

1999 DRAFTING REQUEST

Bill

Received: **01/21/2000**

Received By: **traderc**

Wanted: **Soon**

Identical to LRB:

For: **Neal Kedzie (608) 266-9650**

By/Representing: **Dan Johnson**

This file may be shown to any legislator: **NO**

Drafter: **traderc**

May Contact: **Jack Sullivan, DNR**

Alt. Drafters:

Subject: **Environment - miscellaneous**

Extra Copies:

Pre Topic:

No specific pre topic given

Topic:

National accrediting authority for laboratory certification

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Reauired</u>
/?	traderc 01/31/2000	gilfokm 02/02/2000		_____			S&L
/1			jfrantze 02/04/2000	_____	lrb-docadmin 02/04/2000		S&L
/2	traderc 02/10/2000	gilfokm 02/10/2000	kfollet 02/10/2000	_____	lrb-docadmin 02/10/2000	lrb-docadmin 02/11/2000	

FE Sent For: **02/10/2000.**

<END>

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/1		<i>1/2-2-10-2000</i> King	jfrantze 02/04/2000	_____	lrb_docadmin 02/04/2000		
			<i>Kf</i> <i>2/10</i>	<i>Kjf/km</i> <i>2/10</i>			
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1/?	traderc	<i>1-2-1-2000 KMG</i>	<i>John</i>	<i>8/5/96 5/3</i>			

FE Sent For:

<END>

Tradewell, Beckv

From: Johnson, Dan (Legislature)
Sent: Friday, January 21, 2000 9:47 AM
To: Tradewell, Becky
Subject: Request for legislative proposal

Hello Becky,

Recently, our office has had some discussion with the DNR regarding a bill they would like us to introduce. The bill was actually introduced into the budget but pulled because it had no fiscal impact. It was a proposal to create a national accreditation for state environmental labs.

Jack Sullivan from the DNR has requested this proposal be reintroduced with Representative Kedzie as lead author. We have agreed to do just that. Jack tells me that you drafted the original language for this bill. Now, they would like to make a few minor changes to this bill.

As this is my maiden voyage into introducing legislation, I need some advice on how to proceed. Just for your own information, we are trying to get this proposal included on the calendar for our 2/15/00 Environment committee hearing.

Thanks Becky.

Dan Johnson
Research Assistant
Clerk, Committee on Environment
State Representative Neal Kedzie
43rd Assembly District
(608) 266-9650



Printed on
Recycled Paper

State of Wisconsin
Department of Natural Resources

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299.11 Laboratory accreditation and certification program.

*Long revision of
Change w. state into*

299.1 l(1)

(1) Definitions. As used in this section:

299.11(1)(ae)

(ae) "Accredited" means accredited under sub. (7) or recognized as accredited under sub. (5).

299.11(1)(am)

(a) "Accuracy" means the closeness of a measured value to its generally accepted value or its value based upon an accepted reference standard.

299.11(1)(b)

(b) "Certified laboratory" means ~~a laboratory which performs tests for hire in connection with a covered program and which receives certification certified under sub. (a =)~~; - as a certified laboratory under sub. (5) ST1

299.11 (l)(c)

(c) "Council" means the accreditation and certification standards review council created under s. 15.107 (12).

299.11(1)(d)

(d) "Covered program" means test results submitted in connection with any of the following:

299.11(1)(d)1.

1. A feasibility report, plan of operation or the condition of any license issued for a solid waste facility under subch. III of ch. 289, or hazardous waste facility under s. 291.25 (2) and (3).

299.11(1)(d)2.

2. An application for a mining permit under s. 293.37 (2).

299.11(1)(d)3.

3. Monitoring required by terms and conditions of a permit issued under ch. 283.

299.11(1)(d)4.

4. The replacement of a well or provision of alternative water supplies under s. 281.75 or 281.77.

299.11(1)(d)5.

5. Groundwater monitoring under ch. 160.

299.11(1)(d)6.

6. The management or enforcement of the safe drinking water program under s. 280.13 (1) (b) and (d) or 281.17 (8).

299.11(1)(d)7.

7. The terms of department contracts when specifically required in the contracts.

299.11(1)(d)8.

8. An investigation of a discharge of a hazardous substance under s. 292.11.

299.11(1)(d)9.

9. A regulatory program specified by the department by rule if, after consultation with the council, the department finds that existing quality control programs do not provide consistent and reliable

results and the best available remedy is to require that all laboratories performing the tests for that regulatory program be certified or registered.

299.11(1)(e)

(e) "Laboratory" means a facility which performs tests in connection with a covered program.

299.11(1)(em)

(em) "National Environmental Laboratory Accreditation Conference [AST2]" means the voluntary association of state and federal officials, sponsored by the federal environmental protection agency, with the purpose of establishing national performance standards for environmental laboratories.

299.11(1)(eq)

(eq) "National environmental laboratory accreditation program" means the program of the federal environmental protection agency that oversees the implementation of national performance standards established by the National Environmental Laboratory Accreditation Conference and determines whether to approve state and federal agencies as accrediting authorities for environmental laboratories.

299.11(1)(f)

(f) "Precision" means the closeness of repeated measurements of the same parameter within a sample.

299.11(1)(g)

~~(g) "Registered laboratory" means a laboratory which is registered under sub. (8) or receives recognition as a registered laboratory under sub. (5).~~

299.11(1)(h)

(h) "Results" includes measurements, determinations and information obtained or derived from tests.

299.11(1)(i)

(i) "Test" means any chemical, bacteriological, biological, physical, radiation or microscopic test, examination or analysis conducted by a laboratory on water, wastewater, waste material, soil or hazardous substance.

299.11(1)(j)

(j) "Test category" means one type of test or group of tests specified by rule under sub. (4) for similar materials or classes of materials or which utilize similar methods or related methods.

299.11(1m) [AST3]

(1m) Recognition of the department by the national environmental laboratory accreditation program. The department may apply to the national environmental laboratory accreditation program for recognition as an accrediting authority. The department shall, after considering recommendations by the council, promulgate a rule prescribing criteria and procedures to be used to evaluate laboratories for accreditation consistent with the standards established by the National Environmental Laboratory Accreditation Conference.

299.11(2)

(2) Coordination with department of agriculture, trade and consumer protection.

299.11(2)(a)

(a) The department shall submit to the department of agriculture, trade and consumer protection and to the state laboratory of hygiene any rules proposed under this section that affect the laboratory ~~certification program~~ under s. 93.12 (5), for review and comment. These rules may not take effect unless they are approved by the department of agriculture, trade and consumer protection within 6 months after submission.

see
(8m)(a)

299.11(2)(b)

(b) The department shall enter into a memorandum of understanding with the department of agriculture, trade and consumer protection setting forth the responsibilities of each department in administering the laboratory ~~accreditation~~ ~~certification programs~~ under s. 93.12 (5) and this section. The memorandum of understanding shall include measures to be taken by each department to avoid duplication of application and compliance procedures.
~~certification.~~

299.11(3)

(3) ~~Accreditation and~~ ~~Ccertification~~ standards review council. The council shall review the laboratory ~~accreditation and~~ ~~certification and registration programs~~ and shall make ~~recommendations~~ to the department concerning the specification of test categories, reference sample testing and standards for ~~accreditation, certification, registration,~~ suspension and revocation and other aspects of the program. Recommendations concerning accreditations shall be consistent with the standards established by the National Environmental Laboratory Accreditation Conference[AST4].

299.11(4)

(4) Department may require accreditation or certification ~~or registration.~~

299.11(4)(a)

(a) Applicability. Except as provided in subs. (5) and (6), if results from a test in a specified test category in a covered program are required to be submitted to the department, the department may require by rule that the test be conducted by a laboratory which is accredited or certified ~~or registered to~~ conduct tests in that specified category. The department may require that tests be conducted by an accredited ~~certified laboratory~~ if the requirements for certification ~~registration do~~ not meet the requirements of an applicable federal law.

299.11(4)(b)

(b) Specification of test categories. After considering any recommendations by the council, the department may identify by rule specified test categories.

299.11(4)(c)

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

299.11(5)

(5) Recognition of other accreditation.

299.11(5)(a)

(a) Laboratories ~~certified~~ accredited by the department of agriculture, trade and consumer protection. The department shall recognize the accreditation ~~certification of~~ a laboratory by the department of agriculture, trade and consumer protection under s. 93.12 and shall accept the results of any test conducted by a laboratory accredited ~~certified to~~ conduct that category of test under that section.

299.11(5)(b)

(b) Reciprocity ~~[AST5]~~ with laboratories ~~accredited~~ ~~certified or registered by~~ other governments. The department may recognize the accreditation ~~certification, registration, licensure or approval~~ of a laboratory by another state or an agency of the federal government recognized by the national environmental laboratory accreditation program as an accrediting authority if the standards for certification, registration, licensure or approval are substantially equivalent to those established under this section. The department shall negotiate with and attempt to enter into acceptable agreements with federal agencies and agencies of other states for the purpose of

reciprocal recognition of laboratory ~~accreditation certification and registration~~ under this section. The department may not recognize the ~~accreditation certification, registration, licence or approval~~ of a laboratory by another state or an agency of the federal government unless that state or federal agency recognizes laboratories accredited under this section. ~~laboratories certified under this section. The department may accept the results of any tests conducted by a laboratory which it recognizes under an agreement.~~ The department shall publish periodically a list of those agencies whose ~~accreditations certification or registrations~~ it accepts. Any laboratory which is ~~accredited registered, certified or approved~~ by any such agency may apply to the department ~~for reciprocal accreditation to have the same recognized~~ under this section.

299.11(5)(c)

(c) Private organization agreements. The department may recognize the ~~certification, accreditation or approval~~ of a laboratory by a private nonprofit organization if the organization's standards for ~~certification, accreditation or approval~~ are substantially equivalent to those established by the National Environmental Laboratory Accreditation-Conference ~~under this section. The department may negotiate with and attempt to enter into acceptable agreements~~ [. T h e department shall publish periodically a list of those organizations whose ~~certifications, accreditations or approvals~~ it accepts. The department may accept the results of any tests conducted by a laboratory that it recognizes under an agreement. ~~Any laboratory that is certified, accredited or approved by an organization with which the department has an agreement may apply to the department to be recognized under this paragraph.~~

299.11(5)(d)

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

299.11(6)

(6) Not applicable to other programs. No laboratory is required to be ~~registered accredited or certified~~ under this section for any purpose other than the submission of results under a covered program.

299.11(7)

(7) Accreditation ~~Certification~~ procedures.

299.11(7)(a)

(a) Criteria.. After considering recommendations by the council, the department shall promulgate by rule uniform minimum criteria, as provided in this subsection, to be used to evaluate laboratories for ~~accreditation- CCriteria~~ shall be consistent with nationally recognized criteria to the ~~maximum extent possible and shall~~ be designed to facilitate reciprocal agreements under sub. (5).

299.11(7)(b)

(b) Methodology.

299.11(7)(b)1.

1. 'Accepted methodology.' The department shall prescribe by rule the accepted methodology to be followed in conducting tests in each test category. The department may prescribe by rule accepted sampling protocols and documentation procedures for a specified test ~~category to be~~ followed by the person collecting the samples. The department may prescribe this methodology by reference to standards established by technical societies and organizations as authorized under s. 227.21 (2). The department shall attempt to prescribe this methodology so that it is consistent with any methodology requirements under the resource conservation and recovery act, as defined under s. 289.01 (30), the federal water pollution control act, as amended, 33 USC

1251 to 1376, the safe drinking water act, 42 USC 300f to 300j-10, or the toxic substance control act, 15 USC 2601 to 2629.

299.11(7)(b)2.

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

299.11(7)(b)3.

3. 'Alternative methodology; confidentiality'.

299.11(7)(b)3.a.

a. The department may permit the use of an alternative methodology on a case-by-case basis if the laboratory seeking to use that methodology submits data establishing the accuracy and precision of the alternative methodology and if the accuracy and precision obtained through the use of the alternative methodology equals or exceeds that obtained through use of the accepted methodology. ~~The [AST] department shall establish by rule the data which is required to be submitted and the criteria for evaluating accuracy and precision of alternative methods.~~

299.11(7)(b)3.b.

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

299.11(7)(b)4.

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

299.11(7)(c)

(c) ~~Reference Proficiency testing sample testing [AST7].~~ The department may prescribe by rule criteria for determining the accuracy of tests by accredited s&i&d-laboratories on -proficiency testing samples. The department shall publish lists of approved provide, to the extent reasonably possible, reference proficiency testing sample providers prepared by an independent source for a representative cross section of tests categories which are to be regularly and routinely performed by accredited certified laboratories. ~~The department may require a certified laboratory to analyze not more than 3 reference samples per year for each test category.~~

299.11(7)(d)

(d) Quality control. The department shall establish by rule minimum requirements for a quality control program which ensures that a laboratory complies with criteria for the accuracy and precision of tests ~~in each test category~~ and which specifies procedures to be followed if these criteria are not met. The laboratory shall conduct self-audits and shall establish a quality control program consistent with criteria specified by rule by the department based on standards of the National Environmental Laboratory Accreditation Conference. ~~The department may accept a quality control program based upon standards established by state or federal requirements for similar test categories.~~

299.11(7)(e)

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

299.11(7)(f)

~~(f) Application for accreditations. The department shall specify by rule the criteria accreditations to be met by applicants for certification. A laboratory desiring to be certified for a specified test category shall make application on forms provided by the department.~~

299.11(7)(g)

~~(g) Initial Accreditation certification. The department shall issue an initial accreditation certification to a laboratory for a specified test category if all of the following conditions are met:~~

299.11(7)(g)1.

