

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period, Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 27, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

Division of Health

FROM: (Agency name, Address & Phone No.) Department of Health and Human Resources

State Capitol Complex, Building 3, Room 265, Charleston, WV 25305

Telephone: (304) 558-3223

LEGISLATIVE RULE TITLE: Public Water Systems, 64 CSR 3.

1. Authorizing statute(s) citation: WV Code Section 16-1-9a.

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

June 30, 1998

b. What other notice, including advertising, did you give of the hearing?

The Office of Laboratory Services sent a letter to all currently certified laboratories advising them of the proposed changes, including a page from the current rule showing the proposed changes.

c. Date of Public Hearing(s) or Public Comment Period ended:

July 30, 1998

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached Yes No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing (be exact):

7/31/98

f. Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule (please type):

Marsha Dadisman, Acting Director

Regulatory Development/Department of Health and Human Resources

Building 3, Room 265, Capitol Complex

Charleston, West Virginia 25305

(304) 558-3223 FAX: (304) 558-1130 MDadisman@WVDHHR.ORG

g. IF DIFFERENT FROM ITEM 'f', please give Name, title, address and phone number(s) of agency person(s) who wrote and/or has responsibility for the contents of this rule (please type):

Frank W. Lambert Jr., Dr. P.H.

Director, Office of Laboratory Services

Department of Health and Human Resources

167 11th Avenue

South Charleston, West Virginia 25303 (304) 558-3530

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place a hearing for the taking of evidence and a general description of the issues to be decided.

N/A

- b. Date of hearing or comment period:

N/A

- c. On what date did you file in the State Register the findings and determinations required together with the reasons therefore?

N/A

- d. Attach findings and determinations and reasons:

Attached N/A

BRIEF SUMMARY OF THE RULE

The proposed changes revise Public Water Systems 64 CSR 3 to adopt by reference the newest federal standards for drinking water laboratory certification and to permit approval of laboratories recognized for drinking water examination by the National Environmental Laboratory Accreditation Program. Adoption of these standards will allow the State to retain primacy for the national "Safe Drinking Water Act" which regulates the State's public water supply systems and will assure compliance with all federal and state regulations governing public water supplies.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

This rule adopts by reference the current United States Environmental Protection Agency (EPA) Manual for the Certification of Laboratories Analyzing Drinking Water. The change requested updates the rule to the current 4th Edition published in 1997. The laboratory criteria, procedures and quality assurance items in this procedure are used in certifying laboratories providing official analyses of drinking water samples as part of the EPA required monitoring, under the Safe Drinking Water Act.

The National Environmental Laboratory Accreditation Program (NELAP) is an effort by the EPA to establish a national voluntary accreditation program which will establish uniform standards for laboratories performing laboratory analyses under the various EPA monitoring programs. The Office of Laboratory Services is applying for accreditation as a NELAP accrediting authority. We are one of twenty (20) states who have applied for this accreditation. The requested change in this rule is to permit the West Virginia Drinking Water Certification Program to approve NELAP certified in-state and out-of-state laboratories for drinking water analysis in West Virginia.

TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 3
PUBLIC WATER SYSTEMS

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

SERIES 3
PUBLIC WATER SYSTEMS

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TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

JUL 31 9 27 AM '98

OFFICE OF THE ATTORNEY GENERAL
SECRETARY OF STATE

SERIES 3
PUBLIC WATER SYSTEMS

§64-3-1. General.

1.1. Scope - This legislative rule establishes State standards and procedures and adopts national drinking water standards for public water systems. It establishes standards for the production and distribution of bottled drinking water, and also adopts federal standards for the certification of laboratories performing analyses of drinking water.

1.2. Authority - W.Va. Code §16-1-9a and 16-1-7.

1.3. Filing Date -

1.4. Effective Date -

1.5. Supersession or Repeal of Former Regulations - This rule amends and reenacts Public Water Systems, West Virginia Administrative Rules, Division of Health, 64 CSR 3, 1994.

