401 KAR 5:320. Wastewater Laboratory Certification Program.

RELATES TO: KRS 224.1-010, 224.10-100, 224.10-670, 224.70-100, 224.70-110, 40 C.F.R. 136, 33 U.S.C. 1342

STATUTORY AUTHORITY: KRS 224.10-670

NECESSITY, FUNCTION, AND CONFORMITY: KRS 224.10-670 authorizes the cabinet to promulgate administrative regulations establishing standards for the operation of laboratories, fees for certification and competency evaluation of those laboratories, issuance of certificates of competency, and a certification program for laboratories that submit environmental data as it relates to analyses and laboratory tests for activities subject to 33 U.S.C. 1342. This administrative regulation establishes the wastewater laboratory certification program, standards for the certification of wastewater laboratories, and fees for certification and evaluation of wastewater laboratories.

Section 1. Requirement for Acceptance of Environmental Data. In accordance with KRS 224.10-670(2), environmental data from analyses and laboratory tests submitted to the cabinet for activities subject to 33 U.S.C. 1342 shall be performed:
(1) By a certified wastewater laboratory; and
(2) In compliance with:
   (a) An analytical method in 40 C.F.R. Part 136 or as established in the applicable permit;
   (b) This administrative regulation; and
   (c) The provisions of the Commonwealth of Kentucky Wastewater Laboratory Certification Manual.

Section 2. Certification Requirements. The requirements established in this section shall apply to a wastewater laboratory seeking certification. (1) Application for certification shall be made on the Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification, DEP No. DOW0503, and shall include all information required by that form, and shall be submitted with the applicable fee as established in Section 6 of this administrative regulation as follows:
   (a) If in paper form, to: Kentucky Division of Water; Attn: Laboratory Certification; 300 Sower Boulevard; Frankfort, Kentucky 40601; or
   (b) If in electronic form, via the cabinet’s Web site: www.water.ky.gov.
   (2) The wastewater laboratory shall apply for certification for each analysis category and for each method-analyte pairing for which the wastewater laboratory intends to perform an analysis.

Section 3. Term of Certification Periods for a General Wastewater Laboratory. (1) The initial certification period for a general wastewater laboratory shall be from January 1, 2014, until December 31, 2015, and subsequent certification periods shall be consecutive two (2) year periods, beginning January 1, 2016.
(2) If, beginning January 1, 2016, a general wastewater laboratory applies for initial certification of the wastewater laboratory or for certification for a new method-analyte pairing, the initial certification period shall be the two (2) year period as established in subsection (1) of this section, based upon the date of application receipt by the cabinet.

Section 4. Term of Certification Periods for a Field-Only Wastewater Laboratory. (1) The initial certification period for a field-only wastewater laboratory shall be from January 1, 2015, un-
Section 5. Due Date for Certification Renewal Applications. (1) If a Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification for certification renewal is received by the cabinet by November 15 of the odd-numbered year of the current certification period for a general wastewater laboratory, or November 15 of the even-numbered year of the current certification period for a field-only wastewater laboratory, the application shall be considered timely submitted, and the wastewater laboratory's certification shall continue in effect until the cabinet acts upon the application, unless the certification is otherwise revoked.

(2) If a Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification for certification renewal is received by the cabinet after November 15 but on or before December 15 of the odd-numbered year of the current certification period for a general wastewater laboratory, or after November 15 but on or before December 15 of the even-numbered year of the current certification period for a field-only wastewater laboratory, the application shall not be considered timely submitted, and shall be subject to the surcharge established in Section 6(4) of this administrative regulation. The wastewater laboratory’s certification shall continue in effect until the cabinet acts upon the application, unless the certification is otherwise revoked.

(3) If a Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification for certification renewal is received by the cabinet after December 15 of the odd-numbered year of the current certification period for a general wastewater laboratory, or after December 15 of the even-numbered year of the current certification period for a field-only wastewater laboratory, the application shall not be considered timely submitted, and shall be subject to the surcharge established in Section 6(5) of this administrative regulation. The wastewater laboratory’s certification shall expire after December 31 of that odd-numbered year for a general wastewater laboratory, or after December 31 of that even-numbered year for a field-only wastewater laboratory, and shall not be valid until the cabinet acts upon the renewal application.

Section 6. Annual Certification Fees. (1) The annual certification fees for wastewater laboratory certification shall be established in Table 1 of subsection (2) of this section and shall include:

(a) A nonrefundable administrative fee; and
(b) A fee for each applicable analysis category.

(2) If a follow-up audit is performed to verify the correction of a deficiency identified by an audit pursuant to Section 8 of this administrative regulation, an additional audit fee, established in Table 1, shall be assessed.

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<th>Fee Category</th>
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</tr>
<tr>
<td>Follow-up Audit Fee</td>
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</tbody>
</table>

(3) The applicable certification fee shall be due by November 15 of each year. In odd-numbered years of the certification period for a general wastewater laboratory, or in even-numbered years of the certification period for a field-only wastewater laboratory, the applicable certification fee shall be submitted concurrent with the renewal certification Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification.

