



**PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION**

1        **AN ACT** *to repeal* 299.11 (1) (j); *to amend* 299.11 (3), 299.11 (4), 299.11 (5) (d),  
2            299.11 (7) (a), 299.11 (7) (b), 299.11 (7) (c), 299.11 (7) (d), 299.11 (7) (e), 299.11  
3            (7) (f), 299.11 (7) (g) (intro.), 299.11 (7) (g) 1., 299.11 (7) (g) 2., 299.11 (7) (g) 4.,  
4            299.11 (7) (i), 299.11 (8) (title), 299.11 (8) (a) (intro.), 299.11 (8) (f) (title) and  
5            299.11 (8) (g); *to repeal and recreate* 299.11 (7) (g) 3., 299.11 (8) (b) (title),  
6            299.11 (8) (c), 299.11 (8) (d) and 299.11 (8) (e); and *to create* 299.11 (1) (em),  
7            299.11 (1) (fm), 299.11 (1) (hm), 299.11 (8) (eg) and 299.11 (8) (es) of the statutes;  
8            **relating to:** laboratory accreditation by the Department of Natural Resources  
9            and granting rule-making authority (suggested as remedial legislation by the  
10          Department of Natural Resources).

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***Analysis by the Legislative Reference Bureau***

Under current law, the Department of Natural Resources accredits laboratories to perform certain types of testing.

This bill changes some of the terminology used in the statute relating to laboratory accreditation and changes some of the language in the statute for consistency.

For further information, see the NOTES provided by the Law Revision Committee of the Joint Legislative Council.

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***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

LAW REVISION COMMITTEE PREFATORY NOTE: This bill is a remedial legislation proposal, requested by the Department of Natural Resources and introduced by the Law Revision Committee under s. 13.83 (1) (c) 4. and 5., stats. After careful consideration of the various provisions of the bill, the Law Revision Committee has determined that this bill makes minor substantive changes in the statutes, and that these changes are desirable as a matter of public policy.

1           **SECTION 1.** 299.11 (1) (em) of the statutes is created to read:

2           299.11 (1) (em) “Method” means a set of procedures and techniques for  
3 performing an activity, such as extraction, chemical analysis, or quantification, that  
4 are systematically presented in the order in which they are to be performed.

5           **SECTION 2.** 299.11 (1) (fm) of the statutes is created to read:

6           299.11 (1) (fm) “Proficiency testing” means testing, for the purpose of  
7 evaluating the ability of a laboratory to produce an analytical test result meeting  
8 acceptable performance standards specified by rule, of a sample that is obtained from  
9 an approved proficiency testing provider and the concentration of the analyte of  
10 which is unknown to the laboratory at the time of the analysis.

11           **SECTION 3.** 299.11 (1) (hm) of the statutes is created to read:

12           299.11 (1) (hm) “Technology” means a specific arrangement of analytical  
13 instruments, detection systems, or preparation techniques.

14           **SECTION 4.** 299.11 (1) (j) of the statutes is repealed.

PREFATORY NOTE: This SECTION repeals the definition of “test category,” and SECTIONS 1 to 3 create new definitions of “method,” “proficiency testing,” and “technology,” respectively, for purposes of the laboratory accreditation program of the Department of Natural Resources. SECTIONS 5 to 7, 9, 11 to 18, and 22 modify terminology within the program to reflect the new definitions.

15           **SECTION 5.** 299.11 (3) of the statutes is amended to read:

1           299.11 (3) CERTIFICATION STANDARDS REVIEW COUNCIL. The council shall review  
2 the laboratory certification and registration program and shall make  
3 recommendations to the department concerning the specification of ~~test categories,~~  
4 ~~reference sample testing tests, technologies, methods, proficiency testing,~~ and  
5 standards for certification, registration, suspension, and revocation and other  
6 aspects of the program.

7           **SECTION 6.** 299.11 (4) of the statutes is amended to read:

8           299.11 (4) DEPARTMENT MAY REQUIRE CERTIFICATION OR REGISTRATION. (a)  
9 *Applicability.* Except as provided in subs. (5) and (6), if results from a test in a  
10 specified ~~test category~~ technology or method in a covered program are required to be  
11 submitted to the department, the department may require by rule that the test be  
12 conducted by a laboratory which is certified or registered to conduct tests that test  
13 in that specified ~~category~~ technology or method. The department may require that  
14 tests be conducted by a certified laboratory if the requirements for registration do not  
15 meet the requirements of an applicable federal law.