§64-3-2. Application and Enforcement.

2.1. Application - This rule applies to public drinking water systems, to bottled water treatment plants and distributors and to laboratories desiring certification to perform analytic tests of drinking water.

2.2. Enforcement - This rule is enforced by the director of the division of health.

§64-3-3. Definitions.

3.1. Bottled Water - Any natural or artificial mineral, spring, well, distilled or other water bottled or containerized for use primarily as drinking water.

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3.2. Bottled Water Distributor - A person who buys and sells bottled water on a wholesale basis.

3.3. Community Water System - A public water system which serves at least fifteen (15) service connections used by year-round residents or regularly serves at least twenty-five (25) year-round residents.

3.4. Director - Director of the division of health or his or her designee.

3.5. Non-Community Water System - Any public water system that is not a community water system.

3.6. Person - Individual, partnership, association, syndicate, company, firm, trust, corporation, government corporation, institution, department, division, bureau, agency, federal agency or any other entity recognized by law.

3.7. Public Water System - Any water system or supply which regularly supplies or offers to supply, piped water to the public for human consumption, if serving at least an average of twenty-five (25) individuals per day for at least sixty (60) days per year, or which has at least fifteen (15) service connections and includes:

(1) Any collection, treatment, storage, and distribution facilities under the control of the owner or operator of the system and used primarily in connection with the system, and

(2) Any collection or pretreatment storage facilities not under such control which are used primarily in connection with the system.

A public water system does not include a system which meets all of the following conditions:

(1) which consists only of distribution and storage facilities (and does not have any collection and treatment facilities);

(2) which obtains all of its water from, but is not owned or operated by a public water system which otherwise meets the definition;

(3) which does not sell water to any person; and

(4) which is not a carrier conveying passengers in interstate commerce.

3.8. Sanitary Survey - An on-site review of the water source, facilities, equipment, operation and maintenance of a public water system for the purpose of evaluating the adequacy of the source, design, facilities, equipment, operation and maintenance for producing and distributing drinking water, as described in the federal regulations adopted in this rule.

§64-3-4. Public Water System Construction, Alteration or Renovation; Standards; Exceptions.

4.1. No person may construct, alter, renovate or award a contract for any construction, alteration or renovation of a public water system without obtaining a permit from the director.

4.2. Application for a permit to construct, alter or renovate shall be made to the director on forms prescribed by the director at least forty-five (45) days prior to the date on which approval by the director is desired. The application shall be accompanied by an engineering report, maps, and detailed plans and specifications of the proposed construction, alteration or renovation prepared by or under the direction of a registered professional engineer.

4.3. A permit to construct, alter or renovate may be revoked by the director for failure of the public water system to comply with this rule.

4.4. A permit to construct, alter or renovate is valid for two (2) years from the date of issuance.

4.5. The public water system shall be constructed, altered or renovated in accordance with the plans and specifications approved by the director in accordance with Design Standards for Public Water Supply Systems, West Virginia Administrative Rules, Division of Health, 64 CSR 42.

4.6. To the extent practical, all new or expanded facilities shall be located outside of the one-hundred-year flood plain.

4.7. The director has the authority to issue an order requiring a change in the source of the water supply for the system or in the manner of collection, treatment, storage, or distribution facilities of the system before delivery to the consumer as may be necessary to safeguard the public health.

4.8. A permit to construct, alter or renovate is not required for any minor addition to, or alteration or renovation of an existing public water system which will not significantly affect the quality or quantity of the water supply service rendered. The work shall be done in accordance with the provisions of Design Standards for Public Water Supply Systems, West Virginia Administrative Rules, Division of Health, 64 CSR 42.

A written description of the proposed additions, alterations or renovations shall be submitted to the director no less than ten (10) working days prior to implementing the additions, alterations or renovations under this provision. The director shall notify the system whether or not the proposed additions, alterations or renovations qualify under this provision within five (5) days of receipt of the description.