1. 'Application'. The laboratory submits an application requesting ~~certification~~ accreditation in a specified test category. A laboratory desiring to be accredited for a specified test shall make application on forms provided by the department.

299.11(7)(g)2.

2. 'Methodology'. The laboratory specifies a methodology prescribed or permitted under par. (b) which it intends to utilize in conducting ~~tests in the specified test category.~~

299.11(7)(g)3.

3. '-Proficiency testing. If the department ~~provides~~ requires a -proficiency testing sample, the laboratory conducts a test on the sample and obtains results which comply with the minimum acceptance criteria for accuracy for that specified test, category.

299.11(7)(g)4.

4. 'Quality control'. The laboratory has or agrees to implement a quality control program which meets minimum requirements under par. (d) for the specified test ~~category and~~ which is to commence no later than the date of accreditation.

299.11(7)(g)5.

5. 'On-site assessment'. The laboratory allows a department representative to perform an on-site assessment to evaluate compliance with the National Environmental Laboratory Accreditation Conference standards, and conclusively resolves any deviations from said standards noted during the assessment.

299.11(7)(gm)

(gm) Interim accreditation. The department may grant interim accreditation to laboratories that meet all the conditions specified under subd. 1, 2, 3, and 4.

299.11(7)(h)

~~(h) Certification Accreditation period. Certification Accreditation of laboratories shall be renewed annually. A certification is valid from the date of issuance until it expires, is revoked or suspended.~~

299.11(7)(hm)

(hm) Interim accreditation period. Interim accreditation shall expire a year after the date in which all the conditions under sub. (7) (gm) are met by a laboratory. Interim accreditation is Valid until it expires, is revoked, is suspended or is superseded by accreditation after completion of a successful on-site assessment.

299.11(7)(i)

(i) Suspension and revocation. After considering recommendations from the council, the department shall establish by rule criteria and procedures for the review and evaluation of the accreditation certification of laboratories and the suspension or revocation of

accreditations.- If, after opportunity for a contested case hearing, the department ~~finds~~ that an ~~certified accredited~~ laboratory has falsified results or has materially and consistently failed to ~~comply with the criteria and procedures established by rule~~ provided under par. (d), it may suspend or revoke the ~~certification accreditation~~ of the laboratory. A person ~~AST9~~ whose accreditation ~~certification is~~ suspended or revoked may reapply for ~~accreditation certification~~ upon ~~a showing~~ that the person meets the applicable criteria for ~~accreditation certification~~ and has corrected the deficiencies that led to the suspension or revocation.

299.11(8)

(8) ~~Registration Certification~~ procedure.

299.11(8)(a)

(a) Criteria. After considering recommendations by the council, the department shall promulgate by rule uniform minimum criteria, as provided in this subsection, to be used to evaluate ~~laboratories for certification~~. ~~Upon application, t~~ he department shall ~~register certify~~ a laboratory if the laboratory complies with the requirements of this subsection, if the ~~laboratory does~~ not perform tests commercially for hire, if the laboratory performs works solely for compliance with ch. 283, and if:

299.11(8)(a)1.

1. The laboratory performs tests solely on its own behalf or on behalf of a subsidiary or other corporation under common ownership or control; or

299.11(8)(a)2.

2. The laboratory is owned or controlled by a municipality or ~~2 or more municipalities~~ and performs tests solely on behalf of ~~the municipality or municipalities~~ for selected test categories specified by rule.

299.11(8)(b)

(b) Methodology. Testing by a ~~registered certified~~ laboratory conducted in connection with a covered program shall be carried out in accordance with sub. (7) (b).

299.11(8)(c)

(c) Reference sample testing. The department may require by rule reference sample test results that comply with the minimum criteria for accuracy for that specified test ~~6~~ upon application and annually thereafter. If results from these tests do not meet minimum criteria established by rule, the department may require additional reference sample testing. The department shall publish lists of approved reference sample providers for tests which are to be regularly and routinely performed by certified laboratories. ~~If the laboratory participates in a joint or split sampling program with the federal environmental protection agency, or otherwise obtains independent reference samples, the department may accept those results instead of its own reference samples.~~

299.11(8)(d)

(d) Quality control. The laboratory shall conduct self-audits and shall establish a quality control program consistent with criteria specified by rule by the department and based on methods and standards prescribed by rule and considering criteria used by the federal environmental protection agency, the American Society for Testing and Materials, ~~the national council on air and stream improvement, the national academy of sciences~~ or other equivalent agency or organization recognized by the department.

299.11(8)(e)

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

299.11(8)(f)

~~(f) (f) Registration Application for certification.~~ - The department shall specify by rule the criteria and standards to be met by applicants for certification ~~[AST10]~~.

299.11(8)(fm)

(fm) Certification. The department shall issue certification to a laboratory for a specified test category if all of the following conditions are met:

299.11(8)(fm)1.

1. 'Application'. The laboratory submits an application requesting certification in a specified test category on forms provided by the department.

299.11(8)(fm)2.

2. 'Methodology'. The laboratory specifies a methodology prescribed or permitted under par. (b) which it intends to utilize in conducting tests in the specified test category.

299.11(8)(fm)3.

3. 'Reference samples'. The laboratory conducts a test on an approved reference sample and obtains results which comply with the minimum criteria for accuracy for that specified test category.

299.11(8)(fm)4.

4. 'Quality control'. The laboratory has or agrees to implement a quality control program which meets the minimum requirements under par. (d) for the specified test category and which is to commence no later than the date of certification.

299.11(8)(fm)5.

5. 'On-site evaluation'. The laboratory allows a department representative to perform an on-site evaluation to determine compliance with the criteria and standards promulgated by rule for certified laboratories, and conclusively resolves any deviations from said criteria and standards noted during the evaluation. The department may waive this condition on a case-by-case basis when a laboratory has already been successfully evaluated on-site for similar tests or test categories.

299.11(8)(fq)

~~(fq). -Registration Certification period. Certification of laboratories shall be renewed annually. A certification is valid from the date of issuance until it expires, is revoked or suspended. of laboratories shall be renewed annually. A registration is valid from the date of issuance until it expires, is revoked or suspended. [AST1]-~~

299.11(8)(g)

(g) Suspension or revocation of certification registration. If, after opportunity for a contested case hearing, the department finds that a certified registered laboratory has falsified results or has materially and consistently failed to comply with the self-audit procedures and quality control programs provided in par. (d), it may suspend or revoke the registration of the laboratory. A person ~~[AST12] whose registration certification~~ is suspended or revoked may reapply for certification registration upon a showing that the person meets the applicable criteria for certification registration and has corrected the deficiencies that led to the suspension or revocation.

299.11(8)(h)

(h) Accreditation- option. A laboratory which is otherwise eligible to seek certification registration may elect to apply for accreditation certification under sub. (7).

299.11(9)

(9) Fees. The department shall promulgate by rule a graduated schedule of fees for accredited and certified laboratories which are designed to recover the costs of administering

this section. The fees collected for laboratory accreditation shall be used to administer a laboratory accreditation program. The fees collected for laboratory certification shall be used to administer a laboratory certification program. *

299.11 - ANNOT.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

Other Chapters of the Statutes Dealing With Laboratory Accreditation and Certification

NOTE: In these sections the double underline does not represent additions. The bold letters do. In these items the word accreditation or accredited have been added.

93.12 (9) The department shall recognize the certification or registration accreditation of a laboratory by the department of natural resources under s. 299.11 and shall accept the results of any test conducted by a laboratory certified or registered accredited to conduct that category of test under that section.

97.34 (2) (c) The department may require testing of bottled drinking water for substances subject to any standard under par. (b) and for any other substance if the department determines that the water system used as the source of the bottled drinking water has a potential of being contaminated, based on contamination of other water systems or groundwater in the vicinity. The department shall adopt by rule requirements for periodic sampling and analysis for the purposes of this subsection. The department shall require all analyses to be conducted by a laboratory certified or accredited under s. 299.11.

281.75 (6) (a) Contamination of a private water supply, as defined under sub. (1)(b) 1. or 2., is required to be established by analysis of at least 2 samples of water, taken at least 2 weeks apart, in a manner which assures the validity of the test results. The samples shall be tested by a laboratory certified or accredited under s. 299.11.

299.11 Laboratory accreditation and certification program.

*Long revision of
changed "clear".*

299.11(1)

(1) Definitions. As used in this section:

299.11(1)(ae)

(ae) "Accredited" means accredited under sub. (7) or recognized as accredited under sub. (5).

299.11(1)(am)

(a) "Accuracy" means the closeness of a measured value to its generally accepted value or its value based upon an accepted reference standard.

299.11(1)(b)

(b) "Certified " means certified under sub. (8).

299.11 (l)(c)

(c) "Council" means the accreditation and certification standards review council created under s. 15.107 (12).

299.11(1)(d)

(d) "Covered program" means test results submitted in connection with any of the following:

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1. A feasibility report, plan of operation or the condition of any license issued for a solid waste facility under **subch. III** of ch. 289, or hazardous waste facility under s. 291.25 (2) and (3).

299.11(1)(d)2.

2. An application for a mining permit under s. 293.37 (2).

299.11(1)(d)3.

3. Monitoring required by terms and conditions of a permit issued under ch. 283.

299.11(1)(d)4.

4. The replacement of a well or provision of alternative water supplies under s. 281.75 or 281.77.

299.11(1)(d)5.

5. Groundwater monitoring under ch. 160.

299.11(1)(d)6.

6. The management or enforcement of the safe drinking water program under s. 280.13 (1) (b) and (d) or 281.17 (8).

299.11(1)(d)7.

7. The terms of department contracts when specifically required in the contracts.

299.11(1)(d)8.

8. An investigation of a discharge of a hazardous substance under s. 292.11.

299.11(1)(d)9.

9. A regulatory program specified by the department by rule if, after consultation with the council, the department finds that existing quality control programs do not provide consistent and reliable results and the best available remedy is to require that all laboratories performing the tests for that regulatory program be certified or registered.

299.1 l(l)(e)

(e) "Laboratory" means a facility which performs tests in connection with a covered program.

299.11(1)(em)

(em) "National Environmental Laboratory Accreditation Conference" means the voluntary association of state and federal officials, sponsored by the federal environmental protection agency, with the purpose of establishing national performance standards for environmental laboratories.

299.11(1)(eq)

(eq) "National environmental laboratory accreditation program" means the program of the federal environmental protection agency that oversees the implementation of national performance standards established by the National Environmental Laboratory Accreditation Conference and determines whether to approve state and federal agencies as accrediting authorities for environmental laboratories.

299.11(1)(f)

(f) "Precision" means the closeness of repeated measurements of the same parameter within a sample.

299.11 l(l)(g)

(

299.11(1)(h)

(h) "Results" includes measurements, determinations and information obtained or derived from tests.

299.11(l)(i)

(i) "Test" means any chemical, bacteriological, biological, physical, radiation or microscopic test, examination or analysis conducted by a laboratory on water, wastewater, waste material, soil or hazardous substance.

299.11(l)(j)

(j) "Test category" means one type of test or group of tests specified by rule under sub. (4) for similar materials or classes of materials or which utilize similar methods or related methods.

299.11(1m)

(1 m) Recognition of the department by the national environmental laboratory accreditation program. The department may apply to the national environmental laboratory accreditation program for recognition as an accrediting authority. The department shall, after considering recommendations by the council, promulgate a rule prescribing criteria and procedures to be used to evaluate laboratories for accreditation consistent with the standards established by the National Environmental Laboratory Accreditation Conference.

299.1 l(2)

(2) Coordination with department of agriculture, trade and consumer protection.

299.11(2)(a)

(a) The department shall submit to the department of agriculture, trade and consumer protection and to the state laboratory of hygiene any rules proposed under this section that affect the laboratory program under s. 93.12 (5), for review and comment. These rules may not take effect unless they are approved by the department of agriculture, trade and consumer protection within 6 months after submission.

299.11(2)(b)

(b) The department shall enter into a memorandum of understanding with the department of agriculture, trade and consumer protection setting forth the responsibilities of each department in

administering the laboratory accreditation programs under s. 93.12 (5) and this section, The memorandum of understanding shall include measures to be taken by each department to avoid duplication of application and compliance procedures.

299.11(3)

(3) Accreditation and certification standards review council. The council shall review the laboratory accreditation and certification programs and shall make recommendations to the department concerning the specification of test categories, reference sample testing and standards for accreditation, certification, , suspension and revocation and other aspects of the program. Recommendations concerning accreditations shall be consistent with the standards established by the National Environmental Laboratory Accreditation Conference.

299.11(4)

(4) Department may require accreditation or certification .

299.11(4)(a)

(a) Applicability. Except as provided in subs. (5) and (6), if results from a test in a specified test category in a covered program are required to be submitted to the department, the department may require by rule that the test be conducted by a laboratory which is accredited or certified to conduct tests in that specified category. The department may require that tests be conducted by an accredited laboratory if the requirements for certification do not meet the requirements of an applicable federal law.

299.11(4)(b)

(b) Specification of test categories. After considering any recommendations by the council, the department may identify by rule specified test categories.

