

CHAPTER 64E-1 CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

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64E-1.0015 Laboratory Certification Standards.

(1) Any environmental testing laboratory certified or seeking certification pursuant to this rule shall comply with Sections 4.1.3, 4.6.1, 5.5.2.6, 6.2.2, and 6.8, National Environmental Laboratory Accreditation Conference (NELAC) Standards adopted June 5, 2003, which are incorporated herein by reference, and are available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09889>.

(2) Additionally, any environmental testing laboratory certified or seeking certification pursuant to this rule shall comply with the following modules of Volume 1, “Management and Technical Requirements for Laboratories Performing Environmental Analysis,” of the NELAC Institute, National Environmental Laboratory Accreditation Program (TNI NELAP), hereinafter referred to as “the TNI Standards”: Module 1, “Proficiency Testing” (EL-V1M1-2016-Rev2.1) and Module 2 “Quality Systems General Requirements” (EL-V1M2-ISO-2016-Rev2.1). In addition to these TNI Standards, and as applicable, any environmental testing laboratory certified or seeking certification in the following disciplines pursuant to paragraphs 64E-1.007(2)(a) and (b) of this chapter shall comply with Module 3, “Quality Systems for Asbestos Testing” (EL-V1M3-2016-Rev2.1), Module 4, “Quality Systems for Chemical Testing” (EL-V1M4-2017-Rev2.2), Module 5, “Quality Systems for Microbiological Testing” (EL-V1M5-2016-Rev2.0), Module 6, “Quality Systems for Radiochemical Testing” (EL-V1M6-2016-Rev2.0), and Module 7, “Quality Systems for Toxicity Testing” (EL-V1M7-2016-Rev 1.0) of Volume 1 referenced above. All of the standards referenced in this subsection are incorporated herein by reference. These standards may be examined and inspected at the Florida Department of State, Room 701, The Capitol, Tallahassee, Florida 32399-0250 and at the Florida Department of Health, Bureau of Public Health Laboratories, 1217 North Pearl Street, Jacksonville, Florida 32202. The agency has determined that posting these publications on the internet for purposes of public inspection and examination would constitute a violation of federal copyright law.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (3), 403.863(1), (2), (3), (7), 403.8635(1), (2) FS. History—New 4-16-00, Amended 6-30-03, 1-24-05, 9-26-18.

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

(1) Laboratories shall maintain analytical performance according to Volume 1 of the TNI Standards, referenced in rule 64E-1.0015, F.A.C., for those Fields of Accreditation (i.e., Matrix category group-test method-analyte combinations), for which they have been certified or are seeking certification, through demonstrations of capability performed annually or within the past year, respectively. Each certified laboratory shall maintain the documentation required in Volume 1, Module 2 of the TNI Standards and comply with the laboratory report format and content requirements in Section 5.10 of Volume 1, Module 2 of the TNI 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., December 30, 2011, incorporated herein by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-09890>, 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(9)(b), F.A.C., July 7, 2015, incorporated herein by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09891>, the replacement sample must be analyzed by a Department of Health (DOH)-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, F.A.C., July 7, 2015, or in rule 62-550.320, F.A.C., November 27, 2001, which are incorporated herein by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09892> and <https://www.flrules.org/Gateway/reference.asp?No=Ref-09893>, 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 rule.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (3), 403.851, 403.863(1), (2), (3), (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, 9-26-18.

64E-1.007 Fees and Certification Categories.

(1) Application Fee – An applicant for certification must submit to the DOH a fee of \$200.00 for the evaluation and processing of each application. The DOH shall assess an additional fee of \$200 for each subsequent application for additional Fields of Accreditation, as defined in Volume 1, Module 2 of the TNI Standards, referenced in rule 64E-1.0015, F.A.C.

(2) Certification Fee – In addition to the application processing fee, the DOH shall charge 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) Chemical Testing, Asbestos Testing, Toxicity Testing, and Microbiological Testing: One category – \$400, Two categories – \$800, Three categories – \$1,200, and Four or more categories – \$1,600.

(b) Radiochemical Testing – \$400.

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

(4) Except for inspections conducted for the purposes of contract oversight of the DOH contract assessment providers, the DOH shall charge the travel expenses it incurs as a result of on-site inspections to both the in-state and out-of-state laboratories, in addition to the application and certification fees in this section.

(5) The laboratory shall pay all fees required by subsections (2) through (4) of this rule 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 rule by July 1 of each calendar year.

