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SFA BILL ANALYSIS

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Senate Bill 839 (as introduced 1-14-98)
Sponsor: Senator Philip E. Hoffman
Committee: Natural Resources and Environmental Affairs

Date Completed: 5-14-98

CONTENT

The bill would add Part 205 (Laboratory Accreditation) to the Natural Resources and Environmental Protection Act (NREPA). Under the bill, the Department of Environmental Quality (DEQ) could require analytical data submitted for environmental monitoring or compliance purposes to be produced or developed by a laboratory accredited by the Department for the categories, parameters, analytes, or methods for which the analytical data were submitted; require accreditation of a laboratory operated by the DEQ for environmental regulatory monitoring or compliance purposes; specify the procedures for an application for laboratory accreditation; allow the renewal, augmentation, and transfer of accreditation within categories, parameters, analytes, or methods; require an applicant to participate in PT (proficiency testing) for which the laboratory was accredited and establish a PT program; require an on-site assessment of the laboratory to be accredited; specify the policy for denial or revocation of accreditation; allow the DEQ to require certain information from the accredited laboratory for public access; specify the penalties and fines for violations of the bill; and require the DEQ to report on a national laboratory program.

("Accreditation" would mean the process by which the Department recognized a laboratory as meeting qualifications that complied with accreditation requirements, "laboratory" would mean a laboratory that analyzed environmental samples for monitoring or compliance with State environmental law, and "PT" would mean proficiency testing, which would be a test to determine whether the laboratory could produce analytical results within specified performance limits. "Analyte" would mean the substance or physical property contained in a sample for which analysis was performed.)

Accredited Laboratory

Each laboratory would have to be individually accredited.

Mobile laboratories owned and operated by a stationary laboratory and under the control of its laboratory director could, at the option of the stationary laboratory, be considered part of the stationary laboratory for purposes of accreditation but would be separate for purposes of satisfying the PT testing, on-site assessment, and other requirements of accreditation. Mobile laboratories that were owned by the same person but did not meet this description could, at the owner's option, be considered a single laboratory unit for purposes of accreditation, but would be separate laboratories for purposes of the PT testing, on-site assessment, and other accreditation requirements.

An accredited laboratory could not subcontract sample analyses performed for the purpose of demonstrating compliance with any environmental law, regulation, or rule implemented by the DEQ, unless the subcontractor laboratory were accredited for the necessary categories, parameters, analytes, or methods.

An accredited laboratory would not be eligible to contract with the DEQ for on-site laboratory assessment of laboratories or to provide PT samples under contract to or otherwise approved by the DEQ. Department on-site assessment contractors and providers of PT samples would not be eligible for accreditation.

The bill would not prohibit other State certification, accreditation, licensing, or registration programs established before the bill's effective date. The State drinking water laboratory certification program under the Safe Drinking Water Act would be unaffected by the bill unless otherwise provided by rule.

The DEQ could exempt analytical data from laboratories that had current contracts with the Environmental Protection Agency (EPA) Superfund Contract Laboratory Program if the data were submitted by those laboratories to the State or Federal government, pertained to cleanup activities under a Superfund site, and were consistent with the EPA Superfund Laboratory Contract in effect at the time the data were produced.

The Department could accept sample results produced by a nonaccredited laboratory if a written request for a variance were submitted to the DEQ by the person who was required to submit the data for regulatory purposes explaining why a variance was necessary and why such sample results were not or could not be produced by an accredited laboratory, and the sample results were submitted with the method and all method validation data, calibration data, raw data, and quality control data, or at the option of the Department, with a data validation report from an on-site assessment contractor under contract to the Department.

Application Procedure

Upon request from a laboratory seeking accreditation, the Department would have to make an application package available to the laboratory. The package would consist of materials and information including the application form, a copy of the bill and applicable rules, an accreditation manual, the accreditation categories, a listing of acceptable methods, listing of analytes for which accreditation was available, identification of each PT program, and the name of on-site assessment contractors under contract.

