

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION
Form #3

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE

AND

FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Division of Environmental Protection, Office of Water Resources TITLE NUMBER: 47

CITE AUTHORITY §22-1-15

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 32

TITLE OF RULE BEING PROPOSED: Regulations Governing Environmental Laboratories Certification and Standards of Performance

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Roger J. Hall

David C. Callaghan, Director
Division of Environmental Protection

13.40



DIVISION OF ENVIRONMENTAL PROTECTION

10 McJunkin Road
Nitro, WV 25143-2506

GASTON CAPERTON
GOVERNOR

DAVID C. CALLAGHAN
DIRECTOR

August 15, 1994

Ms. Judy Cooper
Director, Administrative Law Division
Secretary of State's Office
Building 1, Suite 157K
Charleston, West Virginia 25305

RE: CSR-47-32 - Regulations Governing Environmental
Laboratories Certification and Standards of
Performance

Dear Ms. Cooper:

This is to advise you that I am giving approval for the filing of the above-captioned rule with your Office and with Legislative Rule-Making Review Committee as an agency approved rule.

Your cooperation in this regard is very much appreciated. If you have any questions or require additional information, please feel free to contact Roger T. Hall at 759-0515.

Sincerely yours,

A handwritten signature in black ink, appearing to read "D. Callaghan", written over the typed name.

David C. Callaghan
Commissioner
Bureau of Environment

DCC;RTH:cc

Attachment

**Statement of Circumstances
Requiring this Rule**

This rule is being proposed in response to the enactment of W Va Code §22-1-15 (a).

FISCAL NOTE FOR PROPOSED RULE

Rule Title: Regulations Governing Environmental Laboratories Certification and Standards of Performance

47 C.S.R.32

Type of Rule: X Legislative Interpretive Procedural

Agency: Division of Environmental Protection, Office of Water Resources

Address: 1201 Greenbrier Street, Charleston, WV 25311-1088

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$182,700		\$182,700	\$225,000	\$225,000
Personal Services	\$118,800		\$118,800	\$158,000	same
Current Expenses	\$ 63,900		\$ 63,900	\$ 67,000	same
Repairs & Alterations	\$ -				
Equipment	\$ -				
Other	\$ -				

2. Explanation of above estimates: Fees allowed by law are capped at \$150,000. At this time it is estimated that an additional \$32,700 will be required to carry out the provisions of the law.

3. Objectives of this rule: This rule governs the certification of laboratories conducting environmental analysis of waste and wastewater performed as required by rules or orders issued pursuant to the covered statutory programs. The rule establishes the provisions for obtaining and maintaining laboratory certifications and the criteria and procedures laboratories will be required to follow in analyzing samples.

4. Explanation of Overall Economic Impact of Proposed Rule. It is estimated that program costs will exceed fees allowed.

A. Economic Impact on State Government. Fees derived from those allowed by this rule will not cover program costs.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of citizens. Fees will be charged to Environmental Testing Laboratories for certification that methods and procedures used in testing comply with the requirements of the proposed rule.

C. Economic Impact on Citizens/ Public at Large. Small impact will occur as a result of increased product and service pricing by industry affected by this rule.

Date:

Signature of Agency Head or Authorized Representative


 Director, Division of Environmental Protection

DATE: August 15, 1994

TO: Legislative Rule-Making Review Committee

FROM: Division of Environmental Protection, Office of Water Resources

LEGISLATIVE RULE TITLE: Regulations Governing Environmental Laboratories

Certification and Standards of Performance

1. Authorizing statute(s) citation: §22-1-15
- 2.a. Date filed in State Register with Notice of Hearing: 6/30/94
- 2.b. What other notice, including advertizing, did you give of the hearing? _____

Notices of Hearing and comment period placed in newspapers statewide.

- 2.c. Date of hearing(s): 8/1/94
- 2.d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments;
Attached XX No comments received _____
- 2.e. Date agency approved proposed Legislative Rule filed in State Register following public hearing: 8/19/94
- 2.f. Name and telephone of agency contact: Mark Scott, 558-2107
3. If the statute under which the rule was promulgated and submitted requires certain findings and determinations to be made as a condition precedent to their promulgation: N.A.
- 3.a. Date on which a notice of the time and place of hearing for the taking of evidence and a general description of the issues to be decided was filed in the State Register:

- 3.b. Date of hearing: _____
- 3.c. Date the required findings and determinations together with reasons therefor were filed in the State Register: _____
- 3.d. Findings and determinations, and reasons (attached).

**PREAMBLE TO A PROPOSED RULE
CONCERNING
REGULATIONS GOVERNING ENVIRONMENTAL LABORATORIES
CERTIFICATION AND STANDARDS OF PERFORMANCE**

- AGENCY:** Bureau of Environment; Division of Environmental Protection.
- REGULATION:** 47 CSR32 "Regulations Governing Environmental Laboratories Certification and Standards of Performance."
- ACTION:** Filing of a Proposed Rule, Notice of a Public Hearing, and Notice of a Public Comment Period.
- SUMMARY:** The proposed rule is new and is being promulgated in response to enactment of W Va Code §22-1-15. This rule will insure that the results of environmental analyses are accurate, reproducible and verifiable by: Establishing the administrative procedures to be followed by certified laboratories and laboratories seeking certification; Establishing the categories and parameters in which laboratories may be certified; Establishing the minimum requirements, criteria and procedures for laboratory equipment and supplies, practices, methodology, quality control, personnel, facilities, data reporting, and laboratory and record maintenance, which a certified laboratory shall continually meet; and Establishing the enforcement procedures the division will follow to ensure that all certified laboratories or laboratories seeking certification are in compliance with this rule.

A Public Hearing will be held as follows:

August 1, 1994, 3:00 p.m.

Division of Environmental Protection
Nitro Office - Training Room
10 McJunkin Road
Nitro, West Virginia

Written comments with postmarks prior to 4:00 pm, August 8, 1994 will be accepted. Written comments should be sent to:

Don Caldwell
Division of Environmental Protection
Office of Water Resources
1201 Greenbrier Street
Charleston, West Virginia 25311

RESPONSE TO WRITTEN COMMENTS
ENVIRONMENTAL LABORATORY CERTIFICATION
47 CSR 32

1.0 INCORPORATION BY REFERENCE. The phrase "or any other such methods..." should be changed to "and any other such methods..."

RESPONSE: This change will be made.

1.1 Add the paragraph: "Unless otherwise indicated, where reference to a federal regulation or standard appears in this rule, such regulation or standard will, for purposes of this rule, be construed as that version in effect as of July 1, 1994."

RESPONSE: Federal regulations and standards are in effect as of the day they appear in the federal register. To add the above paragraph will cause laboratories to have to comply with two standards for most of the year until the legislature can incorporate the new federal regulations and standards into the West Virginia rules. This is too much of a burden for the regulated laboratories.

2.0 PURPOSE OF THE RULE - 1.7.3. Delete "which a certified laboratory shall continually meet,"

RESPONSE: We see nothing wrong with this statement.

3.0. DEFINITIONS - 2. Phrase should be changed to "latest approved edition of the methods in effect as of July 1, 1994"

RESPONSE: This manual is updated periodically. It then is approved for use by the U.S. Environmental Protection Agency. It must be used beginning on the date of US-EPA approval. Once again it would be a burden for laboratories to have to comply with two sets of test methods in order to satisfy both the State and federal government. This statement should not be added to the regulations.

3.1. "Covered Statutory Programs" - 2.14. The words "one of" should be deleted for clarity.

RESPONSE: Agree. "one of" will be removed.

3.2. "Director" - 2.16. The definition provides that the Director may designate the Chief of the Office of Water Resources to administer the rule. Director's authority should be moved to the body of the rule itself.

RESPONSE: Such a move is not necessary. It must be said somewhere and here is a logical place to say it.

3.3. "Person, Persons, or applicant" - 2.23. The definition provides a list of entities...the word "including" should be changed to the phrase, "including, but not limited to,".

RESPONSE: Word "including" will be changed to "including, but not limited to,".

3.4. Personal and direct supervision - 2.24. Delete "qualified".

RESPONSE: Removal will be done.

3.5. "Standard Curve" - 2.29. Subsection should be revised as follows: "Standard Curve" means a curve plotting concentrations of a known parameter minus a blank. Standard curve does not include other concentration measurements, including, but not limited to, instrument response, the absorbance parameter of the standard, or the percent transmittance of the standard."

RESPONSE: A standard curve does include instrument response, absorbance parameter of the standard, and percent transmittance of the standard. Without these it is impossible to draw the curve. This change should not be made.

4.0. Rules should specify the term of certification.

RESPONSE: The term is specified as 365 days in section 2.9.

4.1. "Laboratory proper" should have the word "proper" deleted.

RESPONSE: "proper" is used by the WVMA in the very next comment and recommends that the word be used in the next statement of change. Proper is a clarifying word and should not be deleted.

5.0. Requirements and Exceptions - 3.1.1. WVMA wants a clarifying statement "With the exception of those tests not normally performed in a laboratory proper, including, but not limited to, turbidity, chlorine residual, fluoride concentration, pH, temperature and conductivity analyses,"

RESPONSE: Turbidity, Fluoride concentration and Conductivity ARE laboratory procedures. Turbidity requires ultra clean apparatus for testing, Fluoride requires distillation before testing, and Conductivity requires a stable temperature of 25 degrees centigrade. This change will not be made.

6.0. Reciprocal State Certification - 3.1.2. WVMA wants the regulations to specify the factors the agency will consider when making equivalency determinations in accepting or rejecting other state programs for reciprocity recognition.

RESPONSE: The West Virginia rules and regulations themselves will be the factors considered. No change is necessary.

7.0. Requirements for Application - 3.3.1. WVMA feels that the word "person" implies that an individual and not the laboratory is being certified. They want to change the entire sentence just to remove the word "person".

RESPONSE: Go back to the definition of "Person". There is no problem with the wording. No change will be made.

8.0. Performance Evaluation and Inspection - 3.3.4. "[T]his inspection" should be changed to "the inspection contemplated in subsection 3.3.2 of this rule".

RESPONSE: "[T]his inspection" does not appear in section 3.3.4. We do not know the meaning of this comment and therefore cannot respond.

9.0. Denial of Application - 3.3.6. "[C]hapter" should be changed to "rule".

RESPONSE: Change will be made.

9.1. 3.3.6.a. "Officer should be changed to "Office"

RESPONSE: Change will be made.

10.0. Program Phase-in Provisions - 3.3.8. To require a laboratory to conform to ALL EPA methods for a particular analyte is unnecessary.

RESPONSE: EPA REQUIRES laboratories to conform. West Virginia has no alternative but to require this.

10.1. The sixty-day phase in period is inadequate.

RESPONSE: Applications received from the most complicated laboratories have been submitted within 30 days of receipt of the application. Surely, sixty days is adequate if the laboratories are preparing applications now in just 30 days. No change will be made.

10.2. Laboratories should not be limited to just three opportunities within 120 days to demonstrate acceptable performance.

RESPONSE: If a laboratory cannot demonstrate acceptable performance in three attempts, they have a serious problem and must seek professional help in solving this problem. Laboratories could go on testing environmental samples shoddily for year while they attempted to pass the performance evaluation test samples. This is unacceptable and no change will be made.

10.3. Time to correct deficiencies should be long enough to allow the laboratory to identify the problems at issue and develop a plan of correction.

RESPONSE: The deficiencies are identified for the laboratory through the inspection process. Correction can be started immediately. No change will be made.

