4740.2050 APPLICATION FOR CERTIFICATION.

Subpart 1. **Base certification requirements.**

A. A laboratory may request to be certified by the commissioner for the use of methods to test the analytes eligible for certification according to subpart 3.

B. A laboratory must specify the fields of testing for which it seeks certification. No certification shall be awarded for any field of testing without the laboratory meeting base certification requirements. No laboratory may receive base certification without approval of at least one field of testing.

C. A laboratory must apply on a form that is provided by the commissioner. The laboratory must supply the following information:

(1) the name of the laboratory;

(2) the physical location, postal mailing address, and electronic mailing address of the laboratory;

(3) the owner of the laboratory;

(4) the names and telephone numbers of a designated contact person and the laboratory director;

(5) the names of at least one managing agent with signature attested by a notarial officer; and

(6) the names of supervisory professional staff responsible for the analyses.

D. An application for certification must include:

(1) the form required under item C;

(2) the applicable fees, including a nonrefundable base certification fee and fees for each test category in which the laboratory seeks certification;

(3) a quality assurance manual meeting the standards of part 4740.2085;

(4) a laboratory procedures manual meeting the standards of part 4740.2065;

(5) if the application is an initial request for certification, the most recent proficiency testing result for each field of testing for which the laboratory seeks certification. The proficiency testing samples must be from an approved provider and be analyzed within one year prior to the date that the application is received by the commissioner; and

(6) a list of the laboratory's detection limits and reporting limits for each field of testing for which the laboratory is requesting certification.

E. Except as provided for mobile laboratories in subpart 2, a laboratory that owns or manages laboratory facilities at different locations must submit a separate application for each laboratory location.

F. Applications for renewal of certification must be received no later than 90 days before the expiration of certification. The application must meet the criteria of this subpart. If a laboratory fails to submit a renewal application within 90 days before the expiration of certification, the commissioner must notify the regulatory authorities that receive data that the laboratory did not apply to renew its certification. The laboratory must not report results as certified after its certification expires.

Subp. 2. **Requirements for mobile laboratories.**

A. A mobile laboratory is considered a separate laboratory and is subject to all requirements, including application requirements, of parts 4740.2010 to 4740.2120.

B. In addition to the requirements under subpart 1, a mobile laboratory must submit a vehicle identification number, license plate number, or other uniquely identifying information.

C. A mobile laboratory must designate which fields of testing, equipment, and personnel are associated with the mobile laboratory. Changes to the numbers and types of equipment within the mobile laboratory may require reapplication according to subpart 1. With each change in location, the mobile laboratory must verify that the information provided to the commissioner as required in subpart 1, item D, subitem (6), remains applicable.

Subp. 3. **Notice of availability of analytes for certification.**

A. The commissioner shall maintain and publish a list of analytes eligible for certification.

B. The list of analytes must be made available to the public through notification in the State Register, direct mailing from the commissioner, and posting on the program's Web site.

C. The notification from the commissioner must contain an indication of the changes to the list of analytes and a request for comments on the changes extending for a period of no less than 30 days.

D. The list of analytes must be reviewed at least once every six months.

Subp. 4. **Changes in scope of certification.**

A. The commissioner shall approve a laboratory's application to add a field of testing at any time other than the time of renewal if the laboratory meets the criteria in parts 4740.2010 to 4740.2120 and submits the applicable fees.

B. Requests to add fields of testing for new analytes in response to a notice of availability do not require payment of additional fees if the laboratory holds a certification for that test category and applies for additional analytes within the same test category. Applications for fields of testing for new analytes in response to a notice of availability must meet the requirements of subpart 1 and must be received by the commissioner no later than 180 days after the notice of availability is posted.

C. Requests for the addition of fields of testing received more than 180 days after the notice of availability is posted are subject to fees according to subpart 16.

Subp. 5. **Review of application.** After receiving the application and information required in subpart 1, the commissioner shall:

A. notify the laboratory in writing of any omission or error in the application;

B. deny certification for an initial application or revoke certification for a renewal application if the laboratory does not submit to the commissioner the required information within 15 days after receiving an error notice under item A;

C. award certification according to subpart 7 if the laboratory's application meets the applicable standards of parts 4740.2010 to 4740.2120; or

D. notify the laboratory that its current certification for fields of testing shall be continued until the commissioner fully reviews all documentation for compliance with parts 4740.2010 to 4740.2120.

Subp. 6. **Laboratory inspection.**

A. The commissioner may conduct inspections of certified laboratories or laboratories applying for certification.

B. The commissioner may notify the laboratory prior to arrival at the facility or may conduct an inspection without prior notice at any time during normal business hours to verify compliance with parts 4740.2010 to 4740.2120. When the commissioner provides notification, the notification may be written or oral.

