

1 Department of Health

2

3 Proposed Permanent Rules Relating to General Accreditation

4 Requirements for Laboratories

5

6 Rules as Proposed (all new material)

7

CHAPTER 4740

8

DEPARTMENT OF HEALTH

9

LABORATORIES; ACCREDITATION REQUIREMENTS

10 4740.0100 PURPOSE AND SCOPE.

11 The rules in chapter 4740 contain accreditation procedures
12 and standards for laboratories that perform tests or analyses as
13 required by state or federal law.

14 4740.0110 DEFINITIONS.

15 Subpart 1. Scope. The terms used in parts 4740.0100 to
16 4740.0170 have the meanings given them in this part.

17 Subp. 2. Accreditation. "Accreditation" means licensure
18 or certification of a laboratory to perform specific tests.

19 Subp. 3. Certification. "Certification" means written
20 acknowledgment of the laboratory's demonstrated capability to
21 perform tests for a specific purpose.

22 Subp. 4. Commissioner. "Commissioner" means the
23 commissioner of the Minnesota Department of Health.

24 Subp. 5. Laboratory. "Laboratory" means a person,
25 corporation, or other entity, including a governmental entity,
26 which examines, analyzes, or tests samples.

27 Subp. 6. Licensure. "Licensure" means authorization to
28 perform laboratory tests for a purpose defined by statute.

29 Subp. 7. Out-of-control quality control result.
30 "Out-of-control quality control result" means a result from an
31 internal quality control sample that does not fall within a
32 statistically acceptable range.

33 Subp. 8. Sample. "Sample" means a substance derived from
34 a nonhuman source and collected for the purpose of analysis or a
35 tissue, blood, excretion, or other bodily fluid specimen

1