

NATURAL RESOURCES BOARD AGENDA ITEM

SUBJECT: Request for adoption.
Proposed ammendments NR 149 Laboratory Certification and Registration

FOR: OCTOBER 2007 **BOARD MEETING**

TO BE PRESENTED BY: David Webb

SUMMARY:

The Department proposes to repeal and recreate the chapter in its entirety. It has been 10 years since the chapter was last revised, and many changes have occurred nationally with respect to laboratory certification requirements.

The proposed rule was met with a certain degree of adversity during the public comment period. Several aspects of the rule were of concern to municipal wastewater treatment plant laboratories. They believed the rule imposed numerous new requirements that would result in considerable labor cost. The Department has adjusted the final rule to address the concerns of these facilities. In addition, the rule provides for a delayed effective date (September 1, 2008) which will be used to conduct outreach efforts to clarify the rule revisions for facilities.

RECOMMENDATION: Authorize adoption of proposed ammendments to ch. NR149, Laboratory Certification and Registration

LIST OF ATTACHED MATERIALS:

- | | | | | | |
|----|-------------------------------------|---|-----|-------------------------------------|----------|
| No | <input type="checkbox"/> | Fiscal Estimate Required | Yes | <input checked="" type="checkbox"/> | Attached |
| No | <input checked="" type="checkbox"/> | Environmental Assessment or Impact Statement Required | Yes | <input type="checkbox"/> | Attached |
| No | <input type="checkbox"/> | Background Memo | Yes | <input checked="" type="checkbox"/> | Attached |

APPROVED:

/s/
Bureau Director, Science Services

9/18/07
Date

/s/
Administrator, Enforcement and Science

9/20/07
Date

/s/
Secretary, Matthew J. Frank

10/03/07
Date

DATE: October 6, 2007

TO: Natural Resources Board Members

FROM: Matthew J. Frank - AD/5

SUBJECT: Background Memo for Proposed Amendments to Ch. NR 149, Wis. Adm. Code.

1. Why is rule being proposed?

a. What event or action triggered the proposal?

The last substantial revision of Chapter NR 149 took place in 1994. The Department considered in 2000 to revise the statutes to allow it to become an accrediting authority under the National Environmental Laboratory Accreditation Program (NELAP), a voluntary consortium of states accrediting laboratories by a consensus set of standards under the auspices of the US EPA. Although the Department was not successful in revising the statutes, that effort clarified that the Department wanted to modify Chapter NR 149 and that the regulated community would support a general revision of the rule. The Department and the regulated community supported inclusion of some aspects of the standards used by NELAP. An advisory committee was convened between 2002 and 2004 that advised the Department on drafting the current proposed rule. All key stakeholders and constituents of the Laboratory Certification program were involved in the advisory committee. Substantial consensus was reached with the advisory committee and the resulting draft rule was taken to public hearings in 2006. Some criticism of the advisory committee process and draft rule was received during the public hearings. The Department has worked hard to satisfactorily address comments received and believes the proposed draft represents a rule that will be supported by the stakeholders.

b. What are issues addressed by the rule?

The Department proposes repealing and recreating Chapter NR 149 in its entirety to: make it more efficient to administer, facilitate compliance with it from 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.

This rule revision addresses procedures the Department will use to administer the Laboratory Certification and Registration 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 process, proficiency testing, on-site laboratory evaluations, and laboratory quality systems.

2. Summary of the rule.

This proposal constitutes the most extensive revision of Chapter NR 149 since it was originally adopted in 1986. Highlights of this proposal include:

- Provisions for issuing laboratory certificates that clearly reflect the analytical capabilities of participating laboratories.
- Clarifications and improvements of the application process for participating laboratories.
- Equitable fee schedules for laboratories based on the complexity of the analyses they perform.
- Allowances for incorporating national acceptance criteria for proficiency testing samples.



- Procedures the Department will follow to evaluate laboratories on site.
- Comprehensive requirements that incorporate a systematic approach to ensure the quality of the data submitted to the Department by laboratories.

3. How does this proposal effect existing policy?

This proposal does not violate or negate existing policy. The rule proposal is grounded on the statutory directive to promulgate rules consistent with nationally recognized criteria, to the extent possible. The proposal clarifies existing procedures and requirements for the certification and registration of laboratories. Additionally, the proposal formalizes into rule widely accepted practices for laboratory operations and the administration of laboratory certification, registration, accreditation, and licensure programs of environmental laboratories.

4. Hearing Synopsis

a. When were the hearings held?

The Department held five public hearings from March 23 to April 6, 2006.

b. Where were the hearings held?

Hearings were conducted in Eau Claire, Green Bay, Wausau, Waukesha, and Dodgeville.

c. Number of appearances.

A total of 68 appearances were recorded, with 23 offering oral testimony. Of those registering an appearance, nine (9) identified themselves as “in support” of the rule changes; 46 were “in opposition” to the changes, and 13 did not indicate a position.

d. Summary of hearing comments.

This was a major revision to the rule and the most significant revision since adoption in 1986. As observed by several of those submitting comments, the volume of the rule increased substantially. All of these factors should naturally be expected to heighten the sensitivities of the regulated community. Subsequently, the overall tone of comments received is best described as strong concern that the additional rule volume translated into increased workload with the accompanying fiscal burden.

While numerous public comments were received, the majority of them were related to six specific aspects of the rule revision:

- enforcement,
- the new requirement that all analysts perform an initial demonstration of capability for each analytical parameter,
- record-keeping requirements,
- requirements associated with continuing calibration verification,
- sample handling requirements, including a time limit for preservation of samples and chain-of-custody requirements, and
- verification of standards using second source standards.

As mentioned previously, the intent of this rule revision was to bring the Laboratory Certification and Registration Program inline with quality control concepts and record-keeping requirements that have become generally accepted in the analytical testing community nationally. In addition, we have tried to clearly identify program requirements rather than using broad spectrum code language. Finally, the rule has been designed to incorporate flexibility in how laboratories can document that they are meeting

specific requirements.

Largely, the volume of the rule increased because of clarifications made to existing requirements with which laboratories are currently in compliance. Many of the new requirements can be demonstrated to actually result in cost and labor savings. A delayed effective date (September 1, 2008) has been incorporated into the rule to allow the program sufficient time to develop and present outreach sessions to more fully explain the rule provisions and offer guidance for compliance.

The program values the input received from the laboratory community and effort was made to consider and incorporate appropriate revisions to the rule wherever possible without sacrificing the quality of the compliance data which the rule is designed to ensure. For each of the six major aspects of the rule identified as a concern, we believe we have crafted language which represents a compromise position preserving the quality of data being generated without imparting undue financial or labor burden on the regulated community.

e. Public contacts after hearing.

No public contacts have occurred since the hearings. Revisions made to the final rule are based on public comments received during the public comment period.

5. Information on environmental analysis.

This is a Type III action and as such does not require an environmental assessment or environmental impact statement.

6. Final Regulatory Flexibility Analysis.

A small number of the 428 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. However, a small business analysis is required because the proposed fee changes, reference sample changes and test category changes may have an effect on small businesses.

Very few small businesses commented on the proposed rule. Those commenters representing laboratories that might qualify as a small business under the statutory definition generally favored the rule revisions.

All laboratories are expected to comply with the requirements in ch. NR 149 at the time they become effective. A delayed effective date has been incorporated into the rule to allow the department sufficient opportunity for outreach efforts 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 as a result of these requirements can apply to the Department for a variance from non-statutory requirements under s. NR 149.12, Wis. Adm. Code. 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.

SUMMARY OF COMMENTS ON THE RULE

Public hearings concluded on April 6, 2006 and the written comment period ended on April 14, 2006. The Department held five public hearings on the proposed rule change. A total 68 appearances were recorded, with 23 offering oral testimony. Of those registering an appearance, nine (9) identified themselves as “in support” of the rule changes; 46 were “in opposition” to the changes, and 13 did not indicate a position.

This was a major revision to the rule and the most significant revision since adoption in 1986. As observed by several of those submitting comments, the volume of the rule increased substantially. All of these factors should naturally be expected to heighten the sensitivities of the regulated community. Subsequently, the overall tone of comments received is best described as strong concern that the additional rule volume translated into increased workload with the accompanying fiscal burden.

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A. PUBLIC HEARINGS

The hearings were fairly well attended

Hearings were attended by the following Department Staff:

David Webb, Chief, Science Services,
Joe Renville, Attorney, Bureau of Legal Services
Diane Drinkman, Audit Chemist (Green Bay, Wausau, Waukesha, Eau Claire)
Alfredo Sotomayor, Audit Chemist (Green Bay, Wausau, Waukesha, Eau Claire)
Brenda Howald, Audit Chemist (Dodgeville)

1. Eau Claire, March 23, 2006 1 “as interest may appear”; 6 “in opposition”; 2 “in support”

- Oral comments received from:
 - Kay Marshall, Prairie Farm WI, representing several municipal clients
 - Wally Thom, Rice Lake Wastewater Facility
 - Christopher J. Groh, Eau Claire, WI
 - Darryll Farmer, Eau Claire City-Co. Health
 - Paul G. Kent, Municipal Environmental Group – Wastewater Division

- Appeared but chose not to speak:
 - Jerry Kitelinger, City of Tomah– Wastewater Plant
 - Keith Seaman, Thorp, WI
 - Donald J. Gutting, River Falls Wastewater Treatment
 - Paul Harris, Davy Laboratories

2. Wausau, March 28, 2006 1 “as interest may appear”; 7 “in opposition”; 1 “in support”

- Oral comments received from:
 - Ron Dickrell, Marshfield Wastewater Treatment Plant
 - Rich Boden, Village of Plover– Wastewater Plant

- Appeared but chose not to speak:
 - Patrick Geisendorfer, City of Merrill– Wastewater Plant
 - Matt Saloun, Village of Whiting Utilities
 - James Hall, City of Medford– Wastewater Utility
 - Ben Brooks, City of Medford– Wastewater Utility
 - Terence L. Vanden Heuvel, City of Merrill– Wastewater Plant
 - Jim Riege, Wausau Waterworks – Wastewater Division

3. Waukesha, March 29, 2006 4 “as interest may appear”; 11 “in opposition”; 4 “in support”

- Oral comments received from:
 - Jim Kinscher, Modine Manufacturing
 - Sharon Mertens, Milwaukee Metropolitan Sewerage District
 - Jim Thomas, S-F Analytical Labs, Inc.
 - Kurt Birkett, City of Fort Atkinson– Wastewater Plant
 - Randall Thater, City of Waukesha – Wastewater Plant
 - Judy Tholen, City of Watertown – Wastewater Plant

- Appeared but chose not to speak:
 - James Thalke, Village of Sussex – Wastewater Plant
 - David Kollakowsky, WE Energies
 - Bob Berenson, City of Brookfield – Wastewater Plant
 - Ron Eifler, City of Brookfield WPCC

Rick Wenzel, City of Brookfield WWTP
Kim M. Reilly, Milwaukee Metropolitan Sewerage District
Chester Gdaniec, Palmyra, WI
Erin Tuttle, City of Fort Atkinson– Wastewater Plant
Ryan Wagner, City of Fort Atkinson– Wastewater Plant
Marilyn West, Fontana-Walworth Water Pollution Control Commission
Mark Milanowski, Water Quality Testing Services
Kevin L. Freber, Watertown, WI
Ron Clish, Cedarburg Wastewater Treatment Plant

4. Green Bay, March 30, 2006 4 “as interest may appear”; 13 “in opposition”; 2 “in support”

- Oral comments received from:
 - Carroll Vizecky, Village of Winneconne – Wastewater Plant
 - Robert Manthei, Village of Kewaskum– Wastewater Plant
 - Bill Schill, Campbellsport Wastewater Treatment Plant
 - David Hartmann, Wolf Treatment Plant
 - Jeff L. Deitsch, Village of Jackson– Wastewater Plant
- Appeared but chose not to speak:
 - Michael Hanten, Clean Water Testing LLC
 - Eric Storm, Manitowoc Wastewater Treatment Plant
 - Thomas E. Kruzick, Oshkosh Wastewater Treatment Plant
 - Debra Cawley, Green Bay Metropolitan Sewerage District
 - Jeff Mayou, City of Marinette– Wastewater Plant
 - Chad Giakino, Heart of the Valley Metro Wastewater Treatment Plant
 - Glen H. Geurts, Heart of the Valley Metro Wastewater Treatment Plant
 - Patrick Ahrens, Wisconsin Public Service Corp. – Central Laboratory
 - Tom Gureck, Allenton Wastewater Treatment Plant
 - Bill Ciske, Village of Hortonville – Wastewater Plant
 - Kathy Garfinkel, Village of Luxemburg
 - James Wergin, Village of Casco – Wastewater Plant
 - Melissa Mrotek, Georgia Pacific
 - Albert Kardoskee, De Pere Wastewater Treatment Plant

5. Dodgeville, April 6, 2006 3 “as interest may appear”; 9 “in opposition” 0 “in support”

- Oral comments received from:
 - Paul R. Christensen, City of Fort Atkinson– Wastewater Plant
 - Dan Elwood, CT Laboratories
 - Joe Flanagan, Village of Blanchardville – Wastewater Plant
 - Randy Herwig, Village of Lodi – Wastewater Plant
 - William D. Collins, City of Elroy – Wastewater Plant
- Appeared but chose not to speak:
 - Todd E. Fischer, Richland Center City Utilities
 - Joseph Solawetz, City of Monroe– Wastewater Plant
 - James Sinkule Jr., City of Monroe– Wastewater Plant
 - Michael Suha, City of Appleton– Wastewater Plant
 - Tim Reel, City of Fort Atkinson– Wastewater Plant
 - Craig Shotliff, Village of Belmont – Wastewater Plant
 - Laurie A. Vogt, Alliant Energy – Nelson Dewey

B. Joint Municipal Statement

During a state conference for municipal wastewater systems, the following statement was generated which a number of municipal representatives signed.

“As representatives of the attached list of Cities, Towns, and Villages, we would like to comment on the proposed rule NR 149. After review, we would like to register our opposition to the proposed rule. We feel that the rule, if approved as written, will affect our plants adversely. We feel that the rule, as proposed, is better suited for commercial laboratories, and that proposing rules using a national guidelines (read NELAC) is very inappropriate for small wastewater laboratories that perform analyses for process control and reporting to DNR. Data submitted under the current NR 149 rule provides excellent data quality.

Second comment: If NR 149 is to be revised, wastewater treatment laboratories reporting data to the DNR should be exempted from any of the new revisions. Wastewater treatment laboratories not reporting data to entities outside of the state should not have to follow guidelines from a national standard.”

An individual from each of the following list of municipalities signed the statement cited above. The list is composed of 100 facilities, only 63 of which currently operate a laboratory regulated under ch. NR 149, Wis. Admin. Code. Seven of the facilities also submitted written comments which reflect the issues noted above and which the department has addressed during response to other comments received. The list has been annotated to identify small vs. large facilities, including whether they operate a laboratory certified or registered under ch. NR 149, and those that do not operate a certified or registered laboratory

Algoma Utilities	(small, registered)	Fish Creek	(small, registered)
Amherst, village	(small, registered)	Galesville	(small, No lab)
Antigo	(small, certified)	Hanover	(small, No lab)
Ashland	(small, certified)	Hingham	(small, No lab)
Athens	(small, registered)	Horicon	(small, registered)
Athens, village	(small, registered)	Hortonville	(small, registered)
Baldwin	(small, registered)	Howard, village	(small, No lab)
Barneveld	(small, No lab)	Hudson	(small, registered)
BayCity	(small, No lab)	Independence	(small, No lab)
Bayfield	(small, registered)	Juneau	(small, registered)
Beloit	(small, registered)	Kewaskum	(small, certified)
Black Creek	(small, registered)	Kewaunee	(small, registered)
Bowler	(small, No lab)	LaCrosse	(large, registered)
Boyd	(small, registered)	Ladysmith	(small, certified)
Brillion	(small, certified)	Lake Mills	(small, registered)
Brookfield	(large, certified)	Lake?, village	(small, No lab)
Brooklyn	(small, No lab)	Lincoln San. Dis.	(small, No lab)
Brownsville	(small, No lab)	Lomira	(small, No lab)
Burlington	(large, certified)	Luxemburg	(small, registered)
Cassville	(small, No lab)	Madison	(large, certified)
Chippewa Falls	(small, registered)	Mayville	(small, certified)
Clinton	(small, registered)	Medford	(small, certified)
Clintonville	(small, certified)	Milladore	(small, No lab)
Cochrane(V)	(small, No lab)	Mosinee	(small, registered)
Columbus	(small, registered)	Mount Horeb	(small, registered)
Drummond	(small, No lab)	Oakhill DOC	(small, No lab)
East Troy(V)	(small, registered)	Oconomoc	(small, registered)
Eastman(V)	(small, No lab)	Onion River	(small, registered)
Eden	(small, registered)	Peshtigo	(small, No lab)
Elkhart Lake	(small, No lab)	Pewaukee (V)	(small, No lab)
Geneva Materials	(small, No lab)	Phelps	(small, registered)
Ephraim	(small, certified)	Prairie du Sac	(small, No lab)

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Prairie Farm	(small, No lab)	Theresa	(small, No lab)
Princeton	(small, registered)	Tigerton	(small, registered)
Pulaski	(small, No lab)	Tomah	(small, registered)
Random Lake	(small, registered)	Two Rivers	(small, registered)
Reedsville	(small, No lab)	Union Center	(small, No lab)
Rhineland	(small, registered)	Valders	(small, registered)
Rhineland	(small, registered)	Washburn	(small, No lab)
Richland Center	(small, certified)	Waterford	(small, No lab)
Rochester	(small, No lab)	Waterloo	(small, registered)
Rubicon	(small, No lab)	Waupun	(small, registered)
Shawano	(small, No lab)	Wauzeka	(small, registered)
Sheboygan	(small, registered)	Waverly San Dis	(small, No lab)
Shelby	(small, No lab)	Weyerhauser (V)	(small, No lab)
Sister Bay	(small, registered)	Whitehall	(small, No lab)
So. Milwaukee	(small, registered)	Wittenberg	(small, registered)
Stanley	(small, certified)	Wonewoc	(small, No lab)
Stoughton	(small, registered)		

C. Individual Public Comments Including Department response

Included as an attachment to this document

D. Legislative Rules Clearinghouse Comments Including Department response

Included as an attachment to this document

Summary of Comments and Response to the Legislative Council Rules Clearinghouse Report

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In each case, the Department has either made the change as suggested by the Legislative Rules Clearing house, revised the language or section such that the comment is no longer warranted, or deleted the material in question.

1. General comments on the rule revision.

[W]hen an introduction grammatically leads into following subunits, the introduction clearly should indicate whether any or all of the following subunits must be complied with. For example, in s. NR 149.02 (2) (intro.), the phrase “doing any of the following” should be inserted after the word “laboratories.”

Department Response: **This change has been made.**

Second, if introductory material does not grammatically lead into following subunits, then the material should be numbered as a separate subunit and all of the following subunits should be renumbered accordingly. For example, in s. NR 149.02 (7), the first sentence should be renumbered as par. (a) and the remaining paragraphs should be renumbered pars. (b) and (c).

Department Response: **This change has been made.**

2. Comments received relating to Subchapter I- General Provisions, s. NR 149.02- Applicability.

NR 149.02 (3) The material in s. NR 149.02 (3) should be moved to the definition of the term “laboratory” in s. NR 149.03 (41).

Department Response: **This change has been made.**

3. Comments received relating to Subchapter I- General Provisions, s. NR 149.03- Definitions.

In s. NR 149.03 (11), the word “means” should be replaced by the word “includes.”

Department Response: **This change has been made.**

In s. NR 149.03 (36), the definition should clarify what the tiers are in each type of field of certification.

Department Response: **This change has been made.**

In [s. NR 149.03] sub. (37), a comma should be inserted after “matrix-analytical.”

Department Response: **The suggested punctuation is unnecessary, but the wording has been changed for clarification.**

In [s. NR 149.03] sub. (59), what does the phrase “with a stated level of confidence” mean?

Department Response: **This phrase is not necessary and will be deleted to remove any confusion.**

In [s. NR 149.03] sub. (81), it appears that the word “that” should be replaced by the word “than.”

Department Response: **This change has been made.**

4. Comments received relating to Subchapter II- Program Administration, s. NR 149.06- Certificates.

In s. NR 149.06 (4), a comma should be inserted after the second occurrence of the word “certificate.”

Department Response: **This change has been made.**

5 Comments received relating to Subchapter II- Program Administration, s. NR 149.07- Transfer of certification and registration.

In s. NR 149.07 (1), the word, “may” should be replaced by the word “are.”

Department Response: **This change has been made.**

6. Comments received relating to Subchapter II- Program Administration, s. NR 149.08- Recognition of other certifications, registrations, accreditations, licenses or approvals.

In s. NR 149.08 (3)(d), the rule should indicate where the department will publish this list or how a copy of the list can be obtained. The same issue occurs in sub. (4) (c).

Department Response: **This change has been made.**

NR 149.08 (4)(b) [As with s. NR 149.08 (3) (d)], the rule should indicate where the department will publish this list or how a copy of the list can be obtained. the department must have procedures for evaluating the eligibility of a laboratory for transferring its certifications and registrations by application. This rule is the place for these procedures. At the very least, the rule should indicate whether the procedures now exist and how they may be obtained. [See also ss. NR 149.08 (4) (b) and 149.23 (1).]

Department Response: **This change has been made.**

7. Comments received relating to Subchapter II- Program Administration, s. NR 149.10- Enforcement.

In s. NR 149.10 (1) (a) 3. and (b) 15., it appears that the word “subsection” should be replaced by the word “paragraph.”

Department Response: **This change has been made.**

In s. NR 149.10 (1) (b) 7., more detail should be provided about what "failure to follow approved methods" includes.

Department Response: **The requirement has been revised to offer clarification.**

In Subsection NR 149.10 (1) (c) 2., should specify that the laboratory must submit a petition for a hearing to the department within 30 days of receiving the order.

Department Response: **This change has been made.**

8. Comments received relating to Subchapter II- Program Administration, s. NR 149.12 – Variances.

In s. NR 149.12 (2), a note providing the contact information for the director of the bureau of integrated science services should be included in the rule.

Department Response: **This change has been made.**

9. Comments received relating to Subchapter III- Program Structure, s. NR 149.13 - Fields of certification and registration.

Section NR 149.13 (4) (a) should conclude with the phrase "of this subchapter."

Department Response: **This change has been made.**

10. Comments received relating to Subchapter IV- Certification and Registration Process, s. NR 149.14 - Application for certification or registration.

In s. NR 149.14 (1) (c) (intro.), the phrase "initial, renewed, revised or transfer of" should be replaced with "seeking, renewing, revising or transferring."

Department Response: **This change has been made.**

NR 149.14 (1)(c) 1 *In sub. (1) (c) 1., "when" should be replaced with "if."*

Department Response: **This change has been made.**

NR 149.14 (1)(c) 2 *In sub. (1) (c) 2., "violations" should be changed to "a violation" and the second occurrence of "have" should be replaced by "has."*

Department Response: **This change has been made.**

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" In sub. NR 149.14 (1) (d) *instead of "expire," a better word choice might be "cancel" or "void" or "terminate.*

Section NR 149.14 (1) (d) refers to forms provided by the department. The department should ensure that the requirements of s. 227.14 (3), Stats., are met.

Department Response: **The change to (1) (d) has been made. Availability of applications forms is clearly addressed.**

NR 149.14 (2)(e) " *In sub. (2) (e), can the department provide criteria it will use to determine whether a laboratory is eligible to transfer their certifications or registrations?*

Department Response: **The final rule clarifies eligibility as it exists in the current promulgated version of NR 149: " A change in ownership that involves the purchase or lease of equipment and where less than 60% of the analytical staff are retained shall be treated as an initial application under subs...."**

NR 149.14 (5) " *In sub. (5), can the department provide criteria it will use to determine whether a laboratory is eligible to transfer their certifications or registrations?*

Department Response: **The final rule clarifies eligibility as it exists in the current promulgated version of NR 149: " A change in ownership that involves the purchase or lease of equipment and where less than 60% of the analytical staff are retained shall be treated as an initial application under subs...."**

In sub. (7) (b) 2., either "during the evaluation" or "in the application" should be inserted before the period.

Department Response: **This change has been made.**

NR 149.14 (7)(c) *The material in sub. (7) (c) should be clarified; is the intent not to require on-site evaluations?*

Department Response: **The language has been changed to provide clarification that this section allows the Department to offer partial certification or registration for those tests that are unaffected by deficiencies identified during on-site evaluations.**

11. Comments received relating to Subchapter IV- Certification and Registration Process, s. NR 149.15 - Period, renewal and expiration of certification or registration.

In s. NR 149.15 (2) (intro.), "to" should be deleted.

Department Response: **This change has been made.**

In sub. 149.15 (3) (a), (b), "expire" is an awkward word choice.

Department Response: **The word "expire" has been replaced by "void" in the final rule.**

12. Comments received relating to Subchapter IV - Certification and Registration Process, s. NR 149.18 - Subcontracting of analyses by certified or registered laboratories

In s. NR 149.18 (3), the phrase "shall be responsible for maintaining" should be replaced by the phrase "shall maintain."

Department Response: **This change has been made.**

13. Comments received relating to Subchapter IV - Certification and Registration Process, s. NR 149.19 - Requirements for certification in the drinking water matrix.

The note following s. NR 149.19 (6) provides that the analyses reference in sub. (6) need not be performed by a registered laboratory. Given that sub. (6) makes the same statement with respect to a certified laboratory, and since the note is a substantive statement, the content of the note should be incorporated into the body of the rule. This comment applies to a number of the other notes contained in the rule.

Department Response: **The note has been deleted for the final rule, and the analyses listed in 149.19 (6) have been clarified to link them to their exemption in federal rules.**

14. Comments received relating to Subchapter IV- Certification and Registration Process, s. NR 149.21 - Fees.

In s. NR 149.21 (1) (c) 2. (intro.) , period should be added at the ends of the sentences.

In s. NR 149.21 (1) (c) 4., period should be added at the ends of the sentences.

Department Response: **This change has been made.**

In s. NR 149.21 (7) (a) (intro.), it appears that “may not be subject to a minimum fee” should be added before the colon.

In s. NR 149.21 (7) (b) (intro.), it appears that “may not be subject to a minimum fee” should be added before the colon.

Department Response: **As a result of other changes which must be made to this section, the minimum fee has been eliminated, rendering these comments moot.**

In s. NR 149.21 (11), the rule should specify, through a cross-reference, which types of fees are not refundable.

Department Response: **In the final rule, this has been clarified.**

15. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.22 - Required analyses of proficiency testing samples.

Section NR 149.22 (2) provides that the department must publish a list of required proficiency testing samples and approved proficiency testing sample providers annually. The rule should describe, in a note, how this list may be obtained.

Department Response: **A note indicating where the information may be obtained has been added.**

16. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.23 - Approval of proficiency testing sample providers.

NR 149.23 (1) [As with s. NR 149.07 (1)]... the second sentence states that the department must have procedures for evaluating the eligibility of a laboratory for transferring its certifications and registrations by application. This rule is the place for these procedures. At the very least, the rule should indicate whether the procedures now exist and how they may be obtained.

Department Response: **In the final rule, references to establishing procedures for approval of PT providers have been deleted.**

17. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.27 - Acceptance criteria and grading.

Section NR 149.27 (2) (b) states in part that “the department may develop limits.” Presumably, these limits refer to the term “acceptance limits” as used in par. (a) and as defined in s. NR 149.03 (1). The defined term should be used throughout the rule, including those places where the term “acceptance criteria” is used, unless the term “acceptance criteria” does not have the same meaning as the term “acceptance limits.” [See for example the use of both terms in s. 149.27 (2) (c).]

Department Response: **Consistent terms have been incorporated throughout the final rule. The recognized term for proficiency testing is “acceptance limits”. Other terms have been used wherever possible to clarify the specific requirement in question.**

18. Comments received relating to Subchapter VI- On-Site Laboratory Evaluations, s. NR 149.30 - Evaluation procedures and appraisal.

Section 149.30 (2) refers to forms provided by the department. The department should ensure that the requirements of s. 227.14 (3), Stats., are met.

Department Response: **s. 227.14 (3), Stats. does not apply here, as the referenced form is actually a strictly voluntary survey form used by the Laboratory Certification to obtain feedback regarding the quality of the on-site evaluation process. The language of the rule has been changed to reflect that the form is voluntary.**

19. Comments received relating to Subchapter VI- On-Site Laboratory Evaluations, s. NR 149.31 - Evaluation reports.

In s. NR 149.31 (2), the second sentence should conclude with the word “delay.” A third sentence should state: “The notice shall include an expected delivery date for the report.”

Department Response: **The suggested change has been made.**

20. Comments received relating to Subchapter VI- On-Site Laboratory Evaluations, s. NR 149.32 - Evaluation corrective action.

**Summary of Comments and Response to the
Legislative Council Rules Clearinghouse Report**

page 7 of 8

In s. NR 149.32 (3) (b) (intro.), the phrase “for a second submittal” should be replaced by “for a second corrective action plan to be submitted.”

Department Response: **The suggested change has been made.**

In s. NR 149.32 (3) (b) 3., “on-site” should be inserted before “evaluation.”

Department Response: **The suggested change has been made.**

**21. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.36 –
Laboratory Personnel.**

In s. NR 149.36 (3) 1. and 2., the first instance of “that” should be replaced with “who.”

Department Response: **The suggested change has been made.**

Section NR 149.36 (3) (d) refers to “protocols contained in methods specified by the department.” Is it clear where these protocols may be obtained? If not, a note to the rule should describe the process.

Department Response: **The entire subsection has been revised to clarify the requirements.**

In s. NR 149.36 sub. (3) (f), the first instance of “that” should be replaced with “who.”

Department Response: **The suggested change has been made.**

**22. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.39 –
Records and documents.**

In s. NR 149.39 (2) (b), “under s. NR 149.08” should be added after the comma.

Department Response: **The suggested change has been made.**

In NR 149.39 (2) (f), the rule should identify the source of the “Manual for the Certification of Laboratories Analyzing Drinking Water.”

Department Response: **The suggested change has been made.**

In s. NR 149.39 (3) (c) 13., the note contains substantive material which should be placed in the text of the rule. In addition, the statutory or administrative code citation for this exemption should be provided.

Department Response: **To address this change, the note has been removed and the text of the rule clarifies the requirements.**

**23. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.40 –
Standard operating procedures.**

In s. NR 149.40 (2) (b), “s. NR 149.40” should be replaced with “this section.”

Department Response: **The suggested change has been made.**

**24. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.42 –
Alternative methods.**

In s. NR 149.42 (1-3), it appears that the rule allows a laboratory to use alternative methods if they are approved by EPA without first requesting approval to use these methods from the department; however, both subs. (2) and (3) require a laboratory to request approval first. The department should clarify its intent in these subsections.

Department Response: **In the final rule, this subsection has been revised to clarify Program intent.**

**25. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.44 –
Laboratory equipment.**

Section NR 149.44 (3) (b) refers to “department regulations” where can these be found?

Department Response: **The words “regulations” have been replaced with the word “guidance”**

In s. NR 149.44 (6) (c), the use of the words “and” and “or” following subs. 1. and 2. is confusing and further emphasizes the need to express clearly in the introduction how following subunits are meant to apply.

Department Response: **This paragraph has been re-written and condensed for simplification and ease of interpretation.**

Section NR 149.44 (6) (f) 3. should be incorporated into the material in sub. (6) (f) 2.

Department Response: **This paragraph has been re-written and condensed for simplification and ease of interpretation.**

**26. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.45 –
Measurement traceability.**

In s. NR 149.45 (1), the word “should” should be replaced by the word “shall.”

Department Response: **The suggested change has been made.**

**27. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.46 –
Handling of Samples.**

In s. NR 149.46 (3) (b) (intro.), “This” should be changed to “The sample acceptance policy.”

Department Response: **This section has been re-written to address other comments received.**

**Summary of Comments and Response to the
Legislative Council Rules Clearinghouse Report**

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In s. NR 149.46 (3) (c), “can” should be changed to “are.”

Department Response: **This section has been revised to eliminate references to the timeliness of sample preservation, so the comment is moot.**

**28. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.48 –
Quality control requirements for chemical testing.**

NR 149.48 (4)(e) In s. NR 149.48 (4) (e), it appears that the phrase “at this frequency” should be replaced by the phrase “at the frequency described in par. (a).”

Department Response: **The suggested change has been made.**

Fiscal Estimate — 2007 Session

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected <input type="checkbox"/> Supplemental	LRB Number Bill Number	Amendment Number if Applicable Administrative Rule Number NR 149
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Subject
 Revision of Ch. NR 149, Wisconsin Administrative Code

Fiscal Effect

State: No State Fiscal Effect
 Indeterminate

Check columns below only if bill makes a direct appropriation or affects a sum sufficient appropriation.

- | | |
|--|---|
| <input type="checkbox"/> Increase Existing Appropriation | <input type="checkbox"/> Increase Existing Revenues |
| <input type="checkbox"/> Decrease Existing Appropriation | <input type="checkbox"/> Decrease Existing Revenues |
| <input type="checkbox"/> Create New Appropriation | |

Increase Costs — May be possible to absorb within agency's budget.

Yes No

Decrease Costs

Local: No Local Government Costs

Indeterminate

1. Increase Costs
 Permissive Mandatory
2. Decrease Costs
 Permissive Mandatory

3. Increase Revenues
 Permissive Mandatory
4. Decrease Revenues
 Permissive Mandatory

5. Types of Local Governmental Units Affected:

- Towns Villages Cities
 Counties Others
 School Districts WTCS Districts

Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

Affected Chapter 20 Appropriations

20.370 3(fj)

Assumptions Used in Arriving at Fiscal Estimate

Fiscal Estimate:

There will be no state fiscal impact of this rule revision. The Laboratory Certification and Registration Program is 100% fee funded, and staff time to do the revision has been an additional assignment rather than replacing any responsibilities.

To determine the potential fiscal impact on local government laboratories, the proposed rule was reviewed and items where associated cost could be quantified were identified. Nine local government laboratories from various geographic locations, with differing analytical capability and certification and registration needs, completed two exercises to assess potential fiscal impact: the proposed scope of certification or registration implementing the new structure; and a survey of laboratory practices using some of those elements identified with associated costs. Based on the laboratories' survey responses, the impact of the majority of the changes in the rule will not have a significant financial impact on local governments.

In the interest of providing further details on local government costs, the following information is a listing of items in the rule which do have a potential fiscal impact to local governments:

Certification and Registration Process

The authorized spending authority for the Laboratory Certification and Registration Program is established annually by the Department of Administration. The proposed fee structure remains based on the concept of relative value units. As a result of the modified certification structure, the total number of relative value units will increase; subsequently the cost per relative value unit will decrease. For local government laboratories, the relative value units charged is likely to remain the same as currently assessed. Subsequently, annual certification or registration fees are likely to decrease for local government laboratories.

Long-Range Fiscal Implications

None

Prepared By:	Telephone No.	Agency
Joe Polasek	266-2794	Department of Natural Resources
Authorized Signature	Telephone No.	Date (mm/dd/ccyy)
	266-2794	

Fiscal Estimate — 2007 Session

Page 2 Assumptions Narrative Continued

LRB Number	Amendment Number if Applicable
Bill Number	Administrative Rule Number

Assumptions Used in Arriving at Fiscal Estimate – Continued

Proficiency Testing

The proposed rule will require submittal of proficiency testing sample results for all analytes, by technique, under a laboratory's scope of certification or registration. For most local government laboratories, the additional analytes are already included in the samples they purchase each year for renewal of their certification or registration, so there is likely to be no increased cost for purchases. Some analytical techniques have been exempted from proficiency testing requirements. The proposal will result in cost-savings for a few local government laboratories that maintain certification or registration for these techniques. At this time, the requirement for proficiency testing for the solids matrix is anticipated to be waived as these samples are not yet readily available. Very few local government laboratories analyze solids currently, so any fiscal impact would be negligible when these proficiency testing samples for solids become available.

Record Retention

In response to public comments received, the final rule reverts to the current three-year record retention time. It is noteworthy that, based on experience, most local government units already maintain records in excess of the retention requirements. Inclusion of electronic options will likely reduce the storage space necessary for record retention.

Standard Operating Procedure Requirements

Standard operating procedure requirements are new, however provisions may allow a laboratory to reference an unchanged method or identify specific changes to a method to fulfill the requirement. Many local government laboratories reference unchanged methods or make minor revisions so the impact is anticipated to be minimal. Only if laboratories develop standard operating procedures for methods that vary substantially from published methods will they be required to implement an analytical methods manual. In some laboratories, there will be an initial increase in effort to meet the documentation requirements. It is not anticipated that there will be a significant cost, as the program will supply materials and training.

Initial Calibration

Performing a verification of initial calibration with a second source material, a new concept, may require laboratories to purchase additional standard materials, but exemptions for techniques routinely utilized in local government laboratories reduce the impact. Further, laboratories that perform a second source initial calibration verification are exempt from analyzing external quality control samples three times annually. Laboratories may continue to analyze the quality control samples three times per year, or they can opt to analyze a second source standard to verify initial calibrations. If laboratories choose to use second source standards to verify initial calibrations, they will see a significant cost savings in terms of the cost of the quality control standards and the time and labor involved in analysis. Method blank acceptance criteria has also been expanded, which may reduce the number of samples required to be reanalyzed, resulting in a cost savings.

The overall costs for maintaining a laboratory's quality system will be driven by the selection of the options offered in this proposed rule. Local government laboratories are most likely to experience a reduction in these costs if they choose to modify current practices.

Fiscal Estimate Worksheet — 2007 Session
 Detailed Estimate of Annual Fiscal Effect

Original Updated
 Corrected Supplemental

LRB Number	Amendment Number if Applicable
Bill Number	Administrative Rule Number NR 149

Subject
 Revision of Ch. NR 149, Wisconsin Administrative Code

One-time Costs or Revenue Impacts for State and/or Local Government (do not include in annualized fiscal effect):

Annualized Costs:		Annualized Fiscal Impact on State Funds from:	
		Increased Costs	Decreased Costs
A. State Costs by Category			
State Operations — Salaries and Fringes		\$ 0	\$ - 0
(FTE Position Changes)		(0.00 FTE)	(- 0.00 FTE)
State Operations — Other Costs		0	- 0
Local Assistance		0	- 0
Aids to Individuals or Organizations		0	- 0
Total State Costs by Category		\$ 0	\$ - 0
B. State Costs by Source of Funds		Increased Costs	Decreased Costs
GPR		\$ 0	\$ - 0
FED		0	- 0
PRO/PRS		0	- 0
SEG/SEG-S		0	- 0
State Revenues	Complete this only when proposal will increase or decrease state revenues (e.g., tax increase, decrease in license fee, etc.)	Increased Revenue	Decreased Revenue
GPR Taxes		\$	\$ -
GPR Earned			-
FED			-
PRO/PRS			-
SEG/SEG-S			-
Total State Revenues		\$	\$ -

Net Annualized Fiscal Impact

	<u>State</u>	<u>Local</u>
Net Change in Costs	\$ _____	\$ _____
Net Change in Revenues	\$ _____	\$ _____

Prepared By: Joe Polasek	Telephone No. 266-2794	Agency Department of Natural Resources
Authorized Signature	Telephone No. 266-2794	Date (mm/dd/ccyy)

Summary of and Response to Public Hearing Comments

Public comments were received from the following:

ID	Facility (comment type)	Commenter
	Blanchardville Water Treatment Plant-	
1	verbal	Joe Flanagan
2	Brookfield-Fox River WPC-written	Rick Wenzel
3	Campbellsport WWTP-verbal	Bill Schill
4	Cedarburg WWTP-written	Ron Clish
5	CT Labs-verbal	Dan Elwood
6	Davy Labs-written	Paul Harris
7	Eagle Lake Sewer Utility District #1-written	James T. Bergles
8	Eau Claire City-Co. Health -verbal	Darryl Farmer
9	Edgerton, City of-written	Randall J. Oren
10A	Elroy Water and Wastewater -written	Bill Collins
10B	Elroy Water and Wastewater -verbal	Bill Collins
11	Fontana-Walworth WPC-written	Marilyn West
12A	Fort Atkinson WWTP -written #1	Paul Christensen
12A1	Fort Atkinson WWTP -verbal #1	Paul Christensen
12B	Fort Atkinson WWTP -written #2	Kurt Burkett
12B1	Fort Atkinson WWTP -verbal #2	Kurt Burkett
13	Fredonia WWTP-written	Gary Buntrock
14	Green Bay MSD-written	Debra A. Cawley
		Alfred Fochs, Charles Fochs, Kenneth Boville , Dennis DuPrey
15	Hilbert, Village of -written	DuPrey
16	Independent Consultant-verbal	Kay Marshall
17A	Jackson, Village of -written	Jeff L. Deitsch
17B	Jackson, Village of - verbal	Jeff L. Deitsch
18	Janesville Wastewater Utility -written	Marc Zimmerman, Brian Skaife
19A	Kewaskum, Village of -written	Robert Manthei
19B	Kewaskum, Village of -verbal	Robert Manthei
20	Kiel Wastewater Treatment Facility -written	Michael Geurts
21	Lake Tomahawk Sanitary District-written	Josh Thyne
22	Legislative Council-written	
23	Lodi Public Works -verbal	Randy Herwig
24	Manitowoc WWTF-written	Eric Storm
25	Marshfield Wastewater Utility -verbal	Ron Dickrell
	Municipal Environment Group (MEG)-	
26A	written	Paul Kent
	Municipal Environment Group (MEG)--	
26B	verbal	Paul Kent
27	Merrill Water & Sewage Utility -written	Patrick Geisendorfer
28A	Milwaukee MSD -written	Sharon K. Mertens
28B	Milwaukee MSD -verbal	Sharon K. Mertens
29	Modine Manufacturing -verbal	Jim Kinscher
30	Monroe WWTP -written	James Sinkule
31	Municipalities -multiple (petition)	
32	New Holstein WWTP -written	Donald J. Lintner
33	Northern Lake Service -written	R.T. Krueger
34	OMS Laboratory -written	Bruce Neerhof
35	Orfordville WWTP-written	Jerry Amundson
36A	Plover Wastewater System -written	Rich Boden
36B	Plover Wastewater System -verbal	Rich Boden
37	Port Washington Wastewater Lab -written	Bob Demge
38	Rice Lake Utilities -verbal	Wally Thom
39A	S-F Analytical Labs-written	David Kliber

39B	S-F Analytical Labs-verbal	Jim Thomas
40	Sun Prairie WPCF -written	John Krug
41	Superior Public Works-written	Maxwell Lucci
42	TestAmerica Labs-written	Paul Junio
43	Thilmany LLC -written	Thomas G. Jayne
44	Waterloo WWTP-written	Dennis Hotmar
45A	Watertown WWTP-written	Judy Tholen
45B	Watertown WWTP-verbal	Judy Tholen
46A	Waukesha WWTP-written	Randy Thater
46B	Waukesha WWTP-verbal	Randy Thater
47	WI Rural Water Association	Chris Groh
48	Winneconne, Village of –verbal	Carrol Vizechy
49A	Wolf Treatment Plant-written	David Hartmann
49B	Wolf Treatment Plant-verbal	David Hartmann
50A	Wisconsin State Lab of Hygiene-written#1	George Bowman
50B	Wisconsin State Lab of Hygiene-written#2	George Bowman
50C	Wisconsin State Lab of Hygiene-written#3	Susan Hill
50D	Wisconsin State Lab of Hygiene-written#4	Steve Geis

1. Comments related to concerns about the revision process.

A. Advisory Committee Composition. One comment was received regarding the composition of the Rules Advisory Committee (RAC).

23 " By using a facilitator for the process of developing the rule, the idea of "substantial agreement" was used to promote forward movement to eliminate stagnation of any progress during the RAC meetings. The problem lies with the very concept of "substantial agreement". As a representative of the largest majority of constituents affected by the rule, my "vote" regarding "Substantial Agreement" counted the same as some other person representing the fewest constituents. This concept seems far from fair to both my constituents and to the Department, when you are trying to create a new or revised Rule. It would be my hope that in the future the Department establishes a Revision Advisory Committee that better reflects the number of constituents represented, rather than having a committee consisting of one person per constituency. By choosing to do so, acceptance of the revised rule may be more greatly realized. "

Department Response: **In future rule revisions, the process used to develop an advisory committee will be re-evaluated.**

B. Concerns about the fiscal estimate. Twelve (12) comments that were received expressed concern that the fiscal estimate prepared with the rule package did not adequately address the cost of compliance with the proposed revisions. In addition, several of these commenters felt that a survey, used to generate the fiscal analysis, was inappropriate. The survey was completed by a statistically insignificant group of affected businesses, and these respondents did not accurately reflect the makeup of labs certified or registered under the existing program.

10A " For small wastewater plants the proposed revisions to the lab certification rule has the potential to significantly increase the costs and burdens to the operators. ... I believe that the added paperwork and time it takes to meet the new code changes are not warranted because it will not do anything to improve our lab results it will just add time to the process of getting there. "

- 10B " And the other thing is, we've only got so much money. And I think that, when you look at the percentage of the budget that the laboratory requires, and it's a necessary part of the wastewater plant, what I see happening in a lot of small communities is the wastewater lab is being done away with. ... So this is getting to be a real problem, I think, as far as budgets go. It's already a problem in a lot of communities. You've got wastewater plants that are sitting in tough shape. "
- 16 " ...we feel that this, these changes are going to add to the financial burden of the small wastewater laboratories and eventually force them into sending their samples out, instead of doing their own testing. It's going to take more time to do the testing, and they don't want to forfeit the right to have their own laboratories. The survey that was sent out, I spoke to some of the people that got the original survey, and they also expressed concerns that the questions were confusing. That's one of the reasons that they did not fill them out, did not answer them. "
- 23 " The Fiscal Estimate states; "To determine the fiscal impact on local government laboratories, the proposed rule was reviewed and items where associated cost could be quantified were identified". 9 local government labs were surveyed according to the fiscal impact. The responses gathered from the 9 governmental labs indicate "the impact of the majority of the changes in the rule will not have a significant impact on local governments". What this fiscal survey doesn't tell is, 7 of 9 Governmental Labs surveyed are designed to treat from 2.8 MGD to 50 MGD [million gallons per day]. One would assume that the extra documentation, testing, and record keeping would be relatively easy to absorb in a facility of this size. The remaining two Governmental Labs are within 65 miles of the Wisconsin/Illinois border. This would leave geographically 3/4 of the Governmental Labs under 1 MGD un-surveyed. Additionally the majority of the wastewater labs in the state of Wisconsin are designed to treat <1 MGD, yet over 75% of the plants surveyed were well over this design size. I'm concerned about the validity of the fiscal impact statement as it is written, and would challenge the Department to survey Governmental Labs from the Northern 1/2 of the State regarding the Fiscal impact this would have on them. "
- " The only analysis of the impact of the rule on municipalities was in the accompanying fiscal estimate submitted to the Natural Resources Board. This document stated:
- ' Based on the survey responses provided by the laboratories, the impact of the majority of the changes in the rule will not have a significant financial impact on local governments. '
- 26A As a result of a public records request, MEG discovered that this remarkable statement was based on a survey of nine municipal laboratories, only six of which appear to be municipal wastewater labs. There are two fundamental problems with this survey. First, the NELAC TAC [National Environmental Laboratory Accreditation Conference Technical Advisory Committee] reported that there were approximately 300 municipal labs in Wisconsin. A sample size of six labs is hardly a representative sample from which to draw a conclusion. Second, the survey itself did not ask a single direct question on the cost impacts from the rule, other than fees. The survey contains nine pages of detailed questions about the rule and current lab practices, but the impact of the rule on costs is not asked. "
- 26B " It's not that municipalities aren't willing to spend money and go to their residents in increased costs when there is some water quality reason to do so. But when the reason that's put out to do so is getting better data, that doesn't seem to match up with the kinds of costs that we're looking at, particularly when we've seen nothing presented to date indicating that there are problems with labs, resulting in compliance issues, problems with labs, resulting in water quality issues. So, you know, it's one thing to ask these communities to spend significant additional money. It's another thing to ask them to spend it, when there's really no purpose for doing so. So I think that's an important issue, and one of the reasons why many of our members are as concerned about this. "
- 27 " The City of Merrill Water and Sewer Utility is opposed to the proposed revision of NR 149. There are a number of reasons for this opposition.
1. Costs: Additional cost/year = \$25,820.
 - A. At the City of Merrill Wastewater plant the manpower required to perform the increased testing would be approximately 60 hours/month. 60 hours/month x 12 months/year x \$20.00/hour = \$14,400.00.
 - B. Additional paperwork would be approximately 8 hours/month.
 - C. 8 hrs/month x 12 months/year x \$20.00/hour = \$1,920.00.
 - D. Additional chemical and equipment costs could amount to an additional \$9,500.00.
 3. Other.

