



SENATE BILL No. 947

December 8, 1993, Introduced by Senators Ehlers and Hoffman and referred to the Committee on Natural Resources and Environmental Affairs

A bill to certify and regulate certain environmental laboratories to prescribe the powers and duties of certain state agencies and officials to prescribe fees and to provide remedies

THE PEOPLE OF THE STATE OF MICHIGAN ENACT

1 Sec 1 As used in this act

2 (a) "Accreditation" or "accredited" means the recognition by
3 the department a nongovernmental agency approved by the depart-
4 ment, or a governmental agency other than this state, of the
5 ability of a laboratory to perform analyses of environmental sam-
6 ples with accuracy and precision as required by this act

7 (b) "Analyte" means the known substance or physical property
8 contained in a sample for which analysis is performed

9 (c) "Analytical data" means the qualitative or quantitative
10 measures reported to a state or federal agency as the result of

1 chemical, physical, biological, microbiological, radiological, or
2 other scientific determination

3 (d) "Certification" or "certified" means the official recog-
4 nition by the department of a laboratory's ability to perform
5 analysis of environmental samples covered by this act, based on
6 the department's determination that a laboratory meets the
7 requirements of this act to perform the analysis with accuracy
8 and precision

9 (e) "Department" means the department of public health

10 (f) "Director" means the director of the department or the
11 director's designee

12 (g) "Environmental laboratory" or "laboratory" means a labo-
13 ratory that analyzes samples for compliance with any environmen-
14 tal regulatory statute, rule, or regulation, including, but not
15 limited to, surface waters, groundwaters, soils, sediments, air,
16 industrial waste, municipal waste, hazardous waste, solid waste,
17 and drinking water samples Environmental laboratory or labora-
18 tory includes a mobile laboratory brought to the central labora-
19 tory site

20 (h) "Environmental sample" includes, but is not limited to,
21 samples such as surface water, groundwater, soil, sediment, air,
22 industrial waste, municipal waste, hazardous waste, solid waste,
23 and drinking water

24 (i) "Laboratory director" means the individual employed by
25 an environmental laboratory who has ultimate responsibility for
26 laboratory operations, including, but not limited to, quality
27 control, result reporting, personnel control, and signature

1 authority for the application for certification under section 3,
2 and who is required to sign the validation statement under sec-
3 tion 16

4 (j) "Mandatory analytical method" means a recognized written
5 procedure for acquiring analytical data that is required by law
6 or by a regulatory agency of the federal or state government

7 (k) "Matrix" means the substance in which or from which a
8 material is to be analyzed

9 (l) "Parameter" means a single determination or group of
10 related determinations using a specific written method selected
11 by a laboratory applying for accreditation

12 (m) "Performance audit" means analysis of performance evalu-
13 ation samples or quality control samples, or both, provided to a
14 laboratory by the department or another source approved by the
15 department

16 (n) "Performance evaluation samples" means analytes in known
17 concentrations, unknown to the laboratory, that are provided to a
18 laboratory by the department, or another source approved by the
19 department for analysis to determine if the laboratory can sat-
20 isfactorily perform specific analyses

21 (o) "Person" means an individual, partnership corporation,
22 association, governmental entity or other legal entity

23 (p) "Quality assurance" means activities designed to meet or
24 exceed a uniform minimum standard of quality control that is
25 determined by the department to be effective

26 (q) "Quality assurance manual" means a written record of the
27 policies, organization, objectives, and specific quality control

1 and quality assurance activities established by a laboratory in
2 accordance with the requirements of the department for use in a
3 laboratory to assure the accuracy of the analytical results
4 obtained by the laboratory

5 (r) "Quality control" means those activities designed to
6 assure that analytical data produced by a laboratory meet objec-
7 tives for accuracy, including, but not limited to, routine appli-
8 cation of statistically based procedures to evaluate and control
9 the accuracy of analytical results

10 (s) "Quality control sample" means a sample that includes
11 analytes in exact concentrations that are not known to the labo-
12 ratory and are provided to a laboratory by the department or a
13 source approved by the department to assist in the evaluation of
14 the performance of the laboratory

