

SENATE BILL No. 1135

March 30, 2004, Introduced by Senator GARCIA and referred to the Committee on Natural Resources and Environmental Affairs.

A bill to amend 1994 PA 451, entitled
"Natural resources and environmental protection act,"
(MCL 324.101 to 324.90106) by adding part 205.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 PART 205 V. HARRY ADROUNIE LABORATORY ACCREDITATION ACT

2 Sec. 20501. As used in this part:

3 (a) "Accreditation" means the process by which the department
4 recognizes a laboratory as meeting certain predetermined
5 qualifications or standards under this part.

6 (b) "Accredited laboratory" or "accredited" means or refers
7 to a laboratory that is in compliance with the accreditation
8 requirements of this part.

9 (c) "Analyst" means the designated individual who performs
10 the hands-on analytical methods and associated techniques and who
11 is the one responsible for applying required laboratory practices

1 and other pertinent quality controls to meet the required level
2 of quality.

3 (d) "Analyte" means the substance or physical property
4 contained in a sample for which analysis is performed.

5 (e) "Analytical data" means the qualitative or quantitative
6 measurements reported to a state or federal agency as the result
7 of chemical, physical, biological, microbiological, radiological,
8 or other scientific determination.

9 (f) "Assessment" means a systematic evaluation to determine
10 conformance to quantitative and qualitative specifications of
11 some operational function or activity.

12 (g) "Assessor" means an individual who performs on-site
13 audits to determine the capability and capacity of accrediting
14 authorities and laboratories to meet the department's
15 accreditation standards, by examining the records and other
16 physical evidence for each of the analytical methods for which
17 accreditation has been requested.

18 (h) "Calibration" means a set of operations that establish,
19 under specified conditions, the relationship between values of
20 quantities indicated by a measuring instrument or measuring
21 system, or values represented by a material measure or a
22 reference material, and the corresponding values realized by
23 standards established as follows:

24 (i) In calibration of support equipment, through the use of
25 reference standards that are traceable to the international
26 system of units.

27 (ii) In calibration according to analytical methods,

1 typically through the use of reference materials that are either
2 purchased by the laboratory with a certificate of analysis or
3 purity, or prepared by the laboratory using support equipment
4 that has been calibrated or verified to meet specifications.

5 (i) "Corrective action" means the action taken to eliminate
6 the causes of an existing nonconformity, defect, or other
7 undesirable situation in order to prevent recurrence.

8 (j) "Department" means the department of environmental
9 quality.

10 (k) "Director of the department" means the director of the
11 department or his or her designee.

12 (l) "Fund" means the laboratory accreditation fund.

13 (m) "Laboratory" means a body that engages in calibration or
14 testing, or both.

15 (n) "Laboratory director" means the individual employed by a
16 laboratory who has ultimate responsibility for laboratory
17 operations, including but not limited to quality control, result
18 reporting, and personnel control. Except as used in section
19 20506(1), laboratory director includes a qualified designee of
20 the laboratory director.

21 (o) "NELAC" means the national environmental laboratory
22 accreditation conference, a voluntary organization of state and
23 federal environmental officials and interest groups, whose
24 primary purpose is to establish mutually acceptable standards for
25 accrediting environmental laboratories.

26 (p) "On-site assessment contractor" means a person under
27 contract to the department for the purpose of performing on-site

1 assessments of laboratories to evaluate compliance with this
2 part.

3 (q) "Parameter" means a single determination or group of
4 related determinations using a specific written method.

5 (r) "PT" means proficiency testing, a means of evaluating a
6 laboratory's performance under controlled conditions relative to
7 a given set of criteria through analysis of unknown samples
8 provided by an external source.

9 (s) "PT program" means the aggregate of providing rigorously
10 controlled and standardized environmental samples to a laboratory
11 for analysis, reporting of results, statistical evaluation of the
12 results, and the collective demographics and results summary of
13 all participating laboratories.

14 (t) "PT sample" means a sample, the composition of which is
15 unknown to the analyst and is provided to test whether the
16 analyst and laboratory can produce analytical results within
17 specified acceptance criteria.

