

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

Board Order SS-22-12 amending Ch. NR 149 Laboratory Accreditation

3. Subject

NR 149 establishes a program for registration and certification of laboratories that submit data to the Department for covered programs

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

None

6. Fiscal Effect of Implementing the Rule

No Fiscal Effect Increase Existing Revenues Increase Costs
 Indeterminate Decrease Existing Revenues Could Absorb Within Agency's Budget
 Decrease Cost

7. The Rule Will Impact the Following (Check All That Apply)

State's Economy Specific Businesses/Sectors
 Local Government Units Public Utility Rate Payers
 Small Businesses (if checked, complete Attachment A)

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes No

9. Policy Problem Addressed by the Rule

The revision largely clarifies existing language in NR 149. Some quality control and reporting requirements have been removed to reduce the impact of the rule on businesses. Overall, the volume of the rule is reduced by 4 pages. The proposed rule introduces efficiencies for administering the certification and registration program, improves the structure used for certification and registration of laboratories, identifies clear steps and procedures for the certification and registration process, establishes a more equitable fee structure, clarifies requirements for proficiency testing of laboratories, stipulates procedures for on-site evaluations of laboratories, and adds specificity and flexibility to quality systems requirements for laboratories.

One significant change addressed by this rule is the removal of the cap on fees. Fees are assessed to laboratories based on relative audit workload, the number and type of analytical methods to be audited and certified. Under the current fee schedule, 25 laboratories (7%) have a fee cap and would see an increase in fees if that cap were removed. These laboratories predominantly require a higher relative audit workload during a typical audit cycle. The change in fee structure proposed is revenue neutral so that other laboratories that require relatively less workload in an audit cycle will see a corresponding decrease in fees. Observations by our laboratory auditors indicate that some laboratories keep certifications for methods they do not use. Removing the fee cap may incentivise decisions to reduce the overall number of methods for which certification is maintained by a laboratory. Reducing the number of certifications will make the laboratory accreditation program more efficient and reduce inspection report turnaround time. This rule will make laboratory accreditation and inspection fees more proportional to actual work effort.

10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

Commercial laboratories, industrial laboratories, municipal laboratories and public health laboratories.

11. Identify the local governmental units that participated in the development of this EIA.

Watertown Water Utility, Whitewater Wastewater Treatment Facility, Fort Atkinson Wastewater Treatment Facility, Milwaukee Metropolitan Sewerage District

12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local

ADMINISTRATIVE RULES

Fiscal Estimate & Economic Impact Analysis

Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

We estimate that the economic impact of this rule will be a level 3 (minimal - less than \$50,000) impact. This level of economic impact is based on our assessment of the fees paid by laboratories regulated by the Wisconsin Department of Natural Resources (WDNR) and the estimated relative value units (RVUs) of each laboratory inspection performed in 2016. In our assessment of the fee schedule and RVU data, most of the smaller laboratories that we certify will have their certification fees reduced under this revision. The average fee increase for the 25 laboratories that will be affected by removing the fee cap is \$919 per laboratory. Two laboratories which certify for the maximum analytical methods will see their annual fees increase from \$6,900 to \$8,122. The sum of the revenue that will result from an increase in fees that will be paid by laboratories that require higher RVUs during a typical audit (25 laboratories) is estimated to be \$22,979 per year. For the 326 laboratories which will have a decrease in fees, the average fee reduction will be \$72 per laboratory. The total fee reduction for these 326 laboratories that require less RVUs is estimated to be \$23,339 per year.

Other minor changes such as: removing some reporting requirements, removing some quality assurance manual documentation requirements, removing some standard operating procedure documentation requirements, removing the need for annual calibration, removing the need to perform a quality control sample, and removing some other quality control elements that the program did not see as adding value, will allow the laboratories to save money.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

The rule revision largely clarifies language in NR 149. Some quality control and reporting requirements are removed to lessen the burden of compliance on business. A change in fee structure may incentivise individual laboratory management decisions to reduce the overall number of methods for which certification is maintained. If those decisions are taken, reducing the number of certifications will make the laboratory accreditation program more efficient and reduce inspection report turnaround time. This rule will make laboratory accreditation and inspection fees more proportional to actual work effort.

Alternatively, the fee structure can remain unchanged, continuing to allow the smaller laboratories to subsidize the cost of administering the certification program for the larger laboratories.

14. Long Range Implications of Implementing the Rule

Implementing this rule will provide a more equitable distribution of fees for participation in this program. There will be some minor efficiency benefits for the laboratories and the audit process due to some changes in requirements.

15. Compare With Approaches Being Used by Federal Government

The EPA grants primacy to states with approved programs. Wisconsin is routinely audited by EPA and is in good standing with its certification program.

16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Wisconsin, Illinois, Iowa, and Minnesota have similar laboratory certification programs. Michigan requires certification only for those laboratories analyzing drinking water. To compare fees between the states, we used an average annual proposed fee for the 30 largest commercial laboratories as one category, and used a wastewater laboratory certified for BOD, TSS, Ammonia, and Phosphorous as an indicator of the typical wastewater laboratory fee. Using these two categories, Wisconsin proposed fees are \$5,311/\$1,114 for commercial/wastewater laboratories. Illinois assesses \$8,400/\$3,400 annually for these same types of laboratories. Minnesota's fees are \$10,900/\$1,800. Iowa's fees are lower than WI's for wastewater laboratories, but higher for commercial laboratories (\$10,800/\$800). Michigan charges \$6,729 for certification of drinking water laboratories; no certification for wastewater laboratories is required.

<h4>17. Contact Name</h4>	<h4>18. Contact Phone Number</h4>
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ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

This program currently manages 351 laboratories that submit data to the Department for covered programs. The small businesses we serve include 116 commercial and industrial laboratories. The remaining laboratories are municipal and public health laboratories. Seventy seven (77) of the commercial and industrial laboratories are located in Wisconsin.

In terms of the cost of certification, 23 (32%) of commercial laboratories are expected to see a fee increase. Only 5 Wisconsin commercial laboratories will have a fee increase. The average fee increase for the 23 commercial laboratories (including those outside Wisconsin) is estimated to be \$947 per laboratory per year. The remaining commercial laboratories (68%) are projected to see a decrease in fees, averaging \$124 per year.

Of 45 industrial laboratories in the certification program, only 1 laboratory will see an increase of \$310. The remaining 44 laboratories will see an average decrease of \$56 per year.

On aggregate, the 116 small business laboratories will see an annual fee increase of \$13,429 per year, or a \$5,571 annual increase for the 6 Wisconsin small business laboratories. The average fee change for all 77 Wisconsin commercial and industrial laboratories is a \$14 decrease.

2. Summary of the data sources used to measure the Rule's impact on Small Businesses
Current laboratories' scopes of work and our current program fee structure.

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
- Less Stringent Schedules or Deadlines for Compliance or Reporting
- Consolidation or Simplification of Reporting Requirements
- Establishment of performance standards in lieu of Design or Operational Standards
- Exemption of Small Businesses from some or all requirements
- Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

Other minor changes such as: removing some reporting requirements, removing some quality assurance manual documentation requirements, removing some standard operating procedure documentation requirements, removing the need for annual calibration, removing the need to perform a quality control sample, and removing some other quality control elements that the program did not see as adding value, will allow the laboratories to save money.

5. Describe the Rule's Enforcement Provisions

No changes to the existing rule: Stepped enforcement provisions from NON to NOV to referral to DOJ.

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes No
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