(6) For the Drinking Water Matrix category group, certification is available in the following categories: Microbiology, Primary Inorganic Contaminants, Secondary Inorganic Contaminants, Radiochemistry, Synthetic Organic Contaminants, Dioxin, Other Regulated Contaminants (e.g., Volatile Organic Contaminants), Group I Unregulated Contaminants, Group II Unregulated Contaminants, and 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: Microbiology, Toxicity (Bioassay), Radiochemistry, Metals, General Chemistry, Volatile Organics, Extractable Organics, and Pesticides-Herbicides-PCB's.

(8) For the Solid and Chemical Materials Matrix category group, certification is available in the following categories: Microbiology, Toxicity (Bioassay), Radiochemistry, Metals, General Chemistry, Volatile Organics, Extractable Organics, and Pesticides-Herbicides-PCB's.

(9) For the Air and Emissions Matrix category group, the categories of certification available are: General Chemistry, Volatile

Organics, Extractable Organics, and Pesticides-Herbicides-PCB's.

(10) For the Biological Tissue Matrix category group, certification is available in the following categories: Microbiology, Toxicity (Bioassay), Radiochemistry, Metals, General Chemistry, Volatile Organics, Extractable Organics, and Pesticides-Herbicides-PCB's.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2), 403.8635(3) FS. Law Implemented 381.00591, 403.0625(1), (3), 403.863(2), (3), 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, 9-26-18

64E-1.102 Certification Requirements.

(1) An application for certification shall be made in writing to the Except for inspections conducted for the purposes of contract oversight of the DOH contract assessment providers, the DOH on Form DH 1762, December 2016, "Application for Certification of Environmental Testing Laboratories," which is herein incorporated by reference and is available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09905>. This application must be accompanied by the application fee. The laboratory must arrange for proficiency testing results from the three most recent testing round attempts to be submitted directly to the DOH by the recognized proficiency test provider.

(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 DOH was found to contain all the information required in Form DH 1762, "Application for Certification of Environmental Testing Laboratories," December 2016, referenced in subsection (1), above.

(b) Proficiency test 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.

(c) 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.

(d) 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 Accreditation Body for those Fields of Accreditation in which the laboratory is requesting certification pursuant to this rule,

(b) The laboratory submits to the DOH the application and fee required in subsection (1), above,

(c) The laboratory submits to the DOH a current copy of the laboratory's unexpired certification from the NELAP Accreditation Body 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 (4), above, the DOH determines that the application process is complete and that the laboratory is already certified by its NELAP-recognized primary Accreditation Body for the same Fields of Accreditation requested on its application, the DOH will not require an on-site survey and certification will be granted after the laboratory pays all applicable fees.

(6) If upon review of the documents listed in subsection (4), above, the DOH is unable to determine that the out-of-state certification program is equivalent to the requirements of this rule, the DOH or its authorized representatives will conduct an on-site inspection.

(7) A laboratory is not eligible for certification for any Fields of Accreditation available through the NELAP-recognized Accreditation Body of the state where the laboratory is physically located, unless the laboratory applies for reciprocal certification under subsection (4), above.

(8) All certified or applicant laboratories will be responsible for the expenses incurred by the DOH or its authorized representatives for any on-site inspection.

(9) The laboratory must report to the DOH's Bureau of Public Health Labs (BPHL) within 30 calendar days of the change all significant changes relevant to its certification, including but not limited to its legal, organizational, commercial, or ownership status; the organization, top management, and key personnel; main policies; resources and premises; its certified Fields of Accreditation; and other such matters that may affect the laboratory's ability to fulfill the requirements of this rule.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (3), 403.851, 403.863(1), (2),

(3), (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, 9-26-18.

64E-1.104 On-Site Inspections.

(1) Except as provided in subsection 64E-1.102(5), F.A.C., laboratories shall arrange for and submit to a comprehensive on-site inspection by the DOH's authorized representatives at least once every two years and at such other times the DOH deems necessary to determine continued compliance with this rule.

(2) Inspections will be unannounced in those cases in which the DOH determines this approach necessary to establish compliance.

(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 TNI and 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 DOH's authorized representatives to examine records; observe the laboratory's facilities, procedures, and equipment; and interview staff during the on-site inspection.

(4) Inspections will include onsite proficiency test samples when the DOH is unable to determine compliance using more conventional methods.