11.0. Application Procedures Subsections 3.4.1, 3.4.2, and 3.4.3 contain provisions applicable to certification by reciprocity while subsection 3.4.4. applies to out of state laboratories seeking certification by inspection. Subsections should be combined for clarity.

RESPONSE: They were separated in the beginning for clarity. No change will be made.

11.1. Remove subsections 3.4.1, 3.4.1a-c, 3.4.2 and 3.4.4 to avoid constitutional challenges.

RESPONSE: There is no constitutional violation. These subsections are the same as are commonly used by other states who have laboratory certification programs granting reciprocity. No changes will be made.

11.2. Subsection 3.1.2 is in accordance with the West Virginia code 22-1-15. No change can be made.

12.0. Compile a list of certified laboratories.

RESPONSE: This has been done.

13.0. Federal and State Laboratories should not be exempt from fee requirements.

RESPONSE: We are of the same opinion but federal law exempts federal facilities from fees and taxes. State law does the same.

14.0. Fees - 3.6.3. Fees must be used only for this program.

RESPONSE: This is said in the law. It need not be said here.

14.1. Waste Characteristics: change "parameter" to "procedure".

RESPONSE: Change will be made.

14.2. Single fee for all parameters should be considered. Some laboratory could pay "crippling" fees if it tests multiple categories.

RESPONSE: Would this be fair to the small laboratory? The large, multi-category laboratory is making enormous sums of money for their work and can afford the lab fees as proposed.

15.0. Personnel Qualifications - 3.7. Engineers should be allowed to be managers or supervisors.

RESPONSE: Most engineers do not have the training required.

16.0 Duties of Laboratory Personnel - 3.8. Laboratory manager and supervisor should be better defined.

RESPONSE: They are adequately defined now.

16.1. Laboratory technicians should be permitted to evaluate and pass their own work without supervisory approval.

RESPONSE: This is not an adequate control. A technician can make a gross error in calculations and make the same error upon checking the results, if the results are ever rechecked. No change will be made.

17.0. Effect and Duration of Suspension - 3.13.1. WVMA wants revocations and suspensions to be by test parameter.

RESPONSE: This is the way suspensions are done. Revocations are for gross misconduct by the laboratory which removes all testing from their scope.

17.1. A facility does not "suddenly" find itself with a revoked certification. They know well in advance that certification will be revoked. The wording now used is that of the WVMA three years ago. No change is needed.

18.0. Appeals 3.15. Move appeal section to end of regulations along with severability clause.

RESPONSE: This change will be made.

19.0. Sections 4 and 5 should be deleted.

RESPONSE: These sections are needed because they address laboratory requirements not specifically addressed by the US-EPA in 40CFR136.



DEPARTMENT OF COMMERCE, LABOR & ENVIRONMENTAL RESOURCES
DIVISION OF ENVIRONMENTAL PROTECTION

1201 Greenbrier Street
Charleston, WV 25311-1088

Gaston Caperton
Governor

John M. Ranson
Cabinet Secretary

David C. Callaghan
Director

Laidley Eli McCoy
Deputy Director

August 9, 1994

Judy Cooper
Secretary of State's
Administrative Law Office
Capitol Complex
Charleston, WV 25305

Dear Ms. Cooper:

In accordance with state regulations, the Division of Environmental Protection's Office of Water Resources offers the following information regarding the August 1, 1994 public hearing scheduled to discuss the proposed regulations governing Environmental Laboratory Certification and Performance Standards:

Two individuals attended the 3:00pm public hearing, held at the Division of Environmental Protection's Nitro Office.

Bob Foster, an employee of Charles Ryan & Asso.
1012 Kanawha Blvd, Charleston, WV 25329,
representing the WV Manufacturers Asso.

Paul Sutherland an employee of Bio-Chem Testing,
Inc., Putnam Village Shopping Center, General Delivery,
Teays, West Virginia 25569-9999.
representing himself

The agency would like to take this opportunity to respond to Mr. Foster's comments. Mr. Foster's paraphrased comments will be presented in bold type:

The proposed regulations do not explain the provisions established regarding excess fees that are collected.

A surplus of funds is not anticipated through laboratory certification fee collections. Agency estimates first year program expenditures totaling \$182,700 and successive years cost at \$225,000.

Out-of-state laboratories should be assessed similar fees as in-state laboratories.

Ms. Judy Cooper
August 9, 1994
page two

The proposed fee schedule does not distinguish between in-state and out-of-state laboratories; therefore the fees imposed will be the same.

Per-diem fees charge for out-of-state laboratory inspections may be unconstitutional.

Other states representatives charge very large per diem fees when sent to conduct West Virginia laboratory inspections. This service provided by Quality Assurance/Quality Control personnel is not a legal requirement. However, the services are not provided without cost; therefore, these laboratories should compensate the agency for expenses incurred.

Section 3.1.2 and 3.4 contain language regarding reciprocity which can be deemed inconsistent.

Simply stated, section 3.1.2 establishes the possibility of obtaining, with other states, certification by reciprocity. Section 3.4 stipulates the terms under which reciprocity will be granted.

When incorporating Code of Federal Regulations, Chapter 40, part 136 by reference; are parts 4 and 5 actually required?

40CFR136 describes, in detail, the organic chemical compound analysis requirements. The cited regulation does not address inorganic chemistry, microbiology, or aquatic toxicity testing guidelines. Additionally, the federal regulation does not specify quality control procedures or laboratory record keeping practices.

Bureau of the Environment
Division of Environmental Protection
Office of Water Resources
1201 Greenbrier Street
Charleston, WV 25311-1088
Telephone (304) 558-0320

**NOTICE OF PUBLIC HEARING
AND COMMENT PERIOD:**

**PROPOSED REGULATIONS GOVERNING ENVIRONMENTAL
LABORATORY CERTIFICATION AND PERFORMANCE STANDARDS**

The Division of Environmental Protection (DEP), under the authority of the state Water Pollution Control Act, (Chapter 22-11-1 et. seq.); Hazardous Waste Management Act, (Chapter 22-18-1 et. seq.); Solid Wastement Management Act, (Chapter 22, 15-1 et. seq.); Underground Storage Tank, (Chapter 22-17-1 et. seq.) is proposing regulations governing laboratory certification. These regulations establish procedures for obtaining and maintaining certification. Additionally, standards for sample analyzing criteria and laboratory procedures are detailed. Laboratories located in West Virginia and outside the state conducting environmental analyses performed as referenced by regulations or orders will be affected.

This is a reissuance of the proposed regulations drafted in 1991 and subsequently discussed during a Department of Natural Resources January 17, 1992 public hearing held at the former Water Resources Board Office 1260 Greenbrier Street location.

These regulations are promulgated to ensure that environmental laboratory analyses results are accurate, reproducible and verifiable. This purpose will be achieved by:

- A. Establishing administrative procedures to be followed by certified laboratories and laboratories seeking certification.
- B. Establishing the categories and parameters in which laboratories may be certified.
- C. Establishing minimum requirements, criteria and procedures for laboratory equipment and supplies, practices, methodology, quality control, personnel, facilities, data reporting, laboratory and record maintenance, which a certified laboratory shall continually meet.
- D. Establishing the enforcement procedures the Department shall follow to ensure that all certified laboratories or laboratories seeking certification are in compliance with these regulations.

A laboratory may apply for certification in one or more of the following categories: Atomic Absorption, Limited Chemistry,

Gas Chromatography, Mass Spectrometry, Microbiology, Aquatic Toxicity and Radiological Testing.

These regulations also set forth an annual fee schedule for the aforementioned certification categories. State of West Virginia owned or operated and Federal agency laboratories are exempt from required fees. However, the laboratories must apply for certification.

Education and experience requirements for laboratory personnel are discussed in the proposed regulations. Current employee records shall be maintained.

Laboratories located in West Virginia must observe the following application procedures and requirements.

1. Owners of West Virginia laboratories who wish to be certified shall apply for certification to the Division of Environmental Protection, Office of Water Resources, Quality Assurance Office. The applicant shall submit the appropriate fee(s) when submitting the application.
2. If the appropriate fee(s) are not submitted or all requested information is not provided, the Division shall reject the application without prejudice.
3. If the information submitted meets minimum requirements and the appropriate fee(s) accompany the application, the application shall be accepted. Application acceptance does not authorize the laboratory to perform analyses. Laboratory inspection will determine whether the facility meets or exceeds minimum requirements.
4. Performance evaluation samples shall be part of the inspection.
5. The results of the analyses or performance evaluation samples testing shall be considered in determining certification.

Persons wishing to comment on the proposed Laboratory Certification may submit their concerns in writing or attend a public hearing to submit written or oral statements to the Division of Environmental Protection. Written comments on the proposed regulations will be accepted until 4:00 pm, Monday, August 8, 1994. Comments should be addressed to:

Laboratory Certification
Chief, Office of Water Resources, DEP
Attn: Jim Waycaster, Public Information Specialist
1201 Greenbrier Street
Charleston, West Virginia 25311-1088

Division of Environmental Protection will hold a public hearing on the proposed Laboratory Certification at the following place and time:

Time: 3:00 pm, Monday, August 1, 1994
Place: DEP Office Building - Training Room
(formerly Hecks Corporate Office Building)
10 McJunkin Road
Nitro, West Virginia 25143-2506

The hearing will be held pursuant to Chapter 22, Article 11, Code of West Virginia, and Series II, Section 46-2-12 of the West Virginia Legislative Rules. Oral statements will be heard; however, submission of statement in writing is encouraged for accuracy of the record. All comments will be considered before a final decision is made regarding the proposed Laboratory Certification regulations.

Copies of the proposed regulations can be obtained upon request by contacting the public information office at (304) 558-3615.

The proposed regulations may be inspected, by appointment only, between 7:30 am and 3:30 pm, Monday through Friday, at the Office of Water Resources, at 1201 Greenbrier Street, Charleston, West Virginia. Contact Ms. Anne Howell, Office of Water Resources, to schedule an appointment. Also the proposed regulations may be reviewed, by appointment only, at any of the six DEP District Offices 8:30am - 4:30pm, Monday through Friday: 1) District I, 1304 Goose Run Road (304) 367-2720, Fairmont; 2) District II, 1 Depot Street, Romney (304) 822-3551; 3) District III, French Creek (304) 924-6211; 4) District IV, MacArthur, (304) 256-6850; 5) District V, 694 Winfield Road, St. Albans, (304) 759-0704 and 6) District VI Parkersburg.

Hearing impaired individuals having access to a Telecommunication Device for the Deaf (TDD) may contact our agency by calling (304) 558-2751. Calls must be made 8:30 am to 3:30 pm Monday through Friday.

Additionally, copies of the proposed Laboratory Certification may be obtained for a nominal fee by contacting either the Charleston Office or any of the DEP district office locations.

**COMMENTS OF THE
WEST VIRGINIA MANUFACTURERS ASSOCIATION
REGARDING PROPOSED REGULATIONS GOVERNING
ENVIRONMENTAL LABORATORIES CERTIFICATION AND
STANDARDS OF PERFORMANCE
47 CSR 32**

I. INTRODUCTION.

On June 30, 1994, the West Virginia Division of Environmental Protection ("DEP" or "Division") filed with the Secretary of State a proposed rule that would govern the certification of environmental laboratories in this state and establish performance standards for those laboratories. The Preamble to the proposed rule requested both written and oral comment and scheduled a public hearing. Pursuant to this notice, the West Virginia Manufacturers Association ("WVMA") has undertaken a review of the proposed rule and files these comments.

