

LCB File No. R203-99

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

NOTICE OF PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the State Board of Health will hold public hearing and act on amendments to Nevada Administrative Code (NAC) 449 Residential Facilities for Groups and NAC 445A Certification of Environmental Testing Laboratories. The hearing is scheduled to begin at 9:00 a.m. on Friday, December 10, 1999, at the Grant Sawyer Building, Room 4401, 555 E. Washington Avenue, Las Vegas, Nevada.

RESIDENTIAL FACILITIES FOR GROUPS

In July 1999, the Legislature passed new legislation that pertains to the regulations for Residential Facilities for Groups. On August 2, 1999 the Bureau received #R052-99 that contains modifications to NAC 449.156 to 449.2766. After review of these modifications and in light of the new laws, it has been determined there is a need to make further revisions to these regulations. New language and modifications to existing language has been established in the following areas: NAC 449.163, 449.213(3), 449.2752, 449.2718(1)(b), 449.2734(2), 449.2742(6), 449.2748(1)(2) & (3), 449.2742(3), 449.200(2), 449.2706, and 449.2736.

The proposed regulation changes are meant to clarify current requirements and to provide more specific direction to providers when providing services to residents.

The proposed regulation changes present no anticipated effect to the public. There is no anticipated additional cost to the agency for enforcement of the proposed regulation changes.

The proposed regulation changes will not affect changes to other governmental agencies and do not overlap/duplicate other regulations.

The proposed regulation changes do not have a counterpart in the Code of Federal Regulations. There are no fees associated with the proposed regulation changes.

CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

The purpose of the proposed amendment is to restore the meaning and intent that was lost during LCB formatting of LCB File No. R048-99. The sections in question are sections 26, 29(3), 30(5)(a)(b) & (c), 30(6), 31(4)(b), 32(1), 34(3)(b), 34(4), 35(1), 35(3), 35(4), 35(5), 37(1), 37(7), 39(4), (42)(1)(q), and 44(4).

The affected regulation concerns certification of environmental laboratories analyzing drinking water related samples.

The regulation has beneficial effect upon the regulated business. It defines operating protocol that is consistent with EPA procedures and enables the laboratories to participate in the National Environmental Laboratory Accrediting Program (NELAP) if they desire. It ensures a level playing field with in-state and out-of-state competition.

The regulation has beneficial effect upon the public. It provides the regulatory framework to ensure that drinking water related samples are analyzed properly.

There are no anticipated cost increases associated with enforcement of the proposed regulation changes.

The regulation enables Nevada laboratories to participate in NELAP, which is federally sponsored through the US Environmental Protection Agency (EPA).

The provisions of regulation are in accord with those of the EPA and reference the federal standard.

There are no new fees associated with the regulation change and the existing fee schedule is maintained.

Members of the public may make oral comments at this meeting. Persons wishing to submit written testimony or documentary evidence in excess of two typed, 8-1/2" x 11" pages must submit the material to the Board's Secretary by November 25, 1999.

Secretary, State Board of Health
Nevada State Health Division
Capitol Complex
505 E. King Street, Room 201
Carson City, NV 89701-4797

Written comments, testimony, or documentary evidence in excess of two typed pages will not be accepted at the time of the hearing. The purpose of this requirement is to allow Board members adequate time to review the documents.

Members of the public who are disabled and require special accommodations or assistance at the meeting are required to notify Yvonne Sylva, Secretary, Board of Health, in writing at the Nevada State Health Division, 505 E. King Street, Room 201, Carson City, NV 89701, or by calling (702) 687-4740.

A copy of this notice and the proposed regulation amendments are on file for inspection at the following locations during normal business hours:

Bureau of Licensure and Certification, 1550 E. College Pkwy, Suite 158, Carson City, Nevada (702) 687-4475).

Bureau of Licensure and Certification, 4220 S. Maryland Parkway, Suite 810, Las Vegas, Nevada (702) 486-6515.

Bureau of Licensure and Certification, 1755 E. Plumb Lane, Suite 241, Reno, Nevada (702) 688-2888

Emergency Medical Services, 850 Elm Street, Elko, Nevada (702) 753-1154.