Would require us to purchase a second refrigerator. Would require additional facility storage space for

records. "

32 " The current regulations are more than sufficient to be certain that correct data is being generated. Additional requirements are an unnecessary burden on wastewater plants. Plants with limited manpower/funds will be especially hard pressed to comply with these rules and still be able to keep up with other treatment obligations that are necessary for compliance with permit language. "

45B " We feel that the amount of increased paperwork, QC, all that sort of stuff, is going to increase the cost to the smaller labs. And they, in turn, will contract out all their lab work. "

46A " As one of the laboratories that completed the 'NR 149 Revision Impact Assessment' survey, we feel this survey was constructed and interpreted in a fashion that does not reflect the amount of time, money and effort that will be needed to implement the proposed rule revision. And as a member of the advisory committee, I know that the municipal wastewater community, which makes up the majority of the affect [sic] laboratories, was woefully underrepresented. In my opinion, the concerns of this group were not given due consideration in the rule making effort. "

46B " There remains some problems that need to be fixed, and this revision was intended to address those. Instead, it became this effort, which, instead of just fixing it, totally recreated the rule. The likely result is that the certified registered laboratories will have to totally reassess and potentially will have to reconstruct their own laboratory programs. This could be done at a great cost to the public, since the majority of the affected laboratories are either publicly owned or commercial facilities that derive a large portion of their business serving public entities. "

49B " Another point that does not appear to be considered for smaller registered labs is the cost of materials, training, and labor. These increases can be addressed much easier by commercial or certified labs. They can change their fee structure for the customers to eliminate any extra costs incurred by the changes to the code. But in smaller municipal settings, it's not that easily accomplished. In most cases, it will require a budgetary adjustment, and the costs will eventually be pushed onto the constituents of that community. And we all know how well that goes over. We do not do this for profit. We do this to ensure a quality discharge that will improve the status of the receiving body of water. "

Department Response: The fiscal estimate was prepared in accordance with WDNR procedures, met all requirements for an initial rulemaking proposal, and was approved by agency staff. Specific requirements, with known associated costs, were attempted to be quantified. The rule was revised to change or eliminate many items that the regulated community felt were burdensome.

C. Increased Program Operating Costs. One commenter believed that that the Laboratory Certification Program operating expenses would be increased, although the fiscal estimate, as prepared, suggests that no change in program operating costs is expected.

50A " I am concerned that the proposed rules will increase the operating expenses of the Laboratory Certification program. The proposed rules require annual applications and increased proficiency testing requirements. It is my understanding from the fiscal estimate worksheet that the rule change would not result in an increase in cost or staffing. However, I cannot see how these added tasks can be assimilated without either adding staff or automating the processes. "

Department Response: Program staff recently completed a system which allows PT providers to directly upload PT sample results. A second set of programs would then upload that data into our database, eliminating the need for staff time devoted to PT entry. Other changes have been made to the proposed rule to ensure that no additional staff time is required to meet the provisions of the final rule.

2. General comments related to concerns about the proposed revision

A. Fee Equity. Three (3) commenters expressed concern about the lack of information regarding how the proposed revision would impact annual certification/registration fees. All commenters agreed that the revised NR 149 should be structured such that fee equity between laboratory types is adequately addressed.

34 " I would hope the DNR Laboratory fees would be better distributed between large and small labs. Fees should be based on Laboratory volume of work performed, not just by test categories performed. A DNR auditor can spend a week at a large lab vs. only a few hours at a small lab and the fees are not significantly different. The current system only encourages small labs to go out of business. "

39A " As you make changes in NR 149, I caution you and your associates to be careful to balance QC requirements with the need for the private sector to be profitable and for the public/municipal sector to be efficient with our taxpayers' budgets. Every QC run costs money and must be accounted for in the cost of each sale price "

50A " The first paragraph of the background memo and the rule analysis states that the proposed rule "establish a more equitable fee schedule". The background memo also states the proposal includes "Equitable fee schedules for laboratories based on the complexity of the analyses they perform." However, the fee schedule is not discussed and the estimated total annual fee for the average wastewater, commercial, or industrial laboratory is not given in the background memo. I believe this information would be very useful for laboratories to assess the fiscal impact of the new rules. "

Department Response: **The program has incorporated flexibility into the program structure, allowing any laboratory to select options where it can reduce costs when compared to current requirements. In the final rule, adjustments to the fee schedule have been made to further ensure fee equity. The final rule also considers the "cost-to-benefit ratio" of all new requirements.**

B. Exemption for WWTP labs. Eight (8) commenters suggested that wastewater treatment plant laboratories should be exempted from the detailed new requirements.

9, 17A, 19A, 21, 31 " Data submitted under the current NR149 rule provides excellent data quality. If NR 149 is to be revised, wastewater treatment laboratories reporting data to the DNR should be exempted from any of the new revisions. Wastewater treatment laboratories not reporting data to entities outside the state should not have to follow guidelines from a national standard. "

10A " Adding unnecessary paperwork to small plants is not a good idea. My suggestion would be to exempt plants under a certain size. Whether it is by the size of the community, or the complexity of the plant, you need to seriously consider the end result of this code revision. "

36A " The proposed revisions to NR 149 impose a one size fits all approach to all laboratories from large commercial laboratories to small laboratories whose analyst has responsibilities that range beyond the laboratory. It is unreasonable to treat small wastewater laboratories doing in-house compliance testing on a few samples per day, or week, the same as large commercial laboratories accepting hundreds of samples per day.

Managers of laboratories are best able to provide appropriate training necessary for an analyst to produce valid data. If the initial determination of capability were to provide an exemption from performing quality assurance testing, it might be worth pursuing. As it does not, the initial determination of capability becomes a very expensive exercise that does not directly provide higher confidence levels in data generated. "

37 " I favor exempting requirements as shown in the Power Point document presented ...March 9, 2006. "

Department Response: **All laboratories, regardless of type, are required to generate data of a quality that meets Department Program needs. Revisions to NR 149 only incorporate those changes that are deemed necessary to achieve this goal. In a number of instances, specific changes have been made which will effectively exempt laboratories performing limited testing from certain requirements. These changes were made wherever it is believed that such a change could be made without compromising data quality.**

C. Code Length/Readability Specific Comments

- o **Code language is unclear and confusing.** Three (3) comments were received that felt that the language used in the proposed revisions is unclear or confusing to the layperson.

16 " The code itself, to most of these small registered wastewater labs, is confusing. I've been slowly getting some of my questions answered. Talking to Alfredo, he said that they will make adjustments, and do training and things for the small laboratories. But it's my understanding that, once it is in code, that it can be enforceable. So that is a concern to us. Even though there may be exemptions or adjustments for small lab, it is in code, and that's black and white, if somebody wanted to enforce it. "

44 " The revisions are unclear as to what changes apply to our plant. I would like to see them in plain English. "

" The rules tend to be overly verbose and not very clearly written. For example, NR149.03(47) the term "Matrix spike" has so many exceptions that it is not clear. It should be written in clear and concise terms. This same theme is repeated throughout the code.

50A There are numerous other instances where the code could be simplified. Another example is NR149.38 (1) and (2). These two sections could be condensed down to a few sentences to make them clear and concise. NR149.38(1) and (2) could be simplified as follows: The laboratory shall take corrective action if quality control criteria are exceeded. The corrective action shall identify the source of the problem, correct the problem and have a mechanism to verify the action has had the desired effect. "

Department Response: **Changes were made in the final rule to clarify requirements and improve the readability.**

- o **Increased volume of the proposed code text.** Two (2) commenters expressed concern over the degree to which the revised NR 149 has increased in size.

26B " this was also touched on by some prior speakers, is that, while the rule has gone from 14 pages to some, you know, with appendices, over 100 pages or nearly 100 pages, what we have in this rule is a significant increase in the amount of discretion given to the Department. And I think that there is an increasing distinction between what the Department claims the rules say or what they're going to, how they're going to be interpreted, and what the rules actually say. "

36B " The original code was 14 pages long, and while it is in need of being updated, the proposed regulation, proposed NR 149, is now 55 pages long. And I'm always skeptical of any type of code or regulation that quadruples in size. "

Department Response: **The present list of available certifications comprises approximately 1-1/2 pages. The draft includes 2 appendices of analytes, 46 pages total; subchapters I-V will be reduced by approximately one-half, when formatted as administrative code. The Rules Advisory Committee sought specificity where current language is vague. The Department believes that the merits of clearly identifying program requirements outweigh the length of the rule.**

D. Proposed revisions mirror NELAC standards. Eight (8) Comments were received that voiced opposition because of the belief that the proposed revisions were heavily influenced by the National Environmental Laboratory Accreditation Conference (NELAC) standards. Consensus among the comments was that these national standards are more appropriate for laboratories that are testing samples all across the nation. The Wisconsin Laboratory Certification & Registration Program is comprised predominantly of municipal wastewater treatment plant laboratories that test only their own compliance and process control samples. Commenters felt that data produced under the current NR 149 requirements is comparable to that generated under NELAC standards without the additional cost or workload.

17A, 19A, 31 " After review, I would like to register my opposition to the proposed rule. I feel that the rule, if approved as written, will affect my plant adversely. I feel that the rule, as proposed, is better suited for commercial laboratories, and that proposing rules using a national guidelines (read NELAC) is very inappropriate for small wastewater laboratories that perform analyses for process control and reporting to DNR. Data submitted under the current NR 149 rule provides excellent data quality. "

" There is little dispute that the Department's NR 149 revision is an attempt to incorporate many of the NELAC provisions that it was not able to obtain in 2000. ... Apart from failing to acknowledge the substantial opposition to NELAC by the municipal component of the "regulated communities," the DNR also fails to acknowledge the NELAC process followed an extensive advisory committee study process that resulted in a 19-page advisory committee report. ... Among the findings of that report were the following:

26A o There are 295 small municipal labs in Wisconsin (225 registered and 70 certified), and they are by far the dominant laboratory type in the state. ...
 o All laboratories required to comply with NELAC standards will incur increased internal costs...
 o The 295 small municipal laboratories in Wisconsin would probably incur significant costs and receive few benefits from NELAC. ...
 o The quality of data produced under NELAC as compared to data produced under NR 149 is similar. "

46A " I want to point out a statement in the summary section that, while technically true, may lead to a false perception due to incomplete information. In item 7 –Comparison with Rules in Adjacent States, it states that 'Illinois is a recognized NELAP accrediting authority and its rules agree or are stricter than those the department proposes for ch. NR 149.' What it fails to mention is that the Illinois program is much more limited in scope than the Wisconsin program. The Illinois program offers accreditation for drinking water, wastewater and hazardous waste. But it is only mandatory for drinking water compliance testing. Accreditation for wastewater and hazardous waste testing is voluntary. Municipal and industrial wastewater plants are the largest component in the Wisconsin program, and laboratories serving them are required to be registered or certified. "

46B " I want to point out one thing in the summary section, in the comparison with rules to adjacent states that is used to help justify this, it states that Illinois is a recognized NELAP-accrediting authority and its rules agree or are stricter than those the Department proposes for chapter NR 149. What this statement in this section fails to mention is that the Illinois program is much more limited in scope than the Wisconsin program, both as currently and the new rule would be. The Illinois program offers accreditation for drinking water, wastewater, and hazardous waste, but is only mandatory for drinking water compliance testing. Hence, the Wisconsin program, even now, covers a much wider range. I've personally visited Illinois laboratories and know that they do nowhere near the quality control testing that we currently do, even under the current program. So I think it's important to keep that in mind, when they assess this statement. "

47 " We see this revision as a pretty close mirror to the NELAP, which is a national standards, national environmental standards, put out for larger commercial laboratories that are more staffed than small municipal wastewater treatment labs. "

49B " We feel we have two very distinct groups of labs represented in NR 149. The guidelines that are proposed to facilitate inspections in Wisconsin by auditors from different states with a level of standardization are most likely needed. But to those of us that have no contact with any samples outside our own system, the current proposal, in its entirety, does not make complete sense. Why are the municipal labs being forced to adhere to guidelines that are being put in place for auditing, when we will never see out-of-state auditors that these standardized rules are being created for? "

Department Response: **The Laboratory Certification and Registration program rules (ch. NR 149) have not been updated in 10 years. Since the last revision, efforts have been made at the national level and endorsed by the USEPA to develop nationwide standards governing environmental testing. This effort, known as "the NELAC", incorporates a number of industry recognized advances in both technology and the science of environmental testing. Consequently, it would be a mistake for Wisconsin to ignore such advancements. In the final rule, we have carefully evaluated the national standards and incorporated those that we believe will result in significant improvement to data quality while also balancing the cost of implementation by limiting, where possible, the impact on laboratories.**

E. Increased cost of operation will cause WWTP labs to close. Three (3) comments were received expressing concern that the proposed revisions would create such a fiscal burden on municipal laboratories that the municipal facilities would be forced to cease testing and contract out for their testing.

16 " I know there is a push from a lot of the commercial laboratories to end the testing in the small wastewater labs. I don't feel that some of the accusations are correct that these people don't do a good job, because a lot of them do. "

47 " We also feel that this rule will adversely affect all these wastewater laboratory systems. A great percentage of them will not be able to keep up with these standards. They'll have to quit their testing, they'll lose their process control, and they'll have to depend on commercial testing, which will strap them financially. A lot of these small systems are already financially burdened, so any other burden will have to be passed on to the city constituents. "

49B " Many of the requirements will prove to be an undue burden on smaller wastewater labs. One of the problems that could potentially arise from this update would be a closure of some of the smaller labs, due to budgetary constraints, training, and labor requirements. If they are forced to contract their lab work out to a commercial lab, what becomes of the process control testing? What would they do to ensure that their treatment process is working properly? "

Department Response: **The Department appreciates the value of municipal wastewater laboratories performing their own testing, and the proposed rule changes are designed only to clarify existing requirements and improve the overall quality of environmental testing data. The plan is for a delayed effective date for implementation in order to perform outreach to explain the requirements. In many cases, misinterpretation of requirements led to an assumption that the cost of compliance posed a significant burden. In nearly all cases, laboratories are already in compliance with requirements in the final rule.**

F. Comments regarding reciprocal certification.

6 " We need to evaluate and pursue reciprocity with neighboring states (more of a priority). Currently, Minnesota has an out-of-state audit fee of \$3,750.00 every two years. Under our current or propose revisions, an audit of a Minnesota lab requesting certification in Wisconsin (every three years) may cost \$2,000.00 for an audit. Meanwhile, within that same time frame, we are paying \$5,625.00 for a Minnesota audit. This is exorbitant when compared to our certification audit fees for out-of-state laboratories competing in Wisconsin. This creates unfair competition issues. "

- 6 " Can we obtain partial reciprocity with other states for the SDWA portion of a state program since all state programs must adhere to the same requirements for SDWA certification? We have a separate requirement for SDWA monitoring in our program as well as other states and this would be an opportunity for us to minimize audit time. "

Department Response: **All current reciprocity agreements will be reviewed upon completion of the revision process. As Minnesota recently also changed their rules, we are hoping for the opportunity to execute an agreement with their program.**

The annual fee income that can be collected by the program is established by DOA; we must work within that figure in calculation of annual fees. Other states may have more flexibility in how their fees are determined, but we are limited by statute.

G. Other Comments regarding the Code structure or revision process.

- o **NR 149 needs to be revised more frequently; use a process without a Rules Advisory Committee.**

- 6 " The code needs to be revised at a maximum of once every two years. Additionally, never go back to the RAC concept for code revisions. Completely ineffective and self servicing for most participants. Goal of improving the program is not in the interest of most of the participants. In the future, bring changes to the attention of the Laboratory Certification Review Council and then go directly to public hearing. Try not to change too much. Take "baby steps" to achieve your goals since most of the laboratory regulated community has no science background or training and will resist even adding a period at the end of a sentence. "

Department Response: **The program intends more frequent updates to NR149, as allowed by staffing, laboratory community, and program needs.**

- o **NR 149 should be split into two separate sections, one for commercial labs and the other for wastewater labs.**

- 49A " If the goal, according to the DNR's statement, is to "make it more efficient to administer" and to "identify clear steps and procedures", wouldn't it be advantageous to split the regulation into two similar, yet distinct subclasses. NR149 (a) could apply to Commercial/Certified Labs that perform analysis of samples for outside sources or customers. NR149 (b) would then be applied to registered treatment facilities that perform testing on samples provided from within their own systems. "

Department Response: **NR 149 details requirements necessary to ensure that laboratories are operating in a manner which assures the production of quality defensible data. This applies to all laboratories, so splitting the regulation is not a desired outcome. We have and will continue to clarify those requirements that, by virtue of the limited nature of their testing, do not apply to wastewater facilities. We will also undertake an extensive outreach effort to communicate the changes to all certified and registered laboratories.**

- o **Unfair competition claim.**

- 6 " Public sector laboratories should not be providing services to other communities even if certified. This is unfair competition. Several communities are currently doing this now and it is wrong. "

Department Response: **The Department cannot restrict one segment of the regulated community from providing services if they pay the same fees and are held to the same standard as commercial laboratories.**

H. Request for clarification on quality control requirements.

- " I think we need clarification on what specific QC is required for each method. Will standard methods chapter 1020 still be required for BOD, suspended solids, ammonia, and phosphorus? If not, then I think the revision change concerning this area of QC is a fresh, new way of doing QC that will make dupe [duplicate] spikes and making control charts a part of the past. I think it will save analyst time. It makes sense also, because, if I preserve my ammonias or T-phoses [sic] , and only run them once a month, I'll only have about 12 datasets a year. Then I default to using standard methods 80% to 120% anyway. If so, if chapter 1020 will be required for BOD, [sic] suspense [suspended] solids, ammonia, and phosphorus, then the analyst does not have all the choices that the DNR has been stating since this revision process. We were showed that, if an analyst performed an opening LCS [Laboratory Control Standard] and a closing LCS, he wouldn't need to do duplicate spikes, blinds, or control charts. So I think we need clarification on what specific QC is required for each method. "

Department Response: **These requirements have been clarified in the final rule and will also be communicated through post-promulgation outreach efforts.**

I. Other individual, general comments.

o **Lead accreditation.**

- " And this was five years ago, and it cost us \$4,000 the first year for the certification and \$2,000 a year to maintain that certification. And it seemed rather unnecessary, because NR149 standards were very close to meeting the national accreditation standards.
- 8 And I guess my concern is, is whether or not at least the portion of the NR149 for testing for lead in solids was changed enough so that you could comply with the EPA's national lead laboratory accreditation. Now that is a little different, I know you talked something about, get in with all of these acronyms here, it gets a little confusing. But I think that's a little different than the National Environmental Laboratory Accreditation. There's a very specific criteria for the National Lead Laboratory Accreditation program. And when you look at those criteria, they're very similar to what had existed in NR149. "

Department Response: **Unfortunately, work to obtain recognition with the National Lead Laboratory Accreditation program does not fit within the statutory direction of NR 149. Consequently, this is not an option we could pursue.**

o **Revised Code does not appear to include immunoassay testing.**

- 50A " NR 149.13, NR 149.21, Appendix I, and Appendix II - I cannot find a reference to immunoassay or immunochemistry. "

Department Response: **With the exception of atrazine in drinking water, immunoassay tests are currently recognized as providing only semi-quantitative results suited for field testing. Consequently immunoassay testing is not included at this time. If advances are made in this area, and tests suitable for compliance testing are promulgated, this rule can be revised accordingly.**

o **Inclusion of analytes individually in Appendix I and II.**

" *Appendices I and II: Inclusion of the analytes in appendices in administrative code is problematic for several reasons:*

1. *The analytes available for certification are currently identified in their entirety in the application for certification & registration. The list of test categories in the currently promulgated NR 149 identifies some analytes, some analyte groups, yet for others, such as Category 18 - Drinking Water, there are no analytes identified. The program COULD treat the list of analytes and analyte groups available for certification and registration in a similar manner to that of the approved vendors for annually-required PTs, and publish the list (as the application) upon concurrence of the Laboratory Certification Standards Review Council.*
2. *By identifying each analyte for which it will offer certification or registration in code, the Department will have to undergo a rule revision every time one of the covered programs adds an analyte requiring monitoring, which is likely to result in a 2-year lag time until that particular analyte can be offered up for certification or registration.*
3. *The analytes identified in these appendices are identified elsewhere in administrative code (NR 140, 219, 507, 605, 809, etc) and inclusion in this chapter is redundant.*"

Department Response: **The concern is understood. However, our rules do not allow incorporation by reference in this manner.**

o **Inclusion of Total Residual Chlorine in Appendix I.**

- 50A " *Table 1 and 4 of Appendix I in the proposed NR 149 lists Total Residual Chlorine as an analyte for certification or registration, yet NR 219.06 exempts residual chlorine from certification or registration. This seems unnecessary at this time* "

Department Response: **The program has historically received feedback suggesting that certification/registration for total residual chlorine analysis should be offered. At this time, since requirement for certification to perform this analysis is governed by another chapter, inclusion in NR 149 merely offers an option for laboratories to voluntarily obtain accreditation.**

o **Authoritative method source concern.**

- 6 " *We believe that the lab certification staff (in consulting with the respective DNR program) in certain areas, should take a stance on requiring only one edition of an authoritative source when multiple editions are approved by the federal register. To allow approval of the [Standard Methods] SM 18th edition (1992), the 19th edition (1995), the 20th Edition (1998) and soon now the 21st Edition (2005) for the same method is ridiculous, since there are method changes in each. Labs will always defer to the least stringent requirements in an approved method without regard to the improved science of the revised edition (i.e. BOD). You could specify only one method and one edition because NR 809 has done it with enzymatic test procedures for total coliform when other procedures are approved.* "

Department Response: **Approved methods for testing are driven by those promulgated in 40 CFR Parts 136 and 141. If we restrict editions, it could jeopardize primacy. In addition, some methods do not change from one version of Standard Methods to another-- thus the duplication occurs yet it would not be prudent to disallow one version over another (and require the subsequent investment in new methods manuals) without justification.**

o **Development of a consolidated "methods" code.**

42 " At the onset of the revision process the Department indicated that it was intending to create a "methods code" which would identify all analytes that are regulated by the agency, cross-referenced to analytical technique, method and applicable administrative code. The concept was that this separate code could be easily revised annually - and that the covered programs and RAC had endorsed the concept. Why has the DNR reneged on its commitment to develop and maintain the inherent flexibility necessary for such a complex issue? "

Department Response: **The Department remains committed to the merits of developing a new administrative code for the purpose of consolidating approved methods and target analytes. Such an effort, however, requires agency approval, staff time, and must be accomplished within budgetary constraints.**

3. Comments received relating to Subchapter I- General Provisions, s. NR 149.02
 Applicability.

41 NR 149.02 (7) " In the proposed language, NR 149.02 (7) implies that this chapter does not apply to a laboratory performing bacteriological analysis for a covered program. However, NR 149.02 (7)(a) implies that a laboratory shall be certified to perform bacteriological analysis for a covered program. In an effort to provide clarification from the unintentional contradiction of these two line items, I would propose that the language in NR 149.02 (7)(a) be modified to avoid confusion. I would make the following proposal: add language to NR 149.02 (7)(a) that specifies that for laboratories with bacteriological certification requirements for a covered program, certification (approval) will continue under the stated jurisdictional authority (Department of Agriculture, Trade, and Consumer Protection). "

Department Response: **Changes made to address concerns of the Legislative Council Rules Clearinghouse will address this comment as well.**

43 NR 149.02 (8) "We believe DNR should make a distinction in the QA/QC requirements for large commercial laboratories compared to small registered laboratories such as ours."

Department Response: **Regardless of the size and type of laboratory facility, the Department's data quality needs are the same. Numerous changes are being made from the initial proposal, however, to address the underlying concern.**

4. Comments received relating to Subchapter I- General Provisions, s. NR 149.03-
 Definitions.

50B NR 149.03 " Please add the EPA Office of Water definitions to the rules. These would include (at a minimum): lab fortified blank, lab fortified matrix, quality control sample and instrument performance check. These terms are used exclusively in many EPA methods which are routinely used by most commercial [sic] and public laboratories. They included EPA methods 200.7, 200.8, 200.9 and all of the automated wet chemistry methods used for the analysis of nitrogen and phosphorus. It would be very confusing for both DNR staff and laboratories to interpret how these terms relate to those defined in the proposed code. "

50C NR 149.03 " Regarding the definitions, since the Lab Certification staff will be certifying labs for EPA Office of Water methods, you should include EPA Office of Water definitions in the code (e.g. lab fortified blank, lab fortified matrix, instrument performance check). "

Department Response: **A number of commenters indicated that the Code, as revised, is already lengthy and confusing. Our intent is to define here those items that directly relate to the Wisconsin Laboratory Certification and Registration Program. Since the EPA defines its terms in each individual method, those definitions should be sufficient for a lab to clearly distinguish between method and Program requirements.**

50C NR 149.03 (3) " p.6, NR 149.03, Definitions (3)—“Analysis day” should be defined as the day in which a specific type of analysis is begun. This would take into account analyses that take more than one day to complete. "

Department Response: **The language chosen was based on careful consideration of a number of factors, most important of which are extended, uninterrupted analytical sequences consisting of more than a single calendar day. We did not want to create a situation in which state or federally mandated analytical holding times could be artificially extended based on the definition herein.**

50C NR 149.03 (7, 14, 56) " p. 6, NR 149.03, Definitions—Refer to subsections (7), (14), and (56)—it is confusing to have three different batch definitions, “Analytical batch,” “Batch,” and “preparation batch.” Are all of these really needed? "

6 NR 149.03 (7, 14) " What is the difference between (7) and (14)? Can you give an example of when they would have different meanings? If not, delete one of them. How are you defining batch or analytical batch; by a number? Do we assume 20lbatch or analytical batch? "

Department Response: **The final rule consolidates the three definitions and incorporates language to allow preparation batches up to the number of samples that can be processed in a single set, as with block digesters.**

50C NR 149.03 (17) " p. 7, NR 149.03 Definitions. (17)—A calibration blank will never be “devoid” of target analytes. "

Department Response: **The definition has been revised for simplification.**

50A NR 149.03 (24) " Replace the word 'remuneration' with 'monetary' "

Department Response: **In the final language, the word “remuneration” has been replaced by “payment”, a more generally accepted synonym for remuneration.**

6 NR 149.03 (36, 37) " Delete (36) and (37) and make one (36) to read “Fields of certification and registration” means a unit by which the department grants certification or registration each consisting of three tiers: Matrix-Method-Analyte or Analyte Group. "

Department Response: **The definitions have been revised and consolidated for simplification.**

50B NR 149.03 (38) " NR149.03(38), "Inert matrix" is confusing and has too many exceptions. This term should be re-written in clear and concise english [sic]. Department staff should review all definitions and reassess whether they are clear and concise. "

Department Response: **The definition has been revised to simplify it.**

6 NR 149.03 (44) " (44) “Limit of detection” means the lowest concentration or amount of analyte that can be identified, measured, and reported with a degree of confidence that the concentration is not a false positive value. Add: For department purposes, LOD = MDL and is determined per the method cited in (50). "

28A NR 149.03 (44) " Section 149.03 Definitions (44) “Limit of detection” must have a given statistical degree of confidence that the concentration is not a false positive value. 40 CFR uses 99%. "

Department Response: **The term “limit of detection” was intentionally used to distinguish it from the EPA's "method detection limit". The procedure outlined in 40 CFR is viewed as a starting point for the determination of the LOD. Additional work may be required to address the fact that the EPA procedure is based on precision only. A lab’s LOD may or not be the product of the procedure found in 40 CFR Part 136, which is performed at the 95% confidence interval.**

28A NR 149.03 (45) " Section 149.03 Definitions and 149.48 2) (f) — The current NR 149 defines the LOQ as 10/3 or 3.333 times the limit of detection. The Department has also issued guidance documents with the same requirement. This new revision states that “the LOQ is the lowest concentration for which quantitative results can be obtained with a specified degree of confidence for a given limit of detection.” However, the code doesn’t state what that given degree of confidence should be. Further, section 149.48 (2) (f) states that Laboratories shall establish procedures related to LOD and LOQ. Does this mean that it’s up to the lab or the data user to choose? The Department should provide guidance or clarification in the code on this. "

Department Response: **In recognition of the fact that the limit of quantitation (LOQ) is not a generally acknowledged concept, the definition in this section has been changed to be more in concert with section 149.48.**

50A NR 149.03 (47) " the term "Matrix spike" has so many exceptions that it is not clear. It should be written in clear and concise terms. This same theme is repeated throughout the code. "

50B NR 149.03 (47) " I recommend that the other terms defined in EPA 200.7 be used as models to simplify the definitions listed in the proposed code. For example, I recommend substituting the EPA 200.7 definition of matrix spike for NR149.03 (47). EPA's wording is clear and concise compared to NR149.03(47). "

Department Response: **The definition has been revised to simplify it.**

42 NR 149.03 (50) " 149.03(50) Since the EPA is in the process of reviewing the MDL protocol as specified in 40 CFR 136, Appendix B, is it wise to list that exact protocol in the definition? Might it be better to list that protocol as an example of how to calculate an MDL? "

Department Response: **Currently, 40 CFR 136, Appendix B represents the national standard for determining detection. If the procedure is changed in the future, this rule will be revised to incorporate the changes made to the federal rule.**

42 NR 149.03 (56) " 149.03(56) The limitation of a preparation batch to up to 20 samples does not take into account such preparation devices as Hot Block™ – a metals digestion device that contains (in at least one case of ours) 54 digestion slots. This means that up to 54 samples can be digested at the same time, by the same analyst, using the same reagents. Artificially limiting the batch size to 20 samples in an instance such as this costs money and does not improve data quality. "

Department Response: **We have incorporated language to allow preparation batches up to the number of samples that can be processed in a single set, as in block digestion systems.**

42 NR 149.03 (62) " 149.03(62). Identification of wastewater influent and effluent as separate quality control matrices will do little to increase data quality and will likely result in additional quality control analyses for all laboratories. The Department should consider consolidation into the QC matrix ‘wastewater’. "

6 NR 149.03 (62) " (62) “Quality system matrix” Quality system matrices include, but are not limited to, drinking water, wastewater influent, wastewater effluent, groundwater, leaching procedures extracts, soils, oils, chemical wastes and biosolids. How is this related to the certification matrix tier? We only have aqueous, non- aqueous, solids, and drinking water. Are you saying we need to have QC criteria for all matrices under this definition? "

Department Response: **The matrix “tiers” for certification were established in part to develop a fee structure without making it overly complex. Quality system matrices indeed reflect a more subdivided list necessary for quality control samples. Influent and effluent are both part of a wastewater matrix, but are very different in terms of physical and chemical characteristics. For quality control purposes, excessive grouping of matrix types results in large standard deviations, which in turn translate into excessively broad quality control acceptance criteria.**

6 NR 149.03 (82) " (82) "Subcontract" means the act of sending a sample or portion of a sample by a certified laboratory to another certified laboratory. We think you need a statement here regarding whether one can do extraction or other preparatory steps on a sample before sending it to another lab. There is some disagreement between auditors as to what is correct and we think it needs to be addressed. We feel that we have less control over the sample data if we don't know how or what protocols were followed by the subcontracting laboratory. "

Department Response: **This is difficult to control for the Program as well. One solution to consider in the future is to offer certification/registration for preparatory techniques. Unfortunately, this is not something which has been done elsewhere across the nation. The concerns expressed above apply similarly to sample collection, which does not require any certification.**

5. Comments received relating to Subchapter II- Program Administration, s. NR 149.05- Required certification or registration.

50A NR 149.05 (2) " Should be revised to state "except as provided in s. NR 149.11 and 149.12, Wis. Adm. Code." "

Department Response: **We understand the commenter's concern; however, the suggestion is not warranted as exemptions allowable under s. NR 149.12 relate to use of alternate methods or exemption from specific code requirements rather than approval of specific data, as is covered under this section.**

6. Comments received relating to Subchapter II- Program Administration, s. NR 149.07- Transfer of certification and registration.

50A NR 149.07 (1) " NR 149.07(1) - States that the department must approve such transfers. However, no criteria for approval are listed. The criteria for approval or denial should be established in the rule making process otherwise it will not be enforceable. "

Department Response: **In the final rule, references to procedures for department approval of certification have been deleted.**

7. Comments received relating to Subchapter II- Program Administration, s. NR 149.08- Recognition of other certifications, registrations, accreditations, licenses or approvals.

42 NR 149.08 " Recognitions of other certifications, registrations, accreditations, etc: the Department should include language to prohibit combination of direct certification or registration and reciprocal recognition. "

Department Response: **Historically this has not been a problem, therefore, in the interest of offering flexibility, we do not see a need to make a change at this time.**

6 NR 149.08 (2) " NR 149.08 (2) EPA Agreement. The department shall recognize the certification, registration, licensure or approval by EPA for radiological testing performed by a laboratory submitting or generating data for a covered program. Why is "registered" in this definition. "

Department Response: **Rules do not preclude registered laboratories from obtaining EPA approval for radiological parameters.**

6 NR 149.08 (3) (a,b) " NR 19.08 [149.08] (3) (a) and (b). This is where partial reciprocity for i.e. SDWA certification should be allowed since all state certification programs must be the same. If not, then a statement that reciprocity is based on equivalency for the entire program with no partial certifications given. "

Department Response: **Following promulgation of this rule, the Program will again review procurement of reciprocity agreements. Partial reciprocity for drinking water certifications may be possible; however, the rules of reciprocity have historically limited the scope of our agreements. By definition, reciprocity requires that the other accrediting body accept Wisconsin certification in the same manner as we recognize accreditations offered by that body.**

6 NR 149.08 (3)(c) " We suggest removal of the word "registration" from the definition. "

Department Response: **The Department cannot exclude laboratories from being recognized from a reciprocal agreement on the basis of their accreditation type. This provision is defined by state statute (s. 299.11 (5), Stats.) which can only be modified through the Legislature.**

28A NR 149.08 (3)(c) " The department may not recognize the certification...of a laboratory by another state or an agency of the federal government, unless that state or federal agency recognizes laboratories under this chapter." While I recognize that there are fiscal and political issues to be considered, I would strongly urge the department to consider recognition of certified NELAC laboratories, regardless of whether Wisconsin participates as a NELAC Accrediting Authority. The NELAC standard is a recognized national environmental laboratory standard that is at least as stringent as the Wisconsin program and acceptance of participating laboratories would provide the community that generates and uses laboratory data in the State with more choices for meeting analysis needs. "

Department Response: **Subject to statutory requirements associated with agreements with private non-profit organizations, the program could pursue recognition of NELAC accreditation.**

8. Comments received relating to Subchapter II- Program Administration, s. NR 149.10- Enforcement.

18 individual public comments were received expressing concern with this section, which discusses enforcement provisions.

4 " If there is a need for enforcement, it should be a step-by-step process with no provision for a short cut to speed up the process. Common sense must also play a huge role in the process. With the vast expansion of paperwork that is proposed, it would be very easy to miss a meaningless initialization of some procedure, which would trigger an enforcement action, while a person was trying to get their work done on time. "

7 " Rule 149.10 I am partially in favor of. It should be revised to be less stringent. It sounds like if their [sic] is one violation, all certifications get pulled from the lab. The auditors know the labs that they will have problems. If a lab is willing to work to correct itself there should be room in the rule for those who work to better themselves. "

12A " Enforcement, 149.10 and related sections. This section has almost no due process. Revocation should be a last resort and only after resolution process has been followed. Also, the list of reasons for revocation are too subjective and nitpicky. Revocation or suspension should never be in response to failure to maintain records, until a violation is gross or defiant. "

15 " Causes for revocation too broad and subjective. There should be a procedure for verbal and written warnings first. Should also allow lab to take corrective action. Revamp this section for all labs. "

19B " Another thing we were talking about was the enforcement of the rule. I think it's too harsh that, if you just do something wrong once, that you get nailed for it or you could lose your license or lose

-
- your job. "*
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- 23** *" This section doesnt allow labs to resolve compliance issues outside realm of a contested case hearing. Should include option for an timeline for resolution between lab and auditor. "*
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- 25** *" NR 149.10, enforcement. We see no provisions in this section for any resolution of even non-flagrant issues, such as inadvertent recordkeeping omissions. It has been customary in previous lab audits that at least 30 days are appropriated to correct or address deficiencies. This section should be revised for all labs to include, at a minimum, a notice of non-compliance and/or notice of violation resolution process in a non-confrontational manner. The only option allowed in this proposed rule is a contested case hearing, which only creates further litigation costs for all parties. "*
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- 26A** *" This is a new section added after the end of the Advisory Committee process and has had effectively no input from the regulated community. There are 15 separate causes for revocation and the causes for revocation are extremely broad and subjective. For example, failure to maintain records as required in NR 149.39 is a cause for revocation. The failure to comply with some detail of the numerous record keeping requirements should not be grounds for revocation unless there are recurring problems. The same problem is true for most of the 15 specified grounds. By contrast, there are only three general grounds for suspension. "*
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- 26B** *" In the enforcement section, a facility's license can be revoked, not just suspended or subject to a notice of non-compliance, but can be revoked for any of the following, and there's 15 separate categories for revocation, one of which is the failure to maintain records as required in this chapter. least the way this rule reads, (c)3, for example, preservation status of samples on arrival at the laboratory. If we have a lab that has failed to comply with that requirement, their license can be revoked. Now I'm sure, and what I've heard from the Department, well, is, of course, we would never revoke a license, based upon a single incident like that. Well, that may be the case, but this rule does not provide that. What the rule provides is extraordinary enforcement discretion. "*
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- 27** *" Enforcement violations would be an all or nothing proposition. "*
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- 30** *" Enforcement. NR 149.10 The causes for revocation are very broad and subjective. There should be a notice of non-compliance with a chance for resolution of the issue before suspension occurs. "*
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- 34** *" I agree with MEG on Enforcement. "*
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- 35** *" Having reviewed the NR 149 rule revisions, it appears to me that a great deal of additional effort and some added expense would be required with a seemingly disproportionate amount of benefit gained. For this reason, I want it known that I am not in favor of the proposed revisions- particularly NRs 149.36, .39, .44, .46, .48, and .10, as these seem to be especially unreasonable and unnecessary to smaller labs. I'm afraid these revisions, with the accompanying extra burden of effort and expense, will cause many smaller wastewater plant labs to have to discontinue operating. This may result in many of these smaller plants not being able to justify to their governing boards the need to keep the lab equipment for process control purposes. If this were to happen, efficiency of the treatment process and the quality of the effluent would decrease and that would be detrimental to the environment and to the operation of these smaller plants. "*
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- 36A** *" NR 149.10 Enforcement. This section allows certification or registration to be suspended or revoked for even the most minor violations. This section should be changed to define a step approach to enforcement strategy. This issue is exacerbated because of the greatly expanded scope of the rule, and therefore, more opportunity for enforcement action to take place. "*
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- 36B** *" While the enforcement section of the proposed regulations are substantially the same as I can see, there are more enforceable items that are going to be included. The enforcement strategy, as outlined, appears to be all or nothing. I believe it needs to be adjusted or revised to define a step approach in the code, so that both the regulated community and the regulators understand what the procedures are to take in enforcement action. "*
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38 " Lastly, enforcement of NR149.10, causes for revocation are extremely broad and subjective. For example, failure to maintain records as required in NR149.39 is a cause for revocation. I think the whole gist behind enforcement codes, in general, is to work with the labs and work with the DNR. You know, when you start creating enforcement issues, without having to work with them first, then I think we've got trouble. "

49A, 49B " NR 149.10, we've always been told, there's always been a stigma of the DNR that, oh, the DNR is coming. You know, you guys are there to help us. You know, that's what we've been always been told is, you're there to help us. And with the enforcement rule change, that could potentially change. We, as operators and lab personnel, want to know that, if we're running into trouble, we can count on the DNR to help us. And it's been that way in the past, and we're hoping that this rule change doesn't change that. "

Department Response: **This section was revised, in consultation with Department legal staff, with the intent of ensuring that a timely and measured enforcement action can be successfully undertaken in cases where data quality is affected. The need for quality data is a basic tenet of the program. The program needs to have the enforcement authority to initiate revocation procedures if data is being compromised. It should also be noted that, while lengthy, many items in the list of criteria for revocation do not relate to municipal wastewater facilities. Revisions were made to emphasize that a solitary violation of any given requirement will not result in revocation.**

9. Comments received relating to Subchapter III- Program Structure, s. NR 149.13 - Fields of certification and registration.

6 NR 149.13 (1)(b) " NR 149.13 Fields of certification and registration. (1)(b) Suggest the following change: ~~The second tier of certification or registration designates the analytical techniques or method a laboratory may perform for a given matrix.~~ "

Department Response: **Drinking water certification is offered by specific method only because the federal rules mandate it. Certification by individual method adds complication to an already complex system. The program opted for this approach because whether a laboratory uses an approved EPA, Standard Methods, or another approved method, the absolute technology involved remains constant. It is laboratory's incorporation and performance of this technology that the program certifies through the on-site evaluation process. Individual method differences will be handled during on-site evaluations.**

6 NR 149.13 (2)(b) " Suggest the following change: ~~The second tier of the certification fields shall be method for drinking water matrix and analytical technique for all other certification matrices. We believe that analytical technique is inherent when citing a method and just leads to confusion and misunderstanding especially with the registered labs. Additionally, you do not capture this information when analyzing PT samples. But method is cited and required. Analytical technique may be a good exercise for establishing audit time for RVU cost determinations but is inappropriate for anything else.~~ "

Department Response: **The program opted for this approach because whether a laboratory uses an approved EPA, Standard Methods, or another approved method, the absolute technology involved remains constant. It is laboratory's incorporation and performance of this technology that the program certifies through the on-site evaluation process.**

6 NR 149.13 (3)(b) " Suggest the following change: ~~The second tier of the registration fields shall be analytical technique method.~~ "

Department Response: **The program opted for this approach because whether a laboratory uses an approved EPA, Standard Methods, or another approved method, the absolute technology involved**

remains constant. It is laboratory's incorporation and performance of this technology that the program certifies through the on-site evaluation process.

50A NR 149.13 (4)(a) 19 " *NR 149.13(4)(a)19 - Ultra-low level metals should not be listed as a analytical technique. The analytical techniques for low level metals are already listed in the table. Listing ultra-low level metals is not consistent with the other items listed in the table. "*

Department Response: **The intent here is to offer specific accreditation to perform low-level (ultra-trace) determinations of mercury. As the comment indicates, many existing analytical technologies are applicable to both routine and ultra-trace testing. The differentiation comes in the sample handling processes, and the program opted for this approach as the best means of isolating trace from non-trace determinations.**

50A NR 149.13 (5) " *This subsection on SDWA methods is out of place. This section deals with analytes, analyte groups, and types of instrumentation not methods of analysis. "*

Department Response: **For drinking water, method is the second tier of certification, so this is indeed the proper location.**

50A NR 149.13 (5)(b) " *Is this the appropriate way to list a citation in code? This implies that the code is approving future [sic] all future methods. While I agree this is a great idea, I do not think it is a legally defensible code citation. "*

Department Response: **Independent review of the proposed language did not indicate that the approach was unacceptable.**

10. Comments received relating to Subchapter IV- Certification and Registration Process, s. NR 149.14 - Application for certification or registration.

50A NR 149.14 (6)(d) " *NR 149.14(6)(d) - Should be reworded to: 'he department will not accept a laboratory under a reciprocal agreement unless the certifying entity has performed an on-site evaluation of the laboratory. To verify this, laboratories applying for recognition shall submit a copy of the last on-site evaluation performed by that entity.'* "

Department Response: **The existing language doesn't represent a change from current rule, and provides the program with the necessary information. The suggested language change offers no tangible merit.**

11. Comments received relating to Subchapter IV- Certification and Registration Process, s. NR 149.15 - Period, renewal and expiration of certification or registration.

50A NR 149.15 (2)(a) 1 " *NR 149.15(2)(a)1 - This subsection states that the laboratory shall "Complete an annual renewal application." This is an unnecessary financial burden for both the laboratories and the Department staff. The added effort provides no net gain for the program or data quality. "*

Department Response: **The requirement to submit application materials for annual certification/registration renewal has been eliminated. This requirement may be re-evaluated in future revisions if the labor associated with application process can be minimized through on-line applications and information uploads.**

6 NR 149.15 (2)(b) & (c) " *Prior to September 1, the department shall request that laboratories certified or registered through a reciprocal agreement.... Delete registered. How can registered labs*

get reciprocity? "

Department Response: **This issue has been addressed previously in response to comments associated with s. NR 149.08 (3). The Department cannot exclude laboratories from being recognized from a reciprocal agreement on the basis of their accreditation type. This provision is defined by state statute (s. 299.11 (5), Stats.) which can only be modified through the Legislature.**

12. Comments received relating to Subchapter IV - Certification and Registration Process, s. NR 149.18 - Subcontracting of analyses by certified or registered laboratories

6 NR 149.18 (1) " *Should whole samples only be subcontracted or can extracts, distillates etc. We feel that the preparation technique should be the responsibility of the subcontracted lab. What is the auditor stance on this issue? Make it clear on what and in what form can a sample be subcontracted?* "

Department Response: **Incorporating this suggestion would represent a significant change in philosophical approach. Currently a laboratory can be certified to perform TCLP extractions yet then subcontract the analytical determination to another certified laboratory. Adopting this suggestion would require the addition of digestion and extraction as fields of certification or registration, which would, in turn, require incorporation into the fee structure to maintain fee equity. Consequently, this is a modification which should be considered as part of a future revision to NR 149.**

2 NR 149.18 (2) " *Covered compliance programs where registered labs cannot accept payment should be clarified.* "

Department Response: **Sub (2) was deleted for the final rule. This information is already covered in several places within s. NR 149.03**

50A NR 149.18 (2) " *Replace the word "remuneration" with "monetary".* "

Department Response: **Sub (2) was deleted for the final rule. This information is already covered in several places within s. NR 149.03**

50A NR 149.18 (2) " *By definition a registered lab can not accept payment. This sentence is unnecessary.* "

Department Response: **Sub (2) was deleted for the final rule. This information is already covered in several places within s. NR 149.03**

13. Comments received relating to Subchapter IV- Certification and Registration Process, s. NR 149.21 - Fees.

50A NR 149.21- " *This section is open to interpretation as currently written. Determining the annual fee for a laboratory must be very clearly written in the code. The fees are overly complex.* "

Department Response: **Significant changes have been made to the fee structure to clarify and simplify the fees.**

50A NR 149.21- " *I believe it would be in the interest of the Department to do a detailed fiscal analysis and determine what the total cost of operating the proposed program. Once the operational and initial cost is determined then the fees can be calculated. If this has already been done, it would be useful to provide this information to the laboratory community.* "

Department Response: **Total program operating costs are determined annually as part of the**

budget process, and this process is independent of fees. Fees are simply the principal means of generating enough revenue to cover program operating costs. The cost per relative value unit (RVU) is really at issue here. Changes have been made to the RVU assignments per technology and class to ensure equity.

50A NR 149.21 (2) – “ *This is the subsection on annual fees. Subsections (3)-(8) are parts of the annual fee and therefore should be subs of (2).* “

Department Response: **This section has been completely revised for ease of operation and simplification.**

50A NR 149.21 (2) through (8) - “ *It is not clear that the technique fee is charged for both the aqueous and solid matrixes [sic].* “

Department Response: **The final rule clarifies that the technology fee is charged for each of the aqueous and solid matrix types covered under tier 1 of the fields of certification/registration.**

6 NR 149.21 (5) “ *Suggest replacing: ‘analytical technique fees’ with ‘analytical method fees’* “

Department Response: **The intent is to charge a single fee for each recognized analytical technology. There are many approved methods for each technology, therefore to assess a fee per method would be unwieldy.**

6 NR 149.21 (7)(a) , (b) " *We don't understand the fee exemptions noted. Aren't these required parameters and therefore subject to a fee? The aforementioned items imply no fees. Does this mean a lab doing just BOD and TSS is exempt from a fee?* "

Department Response: **For simplification, the final rule includes numerous changes including the elimination of the minimum fee.**

2 NR 149.21 Table 1 " *Consider adding a category in the fee schedule for wastewater labs that voluntarily seek certification but rarely contract samples. These labs should not pay the full 10 RVU when rarely analyzing outside samples.* "

Department Response: **Program quality control and documentation requirements are the same whether a laboratory is certified or registered. The distinction then becomes a fee which represents the added responsibility incurred when a laboratory performs testing for any facility other than its own. Choosing to become certified vs. registered is a choice which has some cost ramifications.**

6 " NR 149.21 Table 1 – “ *We also believe that the RVU costs are to [sic] low. We feel that some of the analytical techniques are more complicated from an auditing standpoint than was determined by the RAC committee.* "

Department Response: **The final rule includes a number of changes to technology-based relative value units to address this comment.**

50A NR 149.21 Table 1- “ *The ultra-low level metals assay fee should be deleted. A laboratory is being double billed for testing the low level metals based on the technology.* “

Department Response: **The intent is to offer a formal certification/registration to perform ultra-trace metals testing. In the final rule, the fee for this technology has been adjusted to be more in line with the effort required. In addition, a maximum technology fee will ensure that laboratories are not charged excessively for choosing to certify multiple advanced technologies.**

14. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.22 - Required analyses of proficiency testing samples.

50A NR 149.22 (2) “ *The proposal states that “the department shall publish a list of required proficiency testing samples”. A published list is only guidance. To the best of my knowledge, guidance is not enforceable and therefore cannot be considered a program requirement. “*

Department Response: **A note indicating where the information may be obtained has been added.**

2 NR 149.22 (3) “ *PT exemptions for metals analyses. This needs further explaining. Does analysis of a 2nd source LCS during runs cancel out the requirement of analyzing 3 QCS's/year? If not, do labs have the option of testing a yearly PT? How does a lab get certified or registered for these techniques without submitting PT results? “*

Department Response: **The exemption for metals PTs, using some specific technologies, is based on availability of PTs in the normal working ranges of these techniques. Use of LCS, a second source, is not an alternative to QCS for these techniques. Certainly, if a lab wishes to analyze a PT, which could be quite a challenge, that would be acceptable. The final rule clarifies that external QC standards, analyzed three times each year, will be required to demonstrate proficiency.**

6 NR 149.22 (3) (a),(b) “ *We disagree with this option. It would create an unfair competition issue with certified labs certified in other states which require PT samples versus certified labs doing work only instate and not having to purchase PT samples. We think that (3) (a) and (b) should be eliminated. “*

Department Response: **While PT samples may be available, they are not available at concentrations suitable for either gross concentration techniques, such as flame AA or ultra-trace technologies, such as those used for mercury. The alternative specified in rule provides on-going demonstration of capability based on the EPA’s quality control sample (QCS) concept, which actually requires more effort (3 times per year) and similar cost to actual PT samples.**

15. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.23 - Approval of proficiency testing sample providers.

