

## **64E DIVISION OF ENVIRONMENTAL HEALTH AND STATEWIDE PROGRAMS**

### **CHAPTER 64E-1 CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES**

64E-1.001	Definitions. (Repealed)
64E-1.0015	Laboratory Certification Standards.
64E-1.002	Certification - Application, Inspection and Renewal. (Repealed)
64E-1.003	Personnel, Sample Collection and Handling, Methodology, Proficiency Testing and Quality Assurance Requirements. (Repealed)
64E-1.004	Certification of Out-of-State Laboratories. (Repealed)
64E-1.005	Records, Reports, and Contractual Agreements.
64E-1.006	Denial or Decertification. (Repealed)
64E-1.007	Fees and Certification Categories.
64E-1.100	Definitions. (Repealed)
64E-1.101	Categories of Certification. (Repealed)
64E-1.102	Certification Requirements.
64E-1.103	Methodology. (Repealed)
64E-1.104	On-Site Inspections.
64E-1.105	Display of Certificate and Use of Certification.
64E-1.106	Proficiency Testing Requirements.
64E-1.107	Renewal of Annual Certification.
64E-1.108	Contractual Agreements, Records, and Reports. (Repealed)
64E-1.109	Denial or Revocation. (Repealed)
64E-1.110	Fees. (Repealed)

#### **64E-1.0015 Laboratory Certification Standards.**

Any environmental testing laboratory certified or seeking certification pursuant to this rule shall comply with Section 1.8.1; Appendix A to Chapter 1 (Program Policy and Structure); Sections 2.1.3, 2.2.3, 2.4, 2.5, 2.7.2, 2.7.3, 2.7.4, 2.7.6, 3.4.5, 3.4.6, 3.5, 4.0, 4.1, 4.2, 4.3, 4.4, and 4.6; Chapter 5 (Quality Systems) and its Appendices; and Sections 6.2.2, 6.8, and Appendix A to Chapter 6 (Accrediting Authority) of the standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC) on July 12, 2002, which are adopted herein by reference to take effect on January 24, 2005, and with the above same sections of the standards adopted at the NELAC on June 5, 2003 (with the exception of Section 1.8.1, which is renumbered to be 1.6.1), which are adopted herein by reference to take effect on July 1, 2005.

*Specific Authority 381.00591, 403.0625(3), 403.863(2) FS. Law Implemented 381.00591, 403.0625(1), (2), (4), 403.863(3), (4), (7), 403.8635(1), (2) FS. History—New 4-16-00, Amended 6-30-03, 1-24-05.*

#### **64E-1.005 Records, Reports, and Contractual Agreements.**

(1) Laboratories shall maintain analytical performance according to Chapter 5 of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C., for those analytes and test methods with which they have been certified or are seeking certification. Each certified laboratory shall maintain the documentation required in Chapter 5 of the NELAC Standards and comply with the laboratory report format and content requirements in Section 5.5.10 of the NELAC Standards.

(2) For compliance with the Florida Safe Drinking Water Act, the laboratory will report the information described in paragraph 62-550.730(2)(a), F.A.C., revised on 4/3/2003, in the appropriate format approved by the Department of Environmental Protection.

(a) The laboratory may report presumptive positive microbiological results immediately without waiting for total coliform confirmation. The laboratory shall report confirmed positive total coliform results to the supplier of water no later than the end of the next business day after confirmed positive total coliform results are determined. The laboratory shall report positive fecal coliform or *E. coli* results to the supplier of water by the end of the day when the results are determined, unless the results are determined after the water supplier's office is closed, in which case the laboratory shall report the results to the water supplier before the end of the next business day. If a laboratory invalidates a sample due to heterotrophic interference as described in paragraph 62-550.518(10)(b), F.A.C., revised on 4-3-2003, the replacement sample must be analyzed by a Department of Health-certified laboratory using a method less susceptible to heterotrophic interference (e.g., MMO-MUG).

(b) Whenever a sample result, or the average of the results from an initial sample and a confirmation sample, exceeds the maximum contaminant level for nitrate, nitrite, or total nitrate-nitrite, the laboratory shall report the result to the supplier of water by the end of the day when the result was determined, unless the result was determined after the water supplier's office is closed, in which case the laboratory shall report the result to the water supplier before the end of the next business day.

(c) Whenever a sample result exceeds the maximum contaminant level for any other contaminant listed in Rule 62-550.310, revised on 4-25-2003, or 62-550.320, F.A.C., revised on 11-27-01, the laboratory shall report the result to the supplier of water no later than the end of the next business day after the result was determined.

(d) For the purposes of this chapter, a result is considered determined when the laboratory director or his/her designee signs or authenticates the report with the results. The results shall be reported in such a manner that the supplier of water receives the results within the indicated timeframes in paragraphs (2)(a) through (c) of this section.