C. When the commissioner determines after inspection that a certified laboratory does not comply with applicable provisions of parts 4740.2010 to 4740.2120, the commissioner shall notify the laboratory of the deficiencies in writing.

D. A laboratory must remedy any deficiencies and provide documentation of the correction to the commissioner. Within 30 days of receiving the report of deficiencies, the laboratory must submit documentation of corrective actions planned and taken. If the laboratory does not provide acceptable documentation of corrective actions or corrective action plans within 30 days, the commissioner shall notify the laboratory that its certification may be suspended in total or in part according to subpart 9. If the laboratory does not provide

any documentation of deficiency corrections within 30 days, the commissioner shall notify the laboratory that its certification is revoked in total according to subpart 10.

E. A laboratory may not reapply for certification after suspension or revocation until it has corrected all deficiencies. After all deficiencies are corrected, the laboratory may apply for certification according to subpart 1. With its new application, the laboratory must submit written documentation of the steps taken to correct the deficiencies.

Subp. 7. **Awarding certification.**

A. Documentation of a laboratory's certification must include:

(1) a certificate acknowledging the laboratory's compliance with base certification requirements; and

(2) the scope of certification for the laboratory.

B. The certificate and scope of certification must include:

(1) the logo of the Minnesota Department of Health;

(2) the name of the laboratory;

(3) the address of the laboratory;

(4) the laboratory identification number; and

(5) the expiration date of the certification.

C. If a laboratory's scope of certification changes, the commissioner shall issue a new certificate and scope of certification.

D. A laboratory's certification is valid for two years from the date of awarding base certification or renewal of base certification, unless conditions warrant suspension or revocation by the commissioner under subparts 9 and 10.

E. A laboratory must return its certificate to the commissioner upon suspension or revocation of certification.

F. A certified laboratory must not misrepresent its certification on any document, including laboratory reports, catalogs, advertising, business solicitations, proposals, quotations, or other materials.

G. A laboratory must make available its current certificate and corresponding scope of certification upon the request of a client, certification authority, or regulatory agency. The laboratory must not supply a copy of its current certificate without the accompanying copy of its scope of certification.

Subp. 8. **Denial.**

A. The commissioner shall deny certification if a laboratory's initial or renewal application does not meet the requirements of subpart 1 or if a laboratory's request for variance does not satisfactorily address all items in subpart 13.

B. A laboratory that has had its request for certification denied may reapply according to subpart 1. The application and all required documentation must be accompanied by repayment of applicable fees.

C. The commissioner shall not refund fees if an application is denied.

Subp. 9. **Suspension.**

A. When the commissioner determines that there are grounds for suspension, the commissioner must notify the laboratory in writing. A laboratory's certification may be suspended in total or in part for a period not to exceed 180 days and not to extend beyond the expiration date of the current certification. If a laboratory takes corrective action before the end of the suspension period, certification for the suspended fields of testing or for the base certification and fields of testing must be restored if the corrective actions satisfactorily address the deficiencies cited in the notice of suspension, except when contrary to an applicable reciprocity agreement. The laboratory shall retain certification for the fields of testing for which it continues to meet the requirements of parts 4740.2010 to 4740.2120.

B. Grounds for suspension of certification are:

(1) failure to produce acceptable results in two consecutive proficiency testing studies for the same field of testing;

(2) failure to use an approved method or to follow the method in sample analysis;

(3) failure to submit an acceptable corrective action report in response to an inspection or unacceptable proficiency testing results;

(4) failure to notify the commissioner of any changes according to subpart 15;

(5) failure of the laboratory to maintain records that demonstrate the capability of laboratory staff as required by part 4740.2099; or

(6) suspension of certification by a certifying authority with which the commissioner has a reciprocity agreement.

C. The effective date of suspension is the date that the laboratory receives the suspension notice from the commissioner. Upon receiving the notice, the laboratory must notify all clients whose samples have been received or analyzed within 30 days prior to

the notification or back to the date at which the laboratory was in compliance, whichever is greater. Notification is required for all fields of testing for which the laboratory's certification has been suspended. The notification from the laboratory must be in writing. The laboratory must submit copies of each notification to the commissioner at the time that the notification is sent to the client.

D. A laboratory that has had its certification suspended may reapply according to subpart 1. Repayment of fees is not required for reinstatement if the laboratory corrects the deficiencies within the time frame required by the commissioner, not to exceed 180 days or the expiration date of the current certification, whichever is sooner. If the laboratory fails to correct the causes of suspension within the specified time frame, the commissioner shall revoke in total or in part the laboratory's certification according to subpart 10, item A.

