules of the agency, the agency will issue a specific registration authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

11.18.b. The agency may incorporate in any registration at the time of issuance, or thereafter by appropriate rule, or order, such additional requirements and conditions with respect to the registration's receipt, possession, use, and transfer of radioactive material subject to this subsection as it deems appropriate or necessary in order to:

11.18.b.1. Minimize danger to public health and safety or property;

11.18.b.2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the registration as may be appropriate or necessary; and

11.18.b.3. Prevent loss or theft of material subject to this subsection.

11.19. Specific Terms and Conditions of Registrations.

11.19.a. Each registration issued pursuant to this section shall be subject to all the provisions of this rule, now or hereafter in effect, and to all rules, and orders of the agency.

11.19.b. No registration issued or granted under this section and no right to possess or utilize radioactive material granted by any registration issued pursuant to this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any registration to any person unless the agency shall, after securing full information find that the transfer is in accordance with the provisions of the act, now or hereafter in effect, and to all valid rules, and orders of the agency, and shall give its consent in writing.

11.19.c. Each person registered by the agency pursuant to this section shall confine use and possession of the material registered to the locations and purposes authorized in the registration.

11.19.d. Each registrant shall notify the agency in writing when the registrant decides to permanently discontinue all activities involving materials authorized under the registration.

11.19.e. Each registrant shall notify the agency in writing immediately following the filing of a

voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (bankruptcy) of the United States Code by or against:

11.19.e.1. The registrant;

11.19.e.2. An entity (as that term is defined in 11 U.S.C. 101(14)) controlling the registrant or listing the registration or registrant as property of the estate; or

11.19.e.3. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the registrant.

11.19.f. The notification specified in subsection 11.19.e shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of the filing of the petition.

11.20. Expiration and Termination of Registrations

11.20.a. Except as provided in subsection 11.21.b, each specific registration shall expire at the end of the specified day in the month and year stated therein.

11.20.b. Each registrant shall notify the agency immediately, in writing, and request termination of the registration when the registrant decides to terminate all activities involving radioactive material authorized under the registration. This notification and request for termination of the registration must include the reports and information specified in subdivisions 11.20.d.4 and 11.20.d.5.

11.20.c. No less than 30 days before the expiration date specified in the registration, the registrant shall either:

11.20.c.1. Submit an application for registration renewal under section 11.21; or

11.20.c.2. Notify the agency, in writing, if the registrant decides not to renew the registration.

11.20.d. If a registrant does not submit an application for registration renewal under section 11.21, the registrant shall, on or before the expiration date specified in the registration:

11.20.d.1. Terminate use of radioactive material;

11.20.d.2. Remove radioactive contamination to the extent practicable;

11.20.d.3. Properly dispose of radioactive material;

11.20.d.4. Submit a completed Agency Form T; and

11.20.d.5. Submit a radiation survey report to confirm the absence of radioactive material or to establish the levels of residual radioactive contamination, unless the registrant demonstrates the absence of residual radioactive contamination in some other manner. The registrant shall, as appropriate:

11.20.d.5.A. Report levels of radiation in units of microrads per hour of beta and gamma radiation at 1 centimeter and gamma radiation at 1 meter from surfaces and report levels of radioactivity, including alpha, in units of transformations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete; and

11.20.d.5.B. Specify the instrumentation used and certify that each instrument was properly calibrated and tested.

11.20.d.6. If no residual radioactive contamination attributable to activities conducted under the registration is detected, the registrant shall submit a certification that no detectable radioactive contamination was found. The agency will notify the registrant, in writing, of the termination of the registration.

11.20.d.7. If detectable levels of residual radioactive contamination attributable to activities conducted under the registration are found, the registration continues in effect beyond the expiration date, if necessary, with respect to possession of residual radioactive material present as contamination until the agency notifies the registrant in writing that the registration is terminated. During this time the registrant is subject to the provisions of subsection 11.20.e.

11.20.d.8. In addition to the information submitted under subdivisions 11.20.d.4 and 11.20.d.5, the registrant shall submit a plan for decontamination, if required, as regards residual radioactive contamination remaining at the time the registration expires.

11.20.e. Each registrant who possesses residual radioactive material under subdivision 11.20.d.7, following the expiration date specified in the registration shall:

11.20.e.1. Limit actions involving radioactive material to those related to decontamination and other activities related to preparation for release for unrestricted use; and

11.20.e.2. Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the agency notifies the registrant in writing that the registration is terminated.

11.21. Renewal of Registrations.

11.21.a. Applications for renewal of specific registrations shall be filed in accordance with section 11.13.

11.21.b. In any case in which a registrant, not less than 30 days prior to expiration of his existing registration, has filed an application in proper form for renewal or for a new registration authorizing the same activities, such existing registration shall not expire until final action by the agency.

11.22. Amendment of Registrations at Request of Registrant. Applications for amendment of a registration shall be filed in accordance with section 11.13 and shall specify the respects in which the registrant desires the registration to be amended and the grounds for such amendment.

11.23. Agency Action on Applications to Renew or Amend. In considering an application by a registrant to renew or amend the registration, the agency will apply the criteria set forth in sections 11.14 - 11.17 and in sections 8, 12 and 15 of this rule, as applicable.

11.24. Persons Possessing a Registration for Source, Byproduct, or Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass on Effective Date of This rule. Any person who, on the effective date of this rule, possesses a general or specific registration for source, byproduct, or special nuclear material in quantities not sufficient to form a critical mass, issued by the NRC, shall be deemed to possess a like registration issued under this section and this rule, such registration to expire either ninety (90) days after receipt from the agency of a notice of expiration of such registration, or on the date or expiration specified in the NRC registration, whichever is earlier.

11.25. Persons Possessing Naturally Occurring and Accelerator-Produced Radioactive Material (NARM) on Effective Date of This rule. Any person who, on the effective date of this rule, possesses NARM for which a specific registration is required by this rule or this section shall be deemed to possess such a registration issued under this rule and this section. Such registration shall expire 90 days after the

effective date of this rule; provided, however, that if within the 90 days the person possessing such material files an application in proper form for a registration, such existing registration shall not expire until the application has been finally determined by the agency.

11.26. Transfer of Material.

11.26.a. No registrant shall transfer radioactive material except as authorized pursuant to section 11.26.

11.26.b. Except as otherwise provided in his registration and subject to the provisions of subsections 11.26.c and 11.26.d, any registrant may transfer radioactive material:

11.26.b.1. To the agency;

11.26.b.2. To the U.S. department of energy;

11.26.b.3. To any person exempt from this rule to the extent permitted under such exemption;

11.26.b.4. To any person authorized to receive such material under terms of a general registration or its equivalent, or a specific registration or equivalent registration document, issued by the agency, the NRC, any agreement state or any licensing state, or to any person otherwise authorized to receive such material by the federal government or any agency thereof, the agency, an agreement state or a licensing state; or

11.26.b.5. As otherwise authorized by the agency in writing.

11.26.c. Before transferring radioactive material to a specific registration of the agency, the NRC, an agreement state or a licensing state, or to a general registration who is required to register with the agency, the NRC, an agreement state or a licensing state prior to receipt of the radioactive material, the registrant transferring the material shall verify that the transferee's registration authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

11.26.d. Any of the following methods for the verification required by subsection 11.26.c is acceptable:

11.26.d.1. The transferor may possess and read a current copy of the transferee's specific registration or registration certificate.

11.26.d.2. The transferor may possess a written certification by the transferee that the transferee is authorized by registration or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the registration or registration certificate number, issuing agency, and expiration date.

11.26.d.3. For emergency shipments, the transferor may accept oral certification by the transferee that the transferee is authorized by registration or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the registration or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within 10 days.

11.26.d.4. The transferor may obtain other information compiled by a reporting service from official records of the agency, the NRC, an agreement state, or a licensing state regarding the identity of registrants and the scope and expiration dates of licenses and registration.

11.26.d.5. When none of the methods of verification described in subdivisions 11.26.d.1 – 11.26.d.4 are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the agency, the NRC, or an agreement state, or a licensing state that the transferee is registered to receive the radioactive material.

11.26.e. Shipment and transport of radioactive material shall be in accordance with the provisions of section 15 of this rule.

11.27. Modification and Revocation of Registrations.

11.27.a. The terms and conditions of all registrations shall be subject to amendment, revision, or modification or the registration may be suspended or revoked by reason of amendments to this rule, or by reason of rules, rules, and orders issued by the agency.

11.27.b. Any registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of this rule, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a registration on an original application, or for violation of, or failure to observe any of the terms and conditions of this rule, or of the registration, or of any rule, or order of the agency.

11.27.c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

11.28. Reciprocal Recognition of Registrations.

11.28.a. Registrations of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass

11.28.a.1. Subject to this rule, any person who holds a specific registration from the NRC or an agreement state, and issued by the agency having jurisdiction where the registrant maintains an office for directing the registered activity and at which radiation safety records are normally maintained, is hereby granted a general registration to conduct the activities authorized in such registration document within this state for a period not in excess of one hundred 180 days in any calendar year provided that:

11.28.a.1.A. The registration document does not limit the activity authorized by such document to specified installations or locations;

11.28.a.1.B. The out-of-state registrant notifies the agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent registration document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state registrant, the registrant may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general registration provided in subdivision 11.28.a.1;

11.28.a.1.C. The out-of-state registrant complies with all applicable rules of the agency and with all the terms and conditions of the registration document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

11.28.a.1.D. The out-of-state registrant supplies such other information as the agency may request; and

11.28.a.1.E. The out-of-state registrant shall not transfer or dispose of radioactive material possessed or used under the general registration provided in subdivision 11.28.a.1 except by transfer to a person:

11.28.a.1.E.1. Specifically registered by the agency or by the NRC to receive such material, or

11.28.a.1.E.2. Exempt from the requirements for a registration for such material under subsection 11.3.a.

11.28.a.2. Notwithstanding the provisions of subdivision 11.28.a.1, any person who holds a specific registration issued by the NRC or an agreement state authorizing the holder to manufacture, transfer, install, or service a device described in subdivision 11.7.b.1 within areas subject to the jurisdiction of the registration body is hereby granted a general registration to install, transfer, demonstrate, or service such a device in this state provided that:

11.28.a.2.A. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general registration to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

11.28.a.2.B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific registration issued to such person by the NRC or an agreement state;

11.28.a.2.C. Such person shall assure that any labels required to be affixed to the device under rules of the authority which registered manufacture of the device bear a statement that "removal of this label is prohibited"; and

11.28.a.2.D. The holder of the specific registration shall furnish to each general registration to whom he transfers such device or on whose premises he installs such device a copy of the general registration contained in subsection 11.7.b in equivalent rules of the agency having jurisdiction over the manufacture and distribution of the device.

11.28.a.3. The agency may withdraw, limit, or qualify its acceptance of any specific registration or equivalent registration document issued by the NRC or an agreement state, or any product distributed pursuant to such registration document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

11.28.b. Registrations of Naturally Occurring and Accelerator-Produced Radioactive Material

11.28.b.1. Subject to this rule, any person who holds a specific registration from a licensing state, and issued by the agency having jurisdiction where the registrant maintains an office for directing the registered activity and at which radiation safety records are normally maintained, is hereby granted a general registration to conduct the activities authorized in such registration document within this state for a period not in excess of one hundred 180 days in any calendar year provided that:

11.28.b.1.A. The registration document does not limit the activity authorized by such document to specified installations or locations;

11.28.b.1.B. The out-of-state registrant notifies the agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the state, and shall be accompanied by a copy of the pertinent registration document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state registrant, the registrant may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general registration provided in subdivision 11.28.b.1;

11.28.b.1.C. The out-of-state registrant complies with all applicable rules of the agency and with all the terms and conditions of the registration document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

11.28.b.1.D. The out-of-state registrant supplies such other information as the agency may request; and

11.28.b.1.E. The out-of-state registrant shall not transfer or dispose of radioactive material possessed or used under the general registration provided in subdivision 11.28.b.1 except by transfer to a person:

11.28.b.1.E.1. Specifically registered by the agency or by another licensing state to receive such material, or

11.28.b.1.E.2. Exempt from the requirements for a registration for such material under section 11.3.

11.28.b.2. Notwithstanding the provisions of subdivision 11.28.b.1, any person who holds a specific registration issued by a licensing state authorizing the holder to manufacture, transfer, install, or service a device described in subdivision 11.7.b.1 within areas subject to the jurisdiction of the registration body is hereby granted a general registration to install, transfer, demonstrate or service such a device in this state provided that:

11.28.b.2.A. Such person shall file a report with the agency within 30 days after the end of each calendar quarter in which any device is transferred to or installed in this state. Each such report shall identify each general registration to whom such device is transferred by name and address, the type of device transferred, and the quantity and type of radioactive material contained in the device;

11.28.b.2.B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific registration issued to such person by a licensing state;

11.28.b.2.C. Such person shall assure that any labels required to be affixed to the device under rules of the authority which registered manufacture of the device bear a statement that "removal of this label is prohibited"; and

11.28.b.2.D. The holder of the specific registration shall furnish to each general registration to whom he transfers such device or on whose premises he installs such device a copy of the general registration contained in subsection 11.7.b or in equivalent rules of the agency having jurisdiction over the manufacture and distribution of the device.

11.28.b.3. The agency may withdraw, limit, or qualify its acceptance of any specific registration or equivalent registration document issued by a licensing state, or any product distributed pursuant to such registration document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

§64-23-12. Use of Radionuclides in the Healing Arts.

12.1. Scope -- The provisions of this section apply to all registrants who use sealed sources in the healing arts and are in addition to, and not in substitution for, other applicable provisions of this rule.

12.2. Definitions -- As used in section 12 the following definitions apply:

12.2.a. Address of Use -- the building or buildings that are identified on the registration and where radioactive material may be produced, prepared, received, used, or stored.

12.2.b. Area of Use -- a portion of a physical ~~structure~~ address that has been set aside for the purpose of producing, preparing, receiving, using, or storing radioactive material.

12.2.c. Authorized User -- a practitioner of the healing arts who is identified as an authorized user on an agency [or the Nuclear Regulatory Commission] registration or registration that authorizes the medical use of radioactive material.

12.2.d. Brachytherapy -- a method of radiation therapy in which sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, or interstitial application.

12.2.e. Dedicated Check Source -- a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years. This source may also be used for other purposes.

12.2.f. Diagnostic Clinical Procedures Manual -- a collection of written procedures that describes each method (and other instructions and precautions) by which the registrant performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.

12.2.g. Medical Institution -- an organization in which several medical disciplines are practiced.

12.2.h. Medical Use -- the intentional internal or external administration of radioactive material, or the radiation therefrom, to humans in the practice of the healing arts.

12.2.i. Misadministration -- the administration of:

12.2.i.1. A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 μCi) of either sodium iodide, I-125 or I-131:

12.2.i.1.A. Involving the wrong patient or wrong radiopharmaceutical; or

12.2.i.1.B. When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 1.11 megabecquerels (30 μCi);

12.2.i.2. A therapeutic radiopharmaceutical dosage, other than sodium iodide, I-125 or I-131:

12.2.i.2.A. Involving the wrong patient, wrong radiopharmaceutical, or wrong route of administration; or

12.2.i.2.B. When the administered dosage differs from the prescribed dosage by more

than 20 percent of the prescribed dosage;

12.2.i.3. A gamma stereotactic radiosurgery radiation dose:

12.2.i.3.A. Involving the wrong patient or wrong treatment site; or

12.2.i.1.B. When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

12.2.i.4. A teletherapy radiation dose:

12.2.i.4.A. Involving the wrong patient, wrong mode of treatment, or wrong treatment site; or

12.2.i.4.B. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

12.2.i.4.C. When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

12.2.i.4.D. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

12.2.i.5. A brachytherapy radiation dose:

12.2.i.5.A. Involving the wrong patient, wrong radionuclide, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site); or

12.2.i.5.B. Involving a sealed source that is leaking; or

12.2.i.5.C. When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

12.2.i.5.D. When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose;

12.2.i.6. A diagnostic radiopharmaceutical dosage, other than quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131, both:

12.2.i.6.A. Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and

12.2.i.6.B. When the dose to the patient exceeds 50 millisieverts (five rem) effective dose equivalent or 500 millisieverts (50 Rem) dose equivalent to any individual organ.

12.2.j. Mobile Nuclear Medicine Service -- the transportation and medical use of radioactive material.

12.2.k. Output -- the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.

12.2.l. Prescribed Dosage -- the quantity of radiopharmaceutical activity as documented:

12.2.l.1. In a written directive; or

12.1.l.2. Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

12.2.m. Prescribed Dose:

12.2.m.1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive; or

12.2.m.2. For teletherapy, the total dose and dose per fraction as documented in the written directive; or

12.2.m.3. For brachytherapy, either the total source strength and exposure time, or the total dose, as documented in the written directive.

12.2.n. Recordable event -- the administration of:

12.2.n.1. A radiopharmaceutical or radiation without a written directive where a written directive is required;

12.2.n.2. A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

12.2.n.3. A radiopharmaceutical dosage greater than 1.11 megabecquerels (30 μCi) of sodium iodide I-125 or I-131 when both the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and the difference between the administered dosage and the prescribed dosage exceeds 555 kilobecquerels (15 μCi);

12.2.n.4. A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

12.2.n.5. A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

12.2.n.6. A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose.

12.2.o. Teletherapy -- ~~therapeutic irradiation in which the source of radiation is at a distance from the body.~~ method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient.

12.2.p. Visiting Authorized User -- an authorized user who is not identified on the registration of the registrant being visited.

12.2.q. Written Directive -- an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in 12.2.q.iv., containing the following information:

12.2.q.1. For any administration of quantities greater than 1.11 megabecquerels (30 μCi) of

sodium iodide I-125 or I-131: the radionuclide, and dosage; or

12.2.q.2. For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration; or

12.2.q.3. For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; or

12.2.q.4. For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; or

12.2.q.5. For high-dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, and total dose; or

12.2.q.6. For all other brachytherapy,

12.2.q.6.A. Prior to implantation: the radionuclide, number of sources, and source strengths; and

12.2.q.6.B. After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

12.3. Registration Required.

12.3.a. No person shall manufacture, produce, prepare, compound, acquire, receive, possess, use, or transfer radioactive material for medical use except in accordance with a registration issued pursuant to this rule.

12.3.b. Unless prohibited by registration condition, an individual may receive, possess, use, or transfer radioactive material in accordance with the rules in ~~S~~section 11 under the supervision of an authorized user as provided in section 11.10.

12.4. Registration Amendments. A registrant shall apply for and receive a registration amendment:

12.4.a. Before using radioactive material for a method or type of medical use not permitted by the registration issued under section 11;

12.4.b. Before permitting anyone, except a visiting authorized user described in section 11.11, to work as an authorized user under the registration;

12.4.c. Before changing a radiation safety officer or teletherapy physicist;

12.4.d. Before receiving radioactive material in excess of the amount authorized on the registration;

12.4.e. Before adding to or changing the areas of use or address or addresses of use identified in the application or on the registration; and

12.4.f. Before changing statements, representations, and procedures which are incorporated into the registration.

12.5. Notifications. A registrant shall notify the agency in writing within 30 days when an authorized user, radiation safety officer, or teletherapy physicist, permanently discontinues performance of duties under the registration.

12.6. ALARA Program.

12.6.a. Each registrant shall develop and implement a written program to maintain radiation doses and releases of radioactive material in effluents to unrestricted areas as low as reasonably achievable (ALARA) as defined in section 1 of this rule.

12.6.b. To satisfy the requirement of subsection 11.6.a:

12.6.b.1. The management, radiation safety officer, and all authorized users shall participate in the establishment, implementation, and operation of the program as required by this rule or the radiation safety committee; or

12.6.b.2. For registrants that are not medical institutions, management and all authorized users shall participate in the program as required by the radiation safety officer.

12.6.c. The ALARA program shall include an annual review by the radiation safety committee for registrant s that are medical institutions, or management and the radiation safety officer for registrants that are not medical institutions, of summaries of the types and amounts of radioactive material used, occupational dose reports, and continuing education and training for all personnel who work with or in the vicinity of radioactive material. The purpose of the review is to ensure that individuals make every reasonable effort to maintain occupational doses, doses to the general public, and releases of radioactive material as low as reasonably achievable, taking into account the state of technology, and the cost of improvements in relation to benefits.

12.6.d. The registrant shall retain a current written description of the ALARA program for the duration of the registration. The written description shall include:

12.6.d.1. A commitment by management to keep occupational doses as low as reasonably achievable;

12.6.d.2. A requirement that the radiation safety officer brief management once each year on the radiation safety program;

12.6.d.3. Personnel exposure investigational levels as established in accordance with subdivision 11.8.b.8 that, when exceeded, will initiate an investigation by the radiation safety officer of the cause of the exposure; and

12.6.d.4. Personnel exposure action levels that, when exceeded, will initiate a prompt investigation by the radiation safety officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence.

12.7. Radiation Safety Officer.

12.7.a. A registrant shall appoint a radiation safety officer responsible for implementing the radiation safety program. The registrant, through the radiation safety officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the registrant's radioactive material program.

12.7.b. The Radiation Safety Officer shall:

12.7.b.1. Investigate overexposures, misadministrations, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, and disposals, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

12.7.b.2. Implement written policy and procedures for:

12.7.b.2.A. Authorizing the purchase of radioactive material;

12.7.b.2.B. Receiving and opening packages of radioactive material;

12.7.b.2.C. Storing radioactive material;

12.7.b.2.D. Keeping an inventory record of radioactive material;

12.7.b.2.E. Using radioactive material safely;

12.7.b.2.F. Taking emergency action if control of radioactive material is lost;

12.7.b.2.G. Performing periodic radiation surveys;

12.7.b.2.H. Performing checks and calibrations of survey instruments and other safety equipment;

12.7.b.2.I. Disposing of radioactive material;

12.7.b.2.J. Training personnel who work in or frequent areas where radioactive material is used or stored; and

12.7.b.2.K. Keeping a copy of all records and reports required by the agency rules, a copy of this rule, a copy of each registration request and registration and amendments and the written policy and procedures required by the rules; and

12.7.c. For medical use not sited at a medical institution, approve or disapprove radiation safety program changes with the advice and consent of management prior to submittal to the agency for registration action; or

12.7.d. For medical use sited at a medical institution, assist the radiation safety committee in the performance of its duties.

12.8. Radiation Safety Committee. Each medical institution registrant shall establish a radiation safety committee to oversee the use of radioactive material.

12.8.a. The committee shall meet the following administrative requirements:

12.8.a.1. Membership must consist of at least three individuals and shall include an authorized user of each type of use permitted by the registration, the radiation safety officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a radiation safety officer. Other members may be included as the registrant deems appropriate;

12.8.a.2. The committee shall meet at least once each calendar quarter;

12.8.a.3. To establish a quorum and to conduct business, one-half of the committee's membership shall be present, including the radiation safety officer and the management's representative;

12.8.a.4. The minutes of each radiation safety committee meeting shall include:

12.8.a.4.A. The date of the meeting;

12.8.a.4.B. Members present;

12.8.a.4.C. Members absent;

12.8.a.4.D. Summary of deliberations and discussions;

12.8.a.4.E. Recommended actions and the numerical results of all ballots;

12.8.a.4.F. Documentation of any reviews required in subsections 11.6.c and 11.8.b;

12.8.a.4.G. The committee shall provide each member with a copy of the meeting minutes, and retain one copy until the agency authorizes its disposition.

12.8.b. To oversee the use of registered material, the committee shall:

12.8.b.1. Be responsible for monitoring the institutional program to maintain occupational doses as low as reasonably achievable;

12.8.b.2. Review, on the basis of safety and with regard to the training and experience standards of section 11, and approve or disapprove any individual who is to be listed as an authorized user, the radiation safety officer, or teletherapy physicist before submitting a registration application or request for amendment or renewal;

12.8.b.3. Review on the basis of safety and approve or disapprove each proposed method of use of radioactive material;

12.8.b.4. Review on the basis of safety, and approve with the advice and consent of the radiation safety officer and the management representative, or disapprove procedures and radiation safety program changes prior to submittal to the agency for registration action;

12.8.b.5. Review quarterly, with the assistance of the radiation safety officer, occupational radiation exposure records of all personnel working with radioactive material;

12.8.b.6. Review quarterly, with the assistance of the radiation safety officer, all incidents involving radioactive material with respect to cause and subsequent actions taken;

12.8.b.7. Review annually, with the assistance of the radiation safety officer, the radioactive material program; and

12.8.b.8. Establish a Table of investigational and action levels for occupational dose that, when exceeded, will initiate investigations and considerations of action by the radiation safety officer.

12.9. Statement of Authorities and Responsibilities.

12.9.a. A registrant shall provide sufficient authority and organizational freedom to the radiation safety officer and the radiation safety committee to:

12.9.a.1. Identify radiation safety problems;

12.9.a.2. Initiate, recommend, or provide solutions; and

12.9.a.3. Verify implementation of corrective actions.

12.9.b. A registrant shall establish in writing the authorities, duties, responsibilities, and radiation safety activities of the radiation safety officer and the radiation safety committee.

12.10. Supervision.

12.10.a. A registrant who permits the receipt, possession, production, preparation, compounding, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by section 11.3 shall:

12.10.a.1. Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of radioactive material and in the registrant 's written quality management program;

12.10.a.2. Periodically review the supervised individual's use of radioactive material, the records kept to reflect this use, and provide reinstruction as needed;

12.10.a.3. Require an authorized user to be immediately available to communicate with the supervised individual; and

12.10.a.4. Require that only those individuals permitted under state and local rules and specifically trained, and designated by the authorized user, be permitted to administer radionuclides or radiation to patients.

12.10.b. A registrant shall require the supervised individual receiving, possessing, producing, preparing, compounding, using or transferring radioactive material under section 11.3 to:

12.10.b.1. Follow the instructions of the supervising authorized user;

12.10.b.2. Follow the written radiation safety and quality management procedures established by the registrant; and

12.10.b.3. Comply with this rule conditions with respect to the use of radioactive material.

12.11. Visiting Authorized User.

12.11.a. A registrant may permit any visiting authorized user to use registered material for medical use under the terms of the registrant’s registration for 60 days each year if:

12.11.a.1. The visiting authorized user has the prior written permission of the registrant’s management and, if the use occurs on behalf of an institution, the institution's radiation safety committee;

12.11.a.2. The registrant has a copy of an agency, agreement state, licensing state or the Nuclear Regulatory Commission registration that identifies the visiting authorized user by name as an authorized user for medical use; and

12.11.a.3. Only those procedures for which the visiting authorized user is specifically authorized by an agency, agreement state, licensing state or the Nuclear Regulatory Commission registration are performed by that individual.

12.11.b. A registrant need not apply for a registration amendment in order to permit a visiting authorized user to use registered material as described in subsection 11.11.a.

12.11.c. A registrant shall retain copies of the records specified in subsection 11.11.a for three years from the date of the last visit.

12.12. Mobile Nuclear Medicine Service Administrative Requirements.

12.12.a. The agency shall register mobile nuclear medicine services or clients of such services. The mobile nuclear medicine service shall be registered if the service receives, uses or possesses radioactive material. The client of the mobile nuclear medicine service shall be registered if the client receives or possesses radioactive material to be used by a mobile nuclear medicine service.

12.12.b. Mobile nuclear medicine service registrations shall retain for the duration of service a letter signed by the management of each location where services are rendered that authorizes use of radioactive material. If the client is registered, the letter shall document procedures for notification, receipt, storage and documentation of transfer of radioactive material delivered to the client's location for use by the mobile nuclear medicine service.

12.12.c. A mobile nuclear medicine service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client's address of use, unless the client has a registration. Radioactive material delivered to the client's address of use shall be received and handled in conformance with the client's registration.

12.12.d. A mobile nuclear medicine service shall inform a responsible individual, such as a representative of management in charge of the patient or the registered nurse in charge of the nursing unit, who is on site at each client's address of use at the time that radiopharmaceuticals are being administered.

12.13. Quality Management Program.

12.13.a. Each registrant shall establish and maintain a written quality management program to provide assurance that radioactive material or radiation therefrom will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

12.13.a.1. That, prior to administration, a written directive is prepared for:

12.13.a.1.A. Any teletherapy radiation dose;

12.13.a.1.B. Any gamma stereotactic radiosurgery radiation dose;

12.13.a.1.C. Any brachytherapy radiation dose;

12.13.a.1.D. Any administration of quantities greater than 1.11 megabecquerels (30 μCi) of either sodium iodide I-125 or I-131; or

12.13.a.1.E. Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(NOTE: If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within forty 48 hours of the oral revision. Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose. If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is

documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.)

12.13.a.2. That, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive;

12.13.a.3. That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

12.13.a.4. That each administration is in accordance with the written directive; and

12.13.a.5. That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

12.13.b. Each registrant shall:

12.13.b.1. Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

12.13.b.2. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of subsection 11.13.a; and

12.13.b.3. Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

12.13.c. The registrant shall evaluate and respond to each recordable event, within 30 days after discovery of the recordable event, by:

12.13.c.1. Assembling the relevant facts including the cause;

12.13.c.2. Identifying what, if any, corrective action is required to prevent recurrence; and

12.13.c.3. Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

12.13.d. Each registrant shall retain:

12.13.d.1. Each written directive; and

12.13.d.2. A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in subdivision 12.13.a.1, in an auditable form, for three years after the date of administration.

12.13.e. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

12.14. Records, Notifications, and Reports of Misadministrations.

12.14.a. For a misadministration:

12.14.a.1. The registrant shall notify the agency by telephone no later than 24 hours after

discovery of the misadministration;

12.14.a.2. The registrant shall submit a written report to the agency within 15 days after discovery of the misadministration. The written report must include the registrant's name; the prescribing physicians's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient;

12.14.a.3. The registrant shall notify the referring physician and also notify the patient of the misadministration not later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the patient or that, based on medical judgement, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible thereafter. The registrant may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;

12.14.a.4. If the patient was notified, the registrant shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

12.14.a.4.A. A copy of the report that was submitted to the agency; or

12.14.a.4.B. A brief description of both the event and the consequences, as they may affect the patient, provided a statement is included that the report submitted to the agency can be obtained from the registrant.

12.14.b. Each registrant shall retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

12.14.c. Aside from the notification requirement, nothing in subsections 11.14.a and 11.14.b shall affect any rights or duties of registrant s and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

12.15. Suppliers. A registrant shall use for medical use only:

12.15.a. Radioactive material manufactured, produced, labeled, prepared, compounded, packaged, and distributed in accordance with a registration issued pursuant to this rule or the equivalent rules of an agreement state, a licensing state or the Nuclear Regulatory Commission; and

12.15.b. Reagent kits, radiopharmaceuticals, or radiobiologics that have been manufactured, labeled, packaged, and distributed in accordance with an approval issued by the food and drug administration; or

12.15.c. Radiopharmaceuticals compounded from a prescription in accordance with the rules of the State Board of Pharmacy.

12.15.d. Teletherapy and brachytherapy sources manufactured and distributed in accordance with

a registration issued pursuant to this rule, or the equivalent rules of an agreement state, a licensing state, or the Nuclear Regulatory Commission.

12.16. Quality Control of Diagnostic Equipment. Each registrant shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or procedures which have been approved by the agency. The registrant shall conduct quality control procedures in accordance with written procedures.

12.17. Possession, Use, Calibration, and Check of Dose Calibrators.

12.17.a. A medical use registrant authorized to administer radiopharmaceuticals shall possess a dose calibrator and use it to measure the amount of activity administered to each patient. In the case where the ionization type dose calibrator cannot be used effectively to verify administered activity, the registrant shall use an alternative method. Any alternative method to the use of a dose calibrator shall be approved by the agency in writing. Any alternative method shall provide for acceptable verification of constancy, accuracy, linearity, and geometry dependence as applicable.

12.17.b. Each registrant shall establish written quality control procedures for all dose calibrators used for measuring the amount of activity administered to a patient. As a minimum, quality control procedures and frequencies shall be those recommended by the American National Standards Institute in ANSI N42.13-1986 or the registrant shall:

12.17.b.1. Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. The check shall be done on a frequently used setting with a sealed source of not less than one and 1.85 megabecquerels (50 μCi) of any photon-emitting radionuclide with a half-life greater than 90 days;

12.17.b.2. Test each dose calibrator for accuracy upon installation and at intervals not to exceed 12 months thereafter by assaying at least two sealed sources containing different radionuclides with activities of at least 1.85 megabecquerels (50 μCi) each. The activity of one source shall be determined by the manufacturer to be within five percent of the stated activity. All other sources used for this test shall be within 10 percent of the stated activity. All sources used to satisfy the accuracy test shall be calibration sources traceable to the national institute of standards and technology or other standards recognized as being equivalent by the national institute of standards and technology;

12.17.b.3. Test each dose calibrator for linearity upon installation and at intervals not to exceed three months thereafter over the range of use between 370 kilobecquerels (10 μCi) and the highest dosage that will be assayed; and

12.17.b.4. Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The registrant shall keep a record of this test for the duration of the use of the dose calibrator.

12.17.c. A registrant shall mathematically correct dosage readings for any geometry or linearity error that exceeds ten percent if the dosage is greater than 370 kilobecquerels (10 μCi) and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

12.17.d. A registrant shall also perform checks and tests required by subsection ~~11.17.b~~12.17.b following adjustment or repair of the dose calibrator.

12.17.e. A registrant shall retain a record of each check and test required by section ~~11.17~~12.17 or three years. The records required by subsection ~~11.17.b~~12.17.b shall include:

12.17.e.1. For subdivision ~~11.17.b.1~~12.17.b.1, the model and serial number of the dose calibrator, the identity and calibrated activity of the radionuclide contained in the check source, the date of the check, the activity measured, the instrument settings, and the initials of the individual who performed the check;

12.17.e.2. For subdivision ~~11.17.b.2~~12.17.b.2, the model and serial number of the dose calibrator, the model and serial number of each source used and the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, the instrument settings, and the signature of the individual who performed the test;

12.17.e.3. For subdivision ~~11.17.b.3~~12.17.b.3, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the individual who performed the test; and

12.17.e.4. For subdivision ~~11.17.b.4~~12.17.b.4, the model and serial number of the dose calibrator, the configuration and calibrated activity of the source measured, the activity of the source, the activity measured and the instrument setting for each volume measured, the date of the test, and the signature of the individual who performed the test.

12.18. Calibration and Check of Survey Instruments.

12.18.a. A registrant shall ensure that the survey instruments used to show compliance with section 12 have been calibrated before first use, annually, and following repair.

12.18.b. To satisfy the requirements of subsection ~~11.18.a~~12.18.a registrant shall:

12.18.b.1. Calibrate all required scale readings up to 10 millisieverts (1,000 mrem) per hour with a radiation source;

12.18.b.2. For each scale that shall be calibrated, calibrate two readings separated by at least 50 percent of scale rating; and

12.18.b.3. Conspicuously note on the instrument the apparent dose rate from a dedicated check source as determined at the time of calibration, and the date of calibration.

12.18.c. To satisfy the requirements of subsection ~~11.18.b~~12.18.b, the registrant shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 10 percent; and consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent if a correction chart or graph is conspicuously attached to the instrument.

12.18.d. A registrant shall check each survey instrument for proper operation with the dedicated check source before each use. The registrant is not required to keep records of these checks.

12.18.e. The registrant shall retain a record of each calibration required in subsection ~~11.18.a~~12.18.a for three years. The record shall include:

12.18.e.1. A description of the calibration procedure; and

12.18.e.2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

12.18.f. To meet the requirements of subsections ~~11.18.a., b., and c.~~12.18.a – 11.18.c, the registrant may obtain the services of individuals registered by the agency, the Nuclear Regulatory Commission, an agreement state, or a licensing state to perform calibrations of survey instruments. Records of calibrations which contain information required by subsection ~~11.18.e~~12.18.e shall be maintained by the registrant.

12.19. Assay of Radiopharmaceutical Dosages. A registrant shall:

12.19.a. Assay, [within 30 minutes] before medical use, the activity of each radiopharmaceutical dosage that contains more than 370 kilobecquerels (10 μCi) of a photon-emitting radionuclide;

12.19.b. Assay, before medical use, the activity of each radiopharmaceutical dosage emitting alpha and beta radiation or alpha or beta radiation as the radiation of principal interest, unless such radiopharmaceutical has been obtained:

12.19.b.1. In unit dose form, calibrated by the supplier for individual patients; and

12.19.b.2. From a supplier which participates in a measurement quality assurance program with the national institute of standards and technology, and which is designed to ensure that unit doses have a calibration traceable to a national standard;

12.19.c. Retain a record of the assays or calibrations required by subsections 11.19.a. and 11.19.b, for three years. To satisfy this requirement, the record shall contain the:

12.19.c.1. Radiopharmaceutical, or the radionuclide administered;

12.19.c.2. Patient's name, and identification number if one has been assigned;

12.19.c.3. Prescribed dosage and measured activity of the dosage at the time of assay, or a notation that the total activity was determined by a calibration traceable to a national standard;

12.19.c.4. Date and time of the assay or calibration and the date and time of the administration; and

12.19.c.5. Initials of the individual who performed the assay or documentation of the supplier's participation in the measurement quality assurance program specified in subsection ~~11.18.b~~12.18.b.

12.20. Authorization for Calibration and Reference Sources. Any person authorized by section ~~11.3~~12.3 for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration and reference use:

12.20.a. Sealed sources manufactured and distributed by persons specifically registered pursuant to section 11 of this rule or equivalent provisions of the Nuclear Regulatory Commission, agreement state or licensing state and that do not exceed 555 megabecquerels (15 mCi) each;

12.20.b. Any radioactive material [listed in sections 12.31 or 11.33] with a half-life of 100 days or less in individual amounts not to exceed 555 megabecquerels (15 mCi);

12.20.c. Any radioactive material [listed in sections 12.31 or 12.33] with a half-life greater than 100 days in individual amounts not to exceed 7.4 megabecquerels (200 μCi) each; and

12.20.d. Technetium-99m in individual amounts not to exceed 1.85 gigabecquerels (50 mCi).

12.21. Requirements for Possession of Sealed Sources and Brachytherapy Sources.

12.21.a. A registrant in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the agency and shall maintain the instructions for the duration of source use in a legible form convenient to users.

12.21.b. A registrant in possession of a sealed source shall assure that:

12.21.b.1. The source is tested for leakage before its first use unless the registrant has a certificate from the supplier indicating that the source was tested within six months before transfer to the registrant; and

12.21.b.2. The source is tested for leakage at intervals not to exceed six months or at intervals approved by the agency, another agreement state, a licensing state or the Nuclear Regulatory Commission.

12.21.c. To satisfy the leak test requirements of subsection 12.21.b, the registrant shall assure that:

12.21.c.1. Leak tests are capable of detecting the presence of 185 becquerels (0.005 μCi) of radioactive material on the test sample, or in the case of radium, the escape of radon at the rate of 37 becquerels (0.001 μCi) per twenty 24 hours;

12.21.c.2. Test samples are taken from the source or from the surfaces of the device in which the source is mounted or stored on which radioactive contamination might be expected to accumulate; and

12.21.c.3. Test samples are taken when the device containing the source is in the "off" position.

12.21.d. A registrant shall retain leak test records for five years. The records shall contain the model number, and serial number, if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in becquerels (μCi), a description of the method used to measure each test sample, the date of the test, and the signature of the individual who performed the test.

12.21.e. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the registrant shall:

12.21.e.1. Immediately withdraw the sealed source from use and store, repair or dispose of it in accordance with the requirements of subsection 12.21.d of this rule; and

12.21.e.2. File a report with the agency within five days of receiving the leak test results with the agency describing the equipment involved, the test results, and the action taken.

12.21.f. A registrant need not perform a leak test on the following sources:

12.21.f.1. Sources containing only radioactive material with a half-life of less than 30 days;

12.21.f.2. Sources containing only radioactive material as a gas; and

12.21.f.3. Sources containing 3.7 megabecquerels (100 μCi) or less of beta- or photon-

emitting material or 370 kilobecquerels (10 μCi) or less of alpha-emitting material.

12.21.g. A registrant in possession of a sealed source or brachytherapy source shall conduct a physical inventory of all such sources at intervals not to exceed three months. The registrant shall retain each inventory record for five years. The inventory records shall contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its estimated activity, the location of each source, date of the inventory, and the signature of the individual who performed the inventory.

12.21.h. A registrant in possession of a sealed source or brachytherapy source shall survey with a radiation survey instrument at intervals not to exceed 3 months all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

12.21.i. A registrant shall retain a record of each survey required in subsection 12.21.h for three years. The record shall include the date of the survey, a sketch of each area that was surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour, the model number and serial number of the survey instrument used to make the survey, and the signature of the individual who performed the survey.

12.22. Syringe Shields.

12.22.a. A registrant shall keep syringes that contain radioactive material to be administered in an appropriate radiation shield or shielded area.

12.22.b. A registrant shall require each individual who prepares or administers radiopharmaceuticals to use an appropriate syringe radiation shield unless the use of the shield is contraindicated for that patient.

12.23. Syringe Labels. Unless utilized immediately, a registrant shall conspicuously identify each syringe, or syringe radiation shield as to contents or intended patient.

12.24. Vial Shields. A registrant shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield.

12.25. Vial Shield Labels. A registrant shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical with the radiopharmaceutical name or its abbreviation.

12.26. Surveys for Ambient Radiation Dose Rate and Contamination.

12.26.a. A registrant shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are prepared for use or administered.

12.26.b. A registrant shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radioactive wastes are stored.

12.26.c. A registrant shall conduct the surveys required by subsections 12.26.a and 12.26.b so as to able to measure dose rates as low as one microsievert (one-tenth mrem) per hour.

12.26.d. A registrant shall establish dose rate action levels for the surveys required by subsections 12.26.a and 12.26.b and shall require that the individual performing the survey immediately notify the radiation safety officer if a dose rate exceeds an action level.

12.26.e. A registrant shall survey for removable contamination each day of use all areas where radiopharmaceuticals are prepared for use or administered and each week where radioactive materials are

stored.

12.26.f. A registrant shall conduct the surveys required by subsection 12.26.e so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2,000 dpm).

12.26.g. A registrant shall establish removable contamination action levels for the surveys required by subsection 12.26.e and shall require that the individual performing the survey immediately notify the radiation safety officer if contamination exceeds action levels.

12.26.h. A registrant shall retain a record of each survey required by subsections 12.26.a, 12.26.b and 12.26.e for three years. The record must include the date of the survey, a sketch of each area surveyed, action levels established for each area, the measured dose rate at several points in each area expressed in microsieverts (mrem) per hour or the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the serial number and the model number of the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.

12.27. Release of Patients Containing Radiopharmaceuticals or Permanent Implants.

12.27.a. A registrant shall not authorize release from confinement for medical care any patient administered a radiopharmaceutical until either:

12.27.a.1. The dose rate from the patient is less than 50 μSv (five millirems) per hour at a distance of one meter; or

12.27.a.2. The activity in the patient is less than 1.11 GBq (30 millicuries).

12.27.b. A registrant shall not authorize release from confinement for medical care any patient administered a permanent implant until the dose rate from the patient is less than 50 μSv (five millirems) per hour at a distance of one meter.

12.28. Mobile Nuclear Medicine Service Technical Requirements. A registrant providing mobile nuclear medicine service shall:

12.28.a. Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;

12.28.b. Bring into each area of use all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

12.28.c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at an area of use;

12.28.d. In addition to complying with section 12.17 and 12.18, check survey instruments and dose calibrators for constancy and response, and check all other transported equipment for proper function before medical use at each area of use;

12.28.e. Carry a survey meter calibrated in accordance with section 12.18 in each vehicle that is being used to transport radioactive material, and, before leaving a client area of use, survey all areas of radiopharmaceutical use with a radiation detection survey instrument, including a survey for removable contamination, to ensure that all radiopharmaceuticals and all associated radioactive waste have been removed;

12.28.f. Retain a record of each survey required by subsection 12.28.e for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in microsieverts (mrem) per hour, the removable contamination in each area expressed in becquerels (dpm) per 100 square centimeters, the model and serial number of the instrument used to make the survey, and the initials of the individual who performed the survey; and

12.28.g. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the agency for compliance with airborne release standards.

12.29. Storage of Volatiles and Gases.

12.29.a. A registrant shall store volatile radiopharmaceuticals and radioactive gases in the shippers' radiation shield and container.

12.29.b. A registrant shall store and use a multidose container in a properly functioning fume hood.

12.30. Decay-In-Storage.

12.30.a. Before disposal in ordinary trash, a registrant shall hold radioactive material for decay-in-storage and is exempt from the waste disposal requirements of section 6 of this rule if the registrant:

12.30.a.1. Holds radioactive material for decay a minimum of 10 half-lives;

12.30.a.2. Monitors radioactive material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

12.30.a.3. Removes or obliterates all radiation labels; and

12.30.a.4. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

12.30.b. For radioactive material disposed in accordance with subsection 12.30.a, the registrant shall retain a record of each disposal for three years. The record must include the date of the disposal, the date on which the radioactive material was placed in storage, the radionuclides disposed, the model and serial number of the survey instrument used, the background dose rate, the radiation dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

12.31. Use of Radiopharmaceuticals for Uptake, Dilution, or Excretion Studies.

12.31.a. A registrant may use any radioactive material in a radiopharmaceutical for a diagnostic use involving measurements of uptake, dilution, or excretion:

12.31.a.1. Which has been granted acceptance or approval by the Food and Drug Administration; or

12.31.a.2. Which is prepared and compounded in accordance with the rules of the State Board of Pharmacy.

12.32. Possession of Survey Instrument. A registrant authorized to use radioactive material for

uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one (1) microsievert (one-tenth mrem) per hour to 500 microsieverts (50 mrems) per hour. The instrument shall be operable and calibrated in accordance with section 12.18.

12.33. Use of Radiopharmaceuticals, Generators, and Reagent Kits for Imaging and Localization Studies. A registrant may use any radioactive material in a diagnostic radiopharmaceutical (except aerosol or gaseous forms) or any generator or reagent kit for preparation and diagnostic use of a radiopharmaceutical containing radioactive material:

12.33.a. Which has been granted acceptance or approval by the Food and Drug Administration; or

12.33.b. Which has been prepared and compounded in accordance with the rules of the State Board of Pharmacy;

12.33.c. A registrant shall elute generators in compliance with section 12.34;

12.33.d. Provided the conditions of section 12.35 are met, a registrant shall use radioactive aerosols or gases only if specific application is made to and approved by the agency.

12.34. Radionuclide Contaminants.

12.34.a. A registrant shall not administer a radiopharmaceutical containing:

12.34.a.1. More than 0.15 kilobecquerel of Molybdenum-99 per megabecquerel of Technetium-99m (0.15 μCi of Mo-99 per mCi of Tc-99m);

12.34.a.2. More than 0.02 kilobecquerel of Strontium-82 per megabecquerel of Rubidium-82 chloride injection (0.02 μCi of Sr-82 per mCi of Rb-82 chloride);

12.34.a.3. More than 0.2 kilobecquerel of Strontium-85 per megabecquerel of Rubidium-82 chloride injection (0.2 μCi of Sr-85 per mCi of Rb-82).

12.34.b. A registrant preparing radiopharmaceuticals from radionuclide generators shall measure the concentration of radionuclide contaminant in each eluate or extract, as appropriate for the generator system, to determine compliance with the limits specified in subsection 12.34.a.

12.34.c. A registrant who must measure radionuclide contaminant concentration shall retain a record of each measurement for three years. The record shall include, for each elution or extraction tested, the measured activity of the radiopharmaceutical expressed in megabecquerels (mCi), the measured activity of contaminant expressed in kilobecquerels (μCi), the ratio of the measures expressed as kilobecquerels (μCi) of contaminant per megabecquerel (mCi) of radiopharmaceutical, the date of the test, and the initials of the individual who performed the test.

12.34.d. A registrant shall report immediately to the agency each occurrence of radionuclide contaminant concentration exceeding the limits specified in subsection 12.4.a.

12.35. Control of Aerosols and Gases.

12.35.a. A registrant who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in section 6 of this rule.

12.35.b. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

12.35.c. A registrant shall only administer radioactive gases in rooms that are at negative pressure with respect to surrounding rooms.

12.35.d. Before receiving, using, or storing a radioactive gas, the registrant shall calculate the amount of time needed after a release to reduce the concentration in the area of use to the occupational limit listed in Table 64-23 F of this rule. The calculation shall be based on the highest activity of gas handled in a single container and the measured available air exhaust rate.

12.35.e. A registrant shall post the time calculated in subsection 12.35.d at the area of use and require that, in case of a gas spill, individuals evacuate the room until the posted time has elapsed.

12.35.f. A registrant shall check the operation of collection systems monthly and measure the ventilation rates in areas of use at intervals not to exceed six months. Records of these checks and measurements shall be maintained for three years.

12.35.g. A copy of the calculations required in subsection 12.35.d shall be recorded and retained for the duration of the registration.

12.36. Possession of Survey Instruments. A registrant authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range ten microsieverts (one mrem) per hour to 10 millisieverts (1,000 mrems) per hour. The instruments shall be operable and calibrated in accordance with section 12.18.

12.37. Use of Radiopharmaceuticals for Therapy. A registrant may use any radioactive material in a radiopharmaceutical and for a therapeutic use:

12.37.a. Which has been granted acceptance or approval by the Food and Drug Administration; or

12.37.b. Which has been prepared and compounded in accordance with the rules of the State Board of Pharmacy.

12.38. Safety Instruction.

12.38.a. A registrant shall provide oral and written radiation safety instruction for all personnel caring for patients undergoing radiopharmaceutical therapy. Refresher training shall be provided at intervals not to exceed one year.