299.11(4)(c)

(c) Delayed effective date. A rule identifying specified test categories for which tests are required to be conducted by an accredited or certified laboratory may not take effect until at least 120 days after publication. The department may not require a person to resubmit results of tests which were not required to be conducted by an accredited or certified laboratory at the time of the original submission merely because of that fact.

299.11(5)

(5) Recognition of other accreditation.

299.11(5)(a)

(a) Laboratories accredited by the department of agriculture, trade and consumer protection. The department shall recognize the accreditation of a laboratory by the department of agriculture, trade and consumer protection under s. 93.12 and shall accept the results of any test conducted by a laboratory accredited to conduct that category of test under that section.

299.11(5)(b)

(b) Reciprocity with laboratories accredited by other governments. The department may recognize the accreditation of a laboratory by another state or an agency of the federal government recognized by the national environmental laboratory accreditation program as an accrediting authority. The department shall negotiate with and attempt to enter into acceptable agreements with federal agencies and agencies of other states for the purpose of reciprocal recognition of laboratory accreditation under this section. The department may not recognize the accreditation of a laboratory by another state or an agency of the federal government unless that state or federal agency recognizes laboratories accredited under this section. The department shall publish periodically a list of those agencies whose accreditations it accepts. Any laboratory which is accredited by any such agency may apply to the department for reciprocal accreditation under this section.

299.11(5)(c)

(c) Private organization agreements. The department may recognize the accreditation or approval of a laboratory by a private nonprofit organization if the organization's standards for accreditation or approval are substantially equivalent to those established by the National Environmental Laboratory Accreditation Conference. The department shall publish periodically a list of those organizations whose accreditations or approvals it accepts. The department may accept the results of any tests conducted by a laboratory that it recognizes under an agreement.

299.11(5)(d)

(d) Discretionary acceptance. The department may accept the results of a test in a specified test category even though the test was not conducted by an accredited or certified laboratory. The department may charge an extra fee if it is necessary to verify the results of a test submitted under this paragraph.

299.11(6)

(6) Not applicable to other programs. No laboratory is required to be accredited or certified under this section for any purpose other than the submission of results under a covered program.

299.11(7)

(7) Accreditation procedures.

299.11(7)(a)

(a) Criteria. After considering recommendations by the council, the department shall promulgate by rule uniform minimum criteria, as provided in this subsection, to be used to evaluate laboratories for accreditation. Criteria shall be consistent with nationally recognized criteria to the maximum extent possible and shall be designed to facilitate reciprocal agreements under sub.

(5).

299.11(7)(b)

(b) Methodology.

299.11(7)(b)1.

1. 'Accepted methodology.' The department shall prescribe by rule the accepted methodology to be followed in conducting tests in each test category. The department may prescribe by rule accepted sampling protocols and documentation procedures for a specified test to be followed by the person collecting the samples. The department may prescribe this methodology by reference to standards established by technical societies and organizations as authorized under s. 227.21

(2). The department shall attempt to prescribe this methodology so that it is consistent with any methodology requirements under the resource conservation and recovery act, as defined under s. 289.01 (30), the federal water pollution control act, as amended, 33 USC 1251 to 1376, the safe drinking water act, 42 USC 300f to 300j-10, or the toxic substance control act, 15 USC 2601 to 2629.

299.11(7)(b)2.

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

299.11(7)(b)3.

3. 'Alternative methodology; confidentiality'.

299.11(7)(b)3.a.

a. The department may permit the use of an alternative methodology on a case-by-case basis if the laboratory seeking to use that methodology submits data establishing the accuracy and precision of the alternative methodology and if the accuracy and precision obtained through the use of the alternative methodology equals or exceeds that obtained through use of the accepted methodology.

299.11(7)(b)3.b.

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

299.11(7)(b)4.

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

299.11(7)(c)

(c) Proficiency testing sample. The department may prescribe by rule criteria for determining the accuracy of tests by accredited laboratories on proficiency testing samples. The department shall publish lists of approved proficiency testing sample providers for tests which are to be regularly and routinely performed by accredited laboratories.

299.11(7)(d)

(d) Quality control. The department shall establish by rule minimum requirements for a quality control program which ensures that a laboratory complies with criteria for the accuracy and precision of tests and which specifies procedures to be followed if these criteria are not met. The laboratory shall conduct self-audits and shall establish a quality control program consistent with criteria specified by rule by the department based on standards of the National Environmental Laboratory Accreditation Conference. The department may accept a quality control program based upon standards established by federal requirements for similar test categories.

299.11(7)(e)

(e) Records. Where a particular time period is not otherwise specified by law, the department may prescribe by rule the length of time laboratory analysis records and quality control data specified in the laboratory's quality control program are to be retained by the laboratory.

299.11(7)(f)

(f) Application for accreditation. The department shall specify by rule the criteria and standards to be met by applicants for accreditation.

299.11(7)(g)

(g) Accreditation. The department shall issue accreditation to a laboratory for a specified test if all of the following conditions are met:

299.11(7)(g)1.

1. 'Application'. The laboratory submits an application requesting accreditation in a specified test. A laboratory desiring to be accredited for a specified test shall make application on forms provided by the department.

299.11(7)(g)2.

2. 'Methodology'. The laboratory specifies a methodology prescribed or permitted under par. (b) which it intends to utilize in conducting tests.

299.11(7)(g)3.

3. 'Proficiency testing'. If the department requires a proficiency testing sample, the laboratory conducts a test on the sample and obtains results which comply with the minimum acceptance criteria for that specified test.

299.11(7)(g)4.

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

299.11(7)(g)5.

5. 'On-site assessment'. The laboratory allows a department representative to perform an on-site assessment to evaluate compliance with the National Environmental Laboratory Accreditation Conference standards, and conclusively resolves any deviations from said standards noted during the assessment.

299.11(7)(gm)

(gm) Interim accreditation. The department may grant interim accreditation to laboratories that meet all the conditions specified under subd. 1, 2, 3, and 4.

299.11(7)(h)

(h) Accreditation period. Accreditation of laboratories shall be renewed annually. A certification is valid from the date of issuance until it expires, is revoked or suspended.

299.11(7)(hm)

(hm) Interim accreditation period. Interim accreditation shall expire a year after the date in which all the conditions under sub. (7) (gm) are met by a laboratory. Interim accreditation is valid until it expires, is revoked, is suspended or is superseded by accreditation after completion of a successful on-site assessment.

299.11(7)(i)

(i) Suspension and revocation. After considering recommendations from the council, the department shall establish by rule criteria and procedures for the review and evaluation of the accreditation of laboratories and the suspension or revocation of accreditations. If, after opportunity for a contested case hearing, the department finds that an accredited laboratory has falsified results or has materially and consistently failed to comply with the criteria and procedures provided under par. (d), it may suspend or revoke the accreditation of the laboratory. A person whose accreditation is suspended or revoked may reapply for accreditation upon showing that the person meets the applicable criteria for accreditation and has corrected the deficiencies that led to the suspension or revocation.

299.11(8)

(8) Certification procedure.

299.11(8)(a)

(a) Criteria. After considering recommendations by the council, the department shall promulgate by rule uniform minimum criteria, as provided in this subsection, to be used to evaluate laboratories for certification. The department shall certify a laboratory if the laboratory complies with the requirements of this subsection, if the laboratory does not perform tests commercially for hire, if the laboratory performs works solely for compliance with ch. 283, and if:

299.11(8)(a)1.

1. The laboratory performs tests solely on its own behalf or on behalf of a subsidiary or other corporation under common ownership or control; or

299.11(8)(a)2.

2. The laboratory is owned or controlled by a municipality or municipalities and performs tests solely on behalf of municipalities for selected test categories specified by rule.

299.11(8)(b)

(b) Methodology. Testing by a certified laboratory conducted in connection with a covered program shall be carried out in accordance with sub. (7) (b).

299.11(8)(c)

(c) Reference sample testing. The department may require by rule reference sample test results that comply with the minimum criteria for accuracy for that specified test upon application and annually thereafter. If results from these tests do not meet minimum criteria established by rule, the department may require additional reference sample testing. The department shall publish lists of approved reference sample providers for tests which are to be regularly and routinely performed by certified laboratories.

299.11(8)(d)

(d) Quality control. The laboratory shall conduct self-audits and shall establish a quality control program consistent with criteria specified by rule by the department and based on methods and standards prescribed by rule and considering criteria used by the federal environmental protection agency, the American Society for Testing and Materials, or other equivalent agency or organization recognized by the department.

299.11(8)(e)

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

299.11(8)(f)

(f) Application for certification. The department shall specify by rule the criteria and standards to be met by applicants for certification.

299.11(8)(fm)

(fm) Certification. The department shall issue certification to a laboratory for a specified test category if all of the following conditions are met:

299.11(8)(fm)1.

1. 'Application'. The laboratory submits an application requesting certification in a specified test category on forms provided by the department.

299.11(8)(fm)2.

2. 'Methodology'. The laboratory specifies a methodology prescribed or permitted under par. (b) which it intends to utilize in conducting tests in the specified test category.

299.11(8)(fm)3.

3. 'Reference samples'. The laboratory conducts a test on an approved reference sample and obtains results which comply with the minimum criteria for accuracy for that specified test category.

299.11(8)(fm)4.

4. 'Quality control'. The laboratory has or agrees to implement a quality control program which meets the minimum requirements under par. (d) for the specified test category and which is to commence no later than the date of certification.

299.11(8)(fm)5.

5. 'On-site evaluation'. The laboratory allows a department representative to perform an on-site evaluation to determine compliance with the criteria and standards promulgated by rule for certified laboratories, and conclusively resolves any deviations from said criteria and standards noted during the evaluation. The department may waive this condition on a case-by-case basis when a laboratory has already been successfully evaluated on-site for similar tests or test categories.

299.11(8)(fq)

(fq). Certification period. Certification of laboratories shall be renewed annually. A certification is valid from the date of issuance until it expires, is revoked or suspended.

299.11(8)(g)

(g) Suspension or revocation of certification. If, after opportunity for a contested case hearing, the department finds that a certified laboratory has falsified results or has materially and consistently failed to comply with the self-audit procedures and quality control programs provided in par. (d), it may suspend or revoke the registration of the laboratory. A person whose certification is suspended or revoked may reapply for certification upon a showing that the person meets the applicable criteria for certification and has corrected the deficiencies that led to the suspension or revocation.

299.11(8)(h)

(h) Accreditation option. A laboratory which is otherwise eligible to seek certification may elect to apply for accreditation under sub. (7).

299.11(9)

(9) Fees. The department shall promulgate by rule a graduated schedule of fees for accredited and certified laboratories which are designed to recover the costs of administering this section. The fees collected for laboratory accreditation shall be used to administer a laboratory accreditation program. The fees collected for laboratory certification shall be used to administer a laboratory certification program.

299.11 - ANNOT.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27,491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

Other Chapters of the Statutes Dealing With Laboratory Accreditation and Certification

93.12 (9) The department shall recognize the certification or accreditation of a laboratory by the department of natural resources under s. 299.11 and shall accept the results of any test conducted by a laboratory certified or accredited to conduct that category of test under that section.

97.34 (2) (c) The department may require testing of bottled drinking water for substances subject to any standard under par. (b) and for any other substance if the department determines that the water system used as the source of the bottled drinking water has a potential of being contaminated, based on contamination of other water systems or groundwater in the vicinity. The department shall adopt by rule requirements for periodic sampling and analysis for the purposes of this subsection. The department shall require all analyses to be conducted by a laboratory certified or accredited under s. 299.11.

281.75 (6) (a) Contamination of a private water supply, as defined under sub. (1) (b) 1. or 2., is required to be established by analysis of at least 2 samples of water, taken at least 2 weeks apart, in a manner which assures the validity of the test results. The samples shall be tested by a laboratory certified or accredited under s. 299.11.

-4286

Tradewell, Becky

From: Sotomayor, Alfredo
Sent: Thursday, January 27, 2000 2:43 PM
To: Tradewell, Becky
cc: Sullivan, John R (DNR - Central); Renville, Joe W
Subject: NELAC FACT Sheet

Ms. Tradewell,

Attached is the fact sheet we shared with Rep. Kedzie. His office would like to have a public hearing on this on Feb 15.

I know that the deadline is overly optimistic and appreciate all of you have done so far as well as whatever you can continue to do to help us with this matter.

Your questions today were very insightful. Do not hesitate to call me if you have doubts about our intent or our wishes when it comes to the proposed changes. And of course, feel absolutely free to make the changes you know are needed to make the proposal consistent and legal.