E. A laboratory that has had its certification suspended due to unacceptable proficiency testing results must submit acceptable proficiency testing results for the fields of testing from two successive studies to restore certification.

Subp. 10. **Revocation.**

A. When the commissioner determines that there are grounds for partial or total revocation of a laboratory certification, the commissioner must notify the laboratory in writing. The laboratory shall retain certification for the fields of testing for which it continues to meet the requirements of parts 4740.2010 to 4740.2120.

B. Grounds for partial or total revocation of certification are:

(1) failure to respond to deficiencies according to subpart 6;

(2) failure to correct the deficiencies cited in a notice of suspension within the time frame specified by the commissioner;

(3) failure to implement corrective action related to any deficiencies found during a laboratory inspection;

(4) failure to implement corrective action in response to an unacceptable proficiency testing result;

(5) failure to complete proficiency testing studies and maintain a history of successful proficiency testing studies at the frequency specified in part 4740.2070;

(6) revocation of certification by a certifying authority with which the commissioner has a reciprocity agreement; or

(7) failure to comply with applicable standards of parts 4740.2010 to 4740.2120.

C. Grounds for total revocation of a laboratory's certification are:

(1) failure to respond with a report of corrective actions or corrective action plans for deficiencies identified during an on-site inspection within 30 days of receiving the inspection notice of deficiencies;

(2) submittal of proficiency test sample results generated by another laboratory as its own;

(3) reporting sample results without qualification or notation for fields of testing for which the laboratory's certification has been suspended or for which the laboratory has not requested or received certification;

(4) misrepresentation of any material fact pertinent to receiving and maintaining certification;

(5) denial of entry during normal business hours for an inspection as required under subpart 6, unless circumstances endangering safety or welfare prohibit entry;

(6) failure to send written notification of revocation or suspension to clients within the time frame specified in this subpart;

(7) conviction of charges relating to the falsification of any report relating to a laboratory analysis; or

(8) for laboratories certified through reciprocal agreements, failure to notify the commissioner within 30 days after any enforcement action is taken by the reciprocal certifying authority.

D. The effective date of revocation is the date that the laboratory receives the revocation notice from the commissioner. Upon receiving the notice, the laboratory must notify all clients whose samples have been received or analyzed within 30 days prior to the notification or back to the date at which the laboratory was in compliance, whichever is greater. Notification is required for all fields of testing for which the laboratory's certification has been revoked. The notification from the laboratory must be in writing. The laboratory must submit a copy of each notification to the commissioner at the time that the notification is sent to the client.

E. A laboratory that has had its certification revoked must not advertise itself as certified and, when possible, must remove or replace any advertisements that indicate that the laboratory is certified.

F. A laboratory that has had its certification revoked may not reapply for certification until it has corrected all deficiencies. The laboratory may reapply according to subpart 1 and, with the application, must provide documentation of the steps taken to correct the deficiencies.

Subp. 11. **Successor in interest; recertification.** A successor in interest of a laboratory that has had its certification revoked or suspended may not apply for recertification until the end of the term for which the certification was suspended or until all conditions for reapplication after revocation are met.

Subp. 12. **Reciprocity and laboratories in other states.**

A. A laboratory in another state may request certification in Minnesota. In addition to following the application process under subpart 1, the laboratory must submit the appropriate fees with its application, unless a reciprocity agreement exists. Fees include the on-site inspection fee for out-of-state laboratories.

B. The commissioner may enter into agreements with certifying authorities of federal agencies and agencies of other states for reciprocal recognition of laboratory certification programs or portions of programs that are substantially equivalent.

C. A certification program is not considered substantially equivalent if:

(1) inspections of certified laboratories are performed at intervals exceeding three years;

(2) the certifying agency does not require an acceptable corrective action response from the laboratory as required under subpart 6; or

(3) the certifying agency is not the primary authority for necessary enforcement actions, such as suspension or revocation of the laboratory's certification.

D. When a reciprocal agreement exists, the commissioner shall certify an out-of-state laboratory that:

(1) submits an application meeting the requirements of subpart 1;

(2) submits the appropriate fees, not to include an on-site inspection fee for out-of-state laboratories;

(3) provides a copy of current certification from the reciprocal state or private or federal agency; and

(4) provides a copy of the certifying authority's most recent inspection report.

E. A laboratory certified under this subpart must notify the commissioner within 30 days after any enforcement action is taken by the reciprocal certifying authority.

F. Laboratories certified under reciprocity agreements are subject to parts 4740.2010 to 4740.2120, except the fee for out-of-state inspection under subpart 16, item D. Only fixed-base laboratories located within the boundaries of the state represented by the certifying authority may apply under a reciprocal agreement.