12.38.b. To satisfy subsection 12.38.a, the instruction shall describe the registrant 's procedures for:

12.38.b.1. Patient control;

12.38.b.2. Visitor control;

12.38.b.3. Contamination control;

12.38.b.4. Waste control;

12.38.b.5. Notification of the radiation safety officer or authorized user in case of the patient's death or medical emergency; and

12.38.b.6. Training for workers as required by section 13 of this rule.

12.38.c. A registrant shall keep a record of individuals receiving instruction required by subsection 12.38.a, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction. Such record shall be maintained for inspection by the agency for three years.

12.39. Safety Precautions.

12.39.a. For each patient receiving radiopharmaceutical therapy and hospitalized for compliance with section 12.27, a registrant shall:

12.39.a.1. Provide a private room with a private sanitary facility;

12.39.a.2. Post the patient's door with a "Caution: Radioactive Material" sign and note on the door or on the patient's chart where and how long visitors may stay in the patient's room;

12.39.a.3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

12.39.a.4. Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of subsection 12.39.d of this rule and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrem) per hour, the instrument used to make the survey, and the initials of the individual who made the survey;

12.39.a.5. Either monitor material and items removed from the patient's room to determine that any contamination cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle these materials and items as radioactive waste;

12.39.a.6. Instruct the patient and, where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help to keep radiation dose to household members and the public as low as reasonably achievable before authorizing release of the patient;

12.39.a.7. Survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 3.33 becquerels (200 dpm) per 100 square centimeters; and

12.39.a.8. Measure the thyroid burden of each individual who helped prepare or administer a dosage of I-131 within three days after administering the dosage, and retain for the period required by section 6 of this rule a record of each thyroid burden measurement, date of measurement, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. Other procedures acceptable to the agency may be used for individuals who only prepare, but do not administer, doses of stabilized I-131.

12.39.b. For each non-hospitalized patient receiving radiopharmaceutical therapy, the registrant shall instruct the patient and, where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help to keep radiation doses to the household members and the public as low as reasonably achievable.

12.39.c. The radiation safety officer or the authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency.

12.40. Possession of Survey Instruments. A registrant authorized to use radioactive material for radiopharmaceutical therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (one mrem) per hour to 10 millisieverts (1,000 mrems) per hour. The instruments shall be operable and calibrated in accordance with section 12.18.

12.41. Use of Sealed Sources for Diagnosis. A registrant shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions:

12.41.a. Iodine-125 as a sealed source in a device for bone mineral analysis;

12.41.b. Americium-241 as a sealed source in a device for bone mineral analysis;

12.41.c. Gadolinium-153 as a sealed source in a device for bone mineral analysis or in a portable device for imaging; and

12.41.d. Iodine-125 as a sealed source in a portable device for imaging.

12.42. Availability of Survey Instrument. A registrant authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (one mrem) per hour to 10 microsieverts (1,000 mrems) per hour. The instrument shall be operable and calibrated in accordance with section 12.18.

12.43. Use of Sources for Brachytherapy. A registrant shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions:

12.43.a. Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

12.43.b. Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer;

12.43.c. Gold-198 as a sealed source in seeds for interstitial treatment of cancer;

12.43.d. Iodine-125 as a sealed source in seeds for interstitial treatment of cancer;

12.43.e. Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer;

12.43.f. Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and

12.43.g. Palladium-103 as a sealed source in seeds for the interstitial treatment of cancer.

12.44. Safety Instruction.

12.44.a. The registrant shall provide oral and written radiation safety instruction to all personnel caring for a patient receiving implant therapy. Refresher training shall be provided at intervals not to

exceed one year.

12.44.b. To satisfy subsection 12.44.a, the instruction shall describe:

12.44.b.1. Size and appearance of the brachytherapy sources;

12.44.b.2. Safe handling and shielding instructions in case of a dislodged source;

12.44.b.3. Procedures for patient control;

12.44.b.4. Procedures for visitor control;

12.44.b.5. Procedures for notification of the radiation safety officer or authorized user if the patient dies or has a medical emergency; and

12.44.b.6. Training for workers as required by section 13 of this rule.

12.44.c. A registrant shall maintain a record of individuals receiving instruction required by subsection 12.44.a, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

12.45. Safety Precautions.

12.45.a. For each patient receiving implant therapy a registrant shall:

12.45.a.1. Not place the patient in the same room with a patient who is not receiving radiation therapy unless the registrant can demonstrate compliance with the radiation dose limits for individual members of the public as specified in section 6 of this rule at a distance of one meter from the implant;

12.45.a.2. Post the patient's door with a "Caution: Radioactive Materials" sign and note on the door or the patient's chart where and how long visitors may stay in the patient's room;

12.45.a.3. Authorize visits by individuals under 18 years of age only on a case-by-case basis with the approval of the authorized user after consultation with the radiation safety officer;

12.45.a.4. Promptly after implanting the sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with section 6 of this rule and retain for three years a record of each survey that includes the time and date of the survey, a sketch of the area or list of points surveyed, the measured dose rate at several points expressed in microsieverts (mrems) per hour, the instrument used to make the survey, and the initials of the individual who made the survey; and

12.45.a.5. Before authorizing the release of a patient administered a permanent implant, instruct the patient, and where appropriate, the patient's family, orally and in writing concerning radiation safety precautions that will help keep the radiation dose to household members and the public as low as reasonably achievable.

12.45.b. The radiation safety officer or authorized user shall be notified immediately if the hospitalized patient dies or has a medical emergency.

12.46. Brachytherapy Sources Inventory.

12.46.a. Each time brachytherapy sources are returned to an area of storage from an area of use,

the registrant shall immediately count or otherwise verify the number returned to ensure that all sources taken from the storage area have been returned.

12.46.b. A registrant shall make a record of brachytherapy source utilization which includes:

12.46.b.1. The names of the individuals permitted to handle the sources;

12.46.b.2. The number and activity of sources removed from storage, the room number of use and patient's name, the time and date they were removed from storage, the number and activity of sources in storage after the removal, and the initials of the individual who removed the sources from storage; and

12.46.b.3. The number and activity of sources returned to storage, the room number of use and patient's name, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

12.46.c. Immediately after implanting sources in a patient and immediately after removal of sources from a patient, the registrant shall make a radiation survey of the patient and the area of use to confirm that no sources have been misplaced. The registrant shall make a record of each survey.

12.46.d. A registrant shall maintain the records required in subsections 12.46.b and 12.46.c for three years.

12.47. Release of Patients Treated With Temporary Implants.

12.47.a. Immediately after removing the last temporary implant source from a patient, the registrant shall perform a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed. The registrant shall not release from confinement for medical care a patient treated by temporary implant until all sources have been removed.

12.47.b. A registrant shall maintain a record of patient surveys which demonstrate compliance with subsection 12.47.a for three years. Each record shall include the date of the survey, the name of the patient, the dose rate from the patient expressed as microsieverts (mrems) per hour and measured within 1 meter from the patient, and the initials of the individual who made the survey.

12.48. Possession of Survey Instruments. A registrant authorized to use radioactive material for implant therapy shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (one mrem) per hour to 10 millisieverts (1,000 mrems) per hour. The instruments shall be operable and calibrated in accordance with section 12.18.

12.49. Use of a Sealed Source in a Teletherapy Unit. A registrant shall use Cobalt-60 or cesium-137 as a sealed source in a teletherapy unit for medical use in accordance with the manufacturer's radiation safety and operating instructions.

12.50. Maintenance and Repair Restrictions. Only a person specifically licensed by the Nuclear Regulatory Commission, or an agreement state to perform teletherapy unit maintenance and repair shall install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source or maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

12.51. Amendments. In addition to the requirements specified in section 12.4, a registrant shall apply for and receive a registration amendment before:

12.51.a. Making any change in the treatment room shielding;

12.51.b. Making any change in the location of the teletherapy unit within the treatment room;

12.51.c. Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

12.51.d. Relocating the teletherapy unit; or

12.51.e. Allowing an individual not listed on the registrant 's registration to perform the duties of the teletherapy physicist.

12.52. Safety Instruction.

12.52.a. A registrant shall conspicuously post written instructions at the teletherapy unit console. These instructions shall inform the operator of:

12.52.a.1. The procedure to be followed to ensure that only the patient is in the treatment room before turning the primary beam of radiation "on" to begin a treatment or after a door interlock interruption;

12.52.a.2. The procedure to be followed if the operator is unable to turn the primary beam of radiation "off" with controls outside the treatment room or any other abnormal operation occurs; and

12.52.a.3. The names and telephone numbers of the authorized users and radiation safety officer to be immediately contacted if the teletherapy unit or console operates abnormally.

12.52.b. A registrant shall provide instruction in the topics identified in subsection 12.52.a to all individuals who operate a teletherapy unit and shall provide appropriate refresher training to individuals at intervals not to exceed one year.

12.52.c. A registrant shall maintain a record of individuals receiving instruction required by 12.52.b., a description of the instruction, the date of instruction, and the name of the individual who gave the instruction for three years.

12.53. Doors, Interlocks, and Warning Systems.

12.53.a. A registrant shall control access to the teletherapy room by a door at each entrance.

12.53.b. A registrant shall equip each entrance to the teletherapy room with an electrical interlock system that shall:

12.53.b.1. Prevent the operator from turning the primary beam of radiation "on" unless each treatment room entrance door is closed;

12.53.b.2. Turn the beam of radiation "off" immediately when an entrance door is opened; and

12.53.b.3. Prevent the primary beam of radiation from being turned "on" following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.

12.53.c. A registrant shall equip each entrance to the teletherapy room with a conspicuously

visible beam condition indicator light.

12.54. Possession of Survey Instrument. A registrant authorized to use radioactive material in a teletherapy unit shall possess either a portable radiation detection survey instrument capable of detecting dose rates over the range one microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 microsieverts (1 mrem) per hour to 10 microsieverts (1,000 mrems) per hour. The instruments shall be operable and calibrated in accordance with section 12.18.

12.55. Radiation Monitoring Device.

12.55.a. A registrant shall have in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.

12.55.b. Each radiation monitor shall be capable of providing visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source. The visible indicator of high radiation levels shall be observable by an individual entering the teletherapy room.

12.55.c. Each radiation monitor shall be equipped with a backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

12.55.d. A radiation monitor shall be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients.

12.55.e. A registrant shall maintain a record of the check required by subsection 12.55.d for 3 years. The record shall include the date of the check, notation that the monitor indicates when the source is exposed, and the initials of the individual who performed the check.

12.55.f. If a radiation monitor is inoperable, the registrant shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism. The instrument or dosimeter shall be checked with a dedicated check source for proper operation at the beginning of each day of use. The registrant shall keep a record as described in subsection 12.55.e.

12.55.g. A registrant shall promptly repair or replace the radiation monitor if it is inoperable.

12.56. Viewing System. A registrant shall construct or equip each teletherapy room to permit continuous observation of the patient from the teletherapy unit console during irradiation.

12.57. Dosimetry Equipment.

12.57.a. A registrant shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions shall be met:

12.57.a.1. The system shall have been calibrated by the national institute of standards and technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The calibration shall have been performed within the previous two years and after any servicing that may have affected system calibration; or

12.57.a.2. The system shall have been calibrated within the previous four years; 18 to 30 months after that calibration, the system shall have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past 24 months by the national institute of standards and technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine. The intercomparison meeting shall be sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine. The results

of the intercomparison meeting must have indicated that the calibration factor of the registrant's system had not changed by more than two percent. The registrant shall not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating Cobalt-60 teletherapy units, the registrant shall use a teletherapy unit with a Cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating Cesium-137 teletherapy units, the registrant shall use a teletherapy unit with a Cesium-137 source.

12.57.b. The registrant shall have available for use a dosimetry system for spot-check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with subsection 12.57.a This comparison shall have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system shall be the same system used to meet the requirement in subsection 12.57.a.

12.57.c. The registrant shall maintain a record of each calibration, intercomparison, and comparison for the duration of the registration. For each calibration, intercomparison, or comparison, the record shall include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by subsections 12.57.a and 12.57.b, the correction factors that were determined, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by the American Association of Physicists in Medicine.

12.58. Full Calibration Measurements.

12.58.a. A registrant authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

12.58.a.1. Before the first medical use of the unit;

12.58.a.2. Before medical use under the following conditions:

12.58.a.2.A. Whenever spot-check measurements indicate that the output differs by more than five percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;

12.58.a.2.B. Following replacement of the source or following reinstallation of the teletherapy unit in a new location; and

12.58.a.2.C. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

12.58.a.3. At intervals not exceeding one year.

12.58.b. To satisfy the requirement of subsection 12.58.a, full calibration measurements shall include determination of:

12.58.b.1. The output within three percent for the range of field sizes and for the distance or range of distances used for medical use;

12.58.b.2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

12.58.b.3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

12.58.b.4. Timer accuracy, constancy, and linearity;

12.58.b.5. "On-off" error; and

12.58.b.6. The accuracy of all distance measuring and localization devices in medical use.

12.58.c. A registrant shall use the dosimetry system described in section 12.57 to measure the output for one set of exposure conditions. The remaining radiation measurements required in subdivision 12.58.b.1 may then be made using a dosimetry system that indicates relative dose rates.

12.58.d. A registrant shall make full calibration measurements required by subsection 12.58.a in accordance with the measurements required for annual calibration by "Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40," Medical Physics, vol. 21, no. 4, 1994, pp. 581-618.

12.58.e. A registrant shall correct mathematically the outputs determined in subdivision 12.58.b.1 for physical decay for intervals not exceeding one month for Cobalt-60 and intervals not exceeding six months for cesium-137.

12.58.f. Full calibration measurements required by subsection 12.58.a and physical decay corrections required by subsection 12.58.e shall be performed by a teletherapy physicist named on the registrant's registration or authorized by a registration issued by the Nuclear Regulatory Commission or an agreement state to perform such services.

12.58.g. A registrant shall maintain a record of each calibration for the duration of the registration. The record shall include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, Tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the measured timer accuracy for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.

12.59. Periodic Spot Checks.

12.59.a. A registrant authorized to use teletherapy units for medical use shall perform output spot checks on each teletherapy unit at intervals not to exceed one month.

12.59.b. To satisfy the requirement of subsection 12.59.a, spot checks shall include determination of:

12.59.b.1. Timer constancy and timer linearity over the range of use;

12.59.b.2. "On-off" error;

12.59.b.3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

12.59.b.4. The accuracy of all distance measuring and localization devices used for medical use;

12.59.b.5. The output for 1 typical set of operating conditions; and

12.59.b.6. The difference between the measurement made in subdivision 12.59.b.5 and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

12.59.c. A registrant shall use the dosimetry system described in section 12.57 to make the spot check required in subdivision 12.59.b.5.

12.59.d. A registrant shall perform spot checks required by subsection 12.59.a in accordance with procedures established by the teletherapy physicist. The teletherapy physicist does not need to actually perform the output spot-check measurements.

12.59.e. A registrant shall have the teletherapy physicist review the results of each output spot check within 15 days. The teletherapy physicist shall promptly notify the registrant in writing of the results of each output spot check. The registrant shall keep a copy of each written notification for two years.

12.59.f. A registrant authorized to use a teletherapy unit for medical use shall perform safety spot checks of each teletherapy facility at intervals not to exceed one month.

12.59.g. To satisfy the requirement of subsection 12.59.f, safety spot checks shall assure proper operation of:

12.59.g.1. Electrical interlocks at each teletherapy room entrance;

12.59.g.2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation restriction of source housing angulation or elevation, carriage or stand travel, and operation of the beam "on-off" mechanism;

12.59.g.3. Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

12.59.g.4. Viewing systems;

12.59.g.5. Treatment room doors from inside and outside the treatment room; and

12.59.g.6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned "off."

12.59.h. A registrant shall lock the control console in the "off" position if any door interlock malfunctions. No registrant shall use the unit until the interlock system is repaired unless specifically authorized by the agency.

12.59.i. A registrant shall promptly repair any system identified in subsection 12.59.g that is not operating properly. The teletherapy unit shall not be used until all repairs are completed.

12.59.j. A registrant shall maintain a record of each spot check required by subsections 12.59.a and 12.59.f for three years. The record shall include the date of the spot check, the manufacturer's name, model number, and serial number for both the teletherapy unit, and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, the timer constancy and linearity, the calculated "on-off" error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the timer constancy and linearity for a typical treatment time, the calculated "on-off" error, the estimated accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or

mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot check.

12.60. Radiation Surveys for Teletherapy Facilities.

12.60.a. Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by section 12.51, the registrant shall perform radiation surveys with an operable radiation measurement survey instrument calibrated in accordance with section 12.18 to verify that:

12.60.a.1. The maximum and average radiation levels at 1 meter from the teletherapy source with the source in the "off" position and the collimators set for a normal treatment field do not exceed 100 microsieverts (10 mrems) per hour and 20 microsieverts (two mrems) per hour, respectively; and

12.60.a.2. With the teletherapy source in the "on" position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

12.60.a.2.A. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in section 6 of this rule; and

12.60.a.2.B. Radiation levels in unrestricted areas do not exceed the limits specified in Ssection 6. of this rule.

12.60.b. If the results of the surveys required in subsection 12.60.a indicate any radiation levels in excess of the respective limit specified in that Subsection, the registrant shall lock the control in the "off" position and not use the unit:

12.60.b.1. Except as may be necessary to repair, replace, or test the teletherapy unit, the teletherapy unit shielding, or the treatment room shielding; or

12.60.b.2. Until the registrant has received a specific exemption from the agency.

12.60.c. A registrant shall maintain a record of the radiation measurements made following installation of a source for the duration of the registration. The record shall include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the "off" position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in microsieverts (mrems) per hour, the calculated maximum level of radiation over a period of one week for each restricted and unrestricted area, and the signature of the radiation safety officer.

12.61. Safety Spot Checks for Teletherapy Facilities.

12.61.a. A registrant shall promptly check all systems listed in subsection 12.59.g for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by section 12.51.

12.61.b. If the results of the safety spot checks required in subsection 12.61.a indicate the malfunction of any system specified in section 12.59, the registrant shall lock the control console in the "off" position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

12.61.c. A registrant shall maintain a record of the safety spot checks following installation of a source for three (3) years. The record shall include notations indicating the operability of each entrance

door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, doors, and the signature of the radiation safety officer.

12.62. Modification of Teletherapy Unit or Room Before Beginning a Treatment Program. If the survey required by section 12.60 indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by section 6 of this rule, before beginning the treatment program the registrant shall:

12.62.a. Either equip the unit with stops or add additional radiation shielding to ensure compliance with section 6 of this rule;

12.62.b. Perform the survey required by section 12.60 again; and

12.62.c. Include in the report required by section 12.63 the results of the initial survey, a description of the modification made to comply with subsection 12.62.a, and the results of the second survey; or

12.62.d. Request and receive a registration amendment under section 6 of this rule that authorizes radiation levels in unrestricted areas greater than those permitted by section 6 of this rule.

12.63. Reports of Teletherapy Surveys, Checks, Tests, and Measurements. A registrant shall furnish a copy of the records required in sections 12.60 - 12.62, and the output from the teletherapy source expressed as grays (Rads) per hour at 1 meter from the source as determined during the full calibration required in section 12.58 to the agency within 30 days following completion of the action that initiated the record requirement.

12.64. Five-Year Inspection.

12.64.a. A registrant shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism.

12.64.b. This inspection and servicing shall only be performed by persons specifically registered to do so by an agreement state, or the Nuclear Regulatory Commission.

12.64.c. A registrant shall maintain a record of the inspection and servicing for the duration of the registration. The record shall contain the inspector's name, the inspector's registration number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.

12.65. Training Requirements for Radiation Safety Officers. Except as provided in section 12.66, an individual fulfilling the responsibilities of the radiation safety officer as provided in section 12.7 shall:

12.65.a. Be certified by the:

12.65.a.1. American Board of Health Physics in Comprehensive Health Physics; or

12.65.a.2. American Board of Radiology in Radiological Physics, Therapeutic Radiological Physics, or Medical Nuclear Physics; or

12.65.a.3. American Board of Nuclear Medicine; or

12.65.a.4. American Board of Science in Nuclear Medicine; or

12.65.a.5. Board of Pharmaceutical Specialties in Nuclear Pharmacy or Science; or

12.65.a.6. American Board of Medical Physics in Radiation Oncology Physics; or

12.65.a.7. Royal College of Physicians and Surgeons of Canada in Nuclear Medicine; or

12.65.a.8. American Osteopathic Board of Radiology; or

12.65.a.9. American Osteopathic Board of Nuclear Medicine; or

12.65.b. Have had 200 hours of classroom and laboratory training covering:

12.65.b.1. Radiation physics and instrumentation;

12.65.b.2. Radiation protection;

12.65.b.3. Mathematics pertaining to the use and measurement of radioactivity;

12.65.b.4. Radiation biology;

12.65.b.5. Radiopharmaceutical chemistry; and

12.65.b.6. Have had one year of full-time experience in radiation safety at a medical institution under the supervision of the individual identified as the radiation safety officer on an agency, agreement state, licensing state, or the Nuclear Regulatory Commission registration or registration that authorizes the medical use of radioactive material; or

12.65.c. Be an authorized user for those radioactive material uses that come within the radiation safety officer's responsibilities.

12.66. Training for Experienced Radiation Safety Officer. An individual identified as a radiation safety officer on an agency, agreement state, licensing state, or Nuclear Regulatory Commission registration or registration on July 1, 2001 who oversees only the use of radioactive material for which the registrant was authorized on that date need not comply with the training requirements of section 12.65.

12.67. Training for Uptake, Dilution, or Excretion Studies. Except as provided in sections 12.75 and 12.76, the registrant shall require the authorized user of a radiopharmaceutical listed in section 12.31 to be a physician who:

12.67.a. Is certified in:

12.67.a.1. Nuclear medicine by the American Board of Nuclear Medicine; or

12.67.a.2. Diagnostic Radiology by the American Board of Radiology; or

12.67.a.3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

12.67.a.4. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

12.67.a.5. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

12.67.b. Has completed 40 hours of instruction in basic radionuclide handling techniques

applicable to the use of prepared radiopharmaceuticals, and 20 hours of supervised clinical experience.

12.67.b.1. To satisfy the basic instruction requirement, 40 hours of classroom and laboratory instruction shall include:

12.67.b.1.A. Radiation physics and instrumentation;

12.67.b.1.B. Radiation protection;

12.67.b.1.C. Mathematics pertaining to the use and measurement of radioactivity;

12.67.b.1.D. Radiation biology; and

12.67.b.1.E. Radiopharmaceutical chemistry.

12.67.b.2. To satisfy the requirement for 20 hours of supervised clinical experience, training must be under the supervision of an authorized user at a medical institution and shall include:

12.67.b.2.A. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

12.67.b.2.B. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

12.67.b.2.C. Administering dosages to patients and using syringe radiation shields;

12.67.b.2.D. Collaborating with the authorized user in the interpretation of radionuclide test results; and

12.67.b.2.E. Patient followup; or

12.67.b.2.F. Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the accreditation council for graduate medical education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subsection 12.67.b.

12.68. Training for Imaging and Localization Studies. Except as provided in section 12.75 or 12.76, the registrant shall require the authorized user of a radiopharmaceutical, generator, or reagent kit specified in section 12.33 to be a physician who:

12.68.a. Is certified in:

12.68.a.1. Nuclear medicine by the American Board of Nuclear Medicine; or

12.68.a.2. Diagnostic radiology by the American Board of Radiology; or

12.68.a.3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

12.68.a.4. Nuclear medicine by the American Osteopathic Board of Nuclear Medicine; or

12.68.a.5. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

12.68.b. Has completed 200 hours of instruction in basic radionuclide handling techniques

applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, 500 hours of supervised work experience, and 500 hours of supervised clinical experience.

12.68.b.1. To satisfy the basic instruction requirement, 200 hours of classroom and laboratory training shall include:

12.68.b.1.A. Radiation physics and instrumentation;

12.68.b.1.B. Radiation protection;

12.68.b.1.C. Mathematics pertaining to the use and measurement of radioactivity;

12.68.b.1.D. Radiopharmaceutical chemistry; and

12.68.b.1.E. Radiation biology.

12.68.b.2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

12.68.b.2.A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

12.68.b.2.B. Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters;

12.68.b.2.C. Calculating and safely preparing patient dosages;

12.68.b.2.D. Using administrative controls to prevent the misadministration of radioactive material;

12.68.b.2.E. Using emergency procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

12.68.b.2.F. Eluting Technetium-99m from generator systems, assaying and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare Technetium-99m labeled radiopharmaceuticals.

12.68.b.3. To satisfy the requirement for 500 hours of supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

12.68.b.3.A. Examining patients and reviewing their case histories to determine their suitability for radionuclide diagnosis, limitations, or contraindications;

12.68.b.3.B. Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages;

12.68.b.3.C. Administering dosages to patients and using syringe radiation shields;

12.68.b.3.D. Collaborating with the authorized user in the interpretation of radionuclide test results; and

12.68.b.3.E. Patient followup; or

12.68.c. Has successfully completed a six-month training program in nuclear medicine as part of

a training program that has been approved by the accreditation council for graduate medical education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in subsection 12.68.b.

12.69. Training for Therapeutic Use of Radiopharmaceuticals. Except as provided in section 12.75, the registrant shall require the authorized user of a radiopharmaceutical listed in section 12.37 for therapy to be a physician who:

12.69.a. Is certified in:

12.69.a.1. Nuclear medicine by the American Board of Nuclear Medicine; or

12.69.a.2. Radiation oncology, therapeutic radiology, or radiology by the American Board of Radiology; or

12.69.a.3. Nuclear medicine or radiation oncology by the American Osteopathic Board of Radiology after 1984; or

12.69.a.4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

12.69.b. Has completed 80 hours of instruction in basic radionuclide handling techniques applicable to the use of therapeutic radiopharmaceuticals, and has had supervised clinical experience.

12.69.b.1. To satisfy the requirement for instruction, 80 hours of classroom and laboratory training shall include:

12.69.b.1.A. Radiation physics and instrumentation;

12.69.b.1.B. Radiation protection;

12.69.b.1.C. Mathematics pertaining to the use and measurement of radioactivity; and

12.69.b.1.D. Radiation biology;

12.69.b.2. To satisfy the requirement for supervised clinical experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

12.69.b.2.A. Use of Iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals;

12.69.b.2.B. Use of soluble Phosphorus-32 for the treatment of ascites, polycythemia vera, leukemia, or bone metastases in three individuals;

12.69.b.2.C. Use of Iodine-131 for treatment of thyroid carcinoma in three individuals;

12.69.b.2.D. Use of colloidal chromic Phosphorus-32 or of colloidal Gold-198 for intracavitary treatment of malignant effusions in three individuals; and

12.69.b.2.E. Use of strontium-89 as strontium chloride for the treatment of pain associated with bone metastases in three individuals.

12.70. Training for Therapeutic Use of Brachytherapy Sources. Except as provided in section 12.75, the registrant shall require the authorized user using a brachytherapy source specified in section 12.43 for therapy to be a physician who:

12.70.a. Is certified in:

12.70.a.1. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

12.70.a.2. Radiation oncology by the American Osteopathic Board of Radiology; or

12.70.a.3. Radiology, with a specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

12.70.a.4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

12.70.b. Is in the active practice of therapeutic radiology, has completed 200 hours of instruction in basic radionuclide handling techniques applicable to the therapeutic use of brachytherapy sources and 500 hours of supervised work experience and a minimum of three years of supervised clinical experience.

12.70.b.1. To satisfy the requirement for instruction, 200 hours of classroom and laboratory training shall include:

12.70.b.1.A. Radiation physics and instrumentation;

12.70.b.1.B. Radiation protection;

12.70.b.1.C. Mathematics pertaining to the use and measurement of radioactivity; and

12.70.b.1.D. Radiation biology.

12.70.b.2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at a medical institution and shall include:

12.70.b.2.A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

12.70.b.2.B. Checking survey meters for proper operation;

12.70.b.2.C. Preparing, implanting, and removing sealed sources;

12.70.b.2.D. Using administrative controls to prevent the misadministration of radioactive material; and

12.70.b.2.E. Using emergency procedures to control radioactive material.

12.70.b.3. To satisfy the requirement for a period of supervised clinical experience, training shall include one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

12.70.b.3.A. Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;

12.70.b.3.B. Selecting the proper brachytherapy sources, dose, and method of administration;

12.70.b.3.C. Calculating the dose; and

12.70.b.3.D. Post-administration followup and review of case histories in collaboration with the authorized user.

12.71. Training for Ophthalmic Use of Strontium-90. Except as provided in section 12.75, the registrant shall require the authorized user using only Strontium-90 for ophthalmic radiotherapy to be a physician who:

12.71.a. Is certified in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

12.71.b. Is in the active practice of therapeutic radiology or ophthalmology, and has completed 24 hours of instruction in basic radionuclide handling techniques applicable to the use of Strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy.

12.71.b.1. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

12.71.b.1.A. Radiation physics and instrumentation;

12.71.b.1.B. Radiation protection;

12.71.b.1.C. Mathematics pertaining to the use and measurement of radioactivity; and

12.71.b.1.D. Radiation biology.

12.71.b.2. To satisfy the requirement for a period of supervised clinical training in ophthalmic radiotherapy, training shall be under the supervision of an authorized user at a medical institution and shall include the use of strontium-90 for the ophthalmic treatment of five individuals that includes:

12.71.b.2.A. Examination of each individual to be treated;

12.71.b.2.B. Calculation of the dose to be administered;

12.71.b.2.C. Administration of the dose; and

12.71.b.2.D. Followup and review of each individual's case history.

12.72. Training for Use of Sealed Sources for Diagnosis. Except as provided in section 12.75, the registrant shall require the authorized user using a sealed source in a device specified in section 12.41 to be a physician, dentist, or podiatrist who:

12.72.a. Is certified in:

12.72.a.1. Radiology, diagnostic radiology with special competence in nuclear radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

12.72.a.2. Nuclear medicine by the American Board of Nuclear Medicine; or

12.72.a.3. Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or

12.72.a.4. Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

12.72.b. Has completed eight hours of classroom and laboratory instruction in basic radionuclide handling techniques specifically applicable to the use of the device.

12.72.b.1. To satisfy the requirement for instruction, the training shall include:

12.72.b.1.A. Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation;

12.72.b.1.B. Radiation biology; and

12.72.b.1.C. Radiation protection and training in the use of the device for the purposes authorized by the registration.

12.73. Training for Teletherapy. Except as provided in section 12.75, the registrant shall require the authorized user of a sealed source specified in section 12.49 in a teletherapy unit to be a physician who:

12.73.a. Is certified in:

12.73.a.1. Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; or

12.73.a.2. Radiation oncology by the American Osteopathic Board of Radiology; or

12.73.a.3. Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

12.73.a.4. Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

12.73.b. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radionuclide techniques applicable to the use of a sealed source in a teletherapy unit, 500 hours of supervised work experience, and a minimum of three years of supervised clinical experience.

12.73.b.1. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

12.73.b.1.A. Radiation physics and instrumentation;

12.73.b.1.B. Radiation protection;

12.73.b.1.C. Mathematics pertaining to the use and measurement of radioactivity; and

12.73.b.1.D. Radiation biology.

12.73.b.2. To satisfy the requirement for 500 hours of supervised work experience, training shall be under the supervision of an authorized user at an institution and shall include:

12.73.b.2.A. Review of the full calibration measurements and periodic spot checks;

12.73.b.2.B. Preparing treatment plans and calculating treatment times;

12.73.b.2.C. Using administrative controls to prevent misadministrations;

12.73.b.2.D. Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and

12.73.b.2.E. Checking and using survey meters.

12.73.b.3. To satisfy the requirement for a period of supervised clinical experience, training shall include 1 year in a formal training program approved by the residency review committee for radiology of the accreditation council for graduate medical education or the committee on postdoctoral training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution. The supervised clinical experience shall include:

12.73.b.3.A. Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications;

12.73.b.3.B. Selecting the proper dose and how it is to be administered;

12.73.b.3.C. Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' progress and consideration of the need to modify originally prescribed doses as warranted by patients' reaction to radiation; and

12.73.b.3.D. Post-administration followup and review of case histories.

12.74. Training for Teletherapy Physicist. The registrant shall require the teletherapy physicist to:

12.74.a. Be certified by the American Board of Radiology in:

12.74.a.1. Therapeutic radiological physics;

12.74.a.2. Roentgen-ray and gamma-ray physics;

12.74.a.3. X-ray and radium physics; or

12.74.a.4. Radiological physics; or

12.74.b. Be certified by the American Board of Medical Physics in Radiation Oncology Physics; or

12.74.c Hold a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and have completed 1 year of full time training in therapeutic radiological physics and also one (1) year of full time work experience under the supervision of a teletherapy physicist at a medical institution. To meet this requirement, the individual shall have performed the tasks listed in sections 12.21, 12.58, 12.59, and 12.60. under the supervision of a teletherapy physicist during the year of work experience.

12.75. Training for Experienced Authorized Users. Practitioners of the healing arts identified as authorized users for the human use of radioactive material on an agency, the Nuclear Regulatory Commission or agreement state or licensing state registration or registration on July 1, 2001 who perform only those methods of use for which they were authorized on that date need not comply with the training

requirements of sections 12.65 through 12.77.

12.76. Physician Training in a Three-Month Program. A physician who, before July 1, 1984, began a three-month nuclear medicine training program approved by the accreditation council for graduate medical education and has successfully completed the program, is exempted from the requirements of sections 12.67 or 12.68.

12.77. Recentness of Training. The training and experience specified in sections 12.65 - 12.74 shall have been obtained within the five years preceding the date of application or the individual shall have had continuing applicable experience since the required training and experience was completed.

§64-23-13 Notices, Instructions and Reports to Workers; Inspections.

13.1. Purpose and Scope. This section establishes requirements for notices, instructions and reports by registrants to individuals engaged in activities under a registration and options available to such individuals in connection with agency inspections of registrants to ascertain compliance with the provisions of the rules issued thereunder regarding radiological working conditions. The rules in this section apply to all persons who receive, possess, use, own, or transfer sources of radiation registered with agency pursuant to ~~S~~sections 5. and 11. of this rule.

13.2. Posting of Notices to Workers.

13.2.a. Each registrant shall post current copies of the following documents:

13.2.a.1. The rules in this section and in section 6 of this rule;

13.2.a.2. Certificate of registration, conditions or documents incorporated into the registration by reference and amendments thereto;

13.2.a.3. The operating procedures applicable to activities under the registration; and

13.2.a.4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to section 1 of this rule, and any response from the registrant.

13.2.b. If posting of a document specified in subdivisions 13.11.a.1 – 13.11.a.3 is not practicable, the registrant may post a notice which describes the document and states where it may be examined.

13.2.c. Agency Form X "notice to employees" shall be posted by each registrant as required by this rule.

13.2.d. Agency documents posted pursuant to subdivision ~~13.11.a.4.~~13.2.a.4. shall be posted within five working days after receipt of the documents from the agency; the registrant's response, if any, shall be posted within five working days after dispatch from the registrant. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

13.2.e. Documents, notices, or forms posted pursuant to section ~~13.11~~.13.2 shall appear in a sufficient number of places to permit individuals engaged in work under the registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

13.3. Instructions to Workers.

13.3.a. All individuals likely to receive an occupational dose:

13.3.a.1. Shall be kept informed of the storage, transfer, or use of sources of radiation in the registrant's workplace;

13.3.a.2. Shall be instructed in the health protection problems associated with exposure to radiation or radioactive material to the individual and potential offspring, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed;

13.3.a.3. Shall be instructed in, and instructed to observe, to the extent within the worker's control, the applicable provisions of this rule for the protection of personnel from exposures to radiation or radioactive material;

13.3.a.4. Shall be instructed of their responsibility to report promptly to the registrant any condition which may constitute, lead to, or cause a violation of the act, this rule, or any unnecessary exposure to radiation or radioactive material;

13.3.a.5. Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive material; and

13.3.a.6. Shall be advised as to the radiation exposure reports which workers shall be furnished pursuant to section ~~13.13.~~13.4.

13.3.a.7. The information in subsection 13.3.a shall be reviewed, and documentation of such review shall be performed no less then annually.

13.3.b. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the workplace.

13.4. Notifications and Reports to Individuals.

13.4.a. Radiation exposure data for an individual and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this subsection. The information reported shall include data and results obtained pursuant to this rule as shown in records maintained by the registrant pursuant to section 6.46 of this rule. Each notification and report shall:

13.4.a.1. Be in writing;

13.4.a.2. Include appropriate identifying data such as the name of the registrant, the name of the individual, and the individual's identification number, preferably social security number;

13.4.a.3. Include the individual's exposure information; and

13.4.a.4. Contain the following statement: "This report is furnished to you under the provisions of section 13. You should preserve this report for further reference."

13.4.b. Each registrant shall furnish to each worker annually a written report of the worker's dose as shown in records maintained by the registrant or registrant pursuant to section 6.46 of this rule.

13.4.c. Each registrant shall furnish a written report of the worker's exposure to sources of radiation at the request of a worker formerly engaged in activities controlled by the registrant. The report shall include the dose record for each year the worker was required to be monitored pursuant to subsection 13.4.a of this rule. Such report shall be furnished within 30 days from the date of the request,

or within 30 days after the dose of the individual has been determined by the registrant, whichever is later. The report shall cover the period of time that the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the registration in which the worker participated during this period.

13.4.d. When a registrant is required pursuant to sections 6.53, 6.54, or 6.55 of this rule to report to the agency any exposure of an individual to sources of radiation, the registrant shall also provide the individual a written report on the exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the agency.

13.4.e. At the request of a worker who is terminating employment with the registrant in work involving exposure to radiation or radioactive material, during the current year, each registrant shall provide at termination to each such worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the registrant during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose shall be provided together with a clear indication that this is an estimate.

13.5. Presence of Representatives of Registrants and Workers During Inspection.

13.5.a. Each registrant shall afford to the agency at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to this rule.

13.5.b. During an inspection, agency inspectors may consult privately with workers as specified in section ~~13.15.~~13.6 The registrant may accompany agency inspectors during other phases of an inspection.

13.5.c. If, at the time of inspection, an individual has been authorized by the workers to represent them during agency inspections, the registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

13.5.d. Each workers' representative shall be routinely engaged in work under control of the registrant and shall have received instructions as specified in section ~~13.12.~~13.3.

13.5.e. Different representatives of registrants and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

13.5.f. With the approval of the registrant or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative, shall be afforded the opportunity to accompany agency inspectors during the inspection of physical working conditions.

13.5.g. Notwithstanding the other provisions of section ~~13.14.~~13.5, agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to areas containing information classified by an agency of the U.S. government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the registrant or registrant to enter that area.

13.6. Consultation With Workers During Inspections.

13.6.a. Agency inspectors may consult privately with workers concerning matters of

occupational radiation protection and other matters related to applicable provisions of this rule to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

13.6.b. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which the worker has reason to believe may have contributed to or caused any violation of the this rule or any unnecessary exposure of an individual to sources of radiation under the registrant 's or registrant's control. Any such notice in writing shall comply with the requirements of subsection ~~13.6.a.~~13.7.a.

13.6.c. The provisions of subsection ~~13.15.b.~~13.6.b shall not be interpreted as authorization to disregard instructions pursuant to section ~~13.12.~~13.3.

13.7. Requests by Workers for Inspections.

13.7.a. Any worker or representative of workers believing that a violation of this rule exists or has occurred in work under a registration with regard to radiological working conditions in which the worker is engaged may request an inspection by giving notice of the alleged violation to the ~~WV Radiation Control Program~~West Virginia Radiologic Health Program. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the registrant or registrant by the ~~WV Radiation Control Program~~West Virginia Radiologic Health Program no later than at the time of inspection except that, upon the request of the worker giving such notice, such worker's name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the agency, except for good cause shown.

13.7.b. If, upon receipt of such notice, the ~~WV Radiation Control Program~~ West Virginia Radiologic Health Program determines that the complaint meets the requirements set forth in subsection ~~13.16.a~~13.7.a, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable to determine if such alleged violation exists or has occurred. Inspections pursuant to section ~~13.16.~~this subsection need not be limited to matters referred to in the complaint.

13.7.c. No registrant, or contractor or subcontractor of a registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under this rule or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of such worker or others of any option afforded by this section.

13.8. Inspections Not Warranted; Informal Review.

13.8.a. If the ~~WV Radiation Control Program~~ West Virginia Radiologic Health Program determines, with respect to a complaint under section ~~13.16.~~13.7, that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the ~~WV Radiation Control Program~~West Virginia Radiologic Health Program shall notify the complainant in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position with the ~~WV~~West Virginia Office of Environmental Health Services, which~~. Such agency~~ will provide the registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The registrant may submit an opposing written statement of position with the ~~WV~~West Virginia Office of Environmental Health Services. Such agency will provide the complainant with a copy of such statement by certified mail.

13.8.b. Upon the request of the complainant, the ~~WV~~West Virginia Office of Environmental Health Services may hold an informal conference in which the complainant and the registrant may orally present their views. An informal conference may also be held at the request of the registrant or registrant,

but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written and oral views presented, the ~~WV~~West Virginia Office of Environmental Health Services shall affirm, modify, or reverse the determination of the ~~WV Radiation Control Program~~West Virginia Radiologic Health Program and furnish the complainant and the registrant a written notification of the decision and the reason therefor.

13.8.c. If the ~~WV Radiation Control Program~~West Virginia Radiologic Health Program determines that an inspection is not warranted because the requirements of subsection ~~13.16.a.~~13.7.a. have not been met, the complainant shall be notified in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of subsection ~~13.16.a.~~13.7.a.

§64-23-14 Transportation of Radioactive Material.

14.1. Purpose and Scope. The rules in this section establish requirements for packaging, preparation for shipment, and transportation of radioactive material and apply to any person who transports radioactive material or delivers radioactive material to a carrier for transport.

14.2. Definitions. As used in this section, the following definitions apply:

14.2.a. Carrier -- a person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

14.2.b. Closed Transport Vehicle -- a transport vehicle equipped with a securely attached exterior enclosure that during normal transportation restricts the access of unauthorized persons to the cargo space containing the radioactive material. The enclosure may be either temporary or permanent but shall limit access from top, sides, and ends. In the case of packaged materials, it may be of the "see-through" type.

14.2.c. Exclusive use -- the sole use of a conveyance by a single consignor and for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee.[12]

14.2.d. Fissile material -- any special nuclear material consisting of or containing one or more fissile radionuclides. Fissile radionuclides are Plutonium-238, Plutonium-239, Plutonium-241, Uranium-233, and Uranium-235. Neither natural nor depleted uranium is fissile material.[13]

14.2.d.1. Fissile Class I: A package which may be transported in unlimited numbers and in any arrangement, and which requires no nuclear criticality safety controls during transportation. A transport index is not assigned for purposes of nuclear criticality safety but may be required because of external radiation levels.

14.2.d.2. Fissile Class II: A package which may be transported together with other packages in any arrangement but, for criticality control, in numbers which do not exceed an aggregate transport index of 50. These shipments require no other nuclear criticality safety control during transportation. Individual packages may have a transport index not less than 0.1 and not more than 10.

14.2.e. Low specific activity material -- any of the following:

[12] The term "exclusive use" is used interchangeably with the terms "sole use" or "full load" or in other regulations, such as Title 49 of the Code of Federal Regulations.

[13] Agency jurisdiction extends only to special nuclear material if quantities are not sufficient to form a critical mass as defined in W. Va. Code §64-23-1.

14.2.e.1. Uranium or thorium ores and physical or chemical concentrates of those ores;

14.2.e.2. Unirradiated natural or depleted uranium or unirradiated natural thorium;

14.2.e.3. Tritium oxide in aqueous solutions provided the concentration does not exceed five millicuries (185 MBq) per milliliter;

14.2.e.4. Material in which the radioactivity is essentially uniformly distributed and in which the estimated average concentration per gram of contents does not exceed:

14.2.e.4.A. 0.0001 millicurie (3.7 kBq) of radionuclides for which the A_2 quantity in Table 64-23 Ee is not more than 0.05 curie (1.85 GBq);

14.2.e.4.B. 0.005 millicurie (185 kBq) of radionuclides for which the A_2 quantity in Table 64-23 Ee is more than 0.05 curie (1.85 GBq) but not more than one curie (37 GBq); or

14.2.e.4.C. 0.3 millicurie (11.1 MBq) of radionuclides for which the A_2 quantity in Table 64-23 Ee is more than one curie (37 GBq).

14.2.f. Objects of nonradioactive material externally contaminated with radioactive material, provided that the radioactive material is not readily dispersible, and the surface contamination, when averaged over an area of one square meter, does not exceed 0.0001 millicurie per square centimeter (3.7 kBq/cm^2) of radionuclides for which the A_2 quantity in Table 64-23 Ee not more than 0.05 curie (1.85 GBq) or 0.001 millicurie per square centimeter (37 kBq/cm^2) for other radionuclides.

14.2.g. Normal Form Radioactive Material -- radioactive material which has not been demonstrated to qualify as special form radioactive material.

14.2.h. Packaging -- the assembly of components necessary to ensure compliance with the packaging requirements of this section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

14.2.i. Rules of the U.S. Department of Transportation -- the rules in 49 CFR Parts 100-189.

14.2.j. Specific Activity -- of a radionuclide is the radioactivity of a radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

14.2.k. Transport Index -- the dimensionless number, rounded up to the first decimal place, placed on the label of a package to designate the degree of control to be exercised by the carrier during transportation. The transport index is the number expressing the maximum radiation level in millirem per hour at one (1) meter from the external surface of the package.

14.2.l. Type A Quantity -- a quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table 64-23 Ee or may be determined by procedures described in Table 64-23 Ee.

14.2.m. Type B Package -- a Type B packaging together with its radioactive contents.

14.2.n. Type B Packaging -- a packaging designed to retain the integrity of containment and

shielding when subjected to the normal conditions of transport and hypothetical accident test conditions set forth in 10 CFR Part 71.

14.2.o. Type B Quantity -- a quantity of radioactive material greater than a Type A quantity.

14.3. Requirement for Registration. No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific registration issued by the agency or as exempted in section 14.4.

14.4. Exemptions.

14.4.a. Common and contract carriers, freight forwarders, and warehousemen which are subject to the requirements of the U.S. Department of Transportation (DOT) in 49 CFR 170 through 189 or the U.S. Postal Service in the Postal Service Manual (Domestic Mail Manual), Section 124.3 incorporated by reference, 39 CFR 111.11 (1974), and the U.S. Postal Service are exempt from the requirements of this section to the extent that they transport or store radioactive material in the regular course of their carriage for others or storage incident thereto. Common and contract carriers who are not subject to the requirements of the DOT or U.S. Postal Service are subject to section 14.3. and other applicable requirements of this rule.

14.4.b. Any registrant is exempt from the requirements of this section to the extent that the registrant delivers to a carrier for transport a package containing radioactive material having a specific activity not greater than 0.002 microcurie per gram (74 Bq/gm).

14.4.c. With the exception of sections 14.5 and 14.16, a registrant is exempt from all requirements of this section, with respect to shipment or carriage of the following:

14.4.c.1. A package containing no more than a Type A quantity of radioactive material if the package contains no fissile material; or

14.4.c.2. Packages transported between locations within the United States which contain only americium or plutonium in special form with an aggregate radioactivity not to exceed 20 curies (740 GBq).

14.5. Transportation of Registered Material.

14.5.a. Each registrant who transports registered material outside of the confines of the registrant's plant or other place of use, or who delivers registered material to a carrier for transport, shall:

14.5.a.1. Comply with the applicable requirements, appropriate to the mode of transportation, of the regulations of DOT; and

14.5.a.2. Assure that any special instructions needed to safely open the package are sent to or have been made available to the consignee.

14.5.b. If, for any reason, the regulations of the DOT are not applicable to a shipment of registered material, the registrant shall conform to the standards and requirements of those regulations to the same extent as if the shipment was subject to the regulations.

14.6. General Registration for Carriers

14.6.a. A general registration is hereby issued to any common or contract carrier not exempt under section 14.4. to receive, possess, transport, and store radioactive material in the regular course of their carriage for others or storage incident thereto, provided the transportation and storage is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as

such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident reporting.[14]

14.6.b. A general registration is hereby issued to any private carrier to transport radioactive material, provided the transportation is in accordance with the applicable requirements, appropriate to the mode of transport, of the DOT insofar as such requirements relate to the loading and storage of packages, placarding of the transporting vehicle, and incident report.[4]

14.6.c. Persons who transport radioactive material pursuant to the general registration in subsection 14.6.a or 14.6.b are exempt from the requirements of sections 6 and 13 of this rule to the extent that they transport radioactive material.

14.7. General Registration: Approved Packages.

14.7.a. A general registration is hereby issued to any registrant of the agency to transport, or to deliver to a carrier for transport, registered material in a package for which a registration, certificate of compliance, or other approval has been issued by the U.S. Nuclear Regulatory Commission.

14.7.b. This general registration applies only to a registrant who:

14.7.b.1. Has a copy of the specific registration, certificate of compliance, or other approval of the certificate of compliance, or other approval has been issued by the U.S. Nuclear Regulatory Commission.

14.7.b. This general registration applies only to a registrant who:

14.7.b.2. Complies with the terms and conditions of the rules, as applicable, and the applicable requirements of this section;

14.7.b.3. Prior to the registrant's first use of the package, has registered with the NRC; and

14.7.b.4. Has a quality assurance program required by section 14.20 and approved by

14.7.c. The general registration in subsection 14.7.a applies only when the package approval authorizes use of the package under this general registration.

14.7.d. For previously approved Type B packages which are not designated as either B(U) or B(M) in the certificate of compliance, this general registration is subject to additional restrictions of section 14.8.