*Specific Authority 381.00591, 403.0625(3), 403.863(2) FS. Law Implemented 381.00591, 403.0625(1), (2), (4), 403.851, 403.863(3), (4), (7), 403.8635(1), (2) FS. History—New 4-22-79, Amended 3-7-85, Formerly 10D-41.59, Amended 11-14-90, 8-5-93, 4-19-95, 4-25-96, Formerly 10D-41.059, Amended 4-16-00, 6-30-03, 1-24-05.*

#### **64E-1.007 Fees and Certification Categories.**

(1) Application Fee – An applicant for certification must submit to the Department of Health a non-refundable fee of \$200 for the evaluation and processing of each application. The Department of Health shall assess an additional fee of \$200 for each subsequent application for additional Fields of Accreditation, as defined in Appendix A to Chapter 1 of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C.

(2) Certification Fee – In addition to the application processing fee, the Department of Health shall charge nonrefundable fees for the initial certification and on application for annual renewal for each category of certification in each category group in subsections 64E-1.007(6) through 64E-1.007(10), F.A.C., below as follows:

(a) Chemistry, Toxicity, Microscopy, and Microbiology.

1. One category – \$500.

2. Two categories – \$1000.

3. Three categories – \$1500.

4. Four or more categories – \$2000.

(b) Radiochemistry – \$500.

(3) Laboratories approved after July 1 shall have the certification fees prorated on a quarterly basis beginning with the quarter in which department issues certification.

(4) The Department of Health shall assess the travel expenses it incurs as a result of on-site inspection to the out-of-state laboratories, in addition to the application and certification fees in this section. An in-state laboratory shall reimburse the department for on-site inspection travel expenses if the department conducts an inspection, in addition to the inspection conducted pursuant to subsection 64E-1.104(1), F.A.C., at the laboratory's written request. If the department does not conduct the requested inspection within 60 days of the request, the department shall not charge these expenses to the laboratory.

(5) The laboratory shall pay all fees required by subsections (2) through (4) of this section within 90 days of the date of invoice. For annual renewal of certification, the laboratory shall pay the fees required by subsection (2) of this section by July 1 of each calendar year.

(6) For the Drinking Water Matrix category group, certification is available in the following categories:

(a) Microbiology,

(b) Primary Inorganic Contaminants,

(c) Secondary Inorganic Contaminants,

(d) Radiochemistry,

(e) Synthetic Organic Contaminants,

(f) Dioxin,

(g) Other Regulated Contaminants (e.g., Volatile Organic Contaminants),

(h) Group I Unregulated Contaminants,

(i) Group II Unregulated Contaminants, and

(j) Group III Unregulated Contaminants.

(7) For the Non-Potable Water Matrix category group, including ambient monitoring of surface water and groundwater, certification is available in the following categories:

(a) Microbiology,

(b) Toxicity (Bioassay),

(c) Radiochemistry,

(d) Metals,

(e) General Chemistry,

(f) Volatile Organics,

(g) Extractable Organics, and

(h) Pesticides-Herbicides-PCB's.

(8) For the Solid and Chemical Materials Matrix category group, certification is available in the following categories:

(a) Microbiology,

(b) Toxicity (Bioassay),

(c) Radiochemistry,

(d) Metals,

(e) General Chemistry,

- (f) Volatile Organics,
- (g) Extractable Organics, and
- (h) Pesticides-Herbicides-PCB's.
- (9) For the Air and Emissions Matrix category group, the categories of certification available are:
  - (a) General Chemistry,
  - (b) Volatile Organics,
  - (c) Extractable Organics, and
  - (d) Pesticides-Herbicides-PCB's.
- (10) For the Biological Tissue Matrix category group, certification is available in the following categories:
  - (a) Microbiology,
  - (b) Toxicity (Bioassay),
  - (c) Radiochemistry,
  - (d) Metals,
  - (e) General Chemistry,
  - (f) Volatile Organics,
  - (g) Extractable Organics, and
  - (h) Pesticides-Herbicides-PCB's.

*Specific Authority 381.00591, 403.0625(3), 403.863(2) FS. Law Implemented 381.00591, 403.0625(1), (4), 403.863(4), 403.8635(3) FS. History--New 3-7-85, Formerly 10D-41.62, Amended 12-11-89, 8-5-93, 4-19-95, 4-25-96, Formerly 10D-41.062, Amended 4-16-00, 6-30-03.*

#### **64E-1.102 Certification Requirements.**

(1) An application for certification shall be made in writing to the Department of Health on Form DH 1762, accompanied by the application fee, and the laboratory's Quality Manual. If proficiency testing is available for the requested Fields of Testing, the laboratory must arrange for these results from the latest three testing round attempts to be submitted directly to the Department of Health by the recognized proficiency test provider. DH 1762, "Application for Certification of Environmental Testing Laboratories," July 2004 is herein adopted by reference and is available by calling the department's Bureau of Laboratories at (904)791-1599.