50A NR 149.23(2)(c) – “ *There are no procedures determining acceptance limits in s. NR 149.27. Again, if these procedures are not published in code, they are not enforceable. “*

Department Response: **All approved PT providers will follow criteria established by the EPA for determining acceptance limits for PT studies.**

16. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.24 - Schedule of analysis.

50A NR 149.24 (2)(b) - “ *There are no procedures determining acceptance limits in s. NR 149.27. Again, if these procedures are not published in code, they are not enforceable. “*

Department Response: **All approved PT providers will follow criteria established by the EPA for determining acceptance limits for PT studies.**

50A NR 149.24 (3)- “ *The proposal states that laboratories “seeking renewal of certification or registration for aqueous or solid matrices shall analyze at least one proficiency testing sample”. It is unclear if both solid and aqueous proficiency test samples are required. “*

Department Response: **The final rule clarifies that PT samples prepared in a solid matrix are not required to obtain or maintain certification or registration for solid matrices. To obtain or retain certification of registration for technologies and analytes in either aqueous or solid matrices, laboratories need to analyze a PT sample prepared in an aqueous matrix.**

- 6 NR 149.24 (4)(a) " Proficiency testing samples shall be analyzed during the certification or registration period immediately preceding the period for which renewal is sought. What does this mean? How is immediately defined? If stated else where, shouldn't this reference it? "

Department Response: **The final rule clarifies that for certification renewal, which is effective on September 1 of each calendar year, acceptable PT results must have been received no sooner than January 1 or later than August 31 of the same calendar year.**

17. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.25 - Treatment of proficiency testing samples by laboratories.

- 2 NR 149.25 (1) " 149.25 (2) already states how to handle PT samples. This should not be required in QA manuals. "

- 6 NR 149.25 (1) " Laboratories shall specify procedures used to handle and analyze proficiency testing samples in the laboratories' quality manuals. Why? All PT samples are supposed to be run as if it were a sample (after preparation). Does this need to be written down? It should be implied if the laboratory is doing analyses according to the methods. "

Department Response: **This subsection has been deleted in the final rule.**

- 28A NR 149.25 (3) " What should a laboratory do if it utilizes different preparation techniques with the same analytical technique (e.g. separatory funnel and liquid/liquid extraction for semivolatile analysis)? Are separate PT samples required? If so, how should these be reported to PT providers and to the DNR? "

Department Response: **It is the intent of the agency that laboratories will be able to analyze a single PT using multiple analytical techniques for aqueous and solid matrices and multiple methods for the drinking water matrix. The department is not proposing certification or registration for specific extraction or digestion methods of those associated with waste characterization. This issue will be further clarified in Department guidance and outreach efforts following promulgation of the code revision.**

- 28B NR 149.25 (3) " ...states that the laboratories may report multiple results of multiple analyses of a single PT sample when the lab maintains certifications for multiple techniques for any analyte. So it appears you've given us an out, you know, that we can choose to do so or choose not to do so, and it's not clear whether that's your intention or not. I suspect not, but that's not how it reads. You also don't provide guidance for what a laboratory should do, if it utilizes different preparation techniques with the same analytical techniques, such as separatory funnel and liquid-liquid extraction for semivolatile analysis. It's not clear what we should be doing, as far as PT submittals on that. And if that's not covered in the code, I would urge you to at least provide some guidance in the documents that you're preparing. "

Department Response: **PTs are graded based upon analytical method or technique; current PT provider reporting requirements do not even capture information regarding preparatory method. It is not the intent of the program to require preparatory method-specific PTs, regardless of determinative technique. Prior to the effective date of the rule, outreach efforts will be conducted to ensure that these requirements are clear.**

18. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.27 - Acceptance criteria and grading.

- 50A NR 149.27 – " This section does not clearly state what criteria will be used to grade proficiency testing samples. Again, I am concerned that the EPA criteria will not be enforceable if it is not codified. "

Department Response: Department Response: **In the final rule, references to establishing procedures for grading of PT samples have been deleted.**

19. Comments received relating to Subchapter V- Proficiency Testing, s. NR 149.28 - Procedure for correcting unacceptable proficiency testing sample results.

6 NR 149.28 (1)(a) " *We think the time frame should be clarified. We assume that the department and the laboratory will agree on a time frame for completion but we don't think this can go on for a year while the laboratory is still doing work. There has to be a maximum (not to exceed) defined. "*

Department Response: **Multiple consecutive PT failures are not a common occurrence, and there are typically unique circumstances in every case. While not clearly identified in this section of the rule, in the worst case scenario, if multiple consecutive PT failures continues to be an issue, the rule allows the Department to not renew a laboratory's certification in the event that successful PT results are not obtained. By rule, this established a *de facto* maximum time period of less than nine (9) months (January 1 to August 15 in a given calendar year for certification renewal.)**

20. Comments received relating to Subchapter VI- On-Site Laboratory Evaluations, s. NR 149.29 - Purpose, type and frequency.

28A NR 149.29-34 " *Sections 149.29— 149.34—In all of these sections, replace "deficiencies" with "findings" - "Findings" was the term used in the original draft of the code and this more objectively characterizes those items uncovered during the evaluation that are inconsistent with the standard. Evaluation reports are public record and may be read by clients, non-technical personnel and even the general public. The use of the term "deficiency" generally carries a negative connotation, especially to individuals who aren't as familiar with the process. "Evaluation deficiency" is often translated to mean "deficient (or bad) lab." In some cases, the item(s) in question may not even have an impact upon the quality of data generated by the laboratory. "*

Department Response: **The original terminology used was "finding" but was changed to "deficiency" at the request of the Rule Advisory Committee. The regulated community objected to the term "findings" for similar reasons, i.e., that auditors could include many more subjective comments in an evaluation report. The term "deficiency" is appropriate because anything labeled as such should represent a clear deviation from Administrative Code or referenced method requirements.**

NOTE: as the comment indicates, this response applies to the entire subchapter.

21. Comments received relating to Subchapter VI- On-Site Laboratory Evaluations, s. NR 149.30 - Evaluation procedures and appraisal.

2 NR 149.30 (1) " *This is important. The Department needs to come up with a method for training all auditors in the same manner to reach consistency. Auditors need to take their personal preferences out of the equation and be consistent with the entire department. I had an auditor disapprove of a method that was being performed for years, which consequentially was approved by the previous auditor. How come it's ok for one person and not the next? "*

Department Response: **Addressing this issue is outside the scope of this rule. To address auditor consistency, the Program is developing a series of audit checklists and an SOP for the on-site evaluation process. These items are available on its website at <http://www.dnr.state.wi.us/org/es/science/lc/OUTREACH/Checklists.htm>**

22. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.36 – Laboratory Personnel.

21 comments were received expressing concern that the requirements to perform an “initial demonstration of capability” are unnecessary, and create a fiscal burden that was not addressed in the fiscal impact estimate. One commenter supported the rule provision.

1	NR 149.36 (3) " <i>Pertaining to NR 149.36, I am in one of those small plants. I am the only operator. I have an operator in training. The way this sounds, that operator in training would wind up being of no use to me, until he gets the detailed training, even though I consider I trust him to do all the tests. [sic]</i> "
2	NR 149.36 (3) " <i>IDC's. This whole section needs to be omitted. Analysts show through various other QC elements they are capable of performing a test. In addition, it is ridiculous that the proposed limits for IDC's are 50-150% when analysts are routinely meeting 90-110 % for other QC "</i>
3	NR 149.36 (3) " <i>NR 149.36(3), about the requirements of being trained for doing the testing. In a small town, I don't know if sometimes maybe larger places forget about this, Bob mentioned it also about the cross-training. In a small town, like for us, for instance, we bring somebody on board that gets hired for the town, he doesn't get hired just for the wastewater plant. He's also going to be cross-trained. He's going to be running water department, he's going to be plowing snow, doing whatever. ...just get them into weekend duty and do all this, and within a year, a year and a half, this guy decides that the public service isn't the life for him and he's gone. And you invested a lot of time, training costs, and everything else, and you didn't get much out of it. So I think this requirement needs to be not only looked, I think it needs to be eliminated. It doesn't make a lot of sense, especially in the way a small town has to approach it. "</i>
7	NR 149.36 (3) " <i>Rule NR 149.36 is not that big of a problem. If I do take a vacation our samples will be farmed out for the time I am gone. All plumbers are required to have a license. If the Master Plumber is not their [sic] the Journeymen takes over. If the Journeymen is gone an apprentice with 4 years can work unsupervised. "</i>
12B	NR 149.36 (3) " <i>Initial demonstration of capability. This section should be deleted entirely. There are already consequences in place if an analyst does not perform tests properly. If QC is exceeded by anyone, it is recorded on the DMR and corrective action takes place. Wastewater treatment plants have an interest in good data also. "</i>
12A	NR 149.36 (3) " <i>This section and the IDC requirement are completely unnecessary for municipal wastewater labs. We are responsible for the quality of the data that we report on our NPDS permit, it's our discharge permit, and can face legal consequences if that data is not accurate. That is more than enough incentive for managers to ensure that our personnel are trained properly. Staffing and training within our facility should remain at our discretion. This section should be deleted or wastewater utilities exempted. "</i>
13	NR 149.36 (3) " <i>It is the policy of the village of Fredonia to give all their employees an opportunity to complete the operator certification training and testing. I believe that this section should be deleted, or an exemption should be granted for wwtp's. "</i>
15	NR 149.36 (3) " <i>This rule requires that each person running samples must meet the detailed training and certification requirements. We are opposed to this rule change due to the undo financial burden that would be placed on our Wastewater Treatment Plant. Currently, we have one certified operator on staff and one part-time lab tech that perform all of the required testing during the week. All of the effluent testing and outside testing is performed during the week by either one of these two employees. The only weekend testing that is performed by our treatment plant is the testing of BOD's and TSS's for the two industries that we have. These results are used in calculating the surcharges that are assessed on their monthly water and sewer bills. The two individuals that perform the testing during the week work with each other to ensure that at least one of them is available to do the required testing. To place the great financial burden on our treatment plant by requiring that all of our other employees are certified when the only testing that they perform is on the weekends for the industries, which is only for surcharge billing, seems quite unreasonable. The Hilbert Wastewater</i>

	<i>Treatment Plant feels that this section should either be deleted or that treatment plants should be made exempt "</i>
17B	<i>NR 149.36 (3) " Laboratory Personnel NR 149.36 (3) requires that each person running samples meet detailed training and certification requirements. This will be a problem for us with a limited staff, particularly during weekends and vacations, sick days and during initial hiring. It will require additional training of personnel and costs. This section should be exempted for wastewater treatment plant. "</i>
19B	<i>NR 149.36 (3) On NR 149.36, we're against that. It runs into a big problem with us. When you have small plants and you have people that are cross-trained in between departments, it's hard to get everybody trained and get them certified. And it would be a very big cost, so we're totally against that.</i>
20	<i>NR 149.36 (3) " NR 149.36 would require us to train and certify the other operators that rotate on weekends. This takes time and money with little or no benefit to the facility. "</i>
23	<i>NR 149.36 (3) " The cost and time associated with the Initial Demonstration of capability (IDC) would impose a significant financial burden on small wastewater treatment facilities. Additional proficiency testing, record keeping and training would impose a large impact on treatment facilities with only one or two operators. Some facilities may only budget, or employ the equivalent of 1½ positions for their Wastewater plant. To require IDC for the individual that is required to do lab work on an "occasional" basis seems costly for the benefit gained. Additionally the requirement seems unreasonable in light of the fact; many of the small system operators's [sic] are required to cover many facets of small government. Quite often, small Wastewater Plant operators are required to perform additional job duties outside the treatment facility such as Public Works, Parks and Utility functions. In small communities and Sanitary Districts it is not uncommon to have the duties of the Wastewater Operators covered by temporary or part-time employees due to sickness, vacation, family emergencies, or participation in providing Emergency Medical Service or Fire Protection for their communities by the full time Wastewater Operator. "Grandfathering" these Wastewater Operators will only be a temporary fix to a rule that may be in place for years. Wastewater labs need to be exempted from this rule. "</i>
24	<i>NR 149.36 (3) " The Manitowoc WWTF operators are not required to have lab certification and none have expressed the desire to obtain it. However, under the instruction of the City Chemist and Assistant Chemist, the operators have demonstrated excellent ability to accomplish the required weekend lab work. I feel this IDC is unnecessary and would result in conflict between lab personnel and operators who feel it to be not their responsibility. "</i>
25	<i>NR 149.36 (3) NR 149.36, laboratory personnel (3), initial demonstration of capability. The proposed revision for Initial Demonstration of Capability, IDC, would impose a significant additional labor and financial cost for relatively small treatment plants, certified labs, like ours. So I guess I challenge the opening statement that it's going to reduce costs. It's not reality for us. Our plant is staffed with one laboratory technician, who currently complies with the IDC requirements proposed in this section. An additional one of two plant operators can be temporarily assigned to perform the required analyses in his absence. They have been supervisory trained by the laboratory technician to perform whatever analyses they are temporarily assigned. On weekends, one of a possible seven plant operators is assigned lab duties for two hours each day. They only read the five day BOD takedown results, in addition to other process analyses assigned. Each operator is assigned the performance of these analyses on a rotating basis. Five of these operators are grade four certified in the on-site laboratory test in subgrade, and the other two are in the process of obtaining this certification.</i>
27	<i>NR 149.36 (3) " This section would require each employee who would analysis [sic] a sample to meet detailed training and certification requirements. Some of these requirements are redundant as all our operators are Class IV State Certified and have the lab certification. This section should be deleted or wastewater plant labs should be exempt. The inclusion of wastewater labs in this revision amounts to another unfunded mandate by the state. Any increase in costs will have to be passed on to the user in a rate increase. "</i>
30	<i>NR 149.36 (3) " Requiring each person running samples to meet a detailed training and certification, would force our facility to spend additional money for staff training and would not add quality to our data .This is a section geared towards a certified lab and should be deleted from the</i>

	<i>wastewater treatment plant. "</i>
34	NR 149.36 (3) " <i>Agree with MEG [the Municipal Environment Group] "</i>
35	NR 149.36 (3) " <i>I'm afraid these revisions, with the accompanying extra burden of effort and expense, will cause many smaller wastewater plant labs to have to discontinue operating. This may result in many of these smaller plants not being able to justify to their governing boards the need to keep the lab equipment for process control purposes. If this were to happen, efficiency of the treatment process and the quality of the effluent would decrease and that would be detrimental to the environment and to the operation of these smaller plants. "</i>
36A	NR 149.36 (3) " <i>This is another attempt by certain factions within DNR to incorporate NELAC requirements into DNR rule. The purpose of this proposed rule should be to ensure that the data generated by laboratories and reported to DNR is accurate and valid. I strongly support this goal. Data accuracy and validity is verified through quality control testing. The initial determination of capability does nothing to ensure the validity of data. If any analyst follows proper procedures and generates acceptable quality control results, the data is valid, regardless of the analyst's background. "</i>
36B	NR 149.36 (3) " <i>I object to the initial determination of capability for technicians or analysts. I believe it's unnecessary and burdensome. The code should be contained to verifying the validity of the data through the quality control procedures, instead of testing the analysts. The important thing that we all want is valid data. "</i>
40	NR 149.36 (3) " <i>Laboratory personnel (operators) must demonstrate they can accurately perform tests that the lab is certified to perform. The most reliable proof of this is by using Blind Standards that have a known value/result to the tests. Operators must be supervised by a person (chemist) that has already demonstrated capability. "</i>
48	NR 149.36 (3) " <i>These requirements that are laid out by NR 149.36 would require significant additional training of personnel and costs. This section should be deleted, and there should be a wastewater treatment plant exemption. "</i>

Department Response: **This subsection has been revised to specify that only those determinations of capability, which are specified in approved analytical methods, be required. For tests and methods that do not specify such a determination, rule language will offer flexibility, requiring only that laboratories maintain documentation supporting an analyst's ability to perform the test(s) in question.**

A. Other (9) more specific comments received regarding 149.36 (3)

50D	NR 149.36 (3) " <i>The initial demonstration of capability and continuing demonstrations of capabilities as outlined in this section are unachievable in a whole effluent toxicity testing laboratory. It is highly unusual for one analyst to be the sole analyst on any one toxicity test, seeing it through from set. We would suggest either 1) omitting this requirement for whole toxicity testing laboratories or 2) allowing analysts to fulfill this requirement by partial participation in a test, not by requiring each analyst to complete the entire test. "</i>
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Department Response: **NR 149.49(2) states that lab performing tests for alkalinity, ammonia, hardness, pH, conductivity, dissolved oxygen, and total residual chlorine shall follow the quality control requirements specified in s. NR 149.48. There is no initial demonstration of capability requirement for WET assays.**

46A	NR 149.36 (3) (a)(1) " <i>It remains unclear whether this section is intended only to 'grandfather' current laboratory personnel, or allow new personnel to qualify using NR149.36(3)(a)1. This section should be an ongoing alternate procedure for use with new personnel, and that should be clearly spelled out if necessary. "</i>
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Department Response: **This comment has been addressed by revising this subsection and limiting the "initial demonstration of capability" requirements to those methods which specifically**

incorporate them. These methods also include acceptance criteria.

45A NR 149.36 (3)(a) 2 " *It is unclear whether the occasional weekend and holiday work by plant operators will be allowed under the definition of supervision. Is it direct supervision, i.e. visual contact or something else? 149.36 (3) (b) – Demonstrating and recording capabilities for all plant operators that work occasionally in the lab (if required) will add to the current workload. ...The initial demonstrations of capability and corresponding documentation for all operators at a small plant is time consuming and expensive given the importance of other areas of the plant which must be properly run and maintained to avoid a permit violation. "*

Department Response: **This comment has been addressed by revising this subsection and limiting the “initial demonstration of capability” requirements to those methods which specifically incorporate them.**

45A NR 149.36 (3)(b) " *Demonstrating and recording capabilities for all plant operators that work occasionally in the lab (if required) will add to the current workload. ...The initial demonstrations of capability and corresponding documentation for all operators at a small plant is time consuming and expensive given the importance of other areas of the plant which must be properly run and maintained to avoid a permit violation. "*

26A NR 149.36 (3)(c) " *One of the most problematic areas for small municipal labs is the “Initial Demonstration of Capability” (IDC) in NR 149.36(3). This section requires that each person running samples meet the detailed requirements of this section. This is a problem for small communities with limited staff, particularly during weekends and vacation/sick days and during initial hiring. It will require significant additional training of personnel and costs. The grandfathering provision here is extremely unclear. This subsection should be clarified or there should be a wastewater treatment plant exemption. "*

38 NR 149.36 (3)(c) " *One particular area is NR149.36 requires each person running samples to meet the detailed training and certification requirements of this section. This can be a problem for communities with limited staff, like most small wastewater treatment plants, particular during the weekend, vacations, and holidays, requires significant additional training for personnel and cost. In Rice Lake itself, you know, just this calculation, we figured it it's going to be anywhere the first year at least \$5,000 additional cost for us. "*

Department Response: **This comment has been addressed by revising this subsection and limiting the “initial demonstration of capability” requirements to those methods which specifically incorporate them. These methods also include acceptance criteria.**

42 NR 149.36 (3)(c) 1 " *The analysis of 4 replicates should only be allowed as an initial demonstration of capability if the replicates have detectable concentrations present (i.e., 4 replicates of samples with no detectable hits does not prove anything). "*

Department Response: **The merit of the comment is noted, and the suggested clarification will be incorporated into guidance offered by the Department as an option for those methods which do not include demonstration of capability criteria.**

50C NR 149.36 (3)(e) " *It is confusing to say, “...shall demonstrate initial capability by all of the following:” This is followed by two choices, one that is only for methods where analyzing fortified replicates is impossible, and the other only for methods that are amenable to the analysis of fortified replicates. In other words, it is impossible to do ‘all of the following’. "*

Department Response: **This comment has been addressed by revising this subsection and limiting the “initial demonstration of capability” requirements to those methods which specifically incorporate them. These methods also include acceptance criteria. The Department will offer the procedure as optional guidance, rather than a requirement, to demonstrate capability.**

6 NR 149.36 (3)(e)(1) c " *This seems incredibly generous and doesn't promote quality data. 50 to 150%? For inorganics, metals and organics this gap and the requirement of a standard deviation less than 33 is too broad. It might be appropriate for some organic analyses but not for inorganics or metals. This won't demonstrate proficiency or understanding of the method. If it's going to be this wide of a margin for all analyses, then this is truly a meaningless waste of time? We would rather see you classify tighter criteria based on analyte method and class. "*

Department Response: **This comment has been addressed by revising this subsection and limiting the "initial demonstration of capability" requirements to those methods which specifically incorporate them. These methods also include acceptance criteria.**

23. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.37 – Quality manual.

50C NR 149.37(2) NOTE " *There is a mis-placed 'or'; It should read 'Standards of the.....July, 2003, OR..'* "

Department Response: **The suggested change has been made.**

40 NR 149.37 (3) " *I believe that the revisions are not warranted and would place a significant financial burden on the operation of the City's wastewater treatment facility laboratory. "*

45A NR 149.37 (3) " *For many small wastewater plants, the current manual that is followed is crafted after the DNR's document "Quality Assurance Document for a Small Wastewater Lab." The proposed language will expand this basic manual to an extensive document that is very time consuming to create/edit. For small plants doing a limited number of test procedures, the quality of the data will not improve by having such an extensive document, when a basic document already exists. "*

Department Response: **To date, NR 149 has not specified anything other than the requirement to have a written quality assurance plan. The program has provided guidance for wastewater labs, but nothing for other laboratories. In the past 10 years, the EPA has also established minimum information which should be incorporated into a QA Manual. To ensure that such a document retains its value in generating quality results, it is appropriate that the program establish by rule minimum standards for development of an effective Quality Assurance Manual. While this rule will require some effort to update QA Manuals to maintain compliance, we believe that guidance that has been provided should help minimize the costs associated with this effort. In the final rule, changes have also been made to material required to be included in the Quality Manual.**

24. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.38 – Corrective action for quality system and quality control samples.

50A NR 149.38 (1) & (2) " *...could be simplified as follows: 'The laboratory shall take corrective action if quality control criteria are exceeded. The corrective action shall identify the source of the problem, correct the problem and have a mechanism to verify the action has had the desired effect.'* "

Department Response: **The revised rule language was created to clarify that corrective action must not only be taken, in the event of a quality control failure, but that the action taken must be appropriate, and must be evaluated to ascertain that the action taken was that necessary to resolve the non-conformance. For the final rule, further effort has been made to simplify the language.**

25. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.39 – Records and documents.

A. Comments from the regulated community on s. NR 149.39 (1) and (2) and (3) (c) 14. Note

40 NR 149.39 (1) " *The laboratory must have procedures to control and manage all records and documents that form part of its quality system and that are required to demonstrate compliance. A plan must be in place to identify and determine a procedure for retaining records in the event the laboratory loses its registration, records must be stored in a manner that ensures their permanence and security for the required retention period (5 or more years) and prove that these records can be retrieved in proper condition in order to comply with this chapter, a procedure will be written for prevention of unauthorized access or amendments to hardcopy records and documents As stated above for 149.37.3, Some of these procedures are not currently required so they will need to be developed and put into practice before they are documented. 80 hours at \$27.96/hour = \$2237 "*

23 NR 149.39 (1)(c) " *Records retention of 5 years seems rather lengthy when you consider a lab audit is scheduled to happen every three years, and laboratory quality control comments are submitted every month to the DNR Area Engineer, and DNR Central Office on the Wastewater Facilities Discharge Monitoring Report. The fiscal estimate states "Any perceived increase in cost for record retention is mitigated as most local government units already maintain records in excess of the proposed requirements. Inclusion of electronic options will likely reduce the storage space necessary for records retention." This may be true for the current number of records that are stored, but how much more space will be needed for the additional records that are proposed to be required? Electronic storage of records is a nice option, but in reality how many small wastewater facilities in the State have the luxury of even having their first computer? If this portion of the rule makes provisions for their acquisition, then I don't see a problem; otherwise the length of records retention should be reduced. "*

50C NR 149.39 (1)(c) " *Second sentence should read, "The laboratory shall retain records and documents for a longer period if they are necessary to reconstruct analytical results generated during a 5-year period." (The minimum period was stated to be five years; therefore, saying, "...longer minimum period..." doesn't make sense.) "*

Department Response: The rationale for changing from a 3-yr to a 5-yr records retention requirement was largely based on the NELAC requirement. This is a requirement for the lab certification program (vs. the DNR's Watershed management program). In light of comments that we only audit labs every three (3) years, this requirement has been changed back to the original three (3) years. If the Department should choose to become a NELAC Accrediting Authority in the future, this requirement could be revisited at that time.

40 NR 149.39 (2) " *I believe that the revisions are not warranted and would place a significant financial burden on the operation of the City's wastewater treatment facility laboratory. "*

Department Response: Items (e) and (f) have been eliminated from the list as they are already addressed by item (g).

50A NR 149.39 (2)(e) " *This section requires a laboratory to maintain a copy of each version of NR149. This is unnecessary record keeping. Many of the previous versions are no longer available. "*

Department Response: Items (e) and (f) have been eliminated from the list as they are already addressed by item (g).

50A NR 149.39 (2)(f) " *It is an unnecessary burden for laboratories to maintain copies of each version of the EPA drinking water certification manual. If needed, then the Department or EPA should be able to produce older versions. "*

Department Response: **Items (e) and (f) have been eliminated from the list as they are already addressed by item (g).**

50B NR 149.39 (3)(c) 13 NOTE " *The note regarding the expiration of the exemption for emission counts from ICP instruments should be removed. I firmly believe many labs will still be using the older direct reading ICP instruments in 2010. Consequently [sic], they will not be able to reasonably comply with the requirement to capture emission counts. Perhaps this note could be modified to allow an exception for specific instruments. Failure to modify the language may force laboratories to replace instrumentation which could be an economic hardship for some laboratories.* "

Department Response: **The note has been removed in recognition of the significant complexity in converting raw signal emissions to final results associated with ICP technology**

B. Comments from the regulated community specifically on s. NR 149.39 (3)(c)

27 comments were received expressing concern that the proposed revisions would create such a fiscal burden on municipal laboratories that the municipal facilities would be forced to cease testing and contract out for their testing. Commenters generally stated either or both of the following: the proposed changes require too much of an additional burden, or that the information requested here is already documented in other places, and thus is redundant.

1 " *Records and documents, I always thought I had pretty good information on my documents, but the 21 categories of information is going to be hard for me to keep up with it all. I wear many hats in the town. And pretty much everything that is new is going to cost me extra hours. In a small town, we can't afford to raise our rates, because our rates are very high to begin with, when it comes to adding extra personnel. So I'd have to voice my opposition to this process too.* "

2 " *149.39(3)(c) Lists 21 things such as identity and reference to operating conditions of lab equipment will paperwork that is [sic] unnecessary. Most things can be addressed in the Quality manual or SOP.* "

4 " *NR 149.39 Records and Documents. For most labs, a good QA/QC program is already established to ensure proper handling and analysis of samples. Additional paperwork will only create additional paperwork and adds nothing to ensure better results.* "

5 " *under 149.44(3)(d), this is the wording for the calibration of thermometers. I ask that the wording be rewritten to include the allowability [sic] of a greater length of time for the initial calibration. It puts a hardship on the laboratories to buy a certified thermometer. If the time for measuring or for allowable calibration is only set at one year, some of the thermometers we purchase may have been on the distributor's shelf for quite a period of time. The standard in the industry for initial calibration to allow for that would be two years. And I have an example here from one of the vendors. What that would do is allow us to get full use out of the thermometers when purchased.* "

7 " *Rule NR 149.39 I am against. A good lab tech knows his equipment and how it works. Creating more paper work is a step in the wrong direction. The basic log that shows the history for all work done to each piece is sufficient.* "

11 " *Although I oppose some of the other parts of the amendments, I give NR 149.39(3)(c) as an example. All the information that you are purposing to have us record on a daily basis is included in the QC manual and/or SOP's. To record them again, on a daily basis, is repetitive, tedious, and will not improve data quality. It is my opinion, that those who dictate these new purposals are out of touch with the lab as it relates to the plant as a whole.* "

12A " *Records, 149.39. Most of the requirements of this section should be covered already in the required QC manual. The new recordkeeping requirements as proposed extend far beyond what is practical or necessary. It would only increase the hours spent in a lab office, not the quality of the data, and certainly not the quality of our lab equipment.* "

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- 12B " Records and documents. In the morning, I pick up a final and a raw every day for BOD, suspended solids, phosphorous, and ammonia. I record the time I take the sample, the temperature, and that I was the collector. I usually preserve the phosphorous and ammonia, and run the BOD and suspended solids. I record what time the tests are done and how the samples were preserved and by who. What more than this is really needed for a registered wastewater treatment plant? Way too much unneeded data. "
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- 13 " This is already covered in the plants Q.C. documentation and should be eliminated. "
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- 15 " This rule lists 21 categories of information that need to be recorded including factors such as operating conditions of the laboratory equipment and instruments. Currently wastewater treatment plants are required to maintain Quality Control Manuals, which outline steps taken to ensure that the tests being performed are being done accurately. We perform these additional quality control checks for every 20 samples and sometimes even less than this. The results of these have shown over the years that the quality of our testing speaks for itself. We have shown that the sampling that is performed is done accurately and in the right manner as has been required in the past. To put these additional regulations in place would not improve the quality of the testing performed. We feel that this section should be deleted or wastewater treatment plants be made exempt. "
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- 17B "lists 21 categories of information that needs to be recorded including factors such as the operating conditions of the laboratory equipment and instruments. These items should be governed by the QC Manual and do not need to be recorded for each test. This will add paperwork, increase time and cost to running samples and not improve the data quality. This requirement should be deleted or wastewater plants exempted. "
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- 20 " In all the discussions that I have heard on this proposed rule I have heard very little justification for making such sweeping changes. I have heard no claims of wide spread faulty data. Much of this rule seems directed at shoving more business to the commercial labs than addressing shortcomings at the municipal ones. There is a finite amount of money that a municipal utility has to spend on operations. It is imperative that it be used wisely. The more time and money that a facility has to spend to prove that it is protecting the environment, the less time and money it has to actually do it. "
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- 23 " This section lists 21 categories of information that need to be recorded including operating conditions of the laboratory equipment. It is my belief that this is information that is covered in a laboratory's Quality Control manual, and serves little additional purpose other than to increase the amount of paper and record keeping a lab needs to do, with little improvement in laboratory results. These same 21 categories may better serve the laboratories as guidance material for their QC manuals. "
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- 24 " Currently, each sampler in the Facility has a sample logsheet where temperature, sample amount, and operator on duty are recorded. Anytime one has to look back on who worked and what the condition of the sample was can be determined from this logsheet. Records of certification, calibration, and SOPs are currently included. "
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- 25 " The requirements listed in 149.39(3)(c) for 21 categories of information is [sic] onerous. This serves only to further drive up analysis labor costs, without improving data quality. Our lab quality control manual guides the lab technician and those temporarily assigned to provide the needed information. And this section should be deleted or at least exempted for wastewater labs. "
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- 26A " This section is the poster child for unnecessary detail in regulations, particularly for wastewater labs. For example, the 21 categories of information required in NR 149.39(3)(c) are absurd. As one lab noted, one of the 21 categories of information that needs to be recorded is the operating conditions of the laboratory equipment and instruments. Does the lab need to document the condition of all of its pipettes or beakers or thermometers for each test? The list could be endless. These items should be governed by the QC Manual and do not need to be recorded for each test. It will add paperwork, increase time and cost to running samples, and not improve data quality. These requirements should be deleted or wastewater plants exempted. "
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- 26B " NR149.39(3)(c) lists 21 categories of records that are supposed to be maintained. So at least the way this rule reads, (c)3, for example, preservation status of samples on arrival at the laboratory. If we have a lab that has failed to comply with that requirement, their license can be revoked. Now I'm sure, and what I've heard from the Department, well, is, of course, we would never revoke a license, based upon a single incident like that. Well, that may be the case, but this rule does not provide that.
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	<i>What the rule provides is extraordinary enforcement discretion. "</i>
30	<i>" The increased time and paperwork to list the 21 categories [sic] to be recorded for operating conditions of the laboratory equipment and instruments, is [sic] a complete waste of time and is already covered in our QC Manual. This requirement should be deleted or be exempt by the WWTP. Why should WWTP LABS keep their records for 5 years, up from 3 years, when audits are done every 3 years. "</i>
34	<i>" Agree with MEG. "</i>
35	<i>" Having reviewed the NR 149 rule revisions, it appears to me that a great deal of additional effort and some added expense would be required with a seemingly disproportionate amount of benefit gained. For this reason, I want it known that I am not in favor of the proposed revisions- particularly NRs 149.36, .39, .44, .46, .48, and .10, as these seem to be especially unreasonable and unnecessary to smaller labs. "</i>
36B	<i>" The documentation is also going to be an additional burden. The time period that the data needs to be maintained would be increasing from three to five years. And it's an issue of keeping track of everything for that long. Another issue that I object to is, apparently, we would have to verify that standards that were purchased outside the lab for that very purpose are accurate and certified. And the point of purchasing outside standards is to have accurate, certified standards. "</i>
38	<i>" Records and documents section 149.39 lists 21 categories of information needed to be recorded, including factors such as operating conditions of the laboratory equipment and instruments. This item should be governed by the QA/QC program, which we're under right now, and we feel, you know, like I said, I haven't heard that it isn't working well. And so there's a lot of additional costs, again, associated with working under that premise, not only time, equipment, wages, things of that nature. Again, adding in additional costs to the tune of, it could be anywhere up to \$11,000 annually. "</i>
40	<i>" The laboratory must maintain all analytical and technical records containing raw data/derived data (calculations)/original observations that are necessary for historical reconstruction of all laboratory activities that were necessary to generating reported results. Laboratory personnel must identify and record all operating conditions of the laboratory equipment and analytical instruments used, document/prove traceability of each standard and reagent used (includes purchased and internally prepared standards), condition and calibration status of equipment, procedures and techniques for reducing/translating raw data and observations into reportable results, protocols for analyzing quality control samples (including frequency, sensitivity, corrective actions, environmental conditions). Some of these procedures are not currently required so they will need to be developed and put into place before they are documented. "</i>
43	<i>" NR 149.39(3)(c) lists 21 categories of information that need to be recorded including information such as the operating conditions of the laboratory equipment and instruments. These items should be addressed by the Lab QC Manual and should not have to be recorded for each test. This requirement would add to the paperwork, increase time and cost of analyzing samples, and not improve data quality. "</i>
48	<i>" 149.39(3)(c) lists 21 categories of information that need to be recorded, including factors such as operating conditions of the laboratory equipment and instruments. These items should be governed by the Q&C manual, and do not necessarily have to be a record of each test. It will add additional paperwork, increase time, cost of running samples, and not improve data quality. These requirements should be deleted or exempt from wastewater treatment plants. I cannot believe that this is a supportive notation under flexibility, how the DNR says that this is going to provide better flexibility for wastewater treatment plants. And it's limiting the ability by wastewater treatment plants to pull this data together. And there too, again, is going to require significant training, personnel costs. "</i>
49A	<i>" NR 149.39 is duplicating many of the controls for record keeping that exist in the QC manual. Why would we want to create more paperwork? "</i>

49B " NR 149.39 is duplicating many of the controls for record keeping that exist in the QC manual. Why would we want to create more paperwork? We strive to make things easier in all other arenas. The EDMR and the ECMR are great examples of the DNR streamlining procedures. Yet, in this portion of the proposal, we seem to take a step back to extra paperwork. We are not opposed to using information to establish trends, but we are opposed to creating documentation that does not improve data quality. Many of these areas of data gathering would mean very little to a lab that doesn't test outside their own system. "

Department Response: **The intent is not to create redundant paperwork systems. The list of items represents the information for each sample analyzed which must be recorded somewhere. At issue here is the need for traceability of reported results back to the original sample. The intent behind this section was to more formally incorporate into Administrative Code the requirements for record keeping currently appearing as NR 149.06 (1). In the final rule, some items, which are clearly contained in other required documents, have been eliminated. Outreach efforts will be devoted to clarify for the small lab community that no additional records are being required.**

26. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.40 – Standard operating procedures.

6 NR 149.40 (1), (2) " This is a very gray area. We feel that it should be re-written. One should not be allowed to simply copy an approved method. They never contain all the elements that you have defined as a component of an SOP [Standard Operating Procedure]. No method contains all the relative elements so therefore you must write the method you are following incorporating (i.e. quality control criteria, is not found in every method) those elements. Sure, it can be cited else where but you still have to write and edit the method with the appropriate citations of where that info can be found. If you have to create multiple reference to various locations that you have supportive evidence for the method why not just write the method? This would make it easier for review and audit without having to look in multiple areas for documents to find out just what is being done. Requiring a written method containing all of the defined elements in one location is more effective in the long run. "

Department Response: **A laboratory can only use a referenced method as its SOP if the method is followed precisely. The Program will provide guidance to assist laboratories in developing SOPs after final rule adoption.**

27. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.41 – Method selection.

50A " NR 149.41(2) " Shouldn't this paragraph cite appendix III ? "

Department Response: **In the final rule, a note has been added to clarify that, " A list of authoritative sources is provided in Appendix III to this chapter".**

28. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.44 – Laboratory equipment.

A. 12 comments received from the regulated community regarding sections 149.44 (3) through (6)

23 NR 149.44 (3)(g) " The calibration portions of this section are hardly reasonable. An example of this in paragraph (g), requires Analytical Balances used at least once per month to be checked at least once per month against a weight of 1 gram and a weight of 1 milligram. Additionally these same weights are required to be traceable to National Institute of Standards and Technology (NIST), and Certified for accuracy every 3 years by a metrology service, or a new set of weights purchased that are traceable to NIST. A set of NIST traceable weights is over \$1000 for a complete set. If the weights

are checked by the analyst and the balance certified annually, why should labs incur such a large expense for testing 3 influent and 3 effluent solids test a week? There should be an exemption in this section for Wastewater Labs. "

50C NR 149.44 (3)(g) " *Regarding checking analytical balances—instead of saying, ‘...a minimum of one weight in the gram range and a minimum of one weight in the milligram range,’ it would be better to say, ‘...a minimum of two weights in the expected range of use.’ "*

Department Response: **Balance verification criteria are not new requirements; these have been a program standard for many years. The language regarding the number of weights to use has been edited for clarification. The Department will also develop guidance to indicate that labs need not purchase an entire set of certified NIST weights. They need only obtain weights necessary to verify the calibration status of their balance(s).**

12B NR 149.44 (3)(g) 2. " *Calibration and verification support equipment. The weights do not need to be certified every three years, if you internally check them once a year, when your annual service is done. If the weights are stored in a manner that protects their integrity and are checked when the annual service is done, I would think that they would be considered certified accurate. We have had the same weights for over 15 years and have never had them sent out for certification. When the balance guy shows up every year, we have him weigh our weights. They weigh exactly the same every year. "*

2 NR 149.44 (2)(g) 2 " *It's an added expense to send in analytical weights for certification. If labs voluntarily have an outside company check and perform maintenance on their balances every year, they should be exempt from the proposed requirement. These companies usually check the certified weights against theirs. "*

5 NR 149.44 (2)(g) 2 " *... this is the weight requirements for recertifying weights. We request that that be changed from three to five years, to match the national standard. "*

Department Response: **The language has been changed to require re-certification of weights every 5 years, to match the national standard. A provision will be added to require this re-certification sooner if balance checks using these weights suggest that a change in the certified weight has occurred. The re-certification of NIST Type 1 weights must be done under specific controlled conditions that are not available in a standard laboratory environment.**

NR 149.44 (3)(i) " **Requested changes:** *Change ‘quarterly’ to ‘annually’. Add ‘These devices need not be checked for accuracy when they are used in method steps or applications that do not require use of class A glassware.*

46A **Comments:** *Requiring quarterly checks for accuracy is an undue burden. Many labs do not perform these checks in house, the equipment is sent out on a fee basis. Turn around time can be as long as two weeks to a month. Requiring checks when the devices do not require class A accuracy is a wasteful burden. Not having them checked will not adversely affect sample results. "*

Department Response: **Numerous scientific publications cite the need to verify the accuracy of these instruments at least quarterly. However, the exemption for such instruments when they are not used solely in method steps where class A accuracy and precision are not required has been added. Paragraphs (i), (j), and (k) have been rewritten for clarification.**

50C NR 149.44 (3)(k) " *It is stated that, “Disposable pipettes need not be checked for accuracy when they are used in method steps or applications that do not require use of class A glassware.” However, it is also stated (see paragraph i) that mechanical and automatic volumetric dispensing devices need to be checked for accuracy at least quarterly irregardless [sic] of the application for which they are used."*

Department Response: **Paragraphs (i), (j), and (k) have been rewritten for clarification.**

NR 149.44 (6)(f) 3 " *This is one of many examples of sentences that are too complex. Generally, throughout NR 149, there are way too many of the following words: if, or, unless. Sentences run on! They contain too many exception clauses! They become unintelligible! Break sentences down into more concise statements. A person must re-read sentences and paragraphs several times to decipher them.* "

Department Response: **Subdivisions 149.44 (6) (f) 2. and 3. have been combined and rewritten for clarity.**

50C NR 149.44 (6)(h) " *Please explain what you mean by "calibration zeros."* "

Department Response: **The word "blanks" have been substituted for the word "zeros". For colorimetric tests, methods frequently require differing solutions be used for setting the zero, versus instrument blanks or method blanks. In their procedures, laboratories must specify how instruments are "zeroed", solutions used for their instrument calibration blanks, and how they meet the requirements of this chapter for method blanks.**

42 NR 149.44 (6)(i) " *The addition of the word 'or' at the end of item 1., and before item 2., would better serve to indicate that these two items are not BOTH required, rather one or the other would be required as an exemption from the use of a second source check of initial calibrations.* "

Department Response: **Paragraph (i) has been re-structured for clarification.**

50C NR 149.44 (6)(l) " *This sentence, "Laboratories shall quantitate sample results by bringing their associated responses to the ranges specified in this section," is difficult to understand.* "

Department Response: **The language has been changed for clarification.**

50C NR 149.44 (6)(o) " *The note under NR 149.39 (3)(c) 13. (p. 40) should also apply to this section.* "

Department Response: **The language has been revised to reflect the exemption as noted.**

B. Comments received from the regulated lab community specifically regarding s. NR 149.44 (7).

27 comments addressing this section were received. Commenters generally believe that the proposed changes require too much of an additional burden, and that the frequency of re-calibration is excessive in terms of quality improvement of data generated relative to the cost.

2 " *Analysis of a CCV for BOD, CBOD and other tests not amenable to spiking should be specifically exempted from these requirements.* "

4 " *NR 149.44 Laboratory Equipment. For most labs, a good QA/QC program is already established to ensure proper handling and analysis of samples. Additional paperwork will only create additional paperwork and adds nothing to ensure better results.* "

7 " *Rule NR 149.44 will cause unnecessary cost to the lab do to using more standards and needing more time. I do 1 PH test a day and for me to calibrate the meter after I am done with the test is an unnecessary burden to impose on a small scale lab.* "

12A " *Lab equipment, 149.44. The calibration requirements of this section again exceed what is necessary. The existing requirements for calibration, as well as following the equipment manufacturer's operating protocol, have been sufficient in the past to ensure quality data.* "

13 " *An exemption should be granted to WWTPs.* "

15	" In this section regarding the calibration of the testing equipment, the proposed rule would require calibration both prior and after the sample run. Currently, we perform a calibration prior to each sample run performed. We feel that to do an additional calibration after a sample run is not necessary. The current equipment that we use is kept in good repair and they hold the calibration for the entire sample run. If it is found that the testing equipment is not working properly, we either have the testing equipment immediately repaired or the equipment replaced. We feel that all wastewater treatment plants take great pride in the work they perform. Unlike a private lab, which may cut corners on equipment to preserve their bottom line, municipal labs do ensure that they are testing with operational equipment. To require this on municipal labs is unreasonable. We request that this section either be deleted or wastewater treatment labs be made exempt. "
17B	" The calibration portions of NR149.44 are unreasonable and unnecessary. NR 149.44(7) requires recalibration before and after a sample run even if only ONE sample is run per day. There should be an exemption for wastewater labs. "
19B	" Another one is the laboratory equipment. We went through that, with the unnecessary running of the recalibration. We figured it out. It would cost us almost \$30 a day to recalibrate everything. And it would cost total, in a year, \$6,200. And we figured this, and that doesn't even include the benefits for the person running it or the chemical cost. So we're against that. "
20	" In all the discussions that I have heard on this proposed rule I have heard very little justification for making such sweeping changes. I have heard no claims of wide spread faulty data. Much of this rule seems directed at shoving more business to the commercial labs than addressing shortcomings at the municipal ones. There is a finite amount of money that a municipal utility has to spend on operations. It is imperative that it be used wisely. The more time and money that a facility has to spend to prove that it is protecting the environment, the less time and money it has to actually do it. "
26A	" The calibration portions of NR 149.44 are unreasonable and unnecessary, particularly the requirements for recalibration in (7) when few samples are run. There should be an exception for wastewater labs or for analytical runs in dedicated labs where there are runs of less than 10 samples or where the runs take less than 15 minutes to complete. "
27	" The City of Merrill Water and Sewer Utility is opposed to the proposed revision of NR 149. There are a number of reasons for this opposition. 2. Common Sense. (B) The calibration portion of this section are unnecessary and unreasonable. Our lab would end up doing more calibrations than tests. This section should be deleted or wastewater labs be exempted. "
35	" Having reviewed the NR 149 rule revisions, it appears to me that a great deal of additional effort and some added expense would be required with a seemingly disproportionate amount of benefit gained. For this reason, I want it known that I am not in favor of the proposed revisions- particularly NRs 149.36, .39, .44, .46, .48, and .10, as these seem to be especially unreasonable and unnecessary to smaller labs. "
38	" Laboratory equipment, NR149.44 calibration, for example, requires a calibration before and after you ran samples every day. There should be an exemption to the wastewater labs for analytical runs, for runs that are less than ten samples. Again, if we have to repeat all of this information again, we're dealing with another probably \$5,000 additional cost. "
40	" Redundant daily calibrations before sampling/inbetween [sic] samples/prior to turning off equipment (ammonia meter and BOD meter), quarterly verification of equipment accuracy. "
48	" NR 149.44 seems unreasonable and unnecessary. For example, in 149.44(7), requiring recalibration before and after sample running, even if one sample is only run per day. There should be an exempt [sic] for wastewater labs or an analytical run that is dedicated to labs that have ten or less samples. In our particular example in Winneconne, we would typically run six samples overall, three, a final, a GGA, a blank. And that would normally take 25 minutes. According to your guideline that's laid out in the new revision, we would not be able to comply. "
49A, 49B	" We feel the calibration portions of NR 149.44 seem excessive, requiring recalibration before and after a sample run. And this would apply, even if only one sample were analyzed per day. "

Department Response: **Significant revisions have been made to this entire subsection to address the concerns presented. Revisions include elimination of the requirement to perform calibration verification at the end of each analytical run.**

50C NR 149.44 (7)(b) " *'...continuing instrument calibration procedure...'* should be changed to *'...continuing instrument calibration verification procedure...'* "

Department Response: **Significant revisions have been made to this entire subsection to address the concerns presented. Revisions include elimination of the requirement to perform calibration verification at the end of each analytical run.**

NR 149.44 (7)(c) " **Requested change:** *Strike this provision in its entirety, or substitute the word 'may' for 'shall'.*
46A **Comment:** *The need for same source has not been established. A continuing calibration standard will verify the continuing calibration of the instrument, whether it is from the same or different source. Since the initial calibration may be used up to one year, the availability of a same source standard throughout that period is problematic. "*

Department Response: **Significant revisions have been made to this entire subsection to address the concerns presented. Revisions include elimination of the requirement to perform calibration verification at the end of each analytical run.**

50C NR 149.44 (7)(d) " *change 'The number of calibrations standards...'* to *'The number of calibration standards...'* "

Department Response: **Significant revisions have been made to this entire subsection to address the concerns presented. Revisions include elimination of the requirement to perform calibration verification at the end of each analytical run.**

50C NR 149.44 (7)(d) 6 " *Change '...concentration...'* to *'...concentrations...'* "

Department Response: **Significant revisions have been made to this entire subsection to address the concerns presented. Revisions include elimination of the requirement to perform calibration verification at the end of each analytical run.**

NR 149.44 (7)(e) " **Requested change:** *Add the word 'Additional' between '(e)' and 'Continuing'. Strike items 1. and 2. in their entirety.*
46A **Comment:** *NR 149.44(7) (a) already requires a CCV with each batch and each analysis day when no calibration is performed on day of analysis. With small sample batches, this is entirely adequate. Some methods, such as flame AA for metals, are subject to drift and may require additional calibration checks before, during, and after the analysis. In those cases, the methods specifically require this. Since laboratories must follow stricter method specific steps, it is not necessary to require it in the rule"*

Department Response: **Paragraph (e) has been revised and incorporated into 149.44 (7) (a) as suggested by the comment.**

36A NR 149.44 (7)(e)2 " *This requirement has minimal benefit and great additional cost for analyzing small batches of samples. A practical example is completing a continuing calibration of BOD samples. This facility reports 2 BOD test results per day. The analyst spends 5 - 10 minutes calibrating the meter, and about 2 minutes for each sample. Now the analyst has to spend an additional 5-10 minutes or more to recalibrate the meter and document the continuing calibration, 5 to 10 minutes after the first calibration. Instrument drift occurs over time. Recalibration is necessary at some point in time. Allow laboratories to establish guidelines for recalibration based on documented experience. The cost of this requirement is estimated at \$5,468 per year in labor costs, alone. "*

Department Response: **Paragraph (e) has been revised and incorporated into 149.44 (7) (a) as suggested by the comment. The requirement for a continuing calibration verification to be performed at the end of an analytical run has been eliminated.**

- 42 NR 149.44 (7)(f) " *This section states "The laboratory shall establish acceptance criteria for continuing calibration verification. The type of criteria chosen and the acceptance range shall be appropriate for the calibration model selected and reduction technique or algorithm chosen."*
Following this, default criteria are stated in the absence of any method regulation or program criteria. This seems to make the two sentences above moot. I suggest deleting these two sentences in the interest of clarity. "
- 50C NR 149.44 (7)(f) " *'Unless otherwise required by regulation, method, or program...'—from this phrase it is not clear if the lab must use the stricter acceptance criteria for continuing calibration verification, or if they can use either one.* "

Department Response: **The paragraph has been revised to address these comments.**

- 50C NR 149.44 (7)(g) " *The second sentence of this section is a run-on sentence, which makes the meaning unclear. The second sentence could be re-stated as follows: ' If the results of this second calibration verification fail to meet acceptance criteria, the laboratory shall take corrective action. After taking corrective action, the laboratory must perform two consecutive calibration verifications that meet acceptance criteria or must perform another initial calibration.'* "

Department Response: **The suggested change has been made.**

- 46A NR 149.44 (7)(h) " **Requested change:** *add the words 'or qualified.'* after 'reanalyzed' and *strike everything thereafter including subsections 1 through 4.*
Comment: *There are times when it is appropriate to retain results with proper qualification beyond those specifically spelled out in (h)1 through (h)4 Requiring reanalysis under those conditions is a waste of laboratory time and effort. The decision to reanalyze or qualify should be left to the laboratory and client. Example, a CCV fails at 88% on a metals run for an internal pretreatment program. It is not discovered until after the run is complete but with sample still available. Some results are detectable, but all are far below a regulatory or action limit. Requiring reanalysis may be an unacceptable burden. Results reported with proper qualifiers are acceptable.* "

Department Response: **The suggested change has been made.**

29. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.45 – Measurement traceability.