G. The commissioner shall provide a list of reciprocity agreements upon request.

Subp. 13. **Request for variance.**

A. The commissioner may grant a variance from parts 4740.2010 to 4740.2120. Variances from the use of an approved method may be granted according to part 4740.2060. To request a variance, a laboratory must pay the appropriate variance fee and must indicate in writing:

(1) the rule part and language for which the variance is sought;

(2) reasons for the request;

(3) alternate measures that will be taken if the request for a variance is granted;

(4) the length of time of the variance; and

(5) data to ensure analytical results of equal or better reliability.

B. The commissioner shall review information submitted with the variance request. If the laboratory proposes alternatives equivalent or superior to those requirements in the rule, shows that strict enforcement of the rule would cause undue hardship, and shows that the variance will not adversely affect the reliability of the data produced by the laboratory, the commissioner shall grant the variance provided the variance does not conflict with statutory provisions. The commissioner shall grant or deny the variance within 60 days after receipt of the request, giving the laboratory written justification for the decision. The commissioner must specify an expiration date for the variances the commissioner issues.

Subp. 14. **Voluntary withdrawal of certification.**

A. If a laboratory chooses to withdraw its application for certification or its current certification in total or in part, the laboratory must notify the commissioner in writing and specify the effective date of withdrawal.

B. The commissioner shall consider that a laboratory has chosen to voluntarily withdraw its certification if the laboratory has not submitted a complete renewal application within 90 days before the expiration date of its current certification. In this situation, the effective date is the expiration date of the laboratory's current certification.

C. By the effective date of the withdrawal of certification, in total or in part, the laboratory must notify current clients and regulatory agencies of its intent to withdraw its certification and must indicate the effective date of the withdrawal. Notification is required for all fields of testing for which the laboratory has chosen to voluntarily withdraw certification. The notification from the laboratory must be in writing. The laboratory must submit a copy of each notification to the commissioner at the time that the notification is sent to the client.

D. The commissioner shall not refund fees if a current certification is voluntarily withdrawn by the laboratory.

Subp. 15. **Duty to notify.**

A. A laboratory must notify the commissioner in writing within 30 days of a change in:

(1) the name of the laboratory;

(2) the physical location, postal mailing address, and electronic mailing address of the laboratory;

(3) the owner of the laboratory;

(4) the names and telephone numbers of a designated contact person and the laboratory director;

(5) the name of at least one managing agent with signature attested by a notarial officer;

(6) the names of supervisory professional staff responsible for the analyses;

(7) major analytical equipment; or

(8) test methods.

B. With the notification, a laboratory must provide results of proficiency testing samples, or a demonstration of capability, analyzed in the new laboratory location or analyzed under the change in laboratory owner, instrumentation, or methods.

Subp. 16. **Payment of fees.**

A. All applications or requests to change the scope of certification submitted to the commissioner for approval must be accompanied by the fee specified in Minnesota Statutes, section 144.98, subdivision 3.

B. When a laboratory requests certification for additional fields of testing at any time other than the time of initial or renewal application, the laboratory must submit fees equal to the fees for the test category in which the method or analyte is requested. The fee also applies to the addition of methods or analytes for reinstatement after revocation or denial of certification. No fee shall be assessed for the addition of fields of testing in response to a notice of availability when an application is submitted under the conditions specified in subpart 4.

C. When a laboratory requests a variance according to subpart 13, the request must be accompanied by applicable fees according to Minnesota Statutes, section 144.98, subdivision 3.

D. When a laboratory in another state requests certification in Minnesota, the laboratory must submit all applicable fees with its application, to include an out-of-state inspection fee according to Minnesota Statutes, section 144.98, subdivision 3, unless a reciprocity agreement exists between the commissioner and the certifying authority of the state in which the fixed-base laboratory is located.

E. Payment of fees must be in the form of a check, money order, or electronic transfer of funds. When payment is in the form of an electronic transfer of funds, proof of deposit must be verifiable before the date the fees are due to the commissioner.

Subp. 17. **Appeal of administrative decision.**

A. The commissioner shall notify a laboratory in writing of the reasons for a decision to suspend or revoke a certification.

B. A laboratory has 30 days from the date of receiving the decision to appeal the decision. A request to appeal the decision must:

(1) be in writing;

(2) indicate the facts the laboratory disputes;

(3) be signed by the laboratory director; and

(4) be sent to the commissioner.

C. Upon receipt of an appeal request, the commissioner shall initiate the procedure for a contested case hearing according to Minnesota Statutes, chapter 14, and rules of the Office of Administrative Hearings.

Statutory Authority: *MS s 144.97; 144.98*

History: *31 SR 446*

Published Electronically: *October 9, 2006*