February 17, 2000 – Introduced by Representatives Kedzie, Duff, Musser, Stone, Olsen, Albers, Pettis, Kestell, Spillner, Gunderson, Kreuser and Hutchison, cosponsored by Senators Darling and Farrow. Referred to Committee on Environment.

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

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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

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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) Certification Accreditation and certification standards review council. (a) *Creation*. There is created in the department of administration a <u>an accreditation and</u> 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

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

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

93.12 **(9)** The department shall recognize the <u>accreditation</u>, 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 <u>accredited</u>, certified or registered to conduct that category of test under that section.

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

93.12 **(9)** The department shall recognize the accreditation, or 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.

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

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 accredited or certified under s. 299.11.

Section 6. 281.75 (6) (a) of the statutes is amended to read:

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,

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certified under sub. (5) (8).

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: 299.11 (title) Laboratory accreditation and certification program. 11 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 <u>certified</u> under sub. (7) or <u>receives recognition recognized</u> as a certified <u>laboratory</u> 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

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

1	299.11 (1) (c) "Council" means the <u>accreditation and</u> 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

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 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.

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

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

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

299.11 (3) Accreditation and certification standards review council. The council shall review the laboratory certification, registration and accreditation program and shall make recommendations to the department concerning the specification of test categories, reference sample testing and standards for certification, registration, accreditation, suspension and revocation and other

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

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

299.11 (4) (title) Department may require <u>accreditation</u>, certification or registration. (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 <u>accredited</u>, certified or registered to conduct tests in that specified category. The department may require that tests be conducted by a <u>an accredited</u> or certified laboratory if the requirements for registration do not meet the requirements of an applicable federal law.

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

299.11 (4) (title) Department May require accreditation, or certification or registration. (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 or certified laboratory if the requirements for registration certification do not meet the requirements of an applicable federal law.

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

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

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 <u>an accredited</u> , 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, \underline{or} certified \underline{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 <u>accreditation</u> , 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, certification or
19	REGISTRATION.
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

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 <u>an accredited</u> , 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.

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

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

- (am) *Criteria*. If the department is approved as an accrediting authority under par. (a), the department shall, after considering recommendations by the council, promulgate rules establishing uniform minimum criteria, as provided in this subsection, to be used to evaluate laboratories for accreditation. The criteria shall be consistent with nationally recognized criteria to the maximum extent possible.
- (b) *Methodology*. 1. 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 1387, the Safe Drinking Water Act, 42 USC 300f to 300j–26, or the Toxic Substance Control Act, 15 USC 2601 to 2692.
- 2. 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. 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.
- 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. 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) *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 providers of proficiency testing samples for tests that are to be regularly and routinely performed by accredited laboratories.
- (d) *Quality control.* The department shall establish by rule minimum requirements for a quality control program that ensures that a laboratory complies with criteria for the accuracy and precision of tests and that specifies procedures to be followed if these criteria are not met. 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

- laboratory accreditation conference. The department may accept a quality control program based on federal requirements for similar test categories.
- (e) *Records.* If a particular time period is not otherwise specified by law, the department may prescribe by rule the length of time that laboratory analysis records and quality control data specified in the laboratory's quality control program are to be retained by the laboratory.
- (f) *Issuance of accreditation.* The department shall issue an accreditation to a laboratory for a specified test if the laboratory meets all of the following conditions:
- 1. The laboratory submits an application, on a form provided by the department, requesting accreditation for a specified test.
- 2. The laboratory specifies a methodology prescribed or permitted under par.(b) that it intends to utilize in conducting the test.
- 3. If the department requires a proficiency testing sample, the laboratory conducts a test on the sample and obtains results that comply with the minimum acceptance criteria for the specified test.
- 4. The laboratory has or agrees to implement a quality control program that meets minimum requirements under par. (d) for the specified test and that is to commence no later than the date of accreditation.
- 5. The laboratory allows a representative of the department to perform an on–site assessment to evaluate compliance with the criteria established under par. (am) and resolves any deviations from those criteria that are identified during the assessment.
- (g) *Interim accreditation.* The department may grant interim accreditation to a laboratory that meets the conditions in par. (f) 1. to 4.