Emergency Medical Services, 100 Frankie, Tonopah, Nevada (702) 482-3722.

Copies may be obtained in person, by mail, or by calling (702) 687-4475. Copies are also available for review at all physical locations of program offices (see above) or the following main public libraries in each county:

- Carson City Library, 900 North Roop St.
Carson City, NV 89701
- Churchill County Library, 533 S. Main St.
Fallon, NV 89406
- Clark County Library, 4020 Maryland Parkway,
Las Vegas, NV 89119
- Douglas County Library, 1625 Library Lane, (PO Box 337)
Minden, NV 89423
- Elko County Library, 720 Court St.
Elko, NV 89801
- Goldfield Public Library (Esmeralda Co.), Corner of Crook and Ramsey, (PO Box 430)
Goldfield, NV 89013
- Eureka Branch Library, 10190 Monroe St.,
Eureka, NV 89316
- Humboldt County Library, 85 East 5th St.,
Winnemucca, NV 89445
- Battle Mountain Branch Library (Lander Co.), 6255 Broad St.,
Battle Mountain, NV 89820
- Lincoln County Library, 63 Maine St., (PO Box 330)
Pioche, NV 89043
- Lyon County Library, 20 Nevin Way,
Yerington, NV 89447
- Mineral County Library, 125 A St., (PO Box 1390)
Hawthorne, NV 89415
- Pershing County Library, 125 Central, (PO Box 781)
Lovelock, NV 89419
- Storey County Library, 95 South R St., (PO Box 14)
Virginia City, NV 89440
- Tonopah Public Library (Nye Co.), 171 Central, (PO Box 449)
Tonopah, NV 89049

- Washoe County Library, 301 South Center St., (PO Box 2151)

- Reno, NV 89505
- White Pine County Library, 950 Campton St.,
Ely, NV 89301

Per NRS 233B.064(2), upon adoption of any regulations, the agency, if requested to do so by an interested person, either prior to adoption or within 30 days thereafter, shall issue a concise statement of the principal reasons for and against its adoption, and incorporate therein its reason for overruling the consideration urged against its adoption.

PROPOSED REGULATION OF THE STATE BOARD OF HEALTH

ENVIRONMENTAL LABORATORY TESTING (Amends LCB File No. R048-99, filed 9/27/99)

EXPLANATION – Italicized material is new; material in brackets is to be deleted

NOTE: Only those sections being changed are provided in this document.

Sec 1. Sec. 26 is hereby amended to read as follows:

Sec. 26. The following publications are hereby adopted by the state board of health in the forms most recently published unless *the EPA has not yet published notice of approval in the Federal Register or* the state board of health gives notice pursuant to the provisions of section 45 of this regulation that the most recent publication is not suitable for this state:

1. "Annual Book of ASTM Standards, Section 5, Petroleum Products, Lubricants, and Fossil Fuels," which is available from the American Society For Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428-2959, for the price of \$528.

2. "Annual Book of ASTM Standards, Section 11, Water and Environmental Technology," which is available from the American Society For Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428-2959, for the price of \$589.

3. "ISO/IEC Guide 25, General Requirements for the Competence of Calibration and Testing Laboratories," 1990, which is available from Global Engineering Documents, 15 Inverness Way East, Englewood, Colorado 80112, for the price of \$38.

4. "Standard Methods for the Examination of Water and Wastewater," 20th edition, Order Number 10079, which is available from the American Water Works Association, Customer

Service, 6666 West Quincy Avenue, Denver, Colorado 80235, for the price of \$155 for members and \$200 for nonmembers.

Sec. 2. Sec. 29 is hereby amended to read as follows:

Sec. 29. For the purposes of charging and collecting fees and conducting performance evaluations pursuant to the provisions of sections 2 to 45, inclusive, of this regulation, the bureau shall classify each analyte for which a laboratory may be certified into the following categories:

1. Primary inorganic contaminants;
2. Secondary inorganic contaminants;
3. Regulated and unregulated volatile organic contaminants. ~~[, including, without limitation, trihalomethanes;]~~ *(This category includes vinyl chloride and trihalomethanes.)*
4. Regulated and unregulated synthetic organic contaminants;
5. Radiochemical contaminants;
6. Individual primary or secondary inorganic contaminants; or
7. Microbiological contaminants.