15 (t) "Raw data" means the qualitative or quantitative mea-
16 sures recorded from chemical, physical, biological, microbiologi-
17 cal, radiological, or other scientific determinations that are
18 obtained

19 (u) "Reciprocity" means mutual acceptance of a certification
20 or accreditation between the department and another state

21 (v) "Recommended analytical method" means a written proce-
22 dure recognized as an appropriate means of obtaining valid ana-
23 lytical data by a regulatory agency of the federal or state
24 government

25 (w) "Rule" means a rule promulgated pursuant to the adminis-
26 trative procedures act of 1969, Act No 306 of the Public Acts of

1 1969, being sections 24 201 to 24 328 of the Michigan Compiled
2 Laws

3 (x) "System audit" means an on-site inspection of laboratory
4 capabilities by the department, or an entity approved by the
5 department which is external to the laboratory that is the
6 subject of the inspection

7 (y) "Validation statement" means a statement that is pro-
8 vided with each set of results signed by the laboratory director
9 indicating that all of the requirements of this act and rules
10 promulgated under this act are met

11 Sec 2 (1) A person shall not submit analytical data to a
12 state department or agency unless the laboratory that produced or
13 developed the analytical data is certified under this act

14 (2) The department shall not require the use of a certified
15 laboratory for determining a parameter if a mandatory or recom-
16 mended analytical method does not exist

17 (3) Notwithstanding any other provision of this act, a labo-
18 ratory that has a contract with the United States environmental
19 protection agency pursuant to the superfund contract laboratory
20 program is exempt from the requirements of this act when the lab-
21 oratory performs pursuant to that contract at a national priority
22 list site within this state

23 (4) The department shall develop a laboratory certification
24 manual describing the specifics of obtaining certification At a
25 minimum, the manual shall describe in detail the procedures to be
26 followed for all of the following

- 1 (a) Submitting an application
- 2 (b) On-site system audits
- 3 (c) Performance audits
- 4 (d) Reciprocity for out-of-state laboratories
- 5 (e) Nongovernmental certification as authorized by the
6 department
- 7 (f) Determination and payment of fees as provided in
8 section 15
- 9 (g) Issuance, denial, and revocation of certification
- 10 (h) Methods for notifying laboratories and authorized
11 department officials of certification actions
- 12 (i) Record-keeping practices
- 13 (j) The mandatory or recommended analytical methodologies
14 with accepted or approved detection limits for each analyte in
15 each applicable matrix
- 16 (k) The minimum physical requirements for laboratory
17 facilities
- 18 (l) The method of designating key laboratory personnel, and
19 the minimum education, training and experience required of key
20 laboratory personnel who are directly involved in or responsible
21 for quality assurance for the laboratory
- 22 (m) The required content and format of the quality assurance
23 manual
- 24 (5) The department shall make a copy of the laboratory cer-
25 tification manual available to all interested persons upon
26 request and payment of a reasonable cost

1 (6) By certifying an environmental laboratory pursuant to
2 this act, the department does not warrant the accuracy of any
3 particular work done or report issued by the laboratory

4 Sec 3 (1) The department shall prepare a laboratory cer-
5 tification application form The owner or operator of an envi-
6 ronmental laboratory seeking certification under this act shall
7 submit to the department with an application and the fees
8 required in section 15 a copy of their laboratory quality assur-
9 ance manual, results of performance audits, and other documen-
10 tation required by the department, and shall assist the depart-
11 ment during a systems audit required or authorized under this
12 act

13 (2) An application for certification shall include a list of
14 those services that are or will be provided by the laboratory and
15 describe the personnel, equipment, and facilities that are avail-
16 able to successfully perform analytical methods as specified in
17 the application

18 (3) The quality assurance manual developed by a laboratory
19 shall be submitted concurrently with the application and shall be
20 in detail and scope commensurate with the size of and functions
21 undertaken by the laboratory as determined by the department
22 The quality assurance manual shall identify key personnel for the
23 laboratory who are directly involved in or responsible for qual-
24 ity assurance for the laboratory