Alfredo Sotomayor



NELAPStatFactSheet.
doc

FACT SHEET
NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
(NELAP)
WISCONSIN ENVIRONMENTAL LABORATORY ACCREDITATION AND
CERTIFICATION PROGRAM

- The National Environmental Laboratory Accreditation Program (NELAP), an adjunct of the U.S. EPA, oversees the implementation of uniform standards for accreditation of laboratories performing environmental analyses supporting such regulatory programs as the Safe Drinking Water Act (SDWA) and the Clean Water Act (CWA), among others. These standards are crafted by the National Environmental Laboratory Accreditation Conference (NELAC).
- NELAC is a voluntary association of state and federal agencies that establishes and promotes mutually acceptable performance standards for environmental laboratories. The first set of consensus standards was adopted by the Conference in 1997. The Wisconsin Department of Natural Resources has participated in NELAC since the conference's inception in 1995.
- The Department of Natural Resource has operated a Laboratory Certification and Registration Program since 1986. In our current program, laboratories doing environmental analyses for hire are certified, while those doing testing solely on their own behalf are registered.
- The statute changes we are seeking (ch. 299) will allow the Department of Natural Resource to apply for recognition to NELAP and thus enable the DNR to accredit laboratories in accordance with the NELAC standards.
- The NELAC standards require reciprocity among the accrediting authorities and thus meet the spirit and letter of the current statute which requires the Department to actively seek reciprocal agreements for laboratory recognition with other states and federal agencies. This will enable the Department to spend more time accrediting and servicing in-state laboratories. Currently we perform laboratory on-site audits in 19 states.
- As of this date, there are eleven states recognized by NELAP as accrediting authorities: CA, CO, FL, IL, LA, KS, NH, NJ, NY, PA, UT.
- We are also seeking amendments to the statute to eliminate the current registration option and to cover non-commercial laboratories performing work in support of the CWA or the Wisconsin Pollution Elimination Discharge System (WPDES) under a revised certification program.
- The changes we are seeking thus establish a two-tiered system for recognition of laboratories: **certification** for municipal and industrial non-commercial laboratories doing CWA or WPDES compliance work and; **accreditation** by the NELAC standards for all commercial laboratories and for non-commercial laboratories performing work for regulatory programs other than CWA or WPDES.
- This two-tiered system of accreditation and certification is equitable because it allows those laboratories that could benefit from NELAC accreditation to obtain it locally through the Department, while at the same time not affecting the operation of laboratories that would reap little benefit from national accreditation. We are also accordingly proposing fiscal separation of both programs.
- The changes we are seeking are the result of a consensus building process that started in 1998 with the formation of a Technical Advisory Committee, were refined by a series of Focus Groups convened in 1999, and culminated with recommendations from DNR's Secretary Meyer and the Laboratory Certification Standards Review Council (the advisory Council authorized by statute to give the Department advice on laboratory matters) to apply to NELAP for recognition.
We are expecting to apply to NELAP by June 30, 2000. The NELAC Standards currently allow us two years from the time of application to seek statute changes and to craft administrative rules. Currently, this allowance is about to expire after June 30, 2000, which explains our desire to apply by the stated deadline.
- The DNR has made great efforts in meeting with affected parties and in keeping laboratories informed about prospective changes. We expect minimal, if any, opposition to the changes we are seeking in the statute because the changes themselves were arrived through compromise by members of the affected regulatory community.
- For more information, please contact John R. Sullivan, Environmental Science Services Section (ESS) Chief, at (608) 267-9753, or Alfredo Sotomayor, Senior Audit Chemist (ESS) at (608) 266-9257, both with the Department of Natural Resources.

SOON

(into editing 1/31)

DOA: ~~Grinde~~ National accrediting authority for laboratory certification
FOR 1999-01 BUDGET — NOT READY FOR INTRODUCTION

Note

generates
↓

accreditation, certification and registration
of laboratories by the department
of natural resources

1 AN ACT ...; relating to: the budget.

Analysis by the Legislative Reference Bureau

~~ENVIRONMENT~~

~~OTHER ENVIRONMENT~~

that must be

specify

Under current law, the department of natural resources (DNR) may require tests related to programs administered by DNR to be conducted by laboratories certified or registered by DNR or the department of agriculture, trade and consumer protection ~~(DNR)~~ or certified or registered by another state or a federal agency that recognizes laboratory certification by DNR and that uses standards equivalent to this state's standards.

State

This bill authorizes DNR to apply to the federal environmental protection agency to be approved to accredit laboratories under a national environmental laboratory accreditation program. If DNR is approved to accredit laboratories under the national program, an accredited laboratory may conduct tests that currently must be conducted by a certified or registered laboratory. If DNR is approved to accredit laboratories under the national program, this state must accept test results from laboratories accredited by other accrediting authorities and other accrediting authorities must accept test results from laboratories accredited by DNR.

↓
Analysis
insert

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

Insert 2-1
→

1 SECTION 1. 93.12 (9) of the statutes is amended to read:

2 93.12 (9) The department shall recognize the accreditation, certification or
3 registration of a laboratory by the department of natural resources under s. 299.11
4 and shall accept the results of any test conducted by a laboratory accredited, certified
5 or registered to conduct that category of test under that section.

↓
Insert
2-5 →

6 SECTION 2. 97.34 (2) (c) of the statutes is amended to read:

7 97.34 (2) (c) The department may require testing of bottled drinking water for
8 substances subject to any standard under par. (b) and for any other substance if the
9 department determines that the water system used as the source of the bottled
10 drinking water has a potential of being contaminated, based on contamination of
11 other water systems or groundwater in the vicinity. The department shall adopt by
12 rule requirements for periodic sampling and analysis for the purposes of this
13 subsection. The department shall require all analyses to be conducted by a
14 laboratory accredited or certified under s. 299.11.

15 SECTION 3. 281.75 (6) (a) of the statutes is amended to read:

16 281.75 (6) (a) Contamination of a private water supply, as defined under sub.
17 (1) (b) 1. or 2., is required to be established by analysis of at least 2 samples of water,
18 taken at least 2 weeks apart, in a manner which assures the validity of the test
19 results. The samples shall be tested by a laboratory accredited or certified under s.
20 299.11.

21 SECTION 4. 299.07 (1) (a) 11. of the statutes is amended to read:

22 299.07 (1) (a) 11. A certification, accreditation or registration under s. 299.11.

↓
Insert
2-22 →

23 SECTION 5. 299.11 (1) (a) of the statutes is renumbered 299.11 (1) (am).

24 SECTION 6. 299.11 (1) (ae) of the statutes is created to read:

7m

1 299.11 (1) (ae) "Accredited" means accredited under sub. (5) or recognized as
2 accredited under sub. (5).

3 SECTION 7. 299.11 (1) (b) of the statutes is amended to read:

4 299.11 (1) (b) "Certified laboratory" means a laboratory which performs tests
5 for hire in connection with a covered program and which receives certification
6 certified under sub. (7) or receives recognition recognized as a certified laboratory
7 under sub. (5).

Insert
3-7

8 SECTION 8. 299.11 (1) (em) of the statutes is created to read:

9 299.11 (1) (em) "National Environmental Laboratory Accreditation
10 Conference" means the voluntary association of state and federal offkials, sponsored
11 by the federal environmental protection agency, with the purpose of establishing
12 national performance standards for environmental laboratories.

13 SECTION 9. 299.11 (1) (eq) of the statutes is created to read:

14 299.11 (1) (eq) "National environmental laboratory accreditation program"
15 means the program of the federal environmental protection agency that oversees the
16 implementation of national performance standards established by the National
17 Environmental Laboratory Accreditation Conference and determines whether to
18 approve state and federal agencies as accrediting authorities for environmental
19 laboratories.

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

21 299.11 (1) (g) "Registered laboratory" means a laboratory which is registered
22 under sub. (8) or receives recognition recognized as a registered laboratory under
23 sub. (5).

Insert
3-23

24 SECTION 11 . 299.11 (3) of the statutes is amended to read:

CS Accreditation and certification

1 299.11 (3) ~~CERTIFICATION~~ STANDARDS REVIEW COUNCIL. The council shall review
 2 the laboratory certification ~~and~~, registration and accreditation program and shall
 3 make recommendations to the department concerning the specification of test
 4 categories, reference sample testing and standards for certification, registration,
 5 accreditation, suspension and revocation and other aspects of the program.
 6 Recommendations concerning accreditation⁸ shall be consistent with the standards
 7 established by the National Environmental Laboratory Accreditation Conference.

Insert
4-7 →

SECTION 12. 299.11 (4) (title) and (a) of the statutes are amended to read:

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

Insert
4-16 →

SECTION 13. 299.11 (4) (c) of the statutes is amended to read:

18 299.11 (4) (c) *Delayed effective date*. A rule identifying specified test categories
 19 for which tests are required to be conducted by a an accredited, certified or registered
 20 laboratory may not take effect until at least 120 days after publication. The
 21 department may not require a person to resubmit results of tests which were not
 22 required to be conducted by a an accredited, certified or registered laboratory at the
 23 time of the original submission merely because of that fact.

Insert
4-23 →

SECTION 14. 299.11 (5) (title) of the statutes is amended to read:

Inserts-2
(clerk) →

299.11 (5) (title) RECOGNITION OF OTHER ACCREDITATION, CERTIFICATION OR
REGISTRATION.

Section #. RP; 299.11 (5) (b) and (c)

-SECTION 15. 299.11 (5) (cm) of the statutes is created to read:

299.11 (5) (cm) *Reciprocity for national accreditation.* If the department is approved as an accrediting authority under sub. (8m) (a) and another accrediting authority under the national environmental laboratory accreditation program recognizes accreditation by the department under sub. (6m), the department shall recognize a laboratory as accredited to conduct tests in any test category for which the laboratory is accredited by that other accrediting authority.

SECTION 16. 299.11 (5) (d) of the statutes is amended to read:

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

Insert
5-15 →

SECTION 17. 299.11 (6) of the statutes is amended to read:

299.11 (6) NOT APPLICABLE TO OTHER PROGRAMS. No laboratory is required to be accredited, registered or certified under this section for any purpose other than the submission of results under a covered program.

Insert 5-19
(clerk) →

Section #. RP; 299.11 (2) (7m)

SECTION 18. 299.11 (6m) of the statutes is created to read:

299.11 (6m) ACCREDITATION. (a) ^① *accrediting authority.* The department may apply to be approved as an accrediting authority under the national environmental laboratory accreditation program. ^① *Criteria.*

^{am} If the department is approved as an accrediting authority under par. (a), the department shall, after considering recommendations by the council, ^{insert 5-24} promulgate a

1 rule prescribing criteria to be used to evaluate laboratories for accreditation and the
 2 procedures for accrediting laboratories. The criteria shall be consistent with the
 3 standards established by the National Environmental Laboratory Accreditation
 4 Conference.

✓
 Insert
 6-45

SECTION 19. 299.11 (9) of the statutes is amended to read:

6 299.11 (9) FEES. The department shall promulgate by rule a graduated
 7 schedule of fees for accredited, certified and registered laboratories which are
 8 designed to recover the costs of administering this section.

(END)

↓
 Insert
 6-8⁹

Analysis insert ✓

On July 1, 2001, this bill eliminates the current certification under DNR's laboratory program and modifies the current ^{requirements for} registration, which the bill

renames certification. Thus, beginning on July 1, 2001, a laboratory must be accredited by DNR or another accrediting authority under the national program, or certified by DATCP or DNR to conduct tests specified by DNR.

FF FE-5L

on that date,
The bill also eliminates^{es} reciprocal recognition of any kind of ^{laboratory} approval by another state or by a federal agency other than accreditation under the national environmental laboratory program. ^{accreditation}

Section #. 15.107 (12) (title) and (a) of the statutes are amended to read:

Accreditation and certification

15.107 (12) (title) ~~CERTIFICATION~~ STANDARDS REVIEW COUNCIL.

History: 1971 c. 215; 1973 c. 90; 1977 c. 29,419; 1979 c. 34; 1979 c. 361 s. 112; 1981 c. 20, 62, 237; 1983 a. 27,393, 410; 1985 a. 29, 84; 1987 a. 27,142; 1989 a. 31; 1991 a. 32 s. 17; 1991 a. 39, 170,269; 1995 a. 27, ss. 119, 120 and 9116 (5); 1995 a. 227, 433, 442; 1997 a. 27, 35,231; 1999 a. 9.

NOA

(a) *Creation.* There is created in the department of administration an accreditation and certification standards review council consisting of 9 members.

History: 1971 c. 215; 1973 c. 90; 1977 c. 29,419; 1979 c. 34; 1979 c. 361 s. 112; 1981 c. 20, 62, 237; 1983 a. 27,393, 410; 1985 a. 29, 84; 1987 a. 27, 142; 1989 a. 31; 1991 a. 32 s. 17; 1991 a. 39, 170, 269; 1995 a. 27, ss. 119, 120 and 9116 (5); 1995 a. 227, 433, 442; 1997 a. 27, 35,231; 1999 a. 9.



Insert 2-1, p. 2

Section #. 93.12 (5) of the statutes is amended to read:

93.12 (5) The department shall establish uniform minimum standards to be used in the evaluation and certification of laboratory examinations. The department shall submit any rules proposed under this subsection which affect the laboratory accreditation and certification program under s. 299.11 to the department of natural resources and to the state laboratory of hygiene for review and comment. These rules may not take effect unless they are approved by the department of natural resources within 6 months after submission.

History: 1975 c. 39, 198, 224; 1977 c. 29; 1979 c. 34; 1981 c. 291; 1983 a. 410; 1991 a. 178; 1993 a. 16; 1993 a. 27 s. 303; Stats. 1993 s. 252.22; 1995 a. 27 ss. 6324g to 6324k; Stats. 1995 s. 93.12; 1995 a. 227.

end of insert 2-1

Insert 2 - 5

as affected by 1999 Wisconsin Act --- (this act),

Section ^{KA} 93.12 (9) of the statutes is amended to read:

accreditation or

✓ 93.12 (9) The department shall recognize the certification ~~or registration~~ of a laboratory by the department of natural resources under s. 299.11 and shall accept the results of any test conducted by a laboratory ^{accredited or} certified ~~or registered~~ to conduct that category of test under that section.

History: 1975 c. 39, 198,224; 1977 c. 29; 1979 c. 34; 1981 c. 291; 1983 a. 410; 1991 a. 178; 1993 a. 16; 1993 a. 27 s. 303; Stats. 1993 s. 252.22; 1995 a. 27 ss. 6324g to 6324k; Stats. 1995 s. 93.12; 1995 a. 227.