18 (u) "Quality assurance" means an integrated system of
19 activities involving planning, quality control, quality
20 assessment, reporting, and quality improvement to ensure that a
21 product or service meets defined standards of quality with a
22 stated level of confidence.

23 (v) "Quality control" means the overall system of technical
24 activities whose purpose is to measure and control the quality of
25 analytical services so that it meets the needs of users.

26 (w) "Quality system" means a structured and documented
27 management system describing the policies, objectives,

1 principles, organizational authority, responsibilities,
2 accountability, and implementation plan of an organization for
3 ensuring quality in its work processes, products (items), and
4 services. The quality system provides the framework for
5 planning, implementing, and assessing work performed by the
6 organization and for carrying out required quality assurance and
7 quality control.

8 (x) "Sample" means a field or laboratory collected sample and
9 any portion of this sample in the analytical process including a
10 subsample, aliquot, extract, or digestate.

11 (y) "Testing" means a technical operation that consists of
12 the determination of 1 or more characteristics of or the
13 performance of a given product, material, equipment, organism,
14 physical phenomenon, process, or service according to a specified
15 procedure. The result of a test is normally recorded in a
16 document sometimes called a laboratory report or a certificate of
17 analysis.

18 Sec. 20502. (1) Beginning 5 years after the effective date
19 of this part, a person shall not submit to the department
20 analytical data required under this act for environmental
21 regulatory monitoring or compliance purposes unless the
22 analytical data were produced or developed by a laboratory
23 accredited by the department under this part for the categories,
24 parameters, analytes, or methods for which the analytical data
25 are submitted. The department shall begin accepting applications
26 for accreditation within 2 years after the effective date of this
27 part.

1 (2) A department laboratory shall obtain accreditation from
2 an accrediting authority, other than the department, whose
3 accreditation standards are equivalent to or exceed the
4 accreditation standards under this part.

5 (3) This part does not prohibit other state certification,
6 accreditation, licensing, or registration programs established
7 before the effective date of this part.

8 Sec. 20503. (1) The department shall charge accreditation
9 and assessment fees as provided in section 20508 to implement
10 this part. The fees shall be used to fund all costs associated
11 with the department's administration and operation of this
12 program. The department may contract with an approved third
13 party assessor to conduct the on-site assessments. The fees for
14 this service shall be paid to the state and released to the
15 contractor upon approval of completion of the work.

16 (2) Denial of accreditation is governed by section 20511.

17 (3) Accreditation shall remain in effect for 1 year, unless
18 revoked by the department or unless discontinued by action of the
19 accredited laboratory.

20 (4) The director of the department shall issue a certificate
21 of accreditation to a laboratory that complies with the
22 accreditation requirements under this part. The certificate
23 shall include the name of the laboratory and the accreditation
24 expiration date and shall include or shall have appended a list
25 of the categories, parameters, analytes, or methods for which the
26 laboratory is accredited. The certificate is the property of the
27 department and shall be returned to the department upon request.

1 (5) The most current certificate and the most current list of
2 categories, parameters, analytes, or methods for which the
3 laboratory is accredited shall be posted conspicuously in the
4 laboratory and a copy shall be made available by the accredited
5 laboratory, upon request, to any party utilizing or requesting
6 the services of the laboratory.

7 Sec. 20504. (1) Accreditation within categories,
8 parameters, analytes, or methods shall be renewed annually. To
9 be eligible for renewal of accreditation, the accredited
10 laboratory shall remain in compliance with the requirements of
11 this part.

12 (2) An accredited laboratory may augment the categories,
13 parameters, analytes, or methods for which it seeks accreditation
14 during annual renewal of accreditation.

15 (3) At times other than during annual renewal of
16 accreditation, an accredited laboratory may augment the
17 categories, parameters, analytes, or methods for which it is
18 accredited by making a separate application to the department,
19 including payment of any applicable fees.

20 Enacting section 1. This amendatory act does not take
21 effect unless all of the following bills of the 92nd Legislature
22 are enacted into law:

23 (a) Senate Bill No. 1134.

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25 (b) Senate Bill No. 1136.

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27 (c) Senate Bill No. 1133.