25 (4) A laboratory that is certified under this act shall
26 inform the department in writing of a change in any of the
27 following

1 (a) The owner or operator of the laboratory

2 (b) The location of the laboratory, except for a mobile
3 laboratory

4 (c) Major equipment utilized by the laboratory to process
5 samples

6 (d) Key personnel who are directly involved in or responsi-
7 ble for quality assurance for the laboratory

8 Sec 4 (1) Laboratories that apply for certification are
9 required to acquire and analyze performance evaluation samples
10 for parameters specified by the department The source of sam-
11 ples, other than samples from the United States environmental
12 protection agency, shall be approved by the department To the
13 extent feasible as determined by the department, performance
14 evaluation samples already being analyzed by the applicant labo-
15 ratories may be used to fulfill the performance audit require-
16 ments of this act

17 (2) Except as provided in subsection (5) specific require-
18 ments for performance audits shall annually be completed by the
19 laboratory Sufficiency of the audits and matrix of the per-
20 formance evaluation samples shall be determined by the
21 department

22 (3) Submission of raw data, calibration data, and quality
23 control data that have not been processed along with the report
24 of analysis of the performance evaluation sample may be required
25 by the department

26 (4) If performance evaluation samples are not available, the
27 department shall waive performance audits for certain

1 certification parameters until the performance evaluation samples
2 are available

3 (5) If a laboratory fails to accurately analyze a per-
4 formance evaluation sample, the department shall allow the labo-
5 ratory a second performance audit. If necessitated by a second
6 failure, a third performance audit may be authorized by the
7 department if the laboratory has investigated the cause for fail-
8 ure in the preceding audits and completed corrective actions to
9 the satisfaction of the department

10 (6) A laboratory applying for or maintaining certification
11 is responsible for obtaining state approved performance evalu-
12 ation samples from a source approved by the department and shall
13 report all results to the department. The laboratory is respon-
14 sible for all costs of obtaining and analyzing performance evalu-
15 ation samples

16 Sec 5 (1) Prior to certifying a laboratory the department
17 shall conduct a systems audit. A laboratory seeking certifica-
18 tion shall undergo a system audit to assess critical elements as
19 identified in the laboratory certification manual or analytical
20 method. Elements of a laboratory's operations that are the basis
21 of consistent generation of reliable, accurate data are critical
22 elements for certification and shall be the subject of intense
23 scrutiny by the department throughout the certification process.
24 Deficiencies in critical elements shall be the basis for denial
25 or revocation of certification

26 (2) The system audit shall be designed to determine all of
27 the following

1 (a) Whether the laboratory is using the appropriate
2 mandatory or recommended methodologies to analyze each analyte
3 Previously approved state or federal alternative test procedures
4 may be included as approved methodologies

5 (b) Whether sufficient equipment and supplies as required by
6 analytical methods are available, being adequately maintained,
7 and are in a condition to allow successful performance of appli-
8 cable analytical methods

9 (c) Whether managerial, supervisory, and analytical person-
10 nel have the type of training and experience necessary to provide
11 satisfactory completion of analytical procedures and compilation
12 of accurate data

13 (d) Whether laboratory facilities allow efficient generation
14 of accurate data

15 (3) Prior to conducting a system audit, the department shall
16 review quality assurance manuals for adequacy The system audit
17 shall include a review of quality assurance programs and quality
18 control records for programs and projects that the laboratory
19 utilized to generate analytical data for submission to a state
20 department or agency

21 (4) The system audit shall include a review of applicable
22 procedures for receipt, preservation, transportation, and storage
23 of samples A laboratory is responsible only for those elements
24 of sample management over which the laboratory has direct
25 control

26 (5) The department shall bring to the attention of the owner
27 or operator of a laboratory those elements of laboratory

1 operations that could affect efficiency, safety, and other
2 administrative functions, but do not normally affect quality of
3 analytical data. However, individually, such factors are not the
4 basis for denial or revocation of certification.

