

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Environmental Protection Agency

Regulation/Package Title: Laboratory Certification Amendments, 2019

Rule Number(s): 3745-89-01 through 3745-89-12, 3745-81-27 and 3745-81-28

Date _____

Rule Type:

New

5-Year Review

Amended

Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Ohio EPA is proposing to amend several rules in the Ohio Administrative Code (OAC). Chapter 3745-89 contains the laboratory certification rules and rule 3745-81-27 contains the rules for analytical techniques.

- Rule 3745-89-01 incorporates definitions for terms covered in Chapter 3745-89 of the OAC.

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- Rule 3745-89-02 explains the qualifications a laboratory must have in order for its analyses to be acceptable for determining compliance with various drinking water rules in the OAC.
- Rule 3745-89-03 explains the procedure for obtaining laboratory certification, including fee information established in ORC 3745.11. The rule also describes the allowable amounts of unacceptable results, to match U.S. EPA's requirements, and references the latest editions of Ohio EPA's two laboratory manuals for microbiological analyses of public drinking water and chemical analyses of public drinking water.
- Rule 3745-89-04 describes the process and requirements for renewal of a laboratory's certification.
- Rule 3745-89-05 describes the requirements for maintaining laboratory certification.
- Rule 3745-89-06 describes the reasons for which the Director of Ohio EPA may deny, suspend or revoke a laboratory's certification and the process by which issuance, denial, suspension or revocation of certification will occur.
- Rule 3745-89-07 instructs laboratories certified by the state to display their certificate in a prominent location of the laboratory.
- Rule 3745-89-08 outlines the requirements for reporting analytical results, including the method, timing and means of reporting. This rule also addresses out of state laboratories and those labs which subcontract part or all of the analyses.
- Rule 3745-89-09 outlines the procedure for laboratories to gain interim authorization to perform plant control tests or MMO-MUG (SM 9223) tests.
- Rule 3745-89-10 outlines the procedure by which a certified laboratory may be granted interim authorization to perform drinking water analyses for new contaminants and new methods.
- Rule 3745-89-11 establishes certification requirements for laboratories analyzing Cryptosporidium, E. coli and turbidity samples.
- Rule 3745-89-12 establishes requirements for obtaining and renewing alternate acceptance of laboratory certification.
- Rule 3745-81-27 references the analytical techniques and methods required to perform drinking water analyses to determine compliance with the OAC.
- 3745-81-28 outlines exemption of certification requirement for chlorine analysis.

These rules have been reviewed pursuant to the five-year rule requirements set forth in ORC 119.032, and to update rules by reference, adopt new analytical methods and make other

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minor clarifications in Chapter 3745-89. =Rule 3745-81-27 of the Administrative Code will be rescinded, and replaced with a new 3745-81-27. A new rule (3745-89-12) has been added to provide the option to obtain and renew alternate acceptance of laboratory certification. Additional proposed revisions include adjusting terminology to match definition changes, as well as the following:

- 3745-89-01:
 - Addition of definitions for “acceptance of certification,” “analyte” and “violation”.
 - Removal of the definition of “deviation”. “Deviation” was replaced with “violation”.
 - The option to obtain operational certification for certain microbiological analyses was added to the definition of “operational certification”.
- 3745-89-02:
 - Addition of the option of accepting outside NELAC or equivalent accreditation in lieu of Ohio EPA certification.
- 3745-89-03:
 - Update of Ohio EPA lab manuals (chemical and microbiological).
 - Addition of submittal requirements for out of state and NELAC certified labs.
 - Relocation of fee information (section 3745.11 of the Revised Code) from 3745-89-04.
 - Addition of ortho phosphate, total phosphorus, and MPN analyses.
 - Referenced 3745-81-27 to identify required proficiency test (PT) samples and results. Total trihalomethanes, volatile organic chemicals, microbiological contaminants and haloacetic acids were described individually since there are allowable unacceptable PT results (identified within their descriptions).
 - Removed Appendices A and C, renaming B as A.
- 3745-89-04:
 - Add exception for acceptance of certification by referencing 3745-89-12.
- 3745-89-05:
 - Added membrane filtration method.

- 3745-89-06:
 - Added caveats for when certification will expire.
- 3745-89-07:
 - Minor amendment for LSC consistency
- 3745-89-08:
 - Changed Appendix B to Appendix A due to removal of Appendices A and C from rule 3745-89-03.
- 3745-89-09:
 - Clarification of pH and turbidity interim authorization requirements by referring to manuals.
 - Left the option for number of individuals to receive interim authorization open ended.
- 3745-89-11:
 - Referenced analytical techniques in rule 3745-81-27 and certification requirements in Chapter 3745-89.
- 3745-81-27:
 - The rule is being rescinded and replaced as new, removing the list of acceptable methods and referencing USEPA method lists.
- 3745-81-28:
 - Clarification of chlorine certification exemption.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

ORC section 6109.04 paragraph (B)(2), “Adopt, amend, and rescind such rules in accordance with Chapter 119. of the Revised Code as may be necessary or desirable to... Govern public water system to protect the public welfare, including rules governing contaminants in water that may adversely affect the suitability of the water for its intended uses or that may otherwise adversely affect the public health or welfare.”