(4)(a) If a fee is received by the cabinet after November 15 but on or before December 15, the wastewater laboratory shall incur a surcharge of fifteen (15) percent of the applicable certification fee (administrative fee plus analysis category fee).

(b) Payment of this surcharge shall be due thirty (30) days after notice is provided by the cabinet.

(5) If a fee is received by the cabinet after December 15, the wastewater laboratory shall incur a surcharge of twenty-five (25) percent of the applicable certification fee.

(a) The wastewater laboratory’s certification shall expire after December 31 of that year and shall not be valid until the applicable certification fee and the surcharge are received by the cabinet.

(b) Payment of this fee and surcharge shall not reinstate certification for failure to timely submit an application for certification renewal pursuant to the expiration established in Section 5(3) of this administrative regulation.

(6) A wastewater laboratory seeking or obtaining equivalency of certification shall receive a twenty (20) percent reduction of the certification fee.

(7) An in-state laboratory that is also certified for drinking water analysis, as established in 401 KAR 8:040, shall receive a twenty (20) percent reduction of the certification fee.

(8) A wastewater laboratory that provides only field analysis shall be exempt from the annual administrative fee established in Table 1 of subsection (2) of this section.

(9) A wastewater laboratory operated by a facility that has been issued a Kentucky Pollutant Discharge Elimination System permit and that is providing only field analysis for only its own facility shall be exempt from all fees established in this administrative regulation.

(10) A wastewater laboratory operated by a municipality that provides analysis for only its own facility shall receive a reduction to the administrative fee established in Table 1 of subsection (2) of this section, based on its maximum permitted flow value as established in this subsection.

(a) Less than or equal to 0.10 million gallons per day (MGD) shall indicate a 100 percent reduction (no administrative fee).

(b) Less than or equal to 0.50 MGD but greater than 0.10 MGD shall indicate a seventy-five (75) percent reduction.

(c) Less than or equal to one and zero tenths (1.0) MGD but greater than zero and five tenths (0.5) MGD shall indicate a fifty (50) percent reduction.
(d) Less than or equal to two and zero tenths (2.0) MGD but greater than one and zero tenths (1.0) MGD shall indicate a twenty-five (25) percent reduction.
(e) Greater than two and zero tenths (2.0) MGD shall indicate a ten (10) percent reduction.
(11) If more than one (1) reduction pursuant to subsections (6) through (10) of this section applies, only the greatest reduction shall be taken.

Section 7. Interim Certification. (1) If a wastewater laboratory demonstrates that it complies with the requirements established in subparagraphs (a) through (d) of this subsection for a method-analyte pairing, the cabinet shall approve interim certification for that method-analyte pairing.
(a) All information required by the Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification shall be submitted to the cabinet.
(b) The appropriate fee shall be submitted to the cabinet.
(c) A method, including instrumentation, established in 40 C.F.R. Part 136 or the applicable permit shall be used.
(d) A proficiency test study sample shall be analyzed by the primary analyst or technician within the last year and the results shall be within the acceptance limits specified by a proficiency test study provider approved by the American Association for Laboratory Accreditation.
(2) A wastewater laboratory with interim certification may analyze samples for that method-analyte pairing for compliance purposes.

Section 8. Audits. (1) A certified wastewater laboratory shall allow a cabinet auditor to conduct, and shall participate in, an on-site audit during normal business hours.
(2) Wastewater laboratory certification records and supporting documentation shall be retained for five (5) years or until the next on-site audit, whichever is longer.
(3) If the cabinet identifies a deficiency, the certified laboratory shall correct or otherwise address the deficiency within thirty (30) days of receipt of notice of the deficiency.
(4)(a) If an on-site audit of a wastewater laboratory located outside of Kentucky is conducted by the cabinet, the wastewater laboratory shall bear the reasonable cost of the audit.
(b) Payment shall be due thirty (30) days after notice of this cost is provided by the cabinet.

Section 9. Full Certification Requirements. (1) If, after an on-site audit and review of submitted information, all requirements established by this administrative regulation for a method-analyte pairing have been met, the cabinet shall approve full certification for that method-analyte pairing.
(2) To maintain full certification for the method-analyte pairing, the wastewater laboratory shall:
(a) Maintain compliance with the requirements established by this administrative regulation, based upon the cabinet’s review of requested documentation, on-site audit inspection, or both;
(b) Analyze a proficiency test study sample at least annually by the primary analyst or technician and the results shall be within the acceptance limits specified by a proficiency test study provider approved by the American Association for Laboratory Accreditation. If the wastewater laboratory fails a proficiency test study, the wastewater laboratory shall, within ninety (90) days after receiving notice of the failed proficiency test study, analyze a second proficiency test study with the results within the acceptance limits specified by an approved proficiency test study provider;
(c) Notify the cabinet within thirty (30) calendar days of a change in the personnel, equipment, analytical method, or laboratory location identified in its Kentucky Wastewater Laborato-
ry Certification Program Application for Kentucky Laboratory Certification;
(d) Submit documentation or data required by this administrative regulation; and
(e) Submit to the cabinet all fees by the deadlines established in this administrative regulation.