This rulemaking is of special importance to most WVMA members. Many of our members use their own laboratories, and most of our members depend on independent laboratories to conduct compliance monitoring and testing. In addition, many of our members depend on the services of out-of-state laboratories to perform specialized and infrequent testing for which no in-state laboratory provides service.

The WVMA recognizes the efforts of the DEP in developing a laboratory certification rule that will benefit the state, its environmental programs, and the regulated community, and the WVMA offers these comments to assist the DEP in the development of a reasonable, effective, and protective rule.

II. COMMENTS.

1. Incorporation by Reference -- 1.5.

The WVMA recognizes that in this increasingly complex world, regulation is necessary. We strongly encourage DEP, however, to promulgate environmental regulations that are as simple to understand and comply with as possible while accomplishing DEP's regulatory objectives. We commend the DEP for its willingness to incorporate federal regulations by reference, where possible, which greatly eases the administrative burden on the regulated community to compare and comply with divergent state and federal programs.

The proposed rule incorporates by reference the Environmental Protection Agency's (EPA's) Guidelines Establishing Test Procedures for the Analysis of Pollutants, 40 C.F.R. Part 136, EPA's SW 846 Test Methods, "or any other such methods as may be approved by the EPA." The WVMA commends this incorporation by reference; however, the disjunctive "or" should be changed to the conjunctive "and" in this section, to clarify that all approved federal testing methods are incorporated by reference, rather than only one testing method.

To clarify that changes to federal regulations occurring after the effective date of Series 32 will not be applicable until such time as the state incorporates those federal changes through amendment or formal rulemaking, the following sentence should be added to the end of the section:

Unless otherwise indicated, where reference to a federal regulation or standard appears in this rule, such regulation or standard will, for purposes of this rule, be construed as that version in effect as of July 1, 1994.

2. Purpose of the Rule -- 1.7.3.

As a matter of regulatory drafting, the purpose and definitions sections of the rule should not include independent regulatory requirements. Requirements located in these portions of the rule are easily overlooked and increase the likelihood that an inconsistency will occur with other requirements in the body of the rule. Accordingly, the WVMA recommends that the clause, "which a certified laboratory shall continually meet," should be deleted (the intent of the regulation, that minimum standards shall be met by certified laboratories, is clear without this clause) or moved from the statement of purpose section of the rule to the body of the rule.

3. Definitions -- 2.

"APHA Standard Methods" -- 2.4

This section defines "APHA Standard Methods" and "Standard Methods for the Examination of Water and Wastewater" as the methods published by the American Public Health Association. Because these methods are periodically updated in editions, the rule's phrasing should be changed to "latest approved edition of the methods in effect as of July 1, 1994", which is consistent with the description made in section 4 of the rule.

"Covered Statutory Programs" -- 2.14

The words "one of" should be deleted for clarity.

"Director" -- 2.16

This definition provides that the Director may designate the Chief of the Office of Water Resources to administer the rule. While the WVMA has no objection

to such designation occurring, this substantive provision should not be included in the definitions section of the rule, as discussed in Comment 2 above. The WVMA recommends that this statement of the Director's authority be moved to the body of the rule itself.

"Person, Persons, or applicant" -- 2.23

The definition provides a list of entities who may be persons or applicants for purposes of the rule. At a minimum, the plural "applicants" should be removed from the definition's title, to read "Person or Applicant", because the plural is assumed in all other definition titles in this section. In addition, to avoid a possible interpretation of the definition as being exhaustive, the word "including" should be changed to the phrase, "including, but not limited to,".

Other sections of the rule suggest that owners, principal officers, managers, and supervisors are the appropriate, if not only, persons who may apply or reapply for certification. The definition of "Person, Persons or applicant", however, suggests that an applicant may be any of the entities so listed, and may be an organization rather than a human being. The WVMA suggests that the laboratory should be clearly identified as the applicant, and a human being should be identified as the application preparer. If the DEP chooses not to accept this position, the WVMA asks that DEP clarify which persons or entities may function as an applicant.

"Personal and direct supervision" -- 2.24

Because the definition of supervisor in subsection 2.30 presumes that the supervisor has met the qualifications of subsection 3.7, the modifier "qualified" is

redundant here and should be deleted.

"Standard curve" -- 2.29

For clarity, this subsection should be revised as follows:

"Standard curve" means a curve plotting concentrations of a known parameter minus a blank. Standard curve does not include other concentration measurements, including, but not limited to, instrument response, the absorbance parameter of the standard, or the percent transmittance of the standard.

4. Requirements of Certification -- 3.1.

The WVMA urges DEP to set out the time period for which certification and recertification will run. Although the rule anticipates annual fees, it does not establish whether laboratory certification is effective for a one year period.

The WVMA notes that this section refers to a "laboratory proper" while the rule only defines "laboratory" in the definitions section. To avoid confusion, the word "proper" should be deleted from the body of the rule, or "laboratory proper" should be defined in the definitions section.

5. [Requirements and Exceptions] -- 3.1.1.

The WVMA applauds the well-crafted exception for tests not ordinarily performed in a laboratory proper. To clarify further this exception, the WVMA recommends that the rule include the following example:

With the exception of those tests not normally performed in a laboratory proper, *including, but not limited to, turbidity, chlorine residual, fluoride concentration, pH, temperature and conductivity analyses,*

6. [Reciprocal State Certification] -- 3.1.2.

The WVMA commends the Director for recognizing that out-of-state labs may be recognized as certified in West Virginia if the foreign state has a reciprocal certification program. The WVMA recommends that the rule list the factors the agency will consider when making the equivalency determination.

7. [Requirement for Application] -- 3.3.1.

This subsection provides that application for certification in a category must be made to the DEP's Quality Assurance Program. The language of this subsection suggests that a person operating a laboratory may become certified. As outlined more fully in comment 3 above, the WVMA believes that this construction is not the intent of the Director; the laboratory should be the recipient of certification status, not the applicant. This construction is also more consistent with subsection 3.3.6.c, which provides that laboratory certification is transferrable. Accordingly, the WVMA recommends that the first sentence of this subsection be changed to the following:

For a laboratory to obtain certification in one or more categories or parameters, or for laboratories already certified to add certification in another category or parameter, the owner, principal officer, manager, or supervisor of the laboratory must submit an application for certification on behalf of the laboratory with the West Virginia Division of Environmental Protection, Quality Assurance Program.

This change is consistent with subsection 3.3.6.c. of the rule, which provides that certification is transferrable if ownership or management of the laboratory changes.

8. [Performance Evaluation and Inspection] -- 3.3.4.

"[T]his inspection" should be changed to "the inspection contemplated in subsection 3.3.2 of this rule".

9. [Denial of Application] -- 3.3.6.

"[C]hapter" should be changed to "rule".

[Denial of Application] -- 3.3.6.a.

"Officer" should be changed to "Office".

10. [Program Phase-In Provisions] -- 3.3.8.

Laboratories should be required to conform to an acceptable EPA test method for an analyte. To require conformity with all applicable EPA methods for a particular analyte is unnecessary and excessive, and the WVMA does not believe this construction was the intent of the Director. To avoid this construction, the WVMA recommends that the word "all" be omitted from this subsection.

The sixty-day phase-in period provided for in this subsection is inadequate time for facilities that need to identify multiple categories or parameters. The WVMA suggests that the phase-in period be extended to ninety days. The WVMA encourages DEP to allow ample time for laboratories to develop their applications, because any lapse in the operation of a laboratory will have severe consequences for the laboratory, as well as manufacturing, industrial, or other facilities that rely on the laboratory for compliance monitoring data. Facilities relying on such a laboratory would be subject to enforcement or penalties for non-compliance with applicable recordkeeping and reporting requirements.

The WVMA also recommends that laboratories not be limited to three opportunities within a 120-day period to demonstrate acceptable performance on a given parameter, as provided in subsection 3.3.8.b.A. Laboratories should receive certification for parameters successfully completed as they are completed, and should be free to request additional chances to demonstrate acceptable performance at any time for those parameters they have been unsuccessful in performing. This is consistent with other provisions of the rule that allow a certified laboratory to extend the range of tests or analyses offered at any time by demonstrating proficiency in the requested parameters. The WVMA requests that the present language of this section be deleted in its entirety and replaced with the following sentence:

For those parameters for which a laboratory has not successfully completed the performance evaluation, the laboratory shall be reevaluated upon written request.

The WVMA commends the DEP for including a provision in the proposed rule allowing submission of a plan to correct deficiencies. The time period allowed for submitting such a plan, however, should be long enough to identify the laboratory problems at issue and develop such a plan. The fifteen day-period provided in the proposed rule is inadequate to serve these purposes; the WVMA recommends that this time period be thirty days. The rule should also clarify that the laboratory may continue to operate while the plan is pending before the Director.

**11. Application Procedures and Requirements for Laboratories
 Not Located in West Virginia -- 3.4.**

Subsections 3.4.1, 3.4.2, and 3.4.3 apparently contain provisions applicable to laboratories subject to reciprocity, while subsection 3.4.4 applies to out-

of-state laboratories not certified in a reciprocal program. For clarity, one subsection should contain all the provisions applicable to "reciprocal" out-of-state laboratories, and one subsection should contain all the provisions applicable to "non-reciprocal" out-of-state laboratories.

The WVMA recommends that subsections 3.4.1, 3.4.1.a-c, and 3.4.2 be deleted to avoid potential constitutional challenges to regulatory provisions that impose more requirements on out-of-state laboratories than on in-state laboratories. Out-of-state laboratories should be treated in the same manner, to the extent possible, as in-state laboratories. For example, once out-of-state laboratories have been certified through reciprocity, they should be subject to the same renewal of certification provisions as in-state laboratories. They should not be subject to a separate requirement, as established in subsection 3.4.1, to complete annually an application form. This requirement is burdensome and unnecessary to run the program.

Of particular concern is subsection 3.4.4, which requires out-of-state laboratories to pay the state of West Virginia a monetary sum (per diem travel expenses) so that West Virginia can determine whether that state is in compliance with West Virginia regulatory requirements. This subsection could face legal attack by out-of-state laboratories (an out-of-state laboratory in Ashland, Kentucky would be required to pay a per diem fee, while a laboratory further from Charleston, such as Martinsburg, would not be required to pay a per diem fee). The WVMA recommends that the costs of inspectors be included within program costs and not charged

differentially to laboratories based on in-state or out-of-state status. If necessary, DEP should increase the \$150,000.00 fee cap to cover the costs. Accordingly, the last sentence in subsection 3.4.4 should be deleted.

If DEP should retain the provisions of subsection 3.4, the language and requirements should parallel those of 3.1.2. These subsections are currently inconsistent. The current language of subsection 3.1.2 allows reciprocity for a laboratory doing business in a state outside West Virginia and certified by the state in which it does business, while subsection 3.4.1 anticipates reciprocity for a laboratory located in a state outside West Virginia and certified by the state in which it is located. For a laboratory doing business in and certified in Virginia, but physically located in Pennsylvania, subsection 3.1.2 would look to Virginia law to determine reciprocity while subsection 3.4.1 would look to Pennsylvania law.

12. Compilation of List with Equivalent Laboratories Certification Programs.

To facilitate compliance with the provisions of the equivalency section of the rule, the WVMA requests that the DEP compile and distribute to laboratories and permit holders during the first year after implementation of the laboratory certification program a list of states outside West Virginia that have laboratory certification programs equivalent to the requirements of the West Virginia laboratory certification program. This list should include the parameters for which the programs of other states have been determined to be equivalent or nonequivalent. The list should be updated annually, and should be revised whenever the status of another state's laboratory certification program changes. The development of such a list will

help facilities located in West Virginia to select laboratories in other states that will be capable of providing acceptable data and test results to DEP.