Sec 3. Sec. 30 is hereby amended to read as follows:

Sec. 30. 1. To be certified to conduct laboratory testing, a laboratory must comply with the requirements set forth in sections 1.8.3, 4.1.1, 5.0, 5.1 and 5.4 to 5.16, inclusive, of the standards.

2. To be certified in:

(a) Chemistry, a laboratory must comply with the requirements set forth in section 1.8.5 and Appendix D.1 of chapter 5 of the standards;

(b) Microbiology, a laboratory must comply with the requirements set forth in section 1.8.7 and Appendix D.3 of chapter 5 of the standards; or

(c) Radiochemistry, a laboratory must comply with the requirements set forth in section 1.8.8 and Appendix D.4 of chapter 5 of the standards.

3. To be certified pursuant to the program specified in subsection 3 of section 28 of this regulation, a laboratory must comply with the provisions concerning method detection limits, sample containers, holding times, proficiency testing and quality assurance set forth in 40 C.F.R. §§ 141.21(c), 141.21(f), 141.23(k), 141.24(e), 141.24(f)(17), 141.24(f)(20), 141.24(h)(13), 141.24(h)(19), 141.25, 141.30(e), 141.40(g), 141.40(n)(11), 141.40(n)(12), 141.74(a) and 141.89.

4. To be certified for an approved method of testing, a laboratory must comply with the requirements for using that approved method of testing specified in subsection 4 of section 28 of this regulation and the standards. If a conflict occurs between a provision specified in that subsection and the standards concerning an approved method of testing, the standards apply. If a manufacturer provides instructions for maintaining any equipment used for testing or for ensuring the performance of any test or demonstrating the performance of any system of measurement, the laboratory shall comply with those instructions. If a conflict occurs between a provision of those instructions and a provision specified in subsection 4 of section 28 of this regulation or the standards, the provisions specified in that subsection or the standards apply.

5. If a laboratory intends to use a performance-based measurement system or any other alternative method of testing, the laboratory shall, before the bureau conducts an inspection of the laboratory pursuant to the provisions of section 37 of this regulation, submit to the bureau a written statement setting forth the performance-based measurement system or other alternative

method of testing it intends to use. The bureau may approve the performance-based measurement system or alternative method of testing if, as determined by the bureau:

(a) The system or method is equivalent to or exceeds ~~any~~ *the* approved method of testing for accuracy, precision, completeness and comparability relating to determining compliance with ~~any~~ *the* regulatory concentration levels or system conditions; or

(b) An approved method of testing is not available for use by the laboratory to determine the presence of an analyte for which the laboratory requests certification pursuant to the provisions of sections 2 to 45, inclusive, of this regulation~~[-];~~ *or*

(c) the laboratory obtains from the EPA an alternate test procedure approval.

6. To be certified to test for a specific analyte using an approved method of testing, a laboratory must comply with the requirements established by the bureau for the approved method of testing and the standards for initial and continuing test equipment calibrations and demonstrations by analysts of precision, accuracy, ~~and~~ sensitivity, *and low system background* for ~~the~~ *each* analyte. If a conflict occurs between the requirements established by the bureau and the standards, the standards apply.

7. As used in this section:

(a) "Holding times" has the meaning ascribed to it in Appendix B of chapter 5 of the standards.

(b) "Method detection limit" has the meaning ascribed to it in Appendix B of chapter 5 of the standards.

(c) "Quality assurance" has the meaning ascribed to it in Appendix B of the standards.

Sec. 4 Sec. 31. is hereby amended to read as follows:

Sec. 31. 1. A laboratory may apply for certification by the bureau or certification pursuant to the National Environmental Laboratory Accreditation Program.

2. To obtain certification by the bureau, a laboratory must comply with the provisions of sections 2 to 45, inclusive, of this regulation.

3. A laboratory that is certified by the bureau may provide analytical data of an environmental sample originating in this state for each analyte for which the laboratory is certified.