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

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

(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 accreditation. 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), the department may suspend or revoke the accreditation of the laboratory. A person whose accreditation is suspended or revoked may reapply for accreditation upon a showing that the person meets the applicable criteria for accreditation and has corrected the deficiencies that led to the suspension or revocation.

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

299.11 **(8)** (title) Registration Certification procedure. (a) Criteria. Upon application, the After considering recommendations by the council, the department shall promulgate rules establishing uniform minimum criteria, as provided in this subsection, to be used to evaluate laboratories for certification. The 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 tests solely in connection with ch. 283 and if one of the following applies:
 - 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.
 - **SECTION 37.** 299.11 (8) (b) to (e) of the statutes are amended to read:
 - 299.11 **(8)** (b) to (e) *Methodology.* Testing by a registered certified laboratory conducted in connection with a covered program shall be carried out in accordance with sub. (7) (7m) (b).
 - (c) Reference sample testing. The department may require by rule reference sample tests test results, that comply with minimum criteria for accuracy for a 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. 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.
 - (d) *Quality control.* The laboratory shall conduct self–audits and <u>shall</u> <u>establish</u> 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.
- (e) *Records.* Where If a particular time period is not otherwise specified by law, the department may prescribe by rule for each test category the length of time that laboratory analysis records and quality control data specified in the laboratory's quality control program are to be retained by the laboratory.
- **SECTION 38.** 299.11 (8) (er) of the statutes is created to read:
- 299.11 **(8)** (er) *Issuance of certification.* The department shall issue a certification to a laboratory for a specified test category if the laboratory meets all of the following conditions:
- 1. The laboratory submits an application, on a form provided by the department, requesting certification in a specified test category.
 - 2. 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. If the department requires a reference sample test result, the laboratory conducts a test on an approved reference sample and obtains results that comply with the minimum criteria for accuracy for the specified test category.
 - 4. The laboratory has or agrees to implement a quality control program that meets minimum requirements under par. (d) for the specified test category and that is to commence no later than the date of certification.
 - 5. The laboratory allows a representative of the department to perform an on–site evaluation to determine compliance with the criteria under par. (a) and resolves any deviations from those criteria and standards that are identified during

(this act), is amended to read:

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 39. 299.11 (8) (f) to (h) of the statutes are amended to read:
299.11 (8) (f) Registration Certification period. Registration Certification of
laboratories shall be renewed annually. A registration certification is valid from the
date of issuance until it expires, is revoked or <u>is</u> suspended.
(g) Suspension or revocation of registration certification. 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 in <u>under</u> 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.
(h) Certification Accreditation option. A laboratory which that is otherwise
eligible to seek registration certification may elect to apply for certification
<u>accreditation</u> under sub. (7) (7m).
SECTION 40. 299.11 (9) of the statutes is amended to read:
299.11 (9) FEES. The department shall promulgate by rule a graduated
schedule of fees for <u>accredited</u> , certified and registered laboratories which are
designed to recover the costs of administering this section.
SECTION 41. 299.11 (9) of the statutes, as affected by 1999 Wisconsin Act

299.11 (9) FEES. The department shall promulgate by rule a graduated
schedule of fees for accredited, and certified and registered laboratories which are
designed to recover the costs of administering this section.
Section 42. Effective dates. This act takes effect on the day after publication
except as follows:
(1) The treatment of sections 93.12 (9) (by Section 4), 299.07 (1) (a) 11. (by
SECTION 8) and 299.11 (1) (b) (by SECTION 13), (3) (by SECTION 21), (4) (title) (by
SECTION 23), (a) (by SECTION 23) and (c) (by SECTION 25), (5) (title) (by SECTION 27), (b)
(c) and (d) (by Section 31), (6) (by Section 33), (7), (8) (title), (a), (b) to (e), (er) and
(f) to (h) and (9) (by Section 41) of the statutes and the repeal of section 299.11 (1)
(g) of the statutes take effect on July 1, 2001.

(END)