The DEQ could not accept an application for accreditation from a laboratory if accreditation had been denied or revoked for that laboratory and a six-month period had not expired.

The DEQ would have to charge accreditation fees to implement the bill and oversee each contractor hired or approved by the Department to implement the accreditation program and rules. A contractor hired by the DEQ would have to be the lowest responsive bidder qualified. A contractor would have to assess fees as established in the contract. The fees would have to be paid directly by laboratories that were accredited or sought accreditation.

Before submitting an application for accreditation to the Department, an applicant would have to participate in PT. The PT result report would have to be submitted with the application for accreditation. The applicant also would have to undergo an on-site assessment from an on-site assessment contractor.

The application would have to include a certification of compliance statement signed and dated by the applicant acknowledging that the laboratory was continually required to be in compliance with Part 205 and subject to penalties. Authorized representatives of the DEQ could make announced or unannounced inspections of an applicant or accredited laboratory, and review any data required to be submitted to the Department, or any information associated with the data, to determine the extent of compliance with the conditions of accreditation and regulations. In addition, the applicant would authorize the State inspector to make copies of any analyses or other records, and to remove copies from the facility for evaluation or regulatory enforcement.

The application and the certification of compliance statement would have to be signed and dated by a principal executive officer of at least the level of vice president, if the applicant were a corporation; a general partner, if the applicant were a partnership; or the proprietor, if the applicant were a sole proprietorship.

Accreditation

The Department would have to notify the applicant of any additional items that were necessary to make the application administratively complete. Within 30 days after the DEQ determined that the application was complete, the Department would have to review the application, the on-site assessment report, and the results of the applicant's PT samples. Based on the review, the DEQ could approve full accreditation for all requested parameters, approve accreditation for a subset of the requested parameters and deny accreditation for others, or deny accreditation for all requested parameters. The accreditation would remain in effect for one year, unless it was revoked by the Department or unless discontinued by action of the accredited laboratory.

The DEQ Director or his or her designee would have to issue a certificate of accreditation to laboratories that complies with the accreditation requirements. The certificate would have to be returned upon expiration or loss of accreditation. The most current certificate and current list of categories, parameters, analytes, or methods for which the laboratory was accredited would have to be posted conspicuously in the laboratory, and a copy would have to be made available by the accredited laboratory upon request, to any party using or requesting the services of the laboratory.

Transferred Accreditation

The DEQ could enter into agreements with the government of any other state or third party nongovernmental entity for the purpose of recognizing out-of-State accreditation of laboratories if such agreements were authorized by rules promulgated by the Department and the accreditation standards were equivalent to the bill's accreditation standards and rules.

Accreditation Renewal and Augmentation

Accreditation within categories, parameters, analytes, or methods would have to be renewed annually. The accredited laboratory could initiate the renewal by submitting the renewal application and all relevant updated information, accreditation fees, result reports of all PT samples for accredited analytes or parameters within the last year, and a copy of the most recent on-site assessment report.

An accredited laboratory could augment the categories, parameters, analytes, or methods for which it sought accreditation during renewal of accreditation or by making a separate application to the DEQ at times other than during an annual renewal.

An application to augment would have to include all relevant application information required under the bill and a PT result report demonstrating successful participation in PT within six months before applying for accreditation. If a laboratory applied to augment accreditation for two or fewer analytical methods during any one accreditation year, the on-site assessment could be deferred until the next on-site assessment required as a part of the renewal process. The evaluation and approval of such methods would have to be based on review of the written standard operating procedure and the initial demonstration of method performance as specified by rule.

Accreditation could be transferred when the legal status or ownership of an accredited laboratory changed without affecting its staff, equipment, or organization in a manner that prevented the laboratory from maintaining compliance with the bill. Accreditation would have to be transferred if all of the following occurred:

-- The change in ownership of an accredited laboratory was reported to the DEQ within 10 days after the change.
-- The new owner agreed to maintain records, data, and reports for any analyses generated before legal transfer of ownership.
-- The new owner paid a transfer fee to the DEQ.