4.9. All public water supply systems using a raw water source which is open to the atmosphere or subject to surface runoff shall, at a minimum, provide filtration treatment.

§64-3-5. Permit to Operate a Public Water System.

5.1. A public water system shall be operated in accordance with this rule and the federal regulations adopted in this rule.

5.2. The director has the authority to develop a program for the issuing of a permit to operate a public water system. The permit is renewable annually and may be revoked for failure to comply with the requirements of this rule or the federal standards adopted herein. The permit program shall be administered uniformly. No permit shall be granted until after the director has completed a sanitary survey.

5.3. In the event of a proposed change in the ownership of a public water system, a written application to transfer the permit to operate shall be made to the director by the new owner at least fifteen (15) days before the proposed change.

5.4. The current permit to operate shall be posted in a conspicuous place at the public water system's treatment plant or main office.

§64-3-6. Inspections and Sanitary Surveys of Public Water Systems.

6.1. Public water systems shall be inspected as scheduled by the director and sanitary surveys shall be conducted by the director in accordance with the federal regulations adopted in this rule.

6.2. The director has the right of access to all parts of a public water system and shall be furnished access to all information and records required to be kept by this rule and the federal regulations adopted in this rule.

§64-3-7. Public Water System Disinfection Requirements.

7.1. Disinfection with chlorine, chlorine dioxide, chloramine or ozone is required of all public water systems, provided the requirements of Section 7.6 of this rule are met.

7.2. The disinfectant shall be applied during treatment at a point before entering the distribution system which will provide effective contact time.

7.3. The minimum chlorine contact time for groundwater systems not influenced by surface waters is thirty (30) minutes from the point of application to the point of delivery to the first consumer or as stipulated in Design Standards for Public Water Supply Systems, West Virginia Administrative Rules, Division of Health, 64 CSR 42. At the end of the chlorine contact time, minimum free chlorine residuals shall comply with the requirements of Table 64-3A found at the end of this rule. For these systems, the amount of residual disinfectant in the drinking water at the treatment plant and in the distribution system shall be determined at least once per day, or more often if considered necessary by the director.

7.4. Surface water systems and groundwater systems under the direct influence of surface waters shall meet the disinfection requirements of the federal regulations adopted in this rule.

7.5. Chlorine residual testing equipment shall enable measurement of free and total chlorine residuals to the nearest 0.2 milligrams per liter in the range of 0.0 milligrams per liter to 2.0 milligrams per liter.

7.6. For all public water systems, at least 0.2 milligrams per liter of total chlorine residual shall be maintained throughout the distribution system at all times.

7.7. The director has the authority to authorize variances in the chlorine disinfection parameters specified in this section.

§64-3-8. Public Water System Fluoridation.

8.1. Except for water systems operated by public schools, average concentrations of fluoride present in the drinking water of a public water system, which artificially adjusts fluoride concentrations, shall be no less than the minimum and no higher than the maximum concentrations shown in Table 64-3B found at the end of this rule.

8.2. Average concentrations of fluoride present in a public school drinking water system shall be no less than three (3.0) milligrams per liter and no higher than six (6.0) milligrams per liter, with an optimum concentration of four and one-half (4.5) milligrams per liter.

8.3. The drinking water of fluoridated or defluoridated public water systems shall be monitored once per day for fluoride concentration. Records of the monitoring shall be maintained in accordance with Sections 9 and 10 of this rule.

8.4. At least once a month, a sample of drinking water shall be submitted by the public water system to the director or to a certified laboratory for fluoride analysis.

8.5. The requirements of Section 8.2 of this rule supersede the requirements of the National Secondary Drinking Water Regulations, 40 CFR Part 143, as applicable to fluoridation of public school drinking water.