5 (6) If the system audit reveals 1 or more laboratory safety
6 problems that the department considers serious, and the labora-
7 tory does not promptly and completely remedy the problems, the
8 department shall refer the matter to appropriate state or federal
9 agencies.

10 Sec 6 (1) Following receipt of an application, the labo-
11 ratory quality assurance manual, and other documentation required
12 by the department, and completion of a performance audit and
13 system audit, the department shall submit a certification appli-
14 cation review report within 6 months of receipt of complete
15 application, system audit, performance audit, quality assurance
16 manual, and any other required materials to the laboratory con-
17 cerning the results of the overall certification process. The
18 report shall list findings, assess the importance of each find-
19 ing, and make recommendations concerning corrective actions nec-
20 essary to ensure resolution of specified problems.

21 (2) After completing the certification application review
22 report, the department shall make a written determination, based
23 on the finding and recommendations of the report required under
24 subsection (1), as to whether certification should be granted.

25 (3) If the department certifies a laboratory, a certificate
26 shall be issued authorizing the laboratory to submit analytical
27 data to a state department or state agency as specified in an

1 accompanying scope of certification The certification is the
2 property of the department and shall be returned to the depart-
3 ment upon the revocation of certification

4 (4) If the department does not certify a laboratory, the
5 department shall issue a report specifying the areas of defi-
6 ciency and the steps necessary to correct the deficiencies The
7 laboratory has 30 days following receipt of the report to provide
8 documentation to the department demonstrating that the specified
9 deficiencies have been corrected unless the department determines
10 for good cause that an extension of a fixed duration is
11 warranted Based upon the documentation on file with the depart-
12 ment, the department shall decide whether to grant renew deny
13 or revoke certification

14 Sec 7 If because of a deficiency or delay not caused by
15 an action or inaction of the laboratory, the department cannot
16 conduct a complete system audit within 6 months of receipt of an
17 application, an interim certification may be granted by the
18 department based on submission of a completed application and
19 fees by the laboratory, completion of a performance audit if
20 appropriate, and a submission of the laboratory's quality assur-
21 ance manual

22 Sec 8 The department may issue a provisional certifica-
23 tion to a laboratory that has 1 or more deficiencies requiring
24 corrective action but which the department determines can produce
25 valid analytical data If the laboratory corrects the deficien-
26 cies, it may provide evidence of correction to the department or
27 request a reaudit as requested by the department If

1 deficiencies are corrected, the department shall take action to
2 award full certification as provided in section 6

3 Sec 9 (1) The department shall certify environmental lab-
4 oratories within the following categories

5 (a) Inorganic chemistry - nonmetals

6 (b) Inorganic chemistry - metals

7 (c) Organic chemistry - volatile organic

8 chemicals/semivolatile organic chemicals

9 (d) Organic chemistry - dioxins and furans

10 (e) Organic chemistry - PCBs and pesticides

11 (f) Microbiology

12 (g) Bioassay

13 (h) Limited wet chemistry

14 (i) Limited inorganic metals

15 (j) Demands and residue

16 (k) Physical analytes

17 (l) Waste characteristic

18 (2) In addition to the categories listed in subsection (1)
19 to provide for more efficient execution of the certification pro-
20 cess the department may designate by rule additional groupings
21 of categories or subcategories by individual contaminant, subcat-
22 egory, or category or by individual analytical methods

23 (3) The department may require that certification for any
24 subcategory or contaminant is contingent on the concurrent certi-
25 fication within another subcategory or contaminant A laboratory
26 may request certification for any number or combination of

1 contaminants, methodologies, subcategories, or categories unless
2 otherwise restricted by this act

3 (4) The department shall maintain both of the following

4 (a) A listing of all analytes in a category or a
5 subcategory

6 (b) A listing of the mandatory and recommended analytical
7 methodologies for analyzing a contaminant for each matrix