13. Government Owned/Operated Laboratories -- 3.6.2.

Federal and state laboratories should not be exempt from fee requirements.

14. Fees -- 3.6.3.

This subsection should make clear that fees collected under this rule, including unexpended monies, may be used only to administer the laboratory certification program and may not default into general revenue or any other state funds, trusts, or programs. The fees collected under this subsection could exceed the statutory fee cap, and excess fees collected should either be returned to the laboratories or rollover to the next program year.

This section should also make clear that the fee for hazardous characteristics testing is per procedure, not per parameter. A procedure may contain many separate parameters, and such a construction could result in a fee out of proportion with the rest of the regulatory fee structure, and potentially in the thousands of dollars. Small independent laboratories may not be able to afford this type of fee burden.

DEP should also consider providing one fee that would allow a laboratory to be certified in all categories and parameters. With the present fee schedule, it is possible for an individual laboratory to pay crippling fees if that laboratory conducts testing in multiple categories. For example, a laboratory could opt to pay a \$750

annual fee covering all categories for which it could meet certification requirements.

15. Required Laboratory Personnel Qualifications -- 3.7.

The personnel qualification requirements should be revised to allow persons with degrees in engineering to act as a laboratory manager or supervisor.

The WVMA also suggests that a laboratory should not be required to keep a "resume" on file for each employee, as is the condition in subsection 3.7.2; rather, it should be sufficient for each laboratory to maintain the data outlined in the proposed regulation in its ordinary business records or personnel records.

16. Duties and Responsibilities of Laboratory Personnel -- 3.8.

This section of the rule should be revised to clarify the distinction between the laboratory manager and laboratory supervisor, and should clarify whether one person may act as both manager and supervisor. The section should state that a laboratory supervisor may perform tests and analyses in addition to supervising other laboratory analysts. In addition, subsection 3.8.1 should be revised to delete the requirement that the laboratory manager approve all tests and analytical results. It has been the experience of many WVMA members that tests and analytical results are more accurate when the laboratory technician who performs the test or analysis is assigned primary responsibility for ensuring that results are accurate. Approval of each test or analytical result by the laboratory manager gives laboratory technicians a false sense of security, and leads to less accurate analytical results. Manufacturers within the state have found that proper and adequate on-the-job training is the most effective safeguard against mistakes escaping the attention of laboratory technicians.

This revision to the rule would in no way relieve the laboratory manager of ultimate responsibility for the operation and management of a lab.

17. Effect and Duration of Suspension and Revocation -- 3.13.1.

This subsection states that the results of any tests or analyses performed after issuance of a suspension or revocation order shall not be accepted for the use of demonstrating compliance with NPDES reporting requirements. This provision should be revised to state that the results of tests or analyses for those parameters for which a suspension or revocation order has been issued shall not be used for demonstrating compliance.

This section should also be revised to take into account the problems that may occur when a facility suddenly discovers that its laboratory's certification has been suspended or revoked. Facilities generally cannot change laboratories overnight, and in many cases, facilities may be locked into the use of a particular laboratory through contractual arrangements. Facilities should not be punished for the actions of third party laboratories over which they have no control. This section should be revised to grant a grace period to facilities utilizing the laboratory for which the suspension or revocation is issued, during which the facilities may arrange for testing and analyses with other laboratories. The WVMA requests that this section be revised to state as follows:

The results of any tests or analyses performed for the parameters for which certification has been suspended or revoked will not be accepted by the Division as compliance with the requirements for NPDES reporting, except as follows:

When the owner or operator of a laboratory which has had certification revoked or suspended has made reasonable efforts, and been unable, to secure release from its contractual obligations from such laboratory and/or to find alternate laboratories, the results of these tests or analyses will be accepted for purposes of demonstrating compliance for a period of thirty days after the suspension or revocation. The Director may, at his or her discretion, extend this period by an additional thirty days.

18. Appeal to Environmental Quality Board -- 3.15.

The WVMA lauds the DEP for including a specific appeal provision in this rule. We recommend, however, that this provision be placed at the end of the rule along with the severability clause, for administrative convenience and consistency with other administrative rules. We suggest that the following language be added:

The results of the performance evaluation and/or inspection may be appealed to the Environmental Quality Board pending or after the Director's issuance or denial of certification.

An appeal to the Environmental Quality Board will stay the denial, suspension, or revocation of certification or interim approval pending the final determination of the Environmental Quality Board of the matter.

19. Laboratory Requirements -- 4.
Methodology, Quality Control -- 5.1, 5.2.

These sections should be deleted to the extent that they do more than simply incorporate by reference applicable EPA guidelines and analytical methods. Portions of these requirements appear to be taken from federal requirements, which the West Virginia regulated community is already obliged to follow. As environmental regulatory programs proliferate, we cannot urge strongly enough that the DEP seek to streamline its regulations and not restate the same regulatory requirements where

unnecessary. The burden to read and compare an extra five or fifteen pages with federal regulations is not insignificant; the burden to do so in an entire environmental program quickly adds up to a staggering amount of work for the regulated community.

In addition, section 4 overregulates laboratory management requirements, and should be deleted in toto. For example, subsection 4.2.2 provides that "[l]aboratory work areas will be arranged so as to minimize problems in contamination, transportation, and communication." This requirement may not be achievable due to fire, OSHA, or other requirements. Subsection 4.2.10 requires that laboratory glass be borosilicate and that magnetic stirrers use teflon-coated stirring bars. Overly-detailed requirements such as these inhibit laboratories from seeking out or using more cost-effective or advanced equipment.

20. [Analytical Balance Checks] -- 5.2.2.a.

A daily weighing check is unnecessary and may create restrictions on the normal operations of a laboratory. The WVMA suggests that the DEP retain the monthly adjustment of analytical balances.

21. [Thermometer Storage] -- 5.2.2.f.

The WVMA suggests that the suggestion that thermometers be kept in a low vapor pressure liquid is appropriate; however, the DEP should not use the example of 50/50 water/Ethylene Glycol without making it clear that such an illustration is merely an example, not a requirement. It should be noted that some laboratories simply store thermometers in water, and the regulation should recognize that this practice is appropriate.

22. [Documentation of Precision and Accuracy Testing] -- 5.2.2.k.

The WVMA does not object to the taking of spiked samples. Precision and accuracy testing, however, may be unnecessary, and this subsection does not clarify whether such tests are required. The WVMA recommends that the last sentence of this section be changed as follows:

If precision and accuracy testing are conducted, the laboratory must make appropriate documentation.

23. [Standard Deviations] -- 5.2.2.1.

The requirement that standard deviations be conducted in the Limited Chemistry and Atomic Absorption categories is unnecessary. Laboratories that already maintain quality control charts and data should not need to calculate standard deviations as a matter of course. Further, the data is always available if standard deviations need to be run later as an additional check.

24. [Frequency and Procedures for Gas Chromatography] -- 5.2.6.

This subsection should be revised to state that the laboratory may choose to use either SW-846 or the Contract Laboratory Program Statement of Work for Organics Analysis.

25. Records and Data Reporting -- 5.3.

The WVMA recognizes the importance that recordkeeping and data reporting requirements be tailored to the specific needs of DEP to facilitate enforcement efforts. The WVMA requests, however, that subsection 5.3.1 be clarified to indicate the types of data that constitute "raw data." This section should be revised to indicate that computer printouts may serve as raw data if the computer

printout is produced at or near the time of data generation, and is thereafter stored in its physical form for purposes of satisfying the recordkeeping and reporting requirements.

26. [Date and Time of Sampling] -- 5.3.2.c-d.

The time of sample analysis should not be important unless multiple samples are required to be run in one day or unless holding time is significant. Accordingly, the time the laboratory received the sample and conducted the analysis should not be required to be recorded unless these circumstances are present. Further, notation of whether the sample was preserved or unpreserved should not be recorded except in the case of drinking water samples.

III. CONCLUSION.

The WVMA appreciates this opportunity to present its comments and suggestions. It acknowledges the difficulties of keeping pace with changing federal requirements, and endorses the Division's responsible approach of doing this yearly, as necessary. Please address any questions or comments to Robert L. Foster, Chairman, Environmental, Health, and Safety Committee, at 342-0161.

Respectfully submitted August 8, 1994.

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TITLE 47
LEGISLATIVE RULES
BUREAU OF ENVIRONMENT
DIVISION OF ENVIRONMENTAL PROTECTION
OFFICE OF WATER RESOURCES

SERIES 32
REGULATIONS GOVERNING ENVIRONMENTAL LABORATORIES
CERTIFICATION AND STANDARDS OF PERFORMANCE

§47-32-1. General.

1.1. Scope. -- This rule governs the certification of laboratories conducting environmental analysis of waste and wastewater performed as required by rules or orders issued pursuant to the covered statutory programs. The rule establishes the provisions for obtaining and maintaining laboratory certifications and the criteria and procedures laboratories will be required to follow in analyzing samples.

1.2. Authority. -- West Virginia Code §22-1-15.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Incorporation by Reference. -- The Division hereby adopts and incorporates into this rule the approved "Guidelines Establishing Test Procedures for the Analysis of Pollutants" 40 CFR 136, EPA SW 846 Methods, ~~or~~ and such other methods as may be approved by U.S. Environmental Protection Agency (EPA) or the Director.

1.6. Construction. -- This rule shall be liberally construed to permit the division of environmental protection to discharge its statutory functions and to effectuate the purposes of the laboratory certification program.

1.7. Purpose of this Rule. -- This rule is promulgated to insure that the results of environmental analyses are accurate, reproducible and verifiable. This purpose will be achieved by:

1.7.1. Establishing the administrative procedures to be followed by certified laboratories and laboratories seeking certification;

1.7.2. Establishing the categories and parameters in which laboratories may be certified;

1.7.3. Establishing the minimum requirements, criteria and procedures for laboratory equipment and supplies, practices, methodology, quality control, personnel, facilities, data reporting, and laboratory and record maintenance, which a certified laboratory shall continually meet; and

1.7.4. Establishing the enforcement procedures the division will follow to ensure that all certified laboratories or laboratories seeking certification are in compliance with this rule.

1.8. Certification Program Requirements.

1.8.1. A laboratory analyzing samples for compliance with adopted rules, permits, or orders issued pursuant to a covered statutory program will follow the procedures set forth in this rule in order to obtain and maintain certification. The provisions of this rule are only applicable to tests required by State and Federal regulatory programs.

1.8.2. Certified laboratories and laboratories seeking certification will analyze all samples requiring testing under this rule in accordance with the procedures and methods required by this rule.

1.9. Program Information and Communications. -- Questions concerning the requirements of this rule should be directed to the Division of Environmental Protection, Office of Water Resources, Quality Assurance Program, 1201 Greenbrier Street, Charleston, WV 25311. Telephone Number (304) 558-0321.

1.10. Relationship of rule to federal programs -- There is no counterpart federal regulation.

§47-32-2. Definitions.

The following words and terms, when used in this rule have the following meanings unless the context clearly indicates otherwise.

2.1. "Accredited" means an approval conferred upon institutions or programs where appropriate by a nationally recognized accrediting agency or association as determined by the Division.