14.8. General Registration: Previously Approved Type B Packages.

14.8.a. A Type B package previously approved by the NRC, but not designated as B(U) or B(M) in the certificate of compliance, may be used under the general registration of section 14.7 with the following additional limitations:

14.8.a.1. Fabrication of the packaging was satisfactorily completed before August 31, 1986, as demonstrated by application of its model number in accordance with NRC rules; and package issued by the U.S. Nuclear Regulatory Commission and has the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken prior to shipment;

[14] Any notification of incidents referred to in those DOT requirements shall be filled with, or made to the agency.

14.8.a.2. The package may not be used for a shipment to a location outside the United States after August 31, 1986, except approved under special arrangement in accordance with 49 CFR 173.471.

14.9. General Registration: Specification Container.

14.9.a. A general registration is issued to any registrant of the agency to transport, or to deliver to a carrier for transport, registered material in a specification container for a Type B quantity of radioactive material as specified in 49 CFR Parts 173 and 178.

14.9.b. This general registration applies only to a registrant who has a quality assurance program required by section 14.20 and approved by the agency.

14.9.c. This general registration applies only to a registrant who:

14.9.c.1. Has a copy of the specification; and

14.9.c.2. Complies with the terms and conditions of the specification and the applicable requirements of this section.

14.9.d. The general registration in subsection 14.9.a is subject to the limitation that the specification container may not be used for a shipment to a location outside the United States after August 31, 1986 except approved under special arrangements in accordance with 49 CFR 173.472.

14.10. General Registration: Type A, Fissile Class II Package

14.10.a. A general registration is hereby issued to any registrant to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a fissile Class II package.

14.10.b. This general registration applies only when a package contains no more than a Type A quantity of radioactive material, including only one of the following:

14.10.b.1. Up to 40 grams of Uranium-235; or

14.10.b.2. Up to 30 grams of Uranium-233; or

14.10.b.3. Up to 25 grams of the fissile radionuclides of plutonium, except that for encapsulated plutonium-beryllium neutron sources in special form, an A_1 quantity of plutonium may be present; or

14.10.b.4. A combination of fissile radionuclides in which the sum of the ratios of the amount of each radionuclide to the corresponding maximum amounts in

14.10.c. Except as specified in subsection 13.10.d, this general registration applies only when a package containing more than 15 grams of fissile radionuclides is labeled with a transport index not less than the number given by the following equation:

$$\text{Minimum Transport Index} = \frac{(0.4x + 0.67y + z)}{x+y+z} (1 - 15)$$

where the package contains x grams of Uranium-235, y grams of Uranium-233, and z grams of the fissile radionuclides of plutonium.

14.10.d. For a package in which the only fissile material is in the form of encapsulated

plutonium-beryllium neutron sources in special form, the transport index based on criticality considerations may be taken as 0.026 times the number of grams of the fissile radionuclides of plutonium in excess of 15 grams.

14.10.e. In all cases, the transport index must be rounded up to one decimal place and may not exceed 10.

14.11. General Registration: Restricted, Fissile Class II Package.

14.11.a. A general registration is hereby issued to any registrant to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped as a fissile class II package.

14.11.b. This general registration applies only when all of the following requirements are met.

14.11.b.1. The package contains no more than a Type A quantity of radioactive material.

14.11b.2. Neither beryllium nor hydrogenous material enriched in deuterium is present.

14.11.b.3. The total mass of graphite present does not exceed 150 times the total mass of Uranium-235 plus plutonium.

14.11.b.4. Substances having a higher hydrogen density than water are not present, except that polyethylene may be used for packing or wrapping.

14.11.b.5. Uranium-233 is not present, and the amount of plutonium does not exceed one percent of the amount of Uranium-235.

14.11.b.6. The amount of Uranium-235 is limited as follows:

14.11.b.6.A. If the fissile radionuclides are not uniformly distributed, the maximum amount of Uranium-235 per package may not exceed the value given in the Table 64-23 Bb.

14.11.b.6.B. If the fissile radionuclides are distributed uniformly, the maximum amount of Uranium-235 per package may not exceed the value given in the Table 64-23 Cc.

14.11.b.7. The transport index of each package based on criticality considerations is taken as 10 times the number of grams of Uranium-235 in the package divided by the maximum allowable number of grams per package in accordance with Tables 64-23 Bb and Cc as applicable.

14.12. Operating Controls and Procedures.

14.12.a. Fissile material: assumptions as to unknown properties. When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the registrant shall package the fissile material as if the unknown properties had credible values that would cause the maximum nuclear reactivity.

14.12.b. Preliminary Determinations. Prior to the first use of any packaging for the shipment of radioactive material:

14.12.b.1. The registrant shall ascertain that there are no defects which could significantly reduce the effectiveness of the packaging;

14.12.b.2. Where the maximum normal operating pressure will exceed 34.3 kilopascal (five psi) gauge, the registrant shall test the containment system at an internal pressure at least 50 percent

higher than the maximum normal operating pressure to verify the capability of that system to maintain its structural integrity at that pressure;

14.12.b.3. The registrant shall determine that the packaging has been fabricated in accordance with the design approved by the NRC; and

14.12.b.4. The registrant shall conspicuously and durably mark the packaging with its model number, gross weight, and a package identification number assigned by the NRC.

14.13. Routine Determinations. Prior to each shipment of registered material, the registrant shall determine that:

14.13.a. The package is proper for the contents to be shipped;

14.13.b. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

14.13.c. Each closure device of the packaging, including any required gasket, is properly installed and secured and free of defects;

14.13.d. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

14.13.e. Any pressure relief device is operable and set in accordance with written procedures;

14.13.f. The package has been loaded and closed in accordance with written procedures;

14.13.g. Any structural part of the package which could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design five requirements specified by the NRC;

14.13.h. The level of removable radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable. The level of removable radioactive contamination may be determined by wiping an area of 300 square centimeters of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material. Sufficient measurements must be taken in the most appropriate locations to yield a representative assessment of the removable contamination levels. Except as provided in subsection 14.13.i, the amount of radioactivity measured on any single wiping material, when averaged over the surface wiped, must not exceed the limits given in Table 64-23 Dd at any time during transport. Other methods of assessment of equal or greater efficiency may be used. When other methods are used, the detection efficiency of the method used must be taken into account and in no case may the removable contamination on the external surfaces of the package exceed 10 times the limits listed in Table 64-23 Dd.

14.13.i. In the case of packages transported as exclusive use shipments by rail or highway only, the removable radioactive contamination at any time during transport must not exceed ten (10) times the levels prescribed in subsection 14.13.h. The levels at the beginning of transport must not exceed the levels in subsection 14.13.h;

14.13.j. External radiation levels around the package and around the vehicle, if applicable, will not exceed 200 millirems per hour (two mSv/h) at any point on the external surface of the package at any time during transportation. The transport index shall not exceed 10;

14.13.k. For a package transported in exclusive use by rail, highway or water, radiation levels external to the package may exceed the limits specified in subsection 13.14.j, but shall not exceed any of

the following:

14.13.k.1. Two 200 millirems per hour (two mSv/h) on the accessible external surface of the package unless the following conditions are met, in which case the limit is 1,000 millirems per hour (10 mSv/h);

14.13.k.1.A. The shipment is made in a closed transport vehicle,

14.13.k.1.B. Provisions are made to secure the package so that its position within the vehicle remains fixed during transportation, and

14.13.k.1.C. There are no loading or unloading operations between the beginning and end of the transportation.

14.13.k.2. 200 millirems per hour (two mSv/h) at any point on the outer surface of the vehicle, including the upper and lower surfaces, or, in the case of a flat-bed style vehicle, with a personnel barrier[15], at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load [or enclosure, if used], and on the lower external surface of the vehicle;

14.13.k.3. 10 millirems per hour (0.] mSv/h) at any point two meters from the vertical planes represented by the outer lateral surfaces of the vehicle, or, in the case of a flat-bed style vehicle, at any point two meters from the vertical planes projected from the outer edges of the vehicle; and

14.13.k.4. Two millirems per hour (0.02 mSv/h) in any normally occupied positions of the vehicle, except that this provision does not apply to private motor carriers when persons occupying these positions are provided with special health supervision, personnel radiation exposure monitoring devices, and training in accordance with section 13.12. of this rule.

14.13.l. A package must be prepared for transport so that in still air at 100 degrees Fahrenheit (38 degrees Celsius) and in the shade, no accessible surface of a package would have a temperature exceeding 122 degrees Fahrenheit (50 degrees Celsius) in a nonexclusive use shipment or 180 degrees Fahrenheit (82 degrees Celsius) in an exclusive use shipment. Accessible package surface temperatures shall not exceed these limits at any time during transportation.

14.14. Air Transport of Plutonium. Notwithstanding the provisions of any general registration and notwithstanding any exemptions stated directly in this section or included indirectly by citation of the DOT regulations, as may be applicable, the registrant shall assure that plutonium in any form is not transported by air, or delivered to a carrier for air transport, unless:

14.14.a. The plutonium is contained in a medical device designed for individual human application; or

14.14.b. The plutonium is contained in a material in which the specific activity is not greater than 0.002 microcuries per gram (74 Bq/gm) of material and in which the radioactivity is essentially uniformly distributed; or

14.14.c. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with section 14.5; or

14.14.d. The plutonium is shipped in a package specifically authorized for the shipment of

[15] A flat-bed style vehicle with a personnel barrier shall have radiation levels determined at vertical planes. If no personnel barrier, the package cannot exceed 200 millirems per hour (2 mSv/h) at the surface.

plutonium by air in the certificate of compliance for that package issued by the NRC.

14.15. Shipment Records. Each registrant shall maintain for a period of two years after shipment a record of each shipment of registered material not exempt under section 14, showing, where applicable:

14.15.a. Identification of the packaging by model number;

14.15.b. Verification that there were no significant defects in the packaging, as shipped;

14.15.c. Volume and identification of coolant;

14.15.d. Type and quantity of registered material in each package, and the total quantity of each shipment;

14.15.e. Date of the shipment;

14.15.f. Name and address of the transferee;

14.15.g. Address to which the shipment was made; and

14.15.h. Results of the determinations required by section 14.13.

14.16. Reports. The registrant or registrant shall report to the agency within 30 days:

14.16.a. Any instance in which there is significant reduction in the effectiveness of any authorized packaging during use; and

14.16.b. Details of any defects with safety significance in the packaging after first use, with the means employed to repair the defects and prevent their recurrence.

14.17. Advance Notification of Transport of Nuclear Waste

14.17.a. Prior to the transport of any nuclear waste outside of the confines of the registrant's facility or other place of use or storage, or prior to the delivery of any nuclear waste to a carrier for transport, each registrant shall provide advance notification of such transport to the governor, or governor's designee, of each state through which the waste will be transported.

14.17.b. Advance notification is required only when:

14.17.b.1. The nuclear waste is required to be in Type B packaging for transportation;

14.17.b.2. The nuclear waste is being transported to, through, or across state boundaries to a disposal site or to a collection point for transport to a disposal site; and

14.17.b.3. The quantity of registered material in a single package exceeds;

14.17.b.3.A. 5,000 curies (185 TBq) of special form radionuclides;

14.17.b.3.B. 5,000 curies (185 TBq) of uncompressed gases of argon-41, Krypton-85m, Krypton-87, Xenon-131m, or Xenon-135;

14.17.b.3.C. 50,000 curies (1.85 PBq) of argon-37, or of uncompressed gases of Krypton-85 or Xenon-133, or of Hydrogen-3 as a gas, as luminous paint, or absorbed on solid material;

14.17.b.3.D. Twenty (20) curies (seven hundred forty [740] GBq) of other non-special form radionuclides for which A_2 is less than or equal to four (4) curies (one hundred forty-eight [148] GBq); or

14.17.b.3.E. Two hundred (200) curies (seven and four-tenths [7.4] TBq) of other non-special form radionuclides for which A_2 is greater than four (4) curies (one hundred forty-eight [148] Gbq).

14.17.c. Each advance notification required by subsection 14.18.a shall contain the following information:

14.17.c.1. The name, address, and telephone number of the shipper, carrier, and receiver of the shipment;

14.17.c.2. A description of the nuclear waste contained in the shipment as required by 49 CFR 172.202 and 172.203(d);

14.17.c.3. The point of origin of the shipment and the seven-day period during which departure of the shipment is estimated to occur;

14.17.c.4. The seven-day period during which arrival of the shipment at state boundaries is estimated to occur;

14.17.c.5. The destination of the shipment, and the seven-day period during which arrival of the shipment is estimated to occur; and

14.17.c.6. A point of contact with a telephone number for current shipment information.

14.17.d. The notification required by subsection 14.17.a shall be made in writing to the office of each appropriate governor, or governor's designee, and to the agency. A notification delivered by mail must be postmarked at least seven days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A notification delivered by messenger must reach the office of the governor, or governor's designee, at least four days before the beginning of the seven-day period during which departure of the shipment is estimated to occur. A copy of the notification shall be retained by the registrant for one year.

14.17.e. The registrant shall notify each appropriate governor, or governor's designee, and the agency of any changes to schedule information provided pursuant to subsection 14.18.a Such notification shall be by telephone to a responsible individual in the office of the governor, or governor's designee, of the appropriate state or states. The registrant shall maintain for one year a record of the name of the individual contacted.

14.17.f. Each registrant who cancels a nuclear waste shipment, for which advance notification has been sent, shall send a cancellation notice to the governor, or governor's designee, of each appropriate state and to the agency. A copy of the notice shall be retained by the registrant for one year.

14.18. Quality Assurance Requirements.

14.18.a. Each registrant shall establish, maintain, and execute a quality assurance program to verify by procedures such as checking, auditing, and inspection that deficiencies, deviations, and defective material and equipment relating to the shipment of packages containing radioactive material are promptly identified and corrected.

14.18.b. The registrant shall identify the material and components to be covered by the quality assurance program.

14.18.c. Each registrant shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which packaging is used.

14.18.d. Prior to the use of any package for the shipment of radioactive material, each registrant shall obtain approval by the agency of its quality assurance program.

14.18.e. The registrant shall maintain sufficient written records to demonstrate compliance with the quality assurance program. Records of quality assurance pertaining to the use of a package for shipment of radioactive material shall be maintained for a period of two years after shipment.

§64-23-15. Radiation Safety Requirements for Wireline Services Operations and Subsurface Tracer Studies.

15.1. Purpose. The rules in this section establish radiation safety requirements for using sources of radiation for wireline service operations including mineral-logging, radioactive markers, and subsurface tracer studies. The requirements of this section are in addition to, and not in substitution for, the requirements of sections 1, 5, 6, 11, and 13 of this rule.

15.2. Scope. The rules in this section apply to all registrants who use sources of radiation for wireline service operations including mineral-logging, radioactive markers, or subsurface tracer studies.

15.3. Definitions. As used in this section, the following definitions apply:

15.3.a. Field station -- a facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary Job sites.

15.3.b. Injection Tool -- a device used for controlled subsurface injection of radioactive tracer material.

15.3.c. Logging assistant -- any individual who, under the personal supervision of a logging supervisor, handles sealed sources or tracers that are not in logging tools or shipping containers or who performs surveys required by section 15.20.

15.3.d. Logging Supervisor -- the individual who uses sources of radiation or provides personal supervision of the utilization of sources of radiation at the well site.

15.3.e. Logging Tool -- a device used subsurface to perform well-logging.

15.3.f. Mineral Logging -- any logging performed for the purpose of mineral exploration other than oil or gas.

15.3.g. Personal Supervision -- guidance and instruction by the supervisor who is physically present at the jobsite and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

15.3.h. Radioactive Marker -- radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

15.3.i. Source Holder -- a housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

15.3.j. Subsurface Tracer Study -- the release of a substance tagged with radioactive material

for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

15.3.k. Temporary Jobsite -- a location where radioactive materials are present for the purpose of performing wireline service operations or subsurface tracer studies.

15.3.l. Uranium Sinker Bar -- a weight containing depleted uranium used to pull a logging tool down toward the bottom of a well.

15.3.m. Well-bore -- a drilled hole in which wireline service operations or subsurface tracer studies are performed.

15.3.n. Well-logging -- all operations involving the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well or adjacent formations.

15.3.o. Wireline -- a cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

15.3.p. Wireline Service Operation -- any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

15.4. Prohibition. No registrant shall perform wireline service operations with a sealed source or sealed sources unless, prior to commencement of the operation, the registrant has a written agreement with the well-operator, well-owner, drilling contractor, or landowner that:

15.4.a. In the event a sealed source is lodged downhole, a reasonable effort at recovery will be made; and

15.4.b. In the event a decision is made to abandon the sealed source downhole, the requirements of subsection 15.23.c shall be met.

15.5. Limits on Levels of Radiation. Sources of radiation shall be used, stored, and transported in such a manner that the transportation requirements of section 15 and the dose limitation requirements of section 6 of this rule are met.

15.6. Storage Precautions

15.6.a. Each source of radiation, except accelerators, shall be provided with a storage or transport container. The container shall be provided with a lock, or tamper seal for calibration sources, to prevent unauthorized removal of, or exposure to, the source of radiation.

15.6.b. Sources of radiation shall be stored in a manner which will minimize danger from explosion or fire.

15.7. Transport Precautions. Transport containers shall be physically secured to the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal.

15.8. Radiation Survey Instruments.

15.8.a. The registrant shall maintain sufficient calibrated and operable radiation survey instruments at each field station to make physical radiation surveys as required by this section and section 6.5 of this rule. Instrumentation shall be capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 50 milliroentgens (12.9 microcoulombs/kg) per hour. Survey instruments

acquired before July 1, 20016 and capable of measuring 0.1 milliroentgen (25.8 nanocoulombs/kg) per hour through at least 20 milliroentgens (5.16 microcoulombs/kg) per hour also satisfies this requirement July 1, 2006.

15.8.b. Each radiation survey instrument shall be calibrated:

15.8.b.1. At intervals not to exceed six months and after each instrument servicing;

15.8.b.2. For linear scale instruments, at two points located approximately one-third (⅓) and two-thirds (⅔) of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two points of at least one decade; and for digital instruments, at appropriate points; and

15.8.b.3. So that accuracy within 20 percent of the true radiation level can be demonstrated on each scale.

15.8.c. Calibration records shall be maintained for a period of two years for inspection by the agency.

15.9. Leak Testing of Sealed Sources.

15.9.a. Requirements. Each registrant using sealed sources of radioactive material shall have the sources tested for leakage. Records of leak test results shall be kept in units of microcuries (Bq) and maintained for inspection by the agency for six months after the next required leak test is performed or until transfer or disposal of the sealed source.

15.9.b. Method of Testing. Tests for leakage shall be performed only by persons specifically authorized to perform such tests by the agency, the U.S. Nuclear Regulatory Commission (NRC), an agreement state, or a licensing state. The test sample shall be taken from the surface of the source, source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. The test sample shall be analyzed for radioactive contamination, and the analysis shall be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample.

15.9.c. Interval of Testing. Each sealed source of radioactive material shall be tested at intervals not to exceed six months. In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If, for any reason, it is suspected that a sealed source may be leaking, it shall be removed from service immediately and tested for leakage as soon as practical.

15.9.d. Leaking or Contaminated Sources. If the test reveals the presence of 0.005 microcurie (185 Bq) or more of leakage or contamination, the registrant shall immediately withdraw the source from use and shall cause it to be decontaminated, repaired, or disposed of in accordance with this rule. A report describing the equipment involved, the test results, and the corrective action taken shall be filed with the agency within five days of receiving the test results.

15.9.e. Exemptions. The following sources are exempted from the periodic leak test requirements of subsections 15.9.a – 15.9.d:

15.9.e.1. Hydrogen-3 sources;

15.9.e.2. Sources of radioactive material with a half-life of 30 days or less;

15.9.e.3. Sealed sources of radioactive material in gaseous form;

15.9.e.4. Sources of beta- or gamma-emitting radioactive material with an activity of one hundred (100) microcuries (three and seven-tenths [3.7] MBq) or less; and

15.9.e.5. Sources of alpha-emitting radioactive material with an activity of 10 microcuries (0.370 MBq) or less.

15.10. Quarterly Inventory. Each registrant shall conduct a quarterly physical inventory to account for all sources of radiation. Records of inventories shall be maintained for two years from the date of the inventory for inspection by the agency and shall include the quantities and kinds of sources of radiation, the location where sources of radiation are assigned, the date of the inventory, and the name of the individual conducting the inventory.

15.11. Utilization Records. Each registrant shall maintain current records, which shall be kept available for inspection by the agency for two years from the date of the recorded event, showing the following information for each source of radiation:

15.11.a. Make, model number, and a serial number or a description of each source of radiation used;

15.11.b. The identity of the well-logging supervisor or field unit to whom assigned;

15.11.c. Locations where used and dates of use; and

15.11.d. In the case of tracer materials and radioactive markers, the utilization record shall indicate the radionuclide and activity used in a particular well.

15.12. Design, Performance, and Certification Criteria for Sealed Sources Used in Downhole Operations.

15.12.a. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations and manufactured after July 1, 2002 shall be certified by the manufacturer, or other testing organization acceptable to the agency, to meet the following minimum criteria:

15.12.a.1. Be of doubly encapsulated construction;

15.12.a.2. Contain radioactive material whose chemical and physical forms are as insoluble and non-dispersible as practical; and

15.12.a.3. Has been individually pressure tested to at least 24,656 pounds per square inch absolute (170 MN/m^2) without failure.

15.12.b. For sealed sources, except those containing radioactive material in gaseous form, acquired after July 1, 2002, in the absence of a certificate from a transferor certifying that an individual sealed source meets the requirements of section 15.12, the sealed source shall not be put into use until such determinations and testing have been performed.

15.12.c. Each sealed source, except those containing radioactive material in gaseous form, used in downhole operations after [insert a date two years after the effective date of this rule] shall be certified by the manufacturer, or other testing organization acceptable to the agency, as meeting the sealed source performance requirements for oil well-logging as contained in the American National Standard N43.6, "Classification of Sealed Radioactive Sources," (formerly N542, ANSI/NBS 126) in effect on July 1, 2001.

15.12.d. Certification documents shall be maintained for inspection by the agency for a period of

two years after source disposal. If the source is abandoned downhole, the certification documents shall be maintained until the agency authorizes disposition.

15.13. Labeling.

15.13.a. Each source, source holder, or logging tool containing radioactive material shall bear a durable, legible, and clearly visible marking or label, which has, as a minimum, the standard radiation caution symbol, without the conventional color requirement, and the following wording:

DANGER[16]
RADIOACTIVE

This labeling shall be on the smallest component transported as a separate piece of equipment.

15.13.b. Each transport container shall have permanently attached to it a durable, legible, and clearly visible label which has, as a minimum, the standard radiation caution symbol and the following wording:

DANGER[17]
RADIOACTIVE
NOTIFY CIVIL AUTHORITIES [OR NAME OF COMPANY]

15.14. Inspection and Maintenance.

15.14.a. Each registrant shall conduct, at intervals not to exceed six months, a program of inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools to assure proper labeling and physical condition. Records of inspection and maintenance shall be maintained for a period of two years for inspection by the agency.

15.14.b. If any inspection conducted pursuant to subsection 15.14.a reveals damage to labeling or components critical to radiation safety, the device shall be removed from service until repairs have been made.

15.14.c. If a sealed source is stuck in the source holder, the registrant shall not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the registrant is specifically approved by the NRC, an agreement state, or a licensing state to perform this operation.

15.14.d. The repair, opening, or modification of any sealed source shall be performed only by persons specifically authorized to do so by the agency, the NRC, an agreement state or a licensing state.

15.15. Training Requirements.

15.15.a. No registrant shall permit any individual to act as a logging supervisor as defined in this section until such individual has:

15.15.a.1. Received, in a course recognized by the agency, the NRC, an agreement state, or a licensing state, instruction in the subjects outlined in Table 64-23 Ff and demonstrated an understanding thereof;

[16] or CAUTION

[17] or CAUTION

15.15.a.2. Read and received instruction in the rules contained in this section and the applicable sections of sections 1, 6 and 13 of this rule or their equivalent, conditions of appropriate certificate of registration, and the registrant's operating and emergency procedures, and demonstrated an understanding thereof; and

15.15.a.3. Demonstrated competence to use sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

15.15.b. No registrant shall permit any individual to assist in the handling of sources of radiation until such individual has:

15.15.b.1. Read or received instruction in the registrant's operating and emergency procedures and demonstrated an understanding thereof; and

15.15.b.2. Demonstrated competence to use, under the personal supervision of the logging supervisor, the sources of radiation, related handling tools, and radiation survey instruments which will be used on the job.

15.15.c. The registrant shall maintain employee training records for inspection by the agency for two years following termination of the individual's employment.

15.16. Operating and Emergency Procedures. The registrant's operating and emergency procedures shall include instructions in at least the following:

15.16.a. Handling and use of sources of radiation to be employed so that no individual is likely to be exposed to radiation doses in excess of the standards established in section 6 of this rule;

15.16.b. Methods and occasions for conducting radiation surveys;

15.16.c. Methods and occasions for locking and securing sources of radiation;

15.16.d. Personnel monitoring and the use of personnel monitoring equipment;

15.16.e. Transportation to temporary Job sites and field stations, including the packaging and placing of sources of radiation in vehicles, placarding of vehicles, and securing sources of radiation during transportation;

15.16.f. Minimizing exposure of individuals in the event of an accident;

15.16.g. Procedure for notifying proper personnel in the event of an accident;

15.16.h. Maintenance of records;

15.16.i. Use, inspection and maintenance of source holders, logging tools, source handling tools, storage containers, transport containers, and injection tools;

15.16.j. Procedure to be followed in the event a sealed source is lodged downhole;

15.16.k. Procedures to be used for picking up, receiving, and opening packages containing radioactive material;

15.16.l. For the use of tracers, decontamination of the environment, equipment, and personnel;

15.16.m. Maintenance of records generated by logging personnel at temporary job sites;

15.16.n. Notifying proper persons in the event of an accident; and

15.16.o. Actions to be taken if a sealed source is ruptured, including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive material and actions to obtain suitable radiation survey instruments as required by section 15.8.

15.17. Personnel Monitoring.

15.17.a. No registrant shall permit any individual to act as a logging supervisor or to assist in the handling of sources of radiation unless each such individual wears either a film badge or a thermoluminescent dosimeter (TLD). Each film badge or TLD shall be assigned to and worn by only one individual. Film badges must be replaced at least monthly and tlds replaced at least quarterly. After replacement, each film badge or TLD must be promptly processed.

15.17.b. Personnel monitoring records shall be maintained for inspection until the agency authorizes disposition.

15.18. Precautionary Procedures in Logging and Subsurface Tracer Studies

15.18.a. During each logging or tracer application, the logging supervisor or other designated employee shall maintain direct surveillance of the operation to protect against unauthorized or unnecessary entry into a restricted area, as defined in section 1 of this rule.

15.18.b. The registrant shall provide and require the use of tools that will assure remote handling of sealed sources other than low-activity calibration sources.

15.18.c. Protective gloves and other appropriate protective clothing and equipment shall be used by all personnel handling radioactive tracer material. Precautions shall be taken to avoid ingestion or inhalation of radioactive material.

15.18.d. No registrant shall cause the injection of radioactive material into potable aquifers without prior written authorization from the agency.

15.19. Particle Accelerators. No registrant shall permit above-ground testing of particle accelerators, designed for use in well-logging, which results in the production of radiation, except in areas or facilities so controlled or shielded that the requirements of sections 6.4 and 6.5 of this rule, as applicable, are met.

15.20. Radiation Surveys.

15.20.a. Radiation surveys or calculations shall be made and recorded for each area where radioactive materials are used and stored.

15.20.b. Radiation surveys shall be made and recorded for the radiation levels in occupied positions and on the exterior of each vehicle used to transport radioactive material. Such surveys shall include each source of radiation or combination of sources to be transported in the vehicle.

15.20.c. If the sealed source assembly is removed from the logging tool before departing the jobsite, the logging tool detector shall be energized, or a survey meter used, to assure that the logging tool is free of contamination.

15.20.d. Radiation surveys shall be made and recorded at the jobsite or well-head for each tracer operation, except those using Hydrogen-3, Carbon-14, and Sulfur-35. These surveys shall include measurements of radiation levels before and after the operation.

15.20.e. Records required pursuant to subsections 15.20.a – 15.20.d shall include the dates, the identification of individuals making the survey, the identification of survey instruments used, and an exact description of the location of the survey. Records of these surveys shall be maintained for inspection by the agency for two years after completion of the survey.

15.21. Documents and Records Required at Field Stations. Each registrant shall maintain, for inspection by the agency, the following documents and records for the specific devices and sources used at the field station:

15.21.a. Appropriate registration, certificate of registration, or equivalent documents;

15.21.b. Operating and emergency procedures;

15.21.c. Applicable rules;

15.21.d. Records of the latest survey instrument calibrations pursuant to section 15.8;

15.21.e. Records of the latest leak test results pursuant to section 15.9;

15.21.f. Records of quarterly inventories required pursuant to section 15.10;

15.21.g. Utilization records required pursuant to section 15.11;

15.21.h. Records of inspection and maintenance required pursuant to section 15.14;

15.21.i. Survey records required pursuant to section 15.20; and

15.21.j. Training records required pursuant to section 15.15.

15.22. Documents and Records Required at Temporary Job sites. Each registrant conducting operations at a temporary jobsite shall have the following documents and records available at that site for inspection by the agency:

15.22.a. Operating and emergency procedures;

15.22.b. Survey records required pursuant to section 15.20 for the period of operation at the site;

15.22.c. Evidence of current calibration for the radiation survey instruments in use at the site;

15.22.d. When operating in the state under reciprocity, a copy of the appropriate registration, certificate of registration, or equivalent document or documents; and

15.22.e. Shipping papers for the transportation of radioactive material.

15.23. Notification of Incidents, Abandonment, and Lost Sources.

15.23.a. Notification of incidents and sources lost in other than downhole logging operations shall be made in accordance with appropriate provisions of section 6 of this rule.

15.23.b. Whenever a sealed source or device containing radioactive material is lodged downhole, the registrant shall:

15.23.b.1. Monitor at the surface for the presence of radioactive contamination with a

radiation survey instrument or logging tool during logging tool recovery operations; and

15.23.b.2. Notify the agency immediately by telephone and subsequently, within 30 days, by confirmatory letter if the registrant knows or has reason to believe that a sealed source has been ruptured. This letter shall identify the well or other location, describe the magnitude and extent of the escape of radioactive material, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

15.23.c. When it becomes apparent that efforts to recover the radioactive source will not be successful, the registrant shall:

15.23.c.1. Advise the well-operator of an appropriate method of abandonment, which shall include:

15.23.c.1.A. The immobilization and sealing in place of the radioactive source with a cement plug,

15.23.c.1.B. The setting of a whipstock or other deflection device, and

15.23.c.1.C. The mounting of a permanent identification plaque at the surface of the well, containing the appropriate information required by section 15.23.

15.23.c.2. Notify the agency by telephone, giving the circumstances of the loss, and request approval of the proposed abandonment procedures; and

15.23.c.3. File a written report with the agency within 30 days of the abandonment. The registrant shall send a copy of the report to the division of environmental protection that issued permits or otherwise approved of the drilling operation. The report shall contain the following information:

15.23.c.3.A. Date of occurrence;

15.23.c.3.B. A description of the well logging source involved, including the radionuclide and its quantity, chemical, and physical form;

15.23.c.3.C. Surface location and identification of the well;

15.23.c.3.D. Results of efforts to immobilize and seal the source in place;

15.23.c.3.E. A brief description of the attempted recovery effort;

15.23.c.3.F. Depth of the source;

15.23.c.3.G. Depth of the top of the cement plug;

15.23.c.3.H. Depth of the well;

15.23.c.3.I. Any other information, such as a warning statement, contained on the permanent identification plaque; and

15.23.c.3.J. The names of state agencies receiving a copy of this report.

15.23.d. Whenever a sealed source containing radioactive material is abandoned downhole, the

registrant shall provide a permanent plaque[18] for posting the well or well-bore. This plaque shall:

15.23.d.1. Be constructed of long-lasting material, such as stainless steel or monel; and

15.23.d.2. Contain the following information engraved on its face:

15.23.d.2.A. The word "CAUTION";

15.23.d.2.B. The radiation symbol without the conventional color requirement;

15.23.d.2.C. The date of abandonment;

15.23.d.2.D. The name of the well-operator or well-owner;

15.23.d.2.E. The well name and well identification number or numbers or other designation;

15.23.d.2.F. The sealed source or sources by radionuclide and activity;

15.23.d.2.G. The source depth and the depth to the top of the plug; and

15.23.d.2.H. An appropriate warning, depending on the specific circumstances of each abandonment.[19]

15.23.e. The registrant shall immediately notify the agency by telephone and subsequently by confirming letter if the registrant knows or has reason to believe that radioactive material has been lost in or to an underground potable aquifer. Such notice shall designate the well location and shall describe the magnitude and extent of loss of radioactive material, assess the consequences of such loss, and explain efforts planned or being taken to mitigate these consequences.

§64-23-16. Radiation Safety Requirements for Technologically Enhanced Radioactive Materials (TENORM).

16.1. Purpose~~. This Section establishes radiation protection standards for the possession, use, transfer, and disposal of technologically enhanced naturally occurring radioactive materials (TENORM).~~ -- this section establishes radiation protection standards for Technologically Enhanced Naturally Occurring Radioactive Material (TENORM). These standards include the possession, use, processing, manufacture, distribution, transfer, and disposal of TENORM and of products with TENORM. This section also provides for the licensing of TENORM, including license termination. The provisions of this section are in addition to the definitions and applicable requirements of all other provisions of this rule.

16.2. Scope.

16.2.a. This ~~rule apply~~ section applies to any person who receives, owns, possesses, uses, processes, transfers, distributes, or disposes of TENORM.

16.2.b. ~~The rules in this Part~~This section addresses the introduction of TENORM into products in which neither the TENORM, nor the radiation emitted from the TENORM, is considered to be beneficial

[18] An example of the suggested plaque is shown in Table 64-23 Gg.

[19] Appropriate warnings may include: (a) "Do not drill below plug-back depth"; (b) "do not enlarge casting"; or (c) "Do not re-enter the Hole", followed by the words, "before contacting the WV Radiological Health Program".

to the products.

16.2.c. The manufacture and distribution of products containing TENORM, in which the TENORM or its emitted radiation is considered to be a beneficial attribute, are registered under the provisions of section 11 of this rule.

16.2.d. This section ~~does not apply to radionuclides for which NRC retains exclusive jurisdiction~~. does not apply to source material and byproduct material as both are defined in the Atomic Energy Act of 1954, as amended (AEA 42 USC §2011 *et seq.*) and relevant regulations implemented by the Nuclear Regulatory Commission (NRC).

16.2.e. Storage incident to transportation and transportation of TENORM are governed by sections 6 and 14 of this rule.

16.3. Definitions. As used in this section, the following definitions apply:

16.3.a. Beneficial Attribute -- the radioactivity of the product necessary to the use of the product.

16.3.b. Beneficial to the Product -- the radioactivity of the product necessary to the use of the product.

16.3.c. General Environment -- the total terrestrial, atmospheric, and aquatic environments outside the site boundary within which any activity, operation, or process authorized by a general or specific registration issued under this section, is performed.

16.3.d. Institutional Controls: (1) Permanent markers placed at a disposal site, (2) public records and archives, (3) government ownership and rules regarding land or resource use, and (4) other methods of preserving knowledge about the location, design, and contents of a disposal system.

16.3.e. Product -- something produced, made, manufactured, refined, or benefitted.

16.3.f. Reasonably Maximally Exposed Individual -- a representative of a population who is exposed to TENORM at the maximum TENORM concentration measured in environmental media found at a site along with reasonable maximum case exposure assumptions. The exposure is determined by using maximum values for one or more of the most sensitive parameters affecting exposure, based on cautious but reasonable assumptions, while leaving the others at their mean value.

16.3.g. Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) -- ~~naturally occurring radionuclides whose concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include uranium or thorium in "source material" as defined in the aea and US NRC regulations.~~ naturally occurring radioactive material which radionuclide concentrations are increased by or as a result of past or present human practices. TENORM does not include background radiation or the natural radioactivity of rocks or soils. TENORM does not include "source material" and "byproduct material" as both are defined in the Atomic Energy Act of 1954, as amended (AEA 42 USC §2011*et seq.*) and relevant regulations implemented by the NRC.

16.3.h. Transfer -- ~~the physical relocation of NORM containing materials not directly associated with commercial distribution within a business's operation or between general or specific registrants. This term does not include a change in legal title to NORM containing materials that does not involve physical movement of those materials.~~the physical relocation of TENORM within a business operation or between general or specific licensees. This term does not include commercial distribution or a change in

legal title to TENORM that does not involve physical movement of those materials.

16.3.i. Total Effective Dose Equivalent (TEDE) -- the sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

16.4. Exemptions.

16.4.a. Persons who receive, own, possess, use, process, transfer, distribute, or dispose of TENORM are exempt from the requirements of this section with respect to any combination of ^{226}Ra and ^{228}Ra if the materials contain, or are contaminated at, concentrations less than 185 becquerel per kilogram (five pCi/gm) excluding natural background. This does not apply to consumer or retail products which are discussed in subsection 16.12.c and section 16.13. Using purposeful dilution to render TENORM waste exempt shall not be allowed without prior agency approval.

16.4.b. Persons who receive products or materials containing TENORM distributed in accordance with a specific registration issued by the agency pursuant to subsection 16.10.a, or to an equivalent registration issued by another licensing state, are exempt from this rule with regard to those products or materials.

16.4.c. ~~The distribution, including custom blending, possession, and use of fertilizers containing TENORM, is exempt from the requirements of this Section.~~Persons who receive, possess, use, process, transfer and distribute, including the preparation of custom blends for distribution, any phosphate or potash ore-based fertilizers containing TENORM are exempt from this section.

16.4.d. ~~TENORM waste regulated by CERCLA or RCRA (Resources Conservation and Recovery Act) are exempt from this Section.~~Persons who possess TENORM waste regulated by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA 42 USC §9601 *et seq.* as amended) or by the Resource Conservation and Recovery Act (RCRA 42 USC §6901 *et seq.* as amended) or by the West Virginia Division of Environmental Protection are not subject to this section for that TENORM waste.

16.4.e. The transportation and storage incident to transportation are governed by ~~S~~sections 6. and 16. of this rule.

16.4.f. Persons who possess or use TENORM shall shall not be subject to the provisions of this section when a determination has been made by the agency that the reasonably maximally exposed individual will not receive a public dose with a total effective dose equivalent (TEDE) of more than one millisievert (0.1 rem) in one year from all licensed or registered sources of radiation including TENORM.

16.5. Standards for Radiation Protection for TENORM.

16.5.a. No person registered under sections 16.9 and 16.10 shall conduct operations, use, or transfer TENORM in a manner such that a member of the public will receive an annual total effective dose in excess of one millisievert per year (100 mrem/yr.) from all registered sources including TENORM.

16.5.b. Persons subject to a registration under this section shall comply with radiation protection standards set out in section 6 of this rule.

16.5.c. ~~Doses from indoor radon and its progeny shall not be included in total effective dose equivalent calculations.~~Doses from inhalation of indoor radon and its short half-life (less than one hour) progeny shall not be included in calculations of the TEDE, unless the dose is due to effluent releases from licensed operations involving the handling or processing of TENORM.

16.5.d. No person shall release TENORM for unrestricted use in such a manner that the reasonably maximally exposed individual will receive an annual total effective dose equivalent from the released TENORM in excess of 0.5 millisievert per year (50 mrem/yr.) excluding natural background.

16.6. Protection of Workers During Operations. Each person subject to a specific or general registration under this section shall conduct operations in compliance with the standards for radiation protection set out in sections 6 and 13 of this rule.

16.7. Release for Unrestricted Use and Conditional Release. Each person subject to a registration under this section shall:

16.7.a. Not transfer or release for unrestricted use facilities or equipment contaminated with TENORM in excess of levels in Table 64-23 Ii;

16.7.b. Not transfer or release for unrestricted use equipment contaminated with TENORM in excess of a surface gamma radiation level of < 100 microrems/hour including natural background; and

16.7.c. Not transfer land for unrestricted use unless: ~~where the concentration of ^{226}Ra or ^{228}Ra in soilaveraged over any one hundred (100) square meters exceeds the background level by more than one hundred eighty five (185) Bequerel per kilogram (five [5] pCi/gm), averaged over any fifteen (15) cm layer of soil below the surface, unless compliance with Ssubsection 16.5.b. through d. can be demonstrated.~~

16.7.c.1. The average member of the critical group will not receive an annual public dose in excess of 0.25 millisievert (0.025 rem) TEDE from residual radioactive materials on site other than residual TENORM ^{226}Ra and ^{228}Ra and their progeny;

16.7.c.2. The concentration of residual TENORM ^{226}Ra and ^{228}Ra, on land averaged over 100 square meters, is less than 185 becquerel per kilogram (5 pCi/g) above the background concentration, averaged over any 15 cm layer of soil. The 15 cm layers are contiguous depth increments from the surface down. Each of the progeny radionuclides of the residual TENORM ^{226}Ra and ^{228}Ra may also be present in concentrations similar to the residual TENORM ^{226}Ra and ^{228}Ra concentration; or

16.7.c.3. Where residual TENORM ^{226}Ra and ^{228}Ra and their progeny and other residual TENORM radionuclide contamination are present, the sum of fractions shall be used for combining the criteria of subdivisions 16.7.c.1 and 16.7.c.2. The sum of fractions is determined by dividing each average radium concentration by the radium limit of 185 becquerel per kilogram (5 pCi/g) and dividing the estimated annual dose from other residual TENORM radionuclides by 0.25 millisievert (0.025 rem) and then adding the ratios together. The sum of the fractions must be less than, or equal to, one to meet this criterion.

16.7.d. Specific licensees shall meet the requirements of sections 16.12. and 16.17 applicable to remediation and termination of the license.

16.7.e. General licensees shall notify the agency in writing prior to commencing activities to reclaim the site. Decontamination activities require a specific license.

16.7.f. Notification of Site or Area Closure. General licensees permanently or for a period of two years ceasing the use of radioactive materials at a site or portion of a site or facility, the licensee shall, within 60 days, provide the following information in writing to the agency:

16.7.f.1. The location of the site or area; and

16.7.f.2. The plan for reclaiming or decontaminating the site or area.

16.7.g. Actions taken to confine TENORM on site or to remediate sites shall be based on expected longevity-related controls for at least 1,000 years.

16.7.h. Conditional release of metal for recycle. Conditionally released metal for recycle shall be allowed only when metal contaminated with TENORM does not exceed a maximum exposure level of 50 microroentgen per hour, including background radiation, at any accessible location of the metal surface prior to release from the site.

16.7.i. Equipment not released for unrestricted use. Equipment contaminated with TENORM in excess of levels specified in table Ii may be transferred pursuant to section 16.22.

16.8. Disposal and Transfer of Waste for Disposal.

16.8.a. Each person subject to a registration under this rule shall manage and dispose of wastes containing TENORM:

16.8.a.1. By transfer of the wastes for disposal to a facility registration under requirements for uranium or thorium byproduct materials in either 40 CFR 192 or 10 CFR 40 Appendix A; or

16.8.a.2. By transfer of the wastes for disposal to a disposal facility licensed by the US Nuclear Regulatory Commission, an agreement state, or a licensing state; or

16.8.a.3. In accordance with alternate methods authorized by the agency upon application or upon the agency's initiative, consistent with section 16.5 and where applicable the clean water act, safe drinking water act and other requirements of the US Environmental Protection Agency for disposal of such wastes.

16.8.b. Equipment contaminated with TENORM in excess of levels specified in Table ~~Oo~~Ii, which is to be disposed of as waste, shall be disposed of:

16.8.b.1. So as to prevent any reintroduction into commerce or unrestricted use; and

16.8.b.2. ~~Within disposal areas specifically designed to meet the criteria of Subsection 16.8.a.~~Equipment contaminated with TENORM not exceeding a maximum exposure level of 100 microroentgen per hour, including background radiation, at any accessible site may be disposed in a landfill that complies with W. Va. Code §22-15-8.

16.8.c. Transfers of waste containing TENORM for disposal shall be made only to a person specifically authorized by the Nuclear Regulatory Commission, an agreement state or a licensing state, to receive such waste.

16.8.d. Records of disposal, including manifests, shall be maintained pursuant to the provisions of section 6 of this rule.

16.8.e. TENORM waste shall not be diluted for the sole purpose of making the waste exempt from the disposal requirements without prior agency approval. The criteria in section 16.5 shall be used by the agency to determine whether to approve such a request.

16.8.f. Drums or shipping containers of TENORM waste shall not exceed an average concentration of 50.0 picocuries per gram of Radium-226 plus Radium-228, unless the drums or shipping containers containing TENORM are utilized to transfer the TENORM for disposal in another state as approved by an applicable governmental authority; or in accordance with alternate methods authorized by the agency or other applicable state or federal agency.

16.8.g. Containers:

16.8. g.1. TENORM shall be kept in a leak-proof container.

16.8.g.2. The registrant shall use a container made of, or lined with, materials that will not react with, or be incompatible with the TENORM to be stored so that the ability of the container to contain the waste is not impaired or compromised.

16.8.g.3. A container containing TENORM shall always be closed and sealed during storage or while in transport, except when it is necessary to add or remove waste.

16.8.g.4. A container containing TENORM may not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

16.8.g.5. At least quarterly, the registrant shall inspect areas where containers of TENORM are stored, inspecting for leaking or deteriorating containers or containment systems.

16.8.g.6. All containers of TENORM shall be stacked in such a manner that each container identification label can be read from the access aisle or area.

16.8.g.7. Each container of TENORM shall be labeled with the following information prior to storage:

16.8.g.7.A. Name and address of generator;

16.8.g.7.B. Type of material (e.g., sludge, scale, dirt, scrap metal, et cetera);

16.8.g.7.C. Date stored; and

16.8.g.7.D. Labeled as radioactive material.

16.8.g.8. The registrant shall develop a schedule, not less than quarterly, and procedure for assessing the condition of each container of TENORM. The schedule and procedure must be adequate to detect cracks, leaks, corrosion and erosion that may lead to cracks, leaks, or wall thinning to less than the required thickness to maintain vessel integrity. Procedures for emptying a waste container to allow entry, procedures for personnel protection, and inspection of the interior must be established when necessary to detect corrosion of the waste container sides and bottom. Records shall be maintained for a period of at least five years.

16.9. General Registration.

16.9.a. Subject to the requirements of sections 16.5 - 16.8 and section 16.10, a general registration ~~is hereby issued~~ shall be required to possess, own, use, transfer, distribute or dispose of TENORM without regard to quantity.

16.9.b. ~~This~~A general registration does not authorize the manufacturing of products containing TENORM in concentrations greater than those specified in section 16.4 nor the receipt and disposal of wastes from other persons.

16.9.c. The decontamination of equipment, facilities, and land shall be performed only by persons specifically registered by the agency or another licensing state to conduct such work. However, employees or contractors under control and supervision of a general registration can perform routine

maintenance on equipment, facilities, and land owned or controlled by the general registration. Maintenance that provides a different pathway for exposure than is found in daily operations and that increases the potential for additional exposure is not considered routine.

16.9.d. Transfer of material or real property.

16.9.d.1. The transfer of TENORM not exempt from this rule from one general registrant to another general registrant is authorized if:

16.9.d.1.A. The equipment and facilities contaminated with TENORM are to be used by the recipient for the same purpose; or

16.9.d.1.B. The transfer of control or ownership of land contaminated with TENORM includes notice to owners of surface and mineral rights to indicate the presence of TENORM.

16.9.d.2. Transfers not made in accordance with subdivision 16.9.d.1 require prior approval by the agency.

16.9.d.3. Transfers made under subdivision 16.9.d.1 do not relieve the general registrant who makes the transfer from the responsibilities of assessing the extent of TENORM contamination or material present, informing the general registrant receiving the TENORM of these assessments, and maintaining records required by this rule.

16.9.d.4. A general registrant intending to transfer material or real property for unrestricted use shall document compliance with the requirements of section 16.7 of this rule. Records of such compliance shall be kept.

16.9.e. Distribution of TENORM products between general registrants. The distribution of TENORM products not exempt from this rule from one general registration to another general registrant is authorized provided the product is accompanied by labels or manifests which identify the type and amount of TENORM.

16.9.f. The agency ~~Division of Health~~ may, by written notice, require any person authorized by a general registration to apply for and obtain a specific registration. The notice shall state the reason or reasons for requiring a specific registration.

16.10. Specific Registration. Unless otherwise exempt, a specific registration is required to:

16.10.a. Manufacture and distribute any material or product containing TENORM unless authorized by subsection 16.9.e, exempted under the provisions of section 16.4, or registered under the provisions of section 6 of this rule;

16.10.b. Except as provided in subsection 16.9.c, decontaminate equipment or land not otherwise exempted under the provisions of section 16.4 or facilities contaminated with TENORM in excess of the levels set forth in section 16.7, as applicable; for purposes of this section, the term "decontaminate" shall not include maintenance which incidentally results in removal of contamination;

16.10.c. Receive TENORM from other persons for disposal.

16.11. Filing Application for Specific Registration.

16.11.a. Applications for specific registration shall be filed in a manner and on a form prescribed by the agency and include the registration fee.

16.11.b. The agency may at any time after the filing of the original application, and before the expiration of the registration, require further statements in order to enable the agency to determine whether the application should be granted or denied or whether a registration should be modified or revoked.

16.11.c. Each application shall be signed by the applicant or registrant or a person duly authorized to act for and on the registrant's behalf.

16.11.d. An application for a registration may include a request for a registration authorizing one or more activities.

16.11.e. In an application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the agency provided such references are clear and specific.