8 Sec 10 (1) The department shall grant certification for a
9 3-year period from the date of the system audit or provisional
10 certification if the laboratory is in compliance with all of the
11 requirements of this act and the department has completed its
12 review as required under section 6

13 (2) Certification shall be granted for no longer than a
14 12-month period from the date of the system audit for laborato-
15 ries receiving provisional certification A 1-time, 6-month
16 extension of the provisional certification period may be granted
17 by the department to a laboratory that makes a good faith effort
18 to resolve the problems and deficiencies that resulted in the
19 laboratory receiving provisional certification After the prob-
20 lems and deficiencies resulting in the issuance of provisional
21 certification have been resolved, the department may upgrade the
22 status of the laboratory to full certification for the balance of
23 the 3-year certification period

24 Sec 10a All of the following are required of a laboratory
25 that seeks to renew a certification previously granted under sec-
26 tion 6

- 1 (a) Submission of an application
- 2 (b) Payment of appropriate fees required under this act
- 3 (c) Submission of an updated quality assurance manual
- 4 (d) An appropriate performance audit
- 5 (e) A new on-site audit inspection
- 6 (f) Submission of a written response indicating the correc-
- 7 tion of each deficiency listed in the department's audit inspec-
- 8 tion report, if any
- 9 Sec 11 (1) The department shall deny certification,
- 10 renewal of a certification, or upgrading of certification for any
- 11 of the following
- 12 (a) Failing to comply with standards for critical elements
- 13 of the system audit
- 14 (b) Making a false statement or misrepresentation to the
- 15 department
- 16 (c) Misrepresenting its capabilities or failing to disclose
- 17 pertinent information in an application for accreditation
- 18 (d) Falsifying data
- 19 (e) Failing to pay a fee required under this act
- 20 (f) Unsatisfactory analysis of a parameter in the per-
- 21 formance audit
- 22 (g) Failing to comply with this act or a rule promulgated
- 23 under this act
- 24 (h) Failing a systems audit
- 25 (1) Unacceptable quality assurance manual
- 26 (2) A laboratory denied certification may appeal the denial
- 27 pursuant to the administrative procedures act of 1969, Act

1 No 306 of the Public Acts of 1969, being sections 24 201 to
2 24 328 of the Michigan Compiled Laws, or, following correction of
3 deficiencies, the laboratory may reapply for certification A
4 reapplication shall include the required fee under section 15

5 Sec 12 (1) The department may reaudit a certified labora-
6 tory during the 3-year certification period under either of the
7 following circumstances

8 (a) The laboratory is found to be deficient in its ability
9 to provide accurate analytical data In this situation, the
10 department may issue an emergency order to suspend or revoke all
11 or part of a certification

12 (b) A laboratory has deficiencies but the department con-
13 cludes that the laboratory can produce valid analytical data In
14 this situation, the department may downgrade the certification
15 status of the laboratory to be provisionally certified as pro-
16 vided in section 8

17 (2) Actions taken by the department under subsection (1)
18 shall be pursuant to the administrative procedures act of 1969,
19 Act No 306 of the Public Acts of 1969, being sections 24 201 to
20 24 328 of the Michigan Compiled Laws

21 (3) The department may issue an order to a laboratory to
22 provide the department a list of its clients that may be affected
23 by a change in the laboratory's certification status

24 (4) The department may issue an order to a laboratory to
25 notify its clients of a change in its certification status

26 (5) A laboratory that has its certification revoked is not
27 eligible to reapply for certification for a period of at least 1

1 year Certification fees paid prior to certification revocation
2 are not refundable The department shall not grant credit for
3 certification fees that are paid prior to certification revoca-
4 tion when a laboratory reapplies for certification

5 Sec 13 The department may recognize accreditation, certi-
6 fication, registration, licensure, or approval of an out-of-state
7 laboratory by another state with which the department has
8 reciprocity To be certified in this state, an out-of-state lab-
9 oratory shall submit an application and fee as provided in
10 section 15(6) and a copy of accreditation documentation including
11 the scope of accreditation from the state with which the state
12 has reciprocity If the department determines that an environ-
13 mental laboratory applying for certification under this section
14 complies with the requirements of this act and rules promulgated
15 under this act, the laboratory shall be recognized by the depart-
16 ment as authorized to submit analytical data to a state
17 department