§64-3-9. Public Water System Control Tests and Record Maintenance

9.1. Records of microbiological, turbidity, radiological and chemical analyses, or a summary thereof, shall be retained at a convenient location on or near the premises of the public water system. Turbidity, radiological and chemical analytical records shall be kept for ten (10) years. Control test, microbiological and operational records shall be kept for five (5) years. All tests and analyses required by this rule or the federal regulations adopted in this rule, with the exception of on-site water system operational tests, shall be conducted by a laboratory certified by the director.

9.2. The records shall include the date, place and time of sampling; the name of the person who collected the sample; identification as to whether it was a routine distribution system sample, resample, raw or drinking water sample, or other special purpose sample; the date of the analysis; the laboratory and person responsible for performing the analysis; the analytical technique or method used for microbiological testing; and the results of the analysis.

9.3. Records of action taken by the system to correct violations of this rule or the federal regulations adopted in this rule shall be kept for three (3) years after the correction is completed.

9.4. Copies of written reports relating to sanitary surveys of the system shall be kept for ten (10) years.

9.5. Records concerning a variance or exemption from this rule or the federal regulations adopted in this rule shall be kept for at least five (5) years following the expiration of the variance or exemption.

§64-3-10. Adoption of National Regulations.

10.1. The following National Primary Drinking Water Regulations and National Secondary Drinking Water Regulations, promulgated and published prior to January 1, 1994, as final rules are hereby adopted by reference:

10.1.a. 40 C.F.R. Part 141;

10.1.b. Subparts F and G of 40 C.F.R. Part 142, except for Sections 142.57, 142.60, 142.61, and 142.62(c)-142.62(h); and

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10.1.c. 40 C.F.R. Part 143.

10.2. The Director shall use the provisions of 40 C.F.R. Part 142, Subparts F and G, as adopted in this rule as applicable in granting exemptions.

10.3. In the event of a conflict between a federal standard adopted in this rule and a state standard adopted in this rule, the more stringent standard applies, except as stated in Section 8.5 of this rule.

10.4. Copies of these regulations are available from:

U.S. Environmental Protection Agency
Region III
841 Chestnut Building
Philadelphia, PA 19107

§64-3-11. Bottled Water Treatment Plants and Distributors.

11.1. No person may operate a bottled water treatment plant in this State without receiving a permit to bottle and distribute water from the director.

11.2. No person may distribute bottled water in this State without receiving a permit to distribute bottled water from the director.

11.3. Application for a permit to bottle and distribute water shall be made to the director on forms prescribed by the director. Four (4) sets of completed applications, and plans and specifications for the treatment plant shall be submitted to the director for approval at least forty-five (45) days prior to the date on which a permit from the director is desired.

11.4. The source of the water to be bottled and the bottled water shall comply with the requirements of this rule and the requirements of the federal regulations adopted in this rule pertaining to primary and secondary contaminants, sodium, fluoridation, maximum contaminant levels, sampling techniques and monitoring frequencies, for a community water system, except that the monitoring frequency for microbiological contaminants shall be no less than once each week.

11.5. A bottled water treatment plant shall be operated in accordance with the provisions of the federal standards, Current Good Manufacturing Practice in Manufacturing, Packaging or Holding Human Food, 21 CFR Part 110, in effect as of October 30, 1990, and these standards are hereby adopted by reference.

11.6. Each in-State bottled water treatment plant shall be inspected every twelve (12) months or as otherwise determined by the director.

11.7. An out-of-State bottled water treatment plant desiring to distribute bottled water in West Virginia shall apply for a permit to bottle and distribute bottled water on forms approved by the director. Four (4) copies of all materials shall be submitted. The out-of-State treatment plant shall comply with the requirements of this rule and the federal regulations adopted in this rule for in-State bottled water treatment plants. Subsequent to the initial evaluation, monitoring of the treatment plant by the regulatory agency of the state wherein the treatment plant is located is considered acceptable for the purposes of this rule. The out-of-State treatment plant shall notify the director of any corrective action it is required to take by its state regulatory authority and shall notify the director of any change in ownership or in the event that it closes.