16.11.f. Applications and documents submitted to the agency may be made available for public inspection.

16.12. Requirements for the Issuance of Specific Registrations.

16.12.a. A registration application ~~will~~may be approved if the agency determines that:

16.12.a.1. The applicant is qualified by reason of training and experience to use the TENORM in question for the purpose requested in accordance with this rule in such a manner as to protect the public health and safety or property;

16.12.a.2. The applicant's proposed equipment, facilities, and procedures are adequate to protect the public health and safety or property;

16.12.a.3. The issuance of the registrant will not be inimical to the health and safety of the public;

16.12.a.4. The applicant satisfied all applicable special requirements in this section; and

16.12.a.5. The applicant has met the financial surety requirements of section 16.23.

16.12.a.6. The applicant has adequately addressed the following items in the application:

16.12.a.6.A. Procedures and equipment for monitoring and protecting workers;

16.12.a.6.B. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

16.12.a.6.C. Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

16.12.a.6.D. A method for managing the radioactive material removed from contaminated equipment and facilities.

16.12.b. An application for a specific registration to decontaminate equipment, land, or facilities contaminated with TENORM in excess of the levels set forth in subsections 16.4.a, 16.7.b, or Table ~~O~~oII, as applicable, and to dispose of the resulting waste will be approved if:

16.12.b.1. The applicant satisfies the general requirements specified in subsection 16.12.a;

and

16.12.b.2. The applicant has adequately addressed the following items in the application:

16.12.b.2.A. Procedures and equipment for monitoring and protection of workers;

16.12.b.2.B. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

16.12.b.2.C. Operating and emergency procedures, including the identification of contractors expected to be used during emergencies, and procedures for waste reduction and quality assurance of items released for unrestricted use; and

16.12.b.2.D. Method of disposing of the TENORM removed from contaminated equipment, facilities, and land.

16.12.b.2.E. For each site to be listed on the registration as an authorized site, the applicant shall submit either:

16.12.b.2.E.1. A statement that the applicant owns the site where radioactive material is to be used or stored; or

16.12.b.2.E.2. A statement verifying that the site owner has been informed, in writing, of the use or storage of radioactive material at the site, and that the use of such material is subject to the rules of the Bureau.

16.12.c. An application for a specific ~~license~~registration to transfer materials or manufacture or distribute products containing TENORM to persons exempted from this rule pursuant to subsection 16.4.b will be approved if:

16.12.c.1. The applicant satisfies the general requirements specified in subsection 16.22.a;

16.12.c.2. The TENORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being; and

16.12.c.3. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the TENORM material or product to demonstrate that the material or product will meet the safety criteria set forth in section 16.13. The information shall include:

16.12.c.3.A. A description of the material or product and its intended use or uses;

16.12.c.3.B. The type, quantity, and concentration of TENORM in each material or product;

16.12.c.3.C. The chemical and physical form of the TENORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;

16.12.c.3.D. An analysis of the solubility in water and body fluids of the TENORM in the material or product;

16.12.c.3.E. The details of manufacture and design of the material or product relating to

containment and shielding of the TENORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product;

16.12.c.3.F. The degree of access of human beings to the material or product during normal handling, use, and disposal;

16.12.c.3.G. The total quantity of TENORM expected to be distributed annually in the material or product;

16.12.c.3.H. The expected useful life of the material or product;

16.12.c.3.I. The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer or initial transferor of the product and the radionuclides and quantity of TENORM in the material or product;

16.12.c.3.J. The procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;

16.12.c.3.K. The results of the prototype testing of the material or product, including any change in the form of the TENORM contained in it, the extent to which the TENORM may be released to the environment, any change in radiation levels, and any other changes in safety features;

16.12.c.3.L. The estimated external radiation doses and dose commitments relevant to the safety criteria in section 16.13 and the basis for such estimates;

16.12.c.3.M. A determination that the probabilities with respect to doses referred to in section 16.13 meet the safety criteria;

16.12.c.3.N. The quality control procedures to be followed in the production of production lots of the material or product, and the quality control standards the material or product will be required to meet; and

16.12.c.3.O. Any additional information, including experimental studies and tests, required by the agency to facilitate a determination of the radiation safety of the material or product.

16.12.d. Notwithstanding the provisions of subsection 16.13.b, the agency may deny an application for a specific registration if the end uses of the product are frivolous or cannot be reasonably foreseen.

16.13. Safety Criteria for Products. An applicant for a registration under subsection 16.12.c. shall demonstrate that the product is designed and will be manufactured so that:

16.13.a. In normal use and disposal of a single exempt item, and in normal handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, it is unlikely that the TEDE in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the product will not exceed the doses in Column I of table Hh ~~16.14.~~

16.13.b. In use and disposal of a single exempt item and in handling and storage of the quantities of exempt items likely to accumulate in one location during marketing, distribution, installation, and servicing of the product, the probability is low that the containment, shielding, or other safety features of the product would fail under such circumstances that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column II of the Table Hh

~~in Subsection 16.14.~~ and the probability is negligible that a person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in Column III of the Table ~~in Subsection 16.14~~Hh.

16.13.c. It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the product from wear and abuse likely to occur in normal handling and use of the product during its useful life.

16.14. Table of Organ Doses refer to table Hh.

16.15. Issuance of Specific Registrations.

16.15.a. Upon a determination that an application meets the requirements of this rule, the agency ~~will~~may issue a specific registration authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

16.15.b. The agency may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of TENORM subject to this section as it deems appropriate or necessary in order to:

16.15.b.1. Protect public health and safety or property;

16.15.b.2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

16.15.b.3. Prevent loss, theft, or loss of control of TENORM subject to this section.

16.16. Conditions of Specific Registration Issued Under Section 16.12.

16.16.a. General Terms and Conditions.

16.16.a.1. Each registration issued pursuant to this section shall be subject to all the provisions of this rule, now or hereafter in effect, and to all rules, and orders of the agency.

16.16.a.2. No registration issued or granted under this section and no right to possess or utilize TENORM granted by any registration issued pursuant to this section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any registration to any person unless the agency shall, after securing full information, find that the transfer is in accordance with the provisions of this rule, and shall give its consent in writing.

16.16.a.3. Each person registered by the agency pursuant to this section shall confine use and possession of the TENORM registered to the locations and purposes authorized in the registration.

16.16.a.4. Each person registered by the agency pursuant to this section is subject to the general license provisions of sections 16.6, 16.7 and 16.8.

16.16.a.5. Each registrant shall:

16.16.a.5.A. Notify the agency, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title II (bankruptcy) of the United States Code (11 U.S.C.) by or against:

16.16.a.5.A.1. A registrant;

16.16.a.5.A.2. An entity controlling a registrant or listing the registration or registrant as property of the estate; or

16.16.a.5.A.3. An affiliate of the registrant.

16.16.a.5.B. Indicate in their Bankruptcy notification:

16.16.a.5.B.1. The bankruptcy court in which the petition for bankruptcy was filed; and

16.16.a.5.B.2. The date of the filing of the petition.

16.16.a.6. Each licensee shall notify the agency in writing prior to commencing activities to reclaim the licensed facility and site.

16.16.a.7. Notification of Site or Area Closure. When a licensee has permanently ceased use of TENORM and all other radioactive materials at a site or portion of a facility and the licensee has not decontaminated the area, or when an area has not been used for a period of two years, the licensee shall, within 60 days, provide the following information in writing to the agency:

16.16.a.7.A. The location of the facility, site, or area;

16.16.a.7.B. The plan for reclaiming or decontaminating the facility, site or area; and

16.16.a.7.C. An evaluation of any changes to the financial assurance submitted in accordance with section 16.23.

16.16.b. Quality Control, Labeling, and Reports of Transfer. Each person registered under subsection 16.12.c shall:

16.16.b.1. Carry out adequate control procedures in the manufacture of the product to assure that each production lot meets the quality control standards approved by the agency;

16.16.b.2. Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the TENORM in the product can be identified; and

16.16.b.3. Maintain records identifying, by name and address, each person to whom TENORM is transferred for use under subsection 16.4.b or the equivalent regulations of a licensing state, and stating the kinds, quantities, and uses of TENORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific registration shall be filed with the agency. Each report shall cover the year ending December 31, and shall be filed within 90 days thereafter. If no transfers of TENORM have been made pursuant to subsection 16.12.c during the reporting period, the report shall so indicate.

16.17. Expiration and Termination of Specific Registrations.

16.17.a. Except as provided in subdivision 16.17.d.6 and subsection 16.18.b, each specific registration shall expire at the end of the specified day in the month and year stated therein. Any expiration date on a specific license applies only to the authority to engage in licensed activities. Expiration of a specific license shall not relieve the licensee of responsibility for decommissioning its facility and terminating the specific license.

16.17.b. Each registrant shall notify the agency in writing and request termination of the

registration when the registrant decides to terminate all activities involving TENORM authorized under the registration. This notification and request for termination of the registration must include the reports and information specified in subdivision 16.17.d.6. The registrant is subject to the provisions of subsections 16.17.d and 16.17.e, as applicable.

16.17.c. No less than 30 days before the expiration date specified in a specific registration, the registrant shall either:

16.17.c.1. Submit an application for registration renewal under section 16.18; or

16.17.c.2. Notify the agency in writing, under subsection 16.17.b, if the registrant decides to discontinue all activities involving TENORM.

16.17.d. If a registrant does not submit an application for registration renewal under ~~S~~subsection 16.18., the registrant shall, on or before the expiration date specified in the registration:

16.17.d.1. Terminate use of TENORM;

16.17.d.2. Remove TENORM contamination consistent with the requirements of section 16.7.;

16.17.d.3. Properly dispose of TENORM; and

16.17.d.4. Submit a report of disposal of TENORM and radiation surveys to confirm the absence of TENORM or to establish the levels of residual TENORM contamination. The registrant shall, as appropriate:

16.17.d.4.A. Report levels of radiation in units of micro-roentgens per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries or Becquerel per milliliter in water, and picocuries or Becquerels per gram in contaminated solids such as soils or concrete; and

16.17.d.4.B. Specify the instruments used and certify that each instrument is properly calibrated and tested.

16.17.d.5. If levels of residual activity are less than those established in section 16.7, the registrant shall so certify. If the agency determines that this certification and the information submitted under subdivision 16.17.d.4 is adequate and surveys confirm the findings, the agency will notify the registrant in writing that the registration is terminated.

16.17.d.6. If levels of residual TENORM are not in conformance with criteria established in section 16.17, the registration continues in effect beyond the expiration date, if necessary, with respect to possession of residual TENORM until the agency notifies the registrant in writing that the registration is terminated. During this time, the registrant is subject to the provisions of subsection 16.17.e In addition to the information submitted under subdivision ~~17.d.4~~16.d.4, the registrant shall submit a plan, if appropriate, for decontaminating the location or locations and disposing of the residual TENORM.

16.17.e. Each registrant who possesses residual TENORM under subdivision 16.17.d.6, following the expiration date specified in the registration, shall:

16.17.e.1. Be limited to actions involving TENORM related to preparing the locations for release for unrestricted use; and

16.17.e.2. Continue to control entry to restricted areas until the locations are suitable for release for unrestricted use and the agency notifies the registrant in writing that the registration is terminated.

16.18. Renewal of Specific Registrations.

16.18.a. Applications for renewal of specific registrations shall be filed in accordance with section 16.11.

16.18.b. In any case in which a registration, not less than 30 days prior to expiration of an existing registration, has filed an application in proper form for renewal or for a new registration authorizing the same activities, such existing registration shall not expire until final action by the agency.

16.19. Amendment of Specific Registrations at Request of Registrant. Applications for amendment of a registration shall be filed in accordance with section 16.11 and shall specify the respects in which the registrant desires the registration to be amended and the grounds for such amendment.

16.20. Agency Action on Applications to Renew and Amend Specific Registrations. In considering an application by a registrant to renew or amend the registration, the agency will apply the criteria set forth in section 16.12.

16.21. Modification and Revocation of Specific Registrations.

16.21.a. The terms and conditions of all registrations shall be subject to amendment, revision, or modification or the registration may be suspended or revoked by reason of amendments to this rule, or by reason of rules, regulations, and orders issued by the agency.

16.21.b. Any registration may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of this rule, or because of conditions revealed by such application or statement of fact or any report, record, or inspection or other means which would warrant the agency to refuse to grant a registration on an original application, or for violation of, or failure to observe any of the terms and conditions of this rule, or of the registration, or of any rule, regulation, or order of the agency.

16.21.c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, the agency shall not modify, suspend or revoke a registration prior to the institution of proceedings unless facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing and the registrant shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

16.22. Reciprocal Recognition of Specific Registrations. Subject to this rule, any person who holds a specific registration from an agreement state or a licensing state, and issued by the agency having jurisdiction where the registrant maintains an office for directing the registered activity and at which radiation safety records are normally maintained, is hereby granted a general registration to conduct the activities authorized in such registering document within this state for a period not in excess of 180 days in any calendar year provided that:

16.22.a. The registering document does not limit the activity authorized by such document to specified installations or locations;

16.22.b. The out-of-state registrant notifies the agency in writing at least three days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent registering document. If, for a specific case, the three day period would impose an undue hardship on the out-of-state

registrant , the registrant may, upon application to the agency, obtain permission to proceed sooner. The agency may waive the requirement for filing additional written notifications during the remainder of the calendar year following the receipt of the initial notification from a person engaging in activities under the general registration provided in subsection 16.22.a;

16.22.c. The out-of-state registrant complies with all applicable rules of the agency and with all the terms and conditions of the registering document, except any such terms and conditions which may be inconsistent with applicable rules of the agency;

16.22.d. The out-of-state registrant supplies such other information as the agency may request; and

16.22.e. The out-of-state registrant shall not transfer or dispose of TENORM possessed or used under the general registration provided in subsection 16.22.a except by transfer to a person:

16.22.e.1. Specifically registered by the agency or by another licensing state to receive such TENORM; or

16.22.e.2. Exempt from the requirements for a registration for such TENORM under section 16.4.

16.23. Financial Surety Arrangements. ~~Pursuant to §64 CSR 23, e~~Each registrant or applicant for a registration under section 16.12 shall post with the agency financial surety, or security, to ensure the protection of the public health and safety and the environment in the event of abandonment, default, or other inability or unwillingness of the registrant to meet the requirements of this rule. Financial surety arrangements shall:

16.23.a. Consist of cash deposits, certificates of deposit, government securities, irrevocable letters or lines of credit, or any combination of these;

16.23.b. Be in an amount sufficient to meet the applicant's or registrant's obligations ~~under the act and this rule~~for remediation of the facility, land, and equipment, and shall be a minimum of $1,000,000.00, unless based upon agency approved cost estimates, an additional amount is necessary for remediation;

16.23.c. Be established prior to issuance of the registration or the commencement of operations to assure that sufficient funds will be available to carry out the decontamination and decommissioning of the facility;

16.23.d. Be continuous for the duration of the registration and for a period coincident with the applicant or registrant responsibility under this rule;

16.23.e. Be available in West Virginia subject to judicial process and execution in the event required for the purposes set forth; and

16.23.f. Be established within 90 days of July 1, 2001 for registrations in effect on that date.

TABLE 64-23 A

QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed Dose in Gray Equal to one (1) Sv or the Absorbed Dose in Rad Equal to one (1) Rem.

TABLE 64-23 B

MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (Neutrons cm^{-2} Rem^{-1})	Fluence per Unit Dose Equivalent[b] (Neutrons cm^{-2} Sv^{-1})
thermal	2.5E-8	2	980E+6	980E+8
	1E-7	2	980E+6	980E+8
	1E-6	2	810E+6	810E+8
	1E-5	2	810E+6	810E+8
	1E-4	2	840E+6	840E+8
	1E-3	2	980E+6	980E+8
	1E-2	2.5	1010E+6	1010E+8
	1E-1	7.5	170E+6	170E+8
	5E-1	11	39E+6	39E+8
	1	11	27E+6	27E+8
	2.5	9	29E+6	29E+8
	5	8	23E+6	23E+8
	7	7	24E+6	24E+8
	10	6.5	24E+6	24E+8
	14	7.5	17E+6	17E+8
	20	8	16E+6	16E+8
	40	7	14E+6	14E+8
	60	5.5	16E+6	16E+8
	1E+2	4	20E+6	20E+8
	2E+2	3.5	19E+6	19E+8
	3E+2	3.5	16E+6	16E+8
	4E+2	3.5	14E+6	14E+8

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a thirty (30) centimeter diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a thirty (30) centimeter diameter cylinder tissue-equivalent phantom.

TABLE 64-23 C

Organ Dose Weighting Factors

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] Three one-hundredths (0.30) results from six one-hundredths (0.06) for each of five (5) "remainder" organs, excluding the skin and the lens of the eye, that receive the highest doses.

[b] For the purpose of weighting the external whole body dose, for adding it to the internal dose, a single weighting factor, w_T = one (1.0), has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

TABLE 64-23 D

Radionuclide	Activity	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700
Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

TABLE 64-23 E

PROTECTION FACTORS FOR RESPIRATORS [a]

Description [b]	Modes [c] only gases, vapors [e]	Protection Factors [d] Equipment Tested & Certified Particulates Occupational Safety & Health & Mine Safety & Health Administration tests for permissibility	Particulates National Institute for tests for permissibility	
I. AIR-PURIFYING RESPIRATORS [f]				
Facepiece, half-mask [g]	NP	10		CFR 11,
Facepiece, full	NP	50		Subpart K.
Facepiece, half-mask full, or hood	PP	1000		
II. ATMOSPHERE-SUPPLYING RESPIRATORS				
1. Air-line respirator				
Facepiece, half-mask	CF	1000		
Facepiece, half-mask	D		5	
Facepiece, full	CF	2000		
Facepiece, full	D		5	30 CFR 11,
Facepiece, full	PD	2000		Subpart J.
Hood	CF	[h]		
Suit	CF	[I]	[J]	
2. Self-contained breathing apparatus (SCBA)				
Facepiece, full	D		50	
Facepiece, full	PD	10,000 [k]		30 CFR 11,
Facepiece, full			50	Subpart H.
Facepiece, full	RP	5,000 [l]		
III. COMBINATION RESPIRATORS				
Any combination of air-purifying and atmosphere-supplying respirators		Protection factor For type and mode of operation as listed above		30 CFR 11, Sec. 11.63(b).

Footnotes:

[a] For use in the selection of respiratory protective equipment to be used only where the contaminants have been identified and the concentrations, or possible concentrations, are known.

[b] Only for shaven faces and where nothing interferes with the seal of tight-fitting facepieces against the skin. Hoods and suits are excepted.

[c] The mode symbols are defined as follows:

CF = continuous flow
D = demand
NP = negative pressure, that is, negative phase during inhalation
PD = pressure demand, that is, always positive pressure
PP = positive pressure
RD = demand, recirculating or closed circuit
RP = pressure demand, recirculating or closed circuit

[d] i. The protection factor is a measure of the degree of protection afforded by a respirator, defined as the ratio of the concentration of airborne radioactive material outside the respiratory protective equipment to that inside the equipment, usually inside the facepiece, under conditions of use. It is applied to the ambient airborne concentration to estimate the concentrations inhaled by the wearer according to the following formula:

Concentration inhaled = Ambient airborne concentration
Protection factor

ii. The protection factors apply:

(1) Only for individuals trained in using respirators and wearing properly fitted respirators that are used and maintained under supervision in a well-planned respiratory protective program.

(2) For air-purifying respirators only when high efficiency particulate filters, above ninety nine and ninety seven one-hundredths (99.97) percent removal efficiency by thermally generated three tenths (0.3) μm dioctyl phthalate (DOP) test or equivalent, are used in atmospheres not deficient in oxygen and not containing radioactive gas or vapor respiratory hazards.

(3) No adjustment is to be made for the use of sorbents against radioactive material in the form of gases or vapors.

(4) For atmosphere-supplying respirators only when supplied with adequate respirable air. Respirable air shall be provided of the quality and quantity required in accordance with the National Institute for Occupational Safety and Health and the Mine Safety and Health Administration certification described in 30 CFR 11. Oxygen and air shall not be used in the same apparatus.

[e] Excluding radioactive contaminants that present an absorption or submersion hazard. For tritium oxide, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of less than two (2) is appropriate when atmosphere--supplying respirators are used to protect against tritium oxide. If the protection factor for respiratory protective equipment is five (5), the effective protection factor for tritium is about one and four tenths (1.4); with protection factors of ten (10), the effective factor for tritium oxide is about one and seven tenths (1.7); and with protection factors of one hundred (100) or more, the effective factor for tritium oxide is about one and nine tenths (1.9). Air-purifying respirators are not suitable for protection against tritium oxide. See also footnote I/ concerning supplied-air suits.

[f] Canisters and cartridges shall not be used beyond service-life limitations.

[g] Under-chin type only. This type of respirator is not satisfactory for use where it might be possible, such as, if an accident or emergency were to occur, for the ambient airborne concentrations to reach instantaneous values greater than ten (10) times the pertinent values in Table I, Column three (3) of Table 64-23 F. This type of respirator is not suitable for protection against plutonium or other high-toxicity materials. The mask is to be tested for fit prior to use, each time it is donned.

[h] i. Equipment shall be operated in a manner that ensures that proper air flow-rates are maintained. A protection factor of no more than one thousand (1000) may be utilized for tested-and-certified supplied-air hoods when a minimum air flow of six (6) cubic feet per minute seventeen one-hundredths ([0.17] m3/min) is maintained and calibrated air line pressure gauges or flow measuring devices are used. A protection factor of up to tho thousand (2000) may be used for tested and certified hoods only when the air flow is maintained at the manufacturer's recommended maximum rate for the equipment, this rate is greater than six (6) cubic feet per minute seventeen one-hundredths ([0.17] m3/min) and calibrated air line pressure gauges or flow measuring devices are used.

ii. The design of the supplied-air hood or helmet, with a minimum flow of six (6) cubic feet per minute seventeen one-hundredths ([0.17] m3/min) of air, may determine its overall efficiency and the protection it provides. For example, some hoods aspirate contaminated air into the breathing zone when the wearer works with hands-over-head. This aspiration may be overcome if a short cape-like extension to the hood is worn under a coat or overalls. Other limitations specified by the approval agency shall be considered before using a hood in certain types of atmospheres. See footnote [l].

[l] Appropriate protection factors shall be determined, taking into account the design of the suit and its permeability to the contaminant under conditions of use. There shall be a standby rescue person equipped with a respirator or other apparatus appropriate for the potential hazards and communications equipment whenever supplied-air suits are used.

[j] No approval schedules are currently available for this equipment. Equipment is to be evaluated by testing or on the basis of reliable test information.

[k] This type of respirator may provide greater protection and be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitations to permitted exposure, such as skin absorption, must be taken into account in such circumstances.

[l] Quantitative fit testing shall be performed on each individual, and no more than two one-hundredths (0.02) percent leakage is allowed with this type of apparatus. Perceptible outward leakage of gas from this or any positive pressure self-contained breathing apparatus is unacceptable because service life will be reduced substantially. Special training in the use of this type of apparatus shall be provided to the wearer.

Note 1: Protection factors for respirators approved by the Bureau of Mines and the National Institute for Occupational Safety and Health, according to applicable approvals for respirators for type and mode of use to protect against airborne radionuclides, may be used to the extent that they do not exceed the protection factors listed in this table. The protection factors listed in this table may not be appropriate to circumstances where chemical or other respiratory hazards exist in addition to radioactive hazards. The selection and use of respirators for such circumstances should take into account applicable approvals of the Bureau of Mines and the National Institute for Occupational Safety and Health.

Note 2: Radioactive contaminants, for which the concentration values in Table I, Column three (3) of Table 64-23 F are based on internal dose due to inhalation, may present external exposure hazards at higher concentrations. Under these circumstances, limitations on occupancy may have to be governed by external dose limits.

TABLE 64-23 F

Annual Limits on Intake (Ali) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewerage

Introduction

For each radionuclide, table i indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of one (1) μm, micron, and for three classes (D,W,U) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than ten (10) days, for W from ten (10) to one hundred (100) days, and for Y greater than one hundred (100) days. The class (d, w, or y) given in the column headed "class" applies only to the inhalation ALIs and DACs given in Table I, Column 2 and 3. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are presented in the computer "e" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents $6 \times 1O^{2}$ or 600, and 6E+0 represents 6×10^{0} or 6.

Table I "Occupational Values"

Note that the columns in Table I of this appendix captioned "oral ingestion ALI," "inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "reference man" which would result in either (1) a committed effective dose equivalent of five one-hundredths (0.05) Sv (five [5] Rem), stochastic ALI, or (2) a committed dose equivalent of five one-hundredths (0.5) Sv (fifty [50] Rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of five one-hundredths (0.05) Sv (five [5] Rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, t, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in section 2.0. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.
A value of w_T = is one-hundredths (0.06) is applicable to each of the five (5) organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract -- stomach, small intestine, upper large intestine, and lower large intestine -- are to be treated as four (4) separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;
St wall = stomach wall;
Blad wall = bladder wall; and

Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the registrant may use the stochastic ALI to determine the committed effective dose equivalent. However, the registrant shall also ensure that the five tenths (0.5) Sv (fifty [50] Rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, $\sum$ (intake (in μCi) of each radionuclide/ALI_{ns}) $\leq$ one (1.0). If there is an external deep dose equivalent contribution of H_d, then this sum must be less than one (1) - (H_d/50), instead of $\leq$ one (1.0).

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in μCi)/(two thousand [2000] hours per working year x sixty [60] minutes/hour x twenty thousand (2×10^4) ml per minute) =(ALI/two billion four hundred million [2.4×10^9])μCi/ml, where twenty thousand (2×10^4) ml is the volume of air breathed per minute at work by reference man under working conditions of light work.

The DAC values relate to one (1) of two (2) modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.
The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See section 6.6. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as, class D, class W, or class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as class d, w or y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for class D, W and Y compounds, even for very short-lived radionuclides.

Table II "Effluent Concentrations"

The columns in Table II of this table captioned "effluents," "air" and "water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of section 6.14. The concentration values given in columns one (1) and two (2) of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of five tenths (0.5) mSv (five one-hundredths [0.05]

Rem).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in Table 64-23 E.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by two billion four hundred million ($2.4 \times 10^{9)}$ (ml), relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of three hundred 300. The factor of three hundred 300 includes the following components: a factor of fifty (50) to relate the five one-hundredths (0.05) Sv (five [5] Rem) annual occupational dose limit to the ons (1) mSv (one tenth [0.1] Rem) limit for members of the public, a factor of three (3) to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of two (2) to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by two hundred nineteen (219). The factor of two hundred nineteen (219) is composed of a factor of fifty (50), as described above, and a factor of four and thirty eight one-hundredths (4.38) relating occupational exposure for two thousand (2,000) hours per year to full-time exposure (eight thousand seven hundred sixty [8,760] hours per year). Note that an additional factor of tho (2) for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by seventy three million (7.3×10^{7}). The factor of seventy three million (7.3×10^{7}) (ml) includes the following components: the factors of fifty (50) and two (2) described above and a factor of seven hundred thirty thousand (7.3×10^{5}) (ml) which is the annual water intake of reference man.

Note 2 of this table provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table III "Releases to Sewers"

The monthly average concentrations for release to sanitary sewerage are applicable to the provisions in ~~S~~subsection 6.34. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by seven million three hundred thousand (7.3×10^{6}) (ml). The factor of seven million three hundred thousand (7.3×10^{6}) (ml) is composed of a factor of seven hundred thirty thousand (7.3×10^{5}) (ml), the annual water intake by reference man, and a factor of ten (10), such that the concentrations, if the sewage released by the registrant were the only source of water ingested by a reference man during a year, would result in a committed effective dose equivalent of five (5) mSv (five tenths 0.5 Rem).

List of Elements

tomic Name	Symbol	Number	Atomic Name	Symbol	Number
Actinium	Ac	89	Palladium	Pd	46
Aluminum	A	13	Phosphorus	P	15
Americium	Am	95	Platinum	Pt	78
Antimony	Sb	51	Plutonium	Pu	94
Argon	Ar	18	Polonium	Po	84
Arsenic	As	33	Potassium	K	19
Astatine	At	85	Praseodymium	Pr	59
Barium	Ba	56	Promethium	Pm	61
Berkelium	Bk	97	Protactinium	Pa	91
Beryllium	Be	4	Radium	Ra	88
Bismuth	Bi	83	Radon	Rn	86
Bromine	Br	35	Rhenium	Re	75
Cadmium	Cd	48	Rhodium	Rh	45
Calcium	Ca	20	Rubidium	Rb	37
Californium	Cf	98	Ruthenium	Ru	44
Carbon	C	6	Samarium	Sm	62
Cerium	C	58	Scandium	Sc	21
Cesium	C	55	Selenium	Se	34
Chlorine	C	17	Silicon	Si	14
Chromium	C	24	Silver	Ag	47
Cobalt	C	27	Sodium	Na	11
Copper	C	29	Strontium	Sr	38
Curium	C	96	Sulfur	S	16
Dysprosium	D	66	Tantalum	Ta	73
Einsteinium	E	99	Technetium	Tc	43
Erbium	E	68	Tellurium	Te	52
Europium	E	63	Terbium	Tb	65
Fermium	F	100	Thallium	Tl	81
Fluorine	F	9	Thorium	Th	90
Francium	Fr	87	Thulium	Tm	69
Gadolinium	Gd	64	Tin	Sn	50
Gallium	Ga	31	Titanium	Ti	22
Germanium	Ge	32	Tungsten	W	74
Gold	Au	79	Uranium	U	92
Hafnium	Hf	72	Vanadium	V	23
Holmium	Ho	67	Xenon	Xe	54
Hydrogen	H	1	Ytterbium	Yb	70
Indium	In	49	Yttrium	Y	39
Iodine	I	53	Zinc	Zn	30
Iridium	Ir	77	Zirconium	Zr	40
Iron	Fe	26			
Krypton	Kr	36			
Lanthanum	La	57			
Lead	Pb	82			
Lutetium	Lu	71			
Magnesium	Mg	12			
Manganese	Mn	25			
Mendelevium	Md	101			
Mercury	Hg	80			
Molybdenum	Mo	42			
Neodymium	Nd	60			
Neptunium	Np	93			
Nickel	Ni	28			
Niobium	Nb	41			
Osmium	Os	76			