Insert 2-22, p. 1

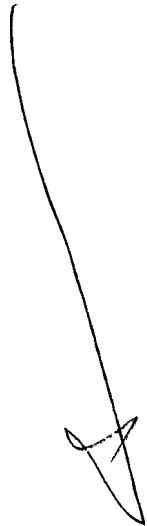
as affected by 1999 Wisconsin Act ... (+ his act),

KB

Section #. 299.07 (1) (a) 11. of the statutes&s amended to read:

j or accreditation.

299.07 (1) (a) 11. A certification ~~for registration~~ under s. 299.11.



History: 1997 a. 237; 1999 a. 9.

Insert 2-22, p. 2 ✓

Section #. 299.11 (title) of the statutes is amended to read:

accreditation and

299.11 (title) **Laboratory certification program.**

History: **1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.**

Insert 3-7, p. 1

1 ~~299.11 (1) (ae) "Accredited" means accredited under sub. (8m) or recognized as~~
2 ~~accredited under sub. (5).~~

3 ~~SECTION 8. 299.11 (1) (b) of the statutes is amended to read:~~

4 299.11 (1) (b) "Certified ~~laboratory~~" means ~~a laboratory which performs tests~~
5 ~~for hire in connection with a covered program and which receives certification~~
6 ~~certified under sub. (7) or receives recognition recognized as a certified laboratory~~
7 ~~under sub. (5).~~ *(8)*

8 ~~SECTION 8. 299.11 (1) (em) of the statutes is created to read:~~

9 299.11 (1) (em) "National Environmental Laboratory Accreditation
10 Conference" means the voluntary association of state and federal officials, sponsored
11 by the federal environmental protection agency, with the purpose of establishing
12 national performance standards for environmental laboratories.

13 ~~SECTION 9. 299.11 (1) (eq) of the statutes is created to read:~~

14 299.11 (1) (eq) "National environmental laboratory accreditation program"
15 means the program of the federal environmental protection agency that oversees the
16 implementation of national performance standards established by the National
17 Environmental Laboratory Accreditation Conference and determines whether to
18 approve state and federal agencies as accrediting authorities for environmental
19 laboratories.

20 ~~SECTION 10. 299.11 (1) (g) of the statutes is amended to read:~~

21 299.11 (1) (g) "Registered ~~laboratory~~" means ~~a laboratory which is registered~~
22 ~~under sub. (8) or receives recognition recognized as a registered laboratory under~~
23 ~~sub. (5).~~

24 ~~SECTION 11. 299.11 (3) of the statutes is~~ ~~to read:~~

as affected by 1999 Wisconsin Act... (this act)

Insert 3-7
3-7
3-7

Insert 3-7
3-7

Insert 3-7, p. 2

Section #. 299.11 (1) (c) of the statutes is amended to read:

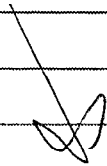
299.11 (1) (c) "Council" means the accreditation and certification standards review council created under s. 15.107 (12).

History: **1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417s.52.**

end of insert 3-7

Insert 2, p. 1

section #, 299.1(1)(g) of the statute, as affected by
1999 Wisconsin Act ... (this act), is repealed.



Insert 3-23, p. 2

Section #. 299.11 (2) of the statutes is amended to read:

299.11 (2) COORDINATION WITH DEPARTMENT OF AGRICULTURE, TRADE AND CONSUMER PROTECTION.

(a) The department shall submit to the department of agriculture, trade and consumer protection and * to the state laboratory of hygiene any rules proposed under this section that affect the laboratory-
* ~~ification~~ program under s. 93.12 (5), for review and comment. These rules **may not take effect** unless they are approved by the department of agriculture, trade and consumer protection within 6 months after submission.

(b) The department shall enter into a memorandum of understanding with the department of agriculture, trade and consumer protection setting forth the responsibilities of each department in
* administering the laboratory ~~certification~~ ^{main} programs under s. 93.12 (5) and this section. The memorandum of understanding shall include measures to be taken by each department to avoid duplication
* of application and compliance procedures ~~for laboratory certification~~.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

end of insert 4-7

^(KD) IN sent 4-7
Section # 299.11(3) of the statutes, as affected by 1999 Wisconsin Act...
Accreditation and certification

SECTION 11

(this act); is amended to read:

1 299.11 (3) ~~CERTIFICATION~~ STANDARDS REVIEW COUNCIL. The council shall review
 2 the laboratory certification ~~and registration and accreditation~~ program and shall
 3 make recommendations to the department concerning the specification of test
 4 categories, reference sample testing and standards for certification, ~~registration,~~
 5 ~~accreditation,~~ suspension and revocation and other aspects of the program.
 6 Recommendations concerning accreditation shall be consistent with the standards
 7 established by the National Environmental Laboratory Accreditation Conference.

↑ strike comma; don't score

~~SECTION 12. 299.11 (4) (title) and (a) of the statutes are amended to read:~~

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

SECTION 13. 299.11 (4) (c) of the statutes is amended to read:

18 299.11 (4) (c) *Delayed effective date.* A rule identifying specified test categories
 19 for which tests are required to be conducted by a an accredited, certified or registered
 20 laboratory may not take effect until at least 120 days after publication. The
 21 department may not require a person to resubmit results of tests which were not
 22 required to be conducted by a an accredited, certified or registered laboratory at the
 23 time of the original submission merely because of that fact.

SECTION 14. 299.11 (5) (title) of the statutes is amended to read:

✓ Inset 4-16

Accreditation and certification

1 ~~299.11 (3) CERTIFICATION STANDARDS REVIEW COUNCIL. The council shall review~~
 2 ~~the laboratory certification and, registration and accreditation program and shall~~
 3 ~~make recommendations to the department concerning the specification of test~~
 4 ~~categories, reference sample testing and standards for certification, registration,~~
 5 ~~accreditation, suspension and revocation and other aspects of the program.~~
 6 ~~Recommendations concerning accreditation shall be consistent with the standards~~
 7 ~~established by the National Environmental Laboratory Accreditation Conference.~~

8 SECTION 12. ^(KE) 299.11 (4) (title) and (a) of the statutes ^{as affected by 1999 Wisconsin Act} are amended to read: ^(this act)

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

17 SECTION 13. 299.11 (4) (c) of the statutes is amended to read: ---

18 ~~299.11 (4) (c) Delayed effective date. A rule identifying specified test categories~~
 19 ~~for which tests are required to be conducted by a an accredited, certified or registered~~
 20 ~~laboratory may not take effect until at least 120 days after publication. The~~
 21 ~~department may not require a person to resubmit results of tests which were not~~
 22 ~~required to be conducted by a an accredited, certified or registered laboratory at the~~
 23 ~~time of the original submission merely because of that fact.~~

24 SECTION 14. 299.11 (5) (title) of the statutes is amended to read:

Insert 4-23 ✓

Accreditation and certification

1 299.11 (3) ~~CERTIFICATION STANDARDS REVIEW COUNCIL.~~ The council shall review
 2 the laboratory certification and, registration and accreditation program and shall
 3 make recommendations to the department concerning the specification of test
 4 categories, reference sample testing and standards for certification, registration,
 5 accreditation, suspension and revocation and other aspects of the program.
 6 Recommendations concerning accreditation shall be consistent with the standards
 7 established by the National Environmental Laboratory Accreditation Conference.

8 SECTION 12. 299.11 (4) (title) and (a) of the statutes are amended to read:

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

17 SECTION 13. 299.11 (4) (c) of the statutes, ^{as affected by 1999 Wisconsin Act...} is amended to read: ^{(+ this act),}

18 299.11 (4) (c) *Delayed effective date.* A rule identifying specified test categories
 19 for which tests are required to be conducted by ^{or} ~~an accredited, certified or registered~~
 20 laboratory may not take effect until at least 120 days after publication. The
 21 department may not require a person to resubmit results of tests which were not
 22 required to be conducted by ^{strike comma} ~~an accredited,~~ ^{or} certified - laboratory at the
 23 time of the original submission merely because of that fact.

24 SECTION 14. 299.11 (5) (title) of the statutes is amended to read:

(KC)

Insert 5-2

✓

Section #. 299.11 (5) (title) of the statutes, as affected by 1999 Wisconsin Act (this act), is amended to read:

Ⓢ accreditation

299.11 (5) (title) **RECOGNITION OF OTHER** ~~CERTIFICATION OR REGISTRATION.~~

History: **1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27,491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.**

Insert 5-15v

Insert 5-2
Section # RP; 299.11(5)(b) and (c)

299.11 (5) (title) RECOGNITION OF OTHER ACCREDITATION, CERTIFICATION OR REGISTRATION.

SECTION 15. 299.11(5) (cm) of the statutes is created to read:

299.11 (5) (cm) *Reciprocity for national accreditation.* If the department is approved as an accrediting authority under sub. (8m) (a) and another accrediting authority, under the national environmental laboratory accreditation program recognizes accreditation by the department under sub. (8m), the department shall recognize a laboratory as accredited to conduct tests in any test category for which the laboratory is accredited by that other accrediting authority.

SECTION 16. 299.11 (5) (d) of the statutes is amended to read:

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

SECTION 17. 299.11 (6) of the statutes is amended to read:

299.11 (6) NOT APPLICABLE TO OTHER PROGRAMS. No laboratory is required to be accredited, registered or certified under this section for any purpose other than the submission of results under a covered program.

SECTION 18. 299.11 (8m) of the statutes is created to read:

299.11, (8m) ACCREDITATION. (a) The department may apply to be approved as an accrediting authority under the national environmental laboratory accreditation program.

^{am} If the department is approved as an accrediting authority under par. (a), the department shall, after considering recommendations by the council, promulgate a

Section # RP; 299.11 (2) ?

insert 5-2c

Insert 5-19 ✓

Inserts 5-2
F.C. (1)

1 299.11 (5) (title) ~~RECOGNITION OF OTHER ACCREDITATION, CERTIFICATION OR~~
2 REGISTRATION.

Section #. RP; 299.11 (5) (b) and (c)

3 SECTION 15. 299.11 (5) (cm) of the statutes is created to read:

4 299.11 (5) (cm) *Reciprocity for national accreditation.* If the department is
5 approved as an accrediting authority under sub. (8m) (a) and another accrediting
6 authority, under the national environmental laboratory accreditation program
7 recognizes accreditation by the department under sub. (8m), the department shall
8 recognize a laboratory as accredited to conduct tests in any test category for which
9 the laboratory is accredited by that other accrediting authority.

10 SECTION 16. 299.11 (5) (d) of the statutes is amended to read:

11 299.11 (5) (d) *Discretionary acceptance.* The department may accept the
12 results of a test in a specified test category even though the test was not conducted
13 by a an accredited, certified or registered laboratory. The department may charge
14 an extra fee if it is necessary to verify the results of a test submitted under this
15 paragraph.

16 SECTION 17. 299.11 (6) of the statutes is amended to read:

as affected by 1999 Wisconsin Act... (this act)

17 299.11 (6) NOT APPLICABLE TO OTHER PROGRAMS. No laboratory is required to be
18 ~~accredited, registered or certified~~ under this section for any purpose other than the
19 submission of results under a covered program.

20 SECTION 18. 299.11 (8m) of the statutes is created to read:

21 299.11 (8m) ACCREDITATION. (a) The department may apply to be approved as
22 an accrediting authority under the national environmental laboratory accreditation
23 program.

24 ^{am} If the department is approved as an accrediting authority under par. (a), the
25 department shall, after considering recommendations by the council, promulgate a

II
18
19
20

~~SECTION 18. 299.11 (8m) of the statutes is created to read:
299.11 (8m) ACCREDITATION. (a) The department may apply to be approved as
an accrediting authority under the national environmental laboratory accreditation
program.
If the department is approved as an accrediting authority under par. (a), the
department shall, after considering recommendations by the council, promulgate a~~

From
Section #. 299.11 (7) of the statutes is amended to read: Insert 5-24, p. 1

~~299.11 (7) CERTIFICATION PROCEDURES. (a) Criteria. After considering recommendations by the council, the department shall promulgate ~~the~~ rule ^{⑤ establishing} uniform minimum criteria, as provided in this subsection, to be used to evaluate laboratories for ~~certification~~ ^{accreditation}. Criteria shall be consistent with nationally recognized criteria to the maximum extent possible and ~~shall be designed to facilitate reciprocal agreements under sub. (5).~~~~

* (b) Methodology. 1. ~~Accepted methodology.~~ The department shall prescribe by rule the accepted methodology to be followed in conducting tests in each test category. The department may prescribe by rule accepted sampling protocols and documentation procedures for a specified test ~~category~~ to be followed by the person collecting the samples. The department may prescribe this methodology by reference to standards established by technical societies and organizations as authorized under s. 227.21 (2). The department shall attempt to prescribe this methodology so that it is consistent with any methodology requirements under the ~~Resource Conservation and Recovery Act~~, as defined under s. 289.01 (30), the Resource Conservation and Recovery Act, as defined under s. 289.01 (30), the federal water pollution control act, as amended, 33 USC 1251 to 1376, the safe drinking water act, 42 USC 300f to 300j-19, or the toxic substance control act, 15 USC 2601 to 2629.