- 36A NR 149.45 (2) " *I fail to see the value of maintaining a log of the reagents and standards up to five years after they have been used up or discarded. I also fail to see the benefit of creating an intricate web of documentation for intermediate and working standards and reagents in our facility when we have one bottle of standard or reagent from which all subsequent intermediate standards and working stocks are prepared. The preparation, handling, and storage life of intermediate standards and working stocks are clearly defined in the laboratory manual. Containers are labeled with the appropriate information. The analyst that performs the analysis is also responsible for preparing and maintaining the intermediate standards and working solutions. The proposed requirement only makes sense in a large lab with multiple analysts. The cost to prepare and maintain this reagent log is estimated to be about \$1,500 per year at this facility.* "
- NR 149.45 (2) " *I am sending you this email to voice my opposition to proposed revisions to NR149 Lab Certification. I believe that the revisions are not warranted and would place a significant financial burden on the operation of the City's wastewater treatment facility laboratory.*
- 40 *The chemist will document all details (lot number, manufacturer date of receipt, etc.) related to each standard, reagent and reference material. Records will be kept that include full detail (originating stock/heat compound/preparation date, preparer etc.) of standard and intermediate reagents. Chemist will need approximately 40 hours to maintain this requirement. 40 hours at \$27.96/hour = \$1118."*

Department Response: **The requirement for maintaining a reagent log can be limited to stock solution, not a record of each day's dilutions of that stock or reagent. Tracking lot numbers can be an invaluable tool when trying to identify a source of an analytical problem. In addition, manufacturers utilize lot numbers to identify faulty preparations and notify users of problems.**

30. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.46 – Handling of samples.

A substantial number of comments were received on each of three key issues within this subsection (bottle cleaning, chain of custody protocols, and time requirements for sample preservation). Comments related to these items have been grouped to make for easier reading.

A. Miscellaneous comments received from the regulated laboratory community regarding s. NR 149.46.

35 NR 149.46 " *Having reviewed the NR 149 rule revisions, it appears to me that a great deal of additional effort and some added expense would be required with a seemingly disproportionate amount of benefit gained. For this reason, I want it known that I am not in favor of the proposed revisions- particularly NRs 149.36, .39, .44, .46, .48, and .10, as these seem to be especially unreasonable and unnecessary to smaller labs. "*

49B NR 149.46 " *NR 149.46 would impose unrealistic controls on chain of custody and sample preservation for smaller wastewater labs. Chain of custody is designed to supply a traceable delivery route for a sample being analyzed. This would only be of importance if the lab were performing the analysis for a customer that would require documentation, proving that that sample is not tampered.*

In addition, the 15 minute window requiring preservation of samples after collection would be nearly impossible for us to achieve. We have remote sampling locations that are more than 15 minutes apart. That would basically require us to pull over and preserve our samples with acid. "

Department Response: **Specificity regarding the 15 minute window for sample preservation has been eliminated in the final rule. In addition, detailed chain-of-custody requirements have been eliminated for those facilities that collect and analyze their own samples.**

23 NR 149.46 (4)(d) " *' Samples are required to be stored separately from all standards, reagents, food and other potentially contaminating sources,' according to the proposed rule. If samples, reagents, and standards were all stored in closed containers the contamination would be minimal and the \$1000 expense for a wastewater lab to have an additional refrigerator would not be necessary. I don't see the reasoning for this requirement of wastewater labs that store their samples, reagents and standards together for a short period of time in closed containers. "*

Department Response: **The intent here was to address both safety and sample or standard contamination issues. The language has been removed in the final rule.**

25 NR 149.46 (3)(f) " *NR 149.46, (3)(f) under handling of samples, sample handling protocols. While we see the value of performing these 13 chain of custody procedures when performing analyses for other entities, we see no practical purpose for this labor-intensive information to be generated for internal use samples. These requirements should be deleted or exempted for wastewater lab internal samples. "*

Department Response: **The entire subsection has been revised to exempt those facilities that collect and analyze their own samples from chain-of-custody procedures. Documentation of critical sample collection information will still be required, but this is addressed elsewhere within this rule.**

- B. NR 149.46 (1)(b): Twelve (12) comments were received from the regulated laboratory community.

This section deals with requirements associated with sample collection bottle cleanliness.

- 2 NR 149.46 (1)(b) " *What is the procedure and frequency for checking carboys, and what is the acceptance criteria for bottle blanks?* "
- 4 " *For most labs, a good QAIQC program is already established to ensure proper handling and analysis of samples. Additional paperwork will only create additional paperwork and adds nothing to ensure better results.* "
- 7 " *Rule NR 149.46 I am against. When the proper rules are followed now, as they are. their should be no problems. If their is a person doing it wrong now they will be doing wrong after the proposed change. Again this will be an extra burden put upon the labs.* "
- 12A " *Handling of samples, 149.46. This section seems to have been written with a commercial lab in mind. Chain of custody forms are wholly unnecessary for internal use at a wastewater facility. We only use them when samples are shipped to outside labs, and these are provided by the analyzing lab.* "
- 12B " *Handling of samples. When it comes to bottle cleaning, I think we need clarification on the wording shall ensure or have the code say that if you have a bottle cleaning procedure in your QC manual, that it must be followed, and then ensure that it is followed.* "
- 28A " *This section requires laboratories to ensure that carboys (sample containers) are free of the analytes of interest. Without further qualification, this could pose an unreasonable burden on laboratories, especially when sensitive methods are used to evaluate containers used for traditionally "high level" samples such as wastewater influent. I would suggest that the department add a clarification to allow for the presence of analytes of interest if they are below levels that could contribute significant interference to the measurement.* "
- 36A " *The sample handling requirements are inappropriate and burdensome for smaller wastewater laboratories. The chain of custody requirement is pointless when one person is responsible for collecting, preparing, and analyzing samples, and documenting results. There is no chain of custody to follow when samples are collected, taken directly to lab, and analyzed by the same individual. The requirement to label each sample with a unique sample ID is also unnecessary for the same reasons listed above. This requirement would force the analyst to re-label permanently marked and dedicated sample containers, daily. This requirement is only appropriate for samples that change custody or samples that are stored for later analysis.* "
- 36B " *The sampling requirements I find to be very objectionable. As I said previously, these requirements should be directed at larger labs, and they're inappropriate for smaller wastewater labs. In our particular circumstance, I have one individual who is responsible for collecting samples and analyzing samples. He typically will leave the lab in the morning and collect the samples, take meter readings, check equipment, observe treatment plant operations. Typically, it takes about one-half of an hour to make that circuit. With the 15 minute limitation on sample temperatures, it would make things very difficult, in order to operate our lab . And I think unnecessary, because the same person who's taking the sample is also the person who is analyzing the samples. The same person takes the samples directly, they go to the lab, they analyze the samples. There's a clause in there about rejecting samples. It's not an option for our wastewater treatment plant. We have to do these samples. They have to be preserved under this regulation, would have to be preserved. We couldn't take the chance that they might be rejected because of the criteria. That would require my lab operator, on a given day, to go out with a cooler full of ice, in order to collect the samples to bring them into the lab, because they would exceed the 15 minute period. And then it's ironic that some of the samples would have to be warmed to room temperature, as soon as they got into the lab, in order to complete the analysis.* "
- 42 " *The Department should clarify the intent of usage of carboys for sample collection versus carboys when used for sample storage. The language does not clarify at what point the carboy becomes a sample container and not a sample collection vessel.* "

- 45A " The lab shall ensure that the containers are free of the analytes of interest. "Ensure that the containers are free" is not defined. This can be interpreted a number of ways; anything from a quick rinse to sterilization and/or testing of water droplets left in the container. "
- " **Requested change:** between 'shall' and ensure' insert the words 'have a system to'
- 46A **Comment:** As written, this section could impose an unsustainable burden on the small municipal laboratory. Potentially a laboratory could be analyzing as many container or trip blanks as analytical samples. The added wording would clarify that the laboratory can satisfy the requirement by instituting a system such as setting a bottle cleaning protocol, without the need for an overly burdensome analytical requirement. "
- 50C " — In the case of inorganic parameters, sample collection containers will usually not be "free" of the analytes of interest, and they will "contribute contaminants." The question is what level of contamination is acceptable (e.g. less than the LOD for a given analyte)? "

Department Response: **The intent is to offer guidance which provides laboratories flexibility in addressing concerns related to sample container cleanliness. The section has been re-written to address the numerous comments received.**

C. NR 149.46 (3) (a,e): Twelve (12) comments were received from the regulated laboratory community.

This section deals with requirements associated with sample chain of custody.

- 2 NR 149.46 (3)(a,e) " Too detailed COC procedures for wastewater labs. Unnecessary and impractical. "
- 15 " This section requires a detailed chain of custody procedures for all samples. Although this may make sense for private labs that have several employees handling samples for several different businesses, individuals or municipalities, to make this a requirement for labs whose main source of testing is for internal use only places undo hardship on these labs. We feel that to require this additional paperwork, places undo hardship on smaller municipal labs such as ours and are not necessary. We feel that this section should be deleted or municipal labs be made exempt. "
- 17B " ... requires detailed chain of custody procedures for all samples that are unnecessary for internal use. This section also requires preserving samples taken more than 15 minutes after collection time. This is unnecessary and wastewater lab exempted. "
- 20 " Some of the other changes require ... chain of custody records on samples more that 15 minutes old, are both unnecessary and time consuming. "
- 23 " While there may be significance to this section for laboratories that take in samples from outside entities, this section has little pertinence to a small wastewater lab. Most Discharge Monitoring Permits require the testing of influent and effluent samples. For most wastewater labs that would mean two sample bottles at one time on their lab bench. The benefit for a small wastewater lab to develop a "unique identification code" would be minimal to the waters of the State of Wisconsin or the quality of the lab data produced. An exemption to wastewater labs or deletion of the requirements should be instituted. "
- " This section may also make sense in large commercial labs, but is of little or no value in small labs. The section of greatest concern is NR 149.46(3) sample handling protocols. The two biggest areas of concern are:
- 26A
- Chain of custody procedures that are unnecessary for internal use.
 - Requirement of preserving samples more than 15 minutes after collection time. This is unnecessary and impractical for many labs with long distances and limited staff. These requirements should be deleted, or wastewater labs exempted. "
- 27 " The chain of custody requirement in our plant is redundant since the person who collects the sample performs the analysis. This section should be deleted or wastewater labs be exempted. "

- 30 " Requires a detailed chain of custody for all samples, including an individual ID CODE for each sample. This is unnesscessary [sic] for a WWTP internal use. The preservation of samples taken more than 15 minutes after collection time is impractical, especially when a test such as BOD requires the samples to be at room temperature before analysis. "
- 38 " Handling of samples, which is NR149.46, requires detailed chain of custody procedures for all samples that are unnecessarily for internal usage. This section also requires preserving samples taken more than 15 minutes after collection. Not only is it unnecessary and impractical for many labs, just with the long distances and limited staffs, this requirement should be deleted from the wastewater labs or at least exempt. "
- 43 " ... requires detailed chain of custody procedures for all samples that are unnecessary for internal use. This section also requires preserving samples taken more than 15 minutes after collection time. Our technicians have to drive out to the effluent treatment plant to pick up the treated effluent composite sample and collect a number of other process samples on their rounds. To avoid the preservation requirement, our technician may have to make two trips. This seems to be an unnecessarily stringent requirement with no proven improvement in data quality. "
- 48 " NR 149.46(3), requirements for the detailed chain of custody procedure for all samples. It's unnecessary for internal use. As an example, our sampling unit is on level two in the plant. The samples never leave the plant. By the time the operator cleans and records the temperature of the sampling unit, and brings them to the upper level, into the lab, that may take as much as 20 minutes. And as spelled out, as to my understanding in NR 149, the samples have to be brought to room temperature, before they can be analyzed. We feel that this requirement should be deleted from the wastewater lab exemption. "
- 49A " NR 149.46 would impose unrealistic controls on chain of custody for smaller wastewater labs. Chain of custody is designed to supply a traceable delivery route for a sample being analyzed. This would only be of importance if the lab were performing the analysis for a customer that would require documentation, proving that that sample is not tampered. "

Department Response: The section has been revised to clarify that formal chain-of-custody documentation will only be required in rare situations that will not apply to a typical small municipal wastewater laboratory. Post-promulgation outreach efforts will clarify that adoption of complex alpha-numeric sample identification protocol is unnecessary. Laboratories shall only be required to incorporate a system by which samples and their results can be quickly linked without confusion.

D. NR 149.46 (3) (b,c) Fifteen (15) comments were received from the regulated laboratory community.

This section deals with establishing a 15-minute window for performing sample preservation.

- 5 NR 149.46 (3)(b,c) " ... the wording is such that the samples received by the laboratory within 15 minutes of collection. This is allowing the non-preservation, thermal preservation of the samples. We request that the time inclusion be inserted somewhere in that wording to allow time for the login. Currently, the wording does not allow any time from the time that the samples, they may have been taken, driven to the laboratory, dropped off, and it may be 14 minutes, and it does not allow any time for the laboratory to log in samples. "
- 12B " Running samples within 15 minutes after collection is way too demanding on wastewater labs. What difference does it make if I run a TSS sample collected at 8:00 a.m., if I run it at 8:15 a.m. or if I run it at 9:30 a.m., after break? And with BOD, the sample needs to be warmed up to 20 degrees Celsius. We slowly warm up our final in a water bath now. We will have to heat it, according to the new code. This needs to be removed for registered wastewater labs. "
- 12A " Another proposed requirement is the preserving of samples 15 minutes after collection. This is just not practical. We transport samples to the lab as soon as we can and always before 30 minutes. In the case of the BOD test, we actually have to bring the sample up to room temperature, before we can run the test. Wastewater labs should be exempted from this requirement or it should be deleted. "

17B	<p>" ... requires detailed chain of custody procedures for all samples that are unnecessary for internal use. This section also requires preserving samples taken more than 15 minutes after collection time. This is unnecessary and wastewater lab exempted. "</p>
18	<p>" Recent telephone discussions with RAC [Rules Advisory Committee] members indicated provision Ch. NR 149.46 (3) (c) was included to coincide with established sample handling protocols listed in Ch. NR 219, which govern analytical test methods and procedures. Sample preservation procedures listed in Ch. NR 219.04 Table F do not associate a time requirement for chemical preservation for ammonia and total phosphorus parameters. "</p>
20	<p>" Some of the other changes require additional record keeping (NR149.39), excessive calibrations (NR 149.44), and chain of custody records on samples more that 15 minutes old, are both unnecessary and time consuming. "</p>
25	<p>" NR 149.46, handling of samples, (3)(c), sampling handling protocols. We receive samples for permitted entities that transport their collected samples to our laboratory immediately after collection. Their transport time is never more than 20 or 30 minutes. It would be impractical for them to attempt thermal preservation, since, in that amount of time, the sample may not have even had the opportunity to attain the required thermal preservation level. When a BOD analysis is required, the sample would need to be brought back up to room temperature anyway. When not being analyzed immediately by our lab, transported samples are immediately thermally preserved at our site upon arrival. Standard methods does not even specify an exact time, citing only the shortest possible time. Since standard methods compliance is being met by our current protocol, it would not be viable to qualify this data, given the samples are either being analyzed or preserved in that shortest possible time. Therefore, we believe this provision should either be deleted or wastewater labs should be exempt from this provision. "</p>
26A	<p>" This section may also make sense in large commercial labs, but is of little or no value in small labs. The section of greatest concern is NR 149.46(3) sample handling protocols. The two biggest areas of concern are:</p> <ul style="list-style-type: none"> • Chain of custody procedures that are unnecessary for internal use. • Requirement of preserving samples more than 15 minutes after collection time. This is unnecessary and impractical for many labs with long distances and limited staff. <p>These requirements should be deleted, or wastewater labs exempted. "</p>
30	<p>" Requires a detailed chain of custody for all samples, including an individual ID CODE for each sample. This is unnesscessary [sic] for a WWTP internal use. The preservation of samples taken more than 15 minutes after collection time is impractical, especially when a test such as BOD requires the samples to be at room temperature before analysis. "</p>
34	<p>" Agree with MEG. "</p>
36A	<p>" The maximum allowable 15 minute transport time is problematic in several ways. Analysts in small wastewater laboratories have other responsibilities in addition to laboratory duties. This often results in monitoring equipment, taking meter readings, observing processes and etc. as they are collecting samples. The 15 minute time limit will require personnel to take multiple dedicated trips to collect samples daily, without completing their other duties. Analysts that take longer than 15 minutes for sample collection will be forced to carry ice coolers to hold collected samples in. This is also unrealistic because samples in ice for just a few minutes will not be cooled to 4°C, and thus will fail to meet the thermal preservation requirement. One is left to conclude that DNR wants these samples to be left on ice for several hours to cool to 4°C, then , in many cases warmed to room temperature for analysis, instead of analyzing the samples as soon as reasonably possible after collection. "</p>
38	<p>" This section also requires preserving samples taken more than 15 minutes after collection. Not only is it unnecessary and impractical for many labs, just with the long distances and limited staffs, this requirement should be deleted from the wastewater labs or at least exempt. Again, if that isn't, there is an additional \$2,500 in costs. "</p>
43	<p>" This section also requires preserving samples taken more than 15 minutes after collection time. Our technicians have to drive out to the effluent treatment plant to pick up the treated effluent composite sample and collect a number of other process samples on their rounds. To avoid the preservation requirement, our technician may have to make two trips. This seems to be an unnecessarily stringent requirement with no proven improvement in data quality. "</p>

45A " Language proposed states that samples can be received by the laboratory within 15 minutes of collection and either analyzed or preserved. Many analyses cannot be completed within 15 minutes. Samples need to be warmed. Most often these samples are allowed to slowly warm to room temperature as the tests are set up. This language calls for the unnecessary purchase of a warming oven or bath, and perhaps even another laboratory person in order to get all the analyses done within 15 minutes of collection. After a wastewater sample has been sitting for a day while being composited, another hour or two will not make a big difference in the results if the test (such as BOD or TSS) is not completed within 15 minutes of collection. "

49A " In addition, the 15 minute window requiring preservation of samples after collection would be nearly impossible for us to achieve. We have remote sampling locations that are more than 15 minutes apart. That would basically require us to pull over and preserve our samples with acid. "

Department Response: **This section has been revised to eliminate reference to the timeliness of sample preservation. This issue can be addressed through other mechanisms.**

31. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.47 – Laboratory test reports.

6 NR 149.47 (1)(e)(10) a " NR 149.47 (e) 10.a. We would like this deleted. If the results are above the LOQ then who cares. If something was unusual (i.e. matrix issues etc) then that is why a qualifier can be noted. We don't feel it is necessary to clutter up a report for less than 1% of our clients that would want to know. We don't know of any program within the department that wants to know the dilution factor. Do we report dilution factors for BOD? Clients need results. Not a copy of the bench sheet.

The proposed rule changes are a huge step in the right direction in improving upon the current version of NR 149. No matter how strict the code revision is now or in the future, you are not eliminating anyone from participating. You are establishing the rules of the game; here are the rules and you can play if you abide by them. "

Department Response: **As suggested, the requirement has been eliminated.**

42 NR 149.47(1)(e) (11) " The following NOTE appears at the end of the current NR149.15 Data Reporting: The requirement in sub. (3) becomes effective January 1, 1997 only for those substances with standards specified in chs. NR 105, 140 and 720 that are below the applicable limits of quantitation. Chapter NR 809 requires that this information be reported for all regulated primary drinking water contaminants. The department shall annually publish a list of these substances. Laboratories shall use the best available analytical science to determine whether, in their best professional judgment, a substance has been detected.

This concept has been lost in the revised NR149, and could be construed as an effort to require labs to report all data (including soils and sludges) to the MDL. As there is no effective way to perform an MDL Study that relates to all soils and sludges, and as a manner in assuring that the list of analytes which must be reported to the MDL is maintained, I ask that this NOTE be inserted in the proposed revision of NR149. It could be included following NR149.47(1)(e)11 "

Department Response: **The note referenced by the commenter has been a source of confusion, as it imparts in this rule, authority over data generated for other Department programs. Removal of the reference was intentional in order that this rule be limited to specific requirements governed by the Laboratory Certification and Registration Program. Other Department programs that have specific reporting needs should specify those requirements in their rules.**

36A NR 149.47 (1)(e) (1-14) " This section is completely inappropriate for laboratories that report analytical results directly to DNR. These requirements are only necessary when analytical results are reported to an outside party, who in turn, report the results to DNE. or other regulatory agencies. The requirement would force our laboratory to create a paper report of analytical results, while the our monthly DMR data is submitted to DNR via electronic format. This requirement is senseless, and detracts from the DNR's long range goal of streamlining data submittal through use of electronic reporting. "

Department Response: **Laboratory reports are not required to be issued when laboratories submit data to the department using agency-provided forms or report electronically, using agency software or websites. This exemption is provided in s. NR 149.47 (1)(d).**

32. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.48 – Quality control requirements for chemical testing.

A. Comments from the laboratory community specifically related to s. NR 149.48 (1)(d).

Sixteen (16) comments received specifically related to sub. NR 149.48 (1)(d). This subsection (1) (d) introduces the requirement to employ second source standards to prepare laboratory quality control samples. In addition, several commenters felt that the requirement to analyze a BOD laboratory control standard (LCS) on each day of analysis is excessive.

- | | |
|-----|---|
| 4 | NR 149.48 (1) (d) " <i>Testing a standard? What chemicals do you use to make up reagents to test a standard? Do these chemicals need to be tested against another standard? They are not called standards for no reason. At some point, you have to accept something as being accurate to be used as a starting point. This is totally without relevance and only cost labs, both large and small, additional time and money for absolutely no purpose. "</i> |
| 7 | " <i>Rule NR 149.48 I am against. Retesting a purchased and certified standard is redundant and wasteful The people that make the standards reputation is behind their product. If something must be done for this, have the manufacturer send their own certification slip with it that we would keep on file. That would be the best place to impose this change. I would pay the extra 2 to 3 dollars and just keep the paper work on file here instead of redoing the test just to measure the standard. "</i> |
| 12A | " <i>Quality control for testing, 149.48. Requirement to purchase a second source standard to verify the first standard is needless redundancy. We have been using certified single standards without any problems. This addition will only add labor, as well as chemical costs to the laboratory budget, and should be deleted. "</i> |
| 13 | " <i>We purchase prepared standards from a commercial lab already. This provision needs to be deleted. "</i> |
| 15 | " <i>This section requires that chemical standards be retested to verify that they are accurate. We feel that to place this type of requirement on labs does not make any sense. When chemical standards are purchased, we only purchase them from reputable companies that ensure that they are selling a good product. If it is found that a company is not selling a good product, then we find a new company to get our products from. Companies that sell these chemical standards are in business to provide their customers with quality products. If these companies do not sell quality products, this in turn hurts their business and their bottom line. Our wastewater treatment plant takes extra caution in choosing companies to do business with. We do not do business with "fly-by-night" businesses. Because of this, we feel that the additional costs that would be incurred are not necessary. We feel that this section should be deleted or wastewater treatment plants be made exempt. "</i> |
| 17B | " <i>This section imposes unnecessary requirements on chemical standards. Our lab purchases chemical standards on the assumption that they are what they purport to be (we buy our chemicals from NCLS) [sic]. Retesting a standard is an unnecessary additional cost. "</i> |
| 26A | " <i>This section imposes unnecessary requirements on chemical standards. Labs purchase chemical standards on the assumption they are what they purport to be. Retesting a standard is an unnecessary additional cost. "</i> |
| 27 | " <i>This section seems to be a meaningless exercise, the testing of a standard with a standard? Who will test the primary standard? "</i> |
| 30 | " <i>I purchase chemical standards on the assumption they are what they claim to be. Retesting a standard is a waste of time, when you have a small run of samples. "</i> |
| 34 | " <i>I agree with MEG on QC for chemical testing. "</i> |

- 35 " Having reviewed the NR 149 rule revisions, it appears to me that a great deal of additional effort and some added expense would be required with a seemingly disproportionate amount of benefit gained. For this reason, I want it known that I am not in favor of the proposed revisions- particularly NRs 149.36, .39, .44, .46, .48, and .10, as these seem to be especially unreasonable and unnecessary to smaller labs. "
- 36B " Another issue that I object to is, apparently, we would have to verify that standards that were purchased outside the lab for that very purpose are accurate and certified. And the point of purchasing outside standards is to have accurate, certified standards. "
- 38 " 149.48, this section imposes unnecessary requirements for chemical standards. Labs purchase chemical standards with the assumption that they are purported what they should be. If we have to retest the standards, then where's the logic in that? "
- 42 " The purpose of a second source standard is to verify that the production of standards used for the creation of a calibration curve is correct, both at the manufacturing level and at the bench level. Once this has been done, any requirement to analyze a standard from a second source only results in additional cost to the laboratory at no additional benefit to data quality. As such, NR149.48(1)(d) and NR149.48(4)(d) should be deleted in their entirety. NR149.48(8)(a) should have the following deleted: 'or to fortify laboratory control samples, matrix spikes and matrix spike duplicates,' "
- 23 " The proposed rule requires laboratory control samples to be processed at a frequency of at least one sample per preparation batch. This would require a wastewater lab with a requirement to test BOD three times a week to run a control sample each of the three days the BOD test is run. This section of the Rule, if interpreted correctly, would mean a small wastewater plant could have a 40 % increase in lab time just for the BOD test alone. If this is the case a wastewater exemption should be applied, or the continuation of the old requirement of 1 control sample for each 20 samples run. "
- 24 " Preparing glucose/glutamic acid samples every day for the BOD analysis is unnecessary. The cost in dollars and time invested doesn't make this suggestion worthwhile. Right now most labs do the GGA test once a week, which is adequate. Additionally, running matrix spikes and duplicates per batch would cause problems such as not having enough room in a digester/sterilizer for all Phosphorus samples to be run. "
- 36A " This section is not entirely clear to me, but it seems to indicate that the frequency of quality assurance testing will increase of the current frequency of roughly weekly, to daily. This is an extensive increase in workload for a small laboratory. I estimate that this will cost an additional \$2,300 per year in labor and supplies. Again, it is questionable as to how much the quality of data will improve. "

Department Response: **The final rule clarifies that the use of second source standards is optional, but choosing to use them relieves the laboratory of the requirement to analyze tri-annual blind samples. A significant savings of cost and labor can be realized by making this switch. In addition, the laboratory community does not appear to understand the value of second source standards as a tool for ensuring data quality. The Lab Certification Program will produce guidance documents and schedule outreach sessions to more clearly explain this concept. An exception to the requirement for daily laboratory control standard analysis will be made for BOD analyses. Analysis will be required either weekly or one per 20 samples, whichever is more frequent.**

B. Miscellaneous comments from the laboratory community specifically related to s. NR 149.48.

- 50A NR 149.48 " NR 149.48 - This section has numerous references for **criteria** for quality control limits to be published later. Again, isn't this guidance? If so, it is not enforceable. Shouldn't this be incorporated into code? "

Department Response: **These sections provide for the possibility of establishing, by rule, acceptance criteria for various quality control samples. Such changes would be made in a future revision and would be subject to public comment.**

50C NR 149.48 (1) (b, c) " *These sections contradict each other. Section (c) states that a lab may evaluate quality control samples using lab-generated acceptance criteria (if those criteria are stricter than those contained in approved methods). It doesn't say that labs must use the stricter lab-generated criteria. However, section (b) states that labs shall update the acceptability criteria for quality control samples whenever the performance characteristics change. This seems to require labs to use the strictest limits. "*

Department Response: **The language has been revised to clarify the requirement and, when method criteria differ from those published by rule, which of the two takes precedence.**

50C NR 149.48 (2)(b) " *The established protocol for establishing MDL's is 40 CFR 136, Appendix B. However, it is well known that this procedure produces unrealistic values for highly precise instruments. Therefore, realistic LOD's are often developed to insure that false positives are not reported. There is no regulation or approved method that dictates how this should be done. "*

Department Response: **The Department has previously published guidance to address these situation in the document entitled, "ANALYTICAL DETECTION LIMIT GUIDANCE & Laboratory Guide for Determining Method Detection Limits", available on the Department's website at: [http://www.dnr.state.wi.us/org/es/science/lc/OUTREACH/-Publications/LOD%20Guidance%](http://www.dnr.state.wi.us/org/es/science/lc/OUTREACH/-Publications/LOD%20Guidance%20).**

28A NR 149.48 (2)(f) " *The current NR 149 defines the LOQ as 10/3 or 3.333 times the limit of detection. The Department has also issued guidance documents with the same requirement. This new revision states that "the LOQ is the lowest concentration for which quantitative results can be obtained with a specified degree of confidence for a given limit of detection." However, the code doesn't state what that given degree of confidence should be. Further, section 149.48 (2) (f) states that Laboratories shall establish procedures related to LOD and LOQ. Does this mean that it's up to the lab or the data user to choose? The Department should provide guidance or clarification in the code on this. "*

39B NR 149.48 (2)(f) " *What exactly is meant by this statement? Why is this necessary and how would this be done? The LOQ and the LOD are already related statistically by a factor of 3.2 as described in the DNR PUBL-TS-056-96, dtd [sic] April 1996 titled, ' Analytical Detection Limit Guidance & Laboratory Guide for Determining Detection Limits,' "*

Department Response: **It is the intent of the agency that the LOD/LOQ relationship not be solely limited to the 10/3 relationship. Guidance will be issued to the regulated community following promulgation of this rule to address this issue.**

39B NR 149.48 (3)(c) " *What exactly is meant by 'shall evaluate the nature of the interference and it's effect on each sample in the prep batch? This needs clarification. Exactly how is this done? Is this practical and time effective? The fact is that it would be possible for a high blank to be deemed OK using paragraph 149.48(3)(d) and yet we would be required to run some mysterious investigation to what end?*

Example:

A real worksheet contains the following Chloride results which were obtained using the IC. 8 samples; low=12.0 mg/L; high=63mg/L; LOD 0.1 mg/L; blank= 0.2 mg/L

It seems obvious that we would have to compare our blank (0.2 mg/L) to 10% of the 12.0 sample which would be 1.2. The blank is not higher and thus the need for reanalyzing or qualifying would not be justified, but we would be required to run an investigation of doubtful value. "

Department Response: **The intent here is to ensure that consistent contamination in the testing environment is addressed proactively before it affects data. The language was specifically written to allow flexibility in how laboratories make the evaluation. The commenter's example represents exactly the type of evaluation that is in order; no further "investigation" is necessary.**

2 NR 149.48 (3)(d) " *Needs clarification; different wording. What does "exceed the highest" mean? List various examples. "*

Department Response: **The referenced language is almost identical to language in the current promulgated version of NR 149, and that developed by the EPA. This issue can be clarified through Department guidance.**

39B NR 149.48 (3)(d) 1 " 'A sample [shall be reanalyzed or qualified] ' implies one (1) sample. Which sample does one choose? Should this be all samples in the batch? "

Department Response: **Qualification may be for a single sample, all samples or a subset, based on the variable regulatory limits and measured concentrations. Clarification will be provided in the form of Department guidance following rule adoption.**

39B NR 149.48 (4)(a) " A prep batch is defined as 20 sample etc. The wording here does not state exactly what to do with sample preparations that are larger than 20 and I think this should be spelled out.
 Ex: If a sample preparation consists of 22 samples, I would assume that a control would be run to cover the first twenty and another for the additional 2.
 A wording clarification should be made wherever assigned QC is to be completed based on the definition of a preparation batch. "

Department Response: **This issue has been clarified through changes made to address other comments.**

42 NR 149.48 (4)(d) " When samples are analyzed by methods that do not require a preparation step before analysis, a laboratory control sample, different from a calibration standard, shall be analyzed at a frequency of one per analytical batch.
 The purpose of a second source standard is to verify that the production of standards used for the creation of a calibration curve is correct, both at the manufacturing level and at the bench level. Once this has been done, any requirement to analyze a standard from a second source only results in additional cost to the laboratory at no additional benefit to data quality. As such, NR149.48(1)(d) and NR149.48(4)(d) should be deleted in their entirety. NR149.48(8)(a) should have the following deleted: ' or to fortify laboratory control samples, matrix spikes and matrix spike duplicates...' "

Department Response: **This issue has been clarified through changes made to address other comments regarding this entire subsection.**

46A NR 149.48 (4)(e) " **Requested change:** strike ' if the acceptance...acceptance criteria'.
Comment: The LCS [Laboratory Control Standard] section, as written, constitutes a new and unduly burdensome additional requirement, compared to the current program. The current program relies on sample spike and replicate as the cornerstone of the quality control process. Matrix spikes should be assessed only using the appropriate matrix spike limits. This has served the laboratory control community well in the last twenty years. There is a problem in the current rule, particularly with commercial laboratories that test sample batches with a wide variety of sample sources. For those laboratories, allowing LCS and LCS replicates is a viable alternative. But it should be just an alternative, not a new added requirement. Alternatively to the requested change, sections 4 through 6 should be reordered and rewritten to clearly indicate that sample spike/replicate, or MS/MSD is the preferred requirement, and LCS/LCSR is the alternative. "

Department Response: **The Department agrees with some of the comments, but the main merit of laboratory control standards (LCS) over matrix spikes is that the effect of sample matrix on precision and accuracy is removed, allowing the QC sample to measure only the performance of the laboratory. In some situations, matrix spikes and replicate do serve as valuable measures of performance. It is also important to note that in most cases, LCSs are being proposed as a replacement for, rather than in addition to spikes and replicates. This is particularly true for small wastewater laboratories. Section 149.48 (5)(a) 3. also allows the use of matrix spikes and replicates in lieu of LCS.**

- 2 NR 149.48 (5) " *What control limits does the Department recommend labs use? Calculated, Dept. Limits, Method? Should the most stringent or the widest limits be used? The Department should provide guidance when calculated limits are skewed unreasonably low. "*

Department Response: **The intent here is to offer the labs some flexibility in how they determine the criteria against which these QC samples are to be evaluated. Program guidance will be developed to further explain the options.**

- 2 NR 149.48 (6) " *What control limits does the Department recommend labs use? Calculated, Dept. Limits, Method? Should the most stringent or the widest limits be used? The Department should provide guidance when calculated limits are skewed unreasonably low. "*

Department Response: **The intent here is to offer the labs some flexibility in how they determine the criteria against which these QC samples are to be evaluated. Program guidance will be developed to further explain the options.**

- 42 NR 149.48 (8) " *Under the provisions of this chapter, it appears that a laboratory would be required to analyze quality control samples for tests that cannot be spiked (or spiked easily) with a second source standards. I do not believe that it is the Department's intent for these tests to specifically REQUIRE analysis of QCSs. Clarification in the NOTE following this section would help by addressing that this is not required for those analyses that do not have a calibration curve, for example. "*

Department Response: **The Department believes that the requirements and relative merits of second source standards as addressed in s. 149.48(1)(d) and 149.48(4)(d) have been misunderstood. This section applies only to laboratories that choose not to employ second source standards. This entire subsection could be eliminated, resulting in labor and costs savings, if second source standards are required. This section has also been relocated to facilitate the link to second source standards.**

- 42 NR 149.48 (8)(a) " *Laboratories that do not use second source standards to verify the accuracy of initial calibrations or to fortify laboratory control samples, matrix spikes and matrix spike duplicates, shall analyze known quality control samples 3 times per year at evenly spaced intervals for all certified or registered analytes determined by tests amenable to fortification, and for which known quality control samples are commercially available.*
- 42 *The purpose of a second source standard is to verify that the production of standards used for the creation of a calibration curve is correct, both at the manufacturing level and at the bench level. Once this has been done, any requirement to analyze a standard from second source only results in additional cost to the laboratory at no additional benefit to data quality. As such, NR149.48(1)(d) and NR149.48(4)(d) should be deleted in their entirety. NR149.48(8)(a) should have the following **deleted**: ' or to fortify laboratory control samples, matrix spikes and matrix spike duplicates,' "*

Department Response: **The Department believes that the requirements and relative merits of second source standards as addressed in s. 149.48(1)(d) and 149.48(4)(d) have been misunderstood. This section applies only to laboratories that choose not to employ second source standards. This entire subsection could be eliminated, resulting in labor and costs savings, if second source standards are required. This section has also been relocated to facilitate the link to second source standards.**

- 42 NR 149.48 (9) " *The concepts of selectivity are not limited to organic analytes - establishing procedures for retention time windows is appropriate for all chromatographic techniques, including ion chromatography. Mass spectral tuning is a required element of metals analysis using ICP-MS. Suggest striking "organic" from (a). "*

Department Response: **The suggested change has been made.**

39B NR 149.48 (9)(c) " *As the column ages, retention time shortens. If we set a window of acceptance, we may slide out of that window as the column ages. How often do we check? What is defined as acceptance?* "

Department Response: **Chromatographic windows and acceptance criteria are often established in analytical methods. Clipping columns, as a routine maintenance procedure, will change retention times- at the point where chromatography software does not properly identify peaks; one would have to redefine retention time windows so that the software DOES properly identify peaks.**

5 NR 149.48 (limits?) " *I would like the Department to consider, under 149.48, the inclusion of random, sporadic, marginal failures of 5%, but must be within forced unit deviation of the mean limit for all multi-analyte tests, for example, the volatiles test.* "

Department Response: **The suggested change would be too difficult to codify and administer and would not offer substantial improvement to data quality. This might be a candidate for discussion in future code revisions, but must represent a recognized quality assurance practice.**

33. Comments received relating to Subchapter VII- Quality Systems, s. NR 149.49 – Quality control requirements for whole effluent toxicity testing.

50A NR 149.49(1) – " *Instead of referencing the document, you should reference NR 219.04, table A.* "

Department Response: **The more defensible approach is to cite the document and indicate where it can be obtained. The final rule will contain a notice that the referenced manual can be obtained at <http://dnr.wi.gov/org/water/wm/ww/biomon/>.**

**ORDER OF THE STATE OF WISCONSIN NATURAL RESOURCES BOARD
REPEALING AND RECREATING RULES**

The Wisconsin Department of Natural Resources proposes an order to repeal and recreate NR 149 relating to laboratory certification and registration.

SS-06-06

Analysis Prepared by the Department of Natural Resources

1. **Statutory Authority**

ss. 299.11 (3), 229.11 (4), 299.11 (5), 299.11 (7), 299.11(8), 299.11 (9), Stats.

Section 299.11 (4), Stats. defines the applicability of the certification and registration rules to laboratories submitting data for covered programs. Section 299.11 (7) Stats. authorizes the department to promulgate rules for the certification of laboratories submitting data for covered program. Section 299.11 (8) Stats. authorizes the department to promulgate rules for the registration of laboratories submitting data for covered programs. Section 299.11 (9) Stats. authorizes the department to establish a regulated schedule of fees to cover the costs of administering a laboratory certification and registration program. Section 299.11 (3) Stats. authorizes the department to seek recommendations of the certification standards review council for the general administration of the laboratory certification and registration program. Section 299.11 (5) Stats. allows the department to recognize certifications from other agencies, governments, and private organizations.

Related Statute or Rule

Sections 15.107 (12) and 93.12, Stats. Chs. NR 110, 113, 123, 131, 132, 140, 150, 157, 158, 182, 206, 210, 211, 212, 214, 216, 219, 347, 507, 661, 662, 664, 665, 635, 700, 712, 716, 809, 811, 812, 845, and HFS 46.

2. **Statute Interpreted**

s 299.11, Stats.

3. **Plain Language Rule Analysis**

Chapter NR 149 sets requirements for the certification and registration of laboratories that submit data to the department for covered programs. Since the last major revision of the chapter, laboratory operations have undergone significant advances. Other state and national certification programs have promulgated and revised rules that reflect these advances. This version of ch. NR 149 incorporates many of those changes and, where appropriate, moderates them by incorporating suggestions expressed by our regulated community.

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.

4. **Federal Regulatory Analysis**

The US EPA has established a program for the certification of laboratories that analyze drinking water for compliance with the safe drinking water act. The US EPA delegates the authority to certify laboratories to states that have established equivalent programs. The proposed rule incorporates the latest changes in the

regulations and manual used by EPA to certify drinking water laboratories. Thus this revision makes the Wisconsin certification and registration program current with the US EPA's.

The US EPA sponsors a National Environmental Laboratory Accreditation Program (NELAP) for states that voluntarily seek such recognition. The procedures for accrediting laboratories under NELAP are contained in standards promulgated by the National Environmental Laboratory Accreditation Conference (NELAC). The proposed rule contains elements of the NELAC Standards recommended for incorporation by our regulated community. In most cases, the incorporated elements address standard practices commonly performed by laboratories.

5. **State Regulatory Analysis**

All of the adjacent states, Minnesota, Illinois, Michigan, and Iowa, have primacy from the US EPA to certify laboratories analyzing drinking water. Their rules must mirror federal requirements to maintain the states' authority. Our proposed revision makes the drinking water portion of our chapter current with those of the adjacent states.

As is the case in Wisconsin, Minnesota, Iowa, and Illinois have certification, registration, or accreditation programs for laboratories analyzing wastewater, hazardous waste, and solid waste. Minnesota is currently revising its certification rule to incorporate requirements that are very similar to the ones the department is proposing under this revision. Illinois is a recognized NELAP accrediting authority and its rules agree or are stricter than those the department proposes for ch. NR 149. Iowa has a certification program that is more limited in scope than ours because the state has few laboratories providing environmental analytical services other than the University of Iowa State Hygienic Laboratory.

6. **A Summary of Factual Data**

To create this proposed rule, the Department engaged in a structured process to seek input from all stakeholders. The core of this effort consisted in convening a rule revision advisory committee (RAC) composed of all the members of the Certification Standards Review Council, a body authorized by s. 15.107 (1), Stats., and additional experts nominated by organizations involved with or affected by environmental laboratories.

This final rule incorporates suggested changes based on comments received from the Legislative Rules Clearinghouse, at public hearings, or in writing.

The following table illustrates the methodologies and data considered in producing this proposed rule:

Methodology	Data Considered
Advisory Committee	Input from all stakeholders on all aspects of the Laboratory Certification and Registration Program.
NR 149 RAC Questionnaire	Answers to graded scale of opposites completed by NR 149 RAC to determine focus, form, and general content areas of proposed rule.
Consensus Standards	NR 149 RAC made decisions by reaching substantial agreement and when necessary, registering consensus on a gradient scale.
Model Documents	Alternatives for certification and registration structure, fee structure, applications, and quality systems.
Comparative Analysis	Scope of certification and registration of current laboratories in the program to arrive at equitable fee structure. Analytical technologies for relative difficulty and to arrive at fees to be assessed. Fee structure and assessments of certification programs in other states.
Feasibility and Legal Review	Certification and covered program staff reviewed changes endorsed by RAC to determine feasibility of implementation.

	Legal counsel reviewed draft rule for defensibility.
Public Comments	Finally, comments received at public hearing, during the public comment period, and from the Legislative Council Rules Clearinghouse were incorporated into the final rule.

7. **Regulatory Flexibility Analysis**

Input received from small business laboratories indicates that they feel comfortable in being able to meet the requirements of the proposed rule. The Department believes that its initial survey findings substantiate the perception that most laboratories have already been performing many of the requirements newly incorporated in the rule.

Small business laboratories are not likely to change their scope of certification under the proposed certification structure, as long as the costs for maintaining those certifications do not increase dramatically. The proposed rule maintains these costs as in check. Projected increases in certification fees assessed to laboratories are likely to either decrease or remain stable for most small laboratories. The fee structure established assigns an increasing number of relative value units with increasing complexity of analytical technologies. Consequently, those labs that have the offer a broad spectrum of analytical technologies will absorb a comparatively larger proportion of the program costs. None of the small business laboratories perform any of these higher order technologies.

Most operating costs in laboratories are associated with maintaining staff to perform analyses. The proposed rule does not require increases in staff to ensure compliance with it.

The Department concludes that the proposed rule provides flexibility in meeting many of its requirements. Small businesses may be able to realize some savings in implementing the proposed rule by judiciously selecting among the options contained in it. The proposed rule came to light after considering significant input from regulated small laboratories. The specificity and flexibility contained in the proposed rule bring equity and uniformity to all laboratory operations and are likely to increase the competitiveness of small laboratories providing analytical services in and out of state.

Anticipated Costs Incurred by Private Sector

The anticipated costs to be incurred by the private sector are not significantly different from the additional costs anticipated for small businesses, which as shown in the previous section are relatively small and can be moderated by choosing more economical alternatives allowed within the proposed rule. The Department has data suggesting that for larger commercial and industrial laboratories, the savings afforded by the flexibility in the proposed rule will represent a larger percentage of their quality systems costs. The economies of scale in large private laboratories will tend to reduce adverse economic impacts.

8. **Agency Contact Person**

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SECTION 1. Chapter NR 149 is repealed and recreated to read:

LABORATORY CERTIFICATION AND REGISTRATION

SUBCHAPTER I GENERAL PROVISIONS

NR 149.01 Purpose. The purpose of this chapter is to establish a program for the certification and registration of laboratories performing testing under s. 299.11, Stats.

NR 149.02 Applicability. (1) This chapter specifies requirements for the administration of the laboratory certification and registration program by the department.

(2) Unless otherwise exempted in this section, this chapter applies to laboratories:

(a) Applying for certification and registration.

(b) Holding a certification or a registration.

(c) Submitting data to the department for a covered program.

(d) Generating data that is necessary for the department to determine compliance with a covered program.

Note: Administrative codes and programs requiring analyses to be performed by a certified or registered laboratory are chs. NR 110 – Sewerage Systems, 113 – Servicing Septic Systems, 123 – Well Compensation Program, 131 – Metallic Mineral Prospecting, 132 – Metallic Mineral Mining, 140 – Groundwater Quality, 145 – Private Wells, 150 – Environmental Analysis and Review Procedures, 157 – Management of PCBs, 158 – Hazardous Substance Discharge Notification, 182 – Metallic Mining Waste, 206 – Land Disposal of Municipal and Domestic Wastewaters, 210 – Sewage Treatment Works, 211 – General Pretreatment Requirements, 212 – Wasteload Allocated Effluent Limits, 214 – Land Treatment of Industrial Liquid Wastes, 216 – Stormwater Management, 219 – Analytical Test Methods and Procedures, 347 – Sediment Sampling and Analysis, 507 – Environmental Monitoring for Landfills, 661 – Hazardous Waste Identification and Listing, 662 – Hazardous Waste Generator Standards, 664 – Hazardous Waste Treatment, Storage and Disposal Facility Standards, 665 – Interim License Hazardous Waste Treatment, Storage and Disposal Facility Standards, 700 – General Requirements for Investigation and Remediation of Environmental Contamination, 712 – Environmental Response Actions, 716 – Site Investigations, 809 – Safe Drinking Water, 811 – Design of Community Water Supplies, 845 – County Administration of NR 812 (Private Wells), and HFS 46 – Group Day Care Centers for Children.

(3) The requirements for the certification of laboratories performing analyses for the safe drinking water program covered by ch. NR 809 are specified in s. NR 149.19.

Note: Laboratories performing analyses for the safe drinking water program covered by ch. NR 809 must be certified even if they do not perform or intend to perform tests commercially for hire. Registration is not available for these analyses.

(4) The requirements for the certification and registration of laboratories performing whole effluent toxicity testing are specified in ss. NR 149.20 and 149.49.

(5) This chapter applies to laboratories analyzing industrial pre-treatment samples when the department is the control authority of a pre-treatment ordinance, or when another control authority requires it.