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[a]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	—	2E+4	8E-6	3E-8	—	—
4	Beryllium-10	W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	—	—
		LLI wall	(1E+3)	—	—	—	2E-5	2E-4
		Y, see ^{7}Be	—	1E+1	6E-9	2E-11	—	—
6	Carbon-11[b/]	Monoxide	—	1E+6	5E-4	2E-6	—	—
		Dioxide	—	6E+5	3E-4	9E-7	—	—
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	—	2E+6	7E-4	2E-6	—	—
		Dioxide	—	2E+5	9E-5	3E-7	—	—
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
9	Fluorine-18[b/]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	—	—
		St wall	(5E+4)	—	—	—	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	—	9E+4	4E-5	1E-7	—	—
		Y, lanthanum fluoride	—	8E+4	3E-5	1E-7	—	—
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	—	1E+3	5E-7	2E-9	—	—
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	—	9E+1	4E-8	1E-10	—	—
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and nitrates	—	3E+4	1E-5	5E-8	—	—
		Y, aluminosilicate glass	—	3E+4	1E-5	4E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	—	—
			LLI wall (3E+3)	—	—	—	4E-5	4E-4
		W, see ^{31}Si	—	1E+2	5E-8	2E-10	—	—
		Y, see ^{31}Si	—	5E+0	2E-9	7E-12	—	—
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn^{2+}, S^{3+}, Mg^{2+}, Fe^{3+}, Bi^{3+}, and lanthanides	—	4E+2	2E-7	5E-10	—	—
15	Phosphorus-33	D, see ^{32}P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see ^{32}P	—	—	3E+3	1E-6	4E-9	— —
16	Sulfur-35	Vapor	—	1E+4	6E-6	2E-8	—	—
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	—	—
			LLI wall (8E+3)	—	—	—	1E-4	1E-3
		W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3 —	2E+3	9E-7	3E-9	—	—
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	—	2E+2	1E-7	3E-10	—	—
17	Chlorine-38[b/]	D, see ^{36}Cl	2E+4	4E+4	2E-5	6E-8	—	
			St wall (3E+4)	—	—	—	3E-4	3E-3
		W, see ^{36}Cl	—	5E+4	2E-5	6E-8	—	—
17	Chlorine-39[b/]	D, see ^{36}Cl	2E+4	5E+4	2E-5	7E-8	—	—
			St wall (4E+4)	—	—	—	5E-4	5E-3
		W, see ^{36}Cl	—	6E+4	2E-5	8E-8	—	—
18	Argon-37	Submersion[a]	—	—	1E+0	6E-3	—	—
18	Argon-39	Submersion[a]	—	—	2E-4	8E-7	—	—
18	Argon-41	Submersion[a]	—	—	3E-6	1E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19	Potassium-44[b]	D, all compounds	2E+4	7E+4	3E-5	9E-8	—	—
			St wall (4E+4)	—	—	—	5E-4	5E-3
19	Potassium-45[b]	D, all compounds	3E+4	1E+5	5E-5	2E-7	—	—
			St wall (5E+4)	—	—	—	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	—	—	—
		Bone surf	Bone surf (4E+3)	(4E+3)	—	5E-9	6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	—	—
			LLI wall (3E+3)	—	—	—	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4
21	Scandium-49[b/]	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	—	3E+1	1E-8	4E-11	—	—
		Y, SrTi0	—	6E+0	2E-9	8E-12	—	—
22	Titanium-45	D, see ^{44}Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{44}Ti	—	4E+4	1E-5	5E-8	—	—
		Y, see ^{44}Ti	—	3E+4	1E-5	4E-8	—	—
23	Vanadium-47[b/]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	—	—
			St wall (3E+4)	—	—	—	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	—	1E+5	4E-5	1E-7	—	—
23	Vanadium-48	D, see ^{47}V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
		W, see ^{47}V	—	6E+2	3E-7	9E-10	—	—
23	Vanadium-49	D, see ^{47}V	7E+4	3E+4	1E-5	—	—	—
			LLI wall (9E+4)	Bone surf (3E+4)	—	5E-8	1E-3	1E-2
		W, see ^{47}V	—	2E+4	8E-6	2E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	—	7E+3	3E-6	1E-8	—	—
		Y, oxides and hydroxides	—	7E+3	3E-6	1E-8	—	—
24	Chromium-49[b/]	D, see ^{48}Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{48}Cr	—	1E+5	4E-5	1E-7	—	—
		Y, see ^{48}Cr	—	9E+4	4E-5	1E-7	—	—
24	Chromium-51	D, see ^{48}Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see ^{48}Cr	—	2E+4	1E-5	3E-8	—	—
		Y, see ^{48}Cr	—	2E+4	8E-6	3E-8	—	—
25	Manganese-51[b/]	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	—	6E+4	3E-5	8E-8	—	—
25	Manganese-52m[b]	D, see ^{51}Mn	3E+4 St wall (4E+4)	9E+4	4E-5	1E-7	—	—
				—	—	—	5E-4	5E-3
		W, see ^{51}Mn	—	1E+5	4E-5	1E-7	—	—
25	Manganese-52	D, see ^{51}Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see ^{51}Mn	—	9E+2	4E-7	1E-9	—	—
25	Manganese-53	D, see ^{51}Mn	5E+4 Bone surf (2E+4)	1E+4	5E-6	—	7E-4	7E-3
		—		—	3E-8	—	—	
		W, see ^{51}Mn	—	1E+4	5E-6	2E-8	—	—
25	Manganese-54	D, see ^{51}Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see ^{51}Mn	—	8E+2	3E-7	1E-9	—	—
25	Manganese-56	D, see ^{51}Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{51}Mn	—	2E+4	9E-6	3E-8	—	—
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	—	2E+3	1E-6	3E-9	—	—
26	Iron-55	D, see ^{52}Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see ^{52}Fe	—	4E+3	2E-6	6E-9	—	—
26	Iron-59	D, see ^{52}Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see ^{52}Fe	—	5E+2	2E-7	7E-10	—	—
26	Iron-60	D, see ^{52}Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see ^{52}Fe	—	2E+1	8E-9	3E-11	—	—
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	—	3E+3	1E-6	4E-9	—	—
27	Cobalt-56	W, see ^{55}Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see ^{55}Co	4E+2	2E+2	8E-8	3E-10	—	—
27	Cobalt-57	W, see ^{55}Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see ^{55}Co	4E+3	7E+2	3E-7	9E-10	—	—
27	Cobalt-58m	W, see ^{55}Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see ^{55}Co	—	6E+4	3E-5	9E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
27	Cobalt-58	W, see ^{55}Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see ^{55}Co	1E+3	7E+2	3E-7	1E-9	—	—
27	Cobalt-60m[b]	W, see ^{55}Co	1E+6	4E+6	2E-3	6E-6	—	—
			St wall (1E+6)	—	—	—	2E-2	2E-1
		Y, see ^{55}Co	—	3E+6	1E-3	4E-6	—	—
27	Cobalt-60	W, see ^{55}Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see ^{55}Co	2E+2	3E+1	1E-8	5E-11	—	—
27	Cobalt-61[b/]	W, see ^{55}Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{55}Co	2E+4	6E+4	2E-5	8E-8	—	—
27	Cobalt-62m[b/]	W, see ^{55}Co	4E+4	2E+5	7E-5	2E-7	—	—
			St wall (5E+4)	—	—	—	7E-4	7E-3
		Y, see ^{55}Co	—	2E+5	6E-5	2E-7	—	—
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	—	1E+3	5E-7	2E-9	—	—
		Vapor	—	1E+3	5E-7	2E-9	—	—
28	Nickel-57	D, see ^{56}Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{56}Ni	—	3E+3	1E-6	4E-9	—	—
		Vapor	—	6E+3	3E-6	9E-9	—	—
28	Nickel-59	D, see ^{56}Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see ^{56}Ni	—	7E+3	3E-6	1E-8	—	—
		Vapor	—	2E+3	8E-7	3E-9	—	—
28	Nickel-63	D, see ^{56}Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see ^{56}Ni	—	3E+3	1E-6	4E-9	—	—
		Vapor	—	8E+2	3E-7	1E-9	—	—
28	Nickel-65	D, see ^{56}Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{56}Ni	—	3E+4	1E-5	4E-8	—	—
		Vapor	—	2E+4	7E-6	2E-8	—	—
28	Nickel-66	D, see ^{56}Ni	4E+2	2E+3	7E-7	2E-9	—	—
			LLI wall (5E+2)	—	—	—	6E-6	6E-5
		W, see ^{56}Ni	—	6E+2	3E-7	9E-10	—	—
		Vapor	—	3E+3	1E-6	4E-9	—	—
29	Copper-60[b/]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	—	—
			St wall (3E+4)	—	—	—	4E-4	4E-3
		W, sulfides, halides, and nitrates	—	1E+5	5E-5	2E-7	—	—
		Y, oxides and hydroxides	—	1E+5	4E-5	1E-7	—	—
29	Copper-61	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	—	4E+4	2E-5	6E-8	—	—
		Y, see ^{60}Cu	—	4E+4	1E-5	5E-8	—	—
29	Copper-64	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	—	2E+4	1E-5	3E-8	—	—
		Y, see ^{60}Cu	—	2E+4	9E-6	3E-8	—	—
29	Copper-67	D, see ^{60}Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see ^{60}Cu	—	5E+3	2E-6	7E-9	—	—
		Y, see ^{60}Cu	—	5E+3	2E-6	6E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63[b/]	Y, all compounds	2E+4	7E+4	3E-5	9E-8	—	—
			St wall (3E+4)	—	—	—	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69[b/]	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65[b]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	—	—
			St wall (6E+4)	—	—	—	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	—	2E+5	8E-5	3E-7	—	—
31	Gallium-66	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ^{65}Ga	—	3E+3	1E-6	4E-9	—	—
31	Gallium-67	D, see ^{65}Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ^{65}Ga	—	1E+4	4E-6	1E-8	—	—
31	Gallium-68[b/]	D, see ^{65}Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{65}Ga	—	5E+4	2E-5	7E-8	—	—
31	Gallium-70[b/]	D, see ^{65}Ga	5E+4	2E+5	7E-5	2E-7	—	—
			St wall (7E+4)	—	—	—	1E-3	1E-2
		W, see ^{65}Ga	—	2E+5	8E-5	3E-7	—	—
31	Gallium-72	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{65}Ga	—	3E+3	1E-6	4E-9	—	—
31	Gallium-73	D, see ^{65}Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{65}Ga	—	2E+4	6E-6	2E-8	—	—
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
		W, oxides, sulfides, and halides	—	2E+4	8E-6	3E-8	—	—
32	Germanium-67[b/]	D, see ^{66}Ge	3E+4	9E+4	4E-5	1E-7	—	—
			St wall (4E+4)	—	—	—	6E-4	6E-3
		W, see ^{66}Ge	—	1E+5	4E-5	1E-7	—	—
32	Germanium-68	D, see ^{66}Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see ^{66}Ge	—	1E+2	4E-8	1E-10	—	—
32	Germanium-69	D, see ^{66}Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see ^{66}Ge	—	8E+3	3E-6	1E-8	—	—
32	Germanium-71	D, see ^{66}Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see ^{66}Ge	—	4E+4	2E-5	6E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
32	Germanium-75[b]	D, see ^{66}Ge	4E+4	8E+4	3E-5	1E-7	—	—
			St wall (7E+4)	—	—	—	9E-4	9E-3
		W, see ^{66}Ge	—	8E+4	4E-5	1E-7	—	—
32	Germanium-77	D, see ^{66}Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see ^{66}Ge	—	6E+3	2E-6	8E-9	—	—
32	Germanium-78[b/]	D, see ^{66}Ge	2E+4	2E+4	9E-6	3E-8	—	—
			St wall (2E+4)	—	—	—	3E-4	3E-3
		W, see ^{66}Ge	—	2E+4	9E-6	3E-8	—	—
33	Arsenic-69[b/]	W, all compounds	3E+4	1E+5	5E-5	2E-7	—	—
			St wall (4E+4)	—	—	—	6E-4	6E-3
33	Arsenic-70[b/]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	—	—
			LLI wall (5E+3)	—	—	—	6E-5	6E-4
33	Arsenic-78[b/]	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34	Selenium-70[b]	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	—	—
34	Selenium-73m[b]	D, see ^{70}Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	6E-5	2E-7	—	—
34	Selenium-73	D, see ^{70}Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see ^{70}Se	—	2E+4	7E-6	2E-8	—	—
34	Selenium-75	D, see ^{70}Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see ^{70}Se	—	6E+2	3E-7	8E-10	—	—
34	Selenium-79	D, see ^{70}Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see ^{70}Se	—	6E+2	2E-7	8E-10	—	—
34	Selenium-81m[b/]	D, see ^{70}Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{70}Se	2E+4	7E+4	3E-5	1E-7	—	—
34	Selenium-81[b/]	D, see ^{70}Se	6E+4	2E+5	9E-5	3E-7	—	—
			St wall (8E+4)	—	—	—	1E-3	1E-2
		W, see ^{70}Se	—	2E+5	1E-4	3E-7	—	—
34	Selenium-83[b/]	D, see ^{70}Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	5E-5	2E-7	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
35	Bromine-74m[b/]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	—	—
			St wall (2E+4)	—	—	—	3E-4	3E-3
		W, bromides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	—	4E+4	2E-5	6E-8	—	—
35	Bromine-74[b]	D, see ^{74m}Br	2E+4	7E+4	3E-5	1E-7	—	—
			St wall (4E+4)	—	—	—	5E-4	5E-3
		W, see ^{74m}Br	—	8E+4	4E-5	1E-7	—	—
35	Bromine-75[b/]	D, see ^{74m}Br	3E+4	5E+4	2E-5	7E-8	—	—
			St wall (4E+4)	—	—	—	5E-4	5E-3
		W, see ^{74m}Br	—	5E+4	2E-5	7E-8	—	—
35	Bromine-76	D, see ^{74m}Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see ^{74m}Br	—	4E+3	2E-6	6E-9	—	—
35	Bromine-77	D, see ^{74m}Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see ^{74m}Br	—	2E+4	8E-6	3E-8	—	—
35	Bromine-80m	D, see ^{74m}Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see ^{74m}Br	—	1E+4	6E-6	2E-8	—	—
35	Bromine-80[b/]	D, see ^{74m}Br	5E+4	2E+5	8E-5	3E-7	—	—
			St wall (9E+4)	—	—	—	1E-3	1E-2
		W, see ^{74m}Br	—	2E+5	9E-5	3E-7	—	—
35	Bromine-82	D, see ^{74m}Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{74m}Br	—	4E+3	2E-6	5E-9	—	—
35	Bromine-83	D, see ^{74m}Br	5E+4	6E+4	3E-5	9E-8	—	—
			St wall (7E+4)	—	—	—	9E-4	9E-3
		W, see ^{74m}Br	—	6E+4	3E-5	9E-8	—	—
35	Bromine-84[b/]	D, see ^{74m}Br	2E+4	6E+4	2E-5	8E-8	—	—
			St wall (3E+4)	—	—	—	4E-4	4E-3
		W, see ^{74m}Br	—	6E+4	3E-5	9E-8	—	—
36	Krypton-74[b/]	Submersion[a/]	—	—	3E-6	1E-8	—	—
36	Krypton-76	Submersion[a/]	—	—	9E-6	4E-8	—	—
36	Krypton-77[b]	Submersion[a/]	—	—	4E-6	2E-8	—	—
36	Krypton-79	Submersion[a/]	—	—	2E-5	7E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
36	Krypton-81	Submersion[a/]	—	—	7E-4	3E-6	—	—
36	Krypton-83m[b]	Submersion[a/]	—	—	1E-2	5E-5	—	—
36	Krypton-85m	Submersion[a/]	—	—	2E-5	1E-7	—	—
36	Krypton-85	Submersion[a/]	—	—	1E-4	7E-7	—	—
36	Krypton-87[b]	Submersion[a/]	—	—	5E-6	2E-8	—	—
36	Krypton-88	Submersion[a/]	—	—	2E-6	9E-9	—	—
37	Rubidium-79[b]	D, all compounds	4E+4	1E+5	5E-5	2E-7	—	—
			St wall (6E+4)	—	—	—	8E-4	8E-3
37	Rubidium-81m[b/]	D, all compounds	2E+5	3E+5	1E-4	5E-7	—	—
			St wall (3E+5)	—	—	—	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88[b/]	D, all compounds	2E+4	6E+4	3E-5	9E-8	—	—
			St wall (3E+4)	-	—	—	4E-4	4E-3
37	Rubidium-89[b/]	D, all compounds	4E+4	1E+5	6E-5	2E-7	—	—
			St wall (6E+4)	-	—	—	9E-4	9E-3
38	Strontium-80[b/]	D, all soluble compounds except $SrTiO_3$	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and $SrTi0_3$	—	1E+4	5E-6	2E-8	—	—
38	Strontium-81[b]	D, see ^{80}Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{80}Sr	2E+4	8E+4	3E-5	1E-7	—	—
38	Strontium-82	D, see ^{80}Sr	3E+2	4E+2	2E-7	6E-10	—	—
			LLI wall (2E+2)	—	—	—	3E-6	3E-5
		Y, see ^{80}Sr	2E+2	9E+1	4E-8	1E-10	—	—
38	Strontium-83	D, see ^{80}Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{80}Sr	2E+3	4E+3	1E-6	5E-9	—	—
38	Strontium-85m[b/]	D, see ^{80}Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see ^{80}Sr	—	8E+5	4E-4	1E-6	—	—
38	Strontium-85	D, see ^{80}Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see ^{80}Sr	—	2E+3	6E-7	2E-9	—	—
38	Strontium-87m	D, see ^{80}Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{80}Sr	4E+4	2E+5	6E-5	2E-7	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
38	Strontium-89	D, see ^{80}Sr	6E+2	8E+2	4E-7	1E-9	—	—
			LLI wall (6E+2)	—	—	—	8E-6	8E-5
		Y, see ^{80}Sr	5E+2	1E+2	6E-8	2E-10	—	—
38	Strontium-90	D, see ^{80}Sr	3E+1 Bone surf (4E+1)	2E+1 Bone surf (2E+1)	8E-9 —	— 3E-11	— 5E-7	— 5E-6
		Y, see ^{80}Sr	—	4E+0	2E-9	6E-12	—	—
38	Strontium-91	D, see ^{80}Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see ^{80}Sr	—	4E+3	1E-6	5E-9	—	—
38	Strontium-92	D, see ^{80}Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{80}Sr	—	7E+3	3E-6	9E-9	—	—
39	Yttrium-86m[b/]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	—	5E+4	2E-5	8E-8	—	—
39	Yttrium-86	W, see ^{86m}Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{86m}Y	—	3E+3	1E-6	5E-9	—	—
39	Yttrium-87	W, see ^{86m}Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see ^{86m}Y	—	3E+3	1E-6	5E-9	—	—
39	Yttrium-88	W, see ^{86m}Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see ^{86m}Y	—	2E+2	1E-7	3E-10	—	—
39	Yttrium-90m	W, see ^{86m}Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see ^{86m}Y	—	1E+4	5E-6	2E-8	—	—
39	Yttrium-90	W, see ^{86m}Y	4E+2	7E+2	3E-7	9E-10	—	—
			LLI wall (5E+2)	—	—	—	7E-6	7E-5
		Y, see ^{86m}Y	—	6E+2	3E-7	9E-10	—	—
39	Yttrium-91m[b]	W, see ^{86m}Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see ^{86m}Y	—	2E+5	7E-5	2E-7	—	—
39	Yttrium-91	W, see ^{86m}Y	5E+2	2E+2	7E-8	2E-10	—	—
			LLI wall (6E+2)	—	—	—	8E-6	8E-5
		Y, see ^{86m}Y	—	1E+2	5E-8	2E-10	—	—
39	Yttrium-92	W, see ^{86m}Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{86m}Y	—	8E+3	3E-6	1E-8	—	—
39	Yttrium-93	W, see ^{86m}Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{86m}Y	—	2E+3	1E-6	3E-9	—	—
39	Yttrium-94[b/]	W, see ^{86m}Y	2E+4	8E+4	3E-5	1E-7	—	—
			St wall (3E+4)	—	—	—	4E-4	4E-3
		Y, see ^{86m}Y	—	8E+4	3E-5	1E-7	—	—
39	Yttrium-95[b/]	W, see ^{86m}Y	4E+4	2E+5	6E-5	2E-7	—	—
			St wall (5E+4)	—	—	—	7E-4	7E-3
		Y, see ^{86m}Y	—	1E+5	6E-5	2E-7	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure Effluent Concentrations Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	—	3E+3	1E-6	4E-9	—	—
		Y, carbide	—	2E+3	1E-6	3E-9	—	—
40	Zirconium-88	D, see ^{86}Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see ^{86}Zr	—	5E+2	2E-7	7E-10	—	—
		Y, see ^{86}Zr	—	3E+2	1E-7	4E-10	—	—
40	Zirconium-89	D, see ^{86}Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{86}Zr	—	2E+3	1E-6	3E-9	—	—
		Y, see ^{86}Zr	—	2E+3	1E-6	3E-9	—	—
40	Zirconium-93	D, see ^{86}Zr	1E+3 Bone surf	6E+0 Bone surf	3E-9	—	—	—
			(3E+3)	(2E+1)	—	2E-11	4E-5	4E-4
		W, see ^{86}Zr	—	2E+1	1E-8	—	—	—
			Bone surf					
			—	(6E+1)	—	9E-11	—	—
		Y, see ^{86}Zr	—	6E+1	2E-8	—	—	—
			—	Bone surf (7E+1)	—	9E-11	—	—
40	Zirconium-95	D, see ^{86}Zr	1E+3	1E+2	5E-8	—	2E-5	2E-4
			Bone surf					
			—	(3E+2)	—	4E-10	—	—
		W, see ^{86}Zr	—	4E+2	2E-7	5E-10	—	—
		Y, see ^{86}Zr	—	3E+2	1E-7	4E-10	—	—
40	Zirconium-97	D, see ^{86}Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see ^{86}Zr	—	1E+3	6E-7	2E-9	—	—
		Y, see ^{86}Zr	—	1E+3	5E-7	2E-9	—	—
41	Niobium-88[b]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	—	—
			St wall (7E+4)	—	—	—	1E-3	1E-2
		Y, oxides and hydroxides	—	2E+5	9E-5	3E-7	—	—
41	Niobium-89[b]	W, see ^{88}Nb (66 min)	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see ^{88}Nb	—	4E+4	2E-5	5E-8	—	—
41	Niobium-89	W, see ^{88}Nb (122 min)	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{88}Nb	—	2E+4	6E-6	2E-8	—	—
41	Niobium-90	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see ^{88}Nb	—	2E+3	1E-6	3E-9	—	—
41	Niobium-93m	W, see ^{88}Nb	9E+3	2E+3	8E-7	3E-9	—	—
			LLI wall (1E+4)	—	—	—	2E-4	2E-3
		Y, see ^{88}Nb	—	2E+2	7E-8	2E-10	—	—
41	Niobium-94	W, see ^{88}Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see ^{88}Nb	—	2E+1	6E-9	2E-11	—	—
41	Niobium-95m	W, see ^{88}Nb	2E+3	3E+3	1E-6	4E-9	—	—
			LLI wall (2E+3)	—	—	—	3E-5	3E-4
		Y, see ^{88}Nb	—	2E+3	9E-7	3E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
41	Niobium-95	W, see ^{88}Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see ^{88}Nb	—	1E+3	5E-7	2E-9	—	—
41	Niobium-96	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{88}Nb	—	2E+3	1E-6	3E-9	—	—
41	Niobium-97[b/]	W, see ^{88}Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{88}Nb	—	7E+4	3E-5	1E-7	—	—
41	Niobium-98[b/]	W, see ^{88}Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see ^{88}Nb	—	5E+4	2E-5	7E-8	—	—
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS_2	2E+3	5E+3	2E-6	6E-9	—	—
42	Molybdenum-93m	D, see ^{90}Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see ^{90}Mo	4E+3	1E+4	6E-6	2E-8	—	—
42	Molybdenum-93	D, see ^{90}Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see ^{90}Mo	2E+4	2E+2	8E-8	2E-10	—	—
42	Molybdenum-99	D, see ^{90}Mo	2E+3	3E+3	1E-6	4E-9	—	—
			LLI wall (1E+3)	—	—	—	2E-5	2E-4
		Y, see ^{90}Mo	1E+3	1E+3	6E-7	2E-9	—	—
42	Molybdenum-101[b]	D, see ^{90}Mo	4E+4	1E+5	6E-5	2E-7	—	—
			St wall (5E+4)	—	—	—	7E-4	7E-3
		Y, see ^{90}Mo	—	1E+5	6E-5	2E-7	—	—
43	Technetium-93m[b]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	—	3E+5	1E-4	4E-7	—	—
43	Technetium-93	D, see ^{93m}Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see ^{93m}Tc	—	1E+5	4E-5	1E-7	—	—
43	Technetium-94m[b]	D, see ^{93m}Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{93m}Tc	—	6E+4	2E-5	8E-8	—	—
43	Technetium-94	D, see ^{93m}Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	—	2E+4	1E-5	3E-8	—	—
43	Technetium-95m	D, see ^{93m}Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see ^{93m}Tc	—	2E+3	8E-7	3E-9	—	—
43	Technetium-95	D, see ^{93m}Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	—	2E+4	8E-6	3E-8	—	—
43	Technetium-96m[b/]	D, see ^{93m}Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see ^{93m}Tc	—	2E+5	1E-4	3E-7	—	—
43	Technetium-96	D, see ^{93m}Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{93m}Tc	—	2E+3	9E-7	3E-9	—	—
43	Technetium-97m	D, see ^{93m}Tc	5E+3	7E+3	3E-6	—	6E-5	6E-4
			St wall —	(7E+3)	—	1E-8	—	—
		W, see ^{93m}Tc	—	1E+3	5E-7	2E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
43	Technetium-97	D, see ^{93m}Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m}Tc	—	6E+3	2E-6	8E-9	—	—
43	Technetium-98	D, see ^{93m}Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m}Tc	—	3E+2	1E-7	4E-10	—	—
43	Technetium-99m	D, see ^{93m}Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m}Tc	—	2E+5	1E-4	3E-7	—	—
43	Technetium-99	D, see ^{93m}Tc	4E+3	5E+3	2E-6	—	6E-5	6E-4
			St wall					
			—	(6E+3)	—	8E-9	—	—
		W, see ^{93m}Tc	—	7E+2	3E-7	9E-10	—	—
43	Technetium-101[b/]	D, see ^{93m}Tc	9E+4	3E+5	1E-4	5E-7	—	—
			St wall					
			(1E+5)	—	—	—	2E-3	2E-2
		W, see ^{93m}Tc	—	4E+5	2E-4	5E-7	—	—
43	Technetium-104[b/]	D, see ^{93m}Tc	2E+4	7E+4	3E-5	1E-7	—	—
			St wall					
			(3E+4)	—	—	—	4E-4	4E-3
		W, see ^{93m}Tc	—	9E+4	4E-5	1E-7	—	—
44	Ruthenium-94[b/]	D, all compounds except						
		those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	—	6E+4	3E-5	9E-8	—	—
		Y, oxides and hydroxides	—	6E+4	2E-5	8E-8	—	—
44	Ruthenium-97	D, see ^{94}Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{94}Ru	—	1E+4	5E-6	2E-8	—	—
		Y, see ^{94}Ru	—	1E+4	5E-6	2E-8	—	—
44	Ruthenium-103	D, see ^{94}Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see ^{94}Ru	—	1E+3	4E-7	1E-9	—	—
		Y, see ^{94}Ru	—	6E+2	3E-7	9E-10	—	—
44	Ruthenium-105	D, see ^{94}Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{94}Ru	—	1E+4	6E-6	2E-8	—	—
		Y, see ^{94}Ru	—	1E+4	5E-6	2E-8	—	—
44	Ruthenium-106	D, see ^{94}Ru	2E+2	9E+1	4E-8	1E-10	—	—
			LLI wall					
			(2E+2)	—	—	—	3E-6	3E-5
		W, see ^{94}Ru	—	5E+1	2E-8	8E-11	—	—
		Y, see ^{94}Ru	—	1E+1	5E-9	2E-11	—	—
45	Rhodium-99m	D, all compounds except						
		those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	—	8E+4	3E-5	1E-7	—	—
		Y, oxides and hydroxides	—	7E+4	3E-5	9E-8	—	—
45	Rhodium-99	D, see ^{99m}Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{99m}Rh	—	2E+3	9E-7	3E-9	—	—
		Y, see ^{99m}Rh	—	2E+3	8E-7	3E-9	—	—
45	Rhodium-100	D, see ^{99m}Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{99m}Rh	—	4E+3	2E-6	6E-9	—	—
		Y, see ^{99m}Rh	—	4E+3	2E-6	5E-9	—	—
45	Rhodium-101m	D, see ^{99m}Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{99m}Rh	—	8E+3	4E-6	1E-8	—	—
		Y, see ^{99m}Rh	—	8E+3	3E-6	1E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure Effluent Concentrations Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
45	Rhodium-101	D, see ^{99m}Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{99m}Rh	—	8E+2	3E-7	1E-9	—	—
		Y, see ^{99m}Rh	—	2E+2	6E-8	2E-10	—	—
45	Rhodium-102m	D, see ^{99m}Rh	1E+3	5E+2	2E-7	7E-10	—	—
			LLI wall (1E+3)	—	—	—	2E-5	2E-4
		W, see ^{99m}Rh	—	4E+2	2E-7	5E-10	—	—
		Y, see ^{99m}Rh	—	1E+2	5E-8	2E-10	—	—
45	Rhodium-102	D, see ^{99m}Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see ^{99m}Rh	—	2E+2	7E-8	2E-10	—	—
		Y, see ^{99m}Rh	—	6E+1	2E-8	8E-11	—	—
45	Rhodium-103m[b]	D, see ^{99m}Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m}Rh	—	1E+6	5E-4	2E-6	—	—
		Y, see ^{99m}Rh	—	1E+6	5E-4	2E-6	—	—
45	Rhodium-105	D, see ^{99m}Rh	4E+3	1E+4	5E-6	2E-8	—	—
			LLI wall (4E+3)	—	—	—	5E-5	5E-4
		W, see ^{99m}Rh	—	6E+3	3E-6	9E-9	—	—
		Y, see ^{99m}Rh	—	6E+3	2E-6	8E-9	—	—
45	Rhodium-106m	D, see ^{99m}Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{99m}Rh	—	4E+4	2E-5	5E-8	—	—
		Y, see ^{99m}Rh	—	4E+4	1E-5	5E-8	—	—
45	Rhodium-107[b/]	D, see ^{99m}Rh	7E+4	2E+5	1E-4	3E-7	—	—
			St wall (9E+4)	—	—	—	1E-3	1E-2
		W, see ^{99m}Rh	—	3E+5	1E-4	4E-7	—	—
		Y, see ^{99m}Rh	—	3E+5	1E-4	3E-7	—	—
46	Palladium-100	D, all compound44s except those given for W and4 Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	—	1E+3	5E-7	2E-9	—	—
		Y, oxides and hydroxides	—	1E+3	6E-7	2E-9	—	—
46	Palladium-101	D, see ^{100}Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{100}Pd	—	3E+4	1E-5	5E-8	—	—
		Y, see ^{100}Pd	—	3E+4	1E-5	4E-8	—	—
46	Palladium-103	D, see ^{100}Pd	6E+3	6E+3	3E-6	9E-9	—	—
			LLI wall (7E+3)	—	—	—	1E-4	1E-3
		W, see ^{100}Pd	—	4E+3	2E-6	6E-9	—	—
		Y, see ^{100}Pd	—	4E+3	1E-6	5E-9	—	—
46	Palladium-107	D, see ^{100}Pd	3E+4	2E+4	9E-6	—	—	—
			LLI wall (4E+4)	Kidneys (2E+4)	—	3E-8	5E-4	5E-3
		W, see ^{100}Pd	—	7E+3	3E-6	1E-8	—	—
		Y, see ^{100}Pd	—	4E+2	2E-7	6E-10	—	—
46	Palladium-109	D, see ^{100}Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		W, see ^{100}Pd	—	5E+3	2E-6	8E-9	—	—
		Y, see ^{100}Pd	—	5E+3	2E-6	6E-9	—	—
47	Silver-102[b]	D, all compounds except those given for W and Y	5E+4	2E+5	8E-5	2E-7	—	—
			St wall (6E+4)	—	—	—	9E-4	9E-3
		W, nitrates and sulfides	—	2E+5	9E-5	3E-7	—	—
		Y, oxides and hydroxides	—	2E+5	8E-5	3E-7	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
47	Silver-103[b]	D, see ^{102}Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{102}Ag	—	1E+5	5E-5	2E-7	—	—
		Y, see ^{102}Ag	—	1E+5	5E-5	2E-7	—	—
47	Silver-104m[b]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{102}Ag	—	1E+5	5E-5	2E-7	—	—
		Y, see ^{102}Ag	—	1E+5	5E-5	2E-7	—	—
47	Silver-104[b]	D, see ^{102}Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{102}Ag	—	1E+5	6E-5	2E-7	—	—
		Y, see ^{102}Ag	—	1E+5	6E-5	2E-7	—	—
47	Silver-105	D, see ^{102}Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
		W, see ^{102}Ag	—	2E+3	7E-7	2E-9	—	—
		Y, see ^{102}Ag	—	2E+3	7E-7	2E-9	—	—
47	Silver-106m	D, see ^{102}Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
		W, see ^{102}Ag	—	9E+2	4E-7	1E-9	—	—
		Y, see ^{102}Ag	—	9E+2	4E-7	1E-9	—	—
47	Silver-106[b]	D, see ^{102}Ag	6E+4 St wall (6E+4)	2E+5 —	8E-5 —	3E-7 —	— 9E-4	— 9E-3
		W, see ^{102}Ag	—	2E+5	9E-5	3E-7	—	—
		Y, see ^{102}Ag	—	2E+5	8E-5	3E-7	—	—
47	Silver-108m	D, see ^{102}Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
		W, see ^{102}Ag	—	3E+2	1E-7	4E-10	—	—
		Y, see ^{102}Ag	—	2E+1	1E-8	3E-11	—	—
47	Silver-110m	D, see ^{102}Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
		W, see ^{102}Ag	—	2E+2	8E-8	3E-10	—	—
		Y, see ^{102}Ag	—	9E+1	4E-8	1E-10	—	—
47	Silver-111	D, see ^{102}Ag	9E+2 LLI wall (1E+3)	2E+3 Liver (2E+3)	6E-7 —	— 2E-9	— 2E-5	— 2E-4
		W, see ^{102}Ag	—	9E+2	4E-7	1E-9	—	—
		Y, see ^{102}Ag	—	9E+2	4E-7	1E-9	—	—
47	Silver-112	D, see ^{102}Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{102}Ag	—	1E+4	4E-6	1E-8	—	—
		Y, see ^{102}Ag	—	9E+3	4E-6	1E-8	—	—
47	Silver-115[b,l]	D, see ^{102}Ag	3E+4 St wall (3E+4)	9E+4 —	4E-5 —	1E-7 —	— 4E-4	— 4E-3
		W, see ^{102}Ag	—	9E+4	4E-5	1E-7	—	—
		Y, see ^{102}Ag	—	8E+4	3E-5	1E-7	—	—
48	Cadmium-104[b,l]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, sulfides, halides, and nitrates	—	1E+5	5E-5	2E-7	—	—
		Y, oxides and hydroxides	—	1E+5	5E-5	2E-7	—	—
48	Cadmium-107	D, see ^{104}Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{104}Cd	—	6E+4	2E-5	8E-8	—	—
		Y, see ^{104}Cd	—	5E+4	2E-5	7E-8	—	—
48	Cadmium-109	D, see ^{104}Cd	3E+2 Kidneys (4E+2)	4E+1 Kidneys (5E+1)	1E-8 —	— 7E-11	— 6E-6	— 6E-5
		W, see ^{104}Cd Kidneys	—	1E+2 (1E+2)	5E-8 —	— 2E-10	— —	— —
		Y, see ^{104}Cd	—	1E+2	5E-8	2E-10	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
48	Cadmium-113m	D, see ^{104}Cd	2E+1 Kidneys	2E+0 Kidneys	1E-9	—	—	—
			(4E+1)	(4E+0)	—	5E-12	5E-7	5E-6
		W, see ^{104}Cd	—	8E+0 Kidneys	4E-9	—	—	—
			—	(1E+1)	—	2E-11	—	—
		Y, see ^{104}Cd	—	1E+1	5E-9	2E-11	—	—
48	Cadmium-113	D, see ^{104}Cd	2E+1 Kidneys	2E+0 Kidneys	9E-10	—	—	—
			(3E+1)	(3E+0)	—	5E-12	4E-7	4E-6
		W, see ^{104}Cd	—	8E+0 Kidneys	3E-9	—	—	—
			—	(1E+1)	—	2E-11	—	—
		Y, see ^{104}Cd	—	1E+1	6E-9	2E-11	—	—
48	Cadmium-115m	D, see ^{104}Cd	3E+2 Kidneys	5E+1	2E-8	—	4E-6	4E-5
			—	(8E+1)	—	1E-10	—	—
		W, see ^{104}Cd	—	1E+2	5E-8	2E-10	—	—
		Y, see ^{104}Cd	—	1E+2	6E-8	2E-10	—	—
48	Cadmium-115	D, see ^{104}Cd	9E+2 LLI wall	1E+3	6E-7	2E-9	—	—
			(1E+3)	—	—	—	1E-5	1E-4
		W, see ^{104}Cd	—	1E+3	5E-7	2E-9	—	—
		Y, see ^{104}Cd	—	1E+3	6E-7	2E-9	—	—
48	Cadmium-117m	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	—	2E+4	7E-6	2E-8	—	—
		Y, see ^{104}Cd	—	1E+4	6E-6	2E-8	—	—
48	Cadmium-117	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	—	2E+4	7E-6	2E-8	—	—
		Y, see ^{104}Cd	—	1E+4	6E-6	2E-8	—	—
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	—	6E+4	3E-5	9E-8	—	—
49	Indium-110[b] (69.1 min)	D, see ^{109}In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	—	6E+4	2E-5	8E-8	—	—
49	Indium-110 (4.9 h)	D, see ^{109}In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		W, see ^{109}In	—	2E+4	8E-6	3E-8	—	—
49	Indium-111	D, see ^{109}In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see ^{109}In	—	6E+3	3E-6	9E-9	—	—
49	Indium-112[b]	D, see ^{109}In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see ^{109}In	—	7E+5	3E-4	1E-6	—	—
49	Indium-113m[b]	D, see ^{109}In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see ^{109}In	—	2E+5	8E-5	3E-7	—	—
49	Indium-114m	D, see ^{109}In	3E+2 LLI wall	6E+1	3E-8	9E-11	—	—
			(4E+2)	—	—	—	5E-6	5E-5
		W, see ^{109}In	—	1E+2	4E-8	1E-10	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
49	Indium-115m	D, see ^{109}In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	—	5E+4	2E-5	7E-8	—	—
49	Indium-115	D, see ^{109}In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see ^{109}In	—	5E+0	2E-9	8E-12	—	—
49	Indium-116m[b]	D, see ^{109}In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{109}In	—	1E+5	5E-5	2E-7	—	—
49	Indium-117m[b]	D, see ^{109}In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{109}In	—	4E+4	2E-5	6E-8	—	—
49	Indium-117[b]	D, see ^{109}In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see ^{109}In	—	2E+5	9E-5	3E-7	—	—
49	Indium-119m[b]	D, see ^{109}In	4E+4 St wall (5E+4)	1E+5	5E-5	2E-7	—	—
			—	—	—	—	7E-4	7E-3
		W, see ^{109}In	—	1E+5	6E-5	2E-7	—	—
50	Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	—	1E+4	5E-6	2E-8	—	—
50	Tin-111[b]	D, see ^{110}Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
		W, see ^{110}Sn	—	3E+5	1E-4	4E-7	—	—
50	Tin-113	D, see ^{110}Sn	2E+3 LLI wall (2E+3)	1E+3	5E-7	2E-9	—	—
			—	—	—	—	3E-5	3E-4
		W, see ^{110}Sn	—	5E+2	2E-7	8E-10	—	—
50	Tin-117m	D, see ^{110}Sn	2E+3 LLI wall (2E+3)	1E+3 Bone surf (2E+3)	5E-7	—	—	—
			—	—	—	3E-9	3E-5	3E-4
		W, see ^{110}Sn	—	1E+3	6E-7	2E-9	—	—
50	Tin-119m	D, see ^{110}Sn	3E+3 LLI wall (4E+3)	2E+3	1E-6	3E-9	—	—
			—	—	—	—	6E-5	6E-4
		W, see ^{110}Sn	—	1E+3	4E-7	1E-9	—	—
50	Tin-121m	D, see ^{110}Sn	3E+3 LLI wall (4E+3)	9E+2	4E-7	1E-9	—	—
			—	—	—	—	5E-5	5E-4
		W, see ^{110}Sn	—	5E+2	2E-7	8E-10	—	—
50	Tin-121	D, see ^{110}Sn	6E+3 LLI wall (6E+3)	2E+4	6E-6	2E-8	—	—
			—	—	—	—	8E-5	8E-4
		W, see ^{110}Sn	—	1E+4	5E-6	2E-8	—	—
50	Tin-123m[b]	D, see ^{110}Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
		W, see ^{110}Sn	—	1E+5	6E-5	2E-7	—	—
50	Tin-123	D, see ^{110}Sn	5E+2 LLI wall (6E+2)	6E+2	3E-7	9E-10	—	—
			—	—	—	—	9E-6	9E-5
		W, see ^{110}Sn	—	2E+2	7E-8	2E-10	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
50	Tin-125	D, see ^{110}Sn	4E+2	9E+2	4E-7	1E-9	—	—
			LLI wall (5E+2)	—	—	—	6E-6	6E-5
		W, see ^{110}Sn	—	4E+2	1E-7	5E-10	—	—
50	Tin-126	D, see ^{110}Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
		W, see ^{110}Sn	—	7E+1	3E-8	9E-11	—	—
50	Tin-127	D, see ^{110}Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see ^{110}Sn	—	2E+4	8E-6	3E-8	—	—
50	Tin-128[b]	D, see ^{110}Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{110}Sn	—	4E+4	1E-5	5E-8	—	—
51	Antimony-115[b]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	—	3E+5	1E-4	4E-7	—	—
51	Antimony-116m[b]	D, see ^{115}Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{115}Sb	—	1E+5	6E-5	2E-7	—	—
51	Antimony-116[b]	D, see ^{115}Sb	7E+4	3E+5	1E-4	4E-7	—	—
			St wall (9E+4)	—	—	—	1E-3	1E-2
		W, see ^{115}Sb	—	3E+5	1E-4	5E-7	—	—
51	Antimony-117	D, see ^{115}Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see ^{115}Sb	—	3E+5	1E-4	4E-7	—	—
51	Antimony-118m	D, see ^{115}Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see ^{115}Sb	5E+3	2E+4	9E-6	3E-8	—	—
51	Antimony-119	D, see ^{115}Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{115}Sb	2E+4	3E+4	1E-5	4E-8	—	—
51	Antimony-120[b/] (16 min)	D, see ^{115}Sb	1E+5	4E+5	2E-4	6E-7	—	—
			St wall (2E+5)	—	—	—	2E-3	2E-2
		W, see ^{115}Sb	—	5E+5	2E-4	7E-7	—	—
51	Antimony-120 (5.76 d)	D, see ^{115}Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see ^{115}Sb	9E+2	1E+3	5E-7	2E-9	—	—
51	Antimony-122	D, see ^{115}Sb	8E+2	2E+3	1E-6	3E-9	—	—
			LLI wall (8E+2)	—	—	—	1E-5	1E-4
		W, see ^{115}Sb	7E+2	1E+3	4E-7	2E-9	—	—
51	Antimony-124m[b]	D, see ^{115}Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see ^{115}Sb	2E+5	6E+5	2E-4	8E-7	—	—
51	Antimony-124	D, see ^{115}Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	2E+2	1E-7	3E-10	—	—
51	Antimony-125	D, see ^{115}Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see ^{115}Sb	—	5E+2	2E-7	7E-10	—	—
51	Antimony-126m[b]	D, see ^{115}Sb	5E+4	2E+5	8E-5	3E-7	—	—
			St wall (7E+4)	—	—	—	9E-4	9E-3
		W, see ^{115}Sb	—	2E+5	8E-5	3E-7	—	—
51	Antimony-126	D, see ^{115}Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	5E+2	2E-7	7E-10	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
51	Antimony-127	D, see ^{115}Sb	8E+2	2E+3	9E-7	3E-9	—	—
			LLI wall (8E+2)	—	—	—	1E-5	1E-4
		W, see ^{115}Sb	7E+2	9E+2	4E-7	1E-9	—	—
51	Antimony-128[b] (10.4 min)	D, see ^{115}Sb	8E+4	4E+5	2E-4	5E-7	—	—
			St wall (1E+5)	—	—	—	1E-3	1E-2
		W, see ^{115}Sb	—	4E+5	2E-4	6E-7	—	—
51	Antimony-128 (9.01 h)	D, see ^{115}Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see ^{115}Sb	—	3E+3	1E-6	5E-9	—	—
51	Antimony-129	D, see ^{115}Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see ^{115}Sb	—	9E+3	4E-6	1E-8	—	—
51	Antimony-130[b]	D, see ^{115}Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{115}Sb	—	8E+4	3E-5	1E-7	—	—
51	Antimony-131[b]	D, see ^{115}Sb	1E+4	2E+4	1E-5	—	—	—
			Thyroid (2E+4)	Thyroid (4E+4)	—	6E-8	2E-4	2E-3
		W, see ^{115}Sb	—	2E+4	1E-5		—	—
			Thyroid —	(4E+4)	—	6E-8	—	—
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	—	3E+4	1E-5	4E-8	—	—
52	Tellurium-121m	D, see ^{116}Te	5E+2	2E+2	8E-8	—	—	—
			Bone surf (7E+2)	Bone surf (4E+2)	—	5E-10	1E-5	1E-4
		W, see ^{116}Te	—	4E+2	2E-7	6E-10	—	—
52	Tellurium-121	D, see ^{116}Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{116}Te	—	3E+3	1E-6	4E-9	—	—
52	Tellurium-123m	D, see ^{116}Te	6E+2	2E+2	9E-8	—	—	—
			Bone surf (1E+3)	Bone surf (5E+2)	—	8E-10	1E-5	1E-4
		W, see ^{116}Te	—	5E+2	2E-7	8E-10	—	—
52	Tellurium-123	D, see ^{116}Te	5E+2	2E+2	8E-8	—	—	—
			Bone surf (1E+3)	Bone surf (5E+2)	—	7E-10	2E-5	2E-4
		W, see ^{116}Te	—	4E+2	2E-7	—	—	—
			Bone surf —	(1E+3)	—	2E-9	—	—
52	Tellurium-125m	D, see ^{116}Te	1E+3	4E+2	2E-7	—	—	—
			Bone surf (1E+3)	Bone surf (1E+3)	—	1E-9	2E-5	2E-4
		W, see ^{116}Te	—	7E+2	3E-7	1E-9	—	—
52	Tellurium-127m	D, see ^{116}Te	6E+2	3E+2	1E-7	—	9E-6	9E-5
			Bone surf —	(4E+2)	—	6E-10	—	—
		W, see ^{116}Te	—	3E+2	1E-7	4E-10	—	—
52	Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{116}Te	—	2E+4	7E-6	2E-8	—	—
52	Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ^{116}Te	—	2E+2	1E-7	3E-10	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
52	Tellurium-129[b]	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{116}Te	—	7E+4	3E-5	1E-7	—	—
52	Tellurium-131m	D, see ^{116}Te	3E+2 Thyroid (6E+2)	4E+2 Thyroid (1E+3)	2E-7 —	— 2E-9	— 8E-6	— 8E-5
		W, see ^{116}Te	— Thyroid —	4E+2 (9E+2)	2E-7 —	— 1E-9	— —	— —
52	Tellurium-131[b,l]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 —	— 2E-8	— 8E-5	— 8E-4
		W, see ^{116}Te	— Thyroid —	5E+3 (1E+4)	2E-6 —	— 2E-8	— —	— —
52	Tellurium-132	D, see ^{116}Te	2E+2 Thyroid (7E+2)	2E+2 Thyroid (8E+2)	9E-8 —	— 1E-9	— 9E-6	— 9E-5
		W, see ^{116}Te	—	2E+2 —	9E-8 Thyroid (6E+2)	— —	— 9E-10	— —
52	Tellurium-133m[b]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 —	— 2E-8	— 9E-5	— 9E-4
		W, see ^{116}Te	— Thyroid —	5E+3 (1E+4)	2E-6 —	— 2E-8	— —	— —
52	Tellurium-133[b]	D, see ^{116}Te	1E+4 Thyroid (3E+4)	2E+4 Thyroid (6E+4)	9E-6 —	— 8E-8	— 4E-4	— 4E-3
		W, see ^{116}Te	— Thyroid —	2E+4 (6E+4)	9E-6 —	— 8E-8	— —	— —
52	Tellurium-134[b]	D, see ^{116}Te	2E+4 Thyroid (2E+4)	2E+4 Thyroid (5E+4)	1E-5 —	— 7E-8	— 3E-4	— 3E-3
		W, see ^{116}Te	—	2E+4 Thyroid (5E+4)	1E-5 —	— 7E-8	— —	— —
53	Iodine-120m[b]	D, all compounds	1E+4 Thyroid (1E+4)	2E+4 —	9E-6 —	3E-8 —	— 2E-4	— 2E-3
53	Iodine-120[b]	D, all compounds	4E+3 Thyroid (8E+3)	9E+3 Thyroid (1E+4)	4E-6 —	— 2E-8	— 1E-4	— 1E-3
53	Iodine-121	D, all compounds	1E+4 Thyroid (3E+4)	2E+4 Thyroid (5E+4)	8E-6 —	— 7E-8	— 4E-4	— 4E-3
53	Iodine-123	D, all compounds	3E+3 Thyroid (1E+4)	6E+3 Thyroid (2E+4)	3E-6 —	— 2E-8	— 1E-4	— 1E-3
53	Iodine-124	D, all compounds	5E+1 Thyroid (2E+2)	8E+1 Thyroid (3E+2)	3E-8 —	— 4E-10	— 2E-6	— 2E-5

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Table II Effluent Concentrations Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
53	Iodine-125	D, all compounds	4E+1 Thyroid (1E+2)	6E+1 Thyroid (2E+2)	3E-8 —	— 3E-10	— 2E-6	— 2E-5
53	Iodine-126	D, all compounds	2E+1 Thyroid (7E+1)	4E+1 Thyroid (1E+2)	1E-8 —	— 2E-10	— 1E-6	— 1E-5
53	Iodine-128[b]	D, all compounds	4E+4 St wall (6E+4)	1E+5 —	5E-5 —	2E-7 —	— 8E-4	— 8E-3
53	Iodine-129	D, all compounds	5E+0 Thyroid (2E+1)	9E+0 Thyroid (3E+1)	4E-9 —	— 4E-11	— 2E-7	— 2E-6
53	Iodine-130	D, all compounds	4E+2 Thyroid (1E+3)	7E+2 Thyroid (2E+3)	3E-7 —	— 3E-9	— 2E-5	— 2E-4
53	Iodine-131	D, all compounds	3E+1 Thyroid (9E+1)	5E+1 Thyroid (2E+2)	2E-8 —	— 2E-10	— 1E-6	— 1E-5
53	Iodine-132m[b]	D, all compounds	4E+3 Thyroid (1E+4)	8E+3 Thyroid (2E+4)	4E-6 —	— 3E-8	— 1E-4	— 1E-3
53	Iodine-132	D, all compounds	4E+3 Thyroid (9E+3)	8E+3 Thyroid (1E+4)	3E-6 —	— 2E-8	— 1E-4	— 1E-3
53	Iodine-133	D, all compounds	1E+2 Thyroid (5E+2)	3E+2 Thyroid (9E+2)	1E-7 —	— 1E-9	— 7E-6	— 7E-5
53	Iodine-134[b]	D, all compounds	2E+4 Thyroid (3E+4)	5E+4 —	2E-5 —	6E-8 —	— 4E-4	— 4E-3
53	Iodine-135	D, all compounds	8E+2 Thyroid (3E+3)	2E+3 Thyroid (4E+3)	7E-7 —	— 6E-9	— 3E-5	— 3E-4
54	Xenon-120[b]	Submersion[a]	—	—	1E-5	4E-8	—	—
54	Xenon-121[b]	Submersion[a]	—	—	2E-6	1E-8	—	—
54	Xenon-122	Submersion[a]	—	—	7E-5	3E-7	—	—
54	Xenon-123	Submersion[a]	—	—	6E-6	3E-8	—	—
54	Xenon-125	Submersion[a]	—	—	2E-5	7E-8	—	—
54	Xenon-127	Submersion[a]	—	—	1E-5	6E-8	—	—
54	Xenon-129m	Submersion[a]	—	—	2E-4	9E-7	—	—
54	Xenon-131m	Submersion[a]	—	—	4E-4	2E-6	—	—
54	Xenon-133m	Submersion[a]	—	—	1E-4	6E-7	—	—
54	Xenon-133	Submersion[a]	—	—	1E-4	5E-7	—	—
54	Xenon-135m[b]	Submersion[a]	—	—	9E-6	4E-8	—	—
54	Xenon-135	Submersion[a]	—	—	1E-5	7E-8	—	—
54	Xenon-138[b]	Submersion[a]	—	—	4E-6	2E-8	—	—

Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Table II Effluent Concentrations Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
55	Cesium-125[b]	D, all compounds	5E+4	1E+5	6E-5	2E-7	—	—
			St wall (9E+4)	—	—	—	1E-3	1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130[b]	D, all compounds	6E+4	2E+5	8E-5	3E-7	—	—
			St wall (1E+5)	—	—	—	1E-3	1E-2
55	Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cesium-134m	D, all compounds	1E+5	1E+5	6E-5	2E-7	—	—
			St wall (1E+5)	—	—	—	2E-3	2E-2
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6
55	Cesium-135m[b]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138[b]	D, all compounds	2E+4	6E+4	2E-5	8E-8	—	—
			St wall (3E+4)	—	—	—	4E-4	4E-3
56	Barium-126[b]	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m[b]	D, all compounds	4E+5	1E+6	6E-4	2E-6	—	—
			St wall (5E+5)	—	—	—	7E-3	7E-2
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	—	—
			LLI wall (3E+3)	—	—	—	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139[b]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	—	—
			LLI wall (6E+2)	—	—	—	8E-6	8E-5
56	Barium-141[b]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142[b]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
57	Lanthanum-131[b]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	—	2E+5	7E-5	2E-7	—	—
57	Lanthanum-132	D, see ^{131}La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see ^{131}La	—	1E+4	5E-6	2E-8	—	—
57	Lanthanum-135	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{131}La	—	9E+4	4E-5	1E-7	—	—
57	Lanthanum-137	D, see ^{131}La	1E+4	6E+1	3E-8	—	2E-4	2E-3
			—	(7E+1) Liver	—	1E-10	—	—
		W, see ^{131}La	—	3E+2	1E-7	—	—	—
			—	(3E+2) Liver	—	4E-10	—	—
57	Lanthanum-138	D, see ^{131}La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see ^{131}La	—	1E+1	6E-9	2E-11	—	—
57	Lanthanum-140	D, see ^{131}La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{131}La	—	1E+3	5E-7	2E-9	—	—
57	Lanthanum-141	D, see ^{131}La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see ^{131}La	—	1E+4	5E-6	2E-8	—	—
57	Lanthanum-142[b/]	D, see ^{131}La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{131}La	—	3E+4	1E-5	5E-8	—	—
57	Lanthanum-143[b/]	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	—	—
			(4E+4) St wall	—	—	—	5E-4	5E-3
		W, see ^{131}La	—	9E+4	4E-5	1E-7	—	—
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	—	—
			(6E+2) LLI wall	—	—	—	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	—	—	7E+2	3E-7	9E-10	— —
58	Cerium-135	W, see ^{134}Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ^{134}Ce	—	4E+3	1E-6	5E-9	—	—
58	Cerium-137m	W, see ^{134}Ce	2E+3	4E+3	2E-6	6E-9	—	—
			(2E+3) LLI wall	—	—	—	3E-5	3E-4
		Y, see ^{134}Ce	—	4E+3	2E-6	5E-9	—	—
58	Cerium-137	W, see ^{134}Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ^{134}Ce	—	1E+5	5E-5	2E-7	—	—
58	Cerium-139	W, see ^{134}Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ^{134}Ce	—	7E+2	3E-7	9E-10	—	—
58	Cerium-141	W, see ^{134}Ce	2E+3	7E+2	3E-7	1E-9	—	—
			(2E+3) LLI wall	—	—	—	3E-5	3E-4
		Y, see ^{134}Ce	—	6E+2	2E-7	8E-10	—	—
58	Cerium-143	W, see ^{134}Ce	1E+3	2E+3	8E-7	3E-9	—	—
			(1E+3) LLI wall	—	—	—	2E-5	2E-4
		Y, see ^{134}Ce	—	2E+3	7E-7	2E-9	—	—
58	Cerium-144	W, see ^{134}Ce	2E+2	3E+1	1E-8	4E-11	—	—
			(3E+2) LLI wall	—	—	—	3E-6	3E-5
		Y, see ^{134}Ce	—	1E+1	6E-9	2E-11	—	—

Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
59	Praseodymium-136[b]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	—	—
			St wall (7E+4)	—	—	—	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	—	2E+5	9E-5	3E-7	—	—
59	Praseodymium-137[b]	W, see ^{136}Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ^{136}Pr	—	1E+5	6E-5	2E-7	—	—
59	Praseodymium-138m	W, see ^{136}Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see ^{136}Pr	—	4E+4	2E-5	6E-8	—	—
59	Praseodymium-139	W, see ^{136}Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{136}Pr	—	1E+5	5E-5	2E-7	—	—
59	Praseodymium-142m[b]	W, see ^{136}Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see ^{136}Pr	—	1E+5	6E-5	2E-7	—	—
59	Praseodymium-142	W, see ^{136}Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see ^{136}Pr	—	2E+3	8E-7	3E-9	—	—
59	Praseodymium-143	W, see ^{136}Pr	9E+2	8E+2	3E-7	1E-9	—	—
			LLI wall (1E+3)	—	—	—	2E-5	2E-4
		Y, see ^{136}Pr	—	7E+2	3E-7	9E-10	—	—
59	Praseodymium-144[b]	W, see ^{136}Pr	3E+4	1E+5	5E-5	2E-7	—	—
			St wall (4E+4)	—	—	—	6E-4	6E-3
		Y, see ^{136}Pr	—	1E+5	5E-5	2E-7	—	—
59	Praseodymium-145	W, see ^{136}Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{136}Pr	—	8E+3	3E-6	1E-8	—	—
59	Praseodymium-147[b]	W, see ^{136}Pr	5E+4	2E+5	8E-5	3E-7	—	—
			St wall (8E+4)	—	—	—	1E-3	1E-2
		Y, see ^{136}Pr	—	2E+5	8E-5	3E-7	—	—
60	Neodymium-136[b]	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	—	5E+4	2E-5	8E-8	—	—
60	Neodymium-138	W, see ^{136}Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see ^{136}Nd	—	5E+3	2E-6	7E-9	—	—
60	Neodymium-139m	W, see ^{136}Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see ^{136}Nd	—	1E+4	6E-6	2E-8	—	—
60	Neodymium-139[b]	W, see ^{136}Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see ^{136}Nd	—	3E+5	1E-4	4E-7	—	—
60	Neodymium-141	W, see ^{136}Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see ^{136}Nd	—	6E+5	3E-4	9E-7	—	—
60	Neodymium-147	W, see ^{136}Nd	1E+3	9E+2	4E-7	1E-9	—	—
			LLI wall (1E+3)	—	—	—	2E-5	2E-4
		Y, see ^{136}Nd	—	8E+2	4E-7	1E-9	—	—
60	Neodymium-149[b]	W, see ^{136}Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see ^{136}Nd	—	2E+4	1E-5	3E-8	—	—
60	Neodymium-151[b]	W, see ^{136}Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see ^{136}Nd	—	2E+5	8E-5	3E-7	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
61	Promethium-141[b]	W, all compounds except those given for Y	5E+4 St wall (6E+4)	2E+5 —	8E-5 —	3E-7 —	— 8E-4	— 8E-3
		Y, oxides, hydroxides, carbides, and fluorides	—	2E+5	7E-5	2E-7	—	—
61	Promethium-143	W, see ^{141}Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see ^{141}Pm	—	7E+2	3E-7	1E-9	—	—
61	Promethium-144	W, see ^{141}Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see ^{141}Pm	—	1E+2	5E-8	2E-10	—	—
61	Promethium-145	W, see ^{141}Pm	1E+4 Bone surf	2E+2	7E-8	—	1E-4	1E-3
			—	(2E+2)	—	3E-10	—	—
		Y, see ^{141}Pm	—	2E+2	8E-8	3E-10	—	—
61	Promethium-146	W, see ^{141}Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see ^{141}Pm	—	4E+1	2E-8	6E-11	—	—
61	Promethium-147	W, see ^{141}Pm	4E+3 LLI wall (5E+3)	1E+2 Bone surf (2E+2)	5E-8 —	— 3E-10	— 7E-5	— 7E-4
		Y, see ^{141}Pm	—	1E+2	6E-8	2E-10	—	—
61	Promethium-148m	W, see ^{141}Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see ^{141}Pm	—	3E+2	1E-7	5E-10	—	—
61	Promethium-148	W, see ^{141}Pm	4E+2 LLI wall (5E+2)	5E+2 —	2E-7 —	8E-10 —	— 7E-6	— 7E-5
		Y, see ^{141}Pm	—	5E+2	2E-7	7E-10	—	—
61	Promethium-149	W, see ^{141}Pm	1E+3 LLI wall (1E+3)	2E+3 —	8E-7 —	3E-9 —	— 2E-5	— 2E-4
		Y, see ^{141}Pm	—	2E+3	8E-7	2E-9	—	—
61	Promethium-150	W, see ^{141}Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{141}Pm	—	2E+4	7E-6	2E-8	—	—
61	Promethium-151	W, see ^{141}Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{141}Pm	—	3E+3	1E-6	4E-9	—	—
62	Samarium-141m[b]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141[b]	W, all compounds	5E+4 St wall (6E+4)	2E+5 —	8E-5 —	2E-7 —	— 8E-4	— 8E-3
62	Samarium-142[b]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1 Bone surf (3E+1)	4E-2 Bone surf (6E-2)	1E-11 —	— 9E-14	— 3E-7	— 3E-6
62	Samarium-147	W, all compounds	2E+1 Bone surf (3E+1)	4E-2 Bone surf (7E-2)	2E-11 —	— 1E-13	— 4E-7	— 4E-6
62	Samarium-151	W, all compounds	1E+4 LLI wall (1E+4)	1E+2 Bone surf (2E+2)	4E-8 —	— 2E-10	— 2E-4	— 2E-3
62	Samarium-153	W, all compounds	2E+3 LLI wall (2E+3)	3E+3 —	1E-6 —	4E-9 —	— 3E-5	— 3E-4