Department Responsibilities

The Department would be required to develop an accreditation manual detailing the regulations, requirements, guidance, and procedures for accreditation; define the categories, parameters, analytes, and acceptable methods for which a laboratory could become accredited; and compile and maintain a listing of commercial accredited laboratories.

The DEQ also could approve the use of alternative test procedures if they were approved by the EPA for a similar use; approve the use of alternative test procedures if the applicant documented that the quality of data produced by the proposed method was as good as or better than the quality of data produced by the existing approved method; approve an analytical method if there were no Department approved method or if no method existed; undertake double blind PT studies of accredited laboratories from a PT program or samples from other qualified sources; use PT sample results to select laboratories for further inspection, require analysis of PT samples in presence of Department representatives, require corrective action, and revoke accreditation; and enter into agreements, contracts, or cooperative arrangements under terms and conditions appropriate with other State agencies, Federal agencies, interstate agencies, political subdivisions, educational institutions, local health departments, other public or private organizations, or individuals to administer the bill.

PT Requirements

Laboratory Responsibilities. A laboratory would have to meet the following PT requirements for accreditation:

-- Participate in PT for which the laboratory was accredited and a PT program existed.
-- Pay all costs of PT.
-- Provide the PT result report with the initial application and any application to augment accreditation, and report PT sample results within 30 days after receiving the report.
-- Examine or test the PT samples from the PT program in the same manner as routine environmental samples.
-- Report PT sample results to the PT program within the deadline stated in the sample package.

Each analyst responsible for analysis of a PT

sample would be required to test the PT sample the same number of times that routine tests on environmental samples are performed. The laboratory director and each analyst would have to sign the PT result report or a statement attached to the PT result report attesting that all samples were analyzed in the same manner as routine samples. These signed statements would have to accompany the laboratory results to the PT program.

("PT program" would mean a government entity or a private entity under contract to or otherwise approved by the DEQ that provided rigorously controlled ans standardized PT samples. A PT sample would be a sample whose composition was unknown to the laboratory performing the analysis.)

PT Sample Receipt. Any applicant or accredited laboratory participating in PT could not engage in communications with another laboratory pertaining to the PT sample results before the reporting deadline and could not send a PT sample or a portion of a PT sample to another laboratory for any analysis for which accreditation was sought. Any laboratory that the DEQ determined had referred a PT sample to another laboratory for analysis would be denied accreditation or have its accreditation permanently revoked. Any laboratory that received a PT sample from another laboratory for testing would have to notify the DEQ of the receipt of the PT sample and provide to the DEQ all information associated with the receipt. The DEQ would have to deny or revoke for six months accreditation of an applicant or accredited laboratory that did not report the receipt of a PT sample from another laboratory. A laboratory would have to maintain a copy of all records associated with the analysis of a PT sample, for a minimum of five years. This record would have to include a copy of completed PT result report forms used by the laboratory to record PT results, including the statements signed by the appropriate analysts and the laboratory director.

PT Participation. An applicant would have to participate in PT within six months before making application to the DEQ. A PT sample could consist of either one or two concentrations as determined by the Department. An accredited laboratory seeking to maintain or renew accreditation would have to participate in PT twice.

If the PT sample consisted of one concentration analyzed semiannually, then both semiannual PT sample results would have to be within acceptance limits. If either or both PT results were not within acceptance limits, the laboratory would have to be provisionally accredited and would have to reanalyze a remedial PT sample for restoration of accreditation, if the result were acceptable. If the PT sample consisted of two concentrations analyzed semiannually, then three of the four semiannual PT results would have to be within acceptance limits. If three or fewer of the four PT results were within acceptance limits, then accreditation would be downgraded to provisional and the laboratory would have to reanalyze a remedial PT sample.

The corrective actions taken to resolve unacceptable PT results would have to be thoroughly documented and the documentation maintained by the laboratory for at least five years.

Failure to return PT results to the PT program would be an unacceptable result. The DEQ could extend a deadline, however, if it determined that the cause for not participating was beyond the control of the laboratory.