(5) The laboratory shall submit to the DOH, or the DOH's authorized representatives, as applicable, within 30 calendar days of receiving the written on-site inspection report, a Plan of Correction and estimated completion date for each deficiency noted during the on-site inspection. Proposed corrective-action plans and completion dates must be completed on or attached to the "Statement of Deficiencies and Plan of Correction" form, DH 1137, 12/16, incorporated by reference herein and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09906>.

(6) The DOH or its authorized representatives may conduct on-site inspections of the laboratory at any time.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (3), 403.851, 403.863(1), (2), (3), (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, Amended 4-16-00, 9-26-18.

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

A current "Environmental Testing Laboratory Certificate" that includes the Laboratory Scope of Accreditation and is issued by the DOH shall be displayed at all times in a prominent place in each certified laboratory.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (3), 403.863(1), (2), (3), (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, 9-26-18.

64E-1.106 Proficiency Testing Requirements.

(1) Applicant and certified laboratories shall participate in a proficiency testing program, also known as Performance Evaluation, from a TNI-accredited provider. The list of accredited Proficiency Testing Providers and the tabular listing of analytes available for proficiency testing by matrix, delineated as NELAP Fields of Proficiency Testing, are available at <http://www.nelac-institute.org>. 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. Laboratories certified or seeking certification for Fields of Accreditation in the Drinking Water Matrix category group must also comply with Performance Evaluation requirements in Title 40 Code of Federal Regulations sections 141.23(k)(3), 141.24(f)(17), 141.24(h)(19), 141.89(a)(1), and 141.131(b)(2), 07-01-2016 edition, which are incorporated by reference, and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09907>.

(2) Laboratories shall bear the cost of any subscription to a proficiency testing program required by the DOH for compliance purposes. The DOH shall not be charged a fee for the analysis of any proficiency testing 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 provider, on or prior to the testing round closing date, to submit the proficiency testing results to the DOH concurrently with the submittal of these results to the laboratory. After the closing date, no modification to any aspect of the reported results, method/technology, measurement units, or the associated report information shall be made unless it is necessary due to a documented error made by the accredited proficiency testing program provider.

(4) All Fields of Accreditation within each Matrix 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 accredited proficiency test sample provider. If a laboratory reports more than one result for a Field of Proficiency Testing on a proficiency testing round, any unsatisfactory result constitutes a failed testing attempt for the corresponding certified or pending Field of Accreditation.

(5) A laboratory that meets the requirements of subsection (4) of this rule 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 calendar year, with no more than seven months between consecutive testing rounds in terms of closing dates for each proficiency testing attempt, 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 Volume 1, Module 1 of the TNI Standards, referenced in rule 64E-1.0015, F.A.C., in analyzing proficiency test samples. In addition, 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 compliance with the reporting requirements of Section 11 of Volume 3, "General Requirements for Environmental Proficiency Test Providers," (EL-V3-2009) of the TNI NELAP, which is incorporated by reference. This document may be examined and inspected at the Florida Department of State, Room 701, The Capitol, Tallahassee, Florida 32399-0250 and at the Florida Department of Health, Bureau of Public Health Laboratories, 1217 North Pearl Street, Jacksonville, Florida 32202. The agency has determined that posting this publication on the internet for purposes of public inspection and examination would constitute a violation of federal copyright law.

(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 E. coli must receive acceptable scores for both the total coliforms and for E. coli portions of a proficiency testing round for performance on those Fields of Accreditation in that testing round to be considered acceptable. Acceptable scores are determined using the "Fields of Proficiency Testing Tables," January 2018, incorporated by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09908>.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (3), 403.851, 403.863(1), (2), (3), (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, 9-26-18

64E-1.107 Renewal of Annual Certification.

The DOH will renew certifications after receipt of a "Renewal Confirmation of Compliance" and fee, provided the laboratory is maintaining compliance with this chapter. The "Renewal Confirmation of Compliance," DH 1907, 12/16, is incorporated by reference and available by calling the department's Bureau of Laboratories at (904)791-1599 at <https://www.flrules.org/Gateway/reference.asp?No=Ref-09909>.

(1) Failure to receive a renewal notice from the DOH does not exempt laboratories from meeting the renewal date requirement of July 1 of each year.

(2) All laboratory certifications 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 DH 1907 to the DOH 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.

Rulemaking Authority 381.00591, 403.0625(3), 403.863(1), (2) FS. Law Implemented 381.00591, 403.0625(1), (2), (3), 403.851, 403.863(1), (2), (3), (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, 9-26-18.