ORC section 6109.04 paragraph (C)(6), “Establish and maintain a program for the certification of laboratories conducting analyses of drinking water.”

ORC section 3745.11 paragraph (N)(3) provides the legislation necessary to require laboratory fees.

- 3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

If yes, please briefly explain the source and substance of the federal requirement.

Yes. These regulations enable Ohio EPA to administer the Safe Drinking Water Act (SDWA), as well as retain primary enforcement authority (C.F.R. 40 Part 142.10) from the Federal Government. These rules establish a State program for the certification of laboratories conducting analytical measurements of drinking water contaminants pursuant to the requirements in the SDWA.

- 4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

These rules exceed the scope of federal requirements by including quality control requirements not listed in some original methods.

- 5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

The public purpose for adopting such regulations (as stated in ORC 6109.04) is to establish and maintain a program for the certification of laboratories conducting analyses of drinking water. Having rules that establish a certification program for labs is necessary for Ohio to maintain SDWA primacy. Additionally, these rules help to ensure that approved analytical methods are being used for analysis so that public and environmental health are better protected.

- 6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

Ohio EPA periodically verifies laboratories are meeting laboratory procedures as outlined in OAC Chapter 3745-89, including but not limited to being current on State certification, using approved analytical methods, analyzing results correctly and reporting results in a timely manner, all of which contribute to the accuracy of drinking water analysis used to determine compliance with primary/secondary drinking water standards.

Development of the Regulation

- 7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

If applicable, please include the date and medium by which the stakeholders were initially contacted.

Stakeholders include certified laboratories, public water system owners and operators,

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consultants, environmental organizations and the general public. The only measure someone has to take to be notified of DDAGW's potential rule activity is to request to be added to our electronic or hard-copy mailing list.

Stakeholders were notified of DDAGW's plans to revise these rules on October 1, 2018 by electronic or regular mail in accordance with their request. In addition, DDAGW will be seeking comment from stakeholders during the division's interested party review period. The interested party review period occurs before the rules are filed with JCARR and is used to address any concerns or questions from staff and our stakeholders.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

US EPA Region 5 indicated the acceptance of NELAC accreditation should be optional, this was included in the rules. Pace Analytical Services requested clarification for the NELAC acceptance, state reciprocity, QC criteria, and individual analyst numbers. These will be included in the rules. Greater Cincinnati Water Works expressed concern over 3475-89-08, but this rule had been accepted in a previous rule update.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Ohio EPA obtained statutory authority in Chapters 6109 of the Revised Code and promulgated these rules under Administrative Code Chapter 3745-89. References used include the latest revisions to 40 C.F.R. Parts 141 and 142. The federal counterparts which include the SDWA Amendments of 1996 are the foundation for these rules.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

In order to retain primary enforcement authority, Ohio EPA is required to establish a laboratory certification program and adopt rules. Therefore, Ohio EPA could not consider alternatives to these rules.

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

Yes. Most of the rules in this package are performance-based and contribute to the accuracy of drinking water analysis used to determine compliance with primary/secondary drinking water standards.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

Ohio EPA reviewed internal regulations and determined there are no duplications.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

Ohio EPA conducts in-house training and meetings to help staff be aware of how regulations are to be implemented.

Ohio EPA's outreach for this rule package includes the following:

- Notifying certified laboratories, both public water system and privately owned, of any rule comment periods and rule filings.
- Providing guidance to the regulated community. More specifically, the Division of Environmental Services (DES) notifies certified laboratories when rules and laboratory manuals change.
- Giving presentations on rule updates.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

All drinking water laboratories in the State are certified by Ohio EPA, which include private laboratories and public water systems (PWSs) with their own lab.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Adverse impacts to the rules in this filing will include the following:

- PWS laboratories and private laboratories must be certified by Ohio EPA to analyze drinking water for the purpose of determining PWS compliance with safe drinking water standards in OAC Chapters 3745-9, 3745-81, 3745-82 and 3745-91.
- Laboratories applying to be certified are required to submit a quality assurance plan, documentation of each individual performing the analysis, a certification fee, and undergo an onsite survey. All laboratories that become certified in the State of Ohio are required to renew their certification once

every three years, as well as if or when they apply to be approved for analysis of a different contaminant or addition of analysts.

- Certified laboratories are required to maintain documentation of their analysis, the individuals conducting it, and to report analysis to Ohio EPA as part of complying with their certification.
- Certified laboratories applying for interim authorization for plant control tests, new contaminants and new methods will be required to submit an application and undergo an Ohio EPA onsite survey for approval from the Agency.

c. Quantify the expected adverse impact from the regulation.

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.