(6) Laboratories required to perform bacteriological testing for a covered program shall be certified or approved under ch. ATCP 77 by the department of agriculture, trade, and consumer protection.

(7) Laboratories required to perform radiological testing for a covered program shall be certified or approved by EPA.

(8) This chapter establishes requirements that shall be followed, at a minimum, by all laboratories.

(a) Laboratories are also responsible for following any requirements pertaining to analyses and analytical operations contained in mandated test methods or regulations when those requirements are more stringent than the ones specified in this chapter, unless this chapter grants explicit, alternative allowances.

(b) When it is not apparent whether the minimum requirements of this chapter or those specified in mandated test methods or regulations are more stringent, laboratories shall follow the requirements in mandated test methods or regulations.

(c) The department shall retain the authority to make a decision on the stringency of a laboratory requirement when the applicability of a requirement is disputed.

Note: The order of precedence for the authority of a requirement is statute, code, and method. The order of applicability of a requirement is generally method, code, and statute, whenever each succeeding source contains more general or less stringent requirements that are not in conflict.

NR 149.03 Definitions. In this chapter:

(1) “Acceptance limits” means limits established by the department that are used to determine if a laboratory has analyzed a proficiency testing sample successfully.

(2) “Accuracy” means the closeness of a measured value to an accepted reference value or standard.

(3) “Analysis day” means the day in which a specific type of analysis is performed.

(4) “Analyte” means the chemical substance, physical property or organism analyzed in a sample.

(5) “Analyte group” means a set of analytes that can be determined using the same method or technology and that constitute a unit, acknowledged by the department, of the third tier of certification or registration.

(6) “Analytical balance” means a balance that is capable of measuring masses to at least 4 decimal places.

(7) “Analytical class” means a set of analytes or analyte groups of similar behavior or composition, or a set of analytes or analyte groups regulated under the same provisions of the federal safe drinking water act, that is used to organize the third tier of certification or registration.

(8) “Analytical instruments” means any test instrument used to provide analytical results that is not support equipment.

(9) “Analytical run” means an event consisting of the uninterrupted analysis of a set of samples used to establish the frequency of continuing calibration verification.

(10) “Analytical staff” includes, but is not limited to, laboratory directors, supervisory personnel, quality assurance personnel, technicians, chemists, biologists, personnel performing extractions and analysts.

(11) “Authoritative source” means a publication, text or reference included in Appendix III.

(12) “Aqueous” means a certification or registration matrix designating any aqueous sample that is not a drinking water, and samples with no more than 15% settleable solids.

Note: Samples with more than 10% settleable solids may also be classified as solid.

(13) “Batch” means a set of samples prepared or analyzed together under the same process, instrumentation, personnel, and lots of reagents. An analytical batch refers to a set of any number of prepared samples, such as extracts, digestates or concentrates or samples requiring no preparatory steps analyzed together as a group in an uninterrupted sequence, and may consist of samples of various quality system matrices. A preparation batch refers to a batch of samples, excluding quality control samples, of the same quality system matrix which can be processed simultaneously using the same equipment, reagents and staff. Preparation batch processing shall be completed in a 24-hour period from the start of the processing of the first sample to the start of the processing of the last sample. For laboratories that do not analyze more than 7 samples for a given test and quality system matrix per week, a preparation batch may consist of up to 7 samples, excluding quality control samples, processed during the course of no more than a week.

(14) “Bias” means the consistent deviation of measured values from a true value caused by systematic errors in a procedure or a measurement process.

(15) “Blank” refers to a type of quality control sample optimally containing no detectable levels of the analyte or analyte group of interest, typically used to zero an analytical instrument and ensure that any reagents used do not contribute to overall measurements.

(a) “Calibration blank” means a sample containing insignificant or undetectable levels of target analytes used to establish the analytical zero of a calibration function.

(b) “Method blank” means a sample of a matrix devoid of or having a consistent concentration or amount of the analytes of interest processed simultaneously with and under the same conditions, preparatory and analyses steps as the associated samples.

(c) “Temperature blank” means a sample container, of at least 40 ml. capacity, filled with water and transported with each shipment of collected samples to determine the temperature of other samples in the shipment on arrival at a laboratory.

(16) “Calibration” means the process used to establish an observed relationship between the response of an analytical instrument and a known amount of analyte, or the process used to determine, by measuring or comparison with a reference standard, the correct value of each scale reading in an instrument, meter or measuring device.

(17) “Calibration function” means the specific mathematical relationship established to relate calibration standards to instrument response.

(18) “Certificate” means a document owned by the department and issued to a laboratory that indicates the fields of accreditation granted to a laboratory.

(19) “Certification” means the specific form of accreditation extended by the department to laboratories that perform analyses for hire in connection with a covered program, or to laboratories that perform drinking water analyses.

(20) “Certification matrix” means a matrix type that is part of the first tier of a field of certification. Certification matrices are drinking water, aqueous and solids.

(21) “Certified laboratory” means a laboratory that has been granted certification by the department directly or through reciprocal recognition under this chapter.

(22) “Chain of custody” means the procedures and records that document the possession and handling of samples from collection through disposal. A chain-of-custody form is used to document, with a signature, date and time, transfer of the sample from collector to transport/delivery service and then to the laboratory staff receiving the samples. “Evidentiary chain-of-custody” refers to more stringent sample transfer documentation in which samples are stored in secure storage areas. In addition, a chronological written record shall be maintained of all individuals who have possession of the sample from its initial acquisition until its final disposition.

(23) “Coefficient of determination” means a quantity that measures the degree of agreement between the points in a calibration curve and the quadratic function derived to connect them.

(24) “Commercially for hire” means offering analyses for payment or non-monetary compensation generally available to any party requesting analytical services.

(25) “Confirm” means to verify the identity of a compound by an alternative procedure, column, detector, wavelength, or by a technique that bases detection on a different scientific principle from the one originally identifying the compound.

(26) “Control” means to possess, directly or indirectly, the power to direct or cause the direction of the management and policies of an entity, whether that power is exercised through one or more intermediary entities, or alone, or in conjunction with, or by an agreement with, any other entity, and whether that power is established through a majority or minority ownership or voting of securities, common directors, officers, stockholders, voting

trusts, holding trusts, affiliated companies, or documented agreements between government entities, whether statewide, countywide, citywide or any combination thereof.

(27) “Control authority” means to have direct or delegated responsibility for establishing, implementing or monitoring an industrial waste pre-treatment program.

(28) “Correlation coefficient” means a quantity that measures the degree of agreement between the points in a calibration curve and the linear function derived to connect them.

(29) “Corrective action” means any measure taken to eliminate or prevent the recurrence of the causes of an existing nonconformity, defect or undesirable condition.

(30) “Council” means the certification standards review council created under s. 15.107(12), Stats.

(31) “Covered program” means a program defined by s. 299.11(1) (d), Stats., and includes any department program, project, permit, contract or site investigation that requires analytical work to be performed by a certified or registered laboratory.

Note: Consult the note in s. NR 149.02(2) (d) for a list of department administrative rules of programs requiring certification or registration under this chapter.

(32) “Deficiency” means a documented or verifiable deviation from the requirements of this chapter that is noted during an on-site evaluation or while reviewing analytical data produced by a laboratory.

(33) “Department” means the department of natural resources.

(34) “EPA” means the United States environmental protection agency.

(35) “Field of accreditation” means a unit by which the department grants or recognizes either certification or registration to a laboratory. There are 2 types of fields of accreditation, each consisting of 3 tiers: matrix – analytical technology – analyte or analyte group, and matrix – method – analyte or analyte group.

(a) The matrix – method – analyte or analyte group field of accreditation is limited to the drinking water matrix.

(b) The matrix – analytical technology – analyte or analyte group field of accreditation is available for both aqueous and solid matrices and for either certification or registration.

(c) Registration is available only for aqueous and solid matrices.

(36) “Inert matrix” means a quality control matrix either containing insignificant or undetectable levels of the analytes that will be analyzed in an analytical test. Typical inert matrices are distilled water, deionized water, diatomaceous earth, and Ottawa sand.

(37) “Internal standard” means an analyte added to calibration standards, blanks, quality control and analytical samples as a reference for evaluating and controlling the precision and bias of an analytical test. Responses of internal standards are used to adjust the quantities of analytes reported in tests that employ the standards.

(38) “Laboratory” means a facility that performs tests in connection with a program which requires data from a certified or registered laboratory. A facility consisting of a principal laboratory and annexes within 5 miles of the principal laboratory may be considered a single laboratory at the discretion of the department. When the terms laboratory or laboratories are used unmodified in this chapter, the terms include laboratories certified or registered under this chapter and those seeking certification or registration under this chapter.

(39) “Laboratory control sample” or “LCS” means a sample of an inert matrix or a matrix with a consistent concentration of the analytes of interest, fortified with a verified known amount of the analytes of interest. The purpose of an LCS is to determine whether the methodology is in control and whether the laboratory is capable of making accurate and precise measurements.

Note: In many EPA methods, the term “lab-fortified blank” is substantially equivalent to a laboratory control sample.

(40) “Laboratory equipment” means any support equipment or analytical instrument necessary to or involved in generating the results of an analysis.

(41) “Limit of detection” or “LOD” means the lowest concentration or amount of analyte that can be identified, measured, and reported with confidence that the concentration is not a false positive value. For department purposes, the LOD approximates the MDL and is determined per the method cited in sub. (46).

(42) “Limit of quantitation” means the lowest concentration or amount of an analyte for which quantitative results can be obtained.

(43) “MCL” means maximum contaminant level and is the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

(44) “Matrix spike” or “MS” means a sample prepared by adding a known quantity of analyte to an aliquot of an environmental sample and subjecting the sample to the entire analytical procedure to determine the ability to recover the known analyte or compound. The background concentrations of the analytes in the sample matrix shall be determined in a separate aliquot and the measured values in the matrix spike corrected for background concentrations.

Note: In many EPA methods, the term “lab-fortified matrix” is substantially equivalent to a matrix spike.

(45) “Matrix spike duplicate” or “MSD” means a replicate matrix spike prepared and processed in the laboratory in the same manner as its corresponding matrix spike, and generally used to determine the precision of the recovery of an analyte.

(46) “Method detection limit” or “MDL” means the minimum concentration of an analyte that can be measured and reported with 99% confidence that the stated concentration is greater than zero, determined from analyses of a set of samples containing the analyte in a given matrix. The method detection limit is generated according to the protocol specified in 40 CFR 136, Appendix B.

(47) “NIST” means the National Institute for Standards and Technology.

(48) “Nonconformance” means a documented or verifiable deviation from the requirements of this chapter.

(49) “On-site evaluation” means an assessment conducted by the department at a laboratory seeking or maintaining certifications or registrations to determine actual or potential compliance with the requirements of this chapter.

(50) “Ownership” means owning or controlling, directly or indirectly, a laboratory facility through an equity interest or its equivalent of 10% or more.

(51) “Pesticide” means a chemical substance defined in s. 94.67 (25) and (25m), Stats., an isomer of a pesticide, or a degradation product or metabolic product of a pesticide.

(52) “Precision” means the measure of mutual agreement among individual measurements of a sample, usually under prescribed similar conditions, usually expressed as the standards deviation, variance, or range, in either absolute or relative terms.

(53) “Proficiency testing sample” or “PT sample” means a sample obtained from an approved provider to evaluate the ability of a laboratory to produce an analytical test result meeting the definition of acceptable performance outlined in s. NR 149.27. The concentration of the analyte in the sample is unknown to the laboratory at the time of analysis. PT samples are used to evaluate whether the laboratory can produce analytical results within specified acceptance limits.

Note: Proficiency testing samples are also known as performance evaluation samples or reference samples.

(54) “Qualify” means placing a written statement accompanying or referencing test results identifying anomalies or deviations from this chapter encountered in generating the results.

(55) “Quality assurance” means an integrated system of activities involving planning, control, assessment, reporting and improvement to ensure that a product or service meets defined standards of quality.

(56) “Quality control” means the overall system of technical activities designed to measure and control the quality of a product or service that meets the stated needs of users.

(57) “Quality control standard” or “QCS” means a solution or sample containing method analyte of known concentration, accompanied by specified analytical acceptance limits, and obtained from a source external to the laboratory and different from the source of calibration standards. These samples are distinguished from proficiency test samples in that the acceptance limits are provided with the sample, rather than after analysis. Quality control standards are used to check either laboratory or instrument performance.

(58) “Quality control limit” means the acceptance criteria used to evaluate for quality control samples. Quality control limits may be those published by the department, referenced in an approved method or calculated by a laboratory.

(59) “Quality system matrix” means a type of sample classification used for establishing quality control acceptance criteria. Quality system matrices include, but are not limited to, drinking water, wastewater influent, wastewater effluent, groundwater, leaching procedure extracts, soils, oils, chemical wastes and biosolids.

(60) “Quality system” means a structured and documented management arrangement describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products and services.

(61) “Raw data” means any original information from a measurement activity or study recorded in media that allows the reconstruction and evaluation of the activity or study. Raw data include, but are not limited to, absorbance, emission counts, area counts, peak heights, abundance and millivolts. Raw data may be stored in hard copy or electronically.

(62) “Reagent grade water” means water which has been treated to remove any impurities that may affect the quality of an analysis.

(63) “Received on ice” means a designation to indicate that sample containers arriving at a laboratory have been received surrounded by an ice slurry, crushed, cubed or chipped ice.

(64) “Reference material” means a material that has one or more sufficiently well established properties that can be used for calibrating or verifying the calibration of support equipment or analytical instruments.

(65) “Reference standard” means a standard, generally of the highest metrological quality available, from which measurements made at a laboratory are derived.

(66) “Registration” means the specific form of accreditation extended by the department to a laboratory that submits data in connection with a covered program, that does not perform analyses for hire, and that does not perform drinking water analyses.

(67) “Registration matrix” means a matrix type that is part of the first tier of a field of registration. Registration matrices are aqueous and solids.

(68) “Registered laboratory” means a laboratory that has been granted registration by the department directly or through reciprocal recognition under this chapter. A registered laboratory may be a captive industrial laboratory that performs tests solely on its own behalf or that of a subsidiary under common ownership or control, a municipal laboratory owned by a single municipality, or a municipal laboratory owned by more than one municipality that only performs tests for the owning municipalities.

(69) “Relocation” means a move by a laboratory resulting in a change in the laboratory’s facility identification number.

(70) “Replicate” means 2 or more substantially equal aliquots analyzed independently for the same parameter.

(71) “Reporting limit” means a concentration or amount of analyte required by the department or client above which numerical results must be reported. Reporting limits may be limits of detection, limits of quantitation, practical quantitation limits or other concentrations, and may be specific to a project or investigation.

(72) “Revocation” means cancellation of a laboratory’s certification or registration.

(73) “Results” means the quantitative or qualitative output of an analysis, including, but not limited to, measurements, determinations and information obtained or derived from tests.

(74) “Sample standard deviation” means the standard deviation calculated for a set of samples belonging to a larger population. The sample standard deviation formula contains the quantity “n - 1” in the denominator inside the radical, where n equals the number of samples.

(75) “Second source standard” means a standard procured from a supplier or manufacturer different from the supplier or manufacturer of a laboratory’s calibration standards, or a standard obtained from the same supplier or manufacturer of a laboratory’s calibration standards from a lot verifiably different from the lot of the calibration standards.

(76) “Sensitivity” means the capability of a method or instrument to discriminate between measurement responses representing different levels of analyte, or the capability of a method or instrument to detect an analyte at or above a stated quantity.

(77) “Signature” means the name of a person written by that person, or a distinctive mark or characteristic indicating the identity of that person. Signatures can be provided in hard copy or electronically.

(78) “Solid” means a certification or registration matrix designating samples such as soils, sediments, sludges, organic liquids, oils or aqueous products and by-products of industrial processes, and aqueous samples with more than 10% settleable solids.

Note: Samples containing more than 10% but less than 15% settleable solids may also be classified as aqueous.

(79) “Subcontract” means the act of sending a sample or a portion of a sample by a certified laboratory to another certified laboratory.

(80) “Support equipment” means devices that may not be analytical instruments, but that are necessary to support laboratory tests and operations. These devices include, but are not limited to, autoclaves, balances, ovens, refrigerators, freezers, incubators, water baths, temperature measuring devices, sample preparation devices and volumetric dispensing devices when quantitative results depend on the accuracy of the support equipment.

(81) “Surrogate” means a substance unlikely to be found in environmental samples, with properties similar to those of analytes of interest, which is used to evaluate the bias of an analysis in the fortified sample.

(82) “Suspension” means a temporary cancellation of a laboratory’s certification which may not require an on-site evaluation for reinstatement.

(83) “Test” means any chemical, biological, physical, radiological or microscopic assay, examination or analysis conducted by a laboratory on water, wastewater, groundwater, biosolid, waste material, hazardous substance or any other matrix analyzed to determine compliance with a covered program.

(84) “Traceability of measurement” means the ability of relating a result or measurement to appropriate state, national or international standards through an unbroken chain of documented comparisons.

(85) “Unfamiliar sample” means a sample for which a laboratory has either no information or questionable information from previous characterizations of samples from the same source. The term unfamiliar also describes a sample for which there is no information about the process generating it.

(86) “Ultra-low level metals” means concentrations of metals at sub-microgram per liter or sub-microgram per kilogram concentrations and those required to be determined in clean room environments.

(87) “Waste characteristic extractions” means extractions, such as the toxicity characteristic leaching procedure, performed on any solid or waste to establish whether it exhibits a defined regulatory characteristic.

(88) “Waste characterization assays” means determinative tests, such as Pinsky-Martens closed cup ignitability, corrosivity of liquids and polychlorinated biphenyls screening of organic liquids, performed on any solid or waste to evaluate whether it exhibits a defined regulatory characteristic.

NR 149.04 Disclaimers. A laboratory may not claim or imply that data it generates has department approval solely on the basis of the laboratory’s certification and registration status.

Note: Certification or registration of a laboratory is not an endorsement by the department of the quality or validity of the data generated by a laboratory. Certification or registration does not guarantee the usability of data generated by a laboratory for an intended purpose. The covered programs under this chapter are the ultimate users of laboratory results and determine whether they accept or reject analytical data from any certified or registered laboratory.

SUBCHAPTER II PROGRAM ADMINISTRATION

NR 149.05 Required certification or registration. (1) All laboratories submitting data to the department for a covered program or generating data to determine compliance with a covered program shall be certified or registered under this chapter for the fields of certification or registration corresponding to the submitted or generated data, unless this chapter or a covered program exempts a test from requiring certification or registration.

(2) The department may not accept data required to be generated or submitted by a certified or registered laboratory from a laboratory that is not certified or registered under this chapter except as provided in s. NR 149.11.

NR 149.06 Certificates. (1) The department shall issue certificates to certified and registered laboratories indicating or making reference to the specific fields of certification or registration for which laboratories have been granted certification or registration. The department shall issue certificates annually and whenever the fields for which a laboratory is certified or registered change, and when a laboratory relocates or changes its name.

(2) The department shall issue certificates to the owner or legally responsible party of a laboratory.

(a) The department may not issue certificates to an operating contractor of a laboratory who is not the owner or legally responsible party of a laboratory.

(b) The department may indicate in a certificate that a laboratory is managed by an outside contractor.

(3) Certificates are the property of the department and shall be returned to the department upon request.

(4) Laboratories may not alter or modify certificates issued by the department. Laboratories that alter or modify a certificate, or that misrepresent the fields of certification or registration contained or referenced in a certificate, may be subject to revocation of their entire certifications or registrations.

(5) Certificates shall be displayed conspicuously at the facilities of the laboratories to which they have been issued.

NR 149.07 Transfer of certification and registration. (1) Laboratory certifications and registrations are not transferable to other entities unless the department expressly approves the transfer.

(2) Laboratories shall notify the department of any change of ownership as soon as practicable, but no later than 30 days after the change has occurred. As part of the notification, the laboratory shall provide the department the number of analytical staff working or expected to be working at the facility 30 days before and after the ownership change.

(3) The department shall inform the laboratory within 30 days after the receipt of the notification or the actual transfer of ownership, whichever happens later, whether the laboratory is eligible for having existing certifications or registrations transferred by application, or whether an initial application is required to be submitted by the new laboratory owner.

(a) The laboratory shall submit the type of application the department has determined is appropriate within 30 days after the date of the determination notification.

(b) All certifications and registrations granted to the laboratory changing ownership shall expire 30 days after the department notifies the laboratory of the type of application required to be submitted.

Note: Requirements for initial and transfer applications are contained in s. NR 149.14.

NR 149.08 Recognition of other certifications, registrations, accreditations, licenses or approvals. (1) AGRICULTURE, TRADE, AND CONSUMER PROTECTION AGREEMENT. The department shall recognize the certification, registration, accreditation, licensure or approval by the department of agriculture, trade, and consumer protection for microbiological testing performed by a laboratory submitting or generating data for a covered program.

(2) EPA AGREEMENT. The department shall recognize the certification, registration, licensure or approval by EPA for radiological testing performed by a laboratory submitting or generating data for a covered program.

(3) LABORATORIES CERTIFIED, REGISTERED, ACCREDITED, LICENSED OR APPROVED BY OTHER GOVERNMENTS.
(a) The department shall negotiate with and attempt to enter into agreements with federal agencies and agencies of other states to reciprocally recognize laboratories under this chapter.

(b) The department may recognize the certification, registration, accreditation, licensure or approval of a laboratory by another state or an agency of the federal government if the standards used for the qualification of a laboratory are substantially equivalent to those established in this chapter.

(c) The department may not recognize the certification, registration, accreditation, licensure or approval of a laboratory by another state or an agency of the federal government, unless that state or federal agency recognizes laboratories under this chapter.

(4) PRIVATE ORGANIZATION AGREEMENTS. (a) The department may negotiate with and attempt to enter into agreements with private not for profit organizations to recognize laboratories under this chapter.

(b) The department may recognize the certification, registration, accreditation, licensure or approval of a laboratory by a private not for profit organization if the organization's standards used for the qualification of a laboratory are substantially equivalent to those established in this chapter.

NR 149.09 Certification standards review council. (1) The certification standards review council shall advise the department on the standards used to certify, register, suspend and revoke laboratories.

(2) The certification standards review council shall advise the department on training and outreach activities the department may offer or sponsor to facilitate compliance of laboratories with this chapter.

(3) The department shall prepare annually for review by the certification standards review council:

(a) A summary of laboratory evaluations performed. The certification standards review council shall advise the department on the frequency and scope of evaluations necessary to determine compliance of laboratories with this chapter.

(b) A list of required proficiency testing samples and available sample providers. The department shall seek the advice of the certification standards review council before requiring the analysis of additional proficiency testing samples and approving sample providers.

(c) A summary of fees scheduled to be assessed to laboratories. The department shall seek the advice of the certification standards review council before implementing changes in the fees assessed to laboratories.

(d) A summary of variances issued. The department shall seek the advice of the certification standards review council in granting variances.

NR 149.10 Enforcement. (1) ADMINISTRATIVE PROCEDURES. A laboratory's certification is valid until it expires, is suspended, or revoked. A laboratory's registration is valid until it expires or is revoked. If, after opportunity for a contested case hearing, the department finds that a certified or registered laboratory materially and consistently failed to comply with the provisions of this chapter, the department may suspend or revoke a laboratory's certification or revoke a laboratory's registration by whole or in part by matrix, analytical technology, or analyte or analyte group. Contested case hearings for out-of-state laboratories regulated by this chapter shall be held in Madison, Wisconsin.

(2) SUSPENSION OR REVOCATION OF CERTIFIED LABORATORIES. (a) Causes for suspension of certification include any of the following:

1. Material and consistent failure to comply with the quality program requirements as specified in subch. VII.

2. Reporting data to the department after a laboratory is deemed temporarily incapable of performing analysis in any matrix, analytical technology, or method, analyte, or analyte group.

3. Suspension of certification, accreditation, license or approval by another state or agency of the federal government for which the laboratory holds certification if the grounds for suspension are substantially equivalent to any of those listed in this paragraph.

(b) Causes for revocation of certification include any of the following:

1. Material and consistent failure to maintain records as required in this chapter.

2. Failure to allow the department to perform on site evaluations as specified in subch. VI.

3. Material and consistent failure to comply with the quality program requirements as specified in subch. VII.

4. Material and consistent failure to submit requested records to the department.

5. Material and consistent failure to follow specified procedural or quality control requirements prescribed in approved methods.

6. Falsification of analytical results, testing dates or any other information submitted to the department by the laboratory. Falsification includes alteration or modification of a certificate.

7. Failure of 2 consecutive proficiency testing samples for any method and analyte or analyte group combination for laboratories holding certification in the drinking water matrix.

8. Demonstrated incompetence manifested by the chronic inability to meet the requirements of this chapter.

9. Revocation of certification, registration, accreditation, license or approval by another state or agency of the federal government for which the laboratory holds certification if the grounds for revocation are substantially equivalent to any of those listed in this paragraph.

(3) REVOCATION OF REGISTERED LABORATORIES. Causes for revocation of registration include any of the following:

(a) Falsification of analytical results, testing dates or any other information submitted to the department by the laboratory. Falsification includes alteration or modification of a certificate

(b) Material and consistent failure to maintain records as required in this chapter.

(c) Material and consistent failure to comply with the quality program requirements as specified in subch. VII.

(d) Material and consistent failure to submit requested records to the department.

(e) Material and consistent failure to follow specified procedural or quality control requirements prescribed in approved methods.

(f) Demonstrated incompetence manifested by the chronic inability to meet the requirements of this chapter.

(4) PROCEDURE FOR SUSPENSION OR REVOCATION OF CERTIFICATION OR REVOCATION OF REGISTRATION.

(a) An order suspending or revoking certification or revoking registration shall be mailed to the laboratory and shall state the reasons for suspension or revocation. The order shall include the conditions under which reapplication will be accepted. For orders suspending certification, the order may include a timetable for correcting the deficiencies that led to the suspension. For orders revoking certification or registration, the department may set a time period for the revocation.

(b) An order suspending or revoking a certification or revoking a registration shall take effect on the thirtieth day after the order is mailed, unless the owner of a certified or registered laboratory submits a petition for a hearing. Petitions for a hearing shall be submitted to the department within 30 days of receiving the order. The petition for hearing shall specify the findings or conclusions, or both, which the laboratory disputes and conform to the requirements of s. NR 2.05 (5).

(c) If a request for a hearing is submitted and meets the requirements of s. 227.42, Stats., the suspension or revocation shall be stayed and the department shall conduct a contested case hearing on the matter. At least 10 days prior to the date of the hearing, the department shall send a written notice to the laboratory indicating the date, time, and location of the hearing. The final determination of the department, including the basis for the decision, shall be provided by written order to the laboratory after the hearing.

Note: Refer to ch. NR 2 for additional information on the contested hearing process.

(d) The final determination of the department is subject to review under ch. 227, Stats.

(5) REAPPLICATION FOLLOWING SUSPENSION REVOCATION. (a) A laboratory which has had its certification suspended may reapply for certification or registration if all of the following are met:

1. The deficiencies that led to the suspension have been corrected in accordance with the timetable contained in the order.

2. Any conditions for reapplication specified in the order have been met.

(b) A laboratory which has had its certification or registration revoked may reapply for certification or registration if all of the following have been met:

1. The deficiencies that led to the revocation have been corrected.
2. Conditions contained in the order have been satisfied.
3. The time period for which the revocation is in effect has expired.

(c) Laboratories reapplying for certification or registration following suspension or revocation shall submit an initial application as identified in s. NR 149.14 (1) and (2).

(6) REFERRAL. (a) Any violation of this chapter may be referred to the attorney general's office for enforcement under ss. 299.95 and 299.97, Stats.

(b) Any laboratory operating without proper certification or registration for which analysis results are submitted to the department for compliance monitoring or for analyses which require certification or registration under ch. NR 662, 664 or 665, may be referred by the department to the attorney general's office for enforcement.

NR 149.11 Discretionary acceptance. (1) The department may accept, on a case-by-case basis, the results of tests originating in a laboratory not certified or registered for fields of certification or registration required by a covered program, if the results meet all other requirements of this chapter.

(2) The department may not accept the results of tests originating in a laboratory not certified or registered for the corresponding fields of certification or registration if the results do not meet all other requirements of this chapter.

(3) The department may not accept the results of tests originating in a laboratory not certified for the corresponding fields of certification for any tests associated with monitoring required under ch. NR 809.

(4) The department may charge a fee under s. 299.11(5) (d), Stats., if it is necessary to verify the results of tests for which a laboratory requests discretionary acceptance.

NR 149.12 Variances. (1) **GENERAL.** The department may approve variances from non-statutory requirements of this chapter when the department determines that the variances are essential to or have no effect on the department's objectives. Before granting variances, the department shall take into account factors such as good cause, circumstances beyond the control of the laboratory and financial hardship.

(2) **REQUEST FOR VARIANCE.** Requests for variances shall be submitted to the department's director of the bureau of integrated science services as far in advance as feasible. Each variance request shall contain:

- (a) The name of the applicant or laboratory.
- (b) The section of this chapter from which a variance is sought.
- (c) A description of the circumstances under which the variance will be exercised, including any pertinent background information relevant to making a determination of justification.
- (d) A statement as to whether the same or a similar variance has been requested previously, and if so, the circumstances of the previous request.

Note: Requests for variance should be addressed to: Bureau Director, Science Services
Wisconsin Department of Natural Resources
101 So. Webster Street
PO Box 7921
Madison, WI 53707-7921.

(3) **APPROVAL OF VARIANCE.** The department shall send a letter approving or denying the requested variance to the applicant within 60 days of receiving all the information referenced in sub. (2). If the request is denied, the letter shall state the reasons for the denial. A copy of all letters approving or denying variances shall be

retained in the department's files.

**SUBCHAPTER III
PROGRAM STRUCTURE**

NR 149.13 Fields of accreditation (certification and registration). (1) **GENERAL.** The department shall certify and register laboratories by specific fields of accreditation. Accreditation is offered as either certification or registration. Fields of certification and registration consist of 3 tiers describing the analytical capability of laboratories. Specific fields of certification and registration shall be structured as in Table 1 of this subchapter.

Table 1: Fields of accreditation tiers

	ACCREDITATION TYPE OFFERED		
	CERTIFICATION OR REGISTRATION	CERTIFICATION OR REGISTRATION	CERTIFICATION ONLY
Tier 1– Matrix	Aqueous Matrix	Solid matrix	Drinking water matrix
Tier 2– Analytical technology or method	Analytical technology Ex. BOD assay Colorimetric Cold Vapor AA GC/MS	Analytical technology Ex. ICP GC Waste Char. Extn Waste Char. Extn	Method Ex. EPA 200.9 SM 4500 NO3- D EPA 300.0 EPA 524.2
Tier 3– Analyte or Analyte Group	Analyte or Analyte Group Ex. BOD Total Phosphorus Mercury Volatile Organics	Analyte or Analyte Group Ex. Iron PCB (Aroclors) TCLP Ignitability	Analyte or Analyte Group Ex. Arsenic Nitrate Fluoride VOCs

(2) **TIER 1– MATRIX.** The first tier of certification or registration designates the matrices a laboratory may analyze and shall consist of aqueous, solids, and drinking water matrices.

(3) **TIER 2– TECHNOLOGY OR METHOD.** The second tier of certification or registration shall be analytical technology for aqueous and solid matrices or method for drinking water matrix.

(a) Laboratories analyzing aqueous and solid samples may be certified or registered for the analytical technologies contained in table 2 of this subchapter.

1. The department shall include any associated sample preparation techniques, such as digestions, distillations, extractions, cleanups, concentration, and dilution as part of the certification or registration for a given field of accreditation.

2. Laboratories may employ multiple approved methods of analysis for a given analytical technology under the same field of accreditation.

Table 2: Analytical Technologies for Aqueous and Solid Matrices

#	Analytical Technology
1.	Oxygen Demand assays (BOD or cBOD)
2.	Colorimetric or Nephelometric (turbidimetric)
3.	Combustion or Oxidation
4.	Electrometric Assays (i.e. probe, ion-selective electrode)
5.	Gravimetric Assays – Residue (solids)
6.	Gravimetric Assays – Oil& Grease or Hexane Extractable Materials (HEM)
7.	Ion Chromatography (IC)
8.	Titrimetric or Potentiometric Titration Assays

9.	Cold Vapor Atomic Absorption or Gaseous Hydride Spectrophotometry
10.	Flame Atomic Absorption Spectrophotometry
11.	Graphite Furnace Atomic Absorption Spectrophotometry
12.	Inductively Coupled Plasma Emission Spectrophotometry (ICP)
13.	Inductively Coupled Plasma-Mass Spectrometry (ICP/MS)
14.	Ultra-Low Level Metals Assays
15.	Gas Chromatography (GC)
16.	Gas Chromatography-Mass Spectrometry (GC/MS)
17.	High Resolution Gas Chromatography-Mass Spectrometry (HRGC/MS)
18.	High Performance Liquid Chromatography (HPLC)
19.	Liquid Chromatography-Mass Spectrometry
20.	Waste Characterization Extractions ¹
21.	Waste Characterization Assays ²
22.	Whole Effluent Toxicity Assays ³
23.	Other ⁴

1. Waste characterization extractions offered for solid matrices (Tier 1) only and include extraction procedure toxicity, synthetic precipitation leaching procedure, toxicity characteristic leaching procedure and shake extraction of solid waste with water. Laboratories shall also maintain certification or registration for any analyte to be determined in the resulting extract from any waste characteristic extraction.

2. Waste characterization assays are offered for solid matrices (Tier 1) only and shall include tests required to determine if a material meets the hazardous definition in s. NR 661.03 and those used to fulfill the requirements of waste analysis plans under ch. NR 664 or 665.

3. Certification or registration for this technology is only available for aqueous matrices (Tier 1).

4. The department may offer certification or registration in other analytical technologies if they are approved by EPA or approved by the department as an emerging technology.

(b) Laboratories analyzing drinking water samples shall be certified to perform methods promulgated or approved by the EPA.

1. Methods available for the certification of laboratories analyzing drinking water are contained in ch. NR 809 and the “Manual for the Certification of Laboratories Analyzing Drinking Water”, EPA815-R-05-004, fifth edition, EPA, Office of Groundwater and Drinking Water, January 2005.

2. The department may certify laboratories to analyze drinking water using methods not contained in the sources cited in subd. 1. if EPA has promulgated the methods or has granted approval for their use.

(4) TIER 3– ANALYTE OR ANALYTE GROUP. The third tier of the certification fields shall be analyte or analyte group, when the department determines that offering analyte groups improves the efficiency of administering certifications.

(a) The analytes and analyte groups available for certification and registration are contained in appendices I and II.

(b) The department may offer certification or registration for additional analytes or analyte groups that are not contained in appendices I and II upon request by a covered program or when EPA requires their analysis, after consultation with the certification standards review council.

(c) Analyte groups are organized into classes. Laboratories analyzing aqueous and solid matrices may be certified or registered for analyte groups belonging to the analytical classes contained in Table 3 of this subchapter.

Table 3: Classes of analytes groups for aqueous and solid matrices

Number	Class of analyte group
1.	General Chemistry
2.	Metals
3.	Base, Neutral, and Acid Extractable Semivolatile Compounds, including but not limited to: <ul style="list-style-type: none"> a. Aldehydes and Ketones b. Benzidines c. Chlorinated Hydrocarbons d. Explosive Residues e. Haloethers f. Nitroaromatics and Cyclic Ketones g. Nitrosamines h. Nonhalogenated Organics i. Phenols j. Phthalate Esters
4.	Pesticides and their metabolites, including, but not limited to: <ul style="list-style-type: none"> a. Acid Herbicides b. Nitrogen c. N-Methyl Carbamates and Substituted Ureas d. Organochlorine e. Organophosphorus f. Triazines g. Pesticides Not Otherwise Specified
5.	Petroleum Hydrocarbons
6.	Polychlorinated Biphenyls (as Aroclors, and as Congeners)
7.	Polychlorinated Dibenzo-p-Dioxins and Furans
8.	Polynuclear Aromatic Hydrocarbons
9.	Volatile Organic Compounds

(b) Analyte groups are organized into classes. Laboratories analyzing drinking water may be certified for analytes or analyte groups belonging to the analytical classes contained in Table 4 of this subchapter.

Table 4: Classes of analyte groups for the drinking water matrix

Number	Class of analyte group
1.	Disinfection Byproducts
2.	Primary Inorganic Contaminants (Non-Metals)
3.	Primary Inorganic Contaminants (Metals)
4.	Secondary Contaminants (Non-Metals)
5.	Secondary Contaminants (Metals)
6.	Synthetic Organic Contaminants (SOC) – Dioxin
7.	SOC – Organochlorine Pesticides
8.	SOC – N/P Pesticides
9.	SOC – Herbicides
10.	SOC – Miscellaneous
11.	Trihalomethanes (THM)
12.	Volatile Organic Compounds (VOC)

**SUBCHAPTER IV
CERTIFICATION AND REGISTRATION PROCESS**

NR 149.14 Application for certification or registration. (1) GENERAL REQUIREMENTS. (a) The certification and registration process requires laboratories to:

1. Submit applications for seeking, revising or transferring certifications or registrations.
2. Declare the fields of certification or registration being sought, revised or transferred in corresponding applications.
3. Declare the methods of analysis that will be used to analyze analyte and analyte groups in the fields of certification or registration being sought, revised or transferred.
4. Submit a current analytical instrument list.
5. Submit acceptable results for proficiency testing samples when the department requires the analysis of these samples.
6. Submit a statement of intent to perform analyses for regulatory samples originating in Wisconsin for laboratories that are not physically located in the state of Wisconsin. Intent to perform analyses for regulatory samples originating in Wisconsin can be manifested by:
 - a. Referencing the affiliation of the applicant laboratory with a plant, office, laboratory or engineering firm physically located in the state of Wisconsin.
 - b. Submitting a letter from a potential client requesting the applicant to perform analyses to determine compliance with a covered program.
7. Submit any information identified in an application for a specific field of certification or registration.
8. Allow the department to perform an on-site evaluation, when the department requires it or determines that an evaluation is necessary to determine potential or actual compliance with this chapter.
9. Submit any necessary fees required by this chapter.
10. Agree to comply with this chapter by signing a statement to that purpose in an application.

(b) Laboratories seeking, revising or transferring certifications or registrations shall declare their intent by completing forms provided by the department.

(c) The department may not accept applications seeking, revising or transferring certifications or registrations from laboratories that:

1. Have been issued a notice of violation for nonconformance with this chapter if the nonconformance has not been corrected.
2. Have been issued an administrative order of suspension or revocation for a violation of this chapter when the violation has not been corrected and the suspension or revocation period specified in an order has not elapsed.
3. Are not in compliance with this chapter at the time they voluntarily relinquish their certifications or registrations, the nonconformance existing prior to relinquishing their certifications or registrations has not been resolved, and at least 6 months have not elapsed since the voluntary action was undertaken.

(d) The department shall void any application from laboratories that have not submitted all the information and materials required in an application within a year of the receipt of the application form.

(e) The department may require on a case-by-case basis the submittal with an application of additional information necessary to determine a laboratory's actual or potential compliance with the provisions of this chapter.

(2) INITIAL APPLICATIONS. (a) Laboratories seeking direct certifications or registrations by the department and that have never been certified or registered under this chapter, that have let all their certifications or registrations lapse or expire for more than a year, or that have voluntarily relinquished all their certifications or registrations shall submit initial applications to become certified or registered.

(b) Laboratories seeking certifications or registrations for additional matrices shall submit initial applications for the desired matrices.

(c) Laboratories seeking reinstatement of their certifications or registrations after a suspension or revocation shall submit initial applications for the desired certifications or registrations.

(d) Laboratories seeking to change their valid registrations into certifications shall submit initial applications to effect the conversion.

(e) Laboratories requesting that their certifications or registrations be transferred to a new owner that are ineligible for a transfer shall submit initial applications if they desire to maintain their certifications or registrations. Transfer of ownership transactions involving the purchase or lease of equipment and where less than 60% of the analytical staff are retained are ineligible for transfer of accreditations.

(3) REVISED APPLICATIONS. (a) Laboratories holding valid certifications or registrations shall submit revised applications to seek certifications or registrations in additional:

1. Technologies for a certified or registered matrix.
2. Analytes or analyte groups within a certified or registered analytical technology.
3. Methods for the drinking water matrix.

(b) Laboratories seeking reinstatement of their certifications or registrations within a year after failing to renew them shall submit revised applications for the desired certifications and registrations.

(c) Laboratories seeking to convert their valid certifications into registrations shall submit revised applications to effect the conversion.

(4) APPLICATIONS FOR TRANSFER OF CERTIFICATIONS OR REGISTRATIONS. (a) When the department determines that the valid certifications or registrations of a laboratory are eligible to be transferred to a new owner, the laboratory shall submit an application for transfer of certifications or registrations. Transfer of ownership transactions which do not involve the purchase or lease of equipment and where at least 60% of the analytical staff are retained are eligible for transfer of accreditations.

(b) When the department determines that the valid certifications or registrations of a laboratory are not eligible to be transferred to a new owner, the laboratory shall submit an initial application to be eligible to retain its certifications or registrations.

(5) APPLICATIONS FOR CERTIFICATIONS OR REGISTRATIONS THROUGH RECIPROCAL AGREEMENT RECOGNITION. (a) Laboratories holding valid certifications, registrations, accreditations, licenses or approvals from government bodies or private organizations with which the department has established a reciprocal agreement may have their certifications, registrations, accreditations, licenses or approvals considered for recognition by the department by submitting reciprocity applications.

(b) Laboratories applying for recognition by the department under an existing reciprocal agreement shall submit certificates or official documents of their certifications, registrations, accreditations, licenses or approvals with their applications.

(c) Laboratories applying for recognition by the department under an existing reciprocal agreement shall agree to notify the department of any changes, within 30 days of their occurrence, in the laboratories' certification, registration, accreditation, licensure or approval status with the entity with which the department has the agreement.

(d) Laboratories applying for recognition by the department under an existing reciprocal agreement shall submit a copy of the report of the last on-site evaluation performed by the entity with which the department has the agreement.

(6) PROCEDURES FOR REVISING CERTIFICATION OR REGISTRATION AS A RESULT OF THE 2007 AMENDMENTS.

(a) Prior to the September 1 of the calendar year in which this rule takes effect [revisor insert date] the department shall provide and the laboratories shall complete and submit a one-time status update form to facilitate the conversion of the test categories and demonstrate that the requirements of s. NR 149.15(2) have been met. The department may not assess fees for the conversion to the amended program structure in s. NR 149.13.

(b) The purpose of the status update form is to convert current certifications or registrations under the existing program structure into equivalent certifications or registrations under the revised program structure. The status update form may not be used to add additional analytes or analyte groups to a laboratory's list of certifications or registrations. If the laboratory wishes to become certified or registered in additional test categories, the laboratory shall comply with provisions of s. NR 149.14(3). The laboratory may apply for the additional test categories on the status update form.

Note: Status update forms will be provided to all participating laboratories and will be made available on the department's website at <http://www.dnr.state.wi.us/org/es/science/lc/APPLICATION/AppForms.htm>.

(7) ISSUANCE OF CERTIFICATIONS OR REGISTRATIONS. (a) The department shall issue certifications and registrations to laboratories through certificates that meet the criteria specified in s. NR 149.06.

(b) The department shall issue a certificate to a laboratory submitting an initial, revised or reciprocal application for certification or registration within 30 days of the date by which the laboratory successfully completes an on-site evaluation, or the date by which the department waives an on-site evaluation.

1. The department may not schedule or waive an on-site evaluation of an applicant laboratory until all the requirements of sub. (1) have been completed.

2. A laboratory completes an on-site evaluation successfully when it addresses to the department's satisfaction any deficiencies encountered during the on-site evaluation.

(c) Following an on-site evaluation, the department may issue certification or registration, on a case-by-case basis, for selected fields of certification or registration under application in fields that are unaffected by any deficiencies encountered during the onsite evaluation.

NR 149.15 Period, renewal and expiration of certification or registration. (1) **CERTIFICATION AND REGISTRATION PERIOD.** (a) The certification and registration period shall commence on September 1 and end on August 31 of the following year for all laboratories certified or registered by the department.

(b) The department shall renew the certifications or registration of laboratories that meet the requirements of this section prior to September 1 of each year.

(2) RENEWAL PROCESS. (a) Prior to September 1 of each year each directly certified or registered laboratory shall:

1. Pay the required annual renewal fee and any assessed administrative fees.

2. Submit acceptable proficiency testing sample results as required in subch. V.

(b) Prior to September 1 of each year each laboratory that is certified or registered through a reciprocal agreement shall:

1. Pay the required annual renewal fee and any assessed administrative fees.

2. Submit certificates or official documents of their certifications, registrations, accreditations, licenses or approvals from the entity with which the department has the agreement.

3. Submit a copy of the most recent on-site evaluation report from the entity with which the department has the agreement.

(3) EXPIRATION OF CERTIFICATIONS OR REGISTRATIONS. (a) The department shall void on September 1 of each year the certifications or registrations of laboratories failing to provide the information and fees specified in sub. (2)(a).

(b) The department shall void on September 1 of each year the certifications or registrations of laboratories certified through an existing reciprocal agreement that fail to provide the information and fees specified in sub. (2)(b).

(4) VOLUNTARY WITHDRAWAL OF CERTIFICATIONS OR REGISTRATIONS. Laboratories may voluntarily withdraw certifications or registrations at any time by notifying the department in writing.

NR 149.16 Notification of relocation. (1) Laboratories relocating shall notify the department in writing, at least 30 days prior to the relocation, of their change of address and any changes in their contact information.

(2) The department shall issue a revised certificate to a relocating laboratory within 30 days of receiving the notification or the effective date of the relocation, whichever is later.

(3) Laboratories undergoing a change of ownership, needing to add certifications or registrations, modifying their certification or registration status, changing the entity by or through which they obtained certifications or registrations as a result of a relocation shall comply with the requirements of s. NR 149.14.

(4) The department may perform an on-site evaluation of the relocating laboratory at its new location to determine the laboratory's continued ability to comply with the requirements of this chapter.

NR 149.17 Laboratory name change. (1) Laboratories that change names without changing ownership shall notify the department in writing within 30 days of the effective date of the name change.

(2) The department shall issue a revised certificate to a laboratory changing its name without changing ownership and not seeking additional certifications or registrations within 30 days of receiving notification from the laboratory.

(3) The department may not charge a fee for processing laboratory name changes or for issuing a revised certificate resulting solely from a name change.

NR 149.18 Subcontracting of analyses by certified or registered laboratories. (1) Laboratories needing or desiring to have samples they have received or for which they are responsible be analyzed by another laboratory shall only have the associated samples analyzed in laboratories that have valid certifications or registrations under this chapter.

(2) Laboratories accepting samples under a subcontract from another laboratory shall maintain any analytical records needed to determine compliance with this chapter. The records shall be made available to the laboratory providing the samples and the department upon request.

NR 149.19 Requirements for certification in the drinking water matrix. This section applies to laboratories analyzing drinking water for compliance with the safe drinking water program and that analyze drinking water samples in support of the compliance monitoring required by ch. NR 809.

(1) GENERAL REQUIREMENTS. (a) The minimum criteria and procedures for certification in the drinking water matrix are specified in Chapters III and IV of the “Manual for the Certification of Laboratories Analyzing Drinking Water”, EPA815-R-05-004, fifth edition, EPA, Office of Ground Water and Drinking Water, January 2005, except that:

1. The department may not grant provisional certification to laboratories.
2. The department may not grant interim certification to laboratories.
3. Laboratories shall analyze drinking water replicates or matrix spike duplicates at a frequency of one pair per preparation batch or one per 20 analytical samples in an analytical batch.

(b) Laboratories shall follow any additional criteria and procedures identified in this chapter applying to drinking water analyses.

(2) REQUIREMENTS FOR INORGANIC CONTAMINANTS. To receive certification to conduct analyses of inorganic contaminants, the laboratory shall achieve the method detection limits specified in 40 CFR 141.23 (a) (4) (i) and 40 CFR 141.89 (a) (1) (iii) or 10% of the MCL, for contaminants having an MCL, whichever is greater, for each method of analysis.

(3) REQUIREMENTS FOR VINYL CHLORIDE. To receive certification to conduct analyses of vinyl chloride, the laboratory shall achieve a method detection limit of 0.0003 mg/L for each method of analysis.

(4) REQUIREMENTS FOR OTHER VOLATILE ORGANIC COMPOUNDS. To receive certification to conduct analyses of volatile organic compounds, excluding vinyl chloride, but including trihalomethanes, the laboratory shall achieve method detection limits of 0.0005 mg/L for all regulated compounds for each method of analysis.

(5) REQUIREMENTS FOR SYNTHETIC ORGANIC CONTAMINANTS. To receive certification to conduct analyses of synthetic organic contaminants, the laboratory shall achieve the method detection limits specified in 40 CFR 141.24 (h) (18) or 10% of the MCL, whichever is greater.

(6) EXCLUSIONS FROM REQUIRED CERTIFICATION. Certification is not required to perform any of the following analyses:

- (a) Fluoride analysis required under ch. NR 809.
- (b) Analysis for free chlorine residual and total chlorine residual required under s. NR 809.705.
- (c) Analysis for pH required under s. NR 809.14.
- (d) Analysis for turbidity required under s. NR 809.725, Table A.

(7) NOTIFICATION TO AFFECTED WATER SUPPLY FACILITIES. Laboratories certified under this chapter for the drinking water matrix shall notify water supply facilities that an MCL exceedance has occurred no later than 48 hours after completing analyses whenever compliance samples exceed an MCL for any regulated analyte under ch. NR 809.

NR 149.20 Requirements for certification or registration in the whole effluent toxicity analyte class. This section applies to laboratories certified or registered in the aqueous matrix that perform whole effluent toxicity testing.