Section 10. Provisional Certification. (1) The cabinet shall, upon becoming aware of a failure of a wastewater laboratory to comply with one (1) or more of the requirements established in Section 9(2) of this administrative regulation, provide written notice to the wastewater laboratory of the deficiency and of the cabinet’s intent to change the certification status to provisional certification.
(2) If the deficiency relates to a specific method-analyte pairing, the cabinet may change the status of the wastewater laboratory’s certification to provisional certification. If the status is changed to provisional certification, this changed status shall be for only the analyte that failed to comply with the requirements of Section 9(2) of this administrative regulation, unless the cabinet had certified a group of related analytes based on a limited number of analytes in the group.
(3) The wastewater laboratory shall submit to the cabinet a written corrective action plan to address this deficiency within thirty (30) days of receipt of the notice of intent from the cabinet, specifying the immediate and long-term corrective actions that shall be taken.
(4) The wastewater laboratory shall correct this deficiency as soon as reasonably possible. If the deficiency is not corrected within thirty (30) days of receipt of the notice of intent, the cabinet shall change the certification status to provisional certification, and shall provide written notice to the wastewater laboratory of this action.
(5) A wastewater laboratory with provisional certification may continue to analyze a sample for compliance purposes, but shall notify its client of the wastewater laboratory’s provisional certification status prior to conducting an analysis for that client and shall provide that information in writing to the client.
(6) A wastewater laboratory with provisional certification shall correct the deficiency as soon as is reasonably possible, but within three (3) months of written notification from the cabinet of the change to provisional certification status.
(7) The cabinet shall restore the wastewater laboratory’s provisional certification status to full certification upon making a determination that the deficiency resulting in the provisional certification status has been corrected and shall provide written notice to the wastewater laboratory of this action.

Section 11. Certification Revocation. (1) The cabinet may immediately revoke a wastewater laboratory’s certification for:
(a) Failing to use an analytical method established in 40 C.F.R. Part 136 or in the applicable permit;
(b) Reporting proficiency test study data from another laboratory as its own data;
(c) Engaging in falsification of data or another deceptive practice;
(d) Endangering public health or the environment through an operation associated with the wastewater laboratory;
(e) Refusing to allow or participate in an on-site audit conducted by the cabinet; or
(f) Persistent failure to report accurate compliance data to the cabinet.
(2) If the cabinet revokes a wastewater laboratory’s certification pursuant to subsection (1) of this section, the cabinet shall immediately notify the wastewater laboratory of this action and provide written notice to the wastewater laboratory of this action.
(3) If a wastewater laboratory has not corrected the deficiency resulting in the provisional certification status within three (3) months of written notification from the cabinet of the change to provisional certification, the cabinet shall provide written notice to the wastewater laboratory of the cabinet’s intent to revoke the wastewater laboratory’s certification for any method-analyte pairing involved in the deficiency.

(4) The wastewater laboratory may request, in writing, a redetermination of the cabinet’s intent to revoke certification pursuant to subsection (3) of this section.

(a) If a redetermination is requested, the request shall be made within thirty (30) days of receipt of the notice of intent to revoke.

(b)1. This request shall be submitted to the cabinet and shall explain the basis for the redetermination request and, if appropriate, include a written corrective action plan to address the deficiency identified in the cabinet’s notice of intent to revoke.

2. The request shall be signed by a responsible official of the wastewater laboratory.

(5) The cabinet, having received a request for redetermination pursuant to subsection (4) of this section, shall make a final determination whether or not to continue provisional certification, approve certification, or revoke certification, and shall provide written notice to the wastewater laboratory of this action.

(6) If, within thirty (30) days of receipt of the notice of intent to revoke pursuant to subsection (3) of this section, the wastewater laboratory does not request a redetermination, the cabinet shall revoke the wastewater laboratory’s certification and provide written notification to the wastewater laboratory of this action.

Section 12. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Commonwealth of Kentucky Wastewater Laboratory Certification Manual", August 2018; and

(b) "Kentucky Wastewater Laboratory Certification Program Application for Kentucky Laboratory Certification", DEP No. DOW0503 (March 2018).

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Water, 300 Sower Boulevard, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material may also be obtained through the Division of Water’s Web site at http://water.ky.gov. (27 Ky.R. 2603; 3122; 3239; eff. 6-8-2001; 35 Ky.R. 2337; 2768; 36 Ky.R. 25; eff. 7-31-2009; TAM eff. 4-4-2011; 39 Ky.R. 2094; 40 Ky.R. 33; 282; eff. 9-5-2013; TAM eff. 7-8-2016; 44 Ky.R. 2631; 45 Ky.R. 696, 1012; eff. 11-1-2018.)