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Table II Effluent Concentrations Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
62	Samarium-155[b]	W, all compounds	6E+4	2E+5	9E-5	3E-7	—	—
			(8E+4) St wall	—	—	—	1E-3	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3 Bone surf	9E+1	4E-8	—	5E-5	5E-4
			—	(1E+2)	—	2E-10	—	—
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[b]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[b]	D, all compounds except those given for W	5E+4 St wall	2E+5	6E-5	2E-7	—	—
			(5E+4)	—	—	—	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	—	2E+5	7E-5	2E-7	—	—
64	Gadolinium-146	D, see ^{145}Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see ^{145}Gd	—	3E+2	1E-7	4E-10	—	—
64	Gadolinium-147	D, see ^{145}Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{145}Gd	—	4E+3	1E-6	5E-9	—	—
64	Gadolinium-148	D, see ^{145}Gd	1E+1 Bone surf	8E+3 Bone surf	3E-12	—	—	—
			(2E+1)	(2E-2)	—	2E-14	3E-7	3E-6
		W, see ^{145}Gd	— Bone surf	3E-2	1E-11	—	—	—
			—	(6E-2)	—	8E-14	—	—
64	Gadolinium-149	D, see ^{145}Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see ^{145}Gd	—	2E+3	1E-6	3E-9	—	—
64	Gadolinium-151	D, see ^{145}Gd	6E+3	4E+2 Bone surf	2E-7	—	9E-5	9E-4
			—	(6E+2)	—	9E-10	—	—
		W, see ^{145}Gd	—	1E+3	5E-7	2E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
64	Gadolinium-152	D, see ^{145}Gd	2E+1	1E-2	4E-12	—	—	—
			Bone surf (3E+1)	Bone surf (2E-2)	—	3E-14	4E-7	4E-6
		W, see ^{145}Gd	—	4E-2	2E-11	—	—	—
			Bone surf —	(8E-2)	—	1E-13	—	—
64	Gadolinium-153	D, see ^{145}Gd	5E+3	1E+2	6E-8	—	6E-5	6E-4
			Bone surf —	(2E+2)	—	3E-10	—	—
		W, see ^{145}Gd	—	6E+2	2E-7	8E-10	—	—
64	Gadolinium-159	D, see ^{145}Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{145}Gd	—	6E+3	2E-6	8E-9	—	—
65	Terbium-147[b]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4
65	Terbium-157	W, all compounds	5E+4	3E+2	1E-7	—	—	—
			LLI wall (5E+4)	Bone surf (6E+2)	—	8E-10	7E-4	7E-3
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3	2E+3	7E-7	2E-9	—	—
			LLI wall (2E+3)	—	—	—	3E-5	3E-4
66	Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dysprosium-166	W, all compounds	6E+2	7E+2	3E-7	1E-9	—	—
			LLI wall (8E+2)	—	—	—	1E-5	1E-4
67	Holmium-155[b]	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
67	Holmium-157[b]	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159[b]	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m[b]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162[b]	W, all compounds	5E+5	2E+6	1E-3	3E-6	—	—
			St wall (8E+5)	—	—	—	1E-2	1E-1
67	Holmium-164m[b/]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164[b/]	W, all compounds	2E+5	6E+5	3E-4	9E-7	—	—
			(2E+5)	St wall —	—	—	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	—	—
			(9E+2)	LLI wall —	—	—	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	—	—
			LLI wall (4E+3)	-	—	—	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	—	—
			LLI wall (1E+3)	-	—	—	2E-5	2E-4
69	Thulium-162[b]	W, all compounds	7E+4	3E+5	1E-4	4E-7	—	—
			St wall (7E+4)	-	—	—	1E-3	1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	—	—
			LLI wall (2E+3)	-	—	—	3E-5	3E-4
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	—	—
			LLI wall (1E+3)	-	—	—	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	—	—	—
			LLI wall (1E+4)	Bone surf (6E+2)	—	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	—	—
			LLI wall (8E+2)	-	—	—	1E-5	1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
69	Thulium-175[b]	W, all compounds	7E+4	3E+5	1E-4	4E-7	—	—
			St wall (9E+4)	-	—	—	1E-3	1E-2
70	Ytterbium-162[b]	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		Y, oxides, hydroxides, and fluorides	—	3E+5	1E-4	4E-7	—	—
70	Ytterbium-166	W, see ^{162}Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		Y, see ^{162}Yb	—	2E+3	8E-7	3E-9	—	—
70	Ytterbium-167[b]	W, see ^{162}Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
		Y, see ^{162}Yb	—	7E+5	3E-4	1E-6	—	—
70	Ytterbium-169	W, see ^{162}Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
		Y, see ^{162}Yb	—	7E+2	3E-7	1E-9	—	—
70	Ytterbium-175	W, see ^{162}Yb	3E+3	4E+3	1E-6	5E-9	—	—
			LLI wall (3E+3)	—	—	—	4E-5	4E-4
		Y, see ^{162}Yb	—	3E+3	1E-6	5E-9	—	—
70	Ytterbium-177[b]	W, see ^{162}Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
		Y, see ^{162}Yb	—	5E+4	2E-5	6E-8	—	—
70	Ytterbium-178[b]	W, see ^{162}Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		Y, see ^{162}Yb	—	4E+4	2E-5	5E-8	—	—
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		Y, oxides, hydroxides, and fluorides	—	4E+3	2E-6	6E-9	—	—
71	Lutetium-170	W, see ^{169}Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
		Y, see ^{169}Lu	—	2E+3	8E-7	3E-9	—	—
71	Lutetium-171	W, see ^{169}Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
		Y, see ^{169}Lu	—	2E+3	8E-7	3E-9	—	—
71	Lutetium-172	W, see ^{169}Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
		Y, see ^{169}Lu	—	1E+3	5E-7	2E-9	—	—
71	Lutetium-173	W, see ^{169}Lu	5E+3	3E+2	1E-7	—	7E-5	7E-4
			Bone surf					
			—	(5E+2)	—	6E-10	—	—
		Y, see ^{169}Lu	—	3E+2	1E-7	4E-10	—	—
71	Lutetium-174m	W, see ^{169}Lu	2E+3	2E+2	1E-7	—	—	—
			LLI wall (3E+3)	Bone surf (3E+2)	—	5E-10	4E-5	4E-4
		Y, see ^{169}Lu	—	2E+2	9E-8	3E-10	—	—
71	Lutetium-174	W, see ^{169}Lu	5E+3	1E+2	5E-8	—	7E-5	7E-4
			Bone surf					
			—	(2E+2)	—	3E-10	—	—
		Y, see ^{169}Lu	—	2E+2	6E-8	2E-10	—	—
71	Lutetium-176m	W, see ^{169}Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ^{169}Lu	—	2E+4	9E-6	3E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
71	Lutetium-176	W, see ^{169}Lu	7E+2	5E+0	2E-9	—	1E-5	1E-4
			Bone surf					
			—	(1E+1)	—	2E-11	—	—
		Y, see ^{169}Lu	—	8E+0	3E-9	1E-11	—	—
71	Lutetium-177m	W, see ^{169}Lu	7E+2	1E+2	5E-8	—	1E-5	1E-4
			Bone surf					
			—	(1E+2)	—	2E-10	—	—
		Y, see ^{169}Lu	—	8E+1	3E-8	1E-10	—	—
71	Lutetium-177	W, see ^{169}Lu	2E+3	2E+3	9E-7	3E-9	—	—
			LLI wall					
			(3E+3)	—	—	—	4E-5	4E-4
		Y, see ^{169}Lu	—	2E+3	9E-7	3E-9	—	—
71	Lutetium-178m[b]	W, see ^{169}Lu	5E+4	2E+5	8E-5	3E-7	—	—
			St wall					
			(6E+4)	—	—	—	8E-4	8E-3
		Y, see ^{169}Lu	—	2E+5	7E-5	2E-7	—	—
71	Lutetium-178[b]	W, see ^{169}Lu	4E+4	1E+5	5E-5	2E-7	—	—
			St wall					
			(4E+4)	—	—	—	6E-4	6E-3
		Y, see ^{169}Lu	—	1E+5	5E-5	2E-7	—	—
71	Lutetium-179	W, see ^{169}Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{169}Lu	—	2E+4	6E-6	3E-8	—	—
72	Hafnium-170	D, all compounds except						
		those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides,						
		carbides, and nitrates	—	5E+3	2E-6	6E-9	—	—
72	Hafnium-172	D, see ^{170}Hf	1E+3	9E+0	4E-9	—	2E-5	2E-4
			Bone surf					
			—	(2E+1)	—	3E-11	—	—
		W, see ^{170}Hf	—	4E+1	2E-8	—	—	—
			Bone surf					
			—	(6E+1)	—	8E-11	—	—
72	Hafnium-173	D, see ^{170}Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{170}Hf	—	1E+4	5E-6	2E-8	—	—
72	Hafnium-175	D, see ^{170}Hf	3E+3	9E+2	4E-7	—	4E-5	4E-4
			Bone surf					
			—	(1E+3)	—	1E-9	—	—
		W, see ^{170}Hf	—	1E+3	5E-7	2E-9	—	—
72	Hafnium-177m[b]	D, see ^{170}Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{170}Hf	—	9E+4	4E-5	1E-7	—	—
72	Hafnium-178m	D, see ^{170}Hf	3E+2	1E+0	5E-10	—	3E-6	3E-5
			Bone surf					
			—	(2E+0)	—	3E-12	—	—
		W, see ^{170}Hf	—	5E+0	2E-9	—	—	—
			Bone surf					
			—	(9E+0)	—	1E-11	—	—
72	Hafnium-179m	D, see ^{170}Hf	1E+3	3E+2	1E-7	—	1E-5	1E-4
			Bone surf					
			—	(6E+2)	—	8E-10	—	—
		W, see ^{170}Hf	—	6E+2	3E-7	8E-10	—	—
72	Hafnium-180m	D, see ^{170}Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{170}Hf	—	3E+4	1E-5	4E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
72	Hafnium-181	D, see ^{170}Hf	1E+3	2E+2 Bone surf	7E-8	—	2E-5	2E-4
			—	(4E+2)	—	6E-10	—	—
		W, see ^{170}Hf	—	4E+2	2E-7	6E-10	—	—
72	Hafnium-182m[b]	D, see ^{170}Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see ^{170}Hf	—	1E+5	6E-5	2E-7	—	—
72	Hafnium-182	D, see ^{170}Hf	2E+2 Bone surf	8E-1 Bone surf	3E-10	—	—	—
			(4E+2)	(2E+0)	—	2E-12	5E-6	5E-5
		W, see ^{170}Hf	—	3E+0 Bone surf	1E-9	—	—	—
				—	(7E+0)	—	1E-11	— —
72	Hafnium-183[b]	D, see ^{170}Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{170}Hf	—	6E+4	2E-5	8E-8	—	—
72	Hafnium-184	D, see ^{170}Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{170}Hf	—	6E+3	3E-6	9E-9	—	—
73	Tantalum-172[b]	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	—	1E+5	4E-5	1E-7	—	—
73	Tantalum-173	W, see ^{172}Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{172}Ta	—	2E+4	7E-6	2E-8	—	—
73	Tantalum-174[b]	W, see ^{172}Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	—	9E+4	4E-5	1E-7	—	—
73	Tantalum-175	W, see ^{172}Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see ^{172}Ta	—	1E+4	6E-6	2E-8	—	—
73	Tantalum-176	W, see ^{172}Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see ^{172}Ta	—	1E+4	5E-6	2E-8	—	—
73	Tantalum-177	W, see ^{172}Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see ^{172}Ta	—	2E+4	7E-6	2E-8	—	—
73	Tantalum-178	W, see ^{172}Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see ^{172}Ta	—	7E+4	3E-5	1E-7	—	—
73	Tantalum-179	W, see ^{172}Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ^{172}Ta	—	9E+2	4E-7	1E-9	—	—
73	Tantalum-180m	W, see ^{172}Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{172}Ta	—	6E+4	2E-5	8E-8	—	—
73	Tantalum-180	W, see ^{172}Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ^{172}Ta	—	2E+1	1E-8	3E-11	—	—
73	Tantalum-182m[b]	W, see ^{172}Ta	2E+5 St wall	5E+5	2E-4	8E-7	—	—
			(2E+5)	—	—	—	3E-3	3E-2
		Y, see ^{172}Ta	—	4E+5	2E-4	6E-7	—	—
73	Tantalum-182	W, see ^{172}Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see ^{172}Ta	—	1E+2	6E-8	2E-10	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
73	Tantalum-183	W, see ^{172}Ta	9E+2	1E+3	5E-7	2E-9	—	—
			LLI wall (1E+3)	—	—	—	2E-5	2E-4
		Y, see ^{172}Ta	—	1E+3	4E-7	1E-9	—	—
73	Tantalum-184	W, see ^{172}Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see ^{172}Ta	—	5E+3	2E-6	7E-9	—	—
73	Tantalum-185[b]	W, see ^{172}Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	—	6E+4	3E-5	9E-8	—	—
73	Tantalum-186[b]	W, see ^{172}Ta	5E+4	2E+5	1E-4	3E-7	—	—
			St wall (7E+4)	—	—	—	1E-3	1E-2
		Y, see ^{172}Ta	—	2E+5	9E-5	3E-7	—	—
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
74	Tungsten-179[b/]	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74	Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	—	—
			LLI wall (3E+3)	—	—	—	4E-5	4E-4
74	Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	—	—
			LLI wall (5E+2)	—	—	—	7E-6	7E-5
75	Rhenium-177[b]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	—	—
			St wall (1E+5)	—	—	—	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	—	4E+5	1E-4	5E-7	—	—
75	Rhenium-178[b]	D, see ^{177}Re	7E+4	3E+5	1E-4	4E-7	—	—
			St wall (1E+5)	—	—	—	1E-3	1E-2
		W, see ^{177}Re	—	3E+5	1E-4	4E-7	—	—
75	Rhenium-181	D, see ^{177}Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see ^{177}Re	—	9E+3	4E-6	1E-8	—	—
75	Rhenium-182 (12.7 h)	D, see ^{177}Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
		W, see ^{177}Re	—	2E+4	6E-6	2E-8	—	—
75	Rhenium-182 (64.0 h)	D, see ^{177}Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{177}Re	—	2E+3	9E-7	3E-9	—	—
75	Rhenium-184m	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	—	4E+2	2E-7	6E-10	—	—
75	Rhenium-184	D, see ^{177}Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{177}Re	—	1E+3	6E-7	2E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
75	Rhenium-186m	D, see ^{177}Re	1E+3 St wall (2E+3)	2E+3 St wall (2E+3)	7E-7 —	— 3E-9	— 2E-5	— 2E-4
		W, see ^{177}Re	—	2E+2	6E-8	2E-10	—	—
75	Rhenium-186	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	—	2E+3	7E-7	2E-9	—	—
75	Rhenium-187	D, see ^{177}Re	6E+5 St wall —	8E+5 (9E+5)	4E-4 —	— 1E-6	8E-3 —	8E-2 —
		W, see ^{177}Re	—	1E+5	4E-5	1E-7	—	—
75	Rhenium-188m[b/]	D, see ^{177}Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{177}Re	—	1E+5	6E-5	2E-7	—	—
75	Rhenium-188	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see ^{177}Re	—	3E+3	1E-6	4E-9	—	—
75	Rhenium-189	D, see ^{177}Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see ^{177}Re	—	4E+3	2E-6	6E-9	—	—
76	Osmium-180[b]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	—	5E+5	2E-4	7E-7	—	—
		Y, oxides and hydroxides	—	5E+5	2E-4	6E-7	—	—
76	Osmium-181[b]	D, see ^{180}Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{180}Os	—	5E+4	2E-5	6E-8	—	—
		Y, see ^{180}Os	—	4E+4	2E-5	6E-8	—	—
76	Osmium-182	D, see ^{180}Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see ^{180}Os	—	4E+3	2E-6	6E-9	—	—
		Y, see ^{180}Os	—	4E+3	2E-6	6E-9	—	—
76	Osmium-185	D, see ^{180}Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{180}Os	—	8E+2	3E-7	1E-9	—	—
		Y, see ^{180}Os	—	8E+2	3E-7	1E-9	—	—
76	Osmium-189m	D, see ^{180}Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see ^{180}Os	—	2E+5	9E-5	3E-7	—	—
		Y, see ^{180}Os	—	2E+5	7E-5	2E-7	—	—
76	Osmium-191m	D, see ^{180}Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{180}Os	—	2E+4	8E-6	3E-8	—	—
		Y, see ^{180}Os	—	2E+4	7E-6	2E-8	—	—
76	Osmium-191	D, see ^{180}Os	2E+3 LLI wall (3E+3)	2E+3 —	9E-7 —	3E-9 —	— 3E-5	— 3E-4
		W, see ^{180}Os	—	2E+3	7E-7	2E-9	—	—
		Y, see ^{180}Os	—	1E+3	6E-7	2E-9	—	—
76	Osmium-193	D, see ^{180}Os	2E+3 LLI wall (2E+3)	5E+3 —	2E-6 —	6E-9 —	— 2E-5	— 2E-4
		W, see ^{180}Os	—	3E+3	1E-6	4E-9	—	—
		Y, see ^{180}Os	—	3E+3	1E-6	4E-9	—	—
76	Osmium-194	D, see ^{180}Os	4E+2 LLI wall (6E+2)	4E+1 —	2E-8 —	6E-11 —	— 8E-6	— 8E-5
		W, see ^{180}Os	—	6E+1	2E-8	8E-11	—	—
		Y, see ^{180}Os	—	8E+0	3E-9	1E-11	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
77	Iridium-182[b]	D, all compounds except those given for W and Y	4E+4 St wall (4E+4)	1E+5 —	6E-5 —	2E-7 —	— 6E-4	— 6E-3
		W, halides, nitrates, and metallic iridium	—	2E+5	6E-5	2E-7	—	—
		Y, oxides and hydroxides	—	1E+5	5E-5	2E-7	—	—
77	Iridium-184	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	—	3E+4	1E-5	5E-8	—	—
		Y, see ^{182}Ir	—	3E+4	1E-5	4E-8	—	—
77	Iridium-185	D, see ^{182}Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{182}Ir	—	1E+4	5E-6	2E-8	—	—
		Y, see ^{182}Ir	—	1E+4	4E-6	1E-8	—	—
77	Iridium-186	D, see ^{182}Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{182}Ir	—	6E+3	3E-6	9E-9	—	—
		Y, see ^{182}Ir	—	6E+3	2E-6	8E-9	—	—
77	Iridium-187	D, see ^{182}Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see ^{182}Ir	—	3E+4	1E-5	4E-8	—	—
		Y, see ^{182}Ir	—	3E+4	1E-5	4E-8	—	—
77	Iridium-188	D, see ^{182}Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{182}Ir	—	4E+3	1E-6	5E-9	—	—
		Y, see ^{182}Ir	—	3E+3	1E-6	5E-9	—	—
77	Iridium-189	D, see ^{182}Ir	5E+3 LLI wall (5E+3)	5E+3 —	2E-6 —	7E-9 —	— 7E-5	— 7E-4
		W, see ^{182}Ir	—	4E+3	2E-6	5E-9	—	—
		Y, see ^{182}Ir	—	4E+3	1E-6	5E-9	—	—
77	Iridium-190m[b]	D, see ^{182}Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see ^{182}Ir	—	2E+5	9E-5	3E-7	—	—
		Y, see ^{182}Ir	—	2E+5	8E-5	3E-7	—	—
77	Iridium-190	D, see ^{182}Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see ^{182}Ir	—	1E+3	4E-7	1E-9	—	—
		Y, see ^{182}Ir	—	9E+2	4E-7	1E-9	—	—
77	Iridium-192m	D, see ^{182}Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see ^{182}Ir	—	2E+2	9E-8	3E-10	—	—
		Y, see ^{182}Ir	—	2E+1	6E-9	2E-11	—	—
77	Iridium-192	D, see ^{182}Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see ^{182}Ir	—	4E+2	2E-7	6E-10	—	—
		Y, see ^{182}Ir	—	2E+2	9E-8	3E-10	—	—
77	Iridium-194m	D, see ^{182}Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
		W, see ^{182}Ir	—	2E+2	7E-8	2E-10	—	—
		Y, see ^{182}Ir	—	1E+2	4E-8	1E-10	—	—
77	Iridium-194	D, see ^{182}Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{182}Ir	—	2E+3	9E-7	3E-9	—	—
		Y, see ^{182}Ir	—	2E+3	8E-7	3E-9	—	—
77	Iridium-195m	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	—	3E+4	1E-5	4E-8	—	—
		Y, see ^{182}Ir	—	2E+4	9E-6	3E-8	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
77	Iridium-195	D, see ^{182}Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{182}Ir	—	5E+4	2E-5	7E-8	—	—
		Y, see ^{182}Ir	—	4E+4	2E-5	6E-8	—	—
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	—	—
			LLI wall (3E+4)	—	—	—	4E-5	4E-4
78	Platinum-193	D, all compounds	4E+4	2E+4	1E-5	3E-8	—	—
			LLI wall (5E+4)	—	—	—	6E-4	6E-3
78	Platinum-195m	D, all compounds	2E+3	4E+3	2E-6	6E-9	—	—
			LLI wall (2E+3)	—	—	—	3E-5	3E-4
78	Platinum-197m[b]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Platinum-199[b]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	—	2E+4	9E-6	3E-8	—	—
		Y, oxides and hydroxides	—	2E+4	8E-6	3E-8	—	—
79	Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193}Au	—	5E+3	2E-6	8E-9	—	—
		Y, see ^{193}Au	—	5E+3	2E-6	7E-9	—	—
79	Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{193}Au	—	1E+3	6E-7	2E-9	—	—
		Y, see ^{193}Au	—	4E+2	2E-7	6E-10	—	—
79	Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{193}Au	—	1E+3	5E-7	2E-9	—	—
		Y, see ^{193}Au	—	1E+3	5E-7	2E-9	—	—
79	Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	—	2E+3	8E-7	3E-9	—	—
		Y, see ^{193}Au	—	2E+3	7E-7	2E-9	—	—
79	Gold-199	D, see ^{193}Au	3E+3	9E+3	4E-6	1E-8	—	—
			LLI wall (3E+3)	—	—	—	4E-5	4E-4
		W, see ^{193}Au	—	4E+3	2E-6	6E-9	—	—
		Y, see ^{193}Au	—	4E+3	2E-6	5E-9	—	—
79	Gold-200m	D, see ^{193}Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	—	3E+3	1E-6	4E-9	—	—
		Y, see ^{193}Au	—	2E+4	1E-6	3E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (μCi)	Table I Occupational Values Col. 2 Inhalation ALI (μCi)	Table I Occupational Values Col. 3 DAC (μCi/ml)	Table II Effluent Concentrations Col. 1 Air (μCi/ml)	Table II Effluent Concentrations Col. 2 Water (μCi/ml)	Table III Releases to Sewers Monthly Average Concentration (μCi/ml)
79	Gold-200[b]	D, see ^{193}Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{193}Au	—	8E+4	3E-5	1E-7	—	—
		Y, see ^{193}Au	—	7E+4	3E-5	1E-7	—	—
79	Gold-201[b]	D, see ^{193}Au	7E+4 St wall (9E+4)	2E+5 —	9E-5 —	3E-7 —	— 1E-3	— 1E-2
		W, see ^{193}Au	—	2E+5	1E-4	3E-7	—	—
		Y, see ^{193}Au	—	2E+5	9E-5	3E-7	—	—
80	Mercury-193m	Vapor	—	8E+3	4E-6	1E-8	—	—
		Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, oxides, hydroxides, halides, nitrates, and sulfides	—	8E+3	3E-6	1E-8	—	—
80	Mercury-193	Vapor	—	3E+4	1E-5	4E-8	—	—
		Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		D, see ^{193m}Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{193m}Hg	—	4E+4	2E-5	6E-8	—	—
80	Mercury-194	Vapor	—	3E+1	1E-8	4E-11	—	—
		Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
		D, see ^{193m}Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
		W, see ^{193m}Hg	—	1E+2	5E-8	2E-10	—	—
80	Mercury-195m	Vapor	—	4E+3	2E-6	6E-9	—	—
		Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
		D, see ^{193m}Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
		W, see ^{193m}Hg	—	4E+3	2E-6	5E-9	—	—
80	Mercury-195	Vapor	—	3E+4	1E-5	4E-8	—	—
		Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		D, see ^{193m}Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{193m}Hg	—	3E+4	1E-5	5E-8	—	—
80	Mercury-197m	Vapor	—	5E+3	2E-6	7E-9	—	—
		Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		D, see ^{193m}Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193m}Hg	—	5E+3	2E-6	7E-9	—	—
80	Mercury-197	Vapor	—	8E+3	4E-6	1E-8	—	—
		Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
		D, see ^{193m}Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{193m}Hg	—	9E+3	4E-6	1E-8	—	—
80	Mercury-199m[b]	Vapor	—	8E+4	3E-5	1E-7	—	—
		Organic D	6E+4 St wall (1E+5)	2E+5 —	7E-5 —	2E-7 —	— 1E-3	— 1E-2
		D, see ^{193m}Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
		W, see ^{193m}Hg	—	2E+5	7E-5	2E-7	—	—
80	Mercury-203	Vapor	—	8E+2	4E-7	1E-9	—	—
		Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
		D, see ^{193m}Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		W, see ^{193m}Hg	—	1E+3	5E-7	2E-9	—	—
81	Thallium-194m[b]	D, all compounds	5E+4 St wall (7E+4)	2E+5 —	6E-5 —	2E-7 —	— 1E-3	— 1E-2

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
81	Thallium-194[b]	D, all compounds	3E+5	6E+5	2E-4	8E-7	—	—
		St wall	(3E+5)	—	—	—	4E-3	4E-2
81	Thallium-195[b]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198m[b/]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81	Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Lead-195m[b]	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-199[b]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E-1	2E-1	1E-10	—	—	—
			Bone surf (1E+0)	Bone surf (4E-1)	—	6E-13	1E-8	1E-7
82	Lead-211[b]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1	3E+1	1E-8	5E-11	—	—
			Bone surf (1E+2)	—	—	—	2E-6	2E-5
82	Lead-214[b]	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bismuth-200[b]	D, nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, all other compounds	—	1E+5	4E-5	1E-7	—	—
83	Bismuth-201[b/]	D, see ^{200}Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{200}Bi	—	4E+4	2E-5	5E-8	—	—
83	Bismuth-202[b/]	D, see ^{200}Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{200}Bi	—	8E+4	3E-5	1E-7	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
83	Bismuth-203	D, see ^{200}Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
		W, see ^{200}Bi	—	6E+3	3E-6	9E-9	—	—
83	Bismuth-205	D, see ^{200}Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{200}Bi	—	1E+3	5E-7	2E-9	—	—
83	Bismuth-206	D, see ^{200}Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{200}Bi	—	9E+2	4E-7	1E-9	—	—
83	Bismuth-207	D, see ^{200}Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{200}Bi	—	4E+2	1E-7	5E-10	—	—
83	Bismuth-210m	D, see ^{200}Bi	4E+1 Kidneys (6E+1)	5E+0 Kidneys (6E+0)	2E-9	—	—	—
					—	9E-12	8E-7	8E-6
		W, see ^{200}Bi	—	7E-1	3E-10	9E-13	—	—
83	Bismuth-210	D, see ^{200}Bi	8E+2	2E+2	1E-7	—	1E-5	1E-4
			—	Kidneys (4E+2)	—	5E-10	—	—
		W, see ^{200}Bi	—	3E+1	1E-8	4E-11	—	—
83	Bismuth-212[b]	D, see ^{200}Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see ^{200}Bi	—	3E+2	1E-7	4E-10	—	—
83	Bismuth-213[b]	D, see ^{200}Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see ^{200}Bi	—	4E+2	1E-7	5E-10	—	—
83	Bismuth-214[b]	D, see ^{200}Bi	2E+4 St wall (2E+4)	8E+2	3E-7	1E-9	—	—
				—	—	—	3E-4	3E-3
		W, see ^{200}Bi	—	9E-2	4E-7	1E-9	—	—
84	Polonium-203[b]	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	—	9E+4	4E-5	1E-7	—	—
84	Polonium-205[b]	D, see ^{203}Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see ^{203}Po	—	7E+4	3E-5	1E-7	—	—
84	Polonium-207	D, see ^{203}Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{203}Po	—	3E+4	1E-5	4E-8	—	—
84	Polonium-210	D, see ^{203}Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see ^{203}Po	—	6E-1	3E-10	9E-13	—	—
85	Astatine-207[b]	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	—	2E+3	9E-7	3E-9	—	—
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	—	5E+1	2E-8	8E-11	—	—
86	Radon-220	With daughters removed	—	2E+4	7E-6	2E-8	—	—
		With daughters present	— (or 12 WLM)	2E+1 (or 1.0 WL)	9E-9	3E-11	—	—
86	Radon-222	With daughters removed	—	1E+4	4E-6	1E-8	—	—
		With daughters present	— (or 4 WLM)	1E+2 (or 0.33 WL)	3E-8	1E-10	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
87	Francium-222[b/]	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223[b/]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0	7E-1	3E-10	9E-13	—	—
			Bone surf (9E+0)	—	—	—	1E-7	1E-6
88	Radium-224	W, all compounds	8E+0	2E+0	7E-10	2E-12	—	—
			Bone surf (2E+1)	—	—	—	2E-7	2E-6
88	Radium-225	W, all compounds	8E+0	7E-1	3E-10	9E-13	—	—
			Bone surf (2E+1)	—	—	—	2E-7	2E-6
88	Radium-226	W, all compounds	2E+0	6E-1	3E-10	9E-13	—	—
			Bone surf (5E+0)	—	—	—	6E-8	6E-7
88	Radium-227[b]	W, all compounds	2E+4	1E+4	6E-6	—	—	—
			Bone surf (2E+4)	Bone surf (2E+4)	—	3E-8	3E-4	3E-3
88	Radium-228	W, all compounds	2E+0	1E+0	5E-10	2E-12	—	—
			Bone surf (4E+0)	—	—	—	6E-8	6E-7
89	Actinium-224	D, all compounds except those given for W and Y	2E+3	3E+1	1E-8	—	—	—
			LLI wall (2E+3)	Bone surf (4E+1)	—	5E-11	3E-5	3E-4
		W, halides and nitrates	—	5E+1	2E-8	7E-11	—	—
		Y, oxides and hydroxides	—	5E+1	2E-8	6E-11	—	—
89	Actinium-225	D, see ^{224}Ac	5E+1	3E-1	1E-10	—	—	—
			LLI wall (5E+1)	Bone surf (5E-1)	—	7E-13	7E-7	7E-6
		W, see ^{224}Ac	—	6E-1	3E-10	9E-13	—	—
		Y, see ^{224}Ac	—	6E-1	3E-10	9E-13	—	—
89	Actinium-226	D, see ^{224}Ac	1E+2	3E+0	1E-9	—	—	—
			LLI wall (1E+2)	Bone surf (4E+0)	—	5E-12	2E-6	2E-5
		W, see ^{224}Ac	—	5E+0	2E-9	7E-12	—	—
		Y, see ^{224}Ac	—	5E+0	2E-9	6E-12	—	—
89	Actinium-227	D, see ^{224}Ac	2E-1	4E-4	2E-13	—	—	—
			Bone surf (4E-1)	Bone surf (8E-4)	—	1E-15	5E-9	5E-8
		W, see ^{224}Ac	—	2E-3	7E-13	—	—	—
			Bone surf —	(3E-3)	—	4E-15	—	—
		Y, see ^{224}Ac	—	4E-3	2E-12	6E-15	—	—
89	Actinium-228	D, see ^{224}Ac	2E+3	9E+0	4E-9	—	3E-5	3E-4
			Bone surf —	(2E+1)	—	2E-11	—	—
		W, see ^{224}Ac	—	4E+1	2E-8	—	—	—
			Bone surf —	(6E+1)	—	8E-11	—	—
		Y, see ^{224}Ac	—	4E+1	2E-8	6E-11	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
90	Thorium-226[b]	W, all compounds except those given for Y	5E+3 St wall (5E+3)	2E+2 —	6E-8 —	2E-10 —	— 7E-5	— 7E-4
		Y, oxides and hydroxides	—	1E+2	6E-8	2E-10	—	—
90	Thorium-227	W, see ^{226}Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
		Y, see ^{226}Th	—	3E-1	1E-10	5E-13	—	—
90	Thorium-228	W, see ^{226}Th	6E+0 Bone surf (1E+1)	1E-2 Bone surf (2E-2)	4E-12 —	— 3E-14	— 2E-7	— 2E-6
		Y, see ^{226}Th	—	2E-2	7E-12	2E-14	—	—
90	Thorium-229	W, see ^{226}Th	6E-1 Bone surf (1E+0)	9E-4 Bone surf (2E-3)	4E-13 —	— 3E-15	— 2E-8	— 2E-7
		Y, see ^{226}Th	— Bone surf —	2E-3 (3E-3)	1E-12 —	— 4E-15	— —	— —
90	Thorium-230	W, see ^{226}Th	4E+0 Bone surf (9E+0)	6E-3 Bone surf (2E-2)	3E-12 —	— 2E-14	— 1E-7	— 1E-6
		Y, see ^{226}Th	— Bone surf —	2E-2 (2E-2)	6E-12 —	— 3E-14	— —	— —
90	Thorium-231	W, see ^{226}Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see ^{226}Th	—	6E+3	3E-6	9E-9	—	—
90	Thorium-232	W, see ^{226}Th	7E-1 Bone surf (2E+0)	1E-3 Bone surf (3E-3)	5E-13 —	— 4E-15	— 3E-8	— 3E-7
		Y, see ^{226}Th	— Bone surf	3E-3	1E-12	—	—	—
		-	(4E-3)	—	6E-15	—	—	
90	Thorium-234	W, see ^{226}Th	3E+2 LLI wall (4E+2)	2E+2 —	8E-8 —	3E-10 —	— 5E-6	— 5E-5
		Y, see ^{226}Th	—	2E+2	6E-8	2E-10	—	—
91	Protactinium-227[b]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	—	1E+2	4E-8	1E-10	—	—
91	Protactinium-228	W, see ^{227}Pa	1E+3 Bone surf —	1E+1 (2E+1)	5E-9 —	— 3E-11	2E-5 —	2E-4 —
		Y, see ^{227}Pa	—	1E+1	5E-9	2E-11	—	—
91	Protactinium-230	W, see ^{227}Pa	6E+2 Bone surf (9E+2)	5E+0 —	2E-9 —	7E-12 —	— 1E-5	— 1E-4
		Y, see ^{227}Pa	—	4E+0	1E-9	5E-12	—	—
91	Protactinium-231	W, see ^{227}Pa	2E-1 Bone surf (5E-1)	2E-3 Bone surf (4E-3)	6E-13 —	— 6E-15	— 6E-9	— 6E-8
		Y, see ^{227}Pa	— Bone surf —	4E-3 (6E-3)	2E-12 —	— 8E-15	— —	— —

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
91	Protactinium-232	W, see ^{227}Pa	1E+3 Bone surf	2E+1	9E-9	—	2E-5	2E-4
			—	(6E+1)	—	8E-11	—	—
		Y, see ^{227}Pa	—	6E+1	2E-8	—	—	—
			Bone surf					
			—	(7E+1)	—	1E-10	—	—
91	Protactinium-233	W, see ^{227}Pa	1E+3 LLI wall	7E+2	3E-7	1E-9	—	—
			(2E+3)	—	—	—	2E-5	2E-4
		Y, see ^{227}Pa	—	6E+2	2E-7	8E-10	—	—
91	Protactinium-234	W, see ^{227}Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{227}Pa	—	7E+3	3E-6	9E-9	—	—
92	Uranium-230	D, UF_6, UO_2F_2, $UO_2(NO_3)_2$	4E+0 Bone surf	4E-1 Bone surf	2E-10	—	—	—
			(6E+0)	(6E-1)	—	8E-13	8E-8	8E-7
		W, UO_3, UF_4, UCl_4	—	4E-1	1E-10	5E-13	—	—
		Y, UO_2, U_3O_8	—	3E-1	1E-10	4E-13	—	—
92	Uranium-231	D, see ^{230}U	5E+3 LLI wall	8E+3	3E-6	1E-8	—	—
			(4E+3)	—	—	—	6E-5	6E-4
		W, see ^{230}U	—	6E+3	2E-6	8E-9	—	—
		Y, see ^{230}U	—	5E+3	2E-6	6E-9	—	—
92	Uranium-232	D, see ^{230}U	2E+0 Bone surf	2E-1 Bone surf	9E-11	—	—	—
			(4E+0)	(4E-1)	—	6E-13	6E-8	6E-7
		W, see ^{230}U	—	4E-1	2E-10	5E-13	—	—
		Y, see ^{230}U	—	8E-3	3E-12	1E-14	—	—
92	Uranium-233	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	5E-10	—	—	—
			(2E+1)	(2E+0)	—	3E-12	3E-7	3E-6
		W, see ^{230}U	—	7E-1	3E-10	1E-12	—	—
		Y, see ^{230}U	—	4E-2	2E-11	5E-14	—	—
92	Uranium-234[c]	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	5E-10	—	—	—
			(2E+1)	(2E+0)	—	3E-12	3E-7	3E-6
		W, see ^{230}U	—	7E-1	3E-10	1E-12	—	—
		Y, see ^{230}U	—	4E-2	2E-11	5E-14	—	—
92	Uranium-235[c,f]	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	6E-10	—	—	—
			(2E+1)	(2E+0)	—	3E-12	3E-7	3E-6
		W, see ^{230}U	—	8E-1	3E-10	1E-12	—	—
		Y, see ^{230}U	—	4E-2	2E-11	6E-14	—	—
92	Uranium-236	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	5E-10	—	—	—
			(2E+1)	(2E+0)	—	3E-12	3E-7	3E-6
		W, see ^{230}U	—	8E-1	3E-10	1E-12	—	—
		Y, see ^{230}U	—	4E-2	2E-11	6E-14	—	—
92	Uranium-237	D, see ^{230}U	2E+3 LLI wall	3E+3	1E-6	4E-9	—	—
			(2E+3)	—	—	—	3E-5	3E-4
		W, see ^{230}U	—	2E+3	7E-7	2E-9	—	—
		Y, see ^{230}U	—	2E+3	6E-7	2E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
92	Uranium-238[c]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 —	— 3E-12	— 3E-7	— 3E-6
		W, see ^{230}U	—	8E-1	3E-10	1E-12	—	—
		Y, see ^{230}U	—	4E-2	2E-11	6E-14	—	—
92	Uranium-239[b]	D, see ^{230}U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		W, see ^{230}U	—	2E+5	7E-5	2E-7	—	—
		Y, see ^{230}U	—	2E+5	6E-5	2E-7	—	—
92	Uranium-240	D, see ^{230}U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{230}U	—	3E+3	1E-6	4E-9	—	—
		Y, see ^{230}U	—	2E+3	1E-6	3E-9	—	—
92	Uranium-natural[c]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 —	— 3E-12	— 3E-7	— 3E-6
		W, see ^{230}U	—	8E-1	3E-10	9E-13	—	—
		Y, see ^{230}U	—	5E-2	2E-11	9E-14	—	—
93	Neptunium-232[b]	W, all compounds	1E+5 Bone surf —	2E+3 (5E+2)	7E-7 —	— 6E-9	2E-3 -	2E-2 —
93	Neptunium-233[b]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Neptunium-235	W, all compounds	2E+4 LLI wall (2E+4)	8E+2 Bone surf (1E+3)	3E-7 —	— 2E-9	— 3E-4	— 3E-3
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0 Bone surf (6E+0)	2E-2 Bone surf (5E-2)	9E-12 —	— 8E-14	— 9E-8	— 9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3 Bone surf (4E+3)	3E+1 Bone surf (7E+1)	1E-8 —	— 1E-10	— 5E-5	— 5E-4
93	Neptunium-237	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (1E-2)	2E-12 —	— 1E-14	— 2E-8	— 2E-7
93	Neptunium-238	W, all compounds	1E+3 Bone surf —	6E+1 (2E+2)	3E-8 —	— 2E-10	2E-5 —	2E-4 —
93	Neptunium-239	W, all compounds	2E+3 LLI wall (2E+3)	2E+3 —	9E-7 —	— —	— 2E-5	— 2E-4
93	Neptunium-240[b]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO_2	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO_2	—	2E+2	8E-8	3E-10	—	—
94	Plutonium-235[b]	W, see ^{234}Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ^{234}Pu	—	3E+6	1E-3	3E-6	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
94	Plutonium-236	W, see ^{234}Pu	2E+0 Bone surf (4E+0)	2E-2 Bone surf (4E-2)	8E-12 —	— 5E-14	— 6E-8	— 6E-7
		Y, see ^{234}Pu	—	4E-2	2E-11	6E-14	—	—
94	Plutonium-237	W, see ^{234}Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see ^{234}Pu	—	3E+3	1E-6	4E-9	—	—
94	Plutonium-238	W, see ^{234}Pu	9E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
		Y, see ^{234}Pu	—	2E-2	8E-12	2E-14	—	—
94	Plutonium-239	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
		Y, see ^{234}Pu	— Bone surf —	2E-2 (2E-2)	7E-12 —	— 2E-14	— —	— —
94	Plutonium-240	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
		Y, see ^{234}Pu	— Bone surf —	2E-2 (2E-2)	7E-12 —	— 2E-14	— —	— —
94	Plutonium-241	W, see ^{234}Pu	4E+1 Bone surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 —	— 8E-13	— 1E-6	— 1E-5
		Y, see ^{234}Pu Bone surf	— —	8E-1 (1E+0)	3E-10 —	— 1E-12	— —	— —
94	Plutonium-242	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	7E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
		Y, see ^{234}Pu	— Bone surf —	2E-2 (2E-2)	7E-12 —	— 2E-14	— —	— —
94	Plutonium-243	W, see ^{234}Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see ^{234}Pu	—	4E+4	2E-5	5E-8	—	—
94	Plutonium-244	W, see ^{234}Pu	8E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
		Y, see ^{234}Pu	— Bone surf —	2E-2 (2E-2)	7E-12 —	— 2E-14	— —	— —
94	Plutonium-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see ^{234}Pu	—	4E+3	2E-6	6E-9	—	—
94	Plutonium-246	W, see ^{234}Pu	4E+2 LLI wall (4E+2)	3E+2 —	1E-7 —	4E-10 —	— 6E-6	— 6E-5
		Y, see ^{234}Pu	—	3E+2	1E-7	4E-10	—	—
95	Americium-237[b]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238[b]	W, all compounds	4E+4 Bone surf —	3E+3 (6E+3)	1E-6 —	— 9E-9	5E-4 —	5E-3 —

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
95	Americium-241	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
95	Americium-242m	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
95	Americium-242	W, all compounds	4E+3 Bone surf —	8E+1 (9E+1)	4E-8 —	— 1E-10	5E-5 —	5E-4 —
95	Americium-243	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
95	Americium-244m[b]	W, all compounds	6E+4 St wall (8E+4)	4E+3 Bone surf (7E+3)	2E-6 —	— 1E-8	— 1E-3	— 1E-2
95	Americium-244	W, all compounds	3E+3 Bone surf —	2E+2 (3E+2)	8E-8 —	— 4E-10	4E-5 —	4E-4 —
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m[b]	W, all compounds	5E+4 St wall (6E+4)	2E+5 —	8E-5 —	3E-7 —	— 8E-4	— 8E-3
95	Americium-246[b]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1 Bone surf (8E+1)	6E-1 Bone surf (6E-1)	2E-10 —	— 9E-13	— 1E-6	— 1E-5
96	Curium-241	W, all compounds	1E+3 Bone surf —	3E+1 (4E+1)	1E-8 —	— 5E-11	2E-5 —	2E-4 —
96	Curium-242	W, all compounds	3E+1 Bone surf (5E+1)	3E-1 Bone surf (3E-1)	1E-10 —	— 4E-13	— 7E-7	— 7E-6
96	Curium-243	W, all compounds	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 —	— 2E-14	— 3E-8	— 3E-7
96	Curium-244	W, all compounds	1E+0 Bone surf (3E+0)	1E-2 Bone surf (2E-2)	5E-12 —	— 3E-14	— 3E-8	— 3E-7
96	Curium-245	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
96	Curium-246	W, all compounds	7E-1	6E-3	3E-12	—	—	—
			(1E+0)	Bone surf (1E-2)	Bone surf —	2E-14	2E-8	2E-7
96	Curium-247	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 —	— 2E-14	— 2E-8	— 2E-7
96	Curium-248	W, all compounds	2E-1 Bone surf (4E-1)	2E-3 Bone surf (3E-3)	7E-13 —	— 4E-15	— 5E-9	— 5E-8
96	Curium-249[b]	W, all compounds	5E+4 Bone surf —	2E+4 (3E+4)	7E-6 —	— 4E-8	7E-4 —	7E-3 —
96	Curium-250	W, all compounds	4E-2 Bone surf (6E-2)	3E-4 Bone surf (5E-4)	1E-13 —	— 8E-16	— 9E-10	— 9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 —	— 1E-14	— 2E-8	— 2E-7
97	Berkelium-249	W, all compounds	2E+2 Bone surf (5E+2)	2E+0 Bone surf (4E+0)	7E-10 —	— 5E-12	— 6E-6	— 6E-5
97	Berkelium-250	W, all compounds	9E+3 Bone surf —	3E+2 (7E+2)	1E-7 —	— 1E-9	1E-4 —	1E-3 —
98	Californium-244[b]	W, all compounds except those given for Y	3E+4 St wall (3E+4)	6E+2 —	2E-7 —	8E-10 —	— 4E-4	— 4E-3
		Y, oxides and hydroxides	—	6E+2	2E-7	8E-10	—	—
98	Californium-246	W, see ^{244}Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see ^{244}Cf	—	9E+0	4E-9	1E-11	—	—
98	Californium-248	W, see ^{244}Cf	8E+0 Bone surf (2E+1)	6E-2 Bone surf (1E-1)	3E-11 —	— 2E-13	— 2E-7	— 2E-6
		Y, see ^{244}Cf	—	1E-1	4E-11	1E-13	—	—
98	Californium-249	W, see ^{244}Cf	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 —	— 1E-14	— 2E-8	— 2E-7
		Y, see ^{244}Cf	— Bone surf —	1E-2 (1E-2)	4E-12 —	— 2E-14	—	—
98	Californium-250	W, see ^{244}Cf	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 —	— 3E-14	— 3E-8	— 3E-7
		Y, see ^{244}Cf	—	3E-2	1E-11	4E-14	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
Atomic No.	Radionuclide	Class	Col. 1 Oral Ingestion ALI (μCi)	Col. 2 Inhalation ALI (μCi)	Col. 3 DAC (μCi/ml)	Col. 1 Air (μCi/ml)	Col. 2 Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
98	Californium-251	W, see ^{244}Cf	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 —	— 1E-14	— 2E-8	— 2E-7
		Y, see ^{244}Cf	— Bone surf —	1E-2 (1E-2)	4E-12 —	— 2E-14	— —	— —
98	Californium-252	W, see ^{244}Cf	2E+0 Bone surf (5E+0)	2E-2 Bone surf (4E-2)	8E-12 —	— 5E-14	— 7E-8	— 7E-7
		Y, see ^{244}Cf	—	3E-2	1E-11	5E-14	—	—
98	Californium-253	W, see ^{244}Cf	2E+2 Bone surf (4E+2)	2E+0 —	8E-10 —	3E-12 —	— 5E-6	— 5E-5
		Y, see ^{244}Cf	—	2E+0	7E-10	2E-12	—	—
98	Californium-254	W, see ^{244}Cf Y, see ^{244}Cf	2E+0 —	2E-2 2E-2	9E-12 7E-12	3E-14 2E-14	3E-8 —	3E-7 —
99	Einsteinium-250	W, all compounds	4E+4 Bone surf —	5E+2 (1E+3)	2E-7 —	— 2E-9	6E-4 —	6E-3 —
99	Einsteinium-251	W, all compounds	7E+3 Bone surf —	9E+2 (1E+3)	4E-7 —	— 2E-9	1E-4 —	1E-3 —
99	Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5
99	Einsteinium-254m	W, all compounds	3E+2 LLI wall (3E+2)	1E+1 —	4E-9 —	1E-11 —	— 4E-6	— 4E-5
99	Einsteinium-254	W, all compounds	8E+0 Bone surf (2E+1)	7E-2 Bone surf (1E-1)	3E-11 —	— 2E-13	— 2E-7	— 2E-6
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1 Bone surf (4E+1)	2E-1 Bone surf (2E-1)	7E-11 —	— 3E-13	— 5E-7	— 5E-6
101	Mendelevium-257	W, all compounds	7E+3 Bone surf —	8E+1 (9E+1)	4E-8 —	— 1E-10	1E-4 —	1E-3 —
101	Mendelevium-258	W, all compounds	3E+1 Bone surf (5E+1)	2E-1 Bone surf (3E-1)	1E-10 —	— 5E-13	— 6E-7	— 6E-6
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours	Submersion[a]	—	2E+2	1E-7	1E-9	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Table II Effluent Concentrations Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)	
-	Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours		....	—	2E-1	1E-10	1E-12	1E-8	1E-7
-	Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known		....	—	4E-4	2E-13	1E-15	2E-9	2E-8

Footnotes:

[a] "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[b] These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 µCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See subsection 6.7.)