4. To obtain certification pursuant to the National Environmental Laboratory Accreditation Program:

(a) A laboratory must comply with the provisions of sections 2 to 45, inclusive, of this regulation;

(b) ~~[A person who is approved by the National Environmental Laboratory Accreditation Conference must participate in any inspection of the laboratory that is conducted by the bureau]~~
A laboratory seeking NELAP certification must submit to an initial on-site assessment directed by an approved National Environmental Laboratory Accreditation Program (NELAP) assessor. NELAP assessors will have the qualifications outlined in section 3.2.2 of the standard and will be trained in accordance with section 3.2.3 of the standard. On-site assessments will be performed every second year by NELAP qualified assessors; and

(c) The laboratory must specify in its application for certification at least one approved method of testing and analyte pursuant to the provisions of subsections 4 and 6 of section 28 of this regulation.

5. As used in this section, "National Environmental Laboratory Accreditation Program" has the meaning ascribed to it in Appendix B of chapter 5 of the standards.

Sec. 5. Sec 32. is hereby amended to read as follows:

Sec. 32. 1. To apply for certification pursuant to the provisions of sections 2 to 45, inclusive, of this regulation, the director of the laboratory for which certification is requested must submit an application to the bureau on a form approved by the bureau. The application must be accompanied by the fees prescribed in section 44 of this regulation and include the information specified in section **4.1.7 and** 4.1.9 of the standards.

2. The provisions of this subsection do not require an application and certificate for each building or other portion of a laboratory that is located on the same or adjacent grounds or within the boundaries of the same incorporated city or unincorporated town if, as determined by the bureau, each building or other portion of the laboratory is used to conduct an analysis of the same environmental samples.

3. The bureau shall not consider an application for certification submitted pursuant to this section to be complete unless:

(a) The laboratory specifies in the application the approved methods of testing in accordance with the provisions of section 28 of this regulation; (b) The laboratory satisfactorily analyzes proficiency test samples in accordance with the provisions of section 35 of this regulation;

(c) The laboratory adopts a quality manual and submits the manual to the bureau pursuant to the provisions of section 36 of this regulation;(d) The bureau conducts an inspection of the laboratory for the approved methods of testing and analytes for which the laboratory requests certification pursuant to the provisions of section 37 of this regulation;

(e) If the report of an inspection of the laboratory conducted by the bureau includes any deficiency that must be corrected, the laboratory submits to the bureau a written plan to correct the deficiency in accordance with the provisions of subsection 7 of section 37 of this regulation;

(f) The director of the laboratory is qualified for that position pursuant to the provisions of the manual specified in subsection 6 of section 24 of this regulation; and

(g) The applicable fees prescribed in section 44 of this regulation have been paid.

4. An application for certification shall be deemed withdrawn by the applicant if it is not completed pursuant to the provisions of this section within 1 year after the bureau receives the application. The bureau may extend the period in which an application must be completed pursuant to this subsection if the applicant submits to the bureau a written request for an extension setting forth the reasons for the request.

Sec. 6. Sec. 34 is hereby amended to read as follows:

Sec. 34. The bureau shall accept data relating to the analysis of contaminants regulated pursuant to the provisions of the Federal Act that are submitted from a laboratory located outside this state if:

1. The laboratory has otherwise complied with the requirements set forth in sections 2 to 45, inclusive, of this regulation;

2. The laboratory is certified by:

(a) The state where it is located or, if the state where the laboratory is located does not have a program for certifying laboratories for the analysis of drinking water, by any other state that provides those certifications; or

(b) The Environmental Protection Agency;

3. The bureau determines that the state where the laboratory is located:

(a) Has adopted a program for certifying laboratories for the analysis of drinking water that is equivalent to the program for certifying those laboratories adopted by this state; and

(b) Accepts the results of ~~[evaluations conducted pursuant to that program]~~ *laboratories certified in this state*; and

4. The laboratory submits to the bureau a copy of an acceptable report relating to the most recent evaluation conducted at the laboratory. *This evaluation must be current (within 24 months prior to submission of the application) and conducted* by:

(a) The state where the laboratory is certified;

(b) An independent organization that is approved by the bureau to certify laboratories for the analysis of drinking water; or

(c) The Environmental Protection Agency.