Additional PT Tests. A laboratory would have to test additional PT samples at the request of the DEQ if the DEQ determined that one or more of the following had occurred:

-- A major change in ownership or supervision of the laboratory.
-- Significant allegations of noncompliance with Part 205 by laboratory clients or employees.
-- Unacceptable results on the most recent PT.
-- A need to demonstrate corrective action following an unacceptable on-site assessment.

On-Site Assessment

Evaluation. Applicant and accredited laboratories would have to be evaluated for compliance with the bill's accreditation requirements by an on-site contractor to the DEQ.

Initial or Augmented Accreditation. To obtain initial accreditation or to augment accreditation, the applicant laboratory would have to pass an on-site assessment consistent with the bill's on-site assessment standards and rules within one year before applying for accreditation. The applicant would have to schedule an on-site assessment with the on-site contractor. The contractor would have to perform an on-site assessment of the laboratory, prepare an on-site assessment report, and submit the report to the applicant. If the on-site assessment indicated significant deficiencies, the applicant could correct the deficiencies and repeat the assessment or portion of it. The applicant would have to submit the report to the DEQ as part

of the initial accreditation application or application to augment accreditation. The DEQ could not approve an application for accreditation, unless it had found that the report was acceptable.

Renewal. To renew accreditation, the accredited laboratory would have to pass an on-site assessment within two years before expiration of the current accreditation period. If an on-site assessment were required, the laboratory would have to forward a copy of the report to the DEQ within 10 days after receiving it.

Deficiencies. The on-site assessment contractor would have to provide copies of the assessment to the laboratory and DEQ. The Department would have to review the report and notify the laboratory of any existing deficiencies. The laboratory would have to correct the deficiency and provide documentation, or submit a corrective action plan to the DEQ. If the DEQ determined that the documentation or demonstration remained deficient after the laboratory submitted documentation that the deficiency was corrected, the DEQ could grant the laboratory an additional 20 business days to perform corrective action before the it would revoke accreditation. In addition, if the laboratory submitted a corrective action plan that was rejected by the Department, then the laboratory would have six months to make the recommended changes before accreditation would be revoked.

Additional Assessments. The DEQ could require follow-up assessments, paid for by the laboratory, to verify that the cause of an unsatisfactory on-site assessment had been corrected or to determine the cause of recurring unacceptable PT results. The DEQ could require new or partial on-site assessment if it determined that a major change had occurred at a laboratory in personnel, equipment, or the facility that could impair the capability of the lab. The DEQ would not be required to provide advance notice of an on-site assessment when the assessment was conducted at Department expense.

Fees

DEQ-Assessed Fees. A laboratory applying for initial accreditation or to renew or augment accreditation would have to submit all fees with the application for accreditation. The fees would be nonrefundable except for overpayment. The accreditation fee would have to be the sum of the fee for each accreditation category ($100) plus either the initial application fee ($400), augmentation fee ($150), or renewal application fee ($200).

A fee to augment accreditation would not be required if the laboratory applied to augment accreditation at the same time it applied to renew accreditation. Accreditation could be transferred when ownership of an accredited laboratory changed for a transfer fee of $100.

The accreditation fee for each mobile laboratory unit that was accredited as part of a stationary laboratory would be $100 per unit plus the appropriate category fee or fees.

The DEQ would have to adjust fees each year based on the consumer price index to determine the adjusted amount for each year.

On-Site Assessment Fees. An applicant for accreditation would have to pay the fees as established in the contract between the DEQ and the on-site assessment contractor, and any fees associated with PT. Within 14 days after the DEQ entered into a contract, the DEQ would have to notify the chairpersons of the Senate and House committees primarily responsible for environmental protection legislation of the fees to be charged by the contractor. The fees would have to be deposited in the Environmental Response Fund subaccount of the Cleanup and Redevelopment Fund created under Part 201 (Environmental Remediation) of the Act.