16           (b) *Specification of test categories* ~~tests, technologies, and methods~~. After  
17 considering any recommendations by the council, the department may identify by  
18 rule specified ~~test categories~~ tests, technologies, and methods.

19           (c) *Delayed effective date.* A rule identifying specified ~~test categories~~  
20 technologies and methods for which tests are required to be conducted by a certified  
21 or registered laboratory may not take effect until at least 120 days after publication.  
22 The department may not require a person to resubmit results of tests which were not  
23 required to be conducted by a certified or registered laboratory at the time of the  
24 original submission merely because of that fact.

25           **SECTION 7.** 299.11 (5) (d) of the statutes is amended to read:

1           299.11 (5) (d) *Discretionary acceptance.* The department may accept the  
2 results of a test in a specified ~~test category~~ technology or method even though the test  
3 was not conducted by a certified or registered laboratory. The department may  
4 charge an extra fee if it is necessary to verify the results of a test submitted under  
5 this paragraph.

6           **SECTION 8.** 299.11 (7) (a) of the statutes is amended to read:

7           299.11 (7) (a) *Criteria.* After considering recommendations by the council, the  
8 department shall promulgate by rule uniform minimum criteria, as provided in this  
9 subsection, to be used to evaluate laboratories for certification. Criteria shall be  
10 consistent with nationally recognized criteria to the maximum extent possible and  
11 shall be designed to facilitate reciprocal agreements under sub. (5). Upon  
12 application, the department shall certify a laboratory if the laboratory complies with  
13 the requirements of this subsection.

PREFATORY NOTE: SECTIONS 8, 10, 19 to 21, and 23 to 29 make clarifying  
amendments to the laboratory accreditation program of the Department of Natural  
Resources and provide consistency between laboratory certification and laboratory  
registration.

14           **SECTION 9.** 299.11 (7) (b) of the statutes is amended to read:

15           299.11 (7) (b) *Methodology* Methods. 1. ‘Accepted ~~methodology~~ methods.’ The  
16 department shall prescribe by rule the accepted ~~methodology~~ methods to be followed  
17 in conducting tests ~~in each test category.~~ The department may prescribe by rule  
18 accepted sampling protocols and documentation procedures ~~for a specified test~~  
19 ~~category~~ to be followed by the person collecting the samples. The department may  
20 prescribe ~~this methodology~~ methods by reference to standards established by  
21 technical societies and organizations as authorized under s. 227.21 (2). The  
22 department shall attempt to prescribe ~~this methodology~~ these methods so that it is  
23 they are consistent with any ~~methodology~~ method requirements under the resource

1 conservation and recovery act, as defined under s. 289.01 (30), the federal water  
2 pollution control act, as amended, 33 USC 1251 to 1376, the safe drinking water act,  
3 42 USC 300f to 300j-10, or the toxic substance control act, 15 USC 2601 to 2629.

4 2. 'Revised ~~methodology methods~~.' The department may permit the use of a  
5 revised ~~methodology method~~ consistent with new or revised editions or standards  
6 established by technical societies and organizations on a case-by-case basis.

7 3. 'Alternative ~~methodology methods~~; confidentiality.' a. The department may  
8 permit the use of an alternative ~~methodology method~~ on a case-by-case basis if the  
9 laboratory seeking to use that ~~methodology method~~ submits data establishing the  
10 accuracy and precision of the alternative ~~methodology method~~ and if the accuracy  
11 and precision obtained through the use of the alternative ~~methodology method~~  
12 equals or exceeds that obtained through use of the accepted ~~methodology method~~.  
13 The department shall establish by rule the data which is required to be submitted  
14 and the criteria for evaluating accuracy and precision of alternative methods.

15 b. A laboratory seeking to use an alternative ~~methodology method~~ may request  
16 confidential treatment of any data or information submitted to the department  
17 under this paragraph. The department shall grant confidential status for any data  
18 or information relating to unique methods or processes if the disclosure of those  
19 methods or processes would tend to adversely affect the competitive position of the  
20 laboratory.