Sec. 7 Sec. 35 is hereby amended to read as follows:

Sec. 35.

a) “Data sufficient to validate” means performance of an initial demonstration of capability as defined in the Manual for Certification of Laboratories Analyzing Drinking Water, Fourth Edition, Section 7.2.8.

1. Each laboratory for which an application for certification is submitted and each certified laboratory must participate in a *semi-annual* proficiency testing program. The ~~[administrator of the program must]~~ *laboratory must*

(a) obtain single blind proficiency samples from a provider [be] approved [by the Environmental Protection Agency and shall require the laboratory to] as being compliant with chapter 2 of the standard; and:

~~[(a)]~~ (b) Analyze ~~[a]~~ proficiency test samples ~~[provided by the administrator to the laboratory]~~ *when available*, for each category of certification and analyte that is included in the program; and

~~[(b)]~~ (c) Report the results of the analysis to the ~~[administrator]~~ *approved provider*.

2. Each laboratory specified in subsection 1 shall pay the costs of subscribing to a program specified in that subsection.

3. Each laboratory specified in subsection 1 must satisfactorily analyze each analyte included in the program specified in subsection 3 of section 28 of this regulation on two of the most recent three rounds of testing ~~[conducted by the administrator of the proficiency testing program. A laboratory may participate in consecutive rounds of testing if the date established by the administrator of the proficiency testing program for reporting the results of the test to the administrator is at least 30 days, but not more than 6 months, after the most recent round of testing in which the laboratory participated].~~ *Prior to receipt of test samples to be used for certification purposes* ~~[E]~~each laboratory shall authorize the ~~[administrator of the program]~~ *approved proficiency test provider* to submit to the bureau the results of any test taken pursuant to the provisions of this section. If the laboratory fails to provide that authorization, the bureau may refuse to consider the results of any test taken pursuant to those provisions.

4. The bureau shall consider the results of any test taken pursuant to this section to be satisfactory if the results are within the limits of acceptance established by the ~~[administrator]~~ *approved provider* of the proficiency testing ~~[program]~~ *samples* in accordance with the provisions of Appendix C of chapter 2 of the standards.

5. If the bureau determines that the results of ~~fast~~ *testing* are satisfactory, the laboratory may be certified to use any *approved* method of testing for each analyte that is satisfactorily analyzed by the laboratory if, as determined by the bureau, data sufficient to validate the use of that method of testing are available. If such data are not available, the bureau shall deny or revoke the certification for that method of testing.

6. If a certified laboratory fails:

(a) Two rounds of testing pursuant to subsection 3, the bureau shall suspend the certification of that laboratory for each analyte the laboratory failed to analyze during those rounds; or

(b) Three rounds of testing pursuant to subsection 3, the bureau shall revoke the certification of that laboratory for each analyte the laboratory failed to analyze during those rounds.

7. If the bureau suspends the certification of a certified laboratory pursuant to subsection 6 because the laboratory failed two nonconsecutive rounds of testing, the bureau shall reinstate the certification of that laboratory for the method of testing and analyte for which the certification was suspended if the certified laboratory satisfactorily analyzes the analyte in a proficiency test sample that is approved by the bureau.

8. If the bureau suspends the certification of a certified laboratory pursuant to subsection 6 because the laboratory failed to analyze an analyte on two consecutive rounds of testing, the laboratory must satisfactorily analyze the analyte during each of two rounds of testing conducted after the bureau suspends the certification.

9. If the bureau revokes the certification of a certified laboratory pursuant to subsection 6, the laboratory must:

(a) Analyze satisfactorily the analyte for which the certification was revoked during each of two rounds of testing conducted after the bureau revoked the certification; and

(b) Reapply for certification and pay the applicable fees pursuant to the provisions of sections 2 to 45, inclusive, of this regulation.

10. Each certified laboratory must comply with the requirements concerning enrollment, testing, conduct and participation in the program specified in subsection 1 pursuant to the provisions of sections 2.4, 2.5 and 2.7 of the standards.