Unit Cop. }
K

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

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

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

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

* (c) ~~Reference sample testing~~. The department may prescribe by rule criteria for determining the accuracy of tests by ~~certified~~ ^{accredited} laboratories on ~~reference~~ ^{proficiency testing} samples. The department shall provide, to the extent reasonably possible, reference samples prepared by an independent source for a representative cross section of test categories which are to be regularly and routinely performed by ~~certified~~ ^{accredited} laboratories. ~~The department may require a certified laboratory to analyze not more than 3 reference samples per year for each test category.~~ ^{publish lists of approved providers of proficiency testing} ~~samples for tests that are~~ ^{to be}

* (d) *Quality control*. The department shall establish by rule minimum requirements for a quality control program ~~which~~ ^{that} ensures that a laboratory complies with criteria for the accuracy and precision of tests in ~~each test category~~ ^{that} and ~~which~~ ^{that} specifies procedures to be followed if these criteria are not met. The department may accept a quality control program based ~~on state or federal requirements for similar test categories.~~ ^{on state or federal requirements for similar test categories.} ^{laboratory accreditation conference.}

* (e) *Records*. ~~When~~ ^{if} a particular time period is not otherwise specified by law, the department may prescribe by rule ~~for each test category~~ ^{that} the length of time laboratory analysis records and quality control data specified in the laboratory's quality control program are to be retained by the laboratory.

* (f) ~~Application for certification~~ ^{Criteria accreditation}. The department shall specify by rule the criteria and standards to be met by applicants for ~~certification~~ ^{accreditation}. ~~A laboratory desiring to be certified for a specified test category shall make application on forms provided by the department.~~

A laboratory shall conduct self-audits and shall establish a quality control program that is consistent with criteria specified by rule by the department based on the standards of the national environmental

Insert 5-24-A ✓

Q 5. The laboratory allows a representative of the department to perform an on-site assessment to evaluate compliance with the standards of the national environmental laboratory accreditation conference and resolves any deviations from those standards that are identified during the assessment.

gm
(gm) [Ⓢ] Interim accreditation. The department may grant interim accreditation to a laboratory that meets the conditions in par. (g) 1. to 4. ✓

Insert 5-24-B ✓

(hm) (I) Interim accreditation period. Interim

accreditation expires one year after the date on which
the laboratory meets
all of the conditions specified in par. (gm). Interim

accreditation is valid until it expires, is revoked, is

suspended or is superseded by accreditation after

compliance with par. (g) 5.

① Issuance of accreditation

accreditation

(g) ~~Initial certification~~ The department shall issue an ~~initial certification~~ to a laboratory for a specified test ~~category~~ if all of the following conditions ~~are met~~ ^{the laboratory meets}

*

1. ~~Application~~ The laboratory submits an application ^{(a) on forms provided by the department,} requesting ~~certification~~ ^{accreditation for} a specified test ~~category~~

2. ~~Methodology~~ The laboratory specifies a methodology prescribed or permitted under par.

(b) ~~which~~ ^{that} it intends to utilize in conducting ~~tests~~ ^{the} in the specified test ~~category~~ ^{requires a proficiency testing}

3. ~~Accuracy~~ If the department ~~provides a reference sample~~ ^{requires a proficiency testing}, the laboratory conducts a test on the sample and obtains results ~~which~~ ^{that} comply with the minimum ~~criteria~~ ^{acceptance} for ~~accuracy~~ ^{the} for the specified test ~~category~~

4. ~~Quality control~~ The laboratory has or agrees to implement a quality control program ^{that} which meets minimum requirements under par. (d) for the specified test ~~category~~ ^{that} and ~~which~~ is to commence no later than the date of ~~certification~~ ^{accreditation}

Insert 5-24-A

(h) ~~Certification period~~ ^{① Accreditation} ~~Certification~~ of laboratories shall be renewed annually. ~~A certification~~ ^{accreditation} is valid from the date of issuance until it expires, is revoked or suspended.

Insert 5-24-B

(i) ~~Suspension and revocation~~. After considering recommendations from the council, the department shall establish by rule criteria and procedures for the review and evaluation of the ~~certification~~ ^{accreditation} of laboratories and the suspension or revocation of ~~certifications~~ ^{accreditation}. If, after opportunity for a contested case hearing, the department finds that a ~~certified~~ ^{an accredited} laboratory ~~materially and consistently failed to~~ ^{has fabricated results or has} comply with the criteria and procedures ~~established by rule~~ ^{provided under part (d)}, it may suspend or revoke the ~~certification~~ ^{accreditation} of the laboratory. A person whose ~~certification~~ ^{accreditation} is suspended or revoked ~~may reapply for certification~~ ^{the department} upon a showing that the person meets the applicable criteria for ~~certification~~ ^{accreditation} and has corrected the deficiencies that led to the suspension or revocation.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

End of Ins. 5-24

Section #. 299.11 (8) (title) and (a) ~~to (e)~~ of the statutes are amended to read:

C.S.
Certification

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

History: ~~1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 32; 1985 a. 39; 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.~~

Non

(a) ~~Criteria.~~ Upon application, the department shall register a laboratory if the laboratory complies with the requirements of this subsection, if the laboratory does not perform tests commercially for hire, and if: if the laboratory performs tests solely in connection with

one of the following applies. ch. 283 ³

1. The laboratory performs tests solely on its own behalf or on behalf of a subsidiary or other corporation under common ownership or control; ~~or~~

2. The laboratory is owned or controlled by a municipality or 2 or more municipalities and performs tests solely on behalf of ~~the municipality or municipalities~~ in test categories specified by the department by rule

History: ~~1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.~~

After considering recommendations by the council, the department shall promulgate ~~by~~ rules ^{establishing} uniform minimum criteria, as provided in this subsection, to be used to evaluate ^{lab} laboratories for certification. The

Insert 6-4, p. 2

to
Section #. 299.11 (8) (b), ~~(c), (d)~~ and ~~(e)~~ of the statutes are amended to read:

test results, ^{ES,} that comply with minimum criteria for accuracy for a test.

* 299.11 (8) (b) *Methodology*. Testing by a registered ^{certified} laboratory conducted in connection with a covered program shall be carried out in accordance with sub. ~~(7)~~ ^(2m) (b). ✓

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

* (c) *Reference sample testing*. The department may require by rule reference sample tests upon application and annually thereafter. If results from these tests do not meet minimum criteria established by rule, the department may require additional reference sample testing. ~~If the laboratory participates in a joint or split sampling program with the federal environmental protection agency, or otherwise obtains independent reference samples, the department may accept those results instead of its own reference samples.~~

The department shall publish lists of approved providers of reference samples for tests that are to be regularly and routinely performed by certified laboratories. ✓
History: ~~1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.~~

* (d) *Quality control*. The laboratory shall conduct self-audits and ^{shall establish} a quality control program consistent with criteria specified by rule by the department and based on methods and standards prescribed by rule and considering criteria used by the federal environmental protection agency, the American Society for Testing and Materials, ~~the national council on air and stream improvement,~~ ~~the national academy of sciences~~ or ^{any} other equivalent agency ^{or organization} recognized by the department.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

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

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

Insert 6.4 pp. 3

Section #. (K; 299.11(8) (eg)

299.11(8) (eg) ⁽⁺⁾ Criteria for certification. The

department shall specify by rule the criteria and standards to be met by applicants^s for certification.

↓

er Insert 6-4, p. 4
(s) (er) created

Section #. 299.11 (s) of the statutes is amended to read:

(s)(er) Issuance of

* 299.11 (s) Initial certifications The department shall issue an initial certification to a labora-
* tory for a specified test category if all of the following conditions are met:
* (a) on forms provided by the department,

- * 1. ~~Application~~: The laboratory submits an application, requesting certification in a specified test category.
- 2. ~~Methodology~~: The laboratory specifies a methodology prescribed or permitted under par. (b) ^{that} it intends to utilize in conducting tests in the specified test category.
- 3. ~~Accuracy~~: If the department ^{requires} a reference sample, the laboratory conducts a test on ^{test result} an approved reference ^{that} the sample and obtains results ^{the} which comply with the minimum criteria for accuracy for ^{the} that specified test category.
- 4. ~~Quality control~~: The laboratory has or agrees to implement a quality control program ^{that} which meets minimum requirements under par. (d) for the specified test category and ^{that} which is to commence no later than the date of certification.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

5. The laboratory allows a representative of the department to perform an on-site evaluation to determine compliance with the criteria and standards under par. (e) and resolves any deviations from those criteria and standards that are identified during the evaluation, except that the department may waive this condition if a laboratory has previously had a successful on-site evaluation for similar tests or test categories.

Section #. 299.11 (8) (f) ^{to} ~~(g)~~ and (h) of the statutes are amended to read:

Ⓛ Certification period

299.11 (8) (f) ~~Registration~~ ^{Certification} Registration of laboratories shall be renewed annually. A ~~registration~~ ^{Certification} is valid from the date of issuance until it expires, is revoked or ^{is} suspended.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

Ⓛ (g) Suspension or revocation of registration If, after opportunity for a contested case hearing, the department finds that a ~~registered~~ ^{certified} laboratory has falsified results or has materially and consistently failed to comply with the self-audit procedures and quality control programs provided ^{under} in par. (d), it may suspend or revoke the ~~registration~~ ^{certification} of the laboratory. A person whose ~~registration~~ ^{certification} is suspended or revoked may reapply for ~~registration~~ ^{certification} upon a showing that the person meets the applicable criteria for ~~registration~~ ^{certification} and has corrected the deficiencies that led to the suspension or revocation.

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

Ⓛ (h) Accreditation A laboratory which ^{that} is otherwise eligible to seek ~~registration~~ ^{certification} may elect to apply for ~~certification~~ ^{accreditation} under sub. (7). (7m) ✓

History: 1983 a. 410; 1985 a. 22 s. 11; 1985 a. 29 s. 3202 (39); 1985 a. 84 s. 8; 1985 a. 182 s. 57; 1989 a. 31; 1991 a. 32, 39; 1993 a. 27, 491; 1995 a. 27; 1995 a. 227 s. 818; Stats. 1995 s. 299.11; 1995 a. 417 s. 52.

Insert 6-8, p. 1

1 ~~rule prescribing criteria to be used to evaluate laboratories for accreditation and the~~
 2 ~~procedures for accrediting laboratories. The criteria shall be consistent with the~~
 3 ~~standards established by the National Environmental Laboratory Accreditation~~
 4 ~~Conference.~~

*4
+ m
6-95*

(KS)

*as affected by 1999 Wisconsin Act
... (this out)*

SECTION 19. 299.11 (9) of the statutes is amended to read:

6 299.11 (9) FEES. The department shall promulgate by rule a graduated
 7 schedule of fees for accredited, ^{and} certified ~~and registered~~ laboratories which are
 8 designed to recover the costs of administering this section.

*8
Insert
6-8-95*

(END)



Insert X

WPO:

93.12 (9) (by Section 1), 299.07 (1) (a) II. (by
 Section 1) and 299.11 (1) (b) (by Section 1),
 (3) (by Section 1), 299.14 (4) (title) and (a) (by Section 1),
 299.14 (4) (c) (by Section 1), 299.16 (5) (title) (by Section 1),
 299.14 (5) (b) and (c), 299.14 (5) (d) (by Section 1), 299.16 (6)
 (by Section 1), 299.14 (7), (8) (title), (a), (b) to (e) (reg),
 (e) and (f) to (h) and 299.14 (9) (by Section 1)
 and the repeal of section 299.11 (1) (g)

of the statutes

EFFECTIVE DATE

1. In the component bar: For the action phrase, execute: ... **create** → **action:** → *NS: → **effdate**
For the text, execute: **create** → **text:** → *NS: → **effdateA**
2. Nonstatutory subunits are numbered automatically if "(#1)", "(#2)", etc., is filled in. Below, fill in "____" or "()" only if a "frozen" number is needed.

SECTION # _____ . Effective date.

(#1) () This act takes effect on

1. In the component bar: For the action phrase, execute: . . **create** → **action:** → *NS: → **effdateE**
For the text, execute: **create** → **text:** → *NS: → **effdate**
2. Nonstatutory subunits are numbered automatically if "(#1)", "(#2)", etc., is filled in. Below, fill in "____" or "()" only if a "frozen" number is needed.

SECTION # d_____ . Effective

es

..... This act takes effect on the day after publication, except as follows:

(#1) *mm* The treatment of sections *Insert X* of the statutes take effect on *July 1, 2001*

1. In the component bar: For the budget action phrase, execute:..**create** → **action:** → *NS: → **94XX**
For the text, execute: **create** → **text:** → *NS: → **effdate**
2. Nonstatutory subunits are numbered automatically if "(#1)", "(#2)", etc., is filled in. Below, for the budget, fill in the **9400** department code; and fill in "()" only if a "frozen" number is needed.

SECTION 94_____ . Effective dates;

(#1) () The treatment of sections of the statutes takes effect on



- 42861/dn
RET: Kmg

X Note

This is a draft of DNR's proposal concerning laboratory accreditation and certification. DNR proposes to replace the current certification requirements with accreditation requirements and to modify the current registration requirements and rename "registration" to be "certification". It will take some time ^{for} ~~before~~ DNR ^{to become} ~~is~~ authorized to grant accreditation and for laboratories ^{that} ~~who~~ are now certified to become accredited. Therefore, this draft authorizes the accreditation process to begin now, but doesn't eliminate the current certification provisions until July 1, 2001. ^(The date suggested by Alfredo Sotomayor of DNR) This results in a complex draft (many provisions are amended upon enactment and then amended again

on July 1, 2001), but it allows for an orderly transition to the ~~new~~ revised program. Note, however, that ^{(c)✓} if DNR ~~is~~^{is} not approved as an accrediting authority in time, ✓ the statute will have to be amended again.