(2) Separate application and certification shall be required for all laboratories maintained on separate premises even though operated under the same management; however, separate certification is not required for separate buildings on the same or adjoining grounds.

(3) An application is not completed until the laboratory has fulfilled all of the following requirements:

(a) The application reviewed by the Department of Health was found to contain all the information required in Section 4.1.7 of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C.

(b) The submitted Quality Manual contains all the information required in Section 5.4.2.3 and 5.4.2.4 of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C.

(c) Proficiency samples are successfully analyzed in two of the most recent three testing rounds attempted, if available from a recognized proficiency testing provider, as required in Rule 64E-1.106, F.A.C.

(d) An on-site laboratory inspection has been conducted for the Fields of Accreditation for which the laboratory is seeking certification, as required in Rule 64E-1.104, F.A.C.

(e) All applicable fees are paid as required in Rule 64E-1.007, F.A.C.

(4) An out-of-state laboratory shall be eligible for reciprocal certification provided:

(a) The laboratory is certified by a National Environmental Laboratory Accreditation Program (NELAP) recognized accrediting authority for those Fields of Accreditation in which the laboratory is requesting certification pursuant to this rule,

(b) The laboratory submits to the Department of Health the application and fee required in subsection 64E-1.102(1), F.A.C.,

(c) The laboratory submits to the Department of Health a current copy of the laboratory's unexpired certification from the NELAP accrediting authority and the certifying agency's analyte sheet showing those Fields of Accreditation for which the laboratory is certified.

(5) If upon review of the documents listed in subsection 64E-1.102(5), F.A.C., the Department of Health determines that the application process is complete and that the laboratory is already certified by its NELAP-recognized primary accrediting authority for the same Fields of Accreditation requested on its application, the Department of Health will not require an on-site inspection by its inspectors and certification will be granted after the laboratory pays the certification fees required in Rule 64E-1.007, F.A.C.

(6) If upon review of the documents listed in subsection 64E-1.102(5), F.A.C., the Department of Health is unable to determine that the out-of-state certification program is equivalent to the requirements of this rule, an on-site inspection will be performed by the Department of Health. The laboratory will be responsible for the travel expenses incurred for the on-site inspection.

*Specific Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (4), 403.851, 403.863(3), (4), (7), 403.8635(1), (2) FS. History--New 8-27-86, Amended 10-10-89, 6-29-94, 2-13-96, 4-25-96, Formerly 10D-41.103, Amended 4-16-00, 6-30-03, 1-24-05.*

#### **64E-1.104 On-Site Inspections.**

(1) The Department of Health shall inspect the premises and operations of laboratories certified or seeking certification, except as provided in subsection 64E-1.102(6), F.A.C., and Section 4.6.2. of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C. Such inspections shall occur at least once every 2 calendar years and at such other times as the Department of Health deems necessary to determine continued compliance with this rule.

(2) Inspections will be unannounced in those cases in which the Department of Health determines this approach necessary to establish compliance. Factors such as past record, proficiency test performance, personnel and overall laboratory performance will be considered in making this determination.

(3) The laboratory shall ensure that its Quality Manual, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and all records needed to verify compliance with the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C., and this rule are available for review during the on-site laboratory inspection. The laboratory shall allow the department's authorized personnel to examine records; observe the laboratory's facilities, procedures, and equipment; and interview staff during the on-site inspection.

(4) Inspections will include on-site proficiency test samples when the Department of Health is unable to determine compliance using more conventional methods.

(5) The laboratory shall submit to the Department of Health a Plan of Correction for each deficiency noted during the on-site evaluation. Proposed corrective-action plans must be completed on or attached to the "Statement of Deficiencies and Plan of Correction" form, DH 1137, 3/97, adopted by reference herein.

(6) The Department of Health may conduct on-site inspections of the laboratory at any time.

*Specific Authority 381.00591, 403.0625(3), 403.863(2) FS. Law Implemented 381.00591, 403.0625(1), (2), (4), 403.851, 403.863(3), (4), (7), 403.8635(1), (2) FS. History—New 8-27-86, Amended 10-10-89, 6-29-94, 4-25-96, Formerly 10D-41.105, 4-16-00.*

#### **64E-1.105 Display of Certificate and Use of Certification.**

A current certification document shall be displayed at all times in a prominent place in each certified laboratory. DH 1697, 7/04, which includes the Laboratory Scope of Accreditation and is entitled "Environmental Testing Laboratory Certificate," is adopted by reference herein. The department shall issue the Certificate to the laboratory only upon completion of the requirements of this rule. The laboratory must also comply with Sections 6.8 (a)(1), (2), (3), and (4) and 6.8 (b)(1) and (2) of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C.