Sec. 8 Sec. 37 is hereby amended to read as follows:

Sec. 37. 1. The bureau shall conduct an ~~inspection~~ *on-site assessment* of the premises and operation of each certified laboratory *located in Nevada* or laboratory *located in Nevada* for which an application for certification is submitted pursuant to the provisions of section 32 of this regulation. An inspection conducted pursuant to this section must be conducted in accordance with the provisions of sections 3.4 to 3.7, inclusive, of the standards. If a certified laboratory conducts analyses of drinking water, the laboratory must be inspected in accordance with the manual specified in subsection 6 of section 24 of this regulation. Each certified laboratory shall analyze ~~annually at least one~~ *a* quality control sample for each method of testing and analyte for which it is certified *each time a new calibration curve is generated or annually, whichever is more frequent*.

2. The bureau shall conduct an inspection specified in subsection 1:

(a) Not less than once every 2 years, if the laboratory is a certified laboratory; or

(b) If the laboratory submits an application for certification pursuant to the provisions of section 32 of this regulation, not more than 30 days after the bureau determines that the laboratory has complied with the provisions of paragraphs (a), (b) and (c) of subsection 3 of that section.

3. The bureau may conduct an inspection of a laboratory more than once every 2 years pursuant to this section if:

(a) The bureau receives a complaint concerning the quality of the laboratory from a member of the general public or any public agency;

(b) The bureau has reasonable cause to believe the laboratory is engaging in fraudulent activity;

(c) The bureau identifies deficiencies in the operation of the laboratory after conducting an inspection of the laboratory pursuant to this section;

(d) The laboratory notifies the bureau pursuant to section 33 of this regulation of any changes specified in that section; or

(e) Any circumstance specified in section 3.3 of the standards occurs.

4. An inspection conducted pursuant to the provisions of this section may include, without limitation:

(a) Requiring the laboratory to conduct an analysis of a proficiency test sample; and

(b) Photocopying, photographing or videotaping any part of the laboratory or any equipment, activity, environmental sample, records, results of any test, data concerning the control of the quality of any analysis conducted by the laboratory or any other information required by the bureau to ensure compliance with the provisions of sections 2 to 45, inclusive, of this regulation.

5. Except as otherwise provided in this subsection, the bureau shall announce each inspection conducted pursuant to the provisions of this section. The bureau may conduct an unannounced inspection of a laboratory if the bureau determines that such an inspection is required to ensure compliance by the laboratory with the provisions of sections 2 to 45, inclusive, of this regulation. In determining whether to conduct an unannounced inspection, the bureau shall consider:

(a) The laboratory's record of compliance with the provisions of sections 2 to 45, inclusive, of this regulation;

(b) The results of any proficiency test taken by the laboratory;

(c) The performance of any analyst or other employee of the laboratory in conducting an analysis of an environmental sample pursuant to the provisions of sections 2 to 45, inclusive, of this regulation;

(d) Any complaints concerning the laboratory that the bureau has received from members of the general public or any public agency; and

(e) The performance of the laboratory in conducting analyses pursuant to the provisions of sections 2 to 45, inclusive, of this regulation.

6. If the bureau conducts an inspection of a laboratory pursuant to the provisions of this section, the laboratory shall:

(a) Ensure that any record or other information required by the bureau to conduct the inspection is available for review, including, without limitation:

(1) The quality manual adopted pursuant to the provisions of section 36 of this regulation;

(2) Any information concerning the methods of testing used by the laboratory;

(3) Any data concerning the control of the quality of an analysis conducted by the laboratory; and

(4) Any information concerning any proficiency test taken by the laboratory; and

(b) Allow the bureau to:

(1) Examine any records of the laboratory concerning the operation or certification of the laboratory;

(2) Observe the operation, facilities and equipment of the laboratory;

(3) Interview any employee of the laboratory; and

(4) Engage in any other activity required by the bureau to determine compliance by the laboratory with the provisions of sections 2 to 45, inclusive, of this regulation.

7. If the bureau conducts an inspection of a laboratory, it shall provide to the laboratory a copy of the report of the inspection *within 30 calendar days of the completion of the inspection*.

The report must include any deficiency the bureau discovers during its inspection of the laboratory. The laboratory shall prepare a plan to correct the deficiency specified in the report.