11.8. A person wishing to distribute bottled water in the State who does not operate a bottled water treatment plant shall apply for a permit to distribute bottled water on a form approved by the director. The applicant shall identify the location of the plants from which the bottled water is obtained and any distributor other than the bottled water plant from which the bottled water is obtained and shall provide other information required by the director. The director shall grant a permit to distribute bottled water if the bottled water complies with the requirements of this rule.

11.9. A permit issued by the director may be revoked for failure to comply with provisions of this rule.

§64-3-12. Public Water System Reporting Requirements.

12.1. Unless otherwise specified in this rule or the federal regulations adopted in this rule, the results of any test, measurement or analysis required to be made by this rule or the

federal regulations adopted in this rule shall be reported to the director within forty (40) days of the system's receipt of the test, measurement or analysis.

12.2. Analytical results for total trihalomethane (TTHM) analyses shall be reported to the director within thirty (30) days of the system's receipt of the results.

12.3. Failure to comply with this rule or the federal regulations adopted in this rule shall be reported to the director within forty-eight (48) hours of the discovery of the violation.

12.4. Analytical results of tests performed by the laboratory of the division of health are not required to be reported.

12.5. A written summary of the public water system operation, test data, and other information as may be required by the director shall be submitted to the director at least once per month. The director may require more frequent reports in cases where there are public health concerns.

12.6. All reports and summaries required by this rule or the federal regulations adopted in this rule shall be submitted in a manner or form approved by the director.

12.7. The water supply system shall submit to the director a representative copy of each type of notice distributed, posted or made available to the public or media within seven (7) days following any notification of the public of a violation of this rule or of the federal regulations adopted in this rule.

§64-3-13. Certification of Laboratories to Conduct Drinking Water Tests.

13.1. All laboratories providing drinking water testing results for purposes of this rule or the federal regulations adopted in this rule shall be certified by the director or by the Federal Environmental Protection Agency, or certified by the director if recognized by the National Environmental Laboratory Accreditation Program (NELAP) for the analyses of drinking water.

~~13.2. A certified laboratory shall comply with the requirements of this rule and with the requirements and criteria contained in the sections titled "Local Laboratories," "Other Con-~~

~~siderations for Laboratory Certification," "Requirements for Maintaining Certification Status," "Criteria and Procedures for Downgrading/Revoking Certification Status," and "Training," of Chapter III, and in Chapters IV, V and VI of the federal Environmental Protection Agency's Manual for the Certification of Laboratories Analyzing Drinking Water, Third Edition, April, 1990, Change 1, October, 1991, and Change 2, September, 1992 and these parts of the manual are hereby adopted by reference.~~

13.2. A certified laboratory shall:

13.2.a. Comply with the requirements contained in the federal Environmental Protection Agency's manual for the certification of laboratories analyzing drinking water, fourth edition, March 1997, and such requirements of this manual are hereby incorporated by reference; or

13.2.b. Comply with the requirements of this rule and hold a certificate of recognition from the National Environmental Laboratory Accreditation Program (NELAP) for the analysis of drinking water.

13.3. An in-State laboratory shall submit an application form when seeking initial approval sixty (60) days prior to the date certification is desired.

13.4. A laboratory located outside the boundaries of this State shall be certified by the director if:

13.4.a. It has been certified by the Federal Environmental Protection Agency; or

13.4.b. It has been certified by a program for the certification of laboratories equivalent to the program of this State as determined by the director. If the program of the state in which the laboratory is located is not judged equivalent, the laboratory may request an on-site evaluation and full certification review by the director.

13.5. An out-of-state laboratory shall submit an application form when seeking initial approval and shall include with its application evidence of compliance with Section 13.4.1 or 13.4.2 of this rule. The out-of-state laboratory shall notify the director immediately of any change in its certification sta-

tus under Section 13.4.1 or 13.4.2 of this rule.

