Report From Agency

REPORT TO LEGISLATURE

NR 149, Wis. Adm. Code
Laboratory Accreditation

Board Order No. SS-22-12
Clearinghouse Rule No. 17-046

Basis and Purpose of the Proposed Rule

The basis for the proposed rule is ss. 299.11 (3), 229.11 (4), 299.11 (5), 299.11 (7), 299.11(8), 299.11 (9), Stats.

The Department proposes repealing and recreating Chapter NR 149 in its entirety to: make it more efficient to administer, facilitate compliance with the regulated community, improve the structure used for certifying and registering laboratories, establish a more equitable fee schedule, and introduce options to operational requirements of laboratories that increase regulatory flexibility.

The last substantial revision of Chapter NR 149 took place in 2008. The Department, laboratory certification standards council, and the regulated community support the clarification of Chapter NR 149 since this last revision was published.

This rule revision addresses procedures the Department will use to administer the Laboratory Accreditation Program and specific requirements the Department will apply to laboratories participating in the program. The rule covers details on program administration, program structure, certification and registration processes, proficiency testing, on-site laboratory evaluations, and laboratory quality systems.

Summary of Public Comments

Numerous public comments were received with most them related to editorial clarifications of the rule revision from the legislative clearinghouse. Multiple laboratories commented on the following aspects of the rule revision:

- Technology requirements
- Limit of quantitation requirements
- Limit of detection verifications
- Initial calibration requirements
- Use of expired chemicals
- Documentation
- Clarification questions on the intent of some aspects of the rule

Many changes to requirements, clarifications, and editorial fixes were made in response to the comments received from the public. The Department plans on providing guidance and outreach to laboratories before the new rule is effective.

A summary table of the Department's responses to the comments received is attached.

Modifications Made

Based on public comments the following proposed requirements were removed from the rule:

The five requirements with the most comments were removed from this revision. The next four requirements with the most comments were revised or a Department response was provided to clarify why a revision was not necessary.

Almost all the editorial and clarification comments were addressed by appropriate revision of the rule. Where revisions were not made, the Department response was provided to indicate the reason why a change was not made.

A summary table of the Departments response to the comments received is attached.
Appearances at the Public Hearing

1. Green Bay, July 10, 2017 – DNR Representative – Tom Trainor

Pace Analytical Services-Green Bay: Nils Melberg and Kate Verbeten
Milwaukee MSD: Alfredo Sotomayor and Kim Walden

Oral comments were received from both laboratories and were included in the NR 149 public comments summary attached.

2. Madison, July 10, 2017 – DNR Representative – Richard Mealy

Pace Mobile Lab Services-Madison: Pat Letterer and Karl Olm

Oral comments were received from both laboratories and were included in the NR 149 public comments summary attached.

3. Eau Claire, July 10, 2017 – DNR Representative – Steve Geis

WRR: Eric Gunderson and Becky Anderson

Oral comments were received from both laboratories and were included in the NR 149 public comments summary attached.

Changes to Rule Analysis and Fiscal Estimate

The rule was modified appropriately in response to the public comments and in agreement with the advisory council. There is no change to the original fiscal estimate. There is no net fiscal impact for the State.

Response to Legislative Council Rules Clearinghouse Report

The Legislative Council Rules Clearinghouse submitted comments on October 10, 2017.

Changes to the propose rule were made to address all recommendations by the Legislative Council Rules Clearinghouse by either making the change as suggested, making the change with a revision, or deleting the language in question, except for those discussed below.

- LCRC: In s. NR 149.10 (1), (2), and (3), the department should explain what is meant by "materially and consistently".

  Department Response: After discussion with our division attorney the Department decided that the phrase "materially and consistently" is understood by the public for the purpose of this rule.

- LCRC: In s. NR 149.14 (3) (title), consider replacing the word "applications" with the word "accreditations".

  Department Response: Applications is more appropriate for this rule.

- LCRC: Statutory Authority Section 299.11 (9), Stats., requires the department to promulgate by rule a graduated schedule of fees. However, in s. NR 149.21 (2) (b), the proposed rule appears to allow the department to establish a schedule of fees and revise the schedule annually without promulgating these fees in rule. That provision seems to apply to both the dollar amounts and certain aspects of the formula of a fee schedule. The department should: (a) describe and more clearly delineate its distinction between the dollar amounts and the formula that are the two components used in setting the fee schedule; (b) explain any authority for the dollar amounts to be set by internal policy rather than by rule; and (c) specify that revisions to the formula are limited to only revisions that are made by rule.

Department Response: As required in s. 299.11(9), Stats., the department has established a graduated schedule of fees for certified and registered laboratories designed to recover the costs of administering this chapter. The number of relative value units required for specific elements of accreditation are specified in Tables, 1, 2, and 3. Relative value units are summed every January 1 to determine the dollar amount the department is required to charge per relative value unit for the next fiscal year. Annual dollar amount adjustments, per relative value unit, are reviewed by council and approved by the natural resources board.

A summary table of the Departments response to the comments received is attached.

Final Regulatory Flexibility Analysis

A small number of the 339 regulated laboratories would fit the definition of "small business", as given in s. 227.114 (1) (a), Stats. These laboratories include small in-state and out-of-state commercial laboratories. The remainder of the labs in the program are small municipal labs, public health labs, industrial labs and large commercial lab corporations, for which no regulatory flexibility analysis is required. Many of the proposed changes are clarifications of the code and will not create new requirements.

All laboratories are expected to comply with the requirements in ch. NR 149 at the time they become effective. The Department will provide guidance and outreach to further clarify the rule revision. Section 299.11, Stats., does not allow for less stringent schedules, deadlines, or reporting requirements for different types of laboratories. Small businesses that experience undue hardship because of these requirements can apply to the Department for a variance from non-statutory requirements under s. NR 149.12. The Department is proposing these amendments in part to consolidate and simplify the requirements for applications, renewal, methods, and reference samples, as directed by s. 227.114(1)(c), Stats. These simplifications will benefit all labs, including small businesses. Since procedures for making the requirements less stringent or establishing performance standards in lieu of requirements are not possible with this rule, there is no additional cost to the state in administering this rule to small businesses. Further, there will be no adverse impact on the public health, safety or welfare by administering this rule to small businesses.