The plan must:

(a) Be submitted to the bureau not more than 30 days after the laboratory receives the report from the bureau;

(b) Be submitted on a form approved by the bureau; and

(c) Include, without limitation:

(1) The signature of the person who prepared the plan; and

(2) The proposed date by which the laboratory will correct the deficiency.

8. If, after reviewing the plan submitted pursuant to subsection 7, the bureau determines that the plan is insufficient to correct the deficiency, the bureau shall notify the laboratory of that fact in writing. Upon receipt of the written notice, the laboratory shall, not more than 30 days after receiving the notice, submit a revised plan to the bureau. If, after reviewing the revised plan, the bureau determines that the revised plan is insufficient to correct the deficiency, or if the bureau conducts an inspection of the laboratory and determines that the deficiency has not been corrected, the bureau shall deny the laboratory's application for certification or revoke its certification.

Sec. 9. Sec. 39 is hereby amended to read as follows:

Sec. 39. 1. The bureau may renew the certificate of a certified laboratory if:

(a) The laboratory pays the applicable fee to renew the certificate;

(b) The laboratory submits a statement on a form approved by the bureau indicating that it is in compliance with the provisions of sections 2 to 45, inclusive, of this regulation concerning each category of testing, method of testing and analyte for which it is certified;

(c) The laboratory submits a report to the bureau indicating that it has received satisfactory proficiency test results for each category of testing and analyte for which it is certified; and

(d) The bureau determines that the laboratory is in compliance with the provisions of sections 2 to 45, inclusive, of this regulation.

2. A certificate issued to a laboratory pursuant to the provisions of sections 2 to 45, inclusive, of this regulation expires on June 30 of each year. If the certificate of a certified laboratory expires, the laboratory may reapply for certification in the manner prescribed in section 32 of this regulation.

3. Not later than June 1 of each year, the bureau shall mail to each certified laboratory a notice for the renewal of the certificate and a form to provide a statement of compliance specified in paragraph (b) of subsection 1.

4. Each certified laboratory shall ~~in accordance with the provisions of section 4.3.3 of the standards, maintain any record, document or other information or any equipment or facility used as the basis for obtaining an initial certificate pursuant to the provisions of sections 2 to 45, inclusive, of this regulation~~ *maintain all documentation in accordance with the provisions of section 4.3.3 of the standard.*

Sec. 10 Sec. 42 is hereby amended to read as follows:

Sec. 42. 1. The bureau may deny an application for certification of a laboratory or revoke, suspend or limit the certification of a certified laboratory if the laboratory:

(a) Makes a false statement in:

(1) An application for certification;

(2) A report concerning the analysis of an environmental sample; or

(3) Any other document relating to certification in violation of the provisions of sections 2 to 45, inclusive, of this regulation;

(b) Consistently makes errors in laboratory testing or in any report prepared by the laboratory pursuant to the provisions of sections 2 to 45, inclusive of this regulation;

(c) Falsifies the results of any laboratory testing or misrepresents any information obtained from laboratory testing in violation of the provisions of section 30 or 41 of this regulation;

(d) Fails to use approved sampling protocols or methods of testing while engaging in any activity of the laboratory for which certification is required;

(e) Fails to provide written notice before entering into a contract in violation of the provisions of subsection 4 of section 41 of this regulation;

(f) Fails to maintain the facilities or equipment of the laboratory in accordance with:

(1) The quality manual of the laboratory;

(2) The quality system of the laboratory;

(3) Any approved methods of testing; or

(4) The standards;

(g) Fails to report the results of any test conducted by the laboratory in the form or manner required for that test or fails to maintain any records required for those results in violation of the provisions of section 30 or 41 of this regulation;

(h) Fails to participate satisfactorily in a proficiency testing program, if the program is available, in violation of the provisions of section 35 of this regulation;

(i) Fails to comply with the quality manual of the laboratory in violation of the provisions of section 36 of this regulation;

(j) Falsely claims certification for a method of testing or an analyte for which the laboratory is not certified in violation of the provisions of section 41 of this regulation;

(k) Fails to prepare a plan of correction or to correct any deficiency specified by the bureau within the period specified in the plan in violation of the provisions of section 37 of this regulation;

