

Common Sense Initiative

Mike DeWine, Governor Jim Tressel, Lt. Governor Joseph Baker, Director

MEMORANDUM

TO:	Mandi Payton, Ohio Environmental Protection Agency
FROM:	Caleb White, Business Advocate
DATE:	February 18, 2025
RE:	CSI Review – Laboratory Certification Rules (OAC 3745-81-27, 3745-81-28, 3745-89-01, 3745-89-02, 3745-89-03, 3745-89-04, 3745-89-05, 3745-89-06, 3745-89-07, 3745-89-08, 3745-89-09, 3745-89-10, 3745-89-11, and 3745-89-12)

Pursuant to the authority granted to the Common Sense Initiative (CSI) Office under Ohio Revised Code (ORC) section 107.54, the CSI Office has reviewed the abovementioned administrative rule package and associated Business Impact Analysis (BIA). This memo represents the CSI Office's comments to the Agency as provided for in ORC 107.54.

<u>Analysis</u>

This rule package consists of twelve amended rules, one no-change rule, and one rescinded rule proposed by the Ohio Environmental Protection Agency (OEPA) as part of the statutory five-year review process. This rule package was submitted to the CSI Office on November 4, 2024, and the public comment period was held open through December 4, 2024. Unless otherwise noted below, this recommendation reflects the version of the proposed rules filed with the CSI Office on November 4, 2024.

The rules in this package pertain to certification for laboratories that perform drinking water analyses. These rules contain the definitions, facility requirements, certification requirements, certification renewal requirements, the actions the OEPA's director can take towards certified laboratories including the issuance, suspension, denial, or revocation of a certification, requirements regarding the certificate issued under these rules, analysis and reporting requirements, the conditions and requirements under which a laboratory can obtain interim authorization to perform certain tests, the

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standards for the analysis of certain samples, and the requirements and process for obtaining an alternative certification. These rules contain amendments to add and remove definitions, add language related to penalties for unresolved violations, update the dates of referenced materials, add a referenced material used for acceptable result standards, eliminate effective dates, correct the number of analyses included in standard chemistry, update language surrounding survey requirements, add requirements for the laboratory certification of vinyl chloride, update rule references, add requirements for when an analyst leaves a laboratory, eliminate references to outdated modes of communication, as well as to update and streamline language.

This package also contains a rule with an appendix that establishes reporting limits for various analyses. This appendix is amended to correct certain reporting limits, add reporting limits for perand polyfluoroalkyl substances, add acceptance limits for disinfection by products, as well as to add footnotes pertaining to calibration curves and laboratories that use certain United States Environmental Protection Agency methods. The package also contains one rule which is proposed for rescission. The rescinded rule, OAC 3745-89-10, establishes the process for obtaining interim authorization to perform drinking water analyses by using new methods for new analytes or during certain transition periods. This rule is to be rescinded as it was deemed to not be necessary and may conflict with obligations to the United States Environmental Protection Agency.

During early stakeholder outreach, the OEPA sent electronic notification to its Division of Drinking and Ground Water's rulemaking interested party list on July 11, 2024, and accepted comments through August 11, 2024. During this period the OEPA received comments from Eurofins labs, IDEXX Laboratories, and the City of Orville. These comments requested the removal of the requirement that the Quality Control Manual is approved by the OEPA director, the removal of a requirement for analysts designated on a laboratory certificate to participate proportionally in analyses they are certified for, to add certain additional acceptable test methods, and removing a requirement to obtain real-time approval of changes. Early stakeholder feedback also suggested changing a requirement for the submission of plans and approval procedures for laboratories that are intending to move. The OEPA did clarify the provisions in which it was requested but did not accept any of the requested changes. During the CSI public comment period, the OEPA received one comment from the Southwest Regional Water District who raised concerns that the rescission of OAC 3745-89-10 would not allow laboratories to establish new or amended methods in their laboratory and requested that additional methods be added to the list of analysts that are permitted to receive interim authorization. The OEPA did not make any changes in response to this comment but did clarify that the recission of the rule does not eliminate the ability of a laboratory to add new or amended methods. To assist the commenter, the OEPA outlined the process that is used to add these methods. The OEPA also stated that when there is an immediate need to add a new or amended method, they work with the laboratory to prioritize their application.

The business community impacted by the rules includes water plant laboratories and contract laboratories in the state. The OEPA estimates that there are approximately 370 certified laboratories in Ohio. The adverse impacts created by the rules include the requirement for laboratories to be certified every three years to perform drinking water analyses, proficiency test sampling requirements, the costs associated with developing a quality assurance plan, records retention requirements, analysis and reporting requirements, and required standards laboratories must follow when analyzing Cryptosporidium, E. coli and turbidity samples. The OEPA estimates that labs spend approximately \$479,000.00 in annual fees to maintain their certification and \$190,092.04 in proficiency tests. The OEPA also estimates that the costs to develop a quality assurance plan can range from \$166.90 to \$7,369.20 and can take ten to ninety hours to develop, that the costs to maintain records can range from \$430 to \$79,300 depending on the method used, and that the analysis and reporting costs are approximately \$14.50 a month or \$174.12 annually. The OEPA states that the adverse impacts to business are justified to ensure the public is supplied with a safe and reliable source of drinking water.

Recommendations

Based on the information above, the CSI Office has no recommendations on this rule package.

Conclusion

The CSI Office concludes that the OEPA should proceed in filing the proposed rules with the Joint Committee on Agency Rule Review.