13.6. An on-site inspection of in-State laboratories to determine compliance with this rule and the federal standards adopted in this rule shall be conducted initially prior to certification, and at least every three (3) years thereafter. The division has the right of entry upon proper identification at any time considered necessary during operating hours in order to conduct the inspections.

13.7. Certificates of approval shall be issued upon initial approval and are renewable on an annual basis thereafter pursuant to the conditions listed in this rule. Certificates issued will contain the name and location of the laboratory, a laboratory code number, the name of the laboratory director and the date of expiration of the certificate.

13.8. Certified laboratories shall notify the director when there is a change in ownership, laboratory director, technical personnel or location of the laboratory.

13.9. The director shall administer and use the criteria and procedures of the Section titled "Criteria and Procedures for Downgrading/Revoking Certification Status" of the Manual for the Certification of Laboratories Analyzing Drinking Water referenced in Section 13.2 of this rule.

§64-3-14. Penalties.

Any person who violates any provision of this rule or orders issued under this rule, is guilty of a misdemeanor, and upon conviction thereof, shall be fined not less than twenty-five dollars (\$25) nor more than two hundred dollars (\$200) and each day's violation shall constitute a separate offense. In addition, thereto, the director of health or his or her authorized representative may seek injunctive relief in the circuit court of the county in which all or part of the public water system is situated for threatened or continuing violations. For a willful violation of this rule or orders issued under this rule, a person, upon a finding thereof by the circuit court of the county in which the violation occurs, is subject to a civil penalty of not more than five thousand dollars (\$5,000), and each day's violation is grounds for a separate penalty.

§64-3-15. Administrative Due Process.

Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the Rules of Procedure for Contested Case Hearings and Declaratory Rulings, West Virginia Administrative Rules, Division of Health, 64 CSR 1.

§64-3-16. Severability.

The provisions of this rule are declared to be severable. If any provision of this rule is held invalid, the remaining provisions remain in effect.

TABLE 64-3A.

MINIMUM LEVELS OF FREE CHLORINE RESIDUAL AT VARIOUS
WATER SAMPLE pH LEVELS

pH VALUE	FREE CHLORINE RESIDUAL
Up to 7.0	0.4 mg/l
7.1 to 8.0	0.6 mg/l
8.1 to 9.0	1.0 mg/l

TABLE 64-3B.

AVERAGE ACCEPTABLE RANGE OF FLUORIDE CONCENTRATION
AT VARIOUS ANNUAL AVERAGE MAXIMUM DAILY AIR TEMPERATURES

ANNUAL AVERAGE MAXIMUM DAILY AIR TEMPERATURE	FLUORIDE CONCENTRATION IN MILLIGRAMS PER LITER		
	Lower	Optimum	Upper
53.8 - 58.3° F 12.1 - 14.6° C	0.8	1.1	1.5
58.4 - 63.8° F 14.7 - 17.7° C	0.8	1.0	1.3
63.9 - 70.6° F 17.7 - 21.4° C	0.7	0.9	1.2

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Public Water Systems

Type of Rule: Legislative Interpretive Procedural

Agency: Department of Health and Human Resources

**Address: Building 3, Capitol Complex
Charleston, WEST VIRGINIA 25305**

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$0	\$0
Personal Services					
Current Expense					
Repairs & Alternations					
Equipment					
Other					

2. Explanation of above estimates.

No additional costs are projected because this change only updates the EPA manual included by reference and adds a national accreditation program to the rule.

3. Objectives of this rule:

Includes by reference current EPA manual used for certification of laboratories performing drinking water analysis. It also permits recognition of the National Environmental Laboratory Accreditation Program (NELAP) for certification of in-state and out-of-state laboratories performing drinking water analysis under the Safe Drinking Water Act.

4. **Explanation of Overall Economic Impact of Proposed Rule.**

A. **Economic Impact on State Government.**

Permits the State to retain primacy for the National Safe Drinking Water Act by certifying laboratories performing official analysis of drinking water as part of the EPA required monitoring. NELAP certification permits West Virginia to have reciprocity with other states for accepting the analysis of drinking water from in-state and out-of-state laboratories.