21 4. 'Waiver of the procedure.' The department may waive any procedure  
22 prescribed in the accepted ~~methodology method~~ on a case-by-case basis if the  
23 laboratory seeking this waiver establishes sufficient reasons for the waiver and that  
24 the waiver does not adversely affect the purpose for which the test is conducted.

25 **SECTION 10.** 299.11 (7) (c) of the statutes is amended to read:

1           299.11 (7) (c) ~~Reference sample~~ Proficiency testing. The department may  
2 prescribe by rule criteria for determining the accuracy of tests by certified  
3 laboratories ~~on reference samples~~ performing proficiency testing. The department  
4 shall provide, ~~to the extent reasonably possible, reference samples prepared by an~~  
5 ~~independent source for a representative cross section of test categories which are to~~  
6 ~~be regularly and routinely performed by certified laboratories~~ a list of approved  
7 proficiency testing providers and the tests that require proficiency testing. The  
8 department may require by rule proficiency testing for tests upon application and  
9 annually thereafter. If results do not meet minimum criteria established by rule, the  
10 department may require additional proficiency testing. The department may not  
11 require a certified laboratory to analyze ~~not more than 3 reference samples~~  
12 successful proficiency tests per year for each test category in a specified technology  
13 or method.

14           **SECTION 11.** 299.11 (7) (d) of the statutes is amended to read:

15           299.11 (7) (d) *Quality control*. The department shall establish by rule  
16 minimum requirements for a quality control program which ensures that a  
17 laboratory complies with criteria for the accuracy and precision of tests ~~in each test~~  
18 ~~category and which specifies procedures to be followed if these criteria are not met~~.  
19 The department may accept a quality control program based upon state or federal  
20 requirements for similar ~~test categories~~ tests.

21           **SECTION 12.** 299.11 (7) (e) of the statutes is amended to read:

22           299.11 (7) (e) *Records*. Where a particular time period is not otherwise  
23 specified by law, the department may prescribe by rule ~~for each test category~~ the  
24 length of time laboratory analysis records and quality control data specified in the  
25 laboratory's quality control program are to be retained by the laboratory.

1           **SECTION 13.** 299.11 (7) (f) of the statutes is amended to read:

2           299.11 (7) (f) *Application for certification.* The department shall specify by rule  
3 the criteria and standards to be met by applicants for certification. A laboratory  
4 desiring to be certified for a specified test category in a specified technology or  
5 method shall make application on forms provided by the department.

6           **SECTION 14.** 299.11 (7) (g) (intro.) of the statutes is amended to read:

7           299.11 (7) (g) *Initial certification.* (intro.) The department shall issue an initial  
8 certification to a laboratory for a specified test category in a specified technology or  
9 method if all of the following conditions are met:

10          **SECTION 15.** 299.11 (7) (g) 1. of the statutes is amended to read:

11          299.11 (7) (g) 1. ‘Application.’ The laboratory submits an application  
12 requesting certification ~~in a specified test category for a test in a specified technology~~  
13 or method.

14          **SECTION 16.** 299.11 (7) (g) 2. of the statutes is amended to read:

15          299.11 (7) (g) 2. ‘Methodology Method.’ The laboratory specifies a methodology  
16 method prescribed or permitted under par. (b) which it intends to utilize in  
17 conducting tests in the ~~specified test category~~ technology or method.

18          **SECTION 17.** 299.11 (7) (g) 3. of the statutes is repealed and recreated to read:

19          299.11 (7) (g) 3. ‘Accuracy.’ Proficiency testing results shall be graded in  
20 accordance with criteria established by the department.

21          **SECTION 18.** 299.11 (7) (g) 4. of the statutes is amended to read:

22          299.11 (7) (g) 4. ‘Quality control.’ The laboratory has or agrees to implement  
23 a quality control program which meets minimum requirements under par. (d) for the  
24 test in a specified test category technology or method and which is to commence no  
25 later than the date of certification that accreditation has been granted.