(1) GENERAL REQUIREMENTS. (a) The criteria and procedures for the certification or registration of laboratories performing whole effluent toxicity testing are specified in table A of s. NR 219.04.

Note: Method for analyses for determining the toxicity of effluents are referenced in the “State of Wisconsin Aquatic Life Toxicity

Testing Methods Manual”, 2nd edition. This document can be obtained at www.dnr.state.wi.us/org/water/wm/ww/biomon.

(b) Laboratories shall follow the requirements for quality systems specified in ss. NR 149.36 to 149.49.

(2) CHEMICAL TESTING IN SUPPORT OF WHOLE EFFLUENT TOXICITY TESTING. (a) Any laboratory performing tests for alkalinity, ammonia and hardness conducted in support of regulatory samples analyzed for whole effluent toxicity need not be certified or registered for those tests if the laboratory is certified or registered for performing whole effluent toxicity testing.

(b) Laboratories that are not certified or registered for performing whole effluent toxicity testing shall be certified or registered for performing tests for alkalinity, ammonia and hardness when those tests are undertaken in support of regulatory samples analyzed for whole effluent toxicity.

(c) Laboratories need not be certified or registered to perform tests for pH, conductivity, dissolved oxygen and total residual chlorine, when those tests are undertaken in support of regulatory samples analyzed for whole effluent toxicity.

NR 149.21 Fees. The department shall set a schedule of fees for laboratories participating in the program that is designed to recover the costs of administering this chapter. These costs include those associated with laboratory evaluations, discretionary acceptance of data, reciprocity, training and collection of fees. Fees may not be prorated and, except for overpayment, are not refundable.

(1) TOTAL FEE INCOME. (a) The program’s total fee income shall be designed to generate revenues equal to the department of administration’s approved spending authority for this program. Any amendments to the formulas in this subsection shall be reviewed by the laboratory certification standards review council prior to being proposed as rule amendments.

(b) The department may adjust the fee schedule according to the formulas in this subsection and the relative value unit items specified in tables 1, 2 and 3. Annual fee adjustments shall be reviewed by the laboratory certification standards review council and approved annually by the natural resources board.

(c) The following formulas shall be used to generate and adjust the program’s fee schedule:

1. Fee Income \leq ASA – TR.

a. Fee income is the total of all fees, including application fees, renewal fees and late fees, that are collected in a given fiscal year.

b. TR is the total out-of-state travel reimbursement in a given fiscal year.

c. ASA is the approved spending authority for the given fiscal year. The department may substitute a lesser amount than the ASA if the ASA is greater than the estimated costs of the program.

d. Estimates of the fee income and travel reimbursement shall be calculated according to s. NR 149.21 (1)

(d).

Note: The department of administration approved spending authority is given in s. 20.7379 (2) (fj), Stats., and may be revised by the department of administration to recover program cost.

2. Total # RV Units = \sum (# Laboratories in Item) (RV of Item).

a. Total # RV Units is the total number of relative value (RV) units available for the fiscal year. The relative value units for each fee item (RV of item) are listed in tables 1, 2 and 3.

b. # Laboratories in item is a count of how many laboratories paid the fee for that item for a given fiscal year.

c. Total # of RV Units is calculated by summing the product of (RV of item) and (# laboratories in each item) for each item.

3. Cost per RV = (ASA – TR)/Total # RV Units. The Cost per RV is the dollar value assigned to one RV unit.

4. Cost of Item = (RV Unit of Item) (Cost per RV).

(d) The fees for the upcoming fiscal year shall be based upon program information from the previous fiscal year and upon the approved spending authority for the upcoming fiscal year. The number of laboratories participating in the program shall be determined no earlier than 6 months prior to the billing for the upcoming fiscal year. The estimated travel reimbursement shall be equal to the travel reimbursement from the preceding fiscal year. The calculated fees may not be adjusted during the current fiscal year once laboratories have been billed.

(2) ADMINISTRATIVE FEES. The department shall assess fees to recover the cost of specified administrative functions specified in Table 1 of this subchapter. Any outstanding administrative fees may be included as part of the annual fee.

Table 1: Administrative Fees

Item	Relative Value Units
Discretionary Acceptance (NR 149.11)	Actual Cost
Evaluation Cancellation ¹	Incurred Costs
Evaluation for Enforcement Follow-Up	Actual Cost
Evaluation of Out-of-State Laboratories	Travel Cost
Late Renewal Fee ²	2

1. Out-of-state laboratories may be required to reimburse the program for travel costs incurred by the cancellation or postponement of an evaluation, not limited to airfare, hotel and rental car expenses.

2. Assessed 30 days after payment due date.

(3) APPLICATION FEES. The department shall assess fees for all applications specified in Table 2 of this subchapter. If an application is not completed within a single fiscal year, the department may adjust the fees on the application to recover the difference in fees between the year the application was submitted and the year the application was completed. The laboratory shall pay this difference prior to receiving certifications or registrations.

Table 2: Application Fees

Item	Relative Value Units
Initial Application	6
Revised Application	3
Reciprocity Application	4
Transfer of Ownership Application	4

(4) ANNUAL FEES. The department shall assess an annual fee to each laboratory holding certifications or registrations under this chapter either directly or through recognition agreements. A laboratory's annual fee shall be the sum of all of the following:

(a) The base fee for certification or registration. The department shall assess a base fee to all laboratories holding certifications or registrations under this chapter. The number of relative value units assigned to each type of base fee is specified in Table 3 of this subchapter

(b) The matrix fee. The department shall assess a fee per matrix type to all certified and registered laboratories. The number of relative value units assigned to each type of matrix fee is specified in Table 3 of this subchapter.

(c) Analytical technology or analytical class fees, considering any maximum specified in this subsection.

1. Analytical technology fees. The department shall assess a fee for each analytical technology per matrix to all certified and registered laboratories in fields involving the aqueous and solid matrices. The assessed fee shall be based on the relative value units specified in Table 3 of this subchapter and subject to any maximum fee specified in this subchapter.

a. The maximum analytical technology fee assessed to any lab for the aqueous matrix shall be 22 relative value units (RVU).

b. The maximum analytical technology fee assessed to any lab for the solid matrix shall be 22 relative value units (RVU).

2. Analytical class fees. The department shall assess a fee per analytical class to all certified laboratories in fields involving the drinking water matrix. The assessed fee shall be based on the relative value units specified in Table 3 of this subchapter and subject to any maximum fee specified in this subchapter. The maximum analytical class fee assessed to any lab for the drinking water matrix shall be 31 relative value units (RVU).

(d) Any outstanding administrative fees.

Note: Considering base fees, matrix fees, analytical technology fee maximums, and the analytical class fee maximum, this effectively establishes a maximum annual fee “cap” of 100 RVUs for any laboratory.

Table 3: Annual Fees for Certification and Registration

	Item	Relative Value Units
A.	Administrative Fees	
	Outstanding administrative fees	per Table 1 of this subchapter
B.	Base Fees	
	Base Fee, Certification	10
	Base Fee, Registration	5
C.	Matrix Fees	
	Matrix Fee, Aqueous	5
	Matrix Fee, Drinking Water	5
	Matrix Fee, Solids	5
D.	Analytical Technology Fees for Aqueous and Solid Matrices	
	Electrometric Assays (ion-selective electrodes)	1
	Gravimetric Assays, Residues (solids)	1
	Gravimetric Assays, Oil and Grease (HEM)	2
	Titrimetric or Potentiometric Titration Assays	1
	Colorimetric or Nephelometric Spectrophotometry	2
	Combustion or Oxidation	2
	Oxygen Demand assays (BOD, cBOD)	3
	Ion Chromatography	3
	Waste Characteristic Extractions (<i>Solid Matrix only</i>)	1
	Waste Characterization Assays (<i>Solid Matrix only</i>)	1
	Flame Atomic Absorption Spectrophotometry	2
	Cold Vapor Atomic Absorption or Gaseous Hydride Spectrophotometry	3
	Graphite Furnace Atomic Absorption Spectrophotometry	3
	Ultra-Low Level Metals Assays	3
	Inductively Coupled Plasma Emission Spectrophotometry	4
	Inductively Coupled Plasma-Mass Spectrometry	5

	Gas Chromatography	3
	Gas Chromatography-Mass Spectrometry	4
	High Performance Liquid Chromatography	3
	Liquid Chromatography-Mass Spectrometry	4
	High Resolution Gas Chromatography-Mass Spectrometry	10
	Whole Effluent Toxicity Assays (<i>Aqueous Matrix only</i>)	5
	Other	Not to exceed 10 ¹
E.	Analytical Class Fees for Drinking Water Matrix	
	Disinfection Byproducts	5
	Primary Inorganic Contaminants (Non-Metals)	3
	Primary Inorganic Contaminants (Metals)	6
	Secondary Contaminants (Non-Metals)	2
	Secondary Contaminants (Metals)	3
	SOC – Dioxin	8
	SOC – Organochlorine Pesticides	3
	SOC – N/P Pesticides	3
	SOC – Herbicides	3
	SOC – Miscellaneous	4
	Trihalomethanes (THM)	2
	Volatile Organic Compounds (VOC)	4

1. Actual cost will be determined by the department considering the complexity of the technology.

SUBCHAPTER V PROFICIENCY TESTING

NR 149.22 Required analyses of proficiency testing samples. (1) REQUIREMENTS. (a) Laboratories shall participate in at least one single-concentration proficiency testing study per certification or registration period for each analyte or analyte group identified by the department as specified in sub. (2).

1. For aqueous and solid matrices, laboratories shall analyze aqueous matrix proficiency testing samples for each combination of technique and analyte or analyte group in a laboratory's fields of certification or registration.

2. For the drinking water matrix, laboratories shall analyze proficiency testing samples for each combination of method and analyte or analyte group in a laboratory's fields of certification.

(b) Single-concentration proficiency testing studies may be those offered at set intervals by proficiency testing sample providers, "rapid response" samples or custom formulations approved by the department.

(2) LISTS OF REQUIRED PROFICIENCY TESTING SAMPLES AND APPROVED PROVIDERS. (a) The department shall publish a list of required proficiency testing samples and approved proficiency testing sample providers annually. The department shall seek the advice of the certification standards review council prior to identifying required proficiency testing samples and approved sample providers.

(b) The list shall identify matrix-specific proficiency testing samples required for submittal for renewal of accreditation, or with initial or revised applications and the specific providers approved for supplying each required sample.

Note: Lists of required testing samples and approved proficiency testing sample providers are available on the department's website at <http://www.dnr.state.wi.us/org/es/science/lc/PT/Index.htm>.

(3) EXEMPTIONS. (a) Laboratories performing the following analytical techniques for metals analysis in aqueous and solid matrices shall analyze quality control standards 3 times per year at evenly spaced intervals in lieu of analyzing proficiency testing samples:

1. Flame atomic absorption spectrophotometry.
2. Colorimetric, for analytes other than hexavalent chromium.

(b) Laboratories analyzing ultra-low level metals in aqueous and solid matrices shall analyze quality control standards 3 times per year at evenly spaced intervals in lieu of analyzing proficiency testing samples. Quality control standards shall be diluted to fall within the working concentration of the analytical technique.

NR 149.23 Approval of proficiency testing sample providers. When evaluating a proficiency testing sample provider for approval, the department shall consider criteria including, but not limited to, the provider's:

- (1) Accreditation status by nationally recognized accreditation programs.
- (2) Use of techniques for calculating acceptance limits as specified in s. NR 149.27.
- (3) Ability to submit results to the department in a format specified by the department, including electronic media.

NR 149.24 Schedule of analysis. (1) APPLICATIONS FOR AQUEOUS AND SOLID MATRICES. Laboratories submitting initial or revised applications for certification or registration in aqueous and solid matrices shall analyze proficiency testing samples from an approved proficiency testing sample provider and submit acceptable results for each technique and analyte or analyte group for which the department has identified that proficiency testing samples are required.

(a) Acceptable proficiency testing samples shall be analyzed no more than 6 months prior to the date of application.

(b) The department may not grant a certification or registration unless the associated proficiency testing sample results meet the criteria specified in s. NR 149.27.

(2) APPLICATIONS FOR DRINKING WATER MATRIX. Laboratories submitting initial or revised applications for certification in the drinking water matrix shall analyze proficiency testing samples from an approved proficiency testing sample provider and submit acceptable results for each method and analyte or analyte group.

(a) Acceptable proficiency testing samples shall be analyzed no more than 6 months prior to the date of application.

(b) The department may not grant a certification or registration unless the associated proficiency testing sample results meet the criteria specified in s. NR 149.27.

(3) ANNUAL RENEWAL FOR AQUEOUS AND SOLID MATRICES. Laboratories seeking renewal of certification or registration for aqueous or solid matrices shall analyze at least one proficiency testing sample, prepared in an aqueous matrix, from an approved proficiency testing sample provider and submit acceptable results for each technique and analyte or analyte group for which the department has identified that proficiency testing samples are required. Laboratories with 3 consecutive proficiency testing sample failures in a year for any technique and analyte or analyte group shall submit 2 consecutive acceptable proficiency testing samples from an approved proficiency testing sample provider for that technique and analyte or analyte group.

Note: Proficiency testing samples prepared in a solid matrix are not required at this time to obtain or renew certification or registration for analytes or analyte groups under the solid matrix tier.

(a) For renewal of certifications or registrations, which begin on September 1 of each calendar year, acceptable proficiency testing sample results shall have been reported by an approved PT provider no sooner than January 1 or later than August 15 of the same calendar year.

Note: For example, to renew certification for any parameter effective for the period from September 1, 2009 to August 31, 2010, a laboratory shall have successfully analyzed a PT sample for that parameters reported between January 1 and August 15, 2009.

(b) Reports from proficiency testing sample providers shall be received by the department on or before August 15 of each year.

(c) The department may not renew a certification or registration unless the associated proficiency testing sample results meet the criteria specified in s. NR 149.27.

(4) ANNUAL RENEWAL FOR DRINKING WATER MATRIX. Laboratories seeking renewal of certification for the drinking water matrix shall analyze at least one proficiency testing sample from an approved proficiency testing sample provider and submit acceptable results for each method and analyte or analyte group.

(a) For renewal of certifications or registrations, which begin on September 1 of each calendar year, acceptable proficiency testing sample results shall have been reported by an approved PT provider no sooner than January 1 or later than August 15 of the same calendar year.

(b) Reports from proficiency testing sample providers shall be received by the department on or before August 15 of each year.

(c) The department may not renew a certification or registration unless the associated proficiency testing sample results meet the requirements specified in s. NR 149.27.

NR 149.25 Treatment of proficiency testing samples by laboratories. (1) Proficiency testing samples shall be subjected to any preparatory steps undergone by analytical samples, unless the preparation instructions submitted by a provider specifically instruct omitting a preparatory step.

Note: Preparatory steps include digestions, distillations, extractions, concentrations and dilutions.

(2) Laboratories may report multiple results of multiple analyses of a single proficiency testing sample when a laboratory maintains certifications or registrations for multiple techniques for any analyte or analyte group in aqueous and solid matrices.

(3) Laboratories may report multiple results of a single proficiency testing sample when the laboratory maintains certifications for multiple methods for any analyte or analyte group in the drinking water matrix.

(4) Prior to submitting proficiency testing results to a proficiency testing sample provider:

(a) Laboratories may not send a proficiency testing sample, or portion of a proficiency testing sample to another laboratory for analysis.

(b) Laboratories may not knowingly analyze a proficiency testing sample, or a portion of a proficiency testing sample from another laboratory.

(c) Laboratories may not communicate results of a proficiency testing sample with another laboratory.

NR 149.26 Submittals. (1) Laboratories shall submit proficiency testing sample results to providers in accordance with the dates specified by the providers.

(2) Proficiency testing reports may be submitted to the department directly from the provider or by the laboratory, but it is the laboratory's responsibility to ensure the department receives the necessary reports for initial and revised applications. Reports submitted by the laboratory shall be submitted in their entirety, without modification, to the department.

(3) Results from all proficiency testing reports issued to the department by providers shall be used to determine a laboratory's certification or registration status.

(4) Proficiency testing reports may be amended and reissued by the provider when errors attributable to the proficiency testing sample provider are identified. The department shall accept amended and reissued reports if they are:

- (a) Clearly labeled as revised or reissued.
- (b) Directly submitted to the department by the provider.

NR 149.27 Proficiency testing sample acceptance limits and grading. (1) ACCEPTANCE LIMITS. A laboratory's result for any analyte or analyte group is considered unacceptable if it meets any of the following conditions:

- (a) The result falls outside the acceptance limits.
- (b) The laboratory reports a result for an analyte not present in the proficiency testing sample.
- (c) The laboratory does not report a result for an analyte present in the proficiency testing sample.
- (d) The laboratory fails to submit its results to the proficiency testing sample provider on or before the deadline for the proficiency testing study.

(2) GRADING. (a) Proficiency testing samples for analytes in aqueous and solid matrices shall be graded in accordance with acceptance limits established by the department considering criteria developed by EPA.

(b) For required proficiency testing sample analytes in aqueous and solid matrices for which EPA has not developed acceptance limits, the department may develop acceptance limits based on its experience or information supplied by approved providers.

(c) When an insufficient number of laboratories participate in a study to generate peer-based acceptance limits in a proficiency testing sample with analytes for which EPA has not established acceptance limits, the department may grade results using fixed acceptance limits.

(d) Proficiency testing sample analytes in drinking water shall be graded in accordance with the acceptance limits established in 40 CFR 141.23 (k)(3)(ii), 40 CFR 141.24 (f)(17)(i)(C) and (D), 40 CFR 141.24 (f)(17)(ii)(B), 40 CFR 141.24 (f)(19)(i)(A) and (B) and 40 CFR 141.89 (a)(1)(ii), or developed by EPA.

(e) Where certification or registration in an analyte group is based on passing a representative proficiency testing sample containing more than one analyte, the laboratory shall report acceptable results on at least 80% of the analytes to achieve acceptable results for that sample.

(f) The department shall establish procedures for evaluating false positives and false negatives reported in analyzed proficiency testing samples.

NR 149.28 Procedure for correcting unacceptable proficiency testing sample results. (1) AQUEOUS AND SOLID MATRICES. If a laboratory does not meet the acceptance limits for a particular analyte or analyte group and the laboratory does not have acceptable results on a previous sample analyzed during the same certification or registration period, the department shall require the laboratory to analyze a second proficiency testing sample for that analyte or analyte group.

(a) If the results of a second proficiency testing sample do not meet the acceptance limits, the department may initiate an assessment of the laboratory's quality control records if this action is necessary to validate data generated by the laboratory. After failing 2 consecutive proficiency testing samples, the laboratory shall:

1. Submit a corrective action report and initiate an action plan to correct the problems within 30 days of the date of notification of the second failure. This action plan shall include a timetable for correcting the problems and obtaining a third proficiency testing sample.

2. Analyze a third proficiency testing sample within 60 days of the date of notification of the second failure. If the results of the third proficiency testing sample do not meet the acceptance limits, the laboratory shall analyze 2 subsequent and consecutive acceptable proficiency testing samples.

(b) The department may not renew the certification or registration of those analytes or analyte groups for which a laboratory has failed 3 consecutive proficiency testing samples for those analytes or analyte groups and has not successfully analyzed 2 subsequent and consecutive proficiency testing samples for those analytes or analyte groups prior to September 1.

(c) When applying to have an analyte or analyte group reinstated after non-renewal for failing 3 consecutive proficiency testing samples, the laboratory shall provide acceptable results on 2 subsequent and consecutive proficiency testing sample studies for that analyte or analyte group.

(2) **DRINKING WATER.** If a certified laboratory does not meet the acceptance limits that have been established by the department, the department shall require the laboratory to analyze a second proficiency testing sample and may require the laboratory to submit a corrective action report. If the results of the second sample do not meet the acceptance limits, the department may not renew the laboratory's certification and may revoke the laboratory's certification as specified in s. NR 149.10.

SUBCHAPTER VI ON-SITE LABORATORY EVALUATIONS

NR 149.29 Purpose, type and frequency. (1) The department shall perform on-site evaluations to determine a laboratory's potential, actual or continued ability to comply with the provisions of this chapter.

(2) The department shall conduct announced on-site evaluations of laboratories once every 3 years and:

(a) When a laboratory submits an application to become certified or registered in any field of certification or registration, unless the department waives the requirement to perform an on-site evaluation. When the department does not waive an evaluation, the evaluation shall be performed within 90 days after the department determines that a received application is complete and satisfactory.

(b) When a laboratory changes its location, unless the department waives the requirement to perform an on-site evaluation. When the department does not waive an evaluation, the evaluation shall be performed within 90 days after the department receives notification of the change in location.

(c) When the department determines that an on-site evaluation is necessary to verify corrective action implemented by a laboratory to address deficiencies identified in a previous on-site evaluation.

(d) When the department has reason to believe that a laboratory is not in compliance with this chapter.

(3) The department may conduct unannounced on-site evaluations of a laboratory to verify compliance with this chapter after a notice of violation has been issued to a laboratory.

NR 149.30 Evaluation procedures and appraisal. (1) The department shall perform on-site evaluations of laboratories according to documented procedures that promote consistency in determining a laboratory's potential, actual or continued ability to comply with this chapter.

(2) The department shall provide forms that allow laboratories to voluntarily appraise the evaluation process.

NR 149.31 Evaluation reports. (1) The department shall document the deficiencies of an on-site evaluation in reports issued to the evaluated laboratory.

(2) The report of an on-site evaluation shall be issued to a laboratory within 30 days of the conclusion of the on-site visit. When the department finds it necessary to issue an evaluation report at a date later than 30 days after the conclusion of an on-site visit, the department shall notify the laboratory within 10 days after the conclusion of the 30-day period about the delay. The notice shall include an expected delivery date for the report.

NR 149.32 Evaluation corrective action. (1) A laboratory shall take corrective action to address any deficiencies discovered during an on-site evaluation.

(2) A laboratory shall submit to the department within 30 days from the evaluation report's date a plan of corrective action to address all the deficiencies noted in the report. When a laboratory finds it necessary to submit a corrective action plan at a date later than 30 days after the evaluation report's date, the laboratory shall notify the department about the delay and provide an expected delivery date in consultation with the department.

(3) The department shall review the corrective action plan submitted by a laboratory and inform the laboratory whether the submitted plan addresses satisfactorily all noted deficiencies, or whether additional action or documentation is necessary to determine the laboratory's ability to comply with this chapter.

(a) When the department determines that the submitted corrective action plan addresses all noted deficiencies satisfactorily, the department shall inform the laboratory in writing within 180 days of the conclusion of on-site visit that the evaluation process has been completed.

(b) When the department determines that additional action or documentation is needed to evaluate compliance with this chapter, the department shall agree on a date for a second corrective action plan to be submitted in consultation with the laboratory.

1. When the department determines that the second corrective action plan addresses all noted deficiencies satisfactorily, the department shall inform the laboratory in writing that the evaluation process has concluded.

2. When the department determines that the second corrective action plan does not address all the noted deficiencies satisfactorily, the department may schedule another on-site evaluation to determine the laboratory's compliance with this chapter, terminate any outstanding application that led to the original on-site evaluation or direct enforcement to the laboratory.

3. When a second on-site evaluation is scheduled as a follow-up to a second corrective action plan, the department shall establish deadlines that resolve any remaining unresolved deficiencies expeditiously, but no later than 90 days after the conclusion of the follow-up visit.

NR 149.33 Conflicts of interest. (1) The department shall establish procedures to ensure and document that laboratory evaluators under its employment are free of any conflicts that would render them incapable of performing an objective and unbiased evaluation of a laboratory.

(2) A laboratory may request information and documents used by the department to establish that any evaluator assigned to perform the laboratory's evaluation is free of any conflicts of interest.

NR 149.34 Evaluator qualifications. (1) The department shall develop procedures to establish and evaluate the education, experience and credentials of the laboratory evaluators under its employment.

(2) A laboratory may request information and documents used by the department to establish that any evaluator assigned to perform the laboratory's evaluation has the necessary education, experience, or credentials to perform evaluations competently.

SUBCHAPTER VII QUALITY SYSTEMS

NR 149.35 General requirements. (1) SCOPE. This subchapter establishes personnel, quality assurance, quality control, method selection, sample handling and documentation requirements for laboratories.

(2) **RESPONSIBILITY FOR QUALITY SYSTEM.** Laboratories shall conduct their analytical activities under a quality system that incorporates the provisions of this subchapter. At least one individual, however named, within a laboratory's organization or under the laboratory's employment shall be identified to the department as responsible for establishing, implementing, assessing and revising, as needed, a laboratory's quality system.

NR 149.36 Laboratory personnel. (1) MANAGEMENT AND ANALYTICAL STAFF. The laboratory shall have personnel with education, training or experience that allows them to comply with the requirements of this chapter.

(2) **PERSONNEL INVOLVED IN DRINKING WATER ANALYSES.** Additional education and training requirements of management and analytical staff involved in analyzing drinking water are contained in Chapters III and IV of the "Manual for the Certification of Laboratories Analyzing Drinking Water", EPA 815-R-05-004, fifth edition, EPA, Office of Groundwater and Drinking Water, January 2005.

Note: This document is available at: <http://www.epa.gov/safewater/labcert/labindex.html>.

(3) **DEMONSTRATION OF CAPABILITY. (a)** When laboratories reference methods that contain protocols for demonstrating initial capability, continuing capability or both, personnel performing analyses using these methods shall perform the protocols, meet any associated evaluation criteria and document results.

(b) When a laboratory references an analytical test method that does not contain protocols for demonstrating initial capability, continuing capability or both, the laboratory shall establish demonstration of capability criteria for determining that each person who performs testing on compliance samples using the method has demonstrated the necessary skills and expertise required to generate quality analytical results. The laboratory shall retain documentation that each person performing a given test on compliance samples has satisfied the demonstration of capability criteria established by the laboratory.

NR 149.37 Quality manual. (1) PURPOSE AND GENERAL PROVISIONS. The laboratory's quality system shall be defined in a quality manual, however named. All policies and procedures governing the laboratory's quality system shall be documented or referenced in the quality manual. All laboratory personnel shall follow the policies and procedures established by the quality manual.

(2) **FORMAT.** The quality manual shall have a format, however conceived, that addresses the content elements specified in this section. Content elements may be presented in narrative, tabular, schematic or graphical form. The manual shall be a document in hard copy or electronic format traceable to the laboratory.

Note: Although this section does not require a specific format for quality manuals, the format suggested by the following is acceptable to the department: "Manual for the Certification of Laboratories Analyzing Drinking Water", EPA 815-R-05-004, fifth edition, EPA, Office of Groundwater and Drinking Water, January 2005. This document is available at: <http://www.epa.gov/safewater/labcert/labindex.html>.

(3) **CONTENT.** The quality manual shall include, address or refer to, at a minimum, the following elements:

(a) Organization and management structure of the laboratory.

(b) Procedures for retention, control and maintenance of documents used in or associated with analyses.

(c) Procedures for achieving traceability of standards, reagents and reference materials used to derive any results or measurements.

(d) Procedures for handling samples.

(e) Lists of major analytical instruments and support equipment.

(f) Procedures for calibration, verification and maintenance of major analytical instruments and support equipment.

(g) Procedures for evaluating quality control samples, including, but not limited to, method blanks, laboratory control samples, matrix fortified samples and replicates.

(h) Procedures for initiating, following up on and documenting corrective action addressing quality assurance and quality control failures, discrepancies or nonconformance.

(i) Procedures for reviewing analytical data and reporting analytical results.

(4) REVISIONS. The quality manual shall be kept current by the responsible party, however named, for maintaining the laboratory's quality system. All editions or versions of the quality manual shall indicate the dates in which they were issued or revised.

(5) LABORATORIES ANALYZING DRINKING WATER SAMPLES. Laboratories performing tests in drinking water shall ensure, in addition to the requirements in this section, that the content elements specified in Chapter III of the "Manual for the Certification of Laboratories Analyzing Drinking Water", EPA 815-R-05-004, fifth edition, EPA, Office of Groundwater and Drinking Water, January 2005, are addressed, included, or referenced in their quality manuals.

Note: This document is available at: <http://www.epa.gov/safewater/labcert/labindex.html>.

NR 149.38 Corrective action for quality system and quality control samples. (1) The laboratory shall take corrective action when:

(a) Departures from established policies and procedures in the quality system are identified or become apparent.

(b) Quality control samples, including proficiency testing samples, fail established acceptance limits or evaluation criteria.

(2) The corrective action shall identify the source of the problem, correct the problem, and have a mechanism to verify the action has had the desired effect.

(3) The laboratory shall document corrective action taken to address the nonconformance and any other changes resulting from corrective action investigations. Changes taken to address failures of quality control samples to meet established acceptance criteria shall be those that resolve or address the failure in an expeditious manner before affected results are released or reported by a laboratory.

(4) The laboratory shall monitor the effectiveness of implemented corrective action changes and take additional corrective action when initial and or subsequent corrective action fails to resolve the nonconformance.

NR 149.39 Records and documents. (1) RECORDS AND DOCUMENTS RETENTION AND CONTROL. (a) The laboratory shall establish procedures to control and manage all records and documents that form part of its quality system and that are required to demonstrate compliance with this chapter.

(b) The procedures shall ensure that documents required to perform analyses and to ensure the quality of generated data are available to laboratory personnel, and that records and documents are reviewed periodically for continuing suitability and, when necessary, revised to facilitate compliance with the requirements of this chapter.

(c) The laboratory shall retain all records and documents that are part of its quality system and that are required to demonstrate compliance with this chapter for a minimum of 3 years after the generation of the last entry in a record or document. The laboratory shall retain records and documents for a longer minimum period, if they are necessary to reconstruct analytical results generated during a 3-year period.

(d) The department may require in writing that records be retained for a longer period than that specified in par. (c) if the department has initiated legal action involving test results or the certification or registration status of the laboratory.

(e) The laboratory shall identify to the department a responsible party for retaining documents and records for the required period in the event the laboratory changes ownership or ceases to be certified or registered.

(f) Records and documents shall be handled and stored in a manner that ensures their permanence and security for the required retention period, and that facilitates their retrieval to demonstrate compliance with this chapter.

(g) Records and documents shall be legible and their entries shall be safeguarded against obliteration, erasures, overwriting and corruption.

1. Handwritten records shall be recorded in ink.

2. Records and documents that are stored only on electronic media shall be supported by the hardware and software necessary for their retrieval and reproduction into hard copy.

3. Corrections or other alterations made to entries in records or documents may not obscure the original entry.

4. The laboratory shall have procedures to prevent unauthorized access or amendments to records and documents.

(2) ADMINISTRATIVE RECORDS. Administrative records that laboratories shall maintain include:

(a) Certificates of certification or registration issued by the department, unless the department has requested a laboratory to return them.

(b) Certificates issued to the laboratory by entities with which the department has entered into a reciprocal agreement under s. NR 149.08, if a laboratory is certified or registered for this chapter under any existing agreement.

(c) Records of personnel qualifications, experience and training when personnel are required to possess or maintain specific credentials by s. NR 149.36 (2).

(d) Records of demonstration of capability for each analyst required to perform the demonstrations specified in s. NR 149.36 (3).

(e) Copies of or access to other regulations, standards and documents necessary for the laboratory to operate or to maintain compliance with this chapter.

(3) ANALYTICAL AND TECHNICAL RECORDS. (a) The laboratory shall maintain all analytical and technical records containing raw and derived data, or original observations, necessary to allow historical reconstruction of all laboratory activities that contributed to generating reported results.

(b) The format of the analytical and technical records of a laboratory shall facilitate access to the information in this subsection and may be contained in bench sheets, log books, notebooks, journals, manuals, standard operating procedures and forms, in hard copy or electronic media.

(c) Analytical and technical records retained by the laboratory shall allow access to information that includes:

1. Collection, arrival, processing and analysis dates of samples received for analysis.

2. Collection and analysis time for tests with holding time of 48 hours or less.

3. Preservation status of samples on arrival at the laboratory.

4. Identity of laboratory personnel preparing and testing samples.

5. Identification of the analytes or analyte groups analyzed in samples.

6. Preparatory techniques, such as digestions, extractions and clean-ups, to which samples are submitted.

7. Methods of analysis used for samples.
8. Results of sample analysis.
9. Traceability of standards and reagents used to perform analysis.
10. Calibration verification information and measurements of laboratory support equipment associated with sample analysis and storage.
11. Initial and continuing calibration data associated with samples analyzed.
12. Raw data for analytical instrument calibrations and samples. The department has exempted the retention of emission counts for samples and standards analyzed after an initial calibration for older models of inductively coupled plasma emission spectrophotometers that are incapable of providing that information when operated in the instrument calibration mode.
13. Results of quality control samples associated with samples analyzed.
14. Corrective actions associated with samples analyzed.
15. Maintenance performed on laboratory support equipment and analytical instruments.
16. Environmental conditions crucial to tests performed at laboratory facilities at the time samples are analyzed.
17. Reports of final results submitted to clients or the department.

NR 149.40 Standard operating procedures. (1) GENERAL REQUIREMENTS. (a) Laboratories shall maintain written standard operating procedures that document or reference activities needed to maintain their quality systems and that enable performing or reproducing an analysis in its entirety as performed at the laboratory.

(b) Standard operating procedures may be documents written by laboratory personnel or may consist entirely of copies of published documents, manuals or procedures if the laboratory follows the chosen source exactly.

(c) Standard operating procedures may consist in part of copies of published documents, manuals or procedures if:

1. Modifications to the published source are described in writing in additional documents.
2. Clarifications, changes or choices are completely described in additional documents, when published sources offer multiple options, ambiguous directives or insufficient detail to perform or reproduce an analysis.

(d) Standard operating procedures shall indicate their dates of issue or revision.

(2) ANALYTICAL METHODS MANUAL. (a) The laboratory shall have and maintain a list describing analytical test methods performed for programs covered by this chapter.

(b) The analytical methods manual may consist of published or referenced test methods, or standard operating procedures written by the laboratory as allowed in this section.

(c) The essential elements of test methods required in par. (d) may be presented in narrative, tabular, schematic or graphical form. The analytical methods manual shall be an identifiable document in hard copy or electronic format traceable to the laboratory.

(d) When the analytical methods manual consists of standard operating procedures written by the laboratory, each standard operating procedure shall include, address or refer to, at a minimum, the following elements:

1. Identification of the test method.
2. Applicable analytes.
3. Applicable matrices.
4. Method sensitivity.
5. Potential interferences.
6. Equipment and analytical instruments.
7. Consumable supplies, reagents and standards.
8. Sample preservation, storage and hold time.
9. Quality control samples and frequency of their analysis.
10. Calibration and standardization.
11. Procedure for analysis.
12. Data assessment and acceptance criteria for quality control measures.
13. Corrective actions and contingencies for handling out of control or unacceptable data.

NR 149.41 Method selection. (1) The laboratory shall use methods for environmental testing approved by covered programs under this chapter, and that are suitable for the matrix, type of analyte, expected level of analyte, regulatory limit and potential interferences in the samples to be tested.

(2) When methods are not prescribed by covered programs under this chapter or permits issued by the department, the laboratory shall consult with the department to select a method that is suitable for the matrix, type of analyte, expected level of analyte, regulatory limit and anticipated interferences in the sample.

Note: A list of authoritative sources for methods and quality control information is provided in Appendix III to this chapter.

NR 149.42 Alternative methods. (1) The department may allow the use of alternative methods from those prescribed by programs covered under this chapter, including the safe drinking water program, if a laboratory requests approval and if the environmental protection agency has granted approval for the alternative methods.

(2) On a case-by-case basis, the department may allow the use of methods other than those specified by programs covered under this chapter, for any of the following situations:

- (a) The EPA has granted approval for the alternative methods.
- (b) The applicable covered program, after consultation with the laboratory certification and registration program, determines that the allowance does not result in a detrimental effect on the quality and defensibility of the results to be generated.
- (c) The request is for approval of a method that employs a new or emerging technology and there is documentation which substantiates the validity of the emerging technology for the intended purpose.

(3) The request for consideration of approval for use of an alternative method shall include the reason for seeking the approval, a description of the principles of any new or emerging technology involved, and the potential

scope of application of the method. The department may establish criteria for validating the test method for the specific application and scope requested. If the laboratory's method validation results meet the established validation criteria, the department shall allow the use of the test method for the specific application and scope requested.

(4) The department shall approve or deny the request for consideration of approval for use within 90 days from the receipt of the request. The laboratory certification and registration program shall consider in its decision whether the covered programs that would be the recipients of the data generated have a demonstrated need for allowing the alternative method.

(5) The department may charge a fee under s. 299.11 (5) (d), Stats., if it is necessary to verify the results of any validation data submitted by a laboratory requesting use of an alternative method.

Note: A list of authoritative sources for test methods is provided in Appendix III of this chapter.

NR 149.43 Laboratory facilities. (1) The laboratory shall ensure that the environmental conditions of its facility do not affect adversely the required quality of any measurement.

(a) Laboratory facilities shall ensure effective separation between neighboring areas in which incompatible analytical activities take place. The laboratory shall take measures to prevent cross-contamination.

(b) Access to and use of areas affecting the quality of environmental tests shall be controlled to an extent commensurate with the type of analysis and samples analyzed by a laboratory.

(2) The laboratory shall monitor, control and record environmental conditions when this is required by approved test methods or when they influence the quality of test results.

NR 149.44 Laboratory equipment. (1) GENERAL PROVISIONS. (a) The laboratory shall be furnished with the equipment necessary and required for the correct performance of all the environmental tests and associated preparations and activities it performs.

(b) The equipment and software used for testing and calibration shall achieve the accuracy required to comply with the requirements of approved methods or specifications relevant to the environmental testing performed by the laboratory.

(2) LABORATORY SUPPORT EQUIPMENT. (a) All support equipment shall be kept in working order by submitting it to routine and preventive maintenance.

(b) When support equipment leaves the direct control of the laboratory for maintenance or for any other reason, the laboratory shall ensure that the function and calibration status of that equipment is checked or demonstrated to be satisfactory before the equipment is returned to service.

(3) CALIBRATION AND VERIFICATION OF SUPPORT EQUIPMENT. (a) All support equipment shall be calibrated or verified over its range of use using available reference materials traceable to NIST. When reference materials traceable to NIST are not produced, manufactured or commercially available, the laboratory shall use materials of a quality that will ensure the accuracy of the calibrated or verified support equipment for its intended use.

(b) The acceptability criteria for these calibration verification checks shall be established by approved test methods, department guidance, or in their absence, tolerances established by manufacturers.

Note: Department guidance documents are available for download from the department website at: <http://www.dnr.state.wi.us/org/es/science/lc/OUTREACH/Guidance.htm>.

(c) When the results of the calibration or calibration verification of support equipment do not meet the specifications of the application or method for which the equipment is used, the equipment shall be removed from service until repaired; however, if the deviation from the calibration specifications results in a consistent bias, the equipment may remain in service if correction factors are applied to all measurements made with the deviating equipment.

(d) Devices used to measure the temperature of laboratory ovens, incubators, water baths, refrigerators, freezers and samples received at the laboratory shall be calibrated or verified at least yearly against thermometers traceable to NIST.

(e) The operating temperature of autoclaves, incubators, ovens and water baths used as part of a method shall be checked to meet the temperature requirements of that method each day they are used.

(f) Refrigerators, freezers, ovens and incubators holding samples continuously as part of standard operating conditions shall be checked on each day that laboratory personnel conduct analyses. The laboratory shall endeavor to set equipment settings and conditions that maintain required temperatures on days that personnel do not conduct analyses.

(g) Analytical balances that have been used at least once in a month shall be checked monthly with at least 2 certified weights, one weight in the gram range and one weight in the milligram range. The weights used to perform these checks shall be:

1. Traceable to NIST, and shall be of class or type suitable for verifying the accuracy of analytical balances.

2. Certified for accuracy every 5 years by a metrology service outside the laboratory or new individual weights of suitable class or type traceable to NIST shall be purchased for use. This re-certification shall be performed sooner than every 5 years if balance checks performed using these weights suggest that a change in the certified weight has occurred.

3. Handled and stored in a manner that protects their integrity.

(h) Non-analytical balances that have been used at least once in a month shall be checked monthly with at least one weight in the expected range of their use. The weights used to perform these checks may be traceable to or verified against those traceable to the NIST.

(i) Mechanical and automatic volumetric dispensing devices, including pipettes, micro-pipettes, burettes and automatic dilutors and dispensers shall be checked for accuracy at least quarterly when they are in use.

1. Glass microliter syringes do not need to be checked for accuracy if they are documented to be as accurate as class A glassware.

2. Disposable pipettes and any of the aforementioned devices which are dedicated to use in method steps or applications that do not require use of class A glassware are exempted from the quarterly verification of accuracy.

(4) LABORATORY ANALYTICAL INSTRUMENTS. (a) Laboratory analytical instruments shall be operated by personnel trained in their use. Instructions on the use and maintenance of equipment shall be available to instrument operators.

(b) All instruments shall be properly maintained, inspected and cleaned. The laboratory shall establish procedures for the maintenance of analytical instruments to prevent contamination or deterioration that may affect reported results.

(c) Analytical instruments that give suspect results or that have been shown to be defective or outside of performance specifications shall be taken out of service.

(d) When analytical instruments leave the direct control of the laboratory for maintenance or for any other reason, the laboratory shall ensure that the functional and calibration status of those analytical instruments are checked or demonstrated to be satisfactory before the instruments are returned to service.

(5) INSTRUMENT CALIBRATION GENERAL PROVISIONS AND REQUIREMENTS. (a) All analytical instruments shall be calibrated at least once in any year in which they have been used, and shall be calibrated or their calibration verified before they are used to provide any quantitative results.

(b) When more stringent instrument initial calibration or continuing calibration verification requirements are required in mandated test methods or regulations, laboratories shall follow the more stringent requirements, unless:

1. A test method requires analyzing more than 3 standards to establish a linear calibration, and the laboratory chooses to narrow the calibration range of the determination to no more than 2 orders of magnitude and uses at least 3 standards to generate an initial calibration.

2. A test method requires analyzing more than one continuing calibration verification standard to verify a linear calibration and the laboratory has narrowed the calibration range of the determination to no more than 2 orders of magnitude and uses at least one standard to verify continued calibration.

(6) INITIAL INSTRUMENT CALIBRATION. (a) The details of initial instrument calibration procedures, including, calculations, integrations, acceptance criteria and associated statistics shall be included or referenced in the test method standard operating procedure. When initial instrument calibration procedures are cited by reference in the test method standard operating procedure, the laboratory shall retain the referenced material.

(b) The laboratory shall select a calibration model that is appropriate for the expected behavior of the analytical instrument to be calibrated.

(c) To establish calibration, the laboratory shall select a number of non-zero standard concentrations that is appropriate for the calibration model selected and the expected range of concentrations. The number of calibration standards used shall also be sufficient to establish a relationship or corroborate a universally established theoretical relationship between instrument response and concentration that is appropriate for the specific instrument and its intended use.

(d) The minimum number of standard concentrations selected to establish calibration shall be 3 except for:

1. Dissolved oxygen meters, which shall be calibrated against water-saturated air, air-saturated water at a known temperature and pressure, or by reference to an aliquot of air-saturated water analyzed by the Winkler or iodometric method.

2. Ion selective electrodes and pH meters, the minimum number shall be 2.

3. Inductively coupled plasma emission spectrophotometers and inductively coupled plasma mass spectrometers, the minimum number shall be one.

4. Calibration models that are quadratic, the minimum shall be 5.

5. Calibration models that are cubic, the minimum shall be 7.

(e) The concentration of the standards chosen to establish a calibration function shall be within the same orders of magnitude as the expected concentration of samples to be quantitated with an initial calibration. Laboratories reporting results at levels at or near the limit of detection of an analysis shall include in initial calibrations a standard at a concentration near the limit of quantitation of the analysis.

(f) To generate a calibration function, the laboratory shall select a reduction technique or algorithm that is appropriate for the calibration model and number of standard concentrations selected.

1. The selected algorithm or reduction technique shall be describable mathematically, and shall provide equations, coefficients or parameters necessary to characterize the calibration function uniquely, unless an analytical instrument is tuned to conform to a universally accepted scientific law or scale.

Note: The response of dissolved oxygen meters is generally adjusted to conform to the concentration of oxygen allowable in a given

fluid at a specified temperature and pressure. The response of an ion selective electrode is generally tuned to conform to the Nernst equation. The response of pH meters is tuned to conform to the universally accepted pH scale. When these instruments are adjusted or tuned according to these principles, characterizing the calibration reduction algorithm mathematically is not necessary.

2. The laboratory shall use the simplest linear calibration function unless it has documentation that a non-linear function provides a statistically improved definition of the calibration range. Non-linear functions may not be used to compensate for instrument saturation, insensitivity, or malfunction.

3. The laboratory may use weighted algorithms or reduction techniques, unless they are chosen to compensate for deviations from the expected behavior of a detector of an analytical instrument resulting from instrument saturation, insensitivity or malfunction.

4. The laboratory may not use reiterative reduction techniques or algorithms that force calibration functions through zero.

Note: Reiterative reduction techniques or algorithms that force through zero obtain mathematically, by repeated application, a null response for a zero standard that has a non-zero response, or adjust calibration parameters to obtain a theoretical null response without analysis of a calibration blank. This paragraph does not prohibit the use of average response factors or automatic zeroing as part of an initial calibration, when methods, regulations or covered programs allow those techniques.

(g) The laboratory shall establish acceptability criteria for initial calibrations. The type of criteria chosen and the acceptance range shall be appropriate for the type of analytes to be quantitated, the calibration model selected and reduction technique or algorithm chosen.

1. When average response factors are used to reduce calibration data, the relative standard deviation of the response factors may not exceed 20%, unless an approved method of analysis allows a larger percentage.

2. When linear regression or least squares analysis is used to reduce calibration data for inorganic analytes and metals, the correlation coefficient of the resultant calibration curves shall be at least 0.995.

3. When linear regression or least squares analysis is used to reduce calibration data for organic analytes, the correlation coefficient of the resultant calibration curves shall be at least 0.99.

4. When quadratic regression analysis is used to reduce calibration data for inorganic analytes and metals, the coefficient of determination of the resultant calibration curves shall be at least 0.995.

5. When quadratic regression analysis is used to reduce calibration data for organic analytes, the coefficient of determination of the resultant calibration curves shall be at least 0.99.

(h) The laboratory shall establish procedures for zeroing an instrument and the treatment of calibration blanks, when the referenced analytical method used by the laboratory requires the response of a calibration blank to be part of a calibration function.

(i) Laboratories shall verify all initial instrument calibrations after they are generated but before they are used to quantitate any samples, with a second source standard, unless either of the following conditions exists:

1. An instrument is calibrated by tuning it to conform to a universally accepted scientific law or scale, as is the case with pH meters, ion selective electrodes and dissolved oxygen meters.

2. The laboratory analyzes quality control standards for the analyte or analyte group involved and evaluates them as specified in s. NR 149.48 (5).

(j) Unless otherwise required by regulation, method or program, the acceptance criteria for this second source verification shall be that required under sub. (7) for continuing instrument calibration verification.

(k) Laboratories shall quantitate sample results only from initial instrument calibrations, unless otherwise allowed by regulation, method or covered program.

(L) Laboratories shall quantitate sample results from an instrument response that is within the range of the initial calibration. If sample dilution is required, the dilution shall be the lowest required to obtain an instrument response within the range of the initial calibration.

1. Except for samples analyzed by inductively coupled plasma emission spectrophotometers and inductively coupled plasma mass spectrometers, samples having responses greater than that of the most concentrated standard of an initial calibration allowed to be established with at least 3 different standard concentrations shall be diluted and reanalyzed. When samples cannot be diluted and reanalyzed, sample results shall be reported with appropriate qualifiers or narrative warnings.

2. Samples analyzed by inductively coupled plasma emission spectrophotometers and inductively coupled plasma mass spectrometers having responses at or above 90% of the established upper limit of the linear dynamic range of the instruments shall be diluted and reanalyzed. When samples cannot be diluted and reanalyzed, sample results shall be reported with appropriate qualifiers or narrative warnings.

3. Samples analyzed by inductively coupled plasma emission spectrophotometers and inductively coupled plasma mass spectrometers having responses below 90% of the established upper limit of the linear dynamic range of the instruments but above the response of the highest concentration of standard in an initial calibration may be reported without resorting to dilution.

(m) Once a calibration model is selected, a calibration function is established, and an initial calibration is finalized, a laboratory may not change the model or calibration function after samples have been analyzed without performing another initial calibration.

(n) Laboratories shall perform an initial calibration after instruments undergo non-routine maintenance, when repeated use or other conditions change their expected behavior, and when their continuing calibration cannot be verified.

(o) Except as allowed in s. NR 149.39 (3)(c)12., laboratories shall retain all the raw data necessary to reconstruct or reproduce, independently of analytical instruments, all calibration functions associated with initial calibrations.

(7) CONTINUING INSTRUMENT CALIBRATION VERIFICATION. (a) When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to quantitating samples by continuing calibration verification with each analytical batch and at least once on each analysis day. Continuing calibration verification shall also be performed after the consecutive analysis of each group of 20 samples, if 20 or more samples constitute an analytical run. Continuing calibration verification is not required for analyses that cannot be spiked, such as BOD, cBOD and TSS, or those analyses that do not involve a calibration, such as titrations.

(b) The calibration standards analyzed to demonstrate continuing instrument calibration may be obtained from the same source used to generate an initial calibration.

(c) The number and concentration of calibration standards required to demonstrate continuing instrument calibration is outlined in Table 1 of this subchapter.