B. **Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.**

Environmental laboratories must be certified to perform official analysis of drinking water as required by the Safe Drinking Water Act. NELAP certification permits West Virginia laboratories to do business in other states. Also requirements for certification are standardized from state to state. NELAP standards are expected to become the nationally recognized standards for quality environmental laboratory analysis.

C. **Economic Impact on Citizens/Public at Large.**

Assurance that drinking water monitoring is of high quality because tests are done in officially certified laboratories.

Date: 6/30/98

Signature of Agency Head or Authorized Representative



Joan E. Ohl, Secretary
Department of Health and Human Resources

**RESPONSES TO COMMENTS
AND
CHANGES MADE AS A RESULT OF THE PUBLIC COMMENT PERIOD
July 1998**

A public comment period on the proposed amendments to the Public Water Systems Rule 64-CSR3 was begun June 30, 1998 and ended July 30, 1998. There were two commenters. The comments are summarized and the Department's responses and changes to the rule are detailed below.

Comment: Our most urgent concern is whether other states will also allow Drinking Water Certification status in their respective states for West Virginia certified laboratories who also meet or attain NELAP accreditation.

Response: Acceptance of West Virginia certification or NELAP recognition of a laboratory by another state continues to be the prerogative of the individual state. NELAP recognition only provides another avenue for the environmental laboratory to achieve certification for drinking water analyses by West Virginia.

Comment: Allowing unrestricted certification to out-of-state laboratories without reciprocity, will ultimately reduce the current volume of work currently available to certified in-state laboratories.

Response: The Department does not believe this is a valid concern because the rule change is no more or no less restrictive than the rule that is currently in place. Certification of out-of-state laboratories, whether NELAP recognized or not, continues to be a requirement. Since NELAP represents a nationally recognized standard for environmental laboratory quality, a laboratory in West Virginia who has obtained NELAP accreditation would have a national and international competitive advantage over a non-NELAP accredited laboratory in competing for contracts.

Comment: What impact will this legislation have on the fees that the state charges out-of-state laboratories? A second commenter requests additional assessment of out-of-state laboratories be added to the certification fee.

Response: The fees for certification of laboratories is authorized by 64CSR51 and will not be affected by this rule change. Therefore, the changes in this rule will have no impact on the fee charged out-of-state laboratories nor can additional fees be added.

64-3-13.1 Comment: This section does not say that the lab must be "certified" by the State of West Virginia to conduct these tests. Sections 13.2-13.5 states what steps a laboratory must take to become certified, but according to 3.1 a NELAP recognized lab does not need to be certified. If 13.1 is amended to require all laboratories to be certified, then comments on section 13.2-5 would be appropriate.

Response: The Department agrees that clarification is needed. Section 13.2 gives the criteria

necessary for certification. All laboratories must be certified by the Department. We have modified section 13.1 to clarify the intent of the rule by adding. . ."certified by the director if. . and striking "be" between "or" and "recognized by the National Environmental Laboratory Accreditation Program (NELAP) for the analyses of drinking water." We have also changed the word "analysis" to the plural to indicate multiple analyses are involved in this certification.

64.B.13.4 Comment: This section uses the term "equivalent" to compare certification programs. The commenter says this is too subjective and suggests the Department include ISO Guide 25 into this amendment.

Response: The Department does not see the need to incorporate the ISO Guide into this rule. This section is intended to give the director flexibility in determining equivalence and provides the out-of-state laboratory the ability to request an on-site evaluation and full certification review if the laboratory disagrees with the determination made by the Department. It is our intention to accept as equivalent any laboratory which is NELAP accredited by another state.

COMMENTERS:

Eric L. Botnick CIH, Laboratory Director/General Manager, FREE-COL Laboratories, Ltd.
William F. Kirk, President, Reliance Laboratories, Inc.