*Specific Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(2), (4), 403.863(4), (7), 403.8635(1) FS. History—New 8-27-86, Amended 6-29-94, 4-25-96, Formerly 10D-41.106, Amended 4-16-00, 6-30-03, 1-24-05.*

#### **64E-1.106 Proficiency Testing Requirements.**

(1) Applicant and certified laboratories shall participate in a proficiency testing program from a provider recognized by the Department of Health as being compliant with the procedures and criteria in Sections 2.0, 2.3, 2.6, and 2.7 and in Appendices A, B, C, D, E, F, G, and H to Chapter 2 of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C. Participation means that the laboratory will analyze and report to the provider the results of all proficiency test samples required by the approved program for which the laboratory desires and maintains certification.

(2) Laboratories shall bear the cost of any subscription to a proficiency testing program required by the Department of Health for compliance purposes. The Department of Health shall not be charged a fee for the analysis of any performance evaluation samples.

(3) Unless associated with the submittal of an application form as provided in subsection 64E-1.102(1), F.A.C., the laboratory must authorize the recognized provider, on or prior to the testing round closing date, to submit the proficiency testing results to the department concurrently with the submittal of these results to the laboratory.

(4) All Fields of Accreditation within each category group for which a laboratory is certified or is pending certification must be satisfactorily analyzed, if available, on two of the most recent three proficiency testing rounds attempted. Proficiency test sample results shall be considered satisfactory when they are within the acceptance limits established by the recognized proficiency test sample provider.

(5) A laboratory that meets the requirements of subsection (4) of this section for a particular Field of Proficiency Testing is eligible for obtaining and maintaining certification for the corresponding Field of Accreditation. Otherwise, certification shall be denied, suspended, or revoked for that Field of Accreditation.

(6) A laboratory shall participate in at least two testing rounds from a recognized proficiency test sample provider per fiscal (July 1 – June 30) year, with no more than seven months between consecutive testing rounds, for each available Field of Proficiency Testing that corresponds to a pending or certified Field of Accreditation.

(7) The laboratory shall comply with all requirements in Section 2.5 of the NELAC Standards, referenced in Rule 64E-1.0015, F.A.C., in analyzing proficiency test samples. Pursuant to Section 2.5.1(c) of the NELAC Standards, the laboratory shall not submit proficiency test sample results generated by another laboratory facility as its own.

(8) Proficiency test sample providers shall report laboratory results for proficiency test samples in a format approved by the Florida Department of Health.

(9) In addition to the requirements in subsections (1) through (8) above, laboratories certified or seeking certification for Fields of Accreditation in the Drinking Water Matrix category group for the Microbiology category for total coliforms and/or fecal coliforms (or *E. coli*) must receive acceptable scores for both the total coliforms and for the fecal coliforms (or *E. coli*) portions of a proficiency testing round for performance on those Fields of Accreditation in that testing round to be considered acceptable.

*Specific Authority 381.00591, 403.0625(3), 403.863(2) FS. Law Implemented 381.00591, 403.0625(1), (2), (4), 403.851, 403.863(3), (4), (7), 403.8635(1), (2) FS. History—New 8-27-86, Amended 10-10-89, 6-29-94, 2-13-96, 4-25-96, Formerly 10D-41.107, Amended 4-16-00, 6-30-03, 1-24-05.*

#### **64E-1.107 Renewal of Annual Certification.**

The Department of Health will renew certifications after receipt of a renewal invoice and fee, provided the laboratory is maintaining compliance with this rule, attests to such compliance, and has reported acceptable proficiency test values for the categories certified within the previous year. Laboratories meeting renewal certification criteria will be renewed annually on July 1. The Renewal Attestation of Compliance, DH 1907, 3/98 and Environmental Testing Laboratory Renewal Invoice, DH 1906, 3/98 are both herein adopted by reference and are available by calling the department's Bureau of Laboratories at (904)791-1599.

(1) The Department of Health will mail renewal notices at least 30 days prior to July 1. Failure to receive a renewal notice does not exempt laboratories from meeting the renewal date requirement of July 1 of each year.

(2) All laboratory certification shall expire on July 1 of each calendar year.

(3) The certification of any laboratory which fails to pay the required renewal fee and to return the completed attestation form to the department by July 1 shall automatically expire without notice or further proceeding. A laboratory whose certification has expired may reapply for certification in accordance with subsection 64E-1.102(1), F.A.C.

*Specific Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (4), 403.851, 403.863(3), (4), (7), 403.8635(1), (2), (3) FS. History—New 8-27-86, Amended 6-29-94, 4-25-96, Formerly 10D-41.108, Amended 4-16-00.*