Quality Assurance

An accredited laboratory would have to assure that the quality of analytical data produced by the laboratory was suitable for its intended purpose and supported by appropriate documentation. The laboratory also would have to assure that the quality was maintained within a framework of quality systems in which staff responsibilities and operational procedures were defined, documented, and subjected to audit on a regular basis, with timely corrective action taken by the laboratory as needed.

The quality systems would have to include all quality assurance policies and quality control procedures and be documented in a quality assurance plan. The laboratory would have to meet any additional or more stringent requirements specified by analytical methods or specific regulatory programs for which the data were being used to demonstrate compliance.

Laboratory Results

An accredited laboratory would have to provide the laboratory accreditation number, expiration date, and validation statement signed by the laboratory

director with each set of results. In the validation statement, the laboratory director responsible for laboratory operations would have to certify that the analyses were performed, and the results reported, in compliance with Part 205 and the rules promulgated under it. The laboratory would have to maintain all records associated with accreditation parameters, including raw data associated with each analysis, changes in method standard operating procedures, and the laboratory quality assurance plan, for a minimum of five years. The laboratory director would have to notify the DEQ of any changes in key accreditation criteria including the laboratory location or the loss of key personnel.

Accreditation Denial or Revocation

The DEQ would have to deny an application for initial accreditation or to renew or augment accreditation, if the laboratory did any of the following:

-- Failed to participate or performed unsatisfactorily in PT.
-- Failed to submit the certification of compliance statement with the application.
-- Submitted PT results generated by another laboratory.
-- Falsified any report relating to laboratory analysis.
-- Failed to pay the appropriate accreditation fee.
-- Had an unacceptable on-site assessment.
-- Misrepresented any material fact pertinent to the application process.

The DEQ would have to notify the applicant of its intent to deny accreditation and identify the basis for denial. If the basis of denial were an unacceptable on-site assessment, the applicant would have one opportunity to correct the deficiencies. The DEQ would have to hold the application in abeyance for up to six months (for initial or augmented accreditation) or up to one month (for renewal accreditation) from the Department's denial notification to allow the applicant to demonstrate that deficiencies were corrected.

The DEQ would have to revoke accreditation for categories or analytes if the laboratory did any of the following:

-- Failed to participate in PT for any category, parameter, analyte, or method for which the laboratory was accredited and for which a PT program existed.
-- Incurred two consecutive unacceptable PT results.
-- Submitted PT results generated by another laboratory.
-- Failed to report to the DEQ receipt of PT samples from another laboratory.
-- Lost its accreditation that was gained through a reciprocity agreement with another state agency.
-- Misrepresented any material fact pertinent to receiving accreditation.
-- Misrepresented the categories, parameters, analytes, or methods for which the laboratory was accredited.
-- Denied entry to the DEQ for purposes of laboratory inspection or on-site assessment.
-- Falsified any report of or relating to a laboratory analysis.
-- Received an unacceptable on-site assessment.
-- Failed to pay the appropriate accreditation fees.

A laboratory whose accreditation had been revoked would not be eligible to reapply for reaccreditation until six months after the date of revocation.

The denial or revocation of accreditation would occur for specific categories, parameters, analytes, or methods where unsatisfactory laboratory performance, practices, or actions were specific to such categories, parameters, analytes, or methods. The DEQ would have to determine whether to deny or revoke accreditation after the laboratory had an opportunity for an evidentiary hearing in a contested case proceeding under the Administrative Procedures Act.

Inspections and Investigations

Access. The DEQ or the on-site assessment contractor could require a laboratory director to furnish information to determine the laboratory's ability to produce valid analytical results, evaluate the validity of reported analytical results, or evaluate compliance with the bill's requirements. Privilege and protection from disclosure under Part 148 (Environmental Audit Privilege and Immunity) of the NREPA would not apply to information required to be reported to the DEQ under this provision.

A person required to furnish information would have the option either to grant the DEQ access at all reasonable times to inspect and copy the information, or to copy and furnish the information to the DEQ at no charge. All inspections and investigations would have to be completed with reasonable promptness.