Table 1: Requirements for continuing calibration verification

CALIBRATION FUNCTION	# OF STANDARDS REQUIRED FOR VERIFICATION	CONCENTRATION OF VERIFICATION STANDARD
Tuning an instrument to conform to a universally accepted scientific law or scale (i.e. electrometric techniques)	The laboratory shall analyze at least a single verification standard	The concentration of the standard shall be within the range established during the initial calibration
Average response/ calibration factor, linear regression, least squares analysis, or otherwise obeys a linear model	The laboratory shall analyze at least a single verification standard	The concentration of the standard may be varied within the established calibration range.
Quadratic regression, 2 nd order polynomial, or other quadratic model	The laboratory shall analyze at least 2 verification standards	One of the standard concentrations shall be chosen to verify continuing calibration near the point of inflection of the calibration function
Cubic regression, 3 rd order polynomial, or other cubic model	The laboratory shall analyze at least 3 verification standards	Two of the standard concentrations shall be chosen to verify continuing calibration near the points of inflection of the calibration function
Discrete or non-smooth segments	The laboratory shall analyze one standard per calibration segment	The concentrations of the standards shall be different from the ones used to establish each segment.

(d) The acceptance criteria for continuing calibration verification standards shall be those defined in the method utilized by the laboratory. If the reference method does not contain criteria, the acceptance criteria for continuing calibration shall be:

1. Obtaining concentrations within 10% of the respective actual concentrations of all reportable inorganic analytes and metals from an initial calibration.

2. Obtaining concentrations within 15% of the respective actual concentrations of all reportable organic analytes from an initial calibration.

(e) When the continuing calibration verification results obtained are outside acceptance criteria, the laboratory shall perform another calibration verification if the results of this second calibration verification fail to meet acceptance criteria, the laboratory shall take corrective action. After taking corrective action, the laboratory shall perform 2 consecutive calibration verifications that meet acceptance criteria or shall perform another initial calibration.

(f) Samples associated with a failing calibration verification shall be reanalyzed or reported with appropriate qualifiers.

(g) The details of the continuing instrument calibration procedure, calculations and associated statistics shall be included in the test method standard operating procedure. When continuing calibration verification procedures are cited by reference in the test method standard operating procedure, the laboratory shall retain the referenced material.

NR 149.45 Measurement traceability. (1) STANDARDS, REAGENTS AND REFERENCE MATERIALS. (a) The laboratory shall ensure that results of analyses can be linked to all the standards and reagents used to derive results. Standards and reagents used in analyses shall conform to the purity specifications contained in approved methods of analysis. When approved methods of analysis do not specify the purity of the standards and reagents to be used, the laboratory shall choose standards and reagents of sufficient purity to ensure the validity of reported results.

(b) The laboratory shall certify the accuracy of all reference materials used to calibrate or verify the calibration of analytical support equipment. Reference materials shall be calibrated by a body independent of that in charge of analytical operations that can provide traceability to primary standards maintained by NIST. When reference materials traceable to NIST are not produced, manufactured or commercially available, the laboratory shall use materials of a quality that will ensure the accuracy of the calibrated or verified support equipment for its intended use.

(c) The laboratory may not use standards and reagents beyond their expiration dates, unless the laboratory can verify their reliability in a defensible manner.

(2) DOCUMENTATION AND LABELING OF STANDARDS, REAGENTS AND REFERENCE MATERIALS. (a) The laboratory shall document the identity, source and purity of all standards and reagents used in tests methods performed. The laboratory shall retain records of certificates of analysis or purity, when the records are provided by the supplier, and are necessary to establish the identity, source or purity of standards and reagents.

1. Original containers of standards and reagents shall be labeled with a receipt and an expiration date.

2. The laboratory shall document the lot number, manufacturer, date of receipt and the date of expiration of stock standards and reagents separately from their containers to ensure this information will be retained when the containers are discarded.

3. The laboratory shall maintain records that detail the preparation of intermediate and working standards and reagents. These records shall link the intermediate and working standards and reagents to their respective originating stocks or neat compounds and shall indicate their date of preparation, expiration and the identity of the preparer.

(b) The laboratory shall retain records and certificates that trace reference materials used to calibrate or verify analytical support equipment to the source of the corresponding reference materials. The laboratory shall retain records demonstrating that the accuracy of the reference materials has been certified or verified, at the required frequencies, by a body outside of that in charge of analytical operations.

NR 149.46 Handling of samples. (1) SAMPLE COLLECTION. (a) The laboratory shall retain records supplied by the collector to allow the laboratory to evaluate collection procedures against the laboratory's sample acceptance policy.

(b) When the laboratory provides containers and preservatives for sample collection, including bulk sampling containers such as "carboys", the laboratory shall have standard operating procedures in place which address concerns that the containers are adequately cleaned and not contributing to contamination of samples, do not contain analytes of interest at levels which will affect sample determinations and that the preservatives used are sufficiently pure to maintain the validity of reported results. Containers supplied by the laboratory for sample collection shall allow collecting a sufficient amount of sample to perform all required or requested determinations at the required or desired sensitivity.

Note: The laboratory should establish procedures to ensure and document that the sample containers it provides do not contribute contaminants before they are used for collecting samples.

(2) SAMPLE ACCEPTANCE POLICY. (a) The laboratory shall have and follow a written policy that clearly outlines the conditions under which samples will be accepted or rejected for analysis, or under which associated reported results will be qualified.

1. Drinking water samples received beyond holding time, improperly preserved, in inappropriate containers or showing evidence that they have not been collected according to approved or accepted protocols shall be rejected for analysis, unless the laboratory can document that it has been instructed by the client to proceed with analyses, and all associated results are accompanied by a disclaimer attesting that results may not be used to determine or evaluate compliance with the safe drinking water act.

2. The results of samples that are not drinking waters shall be appropriately qualified if the samples are received improperly preserved, in inappropriate containers, beyond holding time, with insufficient volume to complete requested analyses, or if the laboratory has evidence that the samples have not been collected according to approved or accepted protocols. Alternatively, the laboratory may reject the samples for analysis.

(b) When samples received do not conform to the descriptions provided by a collector, the laboratory shall consult with the collector or sample originator to determine the processing or disposition of the samples.

(3) SAMPLE HANDLING PROTOCOLS. (a) The laboratory shall establish and follow procedures for identifying samples uniquely. The procedures shall ensure that the identity of samples cannot be confused physically or when referenced in records or other documents.

1. Samples received by a laboratory for analysis shall be assigned a unique identification code.
2. The unique identification code shall be placed on a sample container as a durable label.
3. The unique identification code shall be used as a link to associate samples with their complete history, including treatment and analysis, while in the laboratory's possession.

(b) Chain-of-custody documentation shall be required for those facilities that do not perform their own sample collection, transport and analysis.

(c) The laboratory shall apply evidentiary chain of custody procedures when it receives samples that support regulatory investigations or when required to do so in accordance with a written agreement between the laboratory and the client.

(4) SAMPLE PRESERVATION AND HOLDING TIME. (a) Laboratories shall follow the sample preservation procedures and holding times required by state and federal regulations. If the sample preservation procedures and holding times are not required by state or federal regulations, laboratories shall follow the sample preservation procedures and holding times established in the analytical method. If the analytical method does not establish sample preservation procedures or holding times, laboratories shall follow the procedures in the authoritative sources specified in Appendix III of this chapter.

Note: Sample preservation procedures and holding times are given in 40 CFR 136, ch. NR 219, SW-836 "Test Methods for Evaluating Solid Waste" as cited in item 24 of Appendix III of this chapter, and may be specified in the analytical methods.

(b) Samples requiring preservation at 6°C under this section shall be considered preserved if they are received at a temperature from above their freezing point to 6°C or if they are received surrounded by ice. If the samples are not received on ice, the laboratory shall record one of the following at the time of receipt:

1. The temperature of an actual sample.
2. The temperature of a temperature blank shipped with the samples.
3. The temperature of the melt water in the shipping container.

Note: The preservation status of samples may be recorded as "received on ice" only if solid ice is present around samples when they are received at the laboratory. The preservation status of samples refrigerated with ice packs, such as "blue ice", should not be recorded as "received on ice".

(c) When multiple samples requiring thermal preservation at 6°C are received in the same cooler or holding container, the entire set of samples shall be considered preserved if the temperature of a blank or a sample is determined to be from above freezing to 6°C, or if there is ice remaining in the shipment container.

(d) Samples to be analyzed for whole effluent toxicity shall be considered preserved if their temperature on receipt is above freezing and does not exceed 10°C.

(e) Except as specified in pars. (b) to (d), samples requiring thermal preservation at a temperature other than 6°C shall be considered preserved if their temperature on receipt is within plus or minus 2 degrees of the required preservation temperature.

(5) SAMPLE RECEIPT DOCUMENTATION. The laboratory shall document the receipt and condition of all samples in chronological hard copy or electronic records. The records may be maintained in any format that retains the following information:

(a) The identity of the client or entity submitting samples, or the project associated with the received samples.

(b) The dates of sample collection and laboratory receipt.

(c) The times of sample collection and laboratory receipt for samples to be analyzed for tests with holding times equal to or less than 48 hours.

(d) The unique sample identification code assigned by the laboratory.

(e) Documentation of sample preservation status and other sample conditions on receipt.

(f) An unequivocal link between the sample identification code assigned by the laboratory and the field collection identification code assigned by the collector.

(g) The requested analyses, unless the laboratory collects and analyzes its own samples and analyses are directed by permit.

(h) The reference to requested test methods, when the collector or sample originator specifies them.

(i) Any comments resulting from the inspection undertaken to determine whether samples meet the policy in sub. (2).

(6) STORAGE OF SAMPLES. (a) The laboratory shall have procedures and appropriate facilities for avoiding deterioration, contamination, loss or damage of samples during storage.

(b) Samples requiring thermal preservation at temperatures other than 6°C shall be stored under refrigeration within 2 degrees of the specified preservation temperature.

(c) Samples requiring thermal preservations at 6°C may be stored at temperatures from above their freezing point to 6°C.

(d) Samples shall be stored separately from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in areas that prevent or minimize cross-contamination.

(e) Sample extracts, digestates, leachates or concentrates, resulting from any initial preparatory step, shall be stored as specified in this subsection.

NR 149.47 Laboratory test reports. (1) GENERAL PROVISIONS, FORMAT AND CONTENT. (a) The results of each test performed by a laboratory shall be reported in accordance with any requirements or instructions specified in approved methods or by the department.

(b) Laboratory test reports shall have formats that facilitate conveying or reviewing the content elements specified in this section, unless otherwise provided by pars. (c), (d) and (e). Content elements may be presented in narrative, tabular, schematic or graphical form, in hard copy or electronic media.

(c) When tests are performed for internal clients, or when a laboratory has a written agreement with a client, laboratory reports may be issued by the laboratory without all the content elements specified in this section. However, the laboratory shall retain and make available to the department, upon request, records that include the content elements specified in this section.

(d) Laboratories that are operated by a facility whose function is to provide data to monitor the facility's compliance with department programs covered by this chapter shall retain and make available to the department, upon request, records that include the content elements specified in this section. Laboratory reports with all the content elements specified in this section are not required to be issued if:

1. The laboratory is responsible for preparing regulatory reports in a specified format to the department.

2. The laboratory provides information to another individual within the facility for preparation of regulatory reports in a specified format to the department.

(e) Unless otherwise specified by department programs that receive data on behalf of facilities, directly from laboratories, or when provided by pars. (c) and (d), test reports from laboratories shall include at least the following information:

1. The name, address and telephone of the laboratory where tests were performed, as well as the name of a contact.
2. The laboratory's certification or registration identification number.
3. The name and address of the client or entity whose samples were analyzed.
4. The sample codes or identifiers provided by the client or collector.
5. Identification of or reference to the methods used for analysis.
6. The collection date of the samples.
7. The date of receipt of the samples.
8. For samples submitted to pretreatment steps, such as digestions or extractions, with identified holding times in department regulations, the date in which such steps were performed.
9. The date of analysis.
10. Results of analyses with their respective measurement and reporting units.
 - a. For sample results requiring adjustment for dilutions, the dilution factors.
 - b. For sample results reported on a dry weight basis, the solids content and a statement or flag indicating that results have been adjusted for the solids content of the corresponding samples.
11. For tests for which the department requires reporting to the limit of detection, the limits of detection and quantitation of the associated results.
 - a. For sample results requiring adjustment for dilutions, an indication of whether the detection and quantitation limits have been adjusted for the corresponding sample dilutions.
 - b. For sample results reported on a dry weight basis, an indication of whether the detection and quantitation limits have been adjusted for the solids content of the corresponding samples.
12. The names and signatures of responsible parties authorizing reported results.
13. Descriptions of any deviations encountered by the laboratory from chapter requirements or procedures referenced in approved methods, when the deviations affect the validity or the defensibility of reported results.
 - a. Description of these deviations may be communicated through narratives, flags or qualifiers.
 - b. When flags or qualifiers are used to declare these deviations, the laboratory shall include a key to describe the meaning of all used flags and qualifiers.
14. The date of the test report.

(2) AMENDMENTS TO LABORATORY TEST REPORTS. (a) Amendments to test reports already issued by a laboratory shall be made by an authorized laboratory representative in a manner that clearly identifies the reasons for the amendment and that references the original laboratory test report.

(b) Amended reports shall comply with the requirements of this section.

(3) TEST RESULTS OBTAINED FROM SUBCONTRACTORS. (a) When reports contain results of tests performed by subcontractors, the associated results shall include any qualifiers noted by the subcontract laboratory and shall be identified with the subcontractors' facility identification codes.

(b) Subcontractors shall provide upon request of the originating laboratory or the department all the information contained in this section.

NR 149.48 Quality control requirements for chemical testing. (1) GENERAL REQUIREMENTS. (a) Laboratories shall establish a quality control program that includes the analysis of appropriate samples, such as method blanks, laboratory control samples, matrix spikes, matrix spike duplicates, replicates, surrogate spikes and analytical protocols, such as detection limit studies and confirmatory techniques. These quality control procedures shall be used to assess:

1. The level of background contamination associated with the preparation and analysis of all samples.
2. The sensitivity of all tests performed.
3. The level of control of an entire analytical system.
4. The bias contributed to sample results by all preparation and analysis steps.
5. The reproducibility of test results.
6. The selectivity of test methods.

(b) At least annually, laboratories shall review and evaluate the acceptability criteria specified in this section for all quality control samples and measures, and update the criteria whenever the performance characteristics of any of these samples and measures change.

(c) Laboratories may not adjust or correct the sample results by the recoveries of associated laboratory control samples, matrix spikes and surrogates, unless a method or project plan approved by the department requires it. Laboratories may not subtract analyte concentrations found in method blanks from sample results unless a method or project plan approved by the department requires it.

(d) Laboratories shall establish procedures for identifying and documenting preparation batches that facilitate determining compliance with the frequencies of quality control samples required by this subchapter.

(2) LIMITS OF DETECTION AND QUANTITATION. (a) Laboratories shall determine the limit of detection for all tests performed and for all analytes reported except for:

1. Biochemical oxygen demand.
2. Tests for which analyzing a fortified sample is impossible.
3. Titrimetric tests.
4. Gravimetric tests, other than oil and grease as hexane extractable materials.

(b) Laboratories shall determine the limit of detection of an analyte by a protocol established by regulation or as referenced in approved methods of analysis. All sample-processing steps of a test method shall be included in the determination of a limit of detection.

(c) For tests for which this chapter does not require performing a limit of detection, laboratories shall establish estimates of a test's sensitivity based on the intended use of the data for a given application.

(d) Limits of detection shall be determined at least annually unless a laboratory can verify the continued applicability of a previously determined limit of detection by an established and defensible protocol.

(e) Limits of detection shall be determined each time there is a change in a test method or instrumentation that affects the sensitivity of an analysis.

(f) Laboratories shall establish procedures to relate limits of detection to limits of quantitation.

(g) Established limits of quantitation shall be above determined limits of detection.

(3) METHOD BLANK. (a) Method blanks shall be processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch.

Note: Method blanks are not appropriate or required for analysis of pH, alkalinity, conductivity and solids determinations.

(b) Method blanks shall be processed at a frequency of at least one per preparation batch. When samples are analyzed by methods that do not require a preparation step before analysis, a blank, different from a calibration blank, shall be analyzed at the frequency of one per analytical batch.

(c) Whenever a method blank contains analytes of interest above the detection limit of an analysis, the laboratory shall evaluate the nature of the interference and its effect on each sample in a preparation batch.

(d) A sample in a batch shall be reanalyzed or qualified if the concentration of an analyte of interest in the associated method blank exceeds the highest of any of the following values:

1. The limit of detection.
2. Five percent of the regulatory limit for that analyte.
3. Ten percent of the measured concentration in the sample.

(4) LABORATORY CONTROL SAMPLES. (a) Unless otherwise exempted by this subsection, a laboratory control sample shall be processed at a frequency of at least one sample per preparation batch, along with and under the same conditions as the associated samples in a preparation batch. These conditions shall include all sample preparation steps, except waste characteristic extractions.

Note: Waste characteristic samples are fortified after the extraction is completed.

(b) Laboratory control samples for the biochemical oxygen demand and carbonaceous biochemical oxygen demand tests shall be fortified with a mixture of glucose and glutamic acid as specified in approved methods of analysis. These laboratory control samples shall be processed at a frequency of at least one sample per analytical batch for laboratories that analyze more than 20 samples per week. Laboratories that analyze fewer than 20 samples per week shall analyze, at a minimum, one laboratory control sample per week.

(c) Laboratory control samples are not required to be processed for tests for which analyzing a fortified sample is impossible or impractical, or when a laboratory follows par. (e).

Note: Laboratory control samples need not be analyzed for the following tests: pH, solids determinations, chlorophyll a, color, odor, oil and grease as freon extractable material.

(d) Matrix spikes or certified reference materials may be processed for all reported analytes, at the frequency described in par. (a), in place of laboratory control samples, if the acceptance criteria for corresponding laboratory control samples are used to evaluate the matrix spikes and the laboratory takes the corrective action required in this subsection when matrix spikes fail established laboratory control sample acceptance criteria.

(e) For analyses of polychlorinated biphenyls, the laboratory shall fortify a laboratory control sample with at least one Aroclor per preparation batch. For other tests that determine analytes with responses that encompass more than one chromatographic peak, as in the case of toxaphene and chlordane, the laboratory may fortify a

laboratory control sample with a single multi-peak analyte per preparation batch. The laboratory shall ensure that all multi-peak analytes detectable by a method are fortified in laboratory control samples at least once every year that any of those analytes are reported.

(f) The laboratory shall compute the recovery of each fortified analyte in a laboratory quality control sample. The laboratory shall evaluate the results of laboratory control samples against acceptance criteria published by the department, or when the department has not published acceptance criteria, against:

1. Criteria contained in approved methods of analysis.
2. Laboratory generated acceptance criteria when approved methods of analysis do not contain acceptance criteria.
3. Criteria specified in project quality plans approved by the department.

(g) When laboratory control samples do not meet acceptance criteria, the laboratory shall reprocess or reanalyze all samples associated with the failing laboratory control samples or qualify the results of all samples in the preparation batch.

(h) Laboratories may process and analyze replicate laboratory control samples to establish a measure of the ability of an analytical system, independent of matrix effects, to reproduce results. The laboratory may reprocess or reanalyze all samples, or qualify the results of all samples in a preparation batch, if the relative percent difference of laboratory sample control duplicates exceeds criteria established by the laboratory.

(5) QUALITY CONTROL STANDARDS. (a) Laboratories that do not use second source standards to verify the accuracy of initial calibrations shall analyze quality control standards as defined in s. NR 149.03 (57), 3 times per year at evenly spaced intervals for all certified or registered analytes determined by tests amenable to fortification, and for which known quality control samples are commercially available.

Note: Analysis of quality control standards is not required for tests, such as pH, which are performed using instruments calibrated by tuning them to conform to a universally accepted scientific law or scale. These tests are also exempt from initial calibration verification with a second source standard.

(b) Laboratories shall evaluate the results of known quality control samples against the acceptance criteria supplied by the provider. If the results of known quality control samples exceed the acceptance limits issued by a provider, the laboratory shall take corrective action and demonstrate within 30 days, through analysis of another known quality control sample or processed second source standard, the effectiveness of the corrective action taken.

(6) MATRIX SPIKES AND MATRIX SPIKE DUPLICATES. (a) Matrix spikes and matrix spike duplicates corresponding to the quality system matrix to which collected samples are assigned shall be processed and analyzed, unless as allowed in sub. (7) (a), when:

1. Mandated test methods require their analysis and a sufficient volume or amount of sample has been received to permit their analysis.
2. Project plans require their analysis.
3. They are used in place of laboratory control samples to evaluate the level of control of an analytical system.

Note: Matrix spikes need not be analyzed for the following tests: biochemical oxygen demand, carbonaceous biochemical oxygen demand, pH, solids determinations, alkalinity, acidity, chlorophyll a, color, odor, oil and grease as freon extractable material.

(b) When required to be analyzed by par. (a), matrix spikes and matrix spike duplicates shall be:

1. Processed along with and under the same conditions as the associated samples in a preparation batch. These conditions shall include all sample preparation steps, except waste characteristic extractions.

Note: Waste characteristic samples are fortified after the extraction is completed.

2. Processed and analyzed at a frequency of one per preparation batch of samples consisting of the same quality system matrix or at frequency specified by a project plan or client agreement.

3. Fortified with the analytes specified in approved methods, project plans, client agreements or with all reported analytes, except as allowed in sub. (4) (e).

4. Fortified with all reported analytes when matrix spikes are used in place of laboratory control samples.

(c) The laboratory shall compute the recovery of each fortified analyte in a matrix spike and matrix spike duplicate, and the relative percent difference or absolute difference of each fortified analyte in a matrix spike and matrix spike duplicate pair. The laboratory shall evaluate the recoveries, and the relative percent difference or absolute range against acceptance criteria published by the department, or when the department has not published criteria, against:

1. Criteria contained in approved methods of analysis.

2. Laboratory generated acceptance criteria when approved methods of analysis do not contain acceptance criteria.

3. Criteria specified in documented and approved project quality plans, or client agreements.

(d) When matrix spikes or matrix spike duplicates do not meet acceptance criteria, the laboratory shall reprocess, reanalyze or qualify the results of the chosen fortified sample in the preparation batch. When the laboratory determines that the failure of matrix spikes or matrix spike duplicates has affected other samples in the same preparation batch, the laboratory shall reprocess or reanalyze the samples, or qualify their results.

(7) SAMPLE REPLICATES. (a) Sample replicates may be analyzed in place of matrix spike duplicates when there is a high probability that a replicate pair will contain the analytes of interest at or above the limit of quantitation of an analysis.

(b) Sample replicates corresponding to the quality system matrix to which collected samples are assigned, shall be processed and analyzed when:

1. Mandated test methods require their analysis and a sufficient volume or amount of sample has been collected or received to permit their analysis.

2. Project plans require their analysis.

3. Clients, by agreement with a laboratory, require their analysis.

(c) When required to be analyzed by par. (b), sample replicates shall be:

1. Processed along with and under the same conditions, including all sample preparation steps, as the associated samples in a preparation batch.

2. Processed and analyzed at a frequency of one per preparation batch of samples consisting of the same quality system matrix or at a frequency specified by a project plan or client agreement.

(d) The laboratory shall compute the relative percent difference or absolute difference of each pair of sample replicates. The laboratory shall evaluate these results against acceptance criteria published by the department, or when the department has not published acceptance criteria, against:

1. Criteria contained in approved methods of analysis.

2. Laboratory generated acceptance criteria when approved methods of analysis do not contain criteria.

3. Criteria specified in documented and approved project quality plans or client agreements.

(e) When sample replicates do not meet acceptance criteria, the laboratory shall reprocess, reanalyze or qualify the results of the chosen sample analyzed in replicate in the preparation batch. When the laboratory determines that the failure of sample replicates has affected other samples in the same preparation batch, the laboratory shall reprocess or reanalyze the samples or qualify their results.

(8) SURROGATE SPIKES. (a) Surrogate compounds specified in approved methods of analysis or documented and approved project plans shall be added to all samples in a preparation batch, including method blanks, laboratory control samples, matrix spikes, matrix spike duplicates and replicates.

(b) The laboratory shall compute the recovery of all surrogates added to each sample in a preparation batch. The laboratory shall evaluate these results against acceptance criteria published by the department, or when the department has not published acceptance criteria, against:

1. Criteria contained in approved methods of analysis.
2. Laboratory generated acceptance criteria when approved methods of analysis do not contain criteria.
3. Criteria specified in documented and approved project quality plans or client agreements.

(c) When surrogate recoveries do not meet acceptance criteria, the laboratory shall determine whether the failures are the result of matrix interference. If the failures result from matrix interference, the laboratory shall qualify the results of the affected samples. If the failures cannot be attributed to matrix interference, the laboratory shall reprocess and reanalyze the affected samples or qualify sample results.

(9) SELECTIVITY. (a) The laboratory shall establish procedures to confirm the results of organic analytes determined by techniques that, unlike mass spectrometry, do not provide a positive unique identification when:

1. The history of a sample source does not suggest the likely presence of the detected analyte.
2. A client or approved project plan requires it.

(b) The laboratory shall establish procedures and rules for reporting results for samples analyzed by dual column and dual detector systems that declare:

1. Under what conditions a presumptive identification is confirmed.
2. Under what conditions a presumptive identification is reported.
3. The value that will be reported when the dual systems both provide quantitative confirmed results.

(c) The laboratory shall develop and document acceptance criteria, for chromatographic retention time windows, which consider retention time shifts due to routine column maintenance.

(d) The laboratory shall document acceptance criteria for mass spectral tuning.

NR 149.49 Quality control requirements for whole effluent toxicity testing. (1) ACUTE AND CHRONIC WHOLE EFFLUENT TOXICITY TESTING BY SPECIES. Laboratories analyzing whole effluents for acute and chronic toxicity for a given species shall follow the quality control requirements referenced in the "State of Wisconsin Aquatic Life Toxicity Testing Methods Manual", 2nd edition.

Note: The referenced manual can be obtained at <http://dnr.wi.gov/org/water/wm/ww/biomon/>

(2) CHEMICAL TESTING IN SUPPORT OF WHOLE EFFLUENT TOXICITY TESTING. Laboratories performing tests for alkalinity, ammonia, hardness, pH, conductivity, dissolved oxygen and total residual chlorine shall follow the quality control requirements specified in s. NR 149.48 except that laboratories need not analyze matrix spikes or matrix spike duplicates for ammonia, and hardness.

APPENDIX I

ANALYTICAL TECHNOLOGIES, ANALYTES, AND ANALYTE GROUPS FOR CERTIFICATION AND REGISTRATION IN THE AQUEOUS AND SOLID MATRICES

TABLE 1
OXYGEN DEMAND ASSAYS

Analytical Technology	Class	Analyte
Oxygen Demand Assays	General Chemistry	Biochemical Oxygen Demand (BOD) ¹ Carbonaceous BOD ¹

¹ Certification or registration for BOD and cBOD is available only in the aqueous matrix.

TABLE 2
COLORIMETRIC OR NEPHELOMETRIC (TURBIDIMETRIC)

Analytical Technology	Class	Analyte
Colorimetric or Nephelometric (Turbidimetric)	General Chemistry	Ammonia Chemical Oxygen Demand (COD) Chloride Chlorine, Total Residual Chlorophyll Cyanide, Amenable Cyanide, Total Fluoride Hardness, Total as CaCO ₃ Kjeldahl Nitrogen, Total (TKN) Nitrate Nitrate + Nitrite Nitrite Orthophosphate Phenolics, Total Phosphorus, Total Silica Sulfate Sulfide Sulfide Sulfite Surfactants Turbidity
	Metals	Aluminum Arsenic Beryllium Boron Cadmium Chromium, Hexavalent Chromium, Total

Analytical Technology	Class	Analyte
Colorimetric or Nephelometric (Turbidimetric)		
		Copper Iron Lead Magnesium Manganese Nickel Potassium Silicon Silver Zinc
	Pesticides, N-methyl	Carbamates and Substituted Ureas Busan 40 Busan 85 Carbam-S Dazomet KN Methyl Nabam Ziram
	Pesticides, Not Otherwise Specified	Vapam

**TABLE 3
COMBUSTION OR OXIDATION**

Analytical Technology	Class	Analyte
Combustion or Oxidation		
	General Chemistry	Adsorbable Organic Halides (AOX) Organic Carbon, Total (TOC) Organic Halides, Total (TOX)

**TABLE 4
ELECTROMETRIC ASSAYS**

Analytical Technology	Class	Analyte
Electrometric Assays		
	General Chemistry	Ammonia as N Bromide Chloride Chlorine, Total Residual Cyanide, Total Fluoride Kjeldahl Nitrogen, Total (TKN) Nitrate Organic Halides, Extractable (EOX) Organic Halides, Purgeable (POX) Oxygen, Dissolved pH Specific Conductance Sulfide

**TABLE 5
GRAVIMETRIC ASSAYS - RESIDUE**

Analytical Technology	Class	Analyte
Gravimetric Assays		
	General Chemistry	Residue, Filterable (TDS) Residue, Nonfilterable (TSS) Residue, Settleable Residue, Total Residue, Volatile (TVS) Residue, Volatile, Nonfilterable (TVSS) Sulfate

**TABLE 6
GRAVIMETRIC ASSAYS – OIL & GREASE**

Analytical Technology	Class	Analyte
Gravimetric Assays		
	General Chemistry	Oil & Grease, Hexane Extractable Materials (HEM)

**TABLE 7
ION CHROMATOGRAPHY**

Analytical Technology	Class	Analyte
Ion Chromatography		
	Metals	Chromium, Hexavalent
	General Chemistry	Bromide Chloride Fluoride Nitrate Nitrate + nitrite Nitrite Orthophosphate Sulfate

**TABLE 8
TITRIMETRIC OR POTENTIOMETRIC TITRATION ASSAYS**

Analytical Technology	Class	Analyte
Titrimetric or Potentiometric Titrimetric Assays		
	Metals	Calcium
	General Chemistry	Acidity as CaCO ₃ Alkalinity Ammonia as N Bromide Chemical Oxygen Demand (COD) Chloride Chlorine, Total Residual Cyanide, Amenable Cyanide, Total Hardness, Total as CaCO ₃ Kjeldahl Nitrogen, Total (TKN)

Analytical Technology	Class	Analyte
Titrimetric or Potentiometric Titrimetric Assays		
		Sulfide Sulfides, Acid-Soluble and Acid-Insoluble Sulfite

**TABLE 9
COLD VAPOR ATOMIC ABSORPTION OR
GASEOUS HYDRIDE SPECTROPHOTOMETRY**

Analytical Technology	Class	Analyte
Cold Vapor Atomic Absorption or Gaseous Hydride Spectrophotometry		
	Metals	Antimony Arsenic Mercury Selenium

**TABLE 10
FLAME ATOMIC ABSORPTION SPECTROPHOTOMETRY**

Analytical Technology	Class	Analyte
Flame Atomic Absorption Spectrophotometry		
	Metals	Aluminum Antimony Barium Beryllium Cadmium Calcium Chromium, Hexavalent Chromium, Total Cobalt Copper Gold Iridium Iron Lead Lithium Magnesium Manganese Molybdenum Nickel Osmium Palladium Platinum Potassium Rhodium Ruthenium Silver Sodium Strontium Thallium Tin Titanium Vanadium Zinc

Analytical Technology	Class	Analyte
Flame Atomic Absorption Spectrophotometry	General Chemistry	Hardness, Total as CaCO ₃

**TABLE 11
GRAPHITE FURNACE ATOMIC ABSORPTION SPECTROPHOTOMETRY**

Analytical Technology	Class	Analyte
Graphite Furnace Atomic Absorption Spectrophotometry	Metals	Aluminum Antimony Arsenic Barium Beryllium Cadmium Chromium, Total Cobalt Copper Gold Iridium Iron Lead Manganese Molybdenum Nickel Osmium Palladium Platinum Rhodium Ruthenium Selenium Silver Thallium Tin Titanium Vanadium Zinc

**TABLE 12
INDUCTIVELY COUPLED PLASMA EMISSION SPECTROPHOTOMETRY**

Analytical Technology	Class	Analyte or Analyte Group
Inductively Coupled Plasma Emission Spectrophotometry	Metals	Aluminum Antimony Arsenic Barium Beryllium Bismuth Boron Cadmium Calcium Chromium, Total Cobalt Copper

Analytical Technology	Class	Analyte or Analyte Group
Inductively Coupled Plasma Emission Spectrophotometry		
		Gold Iridium Iron Lead Magnesium Manganese Molybdenum Nickel Osmium Palladium Platinum Potassium Rhodium Ruthenium Selenium Silicon Silver Sodium Strontium Thallium Tin Titanium Tungsten Vanadium Zinc Zirconium
	General Chemistry	Hardness, Total as CaCO ₃ Silica

**TABLE 13
INDUCTIVELY COUPLED PLASMA –MASS SPECTROMETRY**

Analytical Technology	Class	Analyte
Inductively Coupled Plasma-Mass Spectrometry		
	Metals	Aluminum Antimony Arsenic Barium Beryllium Cadmium Chromium, Total Cobalt Copper Iron Lead Lithium Manganese Mercury Molybdenum Nickel Selenium Silver Thallium Vanadium Zinc

**TABLE 14
ULTRA-LOW LEVEL METALS ANALYSIS**

Analytical Technology	Class	Analyte
Ultra-Low Level Metals Assays	Metals	Mercury

**TABLE 15
GAS CHROMATOGRAPHY**

Analytical Technology	Class	Analyte or Analyte Group
Gas Chromatography	Base, Neutral, and Acid Extractable Semivolatiles, Aldehydes and Ketones	2-Butanone (Methyl Ethyl Ketone) Crotonaldehyde 2-Hexanone 4-Methyl-2-pentanone (Methyl Isobutyl Ketone) Paraldehyde 2-Pentanone
	Base, Neutral, and Acid Extractable Semivolatiles, Benzidines	Benzidine 3,3'-Dichlorobenzidine 3,3'-Dimethoxybenzidine 3,3'-Dimethylbenzidine
	Base, Neutral, and Acid Extractable Semivolatiles, Chlorinated Hydrocarbons	1,2-Dibromo-3-chloropropane (DBCP) Benzyl Chloride Chloroprene Hexachlorobenzene Hexachlorobutadiene Hexachlorocyclopentadiene Hexachloroethane Pentachlorobenzene 1,2,4,5-Tetrachlorobenzene
	Base, Neutral, and Acid Extractable Semivolatiles, Explosive Residues	1,3-Dinitrobenzene 2,4-Dinitrophenol 2,4-Dinitrotoluene 2,6-Dinitrotoluene Nitrobenzene 1,3,5-Trinitrobenzene
	Base, Neutral, and Acid Extractable Semivolatiles, Haloethers	Bis(2-chloroethoxy)methane Bis(2-chloroethyl) ether Bis(2-chloroisopropyl) ether 4-Bromophenyl phenyl ether 2,2-Oxybis(1-chloropropane)
	Base, Neutral, and Acid Extractable Semivolatiles, Nitroaromatics and Cyclic Ketones	Isophorone Nitrobenzene
	Base, Neutral, and Acid Extractable Semivolatiles, Nitrosamines	N-Nitrosodiethylamine N-Nitrosodimethylamine

Analytical Technology	Class	Analyte or Analyte Group
Gas Chromatography		N-Nitrosodi-n-butylamine N-Nitrosodi-n-propylamine N-Nitrosodiphenylamine N-Nitrosodipropylamine N-Nitrosomethylethylamine N-Nitrosomorpholine N-Nitrosopiperidine N-Nitrosopyrrolidine
	Base, Neutral, and Acid Extractable Semivolatiles, Nonhalogenated Organics	Acetonitrile Acrolein Acrylonitrile Allyl Alcohol Allyl Chloride n-Butyl Alcohol (1-Butanol) t-Butyl Alcohol Diethyl Ether Diethylene Glycol Ethanol Ethyl Acetate Ethyl Methacrylate Ethylene Glycol Ethylene Oxide Hexafluoro-2-methyl-2-propanol Hexafluoro-2-propanol Isobutyl alcohol (2-Methyl-1-propanol) Isopropyl alcohol (2-Propanol) Methacrylonitrile Methanol Methyl Methacrylate 2-Picoline (2-Methylpyridine) 1-Propanol Propionitrile (Ethyl Cyanide) Pyridine o-Toluidine
	Base, Neutral, and Acid Extractable Semivolatiles, Phenols	4-Chloro-3-methylphenol 2-Chlorophenol p-Chloro-m-cresol 2,4-Dichlorophenol 2,4-Dimethylphenol 2-Methyl-4,6-dinitrophenol 2-Nitrophenol 4-Nitrophenol Pentachlorophenol Phenol 2,4,5-Trichlorophenol 2,4,6-Trichlorophenol
	Base, Neutral, and Acid Extractable Semivolatiles, Phthalate Esters	Benzyl Butyl Phthalate Bis(2-ethylhexyl)phthalate Diethyl Phthalate Dimethyl Phthalate Di-n-butyl Phthalate Di-n-octyl Phthalate
	Pesticides, Acid Herbicides	Acifluorfen Chloramben

Analytical Technology	Class	Analyte or Analyte Group
Gas Chromatography		2,4-D 2,4-DB 2,4-DB Salts and Esters Dacthal (DCPA) Dichlorprop Salts and Esters Dinoseb MCPA Salts and Esters MCPP Salts and Esters Picloram 2,4,5-T 2,4,5-TP (Silvex)
	Pesticides, Nitrogen	Alachlor Ametryn Aspon Benfluralin Bentazon Bromacil Salts and Esters Bromoxynil Octanoate Butachlor Chlorothalonil Dalapon Diazinon Dicamba Ethalfluralin Fenarimol Isopropalin Metribuzin Norflurazon Pendimethalin Pronamide Propachlor Propanil Triadimefon Trifluralin
	Pesticides, N-Methyl	Carbamates and Substituted Ureas Barban Busan 41 Busan 85 Carbam-S Carbaryl Carbofuran Dazomet Diallate (cis or trans) Ethyl Carbamate KN Methyl Mexacarbate Nabam Nabonate Sulfallate Tebuthiuron Terbacil Ziram
	Pesticides, Organochlorine	<i>Pesticides, Organochlorine Analyte Group</i> Aldrin alpha-BHC beta-BHC delta-BHC

Analytical Technology	Class	Analyte or Analyte Group
Gas Chromatography		gamma-BHC (Lindane) Captafol Captan Chlordane Chloroneb 4,4'-DDD 4,4'-DDE 4,4'-DDT Dichloran Dieldrin Endosulfan I Endosulfan II Endosulfan Sulfate Endrin Endrin Aldehyde Heptachlor Heptachlor Epoxide Isodrin Kepone Methoxychlor Mirex Pentachloronitrobenzene (PCNB) Perthane Strobane Toxaphene
	Pesticides, Organophosphorus	Acephate Azinphos Ethyl Azinphos Methyl Bolstar Carbophenothion Chlorfenvinphos Chlorpyrifos Chlorpyrifos Methyl Coumaphos Crotoxyphos DEF Demeton-O Demeton-S Diazinon Dichlofenthion Dichlorvos Dicrotophos Dimethoate Dioxathion Disulfoton EPN Ethion Ethoprop Famphur Fenitrothion Fensulfothion Fenthion Fonophos Hexamethylphosphoramide Leptophos Malathion Merphos Methamidophos

Analytical Technology	Class	Analyte or Analyte Group
Gas Chromatography		Mevinphos Monocrotophos Naled Parathion (Parathion Ethyl) Parathion Methyl Phorate Phosalone Phosmet Phosphamidon Ronnel Stirofos Sulfotepp TEPP Thionazin (Zinophos) Tokuthion (Protothiofos) Trichloronate Trichlorphon Tri-o-cresylphosphate (TOCP) Terbufos Tetrachlorvinphos
	Pesticides, Triazines	Atrazine Atraton Cyanazine Deisopropylatrazine Desethylatrazine Diaminoatrazine Prometon Prometryn Propazine Simazine Terbutylazine Terbutryn
	Pesticides, Not Otherwise Specified	Permethrin Vapam
	Petroleum Hydrocarbons	Diesel Range Organics (DRO) Gasoline Range Organics (GRO) Petroleum Volatile Organic Compounds (PVOCs)
	Polychlorinated Biphenyls as Aroclors	Polychlorinated Biphenyls as Aroclors Analyte Group Aroclor 1016 Aroclor 1221 Aroclor 1232 Aroclor 1242 Aroclor 1248 Aroclor 1254 Aroclor 1260
	Polychlorinated Biphenyl Congeners	Polychlorinated Biphenyl Congeners Analyte Group 2,2',3,3',4,4',5,5',6-Nonachlorobiphenyl 2,2',3,3',4,4',5-Heptachlorobiphenyl 2,2',3,4,4',5,5'-Heptachlorobiphenyl 2,2',3,4,4',5,6-Heptachlorobiphenyl 2,2',3,4,4',5'-Hexachlorobiphenyl 2,2',3,4',5,5',6-Heptachlorobiphenyl

Analytical Technology	Class	Analyte or Analyte Group
Gas Chromatography		2,2',3,4,5,5'-Hexachlorobiphenyl 2,2',3,4,5'-Pentachlorobiphenyl 2,2',3,5,5',6-Hexachlorobiphenyl 2,2',3,5'-Tetrachlorobiphenyl 2,2',4,4',5,5'-Hexachlorobiphenyl 2,2',4,5,5'-Pentachlorobiphenyl 2,2',5,5'-Tetrachlorobiphenyl 2,2',5-Trichlorobiphenyl 2,3,3',4',6-Pentachlorobiphenyl 2,3',4,4'-Tetrachlorobiphenyl 2,3-Dichlorobiphenyl 2,4',5-Trichlorobiphenyl Chlorobiphenyl
	Polynuclear Aromatic Hydrocarbons	<i>Polynuclear Aromatic Hydrocarbons Analyte Group</i> Acenaphthene Acenaphthylene Anthracene Benzo(a)anthracene Benzo(a)pyrene Benzo(b)fluoranthene Benzo(g,h,i)perylene Benzo(k)fluoranthene Chrysene Dibenzo(a,h)anthracene Fluoranthene Fluorene Indeno(1,2,3-cd)pyrene Naphthalene Phenanthrene Pyrene
	Volatile Organic Compounds	<i>Volatile Organic Compounds Analyte Group</i> Acetone Benzene Bromoacetone Bromobenzene Bromochloromethane Bromodichloromethane Bromoform Bromomethane n-Butylbenzene sec-Butylbenzene tert-Butylbenzene Carbon Tetrachloride Chlorobenzene Chloroethane 2-Chloroethyl Vinyl Ether Chloroform Chloromethane Chloromethyl Methyl Ether 2-Chloronaphthalene 2-Chlorotoluene 4-Chlorotoluene Dibromochloromethane Dibromomethane (EDB) 1,2-Dichlorobenzene 1,3-Dichlorobenzene

Analytical Technology	Class	Analyte or Analyte Group
Gas Chromatography		1,4-Dichlorobenzene Dichlorobromomethane 1,1-Dichloroethane 1,2-Dichloroethane cis-1,2-Dichloroethene trans-1,2-Dichloroethene 1,2-Dichloropropane 1,3-Dichloropropane 2,2-Dichloropropane 1,3-Dichloro-2-propanol 1,1-Dichloropropene cis-1,3-Dichloropropene trans-1,3-Dichloropropene 2,3-Dichloropropene Dichlorodifluoromethane 1,4-Dioxane Epichlorohydrin Ethylbenzene Isopropylbenzene p-Isopropyltoluene Methyl Bromide Methyl Chloride Methyl Iodide Methyl tert-Butyl Ether Methylene Bromide Methylene Chloride n-Propylbenzene Styrene Tetrachloroethene Toluene 1,1,1,2-Tetrachloroethane 1,1,2,2-Tetrachloroethane 1,2,3-Trichlorobenzene 1,2,4-Trichlorobenzene 1,1,1-Trichloroethane 1,1,2-Trichloroethane Trichloroethene Trichlorofluoromethane 1,2,3-Trichloropropane 1,2,4-Trimethylbenzene 1,3,5-Trimethylbenzene m-Xylene o-Xylene p-Xylene Vinyl Chloride

**TABLE 16
GAS CHROMATOGRAPHY-MASS SPECTROMETRY**

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		<i>Base/Neutral/Acid Extractable Semivolatiles Analyte Group¹</i>
	Base, Neutral, and Acid Extractable Semivolatiles, Aldehydes and Ketones	2-Butanone (Methyl ethyl ketone) Crotonaldehyde 2-Hexanone 4-Methyl-2-pentanone (Methyl Isobutyl Ketone)

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		Paraldehyde 2-Pentanone
	Base, Neutral, and Acid Extractable Semivolatiles, Benzidines	Benzidine 3,3'-Dichlorobenzidine 3,3'-Dimethoxybenzidine 3,3'-Dimethylbenzidine
	Base, Neutral, and Acid Extractable Semivolatiles, Chlorinated Hydrocarbons	Benzyl chloride Chlorobenzilate 3-(Chloromethyl)pyridine Hydrochloride 1-Chloronaphthalene Chloroprene 1,2-Dibromo-3-chloropropane (DBCP) Hexachlorobenzene Hexachlorobutadiene Hexachlorocyclopentadiene Hexachloroethane Hexachlorophene Hexachloropropene Pentachlorobenzene 1,2,4,5-Tetrachlorobenzene
	Base, Neutral, and Acid Extractable Semivolatiles, Explosive Residues	1,3-Dinitrobenzene 2,4-Dinitrophenol 2,4-Dinitrotoluene 2,6-Dinitrotoluene Nitrobenzene 1,3,5-Trinitrobenzene
	Base, Neutral, and Acid Extractable Semivolatiles, Haloethers	4-Bromophenyl Phenyl Ether Bis(2-chloroethoxy)methane Bis(2-chloroethyl)ether Bis(2-chloroethyl)sulfide Bis(2-chloroisopropyl)ether 2,2-Oxybis(1-chloropropane)
	Base, Neutral, and Acid Extractable Semivolatiles, Nitroaromatics and Cyclic Ketones	4-Aminobiphenyl 3-Amino-9-ethylcarbazole 4-Chloroaniline 5-Chloro-2-methylaniline 4-Chloro-1,2-phenylenediamine 4-Chloro-1,3-phenylenediamine 3-Chloropropionitrile 2,4-Diaminotoluene alpha,alpha-Dimethylphenethylamine 1,2-Dinitrobenzene 1,2-Diphenylhydrazine Isophorone 4,4'-Methylenebis(2-chloroaniline) 4,4'-Methylenebis(N,N-dimethylaniline) 1-Naphthylamine 2-Naphthylamine 5-Nitroacenaphthene 2-Nitroaniline 3-Nitroaniline 4-Nitroaniline

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		5-Nitro-o-anisidine 4-Nitrobiphenyl 2-Nitropropane 5-Nitro-o-toluidine 4,4'-Oxydianiline 1,4-Phenylenediamine 2-Picoline (2-Methylpyridine) n-Propylamine 2,4,5-Trimethylaniline
	Base, Neutral, and Acid Extractable Semivolatiles, Nitrosamines	N-Nitrosodiethylamine N-Nitrosodimethylamine N-Nitrosodi-n-butylamine N-Nitrosodi-n-propylamine N-Nitrosodiphenylamine N-Nitrosodipropylamine N-Nitrosomethylethylamine N-Nitrosomorpholine N-Nitrosopiperidine N-Nitrosopyrrolidine
	Base, Neutral, and Acid Extractable Semivolatiles, Nonhalogenated Organics	Acetonitrile Acetophenone 2-Acetylaminofluorene 1-Acetyl-2-thiourea Acrolein Acrylonitrile Allyl Alcohol Allyl Chloride 2-Aminoanthraquinone Aminoazobenzene Aniline o-Anisidine Aramite Benzoic Acid p-Benzoquinone Benzyl Alcohol n-Butanol Carbazole Carbon Disulfide p-Chloroaniline p-Cresidine Dibenzofuran 1,2,3,4-Diepoxybutane Diethyl Ether O,O-Diethyl O-2-pyrazinyl phosphorothionate Diethyl Sulfate Diethylstilbestrol Dihydrosaffrole Dimethylaminoazobenzene Diphenylamine 5,5-Diphenylhydantoin Ethanol Ethyl Acetate Ethyl Methacrylate Ethyl Methanesulfonate Fluchloralin Hydroquinone

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		2-Hydroxypropionitrile Isobutyl Alcohol (2-Methyl-1-propanol) Isopropyl Alcohol (2-Propanol) Isosafrole Maleic Anhydride Malononitrile Mestranol Methacrylonitrile Methanol Methapyrilene Methyl Acrylate Methyl Methacrylate Methyl Methanesulfonate 3-Methylcholanthrene 1,4-Naphthoquinone Nicotine Nitrofen 4-Nitroquinoline 1-oxide Octamethyl Pyrophosphoramidate Phenacetin Phenobarbital Phthalic Anhydride Piperonyl Sulfoxide Propargyl Alcohol β-Propiolactone Propionitrile (Ethyl Cyanide) Propylthiouracil Pyridine Resorcinol Safrole Tetraethyl Dithiopyrophosphate Tetraethyl Pyrophosphate Thiophenol (Benzenethiol) Toluene Diisocyanate o-Toluidine Trimethyl Phosphate O,O,O-Triethyl Phosphorothioate Tri-p-tolyl Phosphate Tris(2,3-dibromopropyl) phosphate
	Base, Neutral, and Acid Extractable Semivolatiles, Phenols	p-Chloro-m-cresol 4-Chloro-3-methylphenol 2-Chlorophenol 2-Cyclohexyl-4,6-dinitro-phenol 2,4-Dichlorophenol 2,6-Dichlorophenol 2,4-Dimethylphenol 4,6-Dinitro-2-methylphenol 4,6-Dinitro-o-cresol 2-Methyl-4,6-dinitrophenol 2-Methylphenol (o-Cresol) 3-Methylphenol (m-Cresol) 4-Methylphenol (p-Cresol) 2-Nitrophenol 4-Nitrophenol Pentachlorophenol Phenol 2,3,4,6-Tetrachlorophenol 2,4,5-Trichlorophenol