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ENVIRONMENTAL
OCCUPATIONAL HEALTH
FOOD SCIENCE
SPECIALISTS



Regulatory Development
Department of Health & Human Resources
Capitol Complex – Building 3, Room 265
Charleston, WV 25305

July 16, 1998

Marsha Dadisman:

The subject of the letter is to comment on the revisions to Public Water Systems 64 CSR 3.

Section 64-3-13.1 says that any lab that is "recognized by the NELAP for the analysis of drinking water" can provide drinking water testing results. This section does not say that the lab must be "certified" by the state of West Virginia to conduct these tests. I think that this is a bold step for the state of West Virginia and I would applaud such forward thinking by a state agency.

Sections 64-3-13.2 – 13.5 states what steps a laboratory must take to become certified, but according to 13.1 a NELAP recognized lab does not need to be certified. If 13.1 is amended to require all laboratories to be certified, then comments on sections 13.2 - 5 would be appropriate. Section 13.4.2 uses the term "equivalent" to compare certification programs. This term can be subjective, as shown by the use of the phrase "judged equivalent". I suggest that a more definitive qualification be used here. If the NELAP recognized state certification meets the requirements of this subsection, than state it clearly. Since the backbone of the NELAP was to design a program that is ISO Guide 58 compliant and one that would ensure the laboratory QA programs were ISO Guide 25 compliant, then perhaps you could incorporate the ISO Guide 25 into this piece of legislation. The ASTM has standards that could be referenced as a tools to evaluate a certification program.

There is no mention of fees in the sheets supplied. What impact will this legislation have on the fees that the state charges to out-of-state laboratories?

The Economic Impact statements should be reconsidered if this revision goes through as stated.

Eric L. Botnick, CIH
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July 27, 1998

Attn: **Marsha Dadisman, Acting Director**
REGULATORY DEVELOPMENT
DEPARTMENT OF HEALTH & HUMAN RESOURCES
Capitol Complex - Building 3, Room 265
Charleston, WV 25305

Re: **Comment on Proposed Rule Change - 64 CSR 3 - Public**
Water Systems

Dear Ms. Dadisman,

As a commercial environmental laboratory certified in West Virginia as an approved Drinking Water Laboratory, we would voice specific concerns relative to the proposed changes in Public Water Systems Rules under 64 CSR 3 as outlined in the "Notice of A Comment Period on a Proposed Rule" received in our offices on Thursday, July 2, 1998. Our interest lies in the change which allows the State of West Virginia to grant analytical Drinking Water Certification status for out-of-state laboratories meeting National Environmental Laboratory Accreditation Program (NELAP) accreditation. Our most urgent concern is whether other states will also allow Drinking Water Certification status in their respective states for West Virginia certified laboratories who also meet or attain NELAP accreditation.

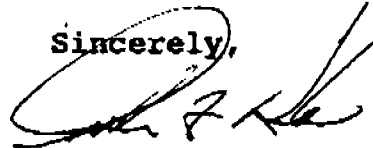
Naturally, our position is to provide jobs and work for skilled chemists and technicians who live and drive the economy in West Virginia. Allowing unrestricted certification to out-of-state laboratories without reciprocation, will ultimately reduce the current volume of work currently available to certified in-state laboratories.

Also, we are deeply concerned by the fact that out-of-state laboratories allowed to operate in West Virginia will not pay taxes that are currently asked of resident laboratories. We feel that specific taxes or

adjusted equivalents for Payroll, Unemployment, Workers Compensation, Business & Occupation, Sales and Use, Corporate License taxes, etc. be assessed these out-of-state laboratories in addition to state of West Virginia Laboratory Certification Fees. It is our position that unfair competition would exist without such an assessment added to certification costs.

As West Virginian's obtaining our livelihood in West Virginia, we would hope specific issues such as this are reviewed closely and considered for the benefit of West Virginia workers and not to the contrary.

Sincerely,



William F. Kirk, President
Reliance Laboratories, Inc.

WFK
enclosure