(l) Fails to pay any fees or expenses of the bureau in violation of the provisions of section 44 of this regulation;

(m) Fails to indicate in any report prepared by the laboratory that the results of a test were obtained by contract in violation of the provisions of subsection 6 of section 41 of this regulation;

(n) Fails to notify the bureau of any changes specified in section 33 of this regulation;

(o) Fails to analyze annually quality control samples for each method of testing and analyte for which the laboratory is certified in violation of the provisions of section 37 of this regulation;

(p) Authorizes a person who is not qualified to perform an analysis in violation of the provisions of section 30 of this regulation;

(q) Communicates with or receives a communication concerning the results of a proficiency test sample from a laboratory on or before the date established for submitting the results of that sample to the ~~[administrator]~~ *provider* of ~~[a]~~ proficiency test ~~[program]~~ *samples* pursuant to the provisions of section 35 of this regulation;

(r) Knowingly receives a proficiency test sample from a laboratory or provides a proficiency test sample to a laboratory on or before the date specified in paragraph (q);

(s) Prohibits an employee of the bureau from conducting an inspection of the laboratory in violation of the provisions of section 37 of this regulation;

(t) Fails to provide to the bureau any information required by the bureau to determine whether the laboratory is operated in compliance with the provisions of sections 2 to 45, inclusive, of this regulation;

(u) Misrepresents any material fact to obtain or maintain certification pursuant to the provisions of sections 2 to 45, inclusive, of this regulation;

(v) Engages in any activity that is a ground for the denial of an application for certification or for the suspension or revocation of the certification of a laboratory set forth in section 4.4 of the standards; or

(w) Otherwise violates or attempts to violate or assists or abets a person in the violation of any provision of sections 2 to 45, inclusive, of this regulation.

2. In determining whether to deny an application for certification or to revoke, suspend or limit the certification of a laboratory pursuant to this section, the bureau shall consider:

(a) The gravity of the violation;

(b) The harm to the health and safety of the members of the general public;

(c) The intent of the person who committed the violation;

- (d) The extent of the violation; and
- (e) Any proposed correction of the violation.

3. As used in this section:

- (a) "Protocol" has the meaning ascribed to it in Appendix B of chapter 5 of the standards
- (b) "Quality system" has the meaning ascribed to it in Appendix B of chapter 5 of the standards.

Sec. 11 Sec. 44 is hereby amended to read as follows:

Sec. 44. 1. Each application for:

- (a) Chemistry certification must include a fee of \$500.
- (b) Microbiology certification must include a fee of \$600.

2. In addition to the fees specified in subsection 1, the bureau shall charge and collect the following fees:

For an application to renew certification \$500

Initial fee or annual renewal fee for certification to analyze primary inorganic contaminants 545

Initial fee or annual renewal fee for certification to analyze secondary inorganic contaminants 545

Initial fee or annual renewal fee for certification to analyze regulated and unregulated volatile organic contaminants, including trihalomethanes *and vinyl chloride* 545

Initial fee or annual renewal fee for certification to analyze regulated and unregulated synthetic organic contaminants 1,090

Initial fee or annual renewal fee for certification to analyze radiochemical contaminants 545

Annual renewal fee for certification to analyze specific primary or secondary

inorganic contaminants, or both.....200

Annual renewal fee for microbiology certification 600

3. The initial or annual renewal fee for certification to analyze any chemical contaminant not set forth in subsection 2 is \$400, plus the per diem allowance and travel expenses provided for state officers and employees generally for each person who conducts an inspection of the laboratory that is required for certification.

4. If an application for certification is received during the fiscal year, the *analyte* fees required to be paid by this section must be prorated by using the following formula:

Fee x .083 x the number of months remaining in the fiscal year.

The month in which the application is submitted must not be counted as a month remaining in the fiscal year. The prorated fee must be rounded to the next highest dollar. *The application fee is not prorated.*

5. In addition to any fees paid by a laboratory located outside this state, each such laboratory shall pay to the bureau the costs incurred by the bureau to conduct an inspection of the laboratory.

6. A fee for certification to analyze a specific contaminant must be paid before a certificate may be issued.

7. Any fee paid pursuant to the provisions of this section is nonrefundable.