[c] For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor (see subsection 6.5.e.). If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) µCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

SA = 3.6E-7 curies/gram U U-depleted

$SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)^2]$ E-6, enrichment > 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

Note:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this table are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this table for any radionuclide that is not known to be absent from the mixture; or

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

Atomic No.	Radionuclide	Class	Table I Occupational Values Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values Col. 2 Inhalation ALI (µCi)	Table I Occupational Values Col. 3 DAC (µCi/ml)	Table II Effluent Concentrations Col. 1 Air (µCi/ml)	Table II Effluent Concentrations Col. 2 Water (µCi/ml)	Table III Releases to Sewers Monthly Average Concentration (µCi/ml)
If it is known that Ac-227-D and Cm-250-W are not present		—	7E-4	3E-13	—	—	—	—
If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present		—	—	7E-3	3E-12	—	—	—
If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present		—	7E-2	3E-11	—	—	—	
If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present		—	—	7E-1	3E-10	—	—	—
If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present		—	—	7E+0	3E-9	—	—	—
If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present		—	—	—	—	1E-14	—	—
If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present		—	—	—	—	1E-13	—	—
If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present		—	—	—	—	1E-12	—	—

Annual Limits on Intake (ALI) and Derived Air Concentrations (DAC) of Radionuclides for Occupational Exposure
Effluent Concentrations
Concentrations for Release to Sanitary Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
Atomic No.	Radionuclide	Class	Oral Ingestion ALI (µCi)	Inhalation ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present			—	—	—	—	1E-6	1E-5

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 µm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture: 6E-11 µCi of gross alpha activity from Uuranium-238, Uuranium-234, Tthorium-230, and Rradium-226 per milliliter of air; 3E-11 µCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows: determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in table 64-23 F for the specific radionuclide when not in a mixture. The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

Example: If radionuclides "A," "B," and "C" are present in concentrations C_A, C_B, and C_C, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} \leq 1$$

TABLE 64-23 E

QUANTITIES[1] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Hydrogen-3	1,000	Iron-52	100
Beryllium-7	1,000	Iron-55	100
Beryllium-10	1	Iron-59	10
Carbon-11	1,000	Iron-60	1
Carbon-14	1,000	Cobalt-55	100
Fluorine-18	1,000	Cobalt-56	10
Sodium-22	10	Cobalt-57	100
Sodium-24	100	Cobalt-58m	1,000
Magnesium-28	100	Cobalt-58	100
Aluminum-26	10	Cobalt-60m	1,000
Silicon-31	1,000	Cobalt-60	1
Silicon-32	1	Cobalt-61	1,000
Phosphorus-32	10	Cobalt-62m	1,000
Phosphorus-33	100	Nickel-56	100
Sulfur-35	100	Nickel-57	100
Chlorine-36	10	Nickel-59	100
Chlorine-38	1,000	Nickel-63	100
Chlorine-39	1,000	Nickel-65	1,000
Argon-39	1,000	Nickel-66	10
Argon-41	1,000	Copper-60	1,000
Potassium-40	100	Copper-61	1,000
Potassium-42	1,000	Copper-64	1,000
Potassium-43	1,000	Copper-67	1,000
Potassium-44	1,000	Zinc-62	100
Potassium-45	1,000	Zinc-63	1,000
Calcium-41	100	Zinc-65	10
Calcium-45	100	Zinc-69m	100
Calcium-47	100	Zinc-69	1,000
Scandium-43	1,000	Zinc-71m	1,000
Scandium-44m	100	Zinc-72	100
Scandium-44	100	Gallium-65	1,000
Scandium-46	10	Gallium-66	100
Scandium-47	100	Gallium-67	1,000
Scandium-48	100	Gallium-68	1,000
Scandium-49	1,000	Gallium-70	1,000
Titanium-44	1	Gallium-72	100
Titanium-45	1,000	Gallium-73	1,000
Vanadium-47	1,000	Germanium-66	1,000
Vanadium-48	100	Germanium-67	1,000
Vanadium-49	1,000	Germanium-68	10
Chromium-48	1,000	Germanium-69	1,000
Chromium-49	1,000	Germanium-71	1,000
Chromium-51	1,000	Germanium-75	1,000
Manganese-51	1,000	Germanium-77	1,000
Manganese-52m	1,000	Germanium-78	1,000
Manganese-52	100	Arsenic-69	1,000
Manganese-53	1,000	Arsenic-70	1,000
Manganese-54	100	Arsenic-71	100
Manganese-56	1,000	Arsenic-72	100

[1] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

QUANTITIES[a] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)
(Continued)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Arsenic-73	100	Strontium-90	0.1
Arsenic-74	100	Strontium-91	100
Arsenic-76	100	Strontium-92	100
Arsenic-77	100	Yttrium-86m	1,000
Arsenic-78	1,000	Yttrium-86	100
Selenium-70	1,000	Yttrium-87	100
Selenium-73m	1,000	Yttrium-88	10
Selenium-73	100	Yttrium-90m	1,000
Selenium-75	100	Yttrium-90	10
Selenium-79	100	Yttrium-91m	1,000
Selenium-81m	1,000	Yttrium-91	10
Selenium-81	1,000	Yttrium-92	100
Selenium-83	1,000	Yttrium-93	100
Bromine-74m	1,000	Yttrium-94	1,000
Bromine-74	1,000	Yttrium-95	1,000
Bromine-75	1,000	Zirconium-86	100
Bromine-76	100	Zirconium-88	10
Bromine-77	1,000	Zirconium-89	100
Bromine-80m	1,000	Zirconium-93	1
Bromine-80	1,000	Zirconium-95	10
Bromine-82	100	Zirconium-97	100
Bromine-83	1,000	Niobium-88	1,000
Bromine-84	1,000	Niobium-89m (66 min)	1,000
Krypton-74	1,000	Niobium-89 (122 min)	1,000
Krypton-76	1,000	Niobium-90	100
Krypton-77	1,000	Niobium-93m	10
Krypton-79	1,000	Niobium-94	1
Krypton-81	1,000	Niobium-95m	100
Krypton-83m	1,000	Niobium-95	100
Krypton-85m	1,000	Niobium-96	100
Krypton-85	1,000	Niobium-97	1,000
Krypton-87	1,000	Niobium-98	1,000
Krypton-88	1,000	Molybdenum-90	100
Rubidium-79	1,000	Molybdenum-93m	100
Rubidium-81m	1,000	Molybdenum-93	10
Rubidium-81	1,000	Molybdenum-99	100
Rubidium-82m	1,000	Molybdenum-101	1,000
Rubidium-83	100	Technetium-93m	1,000
Rubidium-84	100	Technetium-93	1,000
Rubidium-86	100	Technetium-94m	1,000
Rubidium-87	100	Technetium-94	1,000
Rubidium-88	1,000	Technetium-96m	1,000
Rubidium-89	1,000	Technetium-96	100
Strontium-80	100	Technetium-97m	100
Strontium-81	1,000	Technetium-97	1,000
Strontium-83	100	Technetium-98	10
Strontium-85m	1,000	Technetium-99m	1,000
Strontium-85	100	Technetium-99	100
Strontium-87m	1,000	Technetium-101	1,000
Strontium-89	10	Technetium-104	1,000

[a] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

QUANTITIES[a] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)
(Continued)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Ruthenium-94	1,000	Indium-115	100
Ruthenium-97	1,000	Indium-116m	1,000
Ruthenium-103	100	Indium-117m	1,000
Ruthenium-105	1,000	Indium-117	1,000
Ruthenium-106	1	Indium-119m	1,000
Rhodium-99m	1,000	Tin-110	100
Rhodium-99	100	Tin-111	1,000
Rhodium-100	100	Tin-113	100
Rhodium-101m	1,000	Tin-117m	100
Rhodium-101	10	Tin-119m	100
Rhodium-102m	10	Tin-121m	100
Rhodium-102	10	Tin-121	1,000
Rhodium-103m	1,000	Tin-123m	1,000
Rhodium-105	100	Tin-123	10
Rhodium-106m	1,000	Tin-125	10
Rhodium-107	1,000	Tin-126	10
Palladium-100	100	Tin-127	1,000
Palladium-101	1,000	Tin-128	1,000
Palladium-103	100	Antimony-115	1,000
Palladium-107	10	Antimony-116m	1,000
Palladium-109	100	Antimony-116	1,000
Silver-102	1,000	Antimony-117	1,000
Silver-103	1,000	Antimony-118m	1,000
Silver-104m	1,000	Antimony-119	1,000
Silver-104	1,000	Antimony-120 (16 min)	1,000
Silver-105	100	Antimony-120 (5.76 d)	100
Silver-106m	100	Antimony-122	100
Silver-106	1,000	Antimony-124m	1,000
Silver-108m	1	Antimony-124	10
Silver-11Om	10	Antimony-125	100
Silver-111	100	Antimony-126m	1,000
Silver-112	100	Antimony-126	100
Silver-115	1,000	Antimony-127	100
Cadmium-104	1,000	Antimony-128 (10.4 min)	1,000
Cadmium-107	1,000	Antimony-128 (9.O1 h)	100
Cadmium-109	1	Antimony-129	100
Cadmium-113m	0.1	Antimony-130	1,000
Cadmium-113	100	Antimony-131	1,000
Cadmium-115m	10	Tellurium-116	1,000
Cadmium-115	100	Tellurium-121m	10
Cadmium-117m	1,000	Tellurium-121	100
Cadmium-117	1,000	Tellurium-123m	10
Indium-109	1,000	Tellurium-123	100
Indium-110 (69.1 min)	1,000	Tellurium-125m	10
Indium-11O (4.9 h)	1,000	Tellurium-127m	10
Indium-111	100	Tellurium-127	1,000
Indium-112	1,000	Tellurium-129m	10
Indium-113m	1,000	Tellurium-129	1,000
Indium-114m	10	Tellurium-131m	10
Indium-115m	1,000	Tellurium-131	100

[a] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

QUANTITIES[a] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)
(Continued)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Tellurium-132	10	Barium-133m	100
Tellurium-133m	100	Barium-133	100
Tellurium-133	1,000	Barium-135m	100
Tellurium-134	1,000	Barium-139	1,000
Iodine-120m	1,000	Barium-140	100
Iodine-120	100	Barium-141	1,000
Iodine-121	1,000	Barium-142	1,000
Iodine-123	100	Lanthanum-131	1,000
Iodine-124	10	Lanthanum-132	100
Iodine-125	1	Lanthanum-135	1,000
Iodine-126	1	Lanthanum-137	10
Iodine-128	1,000	Lanthanum-138	100
Iodine-129	1	Lanthanum-140	100
Iodine-130	10	Lanthanum-141	100
Iodine-131	1	Lanthanum-142	1,000
Iodine-132m	100	Lanthanum-143	1,000
Iodine-132	100	Cerium-134	100
Iodine-133	10	Cerium-135	100
Iodine-134	1,000	Cerium-137m	100
Iodine-135	100	Cerium-137	1,000
Xenon-120	1,000	Cerium-139	100
Xenon-121	1,000	Cerium-141	100
Xenon-122	1,000	Cerium-143	100
Xenon-123	1,000	Cerium-144	1
Xenon-125	1,000	Praseodymium-136	1,000
Xenon-127	1,000	Praseodymium-137	1,000
Xenon-129m	1,000	Praseodymium-138m	1,000
Xenon-131m	1,000	Praseodymium-139	1,000
Xenon-133m	1,000	Praseodymium-142m	1,000
Xenon-133	1,000	Praseodymium-142	100
Xenon-135m	1,000	Praseodymium-143	100
Xenon-135	1,000	Praseodymium-144	1,000
Xenon-138	1,000	Praseodymium-145	100
Cesium-125	1,000	Praseodymium-147	1,000
Cesium-127	1,000	Neodymium-136	1,000
Cesium-129	1,000	Neodymium-138	100
Cesium-130	1,000	Neodymium-139m	1,000
Cesium-131	1,000	Neodymium-139	1,000
Cesium-132	100	Neodymium-141	1,000
Cesium-134m	1,000	Neodymium-147	100
Cesium-134	10	Neodymium-149	1,000
Cesium-135m	1,000	Neodymium-151	1,000
Cesium-135	100	Promethium-141	1,000
Cesium-136	10	Promethium-143	100
Cesium-137	10	Promethium-144	10
Cesium-138	1,000	Promethium-145	10
Barium-126	1,000	Promethium-146	1
Barium-128	100	Promethium-147	10
Barium-131m	1,000	Promethium-148m	10
Barium-131	100	Promethium-148	10

[a] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

QUANTITIES[a] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)
(Continued)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Promethium-149	100	Dysprosium-155	1,000
Promethium-150	1,000	Dysprosium-157	1,000
Promethium-151	100	Dysprosium-159	100
Samarium-141m	1,000	Dysprosium-165	1,000
Samarium-141	1,000	Dysprosium-166	100
Samarium-142	1,000	Holmium-155	1,000
Samarium-145	100	Holmium-157	1,000
Samarium-146	1	Holmium-159	1,000
Samarium-147	100	Holmium-161	1,000
Samarium-151	10	Holmium-162m	1,000
Samarium-153	100	Holmium-162	1,000
Samarium-155	1,000	Holmium-164m	1,000
Samarium-156	1,000	Holmium-164	1,000
Europium-145	100	Holmium-166m	1
Europium-146	100	Holmium-166	100
Europium-147	100	Holmium-167	1,000
Europium-148	10	Erbium-161	1,000
Europium-149	100	Erbium-165	1,000
Europium-150 (12.62 h)	100	Erbium-169	100
Europium-150 (34.2 y)	1	Erbium-171	100
Europium-152m	100	Erbium-172	100
Europium-152	1	Thulium-162	1,000
Europium-154	1	Thulium-166	100
Europium-155	10	Thulium-167	100
Europium-156	100	Thulium-170	10
Europium-157	100	Thulium-171	10
Europium-158	1,000	Thulium-172	100
Gadolinium-145	1,000	Thulium-173	100
Gadolinium-146	10	Thulium-175	1,000
Gadolinium-147	100	Ytterbium-162	1,000
Gadolinium-148	0.001	Ytterbium-166	100
Gadolinium-149	100	Ytterbium-167	1,000
Gadolinium-151	10	Ytterbium-169	100
Gadolinium-152	100	Ytterbium-175	100
Gadolinium-153	10	Ytterbium-177	1,000
Gadolinium-159	100	Ytterbium-178	1,000
Terbium-147	1,000	Lutetium-169	100
Terbium-149	100	Lutetium-170	100
Terbium-150	1,000	Lutetium-171	100
Terbium-151	100	Lutetium-172	100
Terbium-153	1,000	Lutetium-173	10
Terbium-154	100	Lutetium-174m	10
Terbium-155	1,000	Lutetium-174	10
Terbium-156m (5.O h)	1,000	Lutetium-176m	1,000
Terbium-156m (24.4 h)	1,000	Lutetium-176	100
Terbium-156	100	Lutetium-177m	10
Terbium-157	10	Lutetium-177	100
Terbium-158	1	Lutetium-178m	1,000
Terbium-160	10	Lutetium-178	1,000
Terbium-161	100	Lutetium-179	1,000

[a] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

QUANTITIES[c] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)
(Continued)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Hafnium-170	100	Rhenium-188	100
Hafnium-172	1	Rhenium-189	100
Hafnium-173	1,000	Osmium-180	1,000
Hafnium-175	100	Osmium-181	1,000
Hafnium-177m	1,000	Osmium-182	100
Hafnium-178m	0.1	Osmium-185	100
Hafnium-179m	10	Osmium-189m	1,000
Hafnium-180m	1,000	Osmium-191m	1,000
Hafnium-181	10	Osmium-191	100
Hafnium-182m	1,000	Osmium-193	100
Hafnium-182	0.1	Osmium-194	1
Hafnium-183	1,000	Iridium-182	1,000
Hafnium-184	100	Iridium-184	1,000
Tantalum-172	1,000	Iridium-185	1,000
Tantalum-173	1,000	Iridium-186	100
Tantalum-174	1,000	Iridium-187	1,000
Tantalum-175	1,000	Iridium-188	100
Tantalum-176	100	Iridium-189	100
Tantalum-177	1,000	Iridium-190m	1,000
Tantalum-178	1,000	Iridium-190	100
Tantalum-179	100	Iridium-192m (1.4 min)	10
Tantalum-180m	1,000	Iridium-192 (73.8 d)	1
Tantalum-180	100	Iridium-194m	10
Tantalum-182m	1,000	Iridium-194	100
Tantalum-182	10	Iridium-195m	1,000
Tantalum-183	100	Iridium-195	1,000
Tantalum-184	100	Platinum-186	1,000
Tantalum-185	1,000	Platinum-188	100
Tantalum-186	1,000	Platinum-189	1,000
Tungsten-176	1,000	Platinum-191	100
Tungsten-177	1,000	Platinum-193m	100
Tungsten-178	1,000	Platinum-193	1,000
Tungsten-179	1,000	Platinum-195m	100
Tungsten-181	1,000	Platinum-197m	1,000
Tungsten-185	100	Platinum-197	100
Tungsten-187	100	Platinum-199	1,000
Tungsten-188	10	Platinum-200	100
Rhenium-177	1,000	Gold-193	1,000
Rhenium-178	1,000	Gold-194	100
Rhenium-181	1,000	Gold-195	10
Rhenium-182 (12.7 h)	1,000	Gold-198m	100
Rhenium-182 (64.O h)	100	Gold-198	100
Rhenium-184m	10	Gold-199	100
Rhenium-184	100	Gold-200m	100
Rhenium-186m	10	Gold-200	1,000
Rhenium-186	100	Gold-201	1,000
Rhenium-187	1,000	Mercury-193m	100
Rhenium-188m	1,000	Mercury-193	1,000
		Mercury-194	1
		Mercury-195m	100
		Mercury-195	1,000
		Mercury-197m	100

[c] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

QUANTITIES[a] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)
(Continued)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Mercury-197	1,000	Radium-223	0.1
Mercury-199m	1,000	Radium-224	0.1
Mercury-203	100	Radium-225	0.1
Thallium-194m	1,000	Radium-226	0.1
Thallium-194	1,000	Radium-227	1,000
Thallium-195	1,000	Radium-228	0.1
Thallium-197	1,000	Actinium-224	1
Thallium-198m	1,000	Actinium-225	0.01
Thallium-198	1,000	Actinium-226	0.1
Thallium-199	1,000	Actinium-227	0.001
Thallium-201	1,000	Actinium-228	1
Thallium-200	1,000	Thorium-226	10
Thallium-202	100	Thorium-227	0.01
Thallium-204	100	Thorium-228	0.001
Lead-195m	1,000	Thorium-229	0.001
Lead-198	1,000	Thorium-230	0.001
Lead-199	1,000	Thorium-231	100
Lead-200	100	Thorium-232	100
Lead-201	1,000	Thorium-234	10
Lead-202m	1,000	Thorium-natural	100
Lead-202	10	Protactinium-227	10
Lead-203	1,000	Protactinium-228	1
Lead-205	100	Protactinium-230	0.1
Lead-209	1,000	Protactinium-231	0.001
Lead-210	0.01	Protactinium-232	1
Lead-211	100	Protactinium-233	100
Lead-212	1	Protactinium-234	100
Lead-214	100	Uranium-230	0.01
Bismuth-200	1,000	Uranium-231	100
Bismuth-201	1,000	Uranium-232	0.001
Bismuth-202	1,000	Uranium-233	0.001
Bismuth-203	100	Uranium-234	0.001
Bismuth-205	100	Uranium-235	0.001
Bismuth-206	100	Uranium-236	0.001
Bismuth-207	10	Uranium-237	100
Bismuth-210m	0.1	Uranium-238	100
Bismuth-210	1	Uranium-239	1,000
Bismuth-212	10	Uranium-240	100
Bismuth-213	10	Uranium-natural	100
Bismuth-214	100	Neptunium-232	100
Polonium-203	1,000	Neptunium-233	1,000
Polonium-205	1,000	Neptunium-234	100
Polonium-207	1,000	Neptunium-235	100
Polonium-210	0.1	Neptunium-236 (1.15E+5 y)	0.001
Astatine-207	100	Neptunium-236 (22.5 h)	1
Astatine-211	10	Neptunium-237	0.001
Radon-220	1	Neptunium-238	10
Radon-222	1	Neptunium-239	100
Francium-222	100	Neptunium-240	1,000
Francium-223	100	Plutonium-234	10

[a] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

QUANTITIES[c] OF REGISTERED MATERIAL REQUIRING LABELING
(In Atomic Number Order)
(Continued)

Radionuclide	Quantity (□Ci)[b]	Radionuclide	Quantity (□Ci)[b]
Plutonium-235	1,000	Berkelium-245	100
Plutonium-236		Berkelium-246	100.001
Plutonium-237	100	Berkelium-247	0.001
Plutonium-238	0.001	Berkelium-249	0.1
Plutonium-239	0.001	Berkelium-250	10
Plutonium-240	0.001	Californium-244	100
Plutonium-241	0.01	Californium-246	1
Plutonium-242	0.001	Californium-248	0.01
Plutonium-243	1,000	Californium-249	0.001
Plutonium-244	0.001	Californium-250	0.001
Plutonium-245	100	Californium-251	0.001
Americium-237	1,000	Californium-252	0.001
Americium-238	100	Californium-253	0.1
Americium-239	1,000	Californium-254	0.001
Americium-240	100	Einsteinium-250	100
Americium-241	0.001	Einsteinium-251	100
Americium-242m	0.001	Einsteinium-253	0.1
Americium-242	10	Einsteinium-254m	1
Americium-243	0.001	Einsteinium-254	0.01
Americium-244m	100	Fermium-252	1
Americium-244	10	Fermium-253	1
Americium-245	1,000	Fermium-254	10
Americium-246m	1,000	Fermium-255	1
Americium-246	1,000	Fermium-257	0.01
Curium-238	100	Mendelevium-257	10
Curium-240	0.1	Mendelevium-258	0.01
Curium-241	1		
Curium-242	0.01	Any alpha-emitting radionuclide not	
Curium-243	0.001	listed above or mixtures of alpha	
Curium-244	0.001	emitters of unknown composition	0.001
Curium-245	0.001		
Curium-246	0.001	Any radionuclide other than alpha-	
Curium-247	0.001	emitting radionuclides not listed above, or	
Curium-248	0.001	mixtures of beta emitters of unknown	
Curium-249	1,000	composition	0.01

NOTE: For purposes of ~~S~~subsections 6. 27.e., 6.30.a.1., and 6.53.a. where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed one"1" -- that is, unity.

[a] The quantities listed above were derived by taking one tenth (1/10) of the most restrictive ALI listed in Table I, Columns 1 and 2, of Table 64-23 F, rounding to the nearest factor of ten (10), and constraining the values listed between thirty seven (37) Bq and thirty seven (37) MBq (one one-thousand [0.001] and one thousand [1,000] □Ci). Values of three and seven one-hundredths (3.7) MBq (one hundred [100] □Ci) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, thirty seven (37) MBq (one thousand [1,000] □Ci), to take into account their low specific activity.

[b/] To convert □Ci to kBq, multiply the □Ci value by thirty seven (37).

[c] *See explanation at the end of this listing.*

[b] *To convert μCi to kBq, multiply the μCi value by 37.*

TABLE 64-23 H

REQUIREMENTS FOR TRANSFER OF LOW-LEVEL RADIOACTIVE WASTE FOR DISPOSAL AT LAND DISPOSAL FACILITIES AND MANIFESTS

Section I. - Manifest.

The shipment manifest shall contain the name, address, and telephone number of the person generating the waste. The manifest shall also include the name, address, and telephone number or the name and the environmental protection agency hazardous waste identification number of the person transporting the waste to the land disposal facility. The manifest shall also indicate: a physical description of the waste, the volume, radionuclide identity and quantity, the total radioactivity, and the principal chemical form. The solidification agent shall be specified. Waste containing more than one tenth (0.1) percent chelating agents by weight shall be identified and the weight percentage of the chelating agent estimated. Wastes classified as Class A, Class B, or Class C in ~~S~~section I of Table 64-23 I shall be clearly identified as such in the manifest. The total quantity of the radionuclides Hydrogen-3, Carbon-14, Technetium-99, and Iodine-129 shall be shown. The manifest required by this paragraph may be shipping papers used to meet the Department of Transportation or the Environmental Protection Agency regulations or requirements of the receiver, provided all the required information is included. Copies of manifests required by this section may be legible carbon copies or legible photocopies.

Section II. - Certification.

The waste generator shall include in the shipment manifest a certification that the transported materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the department of transportation and the agency. An authorized representative of the waste generator shall sign and date the manifest.

Section III. - Control and Tracking.

a. Any radioactive waste generator who transfers radioactive waste to a land disposal facility or a registered waste collector shall comply with the requirements in (a)(1) through (8). Any radioactive waste generator who transfers waste to a registered waste processor who treats or repackages waste shall comply with the requirements of (a)(4) through (8). A registrant shall:

1. Prepare all wastes so that the waste is classified according to ~~S~~section I of Table 64-23 I meets the waste characteristics requirements in ~~S~~section II of Table 64-23 I;

2. Label each package of waste to identify whether it is class a waste, Class B waste, or Class C waste, in accordance with ~~S~~section I of Table 64-23 I;

3. Conduct a quality control program to ensure compliance with ~~S~~sections I and II of Table 64-23 K; the program shall include management evaluation of audits;

4. Prepare shipping manifests to meet the requirements of ~~Sections~~sections I and II;

5. Forward a copy of the manifest to the intended recipient, at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation from the collector;

6. Include one copy of the manifest with the shipment;

7. Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of registered material as required by section 11.26. of this rule; and

8. For any shipments or any portion of a shipment for which acknowledgment of receipt has not been received within the times set forth in this section, conduct an investigation in accordance with section III.(e).

b. Any waste collector registrant who handles only prepackaged waste shall:

1. Acknowledge receipt of the waste from the generator within one (1) week of receipt by returning a signed copy of the manifest or equivalent documentation;

2. Prepare a new manifest to reflect consolidated shipments; the new manifest shall serve as a listing or index for the detailed generator manifests. Copies of the generator manifests shall be a part of the new manifest. The waste collector may prepare a new manifest without attaching the generator manifests, provided the new manifest contains for each package the information specified in section I. The collector registrant shall certify that nothing has been done to the waste that would invalidate the generator's certification;

3. Forward a copy of the new manifest to the land disposal facility operator at the time of shipment;

4. Include the new manifest with the shipment to the disposal site;

5. Retain a copy of the manifest and documentation of acknowledgment of receipt as the record of transfer of registered material as required by subsection 11.26. of this rule, and retain information from generator manifest until the registration is terminated and disposition is authorized by the agency; and

6. For any shipments or any portion of a shipment for which acknowledgment of receipt is not received within the times set forth in this section, conduct an investigation in accordance with section III.(e).

c. Any registered waste processor who treats or repackages wastes shall:

1. Acknowledge receipt of the waste from the generator within one (1) week of receipt by returning a signed copy of the manifest or equivalent documentation;

2. Prepare a new manifest that meets the requirements of sections I and II. Preparation of the new manifest reflects that the processor is responsible for the waste;

3. Prepare all wastes so that the waste is classified according to section I of Table 64-23 I and meets the waste characteristics requirements in section II of Table 64-23 I;

4. Label each package of waste to identify whether it is class A waste, class B waste, or class C waste, in accordance with Section I and III of Table 64-23 I;

5. Conduct a quality control program to ensure compliance with sections I and II of Table 64-23 I. The program shall include management evaluation of audits;

6. Forward a copy of the new manifest to the disposal site operator or waste collector at the time of shipment, or deliver to a collector at the time the waste is collected, obtaining acknowledgment of receipt in the form of a signed copy of the manifest or equivalent documentation by the collector;

7. Include the new manifest with the shipment;

8. Retain copies of original manifests and new manifests and documentation of acknowledgment of receipt as the record of transfer of registered material required by section 11.26. of this rule; and

9. For any shipment or portion of a shipment for which acknowledgment is not received within the times set forth in this section, conduct an investigation in accordance with section III.(e).

d. The land disposal facility operator shall:

1. Acknowledge receipt of the waste within one (1) week of receipt by returning a signed copy of the manifest or

equivalent documentation to the shipper. The shipper to be notified is the registrant who last possessed the waste and transferred the waste to the operator. The returned copy of the manifest or equivalent documentation shall indicate any discrepancies between materials listed on the manifest and materials received;

2. Maintain copies of all completed manifests or equivalent documentation until the agency authorizes their disposition; and

3. Notify the shipper, that is, the generator, the collector, or processor, and the agency when any shipment or portion of a shipment has not arrived within sixty (60) days after the advance manifest was received.

e. Any shipment or portion of a shipment for which acknowledgment is not received within the times set forth in this section shall:

1. Be investigated by the shipper if the shipper has not received notification or receipt within twenty (20) days after transfer; and

2. Be traced and reported to whom. The investigation shall include tracing the shipment and filing a report with the agency. Each registrant who conducts a trace investigation shall file a written report with the agency within two (2) weeks of completion of the investigation.

TABLE 64-23 I
CLASSIFICATION AND CHARACTERISTICS OF LOW-LEVEL RADIOACTIVE WASTE

Section i. - Classification of Radioactive Waste for Land Disposal.

a. Considerations. Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

b. Classes of waste.

1. Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of class a waste must meet the minimum requirements set forth in subsection II.(a). If Class a waste also meets the stability requirements set forth in subsection II.(b), it is not necessary to segregate the waste for disposal.

2. Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of class B waste must meet both the minimum and stability requirements set forth in Section II.

3. Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of class C waste must meet both the minimum and stability requirements set forth in Section II.

c. Classification determined by long-lived radionuclides. If the radioactive waste contains only radionuclides listed in Table 64-23 J, classification shall be determined as follows:

1. If the concentration does not exceed 0.1 times the value in Table 64-23 J, the waste is Class A.

2. If the concentration exceeds 0.1 times the value in Table 64-23 J, but does not exceed the value in Table 64-23 J, the waste is Class C.

3. If the concentration exceeds the value in Table 64-23 J, the waste is not generally acceptable for land disposal.

4. For wastes containing mixtures of radionuclides listed in Table J, the total concentration shall be determined by the sum of fractions rule described in subsection I.(g).

TABLE 64-23 J

Rationuclide	Concentration Curie/Cubic[Meter]	Nano curie/[Grab]
C-14	8	
C-14 in activated metal	80	
No-59 in activated metal	220	
Nb-94 in activated metal	0.2	
To-99	3	
I-129	0.08	
Alpha emitting transuranic radionuclides with half-life greater than five years		100
Pu-241		3,500
Cm-242		20,000
Ra-226		100

[a] To convert the Ci/[me] values to gigabecquerel (GBq) per cubic meter, multiply the Ci/[me] value by thirty seven (37).

[b] To convert the nCi/g values to becquerel (Bq) per gram, multiply the nCi/g value by thirty seven (37).

d. Classification determined by short-lived radionuclides. If the waste does not contain any of the radionuclides listed in Table 64-23 J, classification shall be determined based on the concentrations shown in Table 64-23 K. However, as specified in subsection I.(f), if radioactive waste does not contain any nuclides listed in either Table 64-23 J or K, it is Class A.

1. If the concentration does not exceed the value in column 1, the waste is Class A.

2. If the concentration exceeds the value in column 1 but does not exceed the value in column 2, the waste is class B.

3. If the concentration exceeds the value in column 2 but does not exceed the value in column 3, the waste is class C.

4. If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

5. For wastes containing mixtures of the radionuclides listed I Ttable M, the total concentration shall be determined by the sum of fractions rule described in subsection I(g).

TABLE 64-23 K

Radionuclide	Concentration		Curie/Cubic Meter[a]
	Column 1	Column 2	Column 3
Total of all radio-nuclides with less than 5-year half-life	700	*	*
H-3 40	*	*	
Co-60	700	*	*
No-63	3.5	70	700
No-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137 1	44	4600	

[a]AGENCY NOTE: To convert the Ci/meter^3 value to gigabecquerel (GBq) per cubic meter, multiply the Ci/meter^3 value by thirty seven (37). There are no limits established for these radionuclides in class b or c wastes. Practical considerations such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. These wastes shall be class b unless the concentrations of other radionuclides in table 64-23 K determine the waste to be class c independent of these radionuclides.

e. Classification determined by both long- and short-lived radionuclides. If the radioactive waste contains a mixture of radionuclides, some of which are listed in table 64-23 J and some of which are listed in table 64-23 K, classification shall be determined as follows:

1. If the concentration of a radionuclide listed in table 64-23 J is less than one tenth (0.1) times the value listed in table 64-23 J, the class shall be that determined by the concentration of radionuclides listed in table 64-23 K.

2. If the concentration of a radionuclide listed in table 64-23 J exceeds 0.1 times the value listed in table l, but does not exceed the value in table 64-23 J, the waste shall be class c, provided the concentration of radionuclides listed in table 64-23 K does not exceed the value shown in column 3 of table 64-23 K.

f. Classification of wastes with radionuclides other than those listed in tables 64-23 J and K. If the waste does not contain any radionuclides listed in either table 64-23 J or K, it is class a..

g. The sum of the fractions rule for mixtures of radionuclides. For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each radionuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than one (1.0) if the waste class is to be determined by that column. Example: A waste contains Sr-90 in a concentration of one and eighty five one-hundredths (1.85) TBq/^{me} (fifty [50] Ci/^{me}) and Cs-137 in a concentration of eight hundred fourteen (814) GBq/^{me} (twenty two (22) Ci/^{me}). Since the concentrations both exceed the values in Column 1, Table M, they must be compared to Column 2 values. For Sr-90 fraction, fifty one hundredths (50/150) = thirty three one-hundredths (0.33)., for Cs-137 fraction, twenty two forty four one-hundredths (22/44) = fife tenths (0.5); the sum of the fractions = eighty three one-hundredths (0.83). Since the sum is less than one (1.0), the waste is Class B.

h. Determination of concentrations in wastes. The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste, or weight of the waste if the units are expressed as becquerel (nanocurie) per gram.

Section ii. - Radioactive Waste Characteristics.

a. The following are minimum requirements for all classes of waste and are intended to facilitate handling and provide protection of health and safety of personnel at the disposal site.

1. Wastes shall be packaged in conformance with the conditions of the registration issued to the site operator to which the waste will be shipped. Where the conditions of the site registration are more restrictive than the provisions of section 6., the site registration conditions shall govern.

2. Wastes shall not be packaged for disposal in cardboard or fiberboard boxes.

3. Liquid waste shall be packaged in sufficient absorbent material to absorb twice the volume of the liquid.

4. Solid waste containing liquid shall contain as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one (1) percent of the volume.

5. Waste shall not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

6. Waste shall not contain, or be capable of generating, quantities of toxic gases, vapors, or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with ~~Section II.(a)(8)~~paragraph II(a)(8).

7. Waste must not be pyrophoric. Pyrophoric materials contained in wastes shall be treated, prepared, and packaged to be nonflammable.[g]

8. Wastes in a gaseous form shall be packaged at an absolute pressure that does not exceed 1.5 atmospheres at twenty (20)□C. Total activity shall not exceed three and seven tenths (3.7) TBq (one hundred [100] Ci) per container.

9. Wastes containing hazardous, biological, pathogenic, or infectious material shall be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

b. The following requirements are intended to provide stability of the waste. Stability is intended to ensure that the waste does not degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and nondispersible waste.

1. Waste shall have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture, and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

2. Notwithstanding the provisions in ~~S~~section II.(a)(3) and (4), liquid wastes, or wastes containing liquid, shall be converted into a form that contains as little free-standing and non-corrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one (1) percent of the volume of the waste when the waste is in a disposal container designed to ensure stability, or five tenths (0.5) percent of the volume of the waste for waste processed to a stable form.

3. Void spaces within the waste and between the waste and its package shall be reduced to the extent practicable.

Section iii. - Labeling.

Each package of waste shall be clearly labeled to identify whether it is Class A, Class B, or Class C waste, in accordance with section I.

[g] See section 3.66 of these rules for definition of pyrophoric material.

TABLE 64-23 L

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie[a]	Material	Microcurie[a]
Americium-241	0.01	Gallium-72	10
Antimony-122	100	Germanium-71	0
Antimony-124	10	Hafnium-181	10
Antimony-125	10	Holmium-166	100
Arsenic-73	100	Hydrogen-3	1,000
Arsenic-74	10	Indium-113m	100
Arsenic-76	10	Indium-114m	10
Arsenic-77	100	Indium-115m	100
Barium-131	10	Indium-115	10
Barium-133	10	Iodine-125	1
Barium-140	10	Iodine-126	1
Bismuth-210	1	Iodine-129	0.1
Bromine-82	10	Iodine-131	1
Cadmium-109	10	Iodine-132	10
Cadmium-115m	10	Iodine-133	1
Cadmium-115	100	Iodine-134	10
Calcium-45	10	Iodine-135	10
Calcium-47	10	Iridium-192	10
Carbon-14	100	Iridium-194	100
Cerium-141	100	Iron-55	100
Cerium-143	100	Iron-59	10
Cerium-144	1	Krypton-85	100
Cesium-131	1,000	Krypton-87	10
Cesium-134m	100	Lanthanum-140	10
Cesium-134	1	Lutetium-177	100
Cesium-135	10	Manganese-52	10
Cesium-136	10		
Cesium-137	10		
Chlorine-36	10		
Chlorine-38	10		
Chromium-51	1,000		
Cobalt-58m	10		
Cobalt-58	10		
Cobalt-60	1		
Copper-64	100		
Dysprosium-165	10		
Dysprosium-166	100		
Erbium-169	100		
Erbium-171	100		
Europium-152 (9.2 h)	100		
Europium-152 (13 yr)	1		
Europium-154	1		
Europium-155	10		
Florine-18	1,000		
Gadolinium-153	10		
Gadolinium-159	100		

[a] To convert μCi to kBq, multiply the μCi value by 37.

TABLE 64-23 L

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie[a]	Material	Microcurie[a]
Manganese-54	10	Rubidium-86	10
Manganese-56	10	Rubidium-87	10
Mercury-197m	100	Ruthenium-97	100
Mercury-197	100	Ruthenium-103	10
Mercury-203	10	Ruthenium-105	10
Molybdenum-99	100	Ruthenium-106	1
Neodymium-147	100	Samarium-151	10
Neodymium-149	100	Samarium-153	100
Nickel-59	100	Scandium-46	10
Nickel-63	10	Scandium-47	100
Nickel-65	100	Scandium-48	10
Niobium-93m	10	Selenium-75	10
Niobium-95	10	Silicon-31	100
Niobium-97	10	Silver-105	10
Osmium-185	10	Silver-11Om	1
Osmium-191m	100	Silver-111	100
Osmium-191	100	Sodium-22	1
Osmium-193	100	Sodium-24	10
Palladium-103	100	Strontium-85	10
Palladium-109	100	Strontium-89	1
Phosphorus-32	10	Strontium-90	0.1
Platinum-191	100	Strontium-91	10
Platinum-193m	100	Strontium-92	10
Platinum-193	100	Sulfur -35	100
Platinum-197m	100	Tantalum-182	10
Platinum-197	100	Technetium-96	10
Plutonium-239	0.01	Technetium-97m	100
Polonium-210	0.1	Technetium-97	100
Potassium-42	10	Technetium-99m	100
Praseodymium-142	100	Technetium-99	10
Praseodymium-143	100	Tellurium-125m	10
Promethium-147	10	Tellurium-127m	10
Promethium-149	10	Tellurium-127	100
Radium-226	0.01	Tellurium-129m	10
Rhenium-186	100	Tellurium-129	100
Rhenium-188	100	Tellurium-131m	10
Rhodium-103m	100	Tellurium-132	10
Rhodium-105	100	Terbium-160	10

[a] To convert μCi to kBq, multiply the μCi value by 37.

TABLE 64-23 L

QUANTITIES FOR USE WITH DECOMMISSIONING

Material	Microcurie[a]	Material	Microcurie[a]
Thallium-200	100	Yttrium-90	10
Thallium-201	100	Yttrium-92	100
Thallium-202	100	Yttrium-93	100
Thallium-204	10	Zinc-65	10
Thorium (natural)[aa]	100	Zinc-69m	100
Thulium-170	10	Zinc-69	1,000
Thulium-171	10	Zirconium-93	10
Tin-113	10	Zirconium-95	10
Tin-125	10	Zirconium-97	10
Tungsten-181	10		
Tungsten-185	10	Any alpha emitting	
Tungsten-187	100	radionuclide not listed	
Uranium (natural)[aaa]	100	above or mixtures of	
Uranium-233	0.01	alpha emitters of	
Uranium-234	0.01	unknown composition	0.01
Uranium-235	0.01		
Vanadium-48	10	Any radionuclide other	
Xenon-131m	1,000	than alpha emitting	
Xenon-133	100	radionuclides, not	
Xenon-135	100	listed above or mixtures	
Ytterbium-175	100	of beta emitters of	
		unknown composition	0.1

NOTE: Where there is involved a combination of isotopes in known amounts, the limit for the combination should be derived as follows: Determine, for each isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all the isotopes in the combination may not exceed one (1) -- that is, unity.]

[a] To convert μCi to kBq, multiply the μCi value by 37.

[aa] Based on alpha disintegration rate of Th-232, Th-230 and their daughter products.

[aaa] Based on alpha disintegration rate of U-238, U-234, and U-235.

TABLE 64-23 M

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
°C	°F	
26.7	80	2
26.1	79	2
25.6	78	22
25.0	77	22
24.4	76	3
23.9	75	3
23.3	74	32
22.8	73	32
22.2	72	4
21.7	71	4
21.1	70	42
20.6	69	42
20.0	68	5
19.4	67	52
18.9	66	52
18.3	65	6
17.8	64	62
17.2	63	7
16.7	62	8
16.1	61	82
15.6	60	92

TABLE 64-23 N

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
[a/] Immersion time only, no crossover time included.		

TABLE 64-23 O

Design Operating Range	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		Dental Intra-Oral Manufactured Before Aug. 1, 1974 and On or After Dec. 1, 1980	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5
Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

TABLE 64-23 P

DETERMINATION OF COMPETENCE

The following are areas in which the agency considers it important that an individual have expertise for the competent operation of x-ray equipment:

a. Familiarization with equipment
   1. Identification of controls
   2. Function of each control
   3. How to use a technique chart

b. Radiation Protection
   1. Collimation
   2. Filtration
   3. Gonad shielding and other patient protection devices if used
   4. Restriction of x-ray tube radiation to the image receptor
   5. Personnel protection
   6. Grids

c. Film Processing
   1. Film speed as related to patient exposure
   2. Film processing parameters
   3. Quality assurance program

d. Emergency Procedures
   1. Termination of exposure in event of automatic timing device failure

e. Proper Use of Personnel Dosimetry, if Required

f. Understanding Units of Radiation

TABLE 64-23 Q

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

In order for the agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.

a. The plans showing, as a minimum, the following:

1. The normal location of the system's radiation port; the port's travel and traverse limits; general direction or directions of the useful beam; locations of any windows and doors or other openings; the location of the operator's booth; and the location of the control panel;

2. The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room or rooms concerned;

3. The dimensions of the room or rooms concerned;

4. The type of occupancy of all adjacent areas inclusive of space above and below the room or rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present;

5. The make and model of the equipment, the maximum technique factors, and the energy waveform (single phase, three phase, etc.);

6. The type of examination or examinations or treatment or treatments which will be performed with the equipment.

b. Information on the anticipated workload of the system or systems in mA-minutes per week.

c. A report showing all basic assumptions used in the development of the shielding specifications.

TABLE 64-23 R

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

a. Space Requirements:

1. The operator shall be allotted not less than seven tenths (0.70) m5 (seven and five tenths [7.5] square feet) of unobstructed floor space in the booth;

2. The operator's booth may be any geometric configuration with no dimension of less than six tenths (0.6) m (two [2] feet);

3. The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments;

4. The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall-mounted image receptor will not reach the operator's position in the booth.

b. Structural Requirements:

1. The booth walls shall be permanently fixed barriers of at least two (2) m (seven [7] feet) high;

2. When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed;

3. Shielding shall be provided to meet the requirements of ~~S~~section 6. of this rule.

c. Radiation Exposure Control Placement:

1. The radiation exposure control for the system shall be fixed within the booth and:

A. Shall be at least one (1.0) m (forty [40] inches) from any point subject to direct scatter, leakage or primary beam radiation;

B. Shall allow the operator to use the majority of the available viewing windows.

d. Viewing System Requirements:

1. Each booth shall have at least one viewing device which will:

A. Be so placed that the operator can view the patient during any exposure; and

B. Be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "x-ray on" warning sign that will be lighted anytime the rotor of the x-ray tube is activated. Alternatively, an interlock shall be present such that exposures are prevented unless the door is closed.

2. When the viewing system is a window, the following requirements also apply:

A. The window shall have a viewing area of at least 0.09 m5 (1 square foot);

B. Regardless of size or shape, at least nine one-hundredths (0.09) m5 (one (1) square foot) of the window area must be centered no less than six tenths (0.6) m (two [2] feet) from the open edge of the booth and no less than one and five tenths (1.5) m (five (5.0) feet) from the floor;

C. The window shall have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

3. When the viewing system is by mirrors, the mirror or mirrors shall be so located as to accomplish the general requirements of section 6.5.

4. When the viewing system is by electronic means:

A. The camera shall be so located as to accomplish the general requirements of section 6.5.; and

B. There shall be an alternate viewing system as a backup for the primary system.

TABLE 64-23 S

EXEMPTIONS FROM SHIELDING
FOR CERTAIN FLUOROSCOPIC PROCEDURES

a. Angiograms

b. Arthrograms

c. Biliary drainage procedures

d. Fluoroscopic biopsy procedures

e. Myelograms

f. Percutaneous cholangiograms

g. Percutaneous nephrostomies

h. Sinograms or fistulograms

i. T-tube cholangiograms

TABLE 64-23 T

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation:

a. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;

b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;

c. A detailed description of the x-ray examinations proposed in the screening program;

d. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;

e. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;

f. An evaluation by a qualified expert of the x-ray system or systems to be used in the screening program. The evaluation by the qualified expert shall show that such system or systems do satisfy all requirements of this rule. The evaluation shall include a measurement of patient exposures from the x-ray examinations to be performed;

g. A description of the diagnostic x-ray quality control program;

h. A copy of the technique chart for the x-ray examination procedures to be used;

i. The qualifications of each individual who will be operating the x-ray system or systems;

j. The qualifications of the individual who will be supervising the operators of the x-ray system or systems. The extent of supervision and the method of work performance evaluation shall be specified;

k. The name and address of the individual who will interpret the radiographs;

l. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated;

m. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;

n. An indication of the frequency of screening and the duration of the entire screening program.

TABLE 64-23 U

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

a. All ~~Therapeutic~~ Radiation Machines.

1. Basic facility information including: name, telephone number and agency registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; and the street address [including room number] of the therapeutic radiation machine facility. The plan should also indicate whether this is a new structure or a modification to existing structures.

2. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

3. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

~~b. Therapeutic Radiation Machines up to one hundred fifty (150) Kv (photons only). In addition to the requirements listed in section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to one hundred fifty (150) Kv shall submit shielding plans which contain, as a minimum, the following additional information:~~

~~4.~~1. Equipment specifications, including the manufacturer and model number of the ~~therapeutic~~ radiation machine, as well as the maximum technique factors;

5.~~2.~~ Maximum design workload for the facility including total weekly radiation output, [expressed in gray (Rad) or air kerma at 1 meter], total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

6.~~3.~~ A facility blueprint or drawing indicating: scale (0.25 inch = one foot is typical); direction of North; normal location of the ~~therapeutic~~ radiation machine's radiation ports; the port's travel and traverse limits; general directions of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the control panel shall be behind a protective barrier sufficient to ensure compliance with subsection 6.5 of this rule;

7.~~4.~~ The structural composition and thickness or lead or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the rooms concerned;

8~~5.~~ The type of occupancy of all adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present; and

9~~6.~~ At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition i.e.: primary and secondary or leakage barriers, restricted and unrestricted areas, entry doors) and shielding material in the facility:

A. If commercial software is used to generate shielding requirements, please also identify the software used and the version or revision date.

B. If the software used to generate shielding requirements is not in the open literature, please also submit quality control sample calculations to verify the result obtained with the software.

~~c.~~b. Therapeutic Radiation Machines. ~~Over one hundred fifty (150) Kv.~~ In addition to the

requirements listed ~~in section I~~ above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 Kv or electrons shall submit shielding plans which contain, as a minimum, the following additional information:

~~a.~~ A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (Rad) at the isocenter and the energies and types of radiation produced (i.e.: photon, electron). The target to isocenter distance shall be specified;

~~b. Maximum design workload for the facility including total weekly radiation output (expressed in gray [Rad] at one [1] meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;~~

~~c. Facility blueprint or drawing (including both floor plan and elevation views) indicating relative orientation of the therapeutic radiation machine, scale (twenty five one-hundredths [0.25] inch = one [1] foot is typical), types, thickness and minimum density of shielding materials, direction of North, the locations and size of all penetrations through each shielding barrier (ceiling, walls and floor), as well as details of the doors and maze;~~

~~d. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the rooms concerned;~~

~~e. The type of occupancy of all adjacent areas inclusive of space above and below the rooms concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present;~~

~~f.~~ B. Description of all assumptions that were in shielding calculations including, but not limited to, design energy (i.e.: room may be designed for six MV unit although only a four MV unit is currently proposed), work-load, presence of integral beam-stop in unit, occupancy and uses of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor and ceiling) and "allowed" radiation exposure in both restricted and unrestricted areas; and

~~g.~~ C. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e.: primary and secondary or leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors and maze) and shielding material in the facility:

1. If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date; and

2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

~~h.~~c. Neutron Shielding.

A. In addition to the requirements listed ~~in section iii~~ above, therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans which contain, as a minimum, the following additional information:

B. ~~a.~~ The structural composition, thickness, minimum density and location of all neutron shielding material;

C. ~~b.~~ Description of all assumptions that were used in neutron shielding calculations including, but not limited to, neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas; and

D. ~~c.~~ At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e.: restricted and unrestricted areas, entry doors and maze) and neutron shielding material utilized in the facility:

1. If commercial software is used to generate shielding requirements, also identify the software used and the version or revision date; and

2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

E. ~~d.~~ The methods and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

~~e.~~ References

1. NCRP Report 49, "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to 10 MeV" (1976).

2. NCRP Report 51, "Radiation Protection Design Guidelines for 0.1-100 MeV Particle Accelerator Facilities" (1977).

3. NCRP Report 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

TABLE 64-23 V

QUALITY MANAGEMENT PROGRAM

a. In addition to the definitions in subsection 7.12.b., the following definitions are applicable to a quality management program:

1. Misadministration - the administration of an external beam radiation therapy dose:

A. Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

B. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

C. When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

D. When the calculated total administered dose differs from the total prescribed dose by more than twenty (20) percent of the total prescribed dose;

2. Prescribed dose - the total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic radiation machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique;

3. Recordable event - the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

4. Written directive - an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

b. Scope and Applicability. Each applicant or registrant subject to subsection 7.12.f or 7.12.g shall establish and maintain a written quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program shall include written policies and procedures to meet the following specific objectives:

1. Prior to administration, a written directive is prepared for any external beam radiation therapy dose;

A. Notwithstanding section b.1, a written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to administration of the external beam radiation therapy dose or the next external beam radiation therapy fractional dose;

B. Notwithstanding section b.1, if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive shall be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

C. Notwithstanding section b.1, if, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive shall be acceptable, provided that the information contained in the oral directive is documented immediately in

the patient's record and a written directive is prepared and signed by an authorized user within 24 hours of the oral directive.

2. Prior to the administration of each course of radiation treatments, the patient's identity is verified, by more than one method, as the individual named in the written directive;

3. External beam radiation therapy final plans of treatment and related calculations are in accordance with the respective written directives;

4. Each administration is in accordance with the written directive; and

5. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

c. Development of Quality Management Program.

1. Each application for registration subject to subdivisions 7.12.f.g or 7.12.g shall include a quality management program that specifies staff, duties and responsibilities, and equipment and procedures as part of the application required by section 5 of this rule. The registrant shall implement the program upon issuance of a registration by the agency;

2. Each existing registrant subject to subsections 7.12.g or 7.12.h shall, within 30 days of July 1, 2001, submit to the agency a written certification that a quality management program has been implemented.

d. As a part of the quality management program, the registrant shall:

1. Develop procedures for, and conduct a review of, the quality management program including, since the last review, an evaluation of a representative sample of patient administrations, all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program;

2. Conduct these reviews at intervals not to exceed 12 months;

3. Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the requirements of section b; and

4. Maintain records of each review, including the evaluations and findings of the review, in an auditable form, for three years.

e. The registrant shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

1. Assembling the relevant facts including the cause;

2. Identifying what, if any, corrective action is required to prevent recurrence; and

3. Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

f. The registrant shall retain:

1. Each written directive; and

2. A record of each administered radiation dose, in an auditable form, for three years after the

date of administration.

g. The registrant may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased.

h. The registrant shall evaluate each misadministration and shall take the following actions in response to a misadministration:

1. Notify the agency by telephone no later than the next calendar day after discovery of the misadministration;

2. Submit a written report to the agency within 15 days after discovery of the misadministration. The written report shall include: the registrant's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the registrant notified the patient or the patient's responsible relative or guardian (this person will subsequently be referred to as "the patient"), and if not, why not, and if the patient was notified, what information was provided to the patient. The report shall not include the patient's name or other information that could lead to identification of the patient;

3. Notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the patient or that, based on medical judgment, telling the patient would be harmful. The registrant is not required to notify the patient without first consulting with the referring physician. If the referring physician or patient cannot be reached within 24 hours, the registrant shall notify the patient as soon as possible. The registrant shall not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification;

4. Retain a record of each misadministration for five years. The record shall contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence; and

5. If the patient was notified, furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either a copy of the report that was submitted to the agency, or a brief description of both the event and the consequences as they may effect the patient, provided a statement is included that the report submitted to the agency can be obtained from the registrant;

j. Aside from the notification requirement, nothing in subdivision 7.12.e.8 affects any rights or duties of registrants and physicians in relation to each other, patients, or the patient's responsible relatives or guardians.