- 2.2. "Analyte" means an element, ion or compound of interest to the analyst.
- 2.3. "Analytical Reagent Grade" (AR), "ACS reagent grade", and "Reagent Grade" are synonymous terms for reagents which conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society.
- 2.4. "APHA Standard Methods" or "Standard Methods for the Examination of Water and Wastewater" means the methods published by the American Public Health Association, 1015 Fifteenth Street NW, Washington, DC 20005.
- 2.5. "Approved analytical methods" are those analytical or test methods cited in the Code of Federal Regulations as being approved by EPA or such other methods as shall be approved by the Director.
- 2.6. "Category" means a group of parameters for which certification is offered.
- 2.7. "Certification" means the approval granted by the chief authorizing a laboratory to provide environmental compliance data.
- 2.8. "Certification parameter" means a parameter which is identified in a performance evaluation sample test and that is used to evaluate the overall analytical performance of a laboratory on the specific method.
- 2.9. "Certification year" is that period of time following the date upon which the laboratory first receives certification for any parameter or category and lasting for 365 consecutive days.
- 2.10. "Certified thermometer" is a thermometer that has documentation from the manufacturer showing that it has been compared against a National Institute for Standards Testing (NIST) thermometer covering the temperature ranges employed by the laboratory.
- 2.11. "CFR" means the Code of Federal Regulations.
- 2.12. "Chief" means the Chief of the Division of Environmental Protection's Office of Water Resources.
- 2.13. "Compliance analysis" means the analysis of a sample that is required to be analyzed by a division rule, permit or order.
- 2.14. "Covered statutory programs" means one of the regulatory programs developed under statutory authority of one of the following acts of the Legislature:

- 2.14.1. Water Pollution Control Act, WV Code §22-11-1.
- 2.14.2. Hazardous Waste Management Act, WV Code §22-18-1.
- 2.14.3. Hazardous Waste Emergency Response Fund Act, WV Code §22-19-1.
- 2.14.4. Underground Storage Tank Act, WV Code §22-17-1.
- 2.14.5. Solid Waste Management Act, WV Code §22-15-1.
- 2.14.6. Groundwater Protection Act, WV Code §22-12-1.

2.15. "Division" means the West Virginia Division of Environmental Protection, Bureau of Environment.

2.16. "Director" means the director of the West Virginia Division of Environmental Protection, Bureau of Environment. The Director may designate the Chief of the Office of Water Resources to administer this rule.

2.17. "EPA" and "USEPA" means the United States Environmental Protection Agency.

2.18. "Laboratory" means a facility conducting tests or analyses of parameters for which certification is required, where the results of such tests or analyses are used for purposes of demonstrating compliance under the covered statutory programs. Provided; The term "laboratory" shall not include individuals conducting analyses of constituents that must be conducted in the field because of practical constraints; such as, but not limited to pH, dissolved oxygen, total residual chlorine and sulfide.

2.19. "Laboratory pure water" means distilled or deionized water which is free of contaminants that interfere with analytical tests.

2.20. "Laboratory seeking certification" means an uncertified laboratory which has submitted an acceptable application and the appropriate fee.

2.21. "Parameter" means an analytical method or test within a category and for which certification is offered.

2.22. "Performance evaluation sample" means a sample containing a known amount of a specific or combination of parameters used in part to evaluate the

performance of a laboratory.

2.23. "Person, Persons, or applicant" means any industrial user, public or private corporation, institution, association, firm or company organized or existing under the laws of this or any other state or country; state of West Virginia; governmental agency, including federal facilities; political subdivision; county commission; municipal corporation; industry; sanitary district; public service district; drainage district; soil conservation district; watershed improvement district; partnership; trust; estate; person or individual; group of persons or individuals acting individually or as a group; or any legal entity whatever.

2.24. "Personal and direct supervision" means that a ~~qualified~~ supervisor is available either in person or on call at all times when laboratory procedures are being performed.

2.25. "Primary Standard" means a highly pure reagent used as a reference for standardizing other reagent solutions.

2.26. "Quality Assurance Program" means a regulatory program developed to achieve the purposes of subsection 1.7 of this rule for the covered statutory programs of the Division of Environmental Protection.

2.27. "Raw Data" means that data acquired in the process of collecting and analyzing samples for compliance testing purposes. Raw data includes such sampling report forms, sample log books, laboratory bench sheets, calculations and formulas, and analytical data and notes as are used during sample analysis. Raw data may be in the form of graphs, line recorder charts, handwritten data, or computer printouts made at or near the time of the analysis or sample collection.

2.28. "Replicate sample" means a sample prepared by dividing a homogeneous sample into separate parts so that each part is also homogeneous and representative of the original sample.

2.29. "Standard curve" means a curve plotting concentrations of a known parameter standard minus a blank, versus the standard's absorbance or percent transmittance or other instrument response.

2.30. "Supervisor" means that designated person responsible for the technical adequacy and quality of data for a certification category, and who possesses the qualifications required under subsection 3.7 of this rule.

§47-32-3. Certification Program; Application, Procedures, and Requirements.

3.1. Requirements of Certification.

3.1.1. With the exception of those tests not normally performed in a laboratory proper, all sample analyses required by order of the Division or performed for the purpose of determining compliance with chemical, microbiological, aquatic toxicity and radiological requirements of the State's covered statutory programs must be performed in laboratories certified for this purpose pursuant to this rule. Analyses performed in laboratories not so certified shall not be accepted by the Division as being in compliance with the requirements, rules or orders of the Division. All analyses not performed in a laboratory proper must be performed by personnel under the direction of a supervisor from a certified laboratory.

3.1.2. Laboratories doing business in other states where a state certifying agency grants reciprocal certification, approval, or other authorization to laboratories located in West Virginia, and which is certified, approved or authorized by the agency of that state having primary certification responsibility under Federal programs delegated to such other state under conditions equivalent to those required by this rule, are considered to be certified for the purpose of this rule once they have complied with the provisions of Section 3.4. Laboratories doing business in other states where certification is not required, and who are not certified in another state, may be considered for certification by following the conditions and requirements stated in Section 3.3.

3.1.3. Only laboratories certified pursuant to this rule or maintained by the EPA may be called West Virginia Certified Environmental Laboratories and no laboratory may adopt any name or make any oral or written statement intended or likely to mislead the public with respect to its certification status.

3.2. Categories of Certification. -- A laboratory applying for certification in one or more of the following categories must demonstrate acceptable performance on performance evaluation samples, where available, and meet all other requirements of this rule. The laboratory certificate will specify the categories and the parameters within each category for which the laboratory is certified and it must be displayed in a location visible to the public. Tests for all categories, except Aquatic Toxicity, must be conducted in accordance with the method and procedures specified in the Code of Federal Regulations, Chapter 40 as appropriate, or other methods that may be approved by EPA or the Director. The certification categories are:

3.2.1. Atomic Absorption, Emission Spectroscopy, and Flame Photometry -- which comprises tests or analyses for which the atomic absorption methods are

applicable or required.

3.2.2. Limited Chemistry -- which comprises chemical tests or analyses except those for which the atomic absorption, gas chromatography and/or mass spectrometry methods are specifically required.

3.2.3. Gas Chromatography (GC) and Mass Spectrometry (MS) -- which comprises tests for which the GC and MS method is applicable or required.

3.2.4. Microbiology -- which comprises tests for Coliform Bacteria, Fecal Streptococci, Pathogenic Bacteria, Plate counts, Viruses, Paracites and Paracite ova.

3.2.5. Aquatic Toxicity -- testing which must be conducted in accordance with the methods and procedures specified in Standard Methods or EPA 600/4-85-013 et.seq. (acute) or EPA 600/4-89-001 et.seq. (chronic) or other methods that may be approved by EPA or the Director;

3.2.6. Radiological.

3.2.7. Characteristics -- which include Corrosivity, Ignitability, Reactivity, Extraction Procedure Toxicity and Toxic Characteristic Leaching Procedure.

3.3. Application Procedures and Requirements for Laboratories Located in West Virginia.

3.3.1. A person operating a laboratory in West Virginia who wants to be certified in one or more of the categories and parameters thereof or, who if already certified, wants to add a category or a parameter within a category, must apply for certification to the West Virginia Division of Environmental Protection, Quality Assurance Program, refer to subsection (1.9) of this rule for address. The applicant shall submit the appropriate fee with the application for certification.

3.3.2. An application for certification is acceptable when a complete application is submitted. This includes the appropriate fee, and the information requirements of this rule for the category, categories or parameter(s) for which certification is requested. Acceptance of a complete application does not authorize the laboratory to perform analyses regulated by this rule. The applicant will be notified of the acceptance and the laboratory inspected to determine if it is in compliance with the requirements of this chapter prior to the issuance of certification.

3.3.3. An application will be rejected without prejudice for not being a

complete application.

3.3.4. Performance evaluation samples will be a part of this inspection. Proficiency testing will be in accordance with subsection 3.10 of this rule. Following acceptable analytical values for the performance evaluation samples the Quality Assurance office will contact the laboratory to arrange a mutually acceptable date for an on-site inspection. Certified laboratories that desire to extend the range of tests or analyses offered must demonstrate satisfactory results in testing Performance Evaluation samples for these additional parameters.

3.3.5. The results of the analysis or testing of performance evaluation samples shall be considered in determining whether the certification of the laboratory should be granted, renewed, denied, revoked, or suspended. Certification may be granted only for those parameters for which the laboratory performs acceptably.

3.3.6. An applicant for certification who either does not perform acceptably on the performance evaluation samples or does not meet the requirements of this ~~chapter~~ rule shall be notified by Certified Mail that certification has been denied. Laboratories notified of certification denial must immediately cease performing analyses required of a certified laboratory by this rule or the covered statutory programs.

3.3.6.a. Applicants receiving a notification of certification denial may not reapply for certification until the laboratory assures the Quality Assurance ~~Officer~~ Office in writing that all reasons for certification denial have been rectified.

3.3.6.b. Owners, principal officers, managers or supervisors of a laboratory, for which certification has been denied, may not reapply for certification of this same facility by simply changing the company or laboratory name.

3.3.6.c. Certification is transferrable. A laboratory facility must, on a form prescribed by the director, notify the Division at the address listed in subsection 1.9 of this rule that the facility is being sold or has a change of principal officer(s), manager(s) or supervisor(s).

3.3.7. Certifications may contain conditions requiring correction of minor deficiencies identified by the Quality Assurance Officer by a date or dates specified therein.

3.3.8. The following special provisions are applicable to the phase-in of the West Virginia Environmental Laboratory Certification Program:

3.3.8.a. Laboratories in operation upon the effective date of this rule may continue to conduct tests and analyses for compliance purposes for a period of 60 days following the effective date of this rule. Within the 60 days following the effective date of this rule, laboratories that desire to continue performing tests and analyses for compliance purposes must complete and submit, on a form prescribed by the Director, an Application for Certification specifying the tests and analyses for the parameter(s) for which the laboratory seeks certification, along with the appropriate fee for such application, as established under subsection 3.6 of this rule. Laboratories that have submitted a complete application and the appropriate fee to the Director within the 60 days following the effective date of this rule may continue to perform tests and analyses for the parameters listed in the application until the Director takes final action upon the application.

3.3.8.b. Laboratories conducting tests and analyses for compliance purposes prior to certification as provided in subparagraph 3.3.8.a of this rule must follow the procedures and requirements of all applicable EPA test methods or other methods approved by the Director.

3.3.8.b.A. Laboratories that fail to acceptably analyze performance evaluation samples will be granted two additional opportunities within 60 days of notification of such failure to successfully analyze the samples for such parameters that the laboratory has been unsuccessful in analyzing, as provided in paragraph 3.10.7 of this rule.