18 Sec 14 (1) The department may recognize the accreditation
19 of a laboratory by a nongovernmental entity approved by the
20 department, if the department determines that such an accredit-
21 ation is equivalent to certification under this act

22 (2) The department may delegate certain functions which it
23 is required to perform under this act and may enter into contract
24 to perform those functions The contracts may include the per-
25 formance of system audits, preparation of written reports, provi-
26 sion of performance evaluation, and analysis of reagent water or

1 other functions or duties as considered appropriate by the
2 department

3 (3) In-state laboratories are restricted to the use of the
4 department or nongovernmental entities under contract with the
5 department for system audits. In-state laboratories shall not
6 apply for reciprocity by obtaining accreditation in another state
7 and seeking reciprocity under this act. For in-state laborato-
8 ries, all necessary documents, applications, and fees related to
9 certification shall be submitted directly to the department.
10 Copies of the documents may be submitted by the laboratory to the
11 nongovernmental entities approved by the department. The depart-
12 ment shall maintain and make available a list of nongovernmental
13 entities under contract with the department.

14 (4) A laboratory is prohibited from entering into contracts
15 with parties that have a financial interest in the laboratory.

16 (5) Out-of-state laboratories may use the services of any
17 nongovernmental agency approved by the department and shall
18 submit a fee as provided in section 15(6).

19 Sec 15 (1) As used in this section

20 (a) "DW" means the safe drinking water act, Act No 399 of
21 the Public Acts of 1976, being sections 325 1001 to 325 1023 of
22 the Michigan Compiled Laws.

23 (b) "NPDES" means national pollutant discharge elimination
24 system.

25 (c) "MERA" means the environmental response act Act No 307
26 of the Public Acts of 1982, being sections 299 601 to 299 618 of
27 the Michigan Compiled Laws.

1 (d) "RCRA" means the solid waste disposal act, title II of
2 Public Law 89-272

3 (e) "MUST" means the leaking underground storage tank act,
4 Act No 478 of the Public Acts of 1988, being sections 299 831 to
5 299 850 of the Michigan Compiled Laws the Michigan underground
6 storage tank financial assurance act, Act No 518 of the Public
7 Acts of 1988, being sections 299 801 to 299 828 of the Michigan
8 Compiled Laws and the underground storage tank regulatory act,
9 Act No 423 of the Public Acts of 1984, being sections 299 701 to
10 299 712 of the Michigan Compiled Laws

11 (f) "AQ" means the air pollution act, Act No 348 of the
12 Public Acts of 1965, being sections 336 11 to 336 36 of the
13 Michigan Compiled Laws

14 (2) The department shall annually review the fee structure
15 within this subsection and shall report to the legislature if
16 currency value fluctuations or changes in program administration
17 costs indicate the fee structure in this section should be modi-
18 fied beyond the increases authorized in this subsection The fee
19 structure provided in this section is a 3-year fee payable upon
20 submission of an application for certification The fee for per-
21 forming a single category of tests will be based on the number of
22 programs under which the laboratory offers the testing service
23 The fees for performing a single category of tests and the pro-
24 grams under which that category may be offered are indicated in
25 this subsection The total certification fee owed by a labora-
26 tory shall be calculated by adding the appropriate fees as
27 provided in the following fee schedule for performing each

- 1 category of tests offered by the laboratory and applying the
- 2 discounts available under subsection (3) for performing tests in
- 3 2 or more categories