1           **SECTION 19.** 299.11 (7) (i) of the statutes is amended to read:

2           299.11 (7) (i) *Suspension and revocation of certification.* After considering  
3 recommendations from the council, the department shall establish by rule criteria  
4 and procedures for the review and evaluation of the certification of laboratories and  
5 the suspension or revocation of certifications. If, after opportunity for a contested  
6 case hearing, the department finds that a certified laboratory has falsified results or  
7 has materially and consistently failed to comply with the criteria and procedures  
8 established by rule, it may suspend or revoke the certification of the laboratory. A  
9 person whose certification is suspended or revoked may reapply for certification  
10 upon a showing that the person meets the applicable criteria for certification and has  
11 corrected the deficiencies that led to the suspension or revocation.

12           **SECTION 20.** 299.11 (8) (title) of the statutes is amended to read:

13           299.11 (8) (title) ~~REGISTRATION PROCEDURE~~ PROCEDURES.

14           **SECTION 21.** 299.11 (8) (a) (intro.) of the statutes is amended to read:

15           299.11 (8) (a) *Criteria.* (intro.) After considering recommendations by the  
16 council, the department shall promulgate by rule uniform minimum criteria, as  
17 provided in this subsection, to be used to evaluate laboratories for registration.  
18 Criteria shall be consistent with nationally recognized criteria to the maximum  
19 extent possible and shall be designed to facilitate reciprocal agreements under sub.  
20 (5). Upon application, the department shall register a laboratory if the laboratory  
21 complies with the requirements of this subsection, if the laboratory does not perform  
22 tests commercially for hire and if:

23           **SECTION 22.** 299.11 (8) (b) (title) of the statutes is repealed and recreated to  
24 read:

25           299.11 (8) (b) (title) *Methods.*



1           **SECTION 23.** 299.11 (8) (c) of the statutes is repealed and recreated to read:  
2           299.11 (8) (c) *Proficiency testing.* Proficiency testing performed by a registered  
3 laboratory shall be carried out in accordance with sub. (7) (c).

4           **SECTION 24.** 299.11 (8) (d) of the statutes is repealed and recreated to read:  
5           299.11 (8) (d) *Quality control.* Quality control by a registered laboratory shall  
6 be carried out in accordance with sub. (7) (d).

7           **SECTION 25.** 299.11 (8) (e) of the statutes is repealed and recreated to read:  
8           299.11 (8) (e) *Records.* Records retained by a registered laboratory shall be  
9 retained in accordance with sub. (7) (e).

10          **SECTION 26.** 299.11 (8) (eg) of the statutes is created to read:  
11          299.11 (8) (eg) *Application for registration.* The department shall specify by  
12 rule the criteria and standards to be met by applicants for registration. A laboratory  
13 desiring to be registered for a test in a specified technology shall make application  
14 on forms provided by the department.

15          **SECTION 27.** 299.11 (8) (es) of the statutes is created to read:  
16          299.11 (8) (es) *Initial registration.* The department shall issue an initial  
17 registration to a laboratory for a test in a specified technology if all of the following  
18 conditions are met:

19           1. 'Application.' The laboratory submits an application requesting registration  
20 for a test in a specified technology.

21           2. 'Method.' The laboratory specifies a method prescribed or permitted under  
22 par. (b) which it intends to utilize in conducting tests in a specified technology.

23           3. 'Accuracy.' Proficiency testing results shall be graded in accordance with  
24 criteria established by the department.

1 4. 'Quality control.' The laboratory has or agrees to implement a quality control  
2 program which meets minimum requirements under par. (d) for a test in a specified  
3 technology and which is to commence no later than the date accreditation has been  
4 granted.

5 **SECTION 28.** 299.11 (8) (f) (title) of the statutes is amended to read:

6 299.11 (8) (f) (title) *Registration period.*

7 **SECTION 29.** 299.11 (8) (g) of the statutes is amended to read:

8 299.11 (8) (g) *Suspension or revocation of registration.* After considering  
9 recommendations from the council, the department shall establish by rule criteria  
10 and procedures for the review and evaluation of the registration of laboratories and  
11 the suspension or revocation of registrations. If, after opportunity for a contested  
12 case hearing, the department finds that a registered laboratory has falsified results  
13 or has materially and consistently failed to comply with the self-audit procedures  
14 and quality control programs provided in par. (d) criteria and procedures established  
15 by rule, it may suspend or revoke the registration of the laboratory. A person whose  
16 registration is suspended or revoked may reapply for registration upon a showing  
17 that the person meets the applicable criteria for registration and has corrected the  
18 deficiencies that led to the suspension or revocation.

19 (END)