3.3.8.b.B. Laboratories that otherwise fail to meet the requirements of this rule will be allowed to continue to conduct tests and analyses if within 15 days of notification of such deficiencies, the laboratory submits to the Director a plan to correct the deficiencies. A plan accepted by the Director, with or without revision, will afford the laboratory 60 days from the date of notification of acceptance to correct such deviations in accordance with the approved plan. The 60 day period may be extended if the Director determines that more than 60 days is necessary to correct the deficiencies in accordance with the approved plan.

3.4. Application Procedures and Requirements for Laboratories Not Located in West Virginia.

3.4.1. Owners of laboratories located in a state other than West Virginia, which have been certified, approved or otherwise authorized by that state's agency having primary certification, approval or authorization responsibility for laboratory certification programs with conditions equivalent to those required by this rule, and who have entered into a reciprocity agreement with West Virginia, and who wishes to perform analyses

covered by this rule for West Virginia clients shall:

3.4.1.a. Annually complete the application form provided by the Division's Quality Assurance Office;

3.4.1.b. Have the form certified by the state agency having primary certification authorization/enforcement responsibility; and

3.4.1.c. Return the form to the Quality Assurance Office of West Virginia at the address listed in subsection 1.9 of this rule.

3.4.2. The application will be reviewed and if found to be complete the laboratory will be certified or recertified.

3.4.3. If the laboratory's certification, approval or authorization is revoked by the state agency having primary certification, approval or authorization responsibility, the West Virginia certification is automatically canceled for the same parameter(s) as has been revoked in the other state. The laboratory manager shall notify the West Virginia Quality Assurance Office and all clients in West Virginia of the revocation within 48 hours of receipt of notice of revocation.

3.4.4. The owner of a laboratory in a state other than West Virginia which is not certified by that state or is certified under conditions not equivalent to those required by this rule and who wishes to perform analyses for West Virginia clients may apply for certification in accordance with the procedure set forth in subsection 3.3 of this rule. In addition, prior to conducting the on-site laboratory inspection, the laboratory shall submit to the Quality Assurance Office a per diem sum the Division determines to be sufficient to cover the travel, room, and board expenses of the certification inspector(s).

3.5. Renewal of Certification. -- Applications for renewal of certification must be submitted, on forms provided therefor, no later than 60 days before the expiration date of certification, and accompanied by the appropriate fee. A laboratory submitting an application for renewal of certification may continue to operate under the previous certification until the Quality Assurance Office notifies the laboratory of the approval or denial of renewal.

3.6. Fees.

3.6.1. Owners of Laboratories applying for certification or renewal of certification, shall submit the appropriate fee obtained from the following annual fee schedule for each category in which the laboratory seeks certification for one or more

parameters, along with the required application materials. Fees are nonrefundable.

ENVIRONMENTAL LABORATORY CERTIFICATION ANNUAL FEE SCHEDULE

Limited Chemistry	\$25.00 per analyte or parameter
Atomic Absorption	\$10.00 per metal
Gas Chromatography/Mass Spectroscopy	\$500.00 for 600 or SW846 series methods each
Microbiology	\$50.00 per parameter per method
Aquatic Toxicity	\$500.00 Acute or Chronic each
Radiochemistry	\$500.00
Hazardous Waste Characteristics	\$100.00 per <u>parameter procedure</u>

3.6.2. Laboratories owned or operated by the State of West Virginia or an agency of the Federal Government are exempt from the above fees, but shall make appropriate application for certification in accordance with the other provisions of this rule.

3.6.3. All application fees collected under this rule will be paid into a special state treasury fund designated the "Environmental Laboratory Certification Fund" which will be used to defray the cost of administering this rule.

3.7. Required Laboratory Personnel Qualifications.

3.7.1. Each laboratory must have one individual designated as the person responsible or in charge and irrespective of any local title or designation, is herein referred to as the laboratory manager.

3.7.2. Current employee records must include a resume documenting each employee's training, degrees held, experience, duties, and date(s) of relevant employment. This provision is applicable only to the employees laboratory and environmental sampling work history.

EDUCATION & EXPERIENCE REQUIREMENTS
FOR SUPERVISORS

CERTIFICATION CATEGORY	EDUCATION + EXPERIENCE		SPECIAL REQUIREMENTS	
	(years)(1)	(Years)(2)		
Limited Chemistry & Microbiology	12 14 16	+ + +	2 or 1 or 1	ETC Certificate(3)
Atomic Absorption	16	+	2	2 years of which must be in atomic absorption
Gas Chromatography	16	+	2	2 years of which must be in gas chromatography
Mass Spectrometry	16	+	2	2 years of which must be in mass spectrometry
Aquatic Toxicity	16	+	2	2 years of which must be in aquatic toxicity testing
Radiochemistry	16	+	2	2 years of which must be in radiochemistry

Notes:

- (1) 12 years = High School diploma or GED.
14 years = 2 years of college with emphasis in laboratory technology or a natural science.
16 years = Bachelors degree in Chemistry, Biology, Environmental Science, or other natural science.
- (2) Substitution -- 1 year of laboratory experience within the specific certification category may be used for each year of education beyond 12 years.
- (3) ETC Certificate = Environmental Training Center Laboratory Technician Certificate

required of all POTW laboratory supervisors.

3.7.3. Laboratory supervisors who are also laboratory technicians and who do not have the required laboratory experience will be considered a Supervisor-in-Training and must have their work reviewed by an individual meeting the above education and experience requirements for supervisors.

3.7.4. Those persons in a supervisory position upon the effective date of this rule are not subject to the above education requirements of this rule. Those persons who do not meet the above minimum experience requirements upon the effective date of this rule may remain in a supervisory position as a Supervisor-in-Training until such time as experience requirements have been met.

3.8. Duties and Responsibilities of Laboratory Personnel.

3.8.1. The laboratory manager or his designee will administer the operations of the laboratory including the approval of test and analysis results.

3.8.2. Each laboratory supervisor shall provide personal and direct supervision for technical personnel and for the reporting of tests and analyses.

3.9. Management of Laboratories.

3.9.1. A certified laboratory may offer as a service those laboratory tests, analyses, or procedures that are within the category or categories for which it is certified.

3.9.2. A laboratory that is certified shall only report analytical data for samples which are properly labeled, and for which there is reasonable assurance the samples have been collected, preserved, stored and transported in such a manner as to assure identity, stability of the sample, and proper analysis.

3.10. Proficiency Testing.

3.10.1. Except when determined by the Quality Assurance Office that an appropriate performance evaluation test is not readily available, all certified laboratories or laboratories seeking certification shall participate in an annual performance evaluation testing program covering all tests and analyses made available within the category, categories or parameter(s) for which the laboratory is certified or seeks certification.

3.10.2. The Quality Assurance Office or its authorized agent will send to the laboratory, at the laboratory's expense, a set of performance evaluation samples, if

available, for the parameters for which certification is requested, but only following acceptance of the laboratory's application by the Division.

3.10.3. Laboratories certified or those seeking certification must test or analyze the performance evaluation samples and submit the results to the Quality Assurance Office or its authorized agent, as appropriate, within the time frame allowed each participant testing that set of samples for evaluation. Any laboratory found to send performance evaluation samples to another laboratory for testing will be denied certification and not allowed to reapply for certification for a period of five (5) years from the date of the denial.

3.10.4. The laboratory will have satisfied the requirements for testing for a parameter when it acceptably analyzes the range of values for that parameter, within a given set of performance evaluation samples, for which the laboratory seeks certification.

3.10.5. The laboratory will be informed of the results of such evaluation by the agency providing the test samples. For those parameters for which a laboratory has not successfully completed the performance evaluation after three attempts, the laboratory will be reevaluated upon written request.

3.10.6. Acceptable analysis for a value occurs when the reported value falls within the 99 percent confidence interval calculated for that sample from available performance evaluation data.

3.10.7. The laboratory will have three separate opportunities within 90 days to acceptably analyze one of three different sets of performance evaluation samples for any parameter for which the laboratory seeks certification. The laboratory need only repeat performance evaluation tests for those parameters for which the laboratory has failed to perform acceptably. Parameters for Organic Samples shall mean a method, or method subdivision (i.e. Volatiles, Extractables, BTEX, etc.). Laboratories that fail to successfully analyze at least one of the three different sets of performance evaluation samples in the time period allotted will not be reevaluated for a period of one year from the last failure.

3.11. Laboratory Inspections.

3.11.1. As a condition of obtaining and maintaining certification, a laboratory will permit and facilitate inspections by personnel of the Division. This inspection will include the physical facilities as well as laboratory records and reports.

3.11.2. The Division will conduct at least one on-site inspection of a laboratory seeking certification to determine whether or not the laboratory meets the Quality Assurance Office standards as set forth in this rule.

3.11.3. Regular inspections of laboratories certified in accordance with this chapter will be conducted during reasonable hours at intervals of not more than two years.

3.11.4. Authorized representatives of the Division may make inspections of a certified or an interim approved laboratory whenever the Division in its discretion considers such inspections necessary. A laboratory's refusal to allow entry to the Division's representative will be grounds for denial or revocation of certification.

3.11.5. During inspections, consideration will be given to staff competence, working conditions, testing or analytical methods used, quality control procedures, maintenance of records and compliance with the requirements of this rule.

3.11.6. The laboratory will be furnished with a copy of the inspection report which will list deficiencies found, and a listing of the parameters for which the laboratory has demonstrated proficiency during the inspection.

3.12. Cancellation, Suspension, and Revocation of Certification.

3.12.1. Any certified laboratory may cancel its certification in any category or parameter by notifying the Quality Assurance Office in writing of the laboratory's decision to cancel its certification. The laboratory will enclose its Environmental Laboratory Certification with the letter of notification. This cancellation notification will not entitle the laboratory to any refund of fees paid.

3.12.2. Whenever any deviations from the requirements of this rule are found, the laboratory shall comply with the provisions of paragraph 3.3.8 and parts 3.3.8.b.A and 3.3.8.b.B.

3.13. Effect and Duration of Suspension and Revocation.

3.13.1. The results of any tests or analyses performed after the effective date of a suspension or revocation order for any category or parameter will not be accepted by the Division as compliance with the requirements for NPDES reporting.

3.13.2. Suspension or revocation will not be withdrawn until all basis for the suspension or revocation have been eliminated or rectified.

3.14. Notice of Changes -- In the event there are any changes in the name, location, ownership, address, telephone number or supervisory personnel of the laboratory to which the provisions of this rule apply, then the laboratory will immediately submit written notice thereof to the Division. For supervisory personnel this provision applies only to those whose responsibilities include analyses that must be made in compliance with this rule.

~~3.15. Appeal to Environmental Quality Board -- Any person aggrieved or adversely affected by an order or action of the Director made and entered in accordance with the provisions of this rule or by issuance or denial of certification under the provisions of this rule, may appeal to the Environmental Quality Board in the same manner as appeals are taken under W. Va. Code §22B-1-7 to have the order vacated or modified. The filing of a notice of appeal will not automatically stay an order or action of the Director. The Environmental Quality Board will be reimbursed from the Environmental Laboratory Certification Fund for expenses incurred for appeal hearings filed with the Board relative to the provisions of this rule.~~

§47-32-4. Laboratory Requirements.

A certified laboratory or a laboratory seeking certification must continually meet and follow the requirements of this section.

4.1. Laboratories will have on the premises and under the control of the laboratory manager all of the equipment and instruments necessary to analyze each parameter in which the laboratory is certified, or is seeking certification. All equipment must meet the minimum standards required by the test method used.

4.2. General Requirements for All Laboratories.

4.2.1. Adequate laboratory space and facilities must be available to properly carry out the services performed in, or offered by, the laboratory.