Triennial Fee Schedule for Laboratory Certification Program

		Program Certification Fee				Programs				
	Category					DW	NPDES	MERA	RCRA	MUST
	AQ									
		1	2	3	4 or more tests					
Microbiology	\$2080	\$2500			x	x				
Limited Wet Chemistry	\$500	\$600	\$690	\$720	x	x	x	x		
Inorganic Chemistry Metals x	\$2450	\$2820	\$2960	\$3110	x	x	x	x		x
Inorganic Chemistry Nonmetals x	\$2450	\$2690	\$2830	\$2970	x	x	x	x		
Limited Inorganic Metals	\$1230	\$1230			x					x
Demands and Residue	\$1560	\$1640				x			x	
Volatile Organic Chemicals x	\$2450	\$2940	\$3230	\$3400	x	x	x	x		x
Semivolatile and volatile Organic Chemicals x	\$2940	\$3530	\$3840	\$4080	x	x	x	x		x
Organic Chemistry Dioxins/Furans	\$2450	\$2450	\$2450	\$2450	x	x	x	x		
Physical Analytes x	\$1230	\$1290	\$1290					x	x	

1 2 3 4 5 6 7 8 9	Category AQ	Program Certification Fee				Programs				
		1	2	3	4 or more tests	DW	NPDES	MERA	RCRA	MUST

10	Waste									
11	Characteristics	\$2450	\$2450					x	x	
12										
13	Bioassays	\$2450					x			
14										

(3) Except for limited wet chemistry and limited inorganic metals for which no discounts are available under subsection (2), the following discounts are available for fees assessed under subsection (2)

(a) Discount for 2 categories is 25%

(b) Discount for 3 or more categories is 40%

(4) The fees authorized in this section shall be adjusted on October 1 each year following the effective date of this act by applying a percentage adjustment using the Detroit consumer price index

(5) Processing of an application will not commence until the fee as determined under this section has been received

(6) Out-of-state laboratories shall coordinate with the department to determine the anticipated cost of completing the certification process for this state. The fee assessed shall be the projected cost of travel and per diem as determined by the department added to the fee provided in this section

(7) The fee to defray costs to the department for recognition of a laboratory under a reciprocity agreement under section 13 or 14 is \$150.00. The fee shall be reviewed annually

1 as authorized under subsection (2) and may be increased not more
2 than 20% annually

3 Sec 16 An environmental laboratory shall include a vali-
4 dation statement signed by its laboratory director with each set
5 of results signed by the laboratory director attesting to compli-
6 ance with this act and applicable rules promulgated under this
7 act The validation statement shall read, "I certify that I am
8 the laboratory director with ultimate responsibility for labora-
9 tory operations and that these analyses were performed, and the
10 results are reported, in full compliance with this act

11 Sec 17 An environmental laboratory shall retain the fol-
12 lowing information for all environmental samples analyzed for a
13 minimum of 7 years The minimum information required to be main-
14 tained under this section includes, but is not limited to all of
15 the following

16 (a) Analytical data reported from analyzing environmental
17 samples

18 (b) The method or methods used to produce the final labora-
19 tory results from analyzing environmental samples

20 (c) All raw data calibration data, and quality control data
21 associated with analytical data

22 (d) The validation statement required for each set of ana-
23 lyses by section 16

24 (e) The quality assurance manual in effect at the time of
25 the analysis and all subsequent revisions to the manual

26 Sec 18 The director, or any law enforcement official, may
27 enter any premises in which analytical and raw data pertaining to

1 certification under this act are generated or stored, for the
2 purpose of conducting system audits or otherwise enforcing this
3 act Refusal to permit entry for this purpose shall result in
4 denial, revocation, or suspension of certification status pursu-
5 ant to the administrative procedures act of 1969 Act No 306 of
6 the Public Acts of 1969 being sections 24 201 to 24 328 of the
7 Michigan Compiled Laws

8 Sec 19 (1) To determine the ability of an environmental
9 laboratory to produce valid analytical data, to evaluate the
10 validity of any previously reported analytical data or to evalu-
11 ate compliance with the quality assurance manual, analytical
12 method or administrative rules, the director shall require the
13 laboratory director to furnish any information that the environ-
14 mental laboratory is required to maintain as specified by
15 section 17 or as required by its own quality assurance manual

16 (2) A person required to furnish information pursuant to
17 subsection (1) shall at the option of the director do either of
18 the following