If the DEQ were refused entry or information, the

Attorney General could petition the court of appropriate jurisdiction for a warrant authorizing access to the laboratory or records; commence a civil action to compel compliance; and/or seek civil sanctions on behalf of the State for failure to comply with an information or access request.

Public Information. Information obtained by the DEQ would have to be available to the public as provided under the Freedom of Information Act but the provider of information could designate specific information believed to be protected as information of a personal nature. The specifically designated information would have to be submitted separately from other information, and the DEQ would have to determine whether to grant an exemption from disclosure.

The following information obtained by the DEQ would be available to the public: all application information and laboratory final results reported to the DEQ; the method or methods used to produce such results; all raw data, calibration data, and quality control data reported to the DEQ; the laboratory quality assurance manual; all PT results and PT result reports; and the signed certification of compliance statement.

Penalties and Fines

The Attorney General could commence a civil action against a laboratory for recovery of State investigative, sampling, or analytical costs where data were unusable due to analytical errors and/or inadequate laboratory-record keeping; and/or for enforcement of information gathering and entry authority.

A person would be guilty of a felony punishable by imprisonment for up to two years and/or a fine of at least $10,000 but not more than $25,000 for each violation, if the person knowingly made a false statement or representation in any application, record, report, or other document filed with the DEQ under Part 205; destroyed, altered or concealed any record, report, or document; aided, abetted, permitted, or facilitated the submission of any false statement or representation; or represented itself as being accredited in an area in which it was not accredited.

If a conviction were for a violation committed after a first conviction, the person would be guilty of a felony punishable by imprisonment for up to five years and/or a fine of at least $50,000. If the court found that the action of a defendant posed a substantial endangerment to public health, safety, or welfare, the defendant would be guilty of a felony punishable by imprisonment for up to five years and/or a fine of at least $100,000 but not more than $1 million. To find a defendant criminally liable for substantial endangerment, the court would have to determine that the defendant knowingly and recklessly acted in such a manner as to cause a danger of death or serious bodily injury and that either the defendant had an actual awareness, belief, or understanding that the conduct would cause substantial danger of death or serious bodily injury, or the defendant acted in gross disregard of the standard of care that a reasonable person would observe in similar circumstances.

Accreditation Program

The DEQ would have to promulgate rules pertaining to the accreditation program to specify all of the following:

-- Laboratories or regulatory programs subject to accreditation.
-- Accreditation procedures.
-- Accreditation categories, analytes, parameters, and methods.
-- Qualifications for on-site assessment contractors.
-- Qualifications for PT programs.
-- Other necessary accreditation program aspects.

The rules also would have to specify the laboratory requirements for establishing and maintaining acceptable laboratory quality systems; these rules could include laboratory organization and management; establishment of audits, essential quality controls, and data verification; personnel; physical facilities; equipment and reference materials; measurement traceability of standards and regents; method calibration and performance; sample handling, acceptance, receipt, and tracking; record-making and retention; and laboratory report content.

The DEQ could promulgate rules to specify the procedures and conditions under which the DEQ could enter into agreements with the government of any state or third party nongovernmental entity to recognize the accreditation of out-of-State laboratories; the type and amount of documentation to be submitted to support alternative test procedure applications and the review procedure, application process, and applicability of alternative test procedures to specific regulatory programs; and procedures for establishing PT performance limits.

Reports

During January 1999 and every odd-numbered year thereafter, the DEQ would be required to report to the Senate and House committees responsible for environmental protection legislation whether a national laboratory program had been instituted by which laboratories were recognized as meeting certain qualifications or standards. If such a program had been instituted, the DEQ would have to include in the report its recommendations as to whether Part 205 should be amended or repealed.

Proposed MCL 324.20501-324.20519

Legislative Analyst: N. Nagata

FISCAL IMPACT

The bill would result in indeterminate costs to the Department, to be covered by new fees. The amount would depend upon the number of laboratories involved. Fiscal information from the Department of Environmental Quality is not available at this time.

Fiscal Analyst: G. Cutler

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