This draft should be reviewed by DNR personnel in the laboratory certification program.

Please contact me with any questions or redraft instructions.

RLT

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRB-4286/1dn
RCT:kmg:jf

February 3, 2000

This is a draft of DNR's proposal concerning laboratory accreditation and certification. DNR proposes to replace the current certification requirements with accreditation requirements and to modify the current registration requirements and rename "registration" to be "certification". It will take some time for DNR to become authorized to grant accreditation and for laboratories that are now certified to become accredited. Therefore, this draft authorizes the accreditation process to begin now, but doesn't eliminate the current certification provisions until July 1, 2001 (the date suggested by **Alfredo Sotomayor** of DNR). This results in a complex draft (many provisions are amended upon enactment and then amended again on July 1, 2001), but it allows for an orderly transition to the revised program. Note, however, that, if DNR is not approved as an accrediting authority in time, the statutes will have to be amended again.

This draft should be reviewed by DNR personnel in the laboratory certification program.

Please contact me with any questions or redraft instructions.

Rebecca C. Tradewell
Managing Attorney
Phone: (608) 266-7290
E-mail: Becky.Tradewell@legis.state.wi.us



State of Wisconsin
1999 - 2000 LEGISLATURE

LRB-4286/2

RCT:kmg:jf

rmy

10m.

1999 BILL

DNote

regenerate

1 AN ACT *to repeal* 299.11 (1) (g), 299.11 (5) (b) and (c) and 299.11 (7); *to renumber*
2 299.11 (1) (a); *to amend* 15.107 (12) (title) and (a), 93.12(5), 93.12(9), 93.12(9),
3 97.34 (2) (c), 281.75 (6) (a), 299.07 (1) (a) ll., 299.07 (1) (a) ll., 299.11 (title),
4 299.11 (1) (b), 299.11 (1) (b), 299.11 (1) (c), 299.11 (1) (g), 299.11 (2), 299.11 (3),
5 299.11 (3), 299.11 (4) (title) and (a), 299.11 (4) (title) and (a), 299.11 (4) (c), 299.11
6 (4) (c), 299.11 (5) (title), 299.11 (5) (title), 299.11 (5) (d), 299.11 (5) (d), 299.11 (6),
7 299.11 (6), 299.11 (8) (title) and (a), 299.11 (8) (b) to (e), 299.11 (8) (f) to (h),
8 299.11 (9) and 299.11 (9); and *to create* 299.11 (1) (ae), 299.11 (1) (em), 299.11
9 (1) (eq), 299.11 (5) (cm), 299.11 (7m), 299.11 (8) (eg) and 299.11 (8) (er) of the
10 statutes; **relating to:** accreditation, certification and registration of
11 laboratories by the department of natural resources.

Analysis by the Legislative Reference Bureau

Under current law, the department of natural resources (DNR) may specify tests related to programs administered by DNR that must be conducted by laboratories certified or registered by DNR or the department of agriculture, trade and consumer protection (DATCP) or certified or registered by another state or a

BILL

federal agency that recognizes laboratory certification by DNR and that uses standards equivalent to this state's standards.

This bill authorizes DNR to apply to the federal environmental protection agency to be approved to accredit laboratories under a national environmental laboratory accreditation program. If DNR is approved to accredit laboratories under the national program, an accredited laboratory may conduct tests that currently must be conducted by a certified or registered laboratory. If DNR is approved to accredit laboratories under the national program, this state must accept test results from laboratories accredited by other accrediting authorities and other accrediting authorities must accept test results from laboratories accredited by DNR.

On July 1, 2001, this bill eliminates the current certification under DNR's laboratory program and modifies the current requirements for registration, which the bill renames certification. On that date, the bill also eliminates reciprocal recognition of any kind of laboratory approval by another state or by a federal agency other than accreditation under the national environmental laboratory accreditation program. Thus, beginning on July 1, 2001, the laboratory must be accredited by DNR or another accrediting authority under the national program, or certified by DATCP or DNR to conduct tests specified by DNR.

For further information *see* the **state and local** fiscal estimate, which will be printed as an appendix to this bill.

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

SECTION 1. 15.107 (12) (title) and (a) of the statutes are amended to read:

15.107 (12) (title) - ~~ACCREDITATION AND CERTIFICATION~~ STANDARDS
REVIEW COUNCIL. (a) *Creation.* There is created in the department of administration
an accreditation and certification standards review council consisting of 9
members.

SECTION 2. 93.12 (5) of the statutes is amended to read:

93.12 (5) The department shall establish uniform minimum standards to be
used in the evaluation and certification of laboratory examinations. The department
shall submit any rules proposed under this subsection which affect the laboratory
accreditation and certification program under s. 299.11 to the department of natural
resources and to the state laboratory of hygiene for review and comment. These rules

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1 may not take effect unless they are approved by the department of natural resources
2 within 6 months after submission.

3 **SECTION 3.** 93.12 (9) of the statutes is amended to read:

4 93.12 (9) The department shall recognize the ~~accreditation~~, certification or
5 registration of a laboratory by the department of natural resources under s. 299.11
6 and shall accept the results of any test conducted by a laboratory ~~accredited~~, certified
7 or registered to conduct that category of test under that section.

8 **SECTION 4.** 93.12 (9) of the statutes, as affected by 1999 Wisconsin Act (this
9 act), is amended to read:

10 93.12 (9) The department shall recognize the accreditation? ~~or~~ certification ~~or~~
11 ~~registration~~ of a laboratory by the department of natural resources under s. 299.11
12 and shall accept the results of any test conducted by a laboratory accredited? ~~or~~
13 certified ~~or registered~~ to conduct that category of test under that section.

14 **SECTION 5.** 97.34 (2) (c) of the statutes is amended to read:

15 97.34 (2) (c) The department may require testing of bottled drinking water for
16 substances subject to any standard under par. (b) and for any other substance if the
17 department determines that the water system used as the source of the bottled
18 drinking water has a potential of being contaminated, based on contamination of
19 other water systems or groundwater in the vicinity. The department shall adopt by
20 rule requirements for periodic sampling and analysis for the purposes of this
21 subsection. The department shall require all analyses to be conducted by a
22 laboratory ~~accredited or~~ certified under s. 299.11.

23 **SECTION 6.** 281.75 (6) (a) of the statutes is amended to read:

24 281.75 (6) (a) Contamination of a private water supply, as defined under sub.
25 (1) (b) 1. or 2., is required to be established by analysis of at least 2 samples of water,

BILL

1 taken at least 2 weeks apart, in a manner which assures the validity of the test
2 results. The samples shall be tested by a laboratory accredited or certified under s.
3 299.11.

4 SECTION 7. 299.07 (1) (a) 11. of the statutes is amended to read:

5 299.07 (1) (a) 11. A certification, accreditation or registration under s. 299.11.

6 SECTION 8. 299.07 (1) (a) 11. of the statutes, as affected by 1999 Wisconsin Act
7 (this act), is amended to read:

8 299.07 (1) (a) 11. A certification, or accreditation ~~or registration~~ under s.
9 299.11.

10 SECTION 9. 299.11 (title) of the statutes is amended to read:

11 299.11 (title) **Laboratory accreditation and certification program.**

12 SECTION 10. 299.11 (1) (a) of the statutes is renumbered 299.11 (1) (am).

13 SECTION 11. 299.11 (1) (ae) of the statutes is created to read:

14 299.11 (1) (ae) "Accredited" means accredited under sub. (7m) or recognized as
15 accredited under sub. (5).

16 SECTION 12. 299.11 (1) (b) of the statutes is amended to read:

17 299.11 (1) (b) "Certified laboratory" means a ~~laboratory which performs tests~~
18 ~~for hire in connection with a covered program and which receives certification~~
19 certified under sub. (7) or ~~receives recognition~~ recognized as a certified laboratory
20 under sub. (5).

21 SECTION 13. 299.11 (1) (b) of the statutes, as affected by 1999 Wisconsin Act
22 (this act), is amended to read:

23 299.11 (1) (b) "Certified" means certified under sub. ~~(7) or recognized as~~
24 ~~certified under sub. (5)~~ (8).

25 SECTION 14. 299.11 (1) (c) of the statutes is amended to read:

BILL

1 **299.11 (1) (c)** “Council” means the accreditation and certification standards
2 review council created under s. 15.107 (12).

3 **SECTION 15.** 299.11 (1) (em) of the statutes is created to read:

4 299.11 (1) (em) “National Environmental Laboratory Accreditation
5 Conference” means the voluntary association of state and federal officials, sponsored
6 by the federal environmental protection agency, with the purpose of establishing
7 national performance standards for environmental laboratories.

8 **SECTION 16.** 299.11 (1) (eq) of the statutes is created to read:

9 299.11 (1) (eq) “National environmental laboratory accreditation program”
10 means the program of the federal environmental protection agency that oversees the
11 implementation of national performance standards established by the National
12 Environmental Laboratory Accreditation Conference and determines whether to
13 approve state and federal agencies as accrediting authorities for environmental
14 laboratories.

15 **SECTION 17.** 299.11 (1) (g) of the statutes is amended to read:

16 299.11 (1) (g) “Registered ~~laboratory~~” means ~~a laboratory which is~~ registered
17 under sub. (8) or ~~receives recognition~~ recognized as a registered ~~laboratory~~ under
18 sub. (5).

19 **SECTION 18.** 299.11 (1) (g) of the statutes, as affected by 1999 Wisconsin Act
20 (this act), is repealed.

21 **SECTION 19.** 299.11 (2) of the statutes is amended to read:

22 299.11 (2) COORDINATION WITH DEPARTMENT OF AGRICULTURE, TRADE AND
23 CONSUMER PROTECTION. (a) The department shall submit to the department of
24 agriculture, trade and consumer protection and to the state laboratory of hygiene
25 any rules proposed under this section that affect the laboratory ~~certification~~ program

BILL

1 under s. 93.12 (5), for review and comment. These rules may not take effect unless
2 they are approved by the department of agriculture, trade and consumer protection
3 within **6** months after submission.

4 (b) The department shall enter into a memorandum of understanding with the
5 department of agriculture, trade and consumer protection setting forth the
6 responsibilities of each department in administering the laboratory ~~certification~~
7 programs under s. 93.12 (5) and this section. The memorandum of understanding
8 shall include measures to be taken by each department to .avoid duplication of
9 application and compliance procedures ~~for laboratory certification.~~

10 SECTION 20. 299.11 (3) of the statutes is amended to read:

11 299.11 (3) ~~CERTIFICATION~~ ACCREDITATION AND CERTIFICATION STANDARDS REVIEW
12 COUNCIL. The council shall review the laboratory certification ~~and~~, registration and
13 accreditation program and shall make recommendations to the department
14 concerning the specification of test categories, reference sample testing and
15 standards for certification, registration, accreditation, suspension and revocation
16 and other aspects of the program. Recommendations concerning accreditation shall
17 be consistent with the standards established by the National Environmental
18 Laboratory Accreditation Conference.

19 SECTION **21.** 299.11 (3) of the statutes, as affected by 1999 Wisconsin Act
20 (this act), is amended to read:

21 299.11 (3) ACCREDITATION AND CERTIFICATION STANDARDS REVIEW COUNCIL. The
22 council shall review the laboratory certification- and accreditation
23 program and shall make recommendations to the department concerning the
24 specification of test categories, reference sample testing and standards for
25 certification, ~~registration~~, accreditation, suspension and revocation and other

BILL

1 aspects of the program. Recommendations concerning accreditation shall be
2 consistent with the standards established by the National Environmental
3 Laboratory Accreditation Conference.

4 **SECTION 22.** 299.11 (4) (title) and (a) of the statutes are amended to read:

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

13 **SECTION 23.** 299.11 (4) (title) and (a) of the statutes, as affected by 1999
14 Wisconsin Act . . . (this act), are amended to read:

15 299.11 (4) (title) **DEPARTMENT MAY REQUIRE ACCREDITATION; OR CERTIFICATION ~~OR~~**
16 **REGISTRATION.** (a) *Applicability.* Except as provided in subs. (5) and (6), if results from
17 a test in a specified test category in a covered program are required to be submitted
18 to the department, the department may require by rule that the test be conducted
19 by a laboratory which is accredited, or certified ~~or registered~~ to conduct tests in that
20 specified category. The department may require that tests be conducted by an
21 accredited ~~or certified~~ laboratory if the requirements for registration certification do
22 not meet the requirements of an applicable federal law.

23 **SECTION 24.** 299.11 (4) (c) of the statutes is amended to read:

24 299.11 (4) (c) *Delayed effective date.* A rule identifying specified test categories
25 for which tests are required to be conducted by a an accredited, certified or registered

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1 laboratory may not take effect until at least 120 days after publication. The
2 department may not require a person to resubmit results of tests which were not
3 required to be conducted by ~~a~~ an accredited, certified or registered laboratory at the
4 time of the original submission merely because of that fact.

5 **SECTION 25.** 299.11 (4) (c) of the statutes, as affected by 1999 Wisconsin Act
6 (this act), is amended to read:

7 299.11 (4) (c) *Delayed effective date.* A rule identifying specified test categories
8 for which tests are required to be conducted by an accredited, or certified ~~or~~
9 ~~registered~~ laboratory may not take effect until at least 120 days after publication.
10 The department may not require a person to resubmit results of tests which were not
11 required to be conducted by an accredited, or certified ~~or registered~~ laboratory at the
12 time of the original submission merely because of that fact.