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		2,4,6-Trichlorophenol
	Base, Neutral, and Acid Extractable Semivolatiles, Phthalate Esters	Benzyl Butyl Phthalate Bis(2-ethylhexyl)phthalate Diethyl Phthalate Dimethyl Phthalate Di-n-butyl Phthalate Di-n-octyl Phthalate
	Pesticides, Nitrogen	Alachlor Ametryn Aspon Benfluralin Bentazon Bromacil Salts and Esters Bromoxynil Octanoate Butachlor Chlorothalonil Dalapon Diazinon Dicamba Ethalfluralin Fenarimol Isopropalin Metribuzin Norflurazon Pendimethalin Pronamide Propachlor Propanil Triadimefon Trifluralin
	Pesticides, N-Methyl Carbamates and Substituted Ureas	Barban Busan 41 Busan 85 Carbam-S Carbaryl Carbofuran Dazomet Diallate (cis or trans) Ethyl Carbamate KN Methyl Mexacarbate Nabam Nabonate Sulfallate Tebuthiuron Terbacil Ziram
Pesticides, Organochlorine	<i>Pesticides, Organochlorine Analyte Group</i> 4,4'-DDD 4,4'-DDE 4,4'-DDT Aldrin alpha-BHC beta-BHC delta-BHC	

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		gamma-BHC (Lindane) Captafol Captan Chlordane Dichlone Dieldrin Endosulfan I Endosulfan II Endosulfan Sulfate Endrin Endrin Aldehyde Endrin Ketone Heptachlor Heptachlor Epoxide Isodrin Kepone Methoxychlor Mirex Pentachloronitrobenzene (PCNB) Trifluralin
	Pesticides, Organophosphorus	Acephate Azinphos Ethyl Azinphos Methyl Bolstar Carbophenothion Chlorfenvinphos Chlorpyrifos Chlorpyrifos Methyl Coumaphos Crotoxyphos DEF Demeton-O Demeton-S Diazinon Dichlofenthion Dichlorvos Dicrotophos Dimethoate Dioxathion Disulfoton EPN Ethion Ethoprop Famphur Fenitrothion Fensulfothion Fenthion Fonophos Hexamethylphosphoramide Leptophos Malathion Merphos Methamidophos Mevinphos Monocrotophos Naled Parathion (Parathion Ethyl) Parathion Methyl

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		Phosalone Phorate Phosmet Phosphamidon Ronnel Stirofos Sulfotepp TEPP Thionazin (Zinophos) Tokuthion (Protothiofos) Trichloronate Trichlorphon Tri-o-cresylphosphate (TOCP) Terbufos Tetrachlorvinphos
	Pesticides, Triazines	Atrazine Atraton Cyanazine Deisopropylatrazine Desethylatrazine Diaminoatrazine Prometon Prometryn Propazine Simazine Terbutylazine Terbutryn
	Pesticides, Not Otherwise Specified	Endothall Strychnine
	Petroleum Hydrocarbons	Petroleum Volatile Organic Compounds (PVOC)
	Polychlorinated Dibenzo-p-Dioxins and Furans	Polychlorinated Dibenzo-p-Dioxins and Furans Analyte Group²
	Polychlorinated Biphenyls as Aroclors	Polychlorinated Biphenyls as Aroclors Analyte Group Aroclor 1016 Aroclor 1221 Aroclor 1232 Aroclor 1242 Aroclor 1248 Aroclor 1254 Aroclor 1260
	Polychlorinated Biphenyl Congeners	Polychlorinated Biphenyl Congeners Analyte Group 2,6-Dichlorosyringaldehyde 2-Chlorosyringaldehyde 3,3'-Dichlorobiphenyl 3,4,5-Trichlorocatechol 3,4,5-Trichloroguaiacol 3,4,6-Trichlorocatechol 3,4,6-Trichloroguaiacol 3,4-Dichlorocatechol 3,4-Dichloroguaiacol 3,6-Dichlorocatechol 4,5,6-Trichloroguaiacol

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		4,5-Dichlorocatechol 4,5-Dichloroguaiacol 4,6-Dichlorocatechol 4,6-Dichloroguaiacol 4-Chlorocatechol 4-Chloroguaiacol 4-Chlorophenol 5,6-Dichlorovanillin 5-Chlorovanillin 6-Chlorovanillin Tetrachlorocatechol Tetrachloroguaiacol Trichlorosyringol
	Polynuclear Aromatic Hydrocarbons	<i>Polynuclear Aromatic Hydrocarbons Analyte Group</i> 2-Methylnaphthalene 3-Methylcholanthrene 7,12-Dimethylbenz(a)-anthracene Acenaphthene Acenaphthylene Anthracene Benzo(a)anthracene Benzo(a)pyrene Benzo(b)fluoranthene Benzo(g,h,i)perylene Benzo(k)fluoranthene Chrysene Dibenz(a,j)acridine Dibenzo(a,e)pyrene Dibenzo(a,h)anthracene Fluoranthene Fluorene Indeno(1,2,3-cd)pyrene Naphthalene Phenanthrene Pyrene
	Volatile Organic Compounds	<i>Volatile Organic Compounds Analyte Group</i> Acetone Benzene Bromoacetone Bromobenzene Bromochloromethane Bromodichloromethane Bromoform Bromomethane n-Butylbenzene sec-Butylbenzene tert-Butylbenzene Carbon Tetrachloride Chlorobenzene Chloroethane 2-Chloroethyl Vinyl Ether Chloroform Chloromethane Chloromethyl Methyl Ether 2-Chloronaphthalene 2-Chlorotoluene

Analytical Technology	Class	Analyte
Gas Chromatography/Mass Spectrometry		4-Chlorotoluene Dibromochloromethane Dibromomethane (EDB) 1,2-Dichlorobenzene 1,3-Dichlorobenzene 1,4-Dichlorobenzene Dichlorobromomethane 1,1-Dichloroethane 1,2-Dichloroethane cis-1,2-Dichloroethene trans-1,2-Dichloroethene 1,2-Dichloropropane 1,3-Dichloropropane 2,2-Dichloropropane 1,3-Dichloro-2-propanol 1,1-Dichloropropene cis-1,3-Dichloropropene trans-1,3-Dichloropropene 2,3-Dichloropropene Dichlorodifluoromethane 1,4-Dioxane Epichlorohydrin Ethylbenzene Isopropylbenzene p-Isopropyltoluene Methyl Bromide Methyl Chloride Methyl Iodide Methyl tert-Butyl Ether Methylene Bromide Methylene Chloride n-Propylbenzene Styrene Tetrachloroethene Toluene 1,1,1,2-Tetrachloroethane 1,1,2,2-Tetrachloroethane 1,2,3-Trichlorobenzene 1,2,4-Trichlorobenzene 1,1,1-Trichloroethane 1,1,2-Trichloroethane Trichloroethene Trichlorofluoromethane 1,2,3-Trichloropropane 1,2,4-Trimethylbenzene 1,3,5-Trimethylbenzene m-Xylene o-Xylene p-Xylene Vinyl Chloride

¹ Certification or registration for Gas Chromatography/Mass Spectrometry Analytical Technology in the Base/Neutral/Acid Analyte Group is comprised of all analytes in the following classes: Base, Neutral, and Acid Extractable Semivolatiles, Aldehydes and Ketones; Base, Neutral, and Acid Extractable Semivolatiles, Benzidines; Base, Neutral, and Acid Extractable Semivolatiles, Chlorinated Hydrocarbons; Base, Neutral, and Acid Extractable Semivolatiles, Explosive Residues; Base, Neutral, and Acid Extractable Semivolatiles, Haloethers; Base, Neutral, and Acid Extractable Semivolatiles, Nitrosamines; Base, Neutral, and Acid Extractable Semivolatiles, Nonhalogenated Organics; Base, Neutral, and Acid Extractable Semivolatiles, Phenols; Base, Neutral, and Acid Extractable Semivolatiles, Phthalate Esters; and Polynuclear Aromatic Hydrocarbons.

² Certification or registration for individual Polychlorinated-p-dibenzo-Dioxins and Furans analytes in the Gas Chromatography/Mass Spectrometry Analytical Technology available upon request.

TABLE 17
HIGH RESOLUTION GAS CHROMATOGRAPHY- MASS SPECTROMETRY

Analytical Technology	Class	Analyte or Analyte Group
High Resolution Gas Chromatography/Mass Spectrometry	Polychlorinated Dibenzo-p-Dioxins and Furans	<i>Polychlorinated Dibenzo-p-Dioxins and Furans Analyte Group¹</i>
	Polychlorinated Biphenyl Congeners	<i>Polychlorinated Biphenyl Congeners Analyte Group²</i>

¹ Certification or registration for individual Tetra through Octa-Chlorinated Dioxins and Furans in the High Resolution Gas Chromatography/Mass Spectrometry Analytical Technology available upon request.

² Certification or registration for individual Polychlorinated Biphenyl Congeners in the High Resolution Gas Chromatography/Mass Spectrometry Analytical Technology available upon request.

TABLE 18
HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

Analytical Technology	Class	Analyte or Analyte Group
High Performance Liquid Chromatography	Metals	Mercury Organomercury
	Base, Neutral, and Acid Extractable Semivolatiles, Aldehydes and Ketones	Acetaldehyde Acetone Butanal Crotonaldehyde Cyclohexanone Decanal Heptanal Hexanal Isovaleraldehyde Nonanal Octanal o-Tolualdehyde Pentanal (Valeraldehyde) Propanal (Propionaldehyde) m-Tolualdehyde p-Tolualdehyde
	Base, Neutral, and Acid Extractable Semivolatiles, Benzidines	Benzidine 3,3'-Dichlorobenzidine
	Base, Neutral, and Acid Extractable Semivolatiles, Explosive Residues	2-Amino-4,6-dinitrotoluene 4-Amino-2,6-dinitrotoluene 1,3-Dinitrobenzene 2,4-Dinitrotoluene 2,6-Dinitrotoluene HMX

Analytical Technology	Class	Analyte or Analyte Group
High Performance Liquid Chromatography		Nitrobenzene Nitroglycerine 2-Nitrotoluene 3-Nitrotoluene 4-Nitrotoluene RDX Tetryl 1,3,5-Trinitrobenzene 2,4,6-Trinitrotoluene
	Base, Neutral, and Acid Extractable Semivolatiles, Nonhalogenated Organics	Acrolein Acrylamide Acrylonitrile
	Pesticides, Acid Herbicides	2,4-D 2,4-DB Salts and Esters Dichlorprop Salts and Esters Dinoseb MCPA Salts and Esters MCPP Salts and Esters Pentachlorophenol
	Pesticides, N-Methyl Carbamates and Substituted Ureas	Aldicarb Aldicarb Sulfone Aminocarb Barban Benomyl Carbaryl Carbaryl Carbofuran Carbofuran Chloroprotham Dioxacarb Diuron Fenuron Fenuron-TCA 3-Hydroxycarbofuran Linuron Methiocarb Methomyl Mexacarbate Monuron Monuron-TCA Neburon Promecarb Propanil Protham Propoxur Siduron Swep
	Pesticides, Nitrogen	Bromoxynil Sebumenton TCMTB
	Pesticides, Not Otherwise Specified	Diquat Fenvalerate Glyphosate

Analytical Technology	Class	Analyte or Analyte Group
High Performance Liquid Chromatography		Paraquat Pyrethrin I Pyrethrin II
	Polynuclear Aromatic Hydrocarbons	<i>Polynuclear Aromatic Hydrocarbons Analyte Group</i> Acenaphthene Acenaphthylene Anthracene Benzo(a)anthracene Benzo(a)pyrene Benzo(b)fluoranthene Benzo(g,h,i)perylene Benzo(k)fluoranthene Chrysene Dibenzo(a,h)anthracene Fluoranthene Fluorene Indeno(1,2,3-cd)pyrene Naphthalene Phenanthrene Pyrene

TABLE 19
LIQUID CHROMATOGRAPHY-MASS SPECTROMETRY

Analytical Technology	Class	Analyte
Liquid Chromatography/Mass Spectrometry	Base, Neutral, and Acid Extractable Semivolatiles, Benzidines	Benzidine 3,3'-Dichlorobenzidine 3,3'-Dimethoxybenzidine 3,3'-Dimethylbenzidine
	Pesticides, Acid Herbicides	2,4,5-T 2,4,5-T, butoxyethanol Ester 2,4,5-T, Butyl Ester 2,4,5-TP (Silvex) 2,4-D 2,4-D, Butoxyethanol Ester 2,4-D, Ethylhexyl Ester 2,4-DB Dichlorprop Dinoseb MCPA Salts and Esters MCPP Salts and Esters
	Pesticides, Nitrogen	Benzoylprop Ethyl Bromacil Dalapon Dicamba Propachlor
	Pesticides, N-Methyl	Carbamates and Substituted Ureas 3-Hydroxycarbofuran Aldicarb Aldicarb Sulfone Aldicarb Sulfoxide

Analytical Technology	Class	Analyte
Liquid Chromatography/Mass Spectrometry		Aminocarb Asulam Barban Bendiocarb Benomyl Carbaryl Carbendazim Carbofuran Chloroprotham Chloroxuron Diuron Fenuron Fluometuron Linuron Methiocarb Methomyl Mexacarbate Monuron Neburon o-Chlorophenyl Thiourea Oxamyl Protham Propoxur Siduron Tebuthiuron Thiofanox
	Pesticides, Not Otherwise Specified	Rotenone
	Pesticides, Organophosphorus	Dichlorvos Dimethoate Disulfoton Famphur Fensulfoton Merphos Monocrotophos Naled Parathion Methyl Phorate Trichlorphon

**TABLE 20
WASTE CHARACTERIZATION EXTRACTIONS ¹**

Analytical Technology	Class	Analyte
Waste Characterization Extractions	Waste Characterization Extractions	Extraction Procedure Toxicity Test Method Multiple Extraction Procedure Synthetic Precipitation Leaching Procedure Toxicity Characteristic Leaching Procedure

¹ Certification or registration for Waste Characterization Extractions is available only in the solid matrix.

TABLE 21

WASTE CHARACTERIZATION ASSAYS ¹

Analytical Technology	Class	Analyte
Waste Characterization Assays		
	Waste Characterization Assays	Paint Filters Liquids Test PCB Screening in Waste Solvent Corrosivity Toward Steel Corrosivity, Liquids Ignitability of Solids Ignitability, Oxidizers Ignitability, Pinsky-Martens Closed Cup Ignitability, Setaflash Closed Cup Ignitability, Small Scale Closed Cup Waste Analysis, Other Water in Waste by Calcium Hydride Water in Waste by KF Liquid Release Test Procedure

¹ Certification or registration for Waste Characterization Assays is available only in the solid matrix.

TABLE 22 WHOLE EFFLUENT TOXICITY ASSAYS ¹

Analytical Technology	Class	Analyte
Whole Effluent Toxicity Assays		
	Acute Whole Effluent Toxicity	<i>Ceriodaphnia dubia</i> <i>Pimephales promelas</i>
	Chronic Whole Effluent Toxicity	<i>Ceriodaphnia dubia</i> <i>Pimephales promelas</i> <i>Selanastrum capricornutum</i>

¹ Certification or registration for Whole Effluent Toxicity Assays is available only in the aqueous matrix.

APPENDIX II

METHODS, ANALYTES, AND ANALYTE GROUPS FOR CERTIFICATION IN THE DRINKING WATER MATRIX

TABLE A
DISINFECTION BYPRODUCTS

Class	Analytical Method	Analyte
Disinfection Byproducts		
	300.0 ¹	Bromide Chlorite
	300.1 ²	Bromate Bromide Chlorate Chlorite
	317.0 rev. 2.0 ⁸	Bromate Chlorite
	321.8 ⁸	Bromate
	326.0 ⁸	Bromate Chlorite
	327.0 rev. 1.1 ⁸	Chlorite
	552.1 ³	Haloacetic Acids (five)
	552.2 ⁴	Haloacetic Acids (five)
	552.3 ⁸	Haloacetic Acids (five)
	4500-ClO ₂ -D ^{3,4}	Chlorine Dioxide
	4500-ClO ₂ -E ^{5,6}	Chlorite
	4500-ClO ₂ -E ^{3,4}	Chlorine Dioxide
	4500-O ₃ -B ^{3,4}	Ozone
	6251B ⁶	Haloacetic Acids (five)
	D6581-00 ⁷	Bromate

¹ "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA/600/R-930100, August 1993, Available at NTIS, PB 94-121811.

² "Methods for the Determination of Organic and Inorganic Compounds in Drinking Water- Volume I", EPA-815-R-00-014, August 2000. Available from NTIS, PB2000-106981, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.

³ "Methods for the Determination of Organic Compounds in Drinking Water- Supplement II", EPA-600/R-92/129, DATE, Available at NTIS, PB92-207703.

⁴ "Methods for the Determination of Organic Compounds in Drinking Water- Supplement III", EPA-600/R-95/131, DATE, Available at NTIS PB95-261616.

⁵ "Standard Methods for the Examination of Water and Wastewater", American Public Health Association, American Water Works Association, Water Pollution Control Federation, 18th edition, 1989, 1015 Fifteenth Street N.W., Washington DC 20005.

⁶ "Standard Methods for the Examination of Water and Wastewater", American Public Health Association, American Water Works Association, Water Pollution Control Federation, 19th edition, 1995, 1015 Fifteenth Street N.W., Washington DC 20005.

⁷ "Annual Book of ASTM Standards, Vols. 11.01 and 11.02, 2001. Available from the American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103. The same method on the current edition may be used if the date of method revisions is the same as the 1991 edition.

⁸ These methods can be accessed and downloaded directly on-line at <http://www.epa.gov/safewater/methods/sourcalt.html> or at <http://www.epa.gov/safewater/safewater/methods/compmon.html>.

**TABLE B
PRIMARY INORGANICS**

Class	Analytical Method	Analyte
Primary Inorganic Contaminants- Metals	200.7 ²	Barium Beryllium Cadmium Chromium Copper Nickel
	200.8 ²	Antimony Arsenic Barium Beryllium Cadmium Chromium Copper Lead Mercury Nickel Selenium Thallium
	200.9 ²	Antimony Arsenic Beryllium Cadmium Chromium Copper Lead Nickel Selenium Thallium
	245.1 ²	Mercury
	245.2 ³	Mercury
	3111B ^{4,5}	Copper Nickel
	3111B-99 ¹⁶	Copper
		Nickel
	3111D ^{4,5}	Barium
	3111 D-99 ¹⁶	Barium
	3112B ^{4,5}	Mercury
	3112B-99 ¹⁶	Mercury
	3113B ^{4,5}	Antimony Arsenic Barium

Class	Analytical Method	Analyte
		Beryllium Cadmium Chromium Copper Lead Nickel Selenium
	3113B-99 ¹⁶	Antimony Arsenic Barium Beryllium Cadmium Chromium Copper Lead Nickel Selenium
	3114B ^{4,5}	Arsenic Selenium
	3114 B-97 ¹⁶	Arsenic Selenium
	3120B ^{4,5,6}	Barium Beryllium Chromium Copper Nickel
	3120B-99 ¹⁶	Barium Beryllium Chromium Copper Nickel
	D1688-95,02 A ¹¹	Copper
	D1688-95,02 C ¹¹	Copper
	D2972-97,03 B ¹¹	Arsenic
	D2972-97,03 C ¹¹	Arsenic
	D3223-97,02 ¹¹	Mercury
	D3559-96,03 D ¹¹	Lead
	D3645-97,03 B ¹¹	Beryllium
	D3697-92,02 ¹¹	Antimony
	D3859-98,03 A ¹¹	Selenium
	D3859-98,03 B ¹¹	Selenium
	Palintest 1001 ¹⁵	Lead
Primary Inorganic Contaminants- Non-Metals		
	300.0 ¹	Fluoride

Class	Analytical Method	Analyte
		Nitrate Nitrate + Nitrite Nitrite
	300.1 ¹⁷	Fluoride Nitrate Nitrate + Nitrite Nitrite
	335.4 ¹	Cyanide
	353.2 ¹	Nitrate Nitrate + Nitrite Nitrite
	4110B ^{4,5,6}	Fluoride Nitrate Nitrate + Nitrite Nitrite
	4110B-00 ¹⁶	Fluoride Nitrate Nitrate + Nitrite Nitrite
	4500-CN C,E ^{4,5,6}	Cyanide
	4500-CN C,E-99 ¹⁶	Cyanide
	4500-CN C,F ^{4,5,6}	Cyanide
	4500-CN C,F-99 ¹⁶	Cyanide
	4500-CN C,G ^{4,5,6}	Cyanide, Amenable
	4500-CN C,G-99 ¹⁶	Cyanide, Amenable
	4500F B, D ^{4,5,6}	Fluoride
	4500F B, D-97 ¹⁶	Fluoride
	4500F C ^{4,5,6}	Fluoride
	4500F C-97 ¹⁶	Fluoride
	4500F E ^{4,5,6}	Fluoride
	4500F E-97 ¹⁶	Fluoride
	4500-NO2 B ^{4,5,6}	Nitrite
	4500-NO2 B-00 ¹⁶	Nitrite
	4500-NO3 D ^{4,5,6}	Nitrate
	4500-NO3 D-00 ¹⁶	Nitrate
	4500-NO3 E ^{4,5,6}	Nitrate Nitrate + Nitrite Nitrite
	4500-NO3 E-00 ¹⁶	Nitrate Nitrate + Nitrite Nitrite
	4500-NO3 F ^{4,5,6}	Nitrate Nitrate + Nitrite Nitrite

Class	Analytical Method	Analyte
	4500-NO3F-00 ¹⁶	Nitrate Nitrate + Nitrite Nitrite
	QuikChem10-204-00-1-X ⁷	Cyanide
	129-71W ⁸	Fluoride
	380-75WE ⁸	Fluoride
	601 ⁹	Nitrate
	B-1011 ¹⁰	Nitrate Nitrate + Nitrite Nitrite
	D1179-93, 99B ¹¹	Fluoride
	D2036-98A ¹¹	Cyanide
	D2036-98B ¹¹	Cyanide
	D3867-90A ¹¹	Nitrate Nitrate + Nitrite Nitrite
	D3867-90B ¹¹	Nitrate Nitrate + Nitrite Nitrite
	D4327-97, 03 ¹¹	Fluoride Nitrate Nitrate + Nitrite Nitrite
	D6508, Rev 2 ¹⁹	Fluoride Nitrate Nitrate + Nitrite Nitrite
	D6888-04 ¹¹	Cyanide
	I-3300-85 ¹²	Cyanide
	Kelada 01 ¹³	Cyanide
	OIA-1677, DW ¹⁸	Cyanide

¹ "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA-600/R-93-100, August 1993. Available at NTIS PB94-121811.

² "Methods for the Determination of Metals in Environmental Samples- Supplement I", ORD Publications, EPA/600/R-94-111 May 1994. Available from National Technical Information Service, Order #PB94-18492, 5285 Port Royal Road, Springfield, VA 21161.

³ Method 245.2 is available from US EPA, EMSL, Cincinnati, OH 45268. The identical methods were formerly in "Methods for Chemical Analysis of Water and Wastes" EPA-600/4-79-020), March 1983. Available at National Technical Information Service, PB84-128677, 5285 Port Royal Road, Springfield, VA 22161.

⁴ "Standard Methods for the Examination of Water and Wastewater", 18th edition, American Public Health Association, American Water Works Association, 1992. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005.

⁵ "Standard Methods for the Examination of Water and Wastewater", 19th edition, American Public Health Association, American Water Works Association, 1992. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005.

⁶ "Standard Methods for the Examination of Water and Wastewater", 20th edition, American Public Health Association, American Water Works Association, 1998. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005.

⁷ "Digestion and distillation of total cyanide in drinking and wastewaters using MICRO DIST and determination of cyanide by flow injection analysis", Revision 2.1, November 30, 2000, Lachat Instruments, 6645 W. Mill Road, Milwaukee, WI 53218.

- ⁸ The procedures shall be done in accordance with the Industrial Method No 129-71 W, "Fluoride in Water and Wastewater", December 1972 and Method Number 380-75WE, "Fluoride in Water and Wastewater", February 1976, Technicon Industrial Systems. Copies may be obtained from the Technicon Industrial Systems, Tarrytown, NY 10591.
- ⁹ Technical Bulletin 601 "Standard Method of Test for Nitrate in Drinking Water", July 1994, PN 221890-001, Thermo Orion, 500 Cummins Center, Beverly, MA 01915+9846. This method is identical to Orion WeWWG/5580, which is approved for nitrate analysis. ATI Orion republished the method in 1994, and renumbered it as 601, because the 1985 manual, "Orion Guide to Water and Wastewater Analysis," which contained WeWWG/5880, is no longer available.
- ¹⁰ Waters Test Method for the Determination of Nitrate/Nitrite in Water using Single Column Ion Chromatography", Method B-1011, Millipore Corporation, Waters Chromatography Division, 34 Maple Street, Milford, MA 01757.
- ¹¹ The procedures shall be done in accordance with the "Annual Book of ASTM Standards", 1994, Vols 11.01 and 11.02. Copies may be obtained from the American Society for Testing Material, 1916 Race Street, Philadelphia, PA 19103.
- ¹² "Methods for the Analysis of Inorganic Substances in Water and Fluvial Sediments", U.S. Department of the Interior, U.S. Geological Survey, Federal Center, P.O. Box 25425, Denver, CO 80225-0425.
- ¹³ Kelada Automated Test Methods for Total Cyanide, PB 2001-108275. Available from National Technical Information Service, Order #PB2001-108275, 5285 Port Royal Road, Springfield, VA 22161.
- ¹⁴ GLI Method 2, "Turbidity", November 2, 1992. Great Lakes Instruments, Inc. 8855 North 55th Street, Milwaukee, WI 53223.
- ¹⁵ "Method 1001: Lead in Drinking Water by Differential Pulse Anodic Stripping Voltammetry", August 1999, Palintest Ltd, 21 Kenton Lands Road, Erlanger, KY 41018.
- ¹⁶ "Standard Methods Online" are available at <http://www.standardmethods.org>. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.
- ¹⁷ "Methods for the Determination of Organic and Inorganic Compounds in Drinking Water," Vol. 1, EPA 815-R-00-014, August 2000. Available at NTIS, PB2000-106981.
- ¹⁸ "Method OIA-1677, DW", "Available Cyanide by Flow Injection, Ligand Exchange, and Amperometry," January 2004. EPA-821-R-04-001, Available from ALPKEM, A Division of OI Analytical, P.O. Box 9010, College Station, TX 77842-9010.
- ¹⁹ "Method D6508, Rev. 2", "Test Method for Determination of Dissolved Inorganic Anions in Aqueous Matrices Using Capillary Ion Electrophoresis and Chromate Electrolyte," available from Waters Corp, 34 Maple St, Milford, MA, 01757, Telephone: 508/482-2131, Fax: 508/482-3625.

**TABLE C
SECONDARY CONTAMINANTS**

Class	Analytical Method	Analyte
Secondary Contaminants - Metals		
	200.7 ²	Aluminum Calcium Iron Manganese Silica Silver Sodium Zinc
	200.8 ²	Aluminum Manganese Silver Zinc
	200.9 ²	Aluminum Iron Manganese Silver
	3111B ^{3,4}	Calcium Iron Manganese Silver Sodium

Class	Analytical Method	Analyte
		Zinc
	3111B-99 ⁸	Calcium Iron Manganese Silver Sodium Zinc
	3111D ^{3,4}	Aluminum
	3111D-99 ⁸	Aluminum
	3113B ^{3,4}	Aluminum Iron Manganese Silver
	3113B-99 ⁸	Aluminum Iron Manganese Silver
	3120B ^{3,4,5}	Aluminum Calcium Iron Manganese Silica Silver Zinc
	3120B-99 ⁸	Aluminum Calcium Iron Manganese Silica Silver Zinc
	3500-Ca B ⁵	Calcium
	3500-Ca B-97 ⁸	Calcium
	3500-Ca D ^{3,4}	Calcium
	4500-Si-D ^{3,4}	Silica
	4500-Si-E ^{3,4}	Silica
	4500-Si-F ^{3,4}	Silica
	4500-SiO2-C ⁵	Silica
	4500-SiO2-D ⁵	Silica
	4500-SiO2-E ⁵	Silica
	4500-SiO2-C-97 ⁸	Silica
	4500-SiO2-D-97 ⁸	Silica
	4500-SiO2-E-97 ⁸	Silica
	D511-93, 03A ⁶	Calcium

Class	Analytical Method	Analyte
	D511-93, 03B ⁶	Calcium
	D859-94, 00 ⁶	Silica
	D6919-03 ⁶	Calcium Sodium
	I-1700-85 ⁷	Silica
	I-2700-85 ⁷	Silica
	I-3720-85 ⁷	Silver
Secondary Contaminants -NonMetals		
	300.0 ¹	Chloride Orthophosphate Sulfate
	300.1 ¹⁰	Chloride Orthophosphate Sulfate
	365.1 ¹⁰	Orthophosphate
	375.2 ¹	Sulfate
	2320B ^{3,4,5}	Alkalinity
	2320B-97 ⁸	Alkalinity
	2540C ^{3,4,5}	Total Dissolved Solids (TDS)
	2540C-97 ⁸	Total Dissolved Solids (TDS)
	4110B ^{3,4,5}	Chloride Orthophosphate Sulfate
	4110B-00 ⁸	Chloride Orthophosphate Sulfate
	4500-Cl ^{3,4,5} B	Chloride
	4500-Cl ⁸ B-97	Chloride
	4500-Cl ^{3,4,5} D	Chloride
	4500-Cl ⁸ D-97	Chloride
	4500-P ^{3,4,5} E	Orthophosphate
	4500-P ^{3,4,5} F	Orthophosphate
	4500-SO ₄ ²⁻ C, D ^{3,4,5}	Sulfate
	4500-SO ₄ ²⁻ E ^{3,4,5}	Sulfate
	4500-SO ₄ ²⁻ F ^{3,4,5}	Sulfate
	D1067-92, 02 B ⁶	Alkalinity
	D4327-97,03 ⁶	Chloride Orthophosphate Sulfate
	D512-89 (Re-approved 1999)B ⁶	Chloride
	D515-88A ⁶	Orthophosphate
	D516-90, 02 ⁶	Sulfate
	D6508, Rev. 2 ⁹	Chloride

Class	Analytical Method	Analyte
		Orthophosphate Sulfate
	I-1030-85 ⁷	Alkalinity
	I-1601-85 ⁷	Orthophosphate
	I-2598-85 ⁷	Orthophosphate
	I-2601-90 ⁷	Orthophosphate

¹ "Methods for the Determination of Inorganic Substances in Environmental Samples", EPA-600/R-93-100, August 1993. Available from National Technical Information Service, Order # PB94-121811 5285 Port Royal Road, Springfield, VA 21161.

² "Methods for the Determination of Metals in Environmental Samples- Supplement I", ORD Publications, EPA/600/R-94-111 May 1994. Available from National Technical Information Service, Order #PB94-18492, 5285 Port Royal Road, Springfield, VA 21161.

³ "Standard Methods for the Examination of Water and Wastewater", 18th edition, American Public Health Association, American Water Works Association, 1015 Fifteenth Street, N.W., Washington DC 1992.

⁴ "Standard Methods for the Examination of Water and Wastewater", 19th edition, American Public Health Association, American Water Works Association, 1015 Fifteenth Street, N.W., Washington DC 1992.

⁵ "Standard Methods for the Examination of Water and Wastewater", 20th edition, American Public Health Association, American Water Works Association, 1015 Fifteenth Street, N.W., Washington DC 1998.

⁶ "Annual Book of Standards, Section 11.01 and 11.02, Water and Environmental Technology", American Society for Testing Material, 1916 Race Street, Philadelphia, PA 194, 1996 and 1999.

⁷ "Methods for Analysis of Inorganic Substances in Water and Fluvial Sediments", U.S. Department of the Interior, U.S. Geological Survey, Denver, CO, 1989.

⁸ "Standard Methods Online" are available at <http://www.standardmethods.org>. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

⁹ "Method D6508, Rev. 2", "Test Method for Determination of Dissolved Inorganic Anions in Aqueous Matrices Using Capillary Ion Electrophoresis and Chromate Electrolyte," available from Waters Corp, 34 Maple St., Milford, MA, 01757, Telephone: 508/482-2131, Fax: 508/482-3625.

¹⁰ "Methods for the Determination of Organic and Inorganic Compounds in Drinking Water," Vol. 1, EPA 815R-00-014, August 2000. Available at NTIS, PB2000-106981.

TABLE D
SYNTHETIC ORGANIC CONTAMINANTS

Class	Analytical Method	Analyte
Synthetic Organic Contaminants (SOC)- Dioxin		
	1613 ⁷	2,3,7,8-TCDD (Dioxin)
SOC – Organochlorine Pesticides		
	505 ⁴	Aldrin Chlordane Dieldrin Endrin Heptachlor Heptachlor Epoxide Lindane Methoxychlor Toxaphene
	508 ⁴	Aldrin Chlordane Dieldrin Endrin Heptachlor Heptachlor Epoxide

	Lindane Methoxychlor Toxaphene
508.1 ⁴	Aldrin Chlordane Dieldrin Endrin Heptachlor Heptachlor Epoxide Lindane Methoxychlor Toxaphene
525.2 ⁴	Aldrin Chlordane Dieldrin Endrin Heptachlor Heptachlor Epoxide Lindane Methoxychlor Toxaphene
551.1 ⁴	Endrin Heptachlor Heptachlor Epoxide Lindane Methoxychlor
SOC – N/P Pesticides	
505 ⁴	Alachlor Atrazine Simazine
507 ⁴	Alachlor Atrazine Butachlor Metolachlor Metribuzin Propachlor Simazine
508.1 ⁴	Alachlor Atrazine Metolachlor Metribuzin Propachlor Simazine
525.2 ⁴	Alachlor Atrazine

	Butachlor Metolachlor Metribuzin Propachlor Simazine
551.1 ⁴	Alachlor Atrazine Simazine
Syngenta AG-625 ¹¹	Atrazine
SOC Herbicides	
515.1 ¹	2,4,5-TP (Silvex) 2,4-D Dalapon Dicamba Dinoseb Pentachlorophenol Picloram
515.2 ⁴	2,4,5-TP (Silvex) 2,4-D Dicamba Dinoseb Pentachlorophenol Picloram
515.3 ⁵	2,4,5-TP (Silvex) 2,4-D Dalapon Dicamba Dinoseb Pentachlorophenol Picloram
515.4 ⁶	2,4,5-TP (Silvex) 2,4-D Dalapon Dicamba Dinoseb Pentachlorophenol Picloram
525.2 ⁴	Pentachlorophenol
552.1 ³	Dalapon
552.2 ⁴	Dalapon
552.3 ¹³	Dalapon
555 ³	2,4,5-TP (Silvex) 2,4-D Dicamba Dinoseb

		Pentachlorophenol Picloram
D5317-93, 98 (Re-approved 2003) ¹²		2,4,5-TP (Silvex) 2,4-D Pentachlorophenol Picloram
SOC – Miscellaneous		
504.1 ⁴		Dibromochloropropane (DBCP) Ethylene Dibromide (EDB)
505 ⁴		Hexachlorobenzene Hexachlorocyclopentadiene Polychlorinated Biphenyls (as Aroclors)
506 ⁴		Di(2-ethylhexyl)adipate Di(2-ethylhexyl)phthalate
508 ⁴		Hexachlorobenzene Hexachlorocyclopentadiene Polychlorinated Biphenyls (as Aroclors)
508.1 ⁴		Hexachlorobenzene Hexachlorocyclopentadiene
508A ¹		Polychlorinated Biphenyls (as Decachlorobiphenyl)
525.2 ⁴		Benzo(a)pyrene Di(2-ethylhexyl)adipate Di(2-ethylhexyl)phthalate Hexachlorobenzene Hexachlorocyclopentadiene PCB (as decachlorobiphenyl)
531.1 ⁴		3-Hydroxycarbofuran Aldicarb Aldicarb Sulfone Aldicarb Sulfoxide Carbaryl Carbofuran Methomyl Oxamyl (Vydate)
531.2 ¹⁴		3-Hydroxycarbofuran Aldicarb Aldicarb Sulfone Aldicarb Sulfoxide Carbaryl Carbofuran Methomyl Oxamyl (Vydate)
547 ²		Glyphosate
548.1 ³		Endothall
549.2 ⁵		Diquat

550 ²	Benzo(a)pyrene
550.1 ²	Benzo(a)pyrene
551 ¹	Dibromochloropropane (DBCP) Ethylene Dibromide (EDB)
551.1 ⁴	Hexachlorobenzene Hexachlorocyclopentadiene
6610B ^{8,9,10}	3-Hydroxycarbofuran Aldicarb Aldicarb Sulfone Aldicarb Sulfoxide Carbaryl Carbofuran Methomyl Oxamyl (Vydate)
6651B ^{8,9,10}	Glyphosate

¹ “Methods for the Determination of Organic Compounds in Drinking Water” EPA-600/4-88-039, December 1988, Revised July 1991. Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 21161. The toll free number is: 800-553-6847.

² “Methods for the Determination of Organic Compounds in Drinking Water- Supplement I”, EPA-600-4-90-020, July 1990. Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 21161. The toll free number is: 800-553-6847.

³ “Methods for the Determination of Organic Compounds in Drinking Water- Supplement II”, EPA-600/R-92-129, August 1992. Available from National Technical Information Service, Order Port Royal Road, Springfield, VA 21161. The toll free number is: 800-553-6847.

⁴ “Methods for the Determination of Organic Compounds in Drinking Water- Supplement III”, EPA 600/R-95/131, August 1995. Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 21161. The toll free number is: 800-553-6847.

⁵ “Methods for the Determination of Organic and Inorganic Compounds in Drinking Water- Volume 1”, EPA 815-R-00-014, August 2000. Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 21161.

⁶ “Method 515.4 Determination of Chlorinated Acids in Drinking Water by Liquid-Liquid Microextraction, Derivatization, and Fast Gas Chromatography with Electron Capture Detection”, Rev. 1.0, EPA/815/B-00/001. April 2000. Available from Technical Support Center, Office of Groundwater and Drinking Water, US EPA, Cincinnati, OH 45268.

⁷ “Tetra-throughOcta-Chlorinated Dioxins and Furans by Isotope-Dilution HRGC/HRMS,” EPA/821-B-94-005, October 1994. Available from the National Technical Information Service, NTIS PB91-231480, PB91-146027, PB92-207703, PB95-261616 and PB95-104774, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia 22161. The toll free number is: 800-553-6847.

⁸ “Standard Methods for the Examination of Water and Wastewater”, 18th edition, American Public Health Association, American Water Works Association, 1992. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005.

⁹ “Standard Methods for the Examination of Water and Wastewater”, 19th edition, American Public Health Association, American Water Works Association, 1992. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005.

¹⁰ “Standard Methods for the Examination of Water and Wastewater”, 20th edition, American Public Health Association, American Water Works Association, 1998. Copies may be obtained from the American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005.

¹¹ “Method AG-625”, Syngenta Corp., “Atrazine in Drinking Water by Immunoassay,” February 2001, is available from Syngenta Crop Protection, Inc., 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419. Telephone: 336-632-6000.

¹² The procedures shall be done in accordance with the “Annual Book of ASTM Standards”, 1999, Vols 11.01 and 11.02. Copies may be obtained from the American Society for Testing Material, 1916 Race Street, Philadelphia, PA 19103.

¹³ “EPA Method 552.3”, “Determination of Haloacetic Acids and Dalapon in Drinking Water by Liquid-Liquid Microextraction, Derivatization, and Gas Chromatography with Electron Capture Detection,” Revision 1.0, July 2003, EPA 815-B-03-002, can be accessed and downloaded directly online at <http://www.epa.gov/safewater/methods/sourcalt.html>.

¹⁴ Method 531.2 “Measurement of Nmethylcarbamoyloximes and Nmethylcarbamates in Water by Direct Aqueous Injection HPLC with Postcolumn Derivatization,” Revision 1.0, September 2001, EPA 815-B-01-002, can be accessed and downloaded directly online at <http://www.epa.gov/safewater/methods/sourcalt.html>.

**TABLE E
TRIHALOMETHANES**

Class	Analytical Method	Analyte
Trihalomethanes (THM)	502.2 ¹	<i>Trihalomethanes Analyte Group</i> Bromodichloromethane Bromoform Chloroform Dibromochloromethane
	524.2 ¹	<i>Trihalomethanes Analyte Group</i> Bromodichloromethane Bromoform Chloroform Dibromochloromethane
	551.1 ¹	<i>Trihalomethanes Analyte Group</i> Bromodichloromethane Bromoform Chloroform Dibromochloromethane

¹“Methods for the Determination of Organic Compounds in Drinking Water- Supplement III”, EPA 600/R-95/131. Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 21161.

**TABLE F
VOLATILE ORGANIC COMPOUNDS**

Class	Analytical Method	Analyte
Volatile Organic Compounds	502.2 ¹	<i>Volatile Organic Compounds Analyte Group by EPA Method 502.2</i>
		<i>Regulated VOCs</i> 1,1,1-Trichloroethane 1,1,2-Trichloroethane 1,1-Dichloroethylene 1,2,4-Trichlorobenzene 1,2-Dichlorobenzene 1,2-Dichloroethane 1,2-Dichloropropane 1,4-Dichlorobenzene Benzene Carbon Tetrachloride Chlorobenzene cis-1,2-Dichloroethylene Dichloromethane Ethylbenzene Styrene Tetrachloroethylene

Class	Analytical Method	Analyte
		Toluene trans-1,2-Dichloroethylene Trichloroethylene Vinyl Chloride Xylenes (Total)
	524.2 ¹	<hr/> <i>Unregulated VOCs</i> 1,1-Dichloroethane 1,1-Dichloropropene 1,2,3-Trichlorobenzene 1,2,3-Trichloropropane 1,2,4-Trimethylbenzene 1,3,5-Trimethylbenzene 1,3-Dichloropropane 1,3-Dichloropropene (cis, trans) 2,2-Dichloropropane Bromobenzene Bromochloromethane Chloroethane Chloromethane Dibromomethane Dichlorodifluoromethane Fluorotrichloromethane Hexachlorobutadiene Isopropylbenzene m-Dichlorobenzene Naphthalene n-Butylbenzene n-Propylbenzene o-Chlorotoluene p-Chlorotoluene p-Isopropylbenzene sec-Butylbenzene tert-Butylbenzene
		<hr/> <i>Volatile Organic Compounds Analyte Group by EPA Method 524.2</i> <hr/> <i>Regulated VOCs Analyte Group</i> 1,1,1-Trichloroethane 1,1,2-Trichloroethane 1,1-Dichloroethylene 1,2,4-Trichlorobenzene 1,2-Dichlorobenzene 1,2-Dichlorobenzene 1,2-Dichloroethane 1,2-Dichloropropane 1,4-Dichlorobenzene

Class	Analytical Method	Analyte
		Benzene Carbon Tetrachloride Chlorobenzene cis-1,2-Dichloroethylene Dichloromethane Ethylbenzene Styrene Tetrachloroethylene Toluene trans-1,2-Dichloroethylene Trichloroethylene Vinyl Chloride Xylenes (Total)
		<i>Unregulated VOCs Analyte Group</i> 1,1,1,2-Tetrachloroethane 1,1,2,2-Tetrachloroethane 1,1-Dichloroethane 1,1-Dichloropropene 1,2,3-Trichlorobenzene 1,2,3-Trichloropropane 1,2,4-Trimethylbenzene 1,3,5-Trimethylbenzene 1,3-Dichloropropane 1,3-Dichloropropene (cis, trans) 2,2-Dichloropropane Bromobenzene Chloroethane Chloromethane Dibromomethane Dichlorodifluoromethane Fluorotrichloromethane Hexachlorobutadiene Isopropylbenzene m-Dichlorobenzene Naphthalene n-Butylbenzene n-Propylbenzene o-Chlorotoluene p-Chlorotoluene p-Isopropylbenzene sec-Butylbenzene tert-Butylbenzene
	551.1 ¹	Carbon Tetrachloride 1,1,1-Trichloroethane

Class	Analytical Method	Analyte
		1,1,2-Trichloroethane Tetrachloroethylene Trichloroethylene

¹“Methods for the Determination of Organic Compounds in Drinking Water- Supplement III”, EPA 600/R-95/131. Available from National Technical Information Service, 5285 Port Royal Road, Springfield, VA 21161.

APPENDIX III

LIST OF AUTHORITATIVE SOURCES

Note: Methods approved by the department for analyzing samples for compliance with covered programs are contained in chs. NR 157, 219, 661, 662, 664, 665, 700, 716 and 809. Procedures and practices required of laboratories are contained in subchapters I to VII. This list of authoritative sources is provided for information only. Inclusion of a method, procedure, or practice in any of these authoritative sources does not grant it approval by the department. The department may recognize or approve other methods of analysis not contained in these authoritative sources as allowed in ss. NR 149.41 and NR 149.42.

1. “Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater”, EPA/821/B-94-001, EPA, Washington, DC, 1995.
2. “Analytical Methods for the Determination of Pollutants in Pulp and Paper Industry Wastewater” EPA 821-R-93-017, EPA, Washington, DC, 1993.
3. “Annual Book of Standards, Sections 11.01 and 11.02, Water and Environmental Technology”, American Society for Testing and Materials, Philadelphia, PA, 1994, 1996, and 1999.
4. “Code of Federal Regulations, Title 40, Part 136, Appendices A and B”, U.S. Government Printing Office, Washington, DC.
5. “Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures, Quality Assurance”, Fifth Edition, EPA 815-R-05-004, EPA, Cincinnati, OH, 2005.
6. “Method 1613 Tetra- through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS”, EPA-81/B-94-003, EPA, Washington, DC, 1994.
7. “Method 1631, Revision E: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry”, EPA-821-R-02-019, EPA, Washington, DC, 2002.
8. “Method 1664, Revision A; N-Hexane Extractable Material (HEM; Oil and Grease) and Silica Gel Treated N-Hexane Extractable Material (SGT-HEM) by Extraction and Gravimetry”, EPA-821-R-98-002, EPA, Washington DC, 1999.
9. “Method 1668, Revision A: Chlorinated Biphenyl Congeners in Water, Soil, Sediment, and Tissue by HRGC/HRMS”, EPA-821-R-00-002, EPA, Washington, DC, 1999.”
10. “Method 1669: Sampling Ambient Water for Trace Metals at EPA Water Quality Criteria Levels”, EPA/821/R-96-011, EPA, Washington, DC, 1996.
11. “Methods for Analysis of Inorganic Substances in Water and Fluvial Sediments”, U.S. Department of the Interior, U.S. Geological Survey, Denver, CO, 1989.
12. “Methods for Chemical Analysis of Water and Wastes”, EPA-600/-4-79/020, Environmental Monitoring and Support Laboratory, Cincinnati, OH, March 1983.
13. “Methods for the Determination of Inorganic Substances in Environmental Samples” EPA/600/R-93/100, EPA, Washington DC, 1993.
14. “Methods for the Determination of Metals in Environmental Samples”, EPA/600/4-91/010, EPA/600/R-94/111, EPA, Washington, DC, 1991, 1994.
15. “Methods for the Determination of Organic Compounds in Drinking Water”, EPA/600/4-88/039, EPA/600/4-90/020, EPA/600/R-95/131, Environmental Monitoring Systems Laboratory, Cincinnati, OH, 1990, 1991, 1992, 1995.
16. “Methods for the Determination of Organic and Inorganic Compounds in Drinking Water-Volume 1” EPA 815-R-00-014, EPA, Cincinnati, OH, 2000.
17. “Methods for the Determination of Nonconventional Pesticides in Municipal and Industrial Wastewater (Volume 1)”, EPA-821-R-93-010-A, Environmental Monitoring Systems Laboratory, Cincinnati, OH, 1993.
18. “Official Methods of Analysis of the Association of Official Analytical Chemists”, 15th edition, Arlington, VA, 1990.
19. “Modified GRO – Method for Determining Gasoline Range Organics” WI-PUBL-SW-140, Wisconsin Department of Natural Resources, Madison, WI, 1995.
20. “Modified DRO – Method for Determining Diesel Range Organics” WI-PUBL-SW-141, Wisconsin Department of Natural Resources, Madison, WI, 1995.
21. “Principles of Environmental Analysis”, Analytical Chemistry, volume 55, pages 2210-2218, Washington DC, 1983.
22. “Standard Methods for the Examination of Water and Wastewater”, 18th, 19th, and 20th editions, American Public Health Association, Washington DC, 1992, 1995 and 1998.
23. “Test Methods for Evaluating Solid Waste, Physical/Chemical Methods” SW-846, Third Edition, Updates I, II, IIB, III, IVA, IVB, IIIB, EPA, Office of Solid Waste and Emergency Response, Washington DC 1986, 1992, 1994, 1995, 1996, 1998, 2000, 2002.

SECTION 2 EFFECTIVE DATE. This rule shall take effect on the first day of September following publication in the Wisconsin administrative register as provided in s. 227.22(2)(intro.), Stats.

SECTION 3. BOARD ADOPTION. This rule was approved and adopted by the State of Wisconsin Natural Resources Board on _____.

Dated at Madison, Wisconsin _____.

STATE OF WISCONSIN
DEPARTMENT OF NATURAL RESOURCES

By _____
Matthew J. Frank, Secretary

(SEAL)