4.2.2. Laboratory work areas will be arranged so as to minimize problems in contamination, transportation and communication.

4.2.3. Workbench space within the laboratory must be ample for the tests or analyses to be performed, have adequate lighting and be convenient to a sink, water, gas, suction and electrical outlets as necessary to properly carry out the specific tests or analyses to be performed.

4.2.4. Temperature and humidity within the laboratory are to be maintained within the limits required for the proper performance of each test or analysis, the proper operation of the various instruments, and the proper storage of expendable supplies.

4.2.5. Each laboratory will have available adequate equipment and instruments necessary to properly perform the tests and analyses for the parameters within the categories for which the laboratory is certified or is seeking certification.

4.2.6. pH meters must have an accuracy of and scale graduations within 0.1 standard unit.

4.2.7. Analytical and pan balances are to be clean, not corroded, and be provided with Class-S weights. Analytical balances will be capable of weighing to 0.1 milligram minimum. Pan balances will be capable of weighing to 100 milligrams.

4.2.7.a. An analytical balance must be mounted on a heavy, shockproof table. The balance level must be checked frequently and adjusted as necessary;

4.2.7.b. An analytical balance must be located in an area that is not near laboratory traffic and is protected from sudden drafts and humidity changes; and

4.2.7.c. Two Class-S weights are to be available for checking the analytical balance, one in the gram range and one in the milligram range.

4.2.8. Glass or metal thermometers will be graduated in one degree centigrade (or 2 degrees Fahrenheit) increments and readable to 0.5 degrees centigrade (1 degree Fahrenheit) for all analyses except fecal coliform analysis; in which case glass or metal thermometers are to be readable to 0.2 degrees centigrade.

4.2.8.a. Continuous temperature recording devices will be sensitive and accurate to within 1.0 degree centigrade (2 degrees Fahrenheit).

4.2.8.b. The column of liquid in glass thermometers will have no separation.

4.2.8.c. Thermometers must be calibrated annually for glass types and quarterly for metal types against a certified thermometer traceable to a National Institute for Standards Testing thermometer. See also subparagraph 5.2.2.g of this rule for additional thermometer requirements.

4.2.9. Sample storage refrigerators must maintain an internal temperature of 1 to 4 degrees centigrade.

4.2.10. Laboratory glassware, plastic ware, and metal utensils will meet the following requirements:

4.2.10.a. Glassware and metal utensils must resist corrosion, and be capable of withstanding high temperatures, and vigorous cleaning;

4.2.10.b. Flasks, beakers, dilution bottles, culture dishes, culture tubes and other glassware are to be of borosilicate glass and free of chips, cracks, and excessive etching;

4.2.10.c. Volumetric glassware should be Class A and need not be calibrated before use. Non Class A glassware must be calibrated before use; and

4.2.10.d. Metal utensils must be made of stainless steel or other inert material.

4.2.11. Pipettes must meet the following requirements:

4.2.11.a. Glass pipettes are to be made of borosilicate glass.

4.2.11.b. Plastic pipettes must be compatible with the reagents being measured, i.e. will not dissolve or show signs of etching or numbers being removed;

4.2.11.c. Plastic pipettes may be used for microbiological procedures only;

4.2.11.d. Pipettes must deliver the required volume quickly and accurately within a 2.5 percent tolerance; and

4.2.11.e. Pipettes must not be excessively etched, nor the mouthpiece or delivery tips chipped, or the graduation marks illegible.

4.2.12. Magnetic stirrers must have variable speeds, and use Teflon coated stirring bars.

4.3. Criteria and Procedures for Microbiological Testing.

4.3.1. The Division incorporates from the latest approved edition of APHA Standard Methods and Microbiological Methods for Monitoring the Environment, EPA 600/8-78-017 et.seq., or such other methods as may be approved by EPA or the Director, all the standards, criteria, sample and analytical procedures and methodology, quality assurance and quality control specifications for evaluation and certification purposes under subsection 4.3 of this rule.

4.3.2. Laboratory pure water will be analyzed for the parameters listed in the following table. Should the test results for any of the substances exceed the standards set forth in the table, corrective action must be taken and the water retested.

QUALITY OF PURIFIED WATER USED IN MICROBIOLOGY TESTS

Test	Monitoring Frequency	Limit
<u>Chemical Tests:</u>		
Conductivity	With each use	>0.5 megohms resistance or <2 umhos/cm at 25 degrees centigrade
pH	With each use	5.5 - 7.5
Heavy Metals (single)		
Cd, Cr, Cu, Ni, Pb, Zn	Annually	<0.05 mg/L
(total)	Annually	<0.10 mg/L
Ammonia/Organic N	Monthly	<0.10 mg/L
Total Chlorine Residual	with each use	< detection limit
<u>Bacteriological Tests:</u>		
Heterotrophic Plate count	Annually	<1000 colonies/mL

4.4. Criteria for Chemical, Gas Chromatography and Mass Spectrometry Testing and Analysis -- The Division incorporates from the latest approved edition of APHA Standard Methods, Methods for Chemical Analysis of Water and Wastes, EPA-600/4-79-020 et.seq., and US-EPA SW-846 manuals, or such other methods as may be approved by EPA or the Director, all the standards, criteria, sample and analytical

procedures and methodology, quality assurance and quality control specifications for evaluation and certification purposes under subsection 4.4 of this rule

4.5. Criteria and Procedures for Toxicity Testing -- All work is to be performed in accordance with procedures out-lined in APHA Standard Methods and/or in Methods for Measuring the Acute Toxicity of Effluents to Freshwater and Marine Organisms, EPA 600/4-85-013 et.seq., or Short Term Methods for Estimating Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, EPA 600/4-89/001 et.seq. or such other methods as may be approved by EPA or the Director for the test to be performed.

4.6. Criteria and Procedures for Radiochemical Testing.

4.6.1. The types of radiation counting systems needed to comply with this rule are described in 40 CFR 136. Laboratories are required to have on the premises and under the control of the laboratory manager those instruments needed to analyze for those activities or specific radionuclides for which the laboratory is certified.

4.6.2. Laboratories must use the analytical procedures specified in Chapter 40 of the Code of Federal Regulations, or such other procedures as may be approved by EPA or the Director.

§47-32-5. Methodology, Quality Control and Record Keeping.

5.1. Methodology.

5.1.1. Sample collection, handling, and preservation technique specified in Chapter 40 of the Code of Federal Regulations, or other procedures approved by EPA or the Director are to be followed.

5.1.1.a. Samples requiring preservation will be preserved at the time of collection.

5.1.1.b. Sample collection, handling and preservation techniques specified by the analytical methods will be followed for the parameters analyzed by those methods.

5.1.1.c. The sample report form (chain of custody) must be completed immediately after collection and will state the sampling location, date and time of collection, collector's name, and any remarks.

5.1.1.d. After the sample has been collected, the appropriate information as to identity of the sample is to be written on the label. The label must remain affixed to the sample container and is not to be removed until the required analyses have been completed and the surplus sample has been discarded.

5.1.1.e. Immediately upon delivery of the sample to the laboratory, the sample collector will complete the appropriate chain of custody section of the sample report form or chain of custody form. A chain of custody form is not required where the sampler is also the analyst and in situations where the laboratory and the sample site(s) are within the property boundaries of the facility in which the laboratory is located.

5.1.1.f. Prior to accepting custody of a sample, laboratory personnel must be reasonably assured that the sample has met the preservation requirements. If the sample fails to meet these requirements, the sample chain of custody form is to be marked indicating the sample was improperly preserved.

5.1.1.g. When it is necessary to send samples by mail, bus, courier service, or private shipping, the chain of custody form is to be completed by the sampler and is to accompany the samples during shipping. Upon receipt of the samples in the laboratory, the provisions of subparagraph 5.1.1.f of this rule are to be followed.

5.1.2. Test procedures identified in Chapter 40 of the Code of Federal Regulations, or other methods approved by EPA or the Director will be utilized for the analysis of all samples required to be reported to the Division of Environmental Protection.

5.1.2.a. All procedures other than those set forth in paragraph 5.1.2 of this rule are considered alternative analytical methods. Laboratories must make special application to the Division for the use of alternative analytical methods and such application must include a showing of acceptable comparability data.

5.1.2.b. All laboratories which have previously been granted approval to use an alternate analytical method by the US EPA will be allowed to continue using such method after it submits written proof of the approval to the Division.

5.1.3. General Laboratory Practices.

5.1.3.a. Chemistry.

5.1.3.a.A. Laboratories utilizing visual comparison devices must calibrate the standards incorporated into such devices at least once every four months. The laboratory will make and maintain records of the date and method of each such calibration.

5.1.3.a.B. Distilled and deionized water is to have at a minimum, resistivity values between 0.5 - 2.0 megohms-cm (2.0 - 0.5 umhos/cm) at 25 degrees centigrade.

5.1.3.a.C. Analytical Reagent grade chemicals should be used for most analyses. Detailed information on reagent grades is set forth in the approved analytical methods and their recommendations must be followed for the reagent quality to be used for each test or analysis.

5.1.3.a.D. Determine method detection limits for all Limited Chemistry, Atomic Absorption, Gas Chromatography/Mass Spectroscopy parameters tested. Method found in 40 CFR part 136 must be used for this calculation.

5.1.3.a.E. Field blanks, field duplicates and trip blanks must be performed on those test categories named in part 5.1.3.a.D of this rule, at a minimum of two times per year, one during the cold wet season and one during the warm dry season.

5.1.3.b. Microbiology.

5.1.3.b.A. Laboratory sterilization procedures are to meet the requirement of 121 degrees centigrade and the time adjusted for the type and volume of material to be sterilized as specified in the standardized methods.

5.1.3.b.B. Membrane filter assemblies must be sterilized after each sample filtration series, the end of which is marked by the lapse of 30 minutes or more between sample filtrations.

5.1.3.b.C. At least two minutes of ultraviolet light or boiling water may be used on a membrane filter assembly to prevent bacterial carry-over between filtrations.

5.1.3.b.D. Dried glassware may be sterilized in a hot air oven at 170 centigrade for a minimum of two hours.

5.1.3.b.E. Media may be prepared from dehydrated media stock or commercially prepared ampouled media may be used for routine bacteriological procedures.

5.1.3.b.F. Rinse water and dilution water used by the laboratory must be prepared according to instructions in the standardized methods and the final pH adjusted to 7.2 ± 0.1 .

5.1.3.c. Aquatic Toxicity Testing.

5.1.3.c.A. Natural or artificial sources of water may be used, but natural sources are preferred.

5.1.3.c.B. Natural sources are to be free of pollution, low in turbidity, high in dissolved oxygen, low in B.O.D., and the pH must be favorable to the maintenance of the organisms.

5.1.3.c.C. Municipal water supplies are acceptable. Water from a municipal source must be passed through a filter to remove organic chemicals and chlorine before use, and conditioned for the species under test.

5.1.3.c.D. Test organisms are to be fed as outlined in Methods of Measuring Acute Toxicity, EPA manual 600/4-85-013.

5.1.3.c.E. Treatment of diseased or parasitized organisms is to be in accordance with the procedures given in APHA Standard Methods and Methods for Measuring Acute Toxicity, EPA manual 600/4-85-013.

5.1.3.c.F. Organisms treated for disease or parasites are not to be used in aquatic toxicity tests for at least 10 days after treatment.

5.1.3.d. Radiochemistry.

5.1.3.d.A. Analytical reagent grade (AR) chemicals will be used for all analyses, unless otherwise required for an individual analytical procedure.