3745-89-02 to 3745-89-04, 3745-89-09 to 3745-89-10 and 3745-89-12:

Certification Fees

Rules 3745-89-03 and 3745-89-04 require that laboratories in Ohio be certified every three years to perform analysis of drinking water. Approximately 370 certified laboratories exist in Ohio at this time, many of which maintain multiple certifications. County, township and municipal labs account for approximately 92% (341 labs) of the certified laboratories in Ohio. The remaining labs are privately owned. Ohio EPA records indicate that labs spend approximately \$501,389.00 annually in fees to the Agency to maintain their certifications. This amount will decrease if commercial labs choose acceptance over certification as permitted in the revised rules.

Proficiency Testing

As part of the laboratory certification program, labs must perform analysis of proficiency test samples annually. Based on price quotes from various vendors, the annualized costs of performance testing for all labs in Ohio are estimated at \$155,777.82.* This estimate includes the cost of the product. All other costs (e.g., indirect and personnel) are negligible.

Quality Assurance Plan

As part of the certification process, laboratories must submit a quality assurance plan for approval by the director. Depending upon the number and type of certifications for which the lab applies, the cost will vary. Some labs are only certified to perform very basic testing, while others may be certified to perform more extensive testing. High and low estimates for developing the plans are outlined below. These costs were obtained from various labs in Ohio and from Agency personnel. Costs to develop these plans include personnel costs to write the plans and indirect (e.g.,

copying, mailing, updating, etc.) costs. Capital and operations costs are not applicable. Estimates for developing the plans ranged from ten to ninety hours. Estimates on rates of lab personnel who write the plan vary from \$11.89 to \$58.35 per hour.*

Quality Assurance Plan Expenses

Cost Category	Low Estimate	High Estimate
Personnel Costs	10 hours at \$11.89/hour = \$119	90 hours at \$58.35/hour = \$5,251.50
Indirect Costs	15% of \$119 = \$17.84	15% of \$5,251.50 = \$787.72
Totals	\$137	\$6,039

Totals

Total statewide costs for this rule (on an annual basis) are approximately:

Certification Fees: \$501,389.00
 Proficiency Tests: \$155,777.82
 \$657,166.82 (Average of \$1776.13 per lab)

In addition, each lab will spend approximately \$137 to \$6,039 as a one-time cost to develop a quality assurance plan.

*The estimates presented were updated using the U.S. Bureau of Labor Statistics inflation calculator.

3745-89-05:

This rule requires laboratories to maintain records of their compliance with the certification requirements in Chapter 3745-89. The cost associated with record maintenance includes the cost of storage, and will depend on the volume of records to be maintained as well as how they are maintained. Most laboratories use paper records, while some commercial laboratories have adopted electronic record keeping systems.

For a laboratory using paper records, maintenance could require one to several filing cabinets. The cost could range from \$351 to \$1,639 for purchasing filing cabinets or maintaining a large amount of records at an off-site location (e.g., National Centers in Ohio). The cost for an electronic Laboratory Information System (LIMS) database, for a laboratory processing a high volume of samples, is estimated to be between \$43,000 and \$65,000 for hardware and software, and approximately \$293 for an annual software license fee for each person using it.

Please note that commercial laboratories will have LIMS to process all samples regardless of whether or not they are certified for drinking water sampling. This cost is not a direct result of the drinking water laboratory certification program.

3745-89-08:

Certified laboratories are directly affected by this rule and endure the costs to comply with it. Based on a survey of four commercial laboratories, the cost to comply with this rule is approximately \$11.89 a month, or \$143 annually.

3745-89-11:

There is no direct cost of compliance with this rule. Any correlating costs have been established in rule 3745-81-27 of the Administrative Code. The requirements in this rule identifies the requirements a laboratory must complete if they will be analyzing Cryptosporidium, E. coli and turbidity samples, and would include costs for performing the specific method, including reagents, instruments and equipment.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

The Agency considers the overall cost for complying with these regulations to be minor in comparison with ensuring data used to determine compliance with safe drinking water standards is reliable.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Ohio EPA does not find compliance with these rules to be burdensome for smaller entities and businesses. The Agency believes the requirements meet the basic needs for achieving and maintaining acceptable practices and environment for qualified personnel that analyze public drinking water for contaminants.

That being said, a provision to obtain “acceptance of certification” in lieu of complying with rule 3745-89-03 has been added as rule 3745-89-12 for laboratories that are certified by USEPA, NELAP or another environmental laboratory accreditation program acceptable to the Director.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

Ohio EPA does not assign fines and penalties for first-time offenders, and prefers to obtain

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compliance through outreach first and if needed, written notice of violations prior to any type of formal enforcement.

18. What resources are available to assist small businesses with compliance of the regulation?

The majority of certified laboratories in Ohio are owned by PWSs, some being classified as small. Overall, Ohio EPA provides administrative assistance and technical training for all certified laboratories at no cost. On-site training from DES is given as needed (e.g., a lab is newly approved for a microbiological or chemical analyte).