TABLE 64-23 W

ALTERNATIVE QUALITY MANAGEMENT PROGRAM

a. In addition to the definitions in subsection 7.12.b, the following definitions are applicable to a quality management program:

1. Misadministration - the administration of an external beam radiation therapy dose:

A. Involving the wrong patient, wrong treatment modality, or wrong treatment site; or,

B. When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose; or

C. When the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

D. When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

2. Recordable event - the administration of an external beam radiation therapy dose when the calculated weekly administered dose differs by 15 percent or more from the weekly prescribed dose;

3. Written directive - an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information: total dose, dose per fraction, treatment site and overall treatment period.

b. Each registrant shall establish and maintain a written program to provide assurance that radiation is administered to humans as directed by the authorized user. The program shall include the following elements:

1. Procedure for preparing written directives for the administration of radiation, however, a written directive is not required when an authorized user personally administers a dosage provided the pertinent facts are documented as otherwise required;

2. Procedure for verifying by more than one method the identity of the individual to be administered radiation;

3. Procedure for updating the therapy operating and emergency procedures manual;

4. Procedure for verifying that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

5. Procedures assuring that administration of radiation is carried out as specified in the written directive or the therapy operating and emergency procedures manual;

6. Procedures for identifying and evaluating unintended deviations from the written directive or the therapy operating and emergency procedures manual including taking appropriate action for recordable events and misadministrations;

c. Each registrant shall evaluate and respond to misadministrations.

d. Each registrant shall evaluate and respond to recordable events within 30 days after discovery by assembling the relevant facts, identifying the cause of the recordable event, and taking

appropriate action, if any is required, to prevent recurrence.

e. Each registrant shall conduct an annual evaluation of the human administration program including any recommendations for changes to be made as well as any modifications made since the last evaluation and, if required, revise procedures to assure that the radiation is administered as directed by the authorized user. Modifications made to the program shall not decrease the effectiveness of the program.

f. Each registrant shall retain, in auditable form, for three years:

1. Each written directive;

2. A record of each administered radiation dose where a written directive is required;

3. A record of each annual review of the program including the evaluations and findings of the review;

4. A record of each recordable event, the relevant facts, and any corrective actions taken.

TABLE 64-23 X

SUBJECTS FOR INSTRUCTION OF RADIOGRAPHER TRAINEES

Training provided to qualify individuals as radiographer trainees in compliance with subsection 8.14.a. shall be presented on a formal basis. The training shall include the following subjects:

a. Fundamentals of Radiation Safety
    1. Characteristics of radiation
    2. Units of radiation dose and quantity of radioactivity
    3. Significance of radiation dose
        A. Radiation protection standards
        B. Biological effects of radiation
        C. Case histories of radiography accidents
        D. Levels of radiation from sources of radiation
    4. Methods of controlling radiation dose
        A. Working time
        B. Working distances
        C. Shielding

b. Radiation Detection Instrumentation to be Used
    1. Use of radiation survey instruments
        A. Operation
        B. Calibration
        C. Limitations
    2. Survey techniques
    3. Use of personnel monitoring equipment
        A. Film badges
        B. Thermoluminescent dosimeters (TLD's)
        C. Pocket dosimeters

c. The Requirements of Pertinent Federal and State Rules

d. The Registrant's Written Operating and Emergency Procedures

e. Radiographic Equipment to be Used
    1. Remote handling equipment
    2. Operation and control of radiographic exposure devices and sealed sources, including pictures or models of source assemblies (pigtails)
    3. Storage and transport containers, source changers
    4. Operation and control of x-ray equipment
    5. Collimators

TABLE 64-23 Y

EXEMPT CONCENTRATIONS

Element (atomic number)	Column I Radionuclide	Column II Solid Concentration Ci/ml[1]	Column III Liquid and Gas concentration μCi/ml[2]
Antimony (51)	Sb-122		$3X10^{-4}$
	Sb-124		$2X10^{-4}$
	Sb-125		$1X10^{-3}$
Argon (18)	Ar-37	$1X10^{-3}$	
	Ar-41	$4X10^{-7}$	
Arsenic (33)	As-73		$5X10^{-3}$
	As-74		$5X10^{-4}$
	As-76		$2X10^{-4}$
	As-77		$8X10^{-4}$
Barium (56)	Ba-131		$2X10^{-3}$
	Ba-140		$3X10^{-4}$
Beryllium (4)	Be-7		$2X10^{-2}$
Bismuth (83)	Bi-206		$4X10^{-4}$
Bromine (35)	Br-82	$4X10^{-7}$	$3X10^{-3}$
Cadmium (48)	Cd-109		$2X10^{-3}$
	Cd-115m		$3X10^{-4}$
	Cd-115		$3X10^{-4}$
Calcium (20)	Ca-45		$9X10^{-5}$
	Ca-47		$5X10^{-4}$
Carbon (6)	C-14	$1X10^{-6}$	$8X10^{-3}$
Cerium (58)	Ce-141		$9X10^{-4}$
	Ce-143		$4X10^{-4}$
	Ce-144		$1X10^{-4}$
Cesium (55)	Cs-131		$2X10^{-2}$
	Cs-134m		$6X10^{-2}$
	Cs-134		$9X10^{-5}$
Chlorine (17)	Cl-38	$9X10^{-7}$	$4X10^{-3}$
Chromium (24)	Cr-51		$2X10^{-2}$
Cobalt (27)	Co-57		$5X10^{-3}$
	Co-58		$1X10^{-3}$
	Co-60		$5X10^{-4}$

[1] Values are given in Column 1 for those materials normally used as a gas.

[2] μCi/g for solids.

TABLE 64-23 Y

EXEMPT CONCENTRATIONS

Element (atomic number)	Column I Radionuclide	Column II Gas concentration Ci/ml[1]	Liquid and solid concentration μCi/ml[2]
Copper (29)	Cu-64		$3X10^{-3}$
Dysprosium (66)	Dy-165		$4X10^{-3}$
	Dy-166		$4X10^{-4}$
Erbium (68)	Er-169		$9X10^{-4}$
	Er-171		$1X10^{-3}$
Europium (63)	Eu-152(9.2 h)		$6X10^{-4}$
	Eu-155		$2X10^{-3}$
Fluorine (9)	F-18	$2X10^{-6}$	$8X10^{-3}$
Gadolinium (64)	Gd-153		$2X10^{-3}$
	Gd-159		$8X10^{-4}$
Gallium (31)	Ga-72		$4X10^{-4}$
Germanium (32)	Ge-71		$2X10^{-2}$
Gold (79)	Au-196		$2X10^{-3}$
	Au-198		$5X10^{-4}$
	Au-199		$2X10^{-3}$
Hafnium (72)	Hf-181		$7X10^{-4}$
Hydrogen (1)	H-3	$5X10^{-6}$	$3X10^{-2}$
Indium (49)	In-113m		$1X10^{-2}$
	In-114m		$2X10^{-4}$
Iodine (53)	I-126	$3X10^{-9}$	$2X10^{-5}$
	I-131	$3X10^{-9}$	$2X10^{-5}$
	I-132	$8X10^{-8}$	$6X10^{-4}$
	I-133	$1X10^{-8}$	$7X10^{-5}$
	I-134	$2X10^{-7}$	$1X10^{-3}$
Iridium (77)	Ir-190		$2X10^{-3}$
	Ir-192		$4X10^{-4}$
	Ir-194		$3X10^{-4}$
Iron (26)	Fe-55		$8X10^{-3}$
	Fe-59		$6X10^{-4}$
Krypton (36)	Kr-85m	$1X10^{-6}$	
	Kr-85	$3X10^{-6}$	

[1] Values are given in Column 1 for those materials normally used as a gas.

[2] μCi/g for solids.

TABLE 64-23 Y

EXEMPT CONCENTRATIONS

Element (atomic number)	Column I Radionuclide	Column II Gas concentration Ci/ml[1]	Liquid and solid concentration μCi/ml[2]
Lanthanum (57)	La-140		$2X10^{-4}$
Lead (82)	Pb-203		$4X10^{-3}$
Lutetium (71)	Lu-177		$1X10^{-3}$
Manganese (25)	Mn-52		$3X10^{-4}$
	Mn-54		$1X10^{-3}$
	Mn-56		$1X10^{-3}$
Mercury (80)	Hg-197m		$2X10^{-3}$
	Hg-197		$3X10^{-3}$
	Hg-203		$2X10^{-4}$
Molybdenum (42)	Mo-99		$2X10^{-3}$
Neodymium (60)	Nd-147		$6X10^{-4}$
	Nd-149		$3X10^{-3}$
Nickel (28)	Ni-65		$1X10^{-3}$
Niobium (Columbium) (41)	Nb-95		$1X10^{-3}$
	Nb-97		$9X10^{-3}$
Osmium (76)	Os-185		$7X10^{-4}$
	Os-191m		$3X10^{-2}$
	Os-191		$2X10^{-3}$
	Os-193		$6X10^{-4}$
Palladium (46)	Pd-103		$3X10^{-3}$
	Pd-109		$9X10^{-4}$
Phosphorus (15)	P-32		$2X10^{-4}$
Platinum (78)	Pt-191		$1X10^{-3}$
	Pt-193m		$1X10^{-2}$
	Pt-197m		$1X10^{-2}$
	Pt-197		$1X10^{-3}$
Potassium (19)	K-42		$3X10^{-3}$
Praseodymium (59)	Pr-142		$3X10^{-4}$
	Pr-143		$5X10^{-4}$
Promethium (61)	Pm-147	$2X10^{-3}$	
	Pm-149	$4X10^{-4}$	

[1] Values are given in Column 1 for those materials normally used as a gas.

[2] μCi/g for solids.

TABLE 64-23 Y

EXEMPT CONCENTRATIONS

Element (atomic number)	Column I Radionuclide	Column II Gas concentration Ci/ml[1]	Liquid and solid concentration μCi/ml[2]
Rhenium (75)	Re-183		$6X10^{-3}$
	Re-186		$9X10^{-4}$
Selenium (34)	Se-75		$3X10^{-3}$
Silicon (14)	Si-31		$9X10^{-3}$
Silver (47)	Ag-105		$1X10^{-3}$
	Ag-110m		$3X10^{-4}$
	Ag-111		$4X10^{-4}$
Sodium (11)	Na-24		$2X10^{-3}$
Strontium (38)	Sr-85		$1X10^{-3}$
	Sr-89		$1X10^{-4}$
	Sr-91		$7X10^{-4}$
	Sr-92		$7X10^{-4}$
Sulfur (16)	S-35	$9X10^{-8}$	$6X10^{-4}$
Tantalum (73)	Ta-182		$4X10^{-4}$
Technetium (43)	Tc-96m		$1X10^{-1}$
	Tc-96		$1X10^{-3}$
Tellurium (52)	Te-125m		$2X10^{-3}$
	Te-127m		$6X10^{-4}$
	Te-127		$3X10^{-3}$
	Te-129m		$3X10^{-4}$
	Te-131m		$6X10^{-4}$
	Te-132		$3X10^{-4}$
Terbium (65)	Tb-160		$4X10^{-4}$
Thallium (81)	Tl-200		$4X10^{-3}$
	Tl-201		$3X10^{-3}$
	Tl-202		$1X10^{-3}$
	Tl-204		$1X10^{-3}$
Thulium (69)	Tm-170		$5X10^{-4}$
	Tm-171		$5X10^{-3}$
Tin (50)	Sn-113		$9X10^{-4}$
	Sn-125		$2X10^{-4}$
Tungsten (Wolfram) (74)	W-181		$4X10^{-3}$
	W-187		$7X10^{-4}$
Vanadium (23)	V-48		$3X10^{-4}$
Xenon (54)	Xe-131m	$4X10^{-6}$	
	Xe-133	$3X10^{-6}$	
	Xe-135	$1X10^{-6}$	

[1] Values are given in Column 1 for those materials normally used as a gas.

[2] μCi/g for solids.

TABLE 64-23 Y

EXEMPT CONCENTRATIONS

Element (atomic number)	Column I Radionuclide	Column II Gas concentration Ci/ml[1]	Liquid and solid concentration µCi/ml[2]
Ytterbium (70)	Yb-175		$1X10^{-3}$
Yttrium (39)	Y-90		$2X10^{-4}$
	Y-91m		$3X10^{-2}$
	Y-91		$3X10^{-4}$
	Y-92		$6X10^{-4}$
	Y-93		$3X10^{-4}$
Zinc (30)	Zn-65		$1X10^{-3}$
	Zn-69m		$7X10^{-4}$
	Zn-69		$2X10^{-2}$
Zirconium (40)	Zr-95		$6X10^{-4}$
	Zr-97		$2X10^{-4}$
Beta or gamma emitting radioactive material not listed above with half-life of less than three (3) years.		$1X10^{-10}$	$1X10^{-6}$

Note 1: Many radionuclides transform into other radionuclides. In expressing the concentrations in Table 64-23 E, the activity stated is that of the parent radionuclide and takes into account the radioactive decay products.

Note 2: For purposes of section 11.3. where there is involved a combination of radionuclides, the limit for the combination should be derived as follows: Determine for each radionuclide in the product the ratio between the radioactivity concentration present in the product and the exempt radioactivity concentration established in Table 64-23 Y for the specific radionuclide when not in combination. The sum of such ratios may not exceed one (1).

Example:

$$\frac{\text{Concentration of Radionuclide A in Product}}{\text{Exempt concentration of Radionuclide A}} + \frac{\text{Concentration of Radionuclide B in Product}}{\text{Exempt concentration of Radionuclide B}} < 1$$

Note 3: To convert µCi/ml to SI units of megabecquerels per liter multiply the above values by thirty seven (37).

Example: Zirconium (40) Zr-97 (two one-thousandths [$2x10^{-4}$]µCi/ml multiplied by thirty seven (37) is equivalent to seventy four one-thousandths [74×10^{-4}] Mbq/l).

[1] Values are given in Column 1 for those materials normally used as a gas.

[2] μCi/g for solids.

TABLE 64-23 Z

EXEMPT QUANTITIES

Radioactive Material	Microcuries	Radioactive Material	Microcuries
Antimony-122 (Sb 122)	100	Europium-152 (Eu 152)9.2h	100
Antimony-124 (Sb 124)	10	Europium-152 (Eu 152)13 yr	1
Antimony-125 (Sb 125)	10	Europium-154 (Eu 154)	1
Arsenic-73 (As 73)	100	Europium-155 (Eu 155)	10
Arsenic-74 (As 74)	10	Fluorine-18 (F 18)	1,000
Arsenic-76 (As 76)	10	Gadolinium-153 (Gd 153)	10
Arsenic-77 (As 77)	100	Gadolinium-159 (Gd 159)	100
Barium-131 (Ba 131)	10	Gallium-67 (Ga 67)	100
Barium-133 (Ba 133)	10	Gallium-72 (Ga 72)	10
Barium-140 (Ba 140)	10	Germanium-68 (Ge 68)	10
Bismuth-210 (Bi 210)	1	Germanium-71 (Ge 71)	100
Bromine-82 (Br 82)	10	Gold-195 (Au 195)	10
Cadmium-109 (Cd 109)	10	Gold-198 (Au 198)	100
Cadmium-115m (Cd 115m)	10	Gold-199 (Au 199)	100
Cadmium-115 (Cd 115)	100	Hafnium-181 (Hf 181)	10
Calcium-45 (Ca 45)	10	Holmium-166 (Ho 166)	100
Calcium-47 (Ca 47)	10	Hydrogen-3 (H 3)	1,000
Carbon-14 (C 14)	100	Indium-111 (In 111)	100
Cerium-141 (Ce 141)	100	Indium-113m (In 113m)	100
Cerium-143 (Ce 143)	100	Indium-114m (In 114m)	10
Cerium-144 (Ce 144)	1	Indium-115m (In 115m)	100
Cesium-129 (Cs 129)	100	Indium-115 (In 115)	10
Cesium-131 (Cs 131)	1,000	Iodine-123 (I 123)	100
Cesium-134m (Cs 134m)	100	Iodine-125 (I 125)	1
Cesium-134 (Cs 134)	1	Iodine-126 (I 126)	1
Cesium-135 (Cs 135)	10	Iodine-129 (I 129)	0.1
Cesium-136 (Cs 136)	10	Iodine-131 (I 131)	1
Cesium-137 (Cs 137)	10	Iodine-132 (I 132)	10
Chlorine-36 (Cl 36)	10	Iodine-133 (I 133)	1
Chlorine-38 (Cl 38)	10	Iodine-134 (I 134)	10
Chromium-51 (Cr 51)	1,000	Iodine-135 (I 135)	10
Cobalt-57 (Co 57)	100	Iridium-192 (Ir 192)	10
Cobalt-58m (Co 58m)	10	Iridium-194 (Ir 194)	100
Cobalt-58 (Co 58)	10	Iron-52 (Fe 52)	10
Cobalt-60 (Co 60)	1	Iron-55 (Fe 55)	100
Copper-64 (Cu 64)	100	Iron-59 (Fe 59)	10
Dysprosium-165 (Dy 165)	10	Krypton-85 (Kr 85)	100
Dysprosium-166 (Dy 166)	100	Krypton-87 (Kr 87)	10
Erbium-169 (Er 169)	100	Lanthanum-140 (La 140)	10
Erbium-171 (Er 171)	100		

TABLE 64-23 Z

EXEMPT QUANTITIES

Radioactive Material	Microcuries	Radioactive Material	Microcuries
Lutetium-177 (Lu 177)	100	Ruthenium-103 (Ru 103)	10
Manganese-52 (Mn 52)	10	Ruthenium-105 (Ru 105)	10
Manganese-54 (Mn 54)	10	Ruthenium-106 (Ru 106)	1
Manganese-56 (Mn 56)	10	Samarium-151 (Sm 151)	10
Mercury-197m (Hg 197m)	100	Samarium-153 (Sm 153)	100
Mercury-197 (Hg 197)	100	Scandium-46 (Sc 46)	10
Mercury-203 (Hg 203)	10	Scandium-47 (Sc 47)	100
Molybdenum-99 (Mo 99)	100	Scandium-48 (Sc 48)	10
Neodymium-147 (Nd 147)	100	Selenium-75 (Se 75)	10
Neodymium-149 (Nd 149)	100	Silicon-31 (Si 31)	100
Nickel-59 (Ni 59)	100	Silver-105 (Ag 105)	10
Nickel-63 (Ni 63)	10	Silver-110m (Ag 110m)	1
Nickel-65 (Ni 65)	100	Silver-111 (Ag 111)	100
Niobium-93m (Nb 93m)	10	Sodium-22 (Na 22)	10
Niobium-95 (Nb 95)	10	Sodium-24 (Na 24)	10
Niobium-97 (Nb 97)	10	Strontium-85 (Sr 85)	10
Osmium-185 (Os 185)	10	Strontium-89 (Sr 89)	1
Osmium-191m (Os 191m)	100	Strontium-90 (Sr 90)	0.1
Osmium-191 (Os 191)	100	Strontium-91 (Sr 91)	10
Osmium-193 (Os 193)	100	Strontium-92 (Sr 92)	10
Palladium-103 (Pd 103)	100	Sulphur-35 (S 35)	100
Palladium-109 (Pd 109)	100	Tantalum-182 (Ta 182)	10
Phosphorus-32 (P 32)	10	Technetium-96 (Tc 96)	10
Platinum-191 (Pt 191)	100	Technetium-97m (Tc 97m)	100
Platinum-193m (Pt 193m)	100	Technetium-97 (Tc 97)	100
Platinum-193 (Pt 193)	100	Technetium-99m (Tc 99m)	100
Platinum-197m (Pt 197m)	100	Technetium-99 (Tc 99)	10
Platinum-197 (Pt 197)	100	Tellurium-125m (Te 125m)	10
Polonium-210 (Po 210)	0.1	Tellurium-127m (Te 127m)	10
Potassium-42 (K 42)	10	Tellurium-127 (Te 127)	100
Potassium-43 (K 43)	10	Tellurium-129m (Te 129m)	10
Praseodymium-142 (Pr 142)	100	Tellurium-129 (Te 129)	100
Praseodymium-143 (Pr 143)	100	Tellurium-131m (Te 131m)	10
Promethium-147 (Pm 147)	10	Tellurium-132 (Te 132)	10
Promethium-149 (Pm 149)	10	Terbium-160 (Tb 160)	10
Rhenium-186 (Re 186)	100	Thallium-200 (Tl 200)	100
Rhenium-188 (Re 188)	100	Thallium-201 (Tl 201)	100
Rhodium-103m (Rh 103m)	100	Thallium-202 (Tl 202)	100
Rhodium-105 (Rh 105)	100	Thallium-204 (Tl 204)	10
Rubidium-81 (Rb 81)	10	Thulium-170 (Tm 170)	10
Rubidium-86 (Rb 86)	10	Thulium-171 (Tm 171)	10
Rubidium-87 (Rb 87)	10		
Ruthenium-97 (Ru 97)	100		

TABLE 64-23 Z

EXEMPT QUANTITIES

Radioactive Material	Microcuries	Radioactive Material	Microcuries
Tin-113 (Sn 113)	10	Yttrium-92 (Y 92)	100
Tin-125 (Sn 125)	10	Yttrium-93 (Y 93)	100
Tungsten-181 (W 181)	10	Zinc-65 (Zn 65)	10
Tungsten-185 (W 185)	10	Zinc-69m (Zn 69m)	100
Tungsten-187 (W 187)	100	Zinc-69 (Zn 69)	1,000
Vanadium-48 (V 48)	10	Zirconium-93 (Zr 93)	10
Xenon-131m (Xe 131m)	1,000	Zirconium-95 (Zr 95)	10
Xenon-133 (Xe 133)	100	Zirconium-97 (Zr 97)	10
Xenon-135 (Xe 135)	100		
Ytterbium-175 (Yb 175)	100		
Yttrium-87 (Y 87)	10	Any radioactive material	
Yttrium-88 (Y 88)	10	not listed above other than	
Yttrium-90 (Y 90)	10	alpha-emitting radioactive	
Yttrium-91 (Y 91)	10	material	0.1

TABLE 64-23 Z

EXEMPT QUANTITIES

Note 1: For purposes of Paragraph 11.14.e.2. where there is involved a combination of radionuclides, the limit for the combination should be derived as follows:

Determine the amount of each radionuclide possessed and one thousand (1,000) times the amount in Table 64-23 Z for each of those radionuclides when not in combination. The sum of the ratios of those quantities may not exceed one (1).

Example:

$$\frac{\text{Amt. of Radionuclide A possessed}}{\text{1000 x Table 64-23 Z quantity for Radionuclide A}} + \frac{\text{Amt. of Radionuclide B possessed}}{\text{1000 x Table 64-23 Z quantity for Radionuclide B}} \leq 1$$

Note 2: To convert microcuries (μCi) to SI units of kilobecquerels (kBq), multiply the above values by thirty-seven (37).

Example: Zirconium-97 (ten [10] μCi multiplied by thirty-seven [37] is equivalent to three hundred seventy [370] kBq).

TABLE 64-23 Aa

LIMITS FOR BROAD REGISTRATIONS

Radioactive Material	Column I Curies	Column II Curies
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	1.
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1

TABLE 64-23 Aa

LIMITS FOR BROAD REGISTRATIONS

Radioactive Material	Column I Curies	Column II Curies
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1.
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-57	10	0.1
Cobalt-58m	100	1.
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1.
Dysprosium-166	10	0.1
Erbium-171	10	0.1
Europium-152 (9.2 h)	10	0.1
Europium-152 (13 y)	0.1	.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1.
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1.
Indium-113m	100	1.

TABLE 64-23 Aa

LIMITS FOR BROAD REGISTRATIONS

Radioactive Material	Column I Curies	Column II Curies
Indium-114m	10	.01
Indium-115m	100	1.
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1.
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-54	10	0.1
Mercury-197m	10	0.1
Mercury-197	10	0.1
Mercury-203	1	0.01
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	10	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1.
Osmium-185	1	0.01
Osmium-191m	100	1.
Osmium-191	10	0.1
Osmium-193	10	0.1

TABLE 64-23 Aa

LIMITS FOR BROAD REGISTRATIONS

Radioactive Material	Column I Curies	Column II Curies
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1.
Platinum-193	10	0.1
Platinum-197m	100	1.
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-142	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10.
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1.
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10.

TABLE 64-23 Aa

LIMITS FOR BROAD REGISTRATIONS

Radioactive Material	Column I Curies	Column II Curies
Strontium-85	1	0.01
Strontium-89	10	.01
Strontium-90	0.01	0.001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulphur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	1	0.1
Technetium-97	10	0.1
Technetium-99m	100	1.
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1.
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Thallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01

TABLE 64-23 Aa

LIMITS FOR BROAD REGISTRATIONS

Radioactive Material	Column I Curies	Column II Curies
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1.
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than source material, special nuclear material, or alpha emitting radioactive material not listed above.	0.1	0.001

Note 1: To convert curies (Ci) to SI units of gigabecquerels (GBq), multiply the above values by thirty seven (37).

Example: Zirconium-97 (Col. II) (one one-hundredth [0.01] Ci multiplied by thirty seven [37] is equivalent to thirty seven one-thousandths [0.37] GBq).

TABLE 64-23 Bb

Uranium enrichment in weight percent of Uranium-235 not exceeding	Permissible maximum grams of Uranium-235 per package
24	40
20	42
15	45
11	48
10	51
9.5	52
9	54
8.5	55
8	57
7.5	59
7	60
6.5	62
6	65
5.5	68
5	72
4.5	76
4	80
3.5	88
3	100
2.5	120
2	164
1.5	272
1.35	320
1	680 *
0.92	1200 *

TABLE 64-23 Cc

Uranium enrichment in weight percent of Uranium-235 not exceeding	Permissible maximum grams of Uranium-235 per package
4	84
3.5	92
3	112
2.5	148
2	240
1.5	560 *

* Pursuant to the agency's agreement with the NRC, jurisdiction extends only to three hundred fifty (350) grams of uranium.

TABLE 64-23 Dd

Removable External Radioactive Contamination Wipe Limits

Maximum Permissible Limits

Contaminant	μCi/cm²*	dpm/cm²
Beta-gamma emitting radionuclides; all radionuclides with half-lives less than ten days; natural uranium; natural thorium; Uranium-235; Uranium-238; Thorium-232; Thorium-228 and Thorium-230 when contained in ores or physical concentrates	10^{-5}	22
All other alpha emitting radionuclides	10^{-6}	2.2

TABLE 64-23 Ee

DETERMINATION OF A_1 AND A_2

a. Single Radionuclides

1. For a single radionuclide of known identity, the values of A_1 and A_2 are taken from table i if listed there. The values A_1 and A_2 in Table 64-23 Ee A are also applicable for the radionuclide contained in (α,n) or (γ,n) neutron sources.

2. For any single radionuclide whose identity is known but which is not listed in Table 64-23 Ee A, the value of A_1 and A_2 are determined according to the following procedure:

A. If the radionuclide emits only one type of radiation, A_1 is determined according to the following method. For radionuclides emitting different kinds of radiation, A_1 is the most restrictive value of those determined for each kind of radiation. However, in either case, A_1 is restricted to a maximum of one thousand (1000) curies (thirty seven [37] TBq). If a parent nuclide decays into a shorter lived daughter with a half-life not greater than ten (10) days, A_1 is calculated for both the parent and the daughter, and the more limiting of the two values is assigned to the parent nuclide.

B. For gamma emitters, A_1 is determined by the expression:

$$A_1 = \frac{\text{Nine (9) curies}}{\Gamma}$$

where Γ is the gamma-ray constant, corresponding to the dose in roentgens per curie-hour at one (1) meter, and the number nine (9) results from the choice of one (1) Rem per hour at a distance of three (3) meters as the reference dose-equivalent rate.

C. For x-ray emitters, A_1 is determined by the atomic number of the nuclide:

for $Z \leq 55$, A_1 = One thousand (1000) Ci (thirty seven [37] TBq); and

for $Z > 55$, A_1 = Two hundred (200) Ci (seven and four-tenths [7.4] TBq)

where Z is the atomic number of the nuclide.

D. For beta emitters, A_1 is determined by the maximum beta energy (E_{max}) according to Table 64-23 Ee B; and

E. For alpha emitters, A_1 is determined by the expression:

$$A_1 = 1000\ A_3$$

where A_3 is the value listed in Table 63-23 Ee C;

F. A_2 is the more restrictive of the following two values:

1. The corresponding A_1; and

2. The value A_3 obtained from table 64-23 Ee C.

3. For any single radionuclide whose identity is unknown, the value of A_1 is taken to be 2 Ci (74 GBq) and the value of A_2 is taken to be 0.002 Ci (74 MBq). However, if the atomic number of the radionuclide is known to be less than 82, the value of A_1 is taken to be 10 Ci (370 GBq) and the value of A_2 is taken to be 0.4 Ci (14.8 GBq).

b. Mixtures of Radionuclides, Including Radioactive Decay Chains

1. For mixed fission products, the activity limit may be assumed if a detailed analysis of the mixture is not carried out,

A_1 = 10 Ci (370 GBq)

A_2 = 0.4 Ci (14.8 GBq)

2. A single radioactive decay chain is considered to be a single radionuclide when the radionuclides are present in their naturally occurring proportions and no daughter nuclide has a half-life either longer than ten (10) days or longer than that of the parent nuclide. The activity to be taken into account and the A_1 or A_2 value from Table Ee A to be applied are those corresponding to the parent nuclide of that chain. When calculating A_1 or A_2 values, radiation emitted by daughters must be considered. However, in the case of radioactive decay chains in which any daughter nuclide has a half-life either longer than ten (10) days or greater than that of the parent nuclide, the parent and daughter nuclides are considered to be mixtures of different nuclides.

3. In the case of a mixture of different radionuclides, where the identity and activity of each radionuclide are known, the permissible activity of each radionuclide R_1, R_2 . . . R_n is such that $F_1 + F_2 + . . . F_n$ is not greater than unity, where:

F_1 = Total activity of R_1
$A_i(R_1)$

F_2 = Total activity of R_2
$A_i(R_2)$

F_n = Total activity of R_n
$A_i(R_n)$ and

A_i (R_1, R_2. .R_n) is the value of A_1 or A_2 as appropriate for the nuclide R_1, R_2. .R_n.

4. When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the formula given in Paragraph 3. is applied to establish the values of A_1 or A_2 as appropriate. All the radionuclides whose individual activities are not known (their total activity will, however, be known) are classed in a single group and the most restrictive value of A_1 and A_2 applicable to any one of them is used as the value of A_1 or A_2 in the denominator of the fraction.

5. Where the identity of each radionuclide is known but the individual activity of none of the radionuclides is known, the most restrictive value of A_1 or A_2 applicable to any one of the radionuclides present is adopted as the applicable value.

6. When the identity of none of the nuclides is known, the value of A_1 is taken to be two (2) Ci (seventy four [74] GBq) and the value of A_2 is taken to be two one-thousandths (0.002) Ci (seventy four [74] MBq). However, if alpha emitters are known to be absent, the value of A_2 is taken to be four tenths (0.4) Ci (fourteen and eight tenths [14.8] GBq).

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Ac-227	Actinium (89)	1000	0.003	7.2×10^{1}
Ac-228		10	4	2.2×10^{6}
Ag-105	Silver (47)	40	40	3.1×10^{4}
Ag-110m		7	7	4.7×10^{3}
Ag-111	Silver (47)	100	20	1.6×10^{5}
Am-241	Americium (95)	8	0.008	3.2
Am-243		8	0.008	1.9×10^{-1}
Ar-37	(compressed or Argon uncompressed)*	1000	1000	1.0×10^{5}
Ar-41	(uncompressed)*	20	2	4.3×10^{7}
Ar-41	(compressed)*	1	1	4.3×10^{7}
As-73	Arsenic (33)	1000	400	2.4×10^{4}
As-74		20	20	1.0×10^{5}
As-76		10	10	1.6×10^{6}
As-77		300	20	1.1×10^{6}
At-211	Astatine (85)	200	7	2.1×10^{6}
Au-193	Gold (79)	200	200	9.3×10^{5}
Au-196		30	30	1.2×10^{5}
Au-198		40	20	2.5×10^{5}
Au-199		200	25	2.1×10^{5}
Ba-131	Barium (56)	40	40	8.7 x 104
Ba-133		40	40	4.0×10^{2}
Ba-140		20	20	7.3×10^{4}
Be-7	Beryllium (4)	300	300	3.5×10^{5}
Bi-206	Bismuth (83)	5	5	9.9×10^{4}
Bi-207	Bismuth (83)	10	10	2.2×10^{2}
Bi-210 (RaE)		100	4	1.2×10^{5}
Bi-212		6	6	1.5×10^{7}
Bk-249	Berkelium (97)	1000	1	1.8×10^{3}
Br-77	Bromine (35)	70	25	7.1×10^{5}
Br-82		6	6	1.1×10^{6}
C-11	Carbon (6)	20	20	8.4×10^{8}
C-14		1000	60	4.6
Ca-45	Calcium (20)	1000	25	1.9×10^{4}
Ca-47		20	20	5.9×10^{5}
Cd-109	Cadmium (48)	1000	70	2.6×10^{3}
Cd-115m		30	30	2.6×10^{4}
Cd-115		80	20	5.1×10^{5}
Ce-139	Cerium (58)	100	100	6.5×10^{3}
Ce-141		300	25	2.8×10^{4}

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Ce-143		60	20	6.6×10^{5}
Ce-144		10	7	3.2×10^{3}
Cf-249	Californium (98)	2	0.002	3.1
Cf-250		7	0.007	1.3×10^{2}
Cf-252		2	0.009	6.5×10^{2}
Cl-36	Chlorine (17)	300	10	3.2×10^{-2}
Cl-38		10	10	1.3×10^{8}
Cm-242	Curium (96)	200	0.2	3.3×10^{3}
Cm-243		9	0.009	4.2×10^{1}
Cm-244		10	0.01	8.2×10^{1}
Cm-245		6	0.006	1.0×10^{-1}
Cm-246		6	0.006	3.6×10^{-1}
Co-56	Cobalt (27)	5	5	3.0×10^{4}
Co-57		90	90	8.5×10^{3}
Co-58m		1000	1000	5.9×10^{6}
Co-58		20	20	3.1×10^{4}
Co-60		7	7	1.1×10^{3}
Cr-51	Chromium (24)	600	600	9.2×10^{4}
Cs-129	Cesium (55)	40	40	7.6×10^{5}
Cs-131		1000	1000	1.0×10^{5}
Cs-134m		1000	10	7.4×10^{6}
Cs-134		10	10	1.2×10^{3}
Cs-135		1000	25	8.8×10^{-4}
Cs-136		7	7	7.4×10^{4}
Cs-137		30	10	9.8×10^{1}
Cu-64	Copper (29)	80	25	3.8×10^{6}
Cu-67		200	25	7.9×10^{5}
Dy-165	Dysprosium (66)	100	20	8.2×10^{6}
Dy-166		1000	200	2.3×10^{5}
Er-169	Erbium (68)	1000	25	8.2×10^{4}
Er-171		50	20	2.4×10^{6}
Eu-152m	Europium (63)	30	30	2.2×10^{6}
Eu-152		20	10	1.9×10^{2}
Eu-154		10	5	1.5×10^{2}
Eu-155		400	60	1.4×10^{3}
F-18	Fluorine (9)	20	20	9.3×10^{7}
Fe-55		1000	1000	2.2×10^{3}
Fe-59		10	10	4.9×10^{4}
Ga-67	Gallium (31)	100	100	6.0×10^{5}
Ga-68		20	20	4.0×10^{7}
Ga-72		7	7	3.1×10^{6}

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Gd-153	Gadolinium (64)	200	100	3.6×10^3
Gd-159		300	20	1.1×10^6
Ge-68	Germanium (32)	20	10	7.0×10^3
Ge-71		1000	1000	1.6×10^5
H-3Hydrogen (1)	see T-Tritium			
Hf-181	Hafnium (72)	30	25	1.6×10^4
Hg-197m	Mercury (80)	200	200	6.6×10^5
Hg-197		200	200	2.5×10^5
Hg-203		80	25	1.4×10^4
Ho-166	Holmium (67)	30	30	6.9×10^5
I-123	Iodine (53)	50	50	1.9×10^6
I-125		1000	70	1.7×10^4
I-126		40	10	7.8×10^4
I-129		1000	2	1.6×10^{-4}
I-131		40	10	1.2×10^5
I-132		7	7	1.1×10^7
I-133		30	10	1.1×10^6
I-134		8	8	2.7×10^7
I-135		10	10	3.5×10^6
In-111	Indium (49)	30	25	4.2×10^5
In-113m		60	60	1.6×10^7
In-114m		30	20	2.3×10^4
In-115m	Indium (49)	100	20	6.1×10^6
Ir-190	Iridium (77)	10	10	6.2×10^4
Ir-192		20	10	9.1×10^3
Ir-194		10	10	8.5×10^5
K-42	Potassium (19)	10	10	6.0×10^6
K-43		20	10	3.3×10^6
Kr-85m (uncompressed)*	Krypton (36)	100	100	8.4×10^6
Kr-85m (compressed)*		3	3	8.4×10^6
Kr-85 (uncompressed)*		1000	1000	4.0×10^2
Kr-85 (compressed)*		5	5	4.0×10^2
Kr-87 (uncompressed)*		20	20	2.8×10^7
Kr-87 (compressed)*		0.6	0.6	2.8×10^7
La-140	Lanthanum (57)	30	30	5.6×10^5
Lu-177	Lutetium (71)	300	25	1.1×10^5
MFP	Mixed Fission Products	10	0.4	---------
Mg-28	Magnesium (12)	6	6	5.2×10^6
Mn-52	Manganese (25)	5	5	4.4×10^5
Mn-54		20	20	8.3×10^3

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Mn-56		5	5	2.2×10^{7}
Mo-99	Molybdenum (42)	100	20	4.7×10^{5}
N-13	Nitrogen (7)	20	10	1.5×10^{9}
Na-22	Sodium (11)	8	8	6.3×10^{3}
Na-24		5	5	8.7×10^{6}
Nb-93m	Niobium (41)	1000	200	1.1×10^{3}
Nb-95		20	20	3.9×10^{4}
Nb-97		20	20	2.6×10^{7}
Nd-147	Neodymium (60)	100	20	8.0×10^{4}
Nd-149		30	20	1.1×10^{7}
Ni-59	Nickel (28)	1000	900	8.1×10^{-2}
Ni-63		1000	100	4.6×10^{1}
Ni-65		10	10	1.9×10^{7}
Np-237	Neptunium (93)	5	0.005	6.9×10^{-4}
Np-239		200	25	2.3×10^{5}
Os-185	Osmium (76)	20	20	7.3×10^{3}
Os-191		600	200	4.6×10^{4}
Os-191m		200	200	1.2×10^{6}
Os-193		100	20	5.3×10^{5}
P-32	Phosphorus (15)	30	30	2.9×10^{5}
Pa-230	Protactinium (91)	20	0.8	3.2×10^{4}
Pa-231		2	0.002	4.5×10^{-2}
Pa-233	Protactinium (91)	100	100	2.1×10^{4}
Pb-201	Lead (82)	20	20	1.7×10^{6}
Pb-210		100	0.2	8.8×10^{1}
Pb-212		6	5	1.4×10^{6}
Pd-103	Palladium (46)	1000	700	7.5×10^{4}
Pd-109		100	20	2.1×10^{6}
Pm-147	Promethium (61)	1000	25	9.4×10^{2}
Pm-149		100	20	4.2×10^{5}
Po-210	Polonium (84)	200	0.2	4.5×10^{3}
Pr-142	Praseodymium (59)	10	10	1.2×10^{4}
Pr-143		300	20	6.6×10^{4}
Pt-191	Platinum (78)	100	100	2.3×10^{5}
Pt-193m		200	200	2.0×10^{5}
Pt-197m		300	20	1.2×10^{7}
Pt-197		300	20	8.8×10^{5}
Pu-238	Plutonium (94)	3	0.003	1.7×10^{1}
Pu-239		2	0.002	6.2×10^{-2}
Pu-240		2	0.002	2.3×10^{-1}
Pu-241		1000	0.1	1.1×10^{2}

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
Pu-242		3	0.003	3.9×10^{-3}
Ra-223	Radium (88)	50	0.2	5.0×10^{4}
Ra-224		6	0.5	1.6×10^{5}
Ra-226		10	0.05	1.0
Ra-228		10	0.05	2.3×10^{2}
Rb-81	Rubidium (37)	30	24	8.2×10^{6}
Rb-86		30	30	8.1×10^{4}
Rb-87		Unlimited	Unlimited	1.6×10^{-8}
Rb (natural)		Unlimited	Unlimited	1.8×10^{-8}
Re-186	Rhenium (75)	100	20	1.9×10^{5}
Re-187		Unlimited	Unlimited	3.8×10^{-8}
Re-188		10	10	1.0×10^{6}
Re (natural)		Unlimited	Unlimited	2.4×10^{-8}
Rh-103m	Rhodium (45)	1000	1000	3.2×10^{7}
Rh-105		200	25	8.2×10^{5}
Rn-222	Radon (86)	10	2	1.5×10^{5}
Ru-103		30	25	3.2×10^{4}
Ru-105		20	20	6.6×10^{6}
Ru-106		10	7	3.4×10^{3}
S-35	Sulphur (16)	1000	60	4.3×10^{4}
Sb-122	Antimony (51)	30	30	3.9×10^{5}
Sb-124		5	5	1.8×10^{4}
Sb-125		40	25	1.4×10^{3}
Sc-46	Scandium (21)	8	8	3.4×10^{4}
Sc-47		200	20	8.2×10^{5}
Sc-48		5	5	1.5×10^{6}
Se-75	Selenium (34)	40	40	1.4×10^{4}
Si-31	Silicon (14)	100	20	3.9×10^{7}
Sm-147	Samarium (62)	Unlimited	Unlimited	2.0×10^{-8}
Sm-151		1000	90	2.6×10^{1}
Sm-153		300	20	4.4×10^{5}
Sn-113	Tin (50)	60	60	1.0×10^{4}
Sn-119m		100	100	4.4×10^{3}
Sn-125		10	10	1.1×10^{5}
Sr-85m	Strontium (38)	80	80	3.2×10^{7}
Sr-85		30	30	2.4×10^{4}
Sr-87		50	50	1.2×10^{7}
Sr-89		100	10	2.9×10^{4}
Sr-90		10	0.4	1.5×10^{2}
Sr-91		10	10	3.6×10^{6}
Sr-92	Strontium (38)	10	10	1.3×10^{7}

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
T (uncompressed)*	Tritium (1)	1000	1000	9.7×10^3
T (compressed)*		1000	1000	9.7×10^3
T (activated luminous paint)		1000	1000	9.7×10^3
T (adsorbed on solid carrier)		1000	1000	9.7×10^3
T (tritiated water)		1000	1000	9.7×10^3
T (other forms)		20	20	9.7×10^3
Ta-182	Tantalum (73)	20	20	6.2×10^3
Tb-160	Terbium (65)	20	10	1.1×10^4
Tc-96m	Technetium (43)	1000	1000	3.8×10^7
Tc-96		6	6	3.2×10^5
Tc-97m		1000	200	1.5×10^4
Tc-97		1000	400	1.4×10^{-3}
Tc-99m		100	100	5.2×10^6
Tc-99		1000	25	1.7×10^{-2}
Te-125m	Tellurium (52)	1000	100	1.8×10^4
Te-127m		300	20	4.0×10^4
Te-127		300	20	2.6×10^6
Te-129m		30	10	2.5×10^4
Te-129		100	20	2.0×10^7
Te-131m	Tellurium (52)	10	10	8.0×10^5
Te-132		7	7	3.1×10^5
Th-227	Thorium (90)	200	0.2	3.2×10^4
Th-228		6	0.008	8.3×10^2
Th-230		3	0.003	1.9×10^{-2}
Th-231		1000	25	5.3×10^5
Th-232		Unlimited	Unlimited	1.1×10^{-7}
Th-234		10	10	2.3×10^4
Th (natural)		Unlimited	Unlimited	2.2×10^{-7}
Th (irradiated)**		---	---	---
Tl-200	Thallium (81)	20	20	5.8×10^5
Tl-201		200	200	2.2×10^5
Tl-202		40	40	5.4×10^4
Tl-204		300	10	4.3×10^2
Tm-170	Thulium (69)	300	10	6.0×10^3
Tm-171		1000	100	1.1×10^3
U-230	Uranium (92)	100	0.1	2.7×10^4
U-232		30	0.03	2.1×10^1
U-233		100	0.1	9.5×10^{-3}
U-234		100	0.1	6.2×10^{-3}
U-235	Uranium (92)	100	0.2	2.1×10^{-6}
U-236		200	0.2	6.3×10^{-5}
U-238		Unlimited	Unlimited	3.3×10^{-7}

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

Symbol of radionuclide	Element and atomic number	A_1(Ci)	A_2(Ci)	Specific Activity (Ci/g)
U (natural)		Unlimited	Unlimited	(see Table 64-23 Ee D)
U (enriched) <20%		Unlimited	Unlimited	(see Table 64-23 Ee D)
20% or greater		100	0.1	(see Table 64-23 Ee D)
U (depleted)		Unlimited	Unlimited	(see Table 64-23 Ee D)
U (irradiated)***		---	---	---
V-48	Vanadium (23)	6	6	1.7×10^5
W-181	Tungsten (74)	200	100	5.0×10^3
W-185		1000	25	9.7×10^{-3}
W-187		40	20	7.0×10^5
Xe-127 (uncompressed)*	Xenon (54)	70	70	2.8×10^4
Xe-127 (compressed)*		5	5	2.8×10^4
Xe-131m (compressed)*	10	10	1.0×10^5	
Xe-131m (uncompressed)*	100	100	1.0×10^5	
Xe-133 (uncompressed)*	1000	1000	1.9×10^5	
Xe-33 (compressed)*		5	5	1.9×10^5
Xe-135 (uncompressed)*	70	70	2.5×10^5	
Xe-135 (compressed)*		2	2	2.5×10^5
Y-87	Yttrium (39)	20	20	4.5×10^1
Y-90		10	10	2.5×10^5
Y-91m		30	30	4.1×10^7
Y-91		30	30	2.5×10^4
Y-92		10	10	9.5×10^6
Y-93		10	10	3.2×10^6
Yb-19	Ytterbium (70)	80	80	2.3×10^5
Yb-175		400	25	1.8×10^5
Zn-65	Zinc (30)	30	30	8.0×10^3
Zn-69m		40	20	3.3×10^6
Zn-69		300	20	5.3×10^7
Zr-93	Zirconium (40)	1000	200	3.5×10^{-3}
Zr-95		20	20	2.1×10^4
Zr-97		20	20	2.0×10^6

TABLE 64-23 Ee A

A_1 and A_2 Values for Radionuclides
(See Footnotes at end of Table)

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* For the purpose of Table Ee A, compressed gas means a gas at a pressure which exceeds the ambient atmospheric pressure at the location where the containment system was closed.

** The values of A_1 and A_2 must be calculated in accordance with the procedure specified in Table 64-23 Ee, Paragraph ii 3., taking into account the activity of the fission products and of the Uranium-233 in addition to that of the thorium.

*** The values of A_1 and A_2 must be calculated in accordance with the procedure specified in Table 64-23 Ee, Paragraph ii 3., taking into account the activity of the fission products and plutonium isotopes in addition to that of the uranium.

TABLE 64-23 Ee B

Relationship Between A_1 and E_{max} for Beta Emitters

E_{max}(MeV)	A_1(Ci)
< 0.5	1000
0.5 - < 1.0	300
1.0 - < 1.5	100
1.5 - < 2.0	30
≥ 2.0	10

TABLE 64-23 Ee C

Relationship Between A_3 and the Atomic Number of the Radionuclide A_3

Atomic Number	Half-life less than 1000 days	Half-life 1000 days to 10^6 years	Half-life greater than 10^6 years
1 to 81	3 Ci	0.05 Ci	3 Ci
82 and above	0.002 Ci	0.002 Ci	3 Ci

TABLE 64-23 Ee D

Activity-Mass Relationships for Uranium/Thorium

Thorium and Uranium Enrichment* wt % U-235 present	Specific Activity	
Ci/g	g/Ci	
0.45	5.0×10^{-7}	2.0×10^{6}
0.72 (natural)	7.06×10^{-7}	1.42×10^{6}
1.0	7.6×10^{-7}	1.3×10^{6}
1.5	1.0×10^{-6}	1.0×10^{6}
5.0	2.7×10^{-6}	3.7×10^{5}
10.0	4.8×10^{-6}	2.1×10^{5}
20.0	1.0×10^{-5}	1.0×10^{5}
35.0	2.0×10^{-5}	5.0×10^{4}
50.0	2.5×10^{-5}	4.0×10^{4}
90.0	5.8×10^{-5}	1.7×10^{4}
93.0	7.0×10^{-5}	1.4×10^{4}
95.0	9.1×10^{-5}	1.1×10^{4}
Natural Thorium	2.2×10^{-7}	4.6×10^{6}

TABLE 64-23 Ff

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

a. Fundamentals of Radiation Safety

1. Characteristics of radiation
2. Units of radiation dose and quantity of radioactivity
3. Significance of radiation dose
    A. Radiation protection standards
    B. Biological effects of radiation dose
4. Levels of radiation from sources of radiation
5. Methods of minimizing radiation dose

TABLE 64-23 Ff

SUBJECTS TO BE INCLUDED IN TRAINING COURSES FOR LOGGING SUPERVISORS

A. Working time

B. Working distances

C. Shielding

6. Radiation safety practices including prevention of contamination and methods of decontamination

b. Radiation Detection Instrumentation to be Used

1. Use of radiation survey instruments

2. Operation

3. Calibration

4. Limitations

5. Survey techniques

6. Use of personnel monitoring equipment

c. Equipment to be Used

1. Handling equipment

2. Sources of radiation

3. Storage and control of equipment

4. Operation and control of equipment

d. The Requirements of Pertinent Federal and State Regulations

e. The Registrant's Written Operating and Emergency Procedures

f. The Registrant's Record Keeping Procedures

TABLE 64-23 Gg

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES CONTAINING RADIOACTIVE MATERIAL ABANDONED DOWNHOLE

If you desire a copy of the graphic, please contact:

West Virginia Radiological Health Program.
815 Quarrier Street
Charleston, West Virginia 25301
(304) 558-3526

The size of the plaque should be convenient for use on active or inactive wells, e.g., a seven (7) inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., one half (½) inch and one quarter (¼) inch letter size, respectively.

TABLE 64-23 Hh

Part of Body	Column I* Dose	Column II* Dose	Column III* Dose
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.05 mSv (0.005 Rem)	5 mSv (0.5 Rem)	150 mSv (15 Rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	0.75 mSv (0.075 Rem)	75 mSv (7.5 Rem)	2000 mSv (200 Rem)
Other organs	0.15mSv (0.015 Rem)	15 mSv (1.5 Rem)	500 mSv (50 Rem)
*Dose limit is the dose above background from the product.			

TABLE 64-23 Ii

ACCEPTABLE SURFACE CONTAMINATION[1] LEVELS FOR TENORM

	AVERAGE[2, 3, 6]	MAXIMUM[2, 4, 6]	REMOVABLE[2, 3, 5, 6]
Alpha	5,000 dpm/100 cm^2	15,000 dpm /100 cm^2	1,000 dpm /100 cm^2
Beta-gamma	5,000 dpm/100 cm^2	15,000 dpm /100 cm^2	1,000 dpm /100 cm^2

[1] Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

[2] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[3] Measurements of average contamination level should not be averaged over more than one (1) square meter. For objects of less surface area, the average should be derived for each object.

[4] The maximum contamination level applies to an area of not more than one hundred (100) cm^2.

[5] The amount of removable radioactive material per one hundred (100) cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of surface area A (where A is less than one hundred [100] sq. cm) is determined, the entire surface should be wiped and the contamination level multiplied by 100/A to convert to a "per one hundred (100) sq cm" basis.

[6] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed two tenths (0.2) mRad/hr (two [2] μGy/hr) at one (1) cm and one (1.0) mR/hr (ten [10] μGy/hr) at one (1) cm, respectively, measured through not more than seven (7) milligrams per square centimeter of total absorber.