5.1.3.d.B. Radioactive standards and radioactive wastes are to be stored in an enclosed and properly labeled area, either within the laboratory or in a separate room or facility. All radioactive materials must be safely stored in suitable containers.

5.1.3.d.C. Standards and samples are to be prepared in an area of the laboratory specifically designated for and exclusively used for the preparation of radioactive standards and samples. Adequate precautions must be taken in this area to ensure against radioactive contamination.

5.1.3.e. Gas Chromatography / Mass Spectrometry -- Equipment must be capable of meeting the quality control requirements specified in paragraph 5.2.6 of this rule.

5.2. Quality Control Programs -- Each laboratory will develop, and have on file available for inspection a written description of the current laboratory Quality Assurance Program Plan. This written description will outline the procedures which the laboratory uses in meeting the quality control requirements set forth in this subsection. Managers, supervisors, and analysts should participate in developing the quality control program. Each participant within the laboratory is to have access to a copy of the quality control program and the detailed guidelines for implementation of the participant's responsibility. A record of analytical control tests and quality control checks on media, materials, and equipment will be prepared by the laboratory and retained for at least three years.

5.2.1. A written description includes, but need not be limited to, the following for each category:

5.2.1.a. Procedures which the laboratory will use in meeting the quality control requirements of this rule pertaining to laboratory equipment and instrumentation, and the frequency with which such procedures will be performed.

5.2.1.b. Each laboratory will develop a written laboratory procedures manual which sets forth, in detail, the methods which the laboratory will use in chemical analyses for all parameters for which the laboratory is seeking certification.

5.2.1.c. Each laboratory must record and retain all raw data and calculations derived from analyses and quality control procedures in a manner that will provide easy verification of the data and calculations during on-site inspections.

5.2.2. Limited Chemistry and Atomic Absorption laboratories must perform the following internal quality control checks:

5.2.2.a. Each analytical balance, with the exception of electronic balances without internal calibration controls, is to be checked and adjusted annually by a balance service technician. The accuracy of each analytical balance must be checked on each day of use using at least two Class-S weights, one in the gram range and one in the

milligram range. The weights used, weight detected, dates on which checks were performed, analyst, and other pertinent information is to be recorded in a log book. The daily weighing check will be used as an indication of proper operation of electronic balances.

5.2.2.b. The wavelength setting of the spectrophotometer is to be checked yearly by comparing the wavelength setting to the absorption maxima of colored standards of filters such as didymium glass or by using standard Cobalt Chloride solution which has a maximum absorbance at a wavelength of 510 nm. The check data is to be recorded in a log book.

5.2.2.c. pH meters are to be calibrated prior to usage with two pH buffer standards bracketing the value to be measured and the calibration recorded.

5.2.2.d. Conductivity meters must be checked over the range of the instrument using at least five concentrations of standard solutions yearly. The cell constant, k , is to be determined from this data. The meter must be calibrated using at least one standard with each use. The results of these calibrations must be recorded in a log book.

5.2.2.e. A daily record of the drying oven temperature must be maintained for each day on which the drying oven is in use. The oven thermometer must be kept in a sand bed or other inert material.

5.2.2.f. The temperature of each refrigerator and each incubator is to be either recorded continuously or recorded daily from in-place thermometers immersed in liquid and placed on one of the shelves being used. The refrigerator thermometer must be kept in a low vapor pressure liquid such as 50/50 water/Ethylene Glycol.

5.2.2.g. The accuracy of all thermometers used to monitor temperatures will be verified by comparing the readings of such thermometers with the readings of a certified thermometer. Glass thermometers are to be verified yearly and metal thermometers quarterly. A record of each thermometer identification and the results of the test are to be kept in a log book.

5.2.2.h. Standard curves consisting at a minimum of one reagent blank and 4 standards are to be prepared for each analysis requiring such a curve. This curve will be verified in each subsequent analyses by using at least one reagent blank and one standard at or near the concentration levels normally encountered in such analyses. Such verifications are considered satisfactory if the results are within 10 per cent of the

original curve when following vendor approved procedures for instrument calibration.

5.2.2.i. Standard curves used in the analysis of parameters in the Atomic Absorption category will be prepared as stated above in subparagraph 5.2.2.h of this rule except that a minimum of one reagent blank and 2 standards are required.

5.2.2.j. In all cases where possible, replicate sample analyses are to be conducted for parameters in the Limited Chemistry and Atomic Absorption categories to verify the precision of the method. Replicate analyses will be performed at a frequency of 5 percent. Where less than 20 samples are analyzed at one time the analyst is to verify the precision once per analysis batch.

5.2.2.k. In all cases where possible, spiked sample analyses will be conducted to verify the accuracy of the method at the same frequency as set forth in subparagraph 5.2.2.j of this rule. Documentation will be made of both precision and accuracy testing.

5.2.2.l. In all cases where possible, standard deviations are to be calculated and documented for all applicable measurements being conducted in the Limited Chemistry and Atomic Absorption categories (spiked sample recoveries). Standard deviations must be documented in tabular form and on control charts.

5.2.3. Microbiology.

5.2.3.a. A start and finish MF sterile control test of rinse water, media and supplies will be conducted for each sample filtration series. If the control tests indicate contamination, then all data which has been generated through tests involving the use of the contaminated materials will be rejected and the laboratory must request immediate resampling of those waters involved in the laboratory error.

5.2.3.b. The MPN test must be carried through the "confirmed" stage for Fecal Coliform.

5.2.4. Aquatic Toxicity Testing -- An acceptable degree of precision for definitive toxicity tests is the 95 percent confidence level or fiducial intervals within less than ± 30 percent of the 48 hour or incipient LC50 value.

5.2.4.a. A reference toxicant test is to be performed to establish the validity of effluent toxicity data generated by bioassay laboratories.

5.2.4.b. Reference toxicant materials are available from the Environmental Protection Agency, Environmental Support Laboratory, Cincinnati, Ohio. Instructions for their use and the expected LC50 values are provided with the samples.

5.2.4.c. The reference toxicant test must be conducted within 7 days immediately preceding an effluent toxicity test or concurrently with the toxicity test.

5.2.4.d. A control chart, as described in Methods of Measuring Acute Toxicity-EPA manual should be prepared for each reference toxicant/organism combination, and successive LC-50's plotted and examined to determine if the results are within prescribed limits.

5.2.4.e. If the LC-50 of reference toxicant does not fall in the expected range for the test organisms, the sensitivity of the test system is suspect. In this case, the test procedure should be examined for defects, and a different batch of test organisms should be employed in repeating the reference toxicant and effluent toxicity test.

5.2.5. Radiochemistry -- Permanent records must be maintained of preventive maintenance, periodic inspections, testing, and calibration for the proper operation of radiation instruments and analytical balances; validation of methods; evaluation of reagents and volumetric equipment; surveillance of results; and remedial actions taken in response to detected defects. Such records must be kept on file by the laboratory for a period of at least five years.

5.2.5.a. To verify internal laboratory precision, duplicate analyses equal to ten percent of sample analyses shall be performed. The differences between duplicate measurements shall be less than twice the standard deviation of the specific analysis as described in Environmental Radioactivity Laboratory Intercomparison Studies Program, EPA 600/4-77-001 et seq.

5.2.5.b. One background and one calibration standard must be tested each day at a 5 percent level or fraction thereof.

5.2.5.c. Work records of quantitative tests are to indicate final results together with all corresponding instrument readings and calculations. Where instrumentation produces tracings or printouts, such tracings or printouts may serve as the work record.

5.2.6. Gas Chromatography and Mass Spectrometry.

5.2.6.a. The frequency and procedures for satisfying each of the requirements listed in subparagraphs 5.2.6.b and 5.2.6.c of this rule are described in detail in EPA publication SW-846, Chapter 40 of the Code of Federal Regulations, and/or in the US EPA Contract Laboratory Program Statement of Work for Organics Analysis.

5.2.6.b. Minimum quality control operations necessary to satisfy the analytical requirements associated with the determination of semi-volatile and volatile organic compounds by gas chromatographic methods will include the following:

- 5.2.6.b.A. Evaluation of Appropriate Blank Materials.
- 5.2.6.b.B. Surrogate Spike Response Monitoring.
- 5.2.6.b.C. Matrix Spike and Duplicate Analyses.
- 5.2.6.b.D. Verification of Response and Calibration.
- 5.2.6.b.E. Conformational Analysis.

5.2.6.c. Minimum quality control operations to satisfy the analytical requirements associated with gas chromatographic/mass spectrometry determinations of semi-volatile and volatile compounds will be as follows:

- 5.2.6.c.A. Documentation of GC/MS Mass Calibration and Tune Abundance Patterns.
- 5.2.6.c.B. Documentation of GC/MS Response Factor Stability.
- 5.2.6.c.C. Internal Standard Response and Retention Time Documentation.
- 5.2.6.c.D. Surrogate Spike Recovery Monitoring
- 5.2.6.c.E. Matrix Spike and Duplicate Analyses.

5.3. Records and Data Reporting.

5.3.1. Records of analyses, including but not limited to all raw data, calculations, quality control data, and laboratory reports, are to be kept by the laboratory for at least three years unless otherwise specified.

5.3.2. The following information is to be retained by the laboratory as part of the records of analysis and the records of custody:

5.3.2.a. The laboratory number or other form of identification of the sample;

5.3.2.b. The date, time, specific site of sampling, and the name of the person who collected the sample or the laboratory which submitted the sample;

5.3.2.c. The date and time when the laboratory received the sample, whether the sample was received preserved or unpreserved;

5.3.2.d. The date and time of analysis of the sample;

5.3.2.e. The person or persons who performed the analysis;

5.3.2.f. The type of analysis performed and the analytical method or methods employed;

5.3.2.g. The results of the analysis and the raw data generated by the analysis; and

5.3.2.h. The name and address of the laboratory to which the sample was forwarded, if the analysis was not performed at the laboratory which first received the sample.

5.3.3. If the chain of custody information is reported on a chain of custody form, a copy of the form must be attached to the sample report form.

5.3.4. The results of each analysis are to be calculated and entered on the sample report form which is to be forwarded to the person requesting the analysis of the sample. A careful check is to be made to assure that each result entered on the sample report form is the same as the result entered on the bench sheet.

5.3.5. The original or true duplicate of the results of the test or analysis is to be sent promptly to the person who requested such tests or analysis, and must be signed by the laboratory manager or a designee whose designation has been submitted to the Division in writing.

5.3.6. Whenever a laboratory refers samples to another laboratory, the person ordering the examination is to receive the original laboratory report or a true duplicate of that report on the form of the laboratory that actually performed the test or analysis.

5.3.7. If results are entered into a computer storage system, a printout of the data must be verified with the raw data.

§47-32-6. Appeals.

Appeal to Environmental Quality Board -- Any person aggrieved or adversely affected by an order or action of the Director made and entered in accordance with the provisions of this rule or by issuance or denial of certification under the provisions of this rule, may appeal to the Environmental Quality Board in the same manner as appeals are taken under W. Va. Code §22B-1-7 to have the order vacated or modified. The filing of a notice of appeal will not automatically stay an order or action of the Director. The Environmental Quality Board will be reimbursed from the Environmental Laboratory Certification Fund for expenses incurred for appeal hearings filed with the Board relative to the provisions of this rule.

§47-32-6. Severability.

§47-32-7. Severability.

If any section, subsection, provision, clause, or portion of this rule is adjudged unconstitutional or invalid by a court of competent jurisdiction, the remainder of this rule shall not be affected thereby.