13 **SECTION 26.** 299.11 (5) (title) of the statutes is amended to read:

14 299.11 (5) (title) RECOGNITION OF OTHER ACCREDITATION, CERTIFICATION OR
15 REGISTRATION.

16 **SECTION 27.** 299.11 (5) (title) of the statutes, as affected by 1999 Wisconsin Act
17 (this act), is amended to read:

18 299.11 (5) (title) RECOGNITION OF OTHER ACCREDITATION -
19 - .

20 **SECTION 28.** 299.11 (5) (b) and (c) of the statutes are repealed.

21 **SECTION 29.** 299.11 (5) (cm) of the statutes is created to read:

22 299.11 (5) (cm) *Reciprocity for national accreditation.* If the department is
23 approved as an accrediting authority under sub. (7m) (a) and another accrediting
24 authority under the national environmental laboratory accreditation program
25 recognizes accreditation by the department under sub. (7m), the department shall

BILL

1 recognize a laboratory as accredited to conduct tests in any test category for which
2 the laboratory is accredited by that other accrediting authority.

3 **SECTION 30.** 299.11 (5) (d) of the statutes is amended to read:

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

9 **SECTION 31.** 299.11 (5) (d) of the statutes, as affected by 1999 Wisconsin Act
10 (this act), is amended to read:

11 299.11 (5) (d) ***Discretionary acceptance.*** The department may accept the
12 results of a test in a specified test category even though the test was not conducted
13 by an accredited? or certified ~~or registered~~ laboratory. The department may charge
14 an extra fee if it is necessary to verify the results of a test submitted under this
15 paragraph.

16 **SECTION 32.** 299.11 (6) of the statutes is amended to read:

17 299.11 (6) **NOT APPLICABLE TO OTHER PROGRAMS.** No laboratory is required to be
18 accredited, registered or certified under this section for any purpose other than the
19 submission of results under a covered program.

20 **SECTION 33.** 299.11 (6) of the statutes, as affected by 1999 Wisconsin Act
21 (this act), is amended to read:

22 299.11 (6) **NOT APPLICABLE TO OTHER PROGRAMS .** No laboratory is required to be
23 accredited, ~~registered~~ or certified under this section for any purpose other than the
24 submission of results under a covered program.

25 **SECTION 34.** 299.11 (7) of the statutes is repealed.

BILL

1 SECTION 35. 299.11 (7m) of the statutes is created to read:

2 299.11 (7m) ACCREDITATION. (a) *Accrediting authority.* The department may
3 apply to be approved as an accrediting authority under the national environmental
4 laboratory accreditation program.

5 (am) *Criteria.* If the department is approved as an accrediting authority under
6 par. (a), the department shall, after considering recommendations by the council,
7 promulgate rules establishing uniform minimum criteria, as provided in this
8 subsection, to be used to evaluate laboratories for accreditation. The criteria shall
9 be consistent with nationally recognized criteria to the maximum extent possible.

10 (b) *Methodology.* 1. The department shall prescribe by rule the accepted
11 methodology to be followed in conducting tests in each test category. The department
12 may prescribe by rule accepted sampling protocols and documentation procedures
13 for a specified test category to be followed by the person collecting the samples. The
14 department may prescribe this methodology by reference to standards established
15 by technical societies and organizations as authorized under s. 227.21 (2). The
16 department shall attempt to prescribe this methodology so that it is consistent with
17 any methodology requirements under the Resource Conservation and Recovery Act,
18 as defined under s. 289.01 (30), the federal Water Pollution Control Act, as amended,
19 33 USC 1251 to 1387, the Safe Drinking Water Act, 42 USC 300f to 300j-26, or the
20 Toxic Substance Control Act, 15 USC 2601 to 2692.

21 2. The department may permit the use of a revised methodology consistent with
22 new or revised editions or standards established by technical societies and
23 organizations on a case-by-case basis.

24 3. a. The department may permit the use of an alternative methodology on a
25 case-by-case basis if the laboratory seeking to use that methodology submits data

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1 establishing the accuracy and precision of the alternative methodology and if the
2 accuracy and precision obtained through the use of the alternative methodology
3 equals or exceeds that obtained through use of the accepted methodology.

4 b. A laboratory seeking to use an alternative methodology may request
5 confidential treatment of any data or information submitted to the department
6 under this paragraph. The department shall grant confidential status for any data
7 or information relating to unique methods or processes if the disclosure of those
8 methods or processes would tend to adversely affect the competitive position of the
9 laboratory.

10 4. The department may waive any procedure prescribed in the accepted
11 methodology on a case-by-case basis if the laboratory seeking this waiver
12 establishes sufficient reasons for the waiver and that the waiver does not adversely
13 affect the purpose for which the test is conducted.

14 (c) **Proficiency testing sample.** The department may prescribe by rule criteria
15 for determining the accuracy of tests by accredited laboratories on proficiency testing
16 samples. The department shall publish lists of approved providers of proficiency
17 testing samples for tests that are to be regularly and routinely performed by
18 accredited laboratories.

19 (d) **Quality control.** The department shall establish by rule minimum
20 requirements for a quality control program that ensures that a laboratory complies
21 with criteria for the accuracy and precision of tests and that specifies procedures to
22 be followed if these criteria are not met. A laboratory shall conduct self-audits and
23 shall establish a quality control program that is consistent with criteria specified by
24 rule by the department based on the standards of the national environmental

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1 laboratory accreditation conference. The department may accept a quality control
2 program based on federal requirements for similar test categories.

3 (e) *Records.* If a particular time period is not otherwise specified by law, the
4 department may prescribe by rule the length of time that laboratory analysis records
5 and quality control data specified in the laboratory's quality control program are to
6 be retained by the laboratory.

7 (f) *Criteria for accreditation.* The department shall specify by rule the criteria
8 and standards to be met by applicants for accreditation.

9 (g) *Issuance of accreditation.* The department shall issue an accreditation to
10 a laboratory for a specified test if the laboratory meets all of the following conditions:

11 1. The laboratory submits an application, on a form provided by the
12 department, requesting accreditation for a specified test.

13 2. The laboratory specifies a methodology prescribed or permitted under par.
14 (b) that it intends to utilize in conducting the test.

15 3. If the department requires a proficiency testing sample, the laboratory
16 conducts a test on the sample and obtains results that comply with the minimum
17 acceptance criteria for the specified test.

18 4. The laboratory has or agrees to implement a quality control program that
19 meets minimum requirements under par. (d) for the specified test and that is to
20 commence no later than the date of accreditation.

21 5. The laboratory allows a representative of the department to perform an
22 on-site assessment to evaluate compliance with the standards of the national
23 ~~environmental laboratory accreditation conference~~ and resolves any deviations from ^{criteria established under par. (a.m.) (am)}
24 those ~~standards~~ ^{criteria} that are identified during the assessment.

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1 (g) *Interim accreditation.* The department may grant interim accreditation
2 to a laboratory that meets the conditions in par. (g) 1. to 4.

3 (h) *Accreditation period.* Accreditation of a laboratory shall be renewed
4 annually. Accreditation is valid from the date of issuance until it expires, is revoked
5 or is suspended.

6 (hm) *Interim accreditation period.* Interim accreditation expires one year after
7 the date on which the laboratory meets all of the conditions specified in par. (g).
8 Interim accreditation is valid until it expires, is revoked, is suspended or is
9 superseded by accreditation after compliance with par. (h) 5.

10 (i) *Suspension and revocation.* After considering recommendations from the
11 council, the department shall establish by rule criteria and procedures for the review
12 and evaluation of the accreditation of laboratories and the suspension or revocation
13 of accreditation. If, after opportunity for a contested case hearing, the department
14 finds that an accredited laboratory has falsified results or has materially and
15 consistently failed to comply with the criteria and procedures provided under par. (d),
16 the department may suspend or revoke the accreditation of the laboratory. A person
17 whose accreditation is suspended or revoked may reapply for accreditation upon a
18 showing that the person meets the applicable criteria for accreditation and has
19 corrected the deficiencies that led to the suspension or revocation.

20 **SECTION 36.** 299.11 (8) (title) and (a) of the statutes are amended to read:

21 299.11 (8) (title) ~~REGISTRATION~~ CERTIFICATION PROCEDURE. (a) *Criteria.* ~~Upon~~
22 ~~application, the~~ After considering recommendations by the council, the department
23 shall promulgate rules establishing uniform minimum criteria. as provided in this
24 subsection. to be used to evaluate laboratories for certification. The department
25 shall ~~register~~ ^{certify} a laboratory if the laboratory complies with the requirements of this

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1 subsection, if the laboratory does not perform tests commercially for hire, if the
2 laboratory performs tests solely in connection with ch. 283 and if one of the following
3 applies:

4 1. The laboratory performs tests solely on its own behalf or on behalf of a
5 subsidiary or other corporation under common ownership or control; ~~or,~~

6 2. The laboratory is owned or controlled by a municipality or 2 or more
7 municipalities and performs tests solely on behalf of ~~the municipality or~~
8 municipalities in test categories specified by the department by rule.

9 **SECTION 37.** 299.11 (8) (b) to (e) of the statutes are amended to read:

10 299.11 (8) (b) to (e) *Methodology.* Testing by a ~~registered~~ certified laboratory
11 conducted in connection with a covered program shall be carried out in accordance
12 with sub. ~~(7)~~ (7m) (b).

13 (c) *Reference sample testing.* The department may require by rule reference
14 sample tests test results, that comply with minimum criteria for accuracy for a test,
15 upon application and annually thereafter. If results from these tests do not meet
16 minimum criteria established by rule, the department may require additional
17 reference sample testing. ~~If the laboratory participates in a split sampling~~
18 ~~program with the federal environmental protection agency, or otherwise obtains~~
19 ~~independent reference samples, the department may accept those results instead of~~
20 ~~its own reference samples~~ The department shall publish lists of approved providers
21 o_____f
22 certified laboratories.

23 (d) *Quality control.* The laboratory shall conduct self-audits and shall
24 establish a quality control program consistent with criteria specified by rule by the
25 department and based on methods and standards prescribed by rule and considering

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1 criteria used by the federal environmental protection agency, the American Society
2 for Testing and Materials - air and ~~stream improvement~~, the
3 ~~national academy of sciences~~ or any other equivalent agency or organization
4 recognized by the department.

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

9 ~~SECTION 38. 299.11 (8) (eg) of the statutes is created to read:~~
10 ~~299.11 (8) (eg) Criteria for certification. The department shall specify by rule~~
11 ~~the criteria and standards to be met by applicants for certification.~~

12 **SECTION 39.** 299.11 (8) (er) of the statutes is created to read:

13 299.11 (8) (er) *Issuance of certification.* The department shall issue a
14 certification to a laboratory for a specified test category if the laboratory meets all
15 of the following conditions:

16 1. The laboratory submits an application, on a form provided by the
17 department, requesting certification in a specified test category.

18 2. The laboratory specifies a methodology prescribed or permitted under par.
19 (b) that it intends to utilize in conducting tests in the specified test category.

20 3. If the department requires a reference sample test result, the laboratory
21 conducts a test on an approved reference sample and obtains results that comply
22 with the minimum criteria for accuracy for the specified test category.

23 4. The laboratory has or agrees to implement a quality control program that
24 meets minimum requirements under par. (d) for the specified test category and that
25 is to commence no later than the date of certification.

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1 5. The laboratory allows a representative of the department to perform an
2 on-site evaluation to determine compliance with the criteria ~~and standards~~
3 par. ~~(d)~~^a and resolves any deviations from those criteria and standards that are ✓
4 identified during the evaluation, except that the department may waive this
5 condition if a laboratory has previously had a successful on-site evaluation for
6 similar tests or test categories.

7 **SECTION 40.** 299.11 (8) (f) to (h) of the statutes are amended to read:

8 299.11 (8) (f) ~~Registration~~ Certification. ~~Registration~~ Registration Certification of
9 laboratories shall be renewed annually. A ~~registration certification~~ is valid from the
10 date of issuance until it expires, is revoked or is suspended.

11 (g) ~~Suspension or revocation of registration certification~~. Suspension or revocation of registration certification. If, after opportunity
12 for a contested case hearing, the department finds that a ~~registered certified~~
13 laboratory has falsified results or has materially and consistently failed to comply
14 with the self-audit procedures and quality control programs provided ~~in~~ under par.
15 (d), it may suspend or revoke the ~~registration certification~~ of the laboratory. A person
16 whose ~~registration certification~~ is suspended or revoked may reapply for ~~registration~~
17 certification upon a showing that the person meets the applicable criteria for
18 ~~registration certification~~ and has corrected the deficiencies that led to the suspension
19 or revocation.

20 (h) ~~Certification Accreditation option~~. Certification Accreditation option. A laboratory ~~which~~ that is otherwise
21 eligible to seek ~~registration certification~~ may elect to apply for ~~certification~~
22 accreditation under sub. ~~(7)~~ (7m).

23 **SECTION 41.** 299.11 (9) of the statutes is amended to read:

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This ^{re}draft makes minor changes requested by
Alfredo Sotomayor and Joe Renville of DNR.

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**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

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This redraft makes minor changes requested by Alfredo Sotomayor and Joe Renville of DNR.

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