19 (a) Grant the director access at all reasonable times to
20 inspect and copy relevant information

21 (b) Copy and furnish to the director at no cost the relevant
22 information

23 (3) All inspections and investigations undertaken by the
24 director shall be completed with reasonable promptness

25 (4) Information furnished to the department under this act
26 shall be utilized only for the purpose of assuring the competency

1 of the laboratory and that the laboratory is in compliance with
2 this act

3 (5) If the director is refused entry under section 18 or
4 denied information under subsections (1) and (2), for the pur-
5 poses of enforcing the information gathering and entry authority
6 provided in section 18 and in this section, the attorney general,
7 on behalf of the state, may do either of the following

8 (a) Petition the court of competent jurisdiction for an
9 order authorizing access to the environmental laboratory or labo-
10 ratory records described in this section and section 18

11 (b) Commence a civil action to compel compliance with a
12 request for information or entry pursuant to this section and
13 section 18, to authorize information gathering and entry provided
14 for in this act, and to enjoin interference with the exercise of
15 the authority provided in this section

16 (6) Information obtained by the director as authorized under
17 subsection (1) or (2) shall be available to the public to the
18 extent provided by the freedom of information act, Act No 442 of
19 the Public Acts of 1976, being sections 15 231 to 15 246 of the
20 Michigan Compiled Laws The provider of information pursuant to
21 subsection (1) or (2) may designate the information that the pro-
22 vider believes to be entitled to protection as trade secrets or
23 information of a personal nature under section 13(1)(a) or (g) of
24 the freedom of information act, Act No 442 of the Public Acts of
25 1976, being section 15 243 of the Michigan Compiled Laws Such
26 specifically designated information shall be submitted separately
27 from other information required to be provided under this

1 section The department's determination of whether to grant an
2 exemption from disclosure under the freedom of information act
3 will then be made

4 Sec 20 (1) The department shall make certification appli-
5 cations available to environmental laboratories within 6 months
6 after the date on which this act has been enacted

7 (2) A laboratory seeking certification shall return the cer-
8 tification application to the department within 18 months of the
9 enactment of this act to be eligible for interim certification
10 under subsection (3)

11 (3) Within 24 months of the enactment of this act, the
12 department may grant a 1-time extended interim certification to
13 all laboratories returning an application to the department as
14 provided in subsection (2) The department's decision whether to
15 grant interim certification shall be based on determination by
16 the department of the acceptability of the laboratory's quality
17 assurance manual and all pertinent performance evaluation
18 samples If interim certification is denied, the department
19 shall provide a written decision to the applicant detailing the
20 reason for denial If the laboratory is denied interim certifi-
21 cation, the laboratory may reapply for interim certification
22 within 18 months of the enactment of this act

23 (4) Except as otherwise provided in subsection (5), the
24 department shall process applications for certification for the
25 first cycle of certification as follows

1 (a) Approximately the first 1/3 of the anticipated
2 applications received by the department for certification, if
3 eligible, shall be provisionally certified for 3 years

4 (b) Approximately the second 1/3 of the anticipated applica-
5 tions received by the department for certification, if eligible,
6 shall be provisionally certified for 2 years

7 (c) Approximately the last 1/3 of the anticipated applica-
8 tions received by the department for certification, if eligible,
9 shall be certified for 1 year, or until the department is able to
10 complete the full certification process described in this act

11 (5) The certification expiration date of a laboratory cur-
12 rently certified for the analysis of drinking water pursuant to
13 the safe drinking water act, Act No 399 of the Public Acts of
14 1976, being sections 325 1001 to 325 1023 of the Michigan
15 Compiled Laws, is not affected by this legislation Such a labo-
16 ratory that applies to the department for certification in addi-
17 tional categories shall receive a certificate for the other cate-
18 gories from the department that has the same expiration date as
19 the laboratory's drinking water certificate

20 Sec 21 The director may promulgate rules to implement
21 this act

22 Sec 22 This act shall take effect upon the expiration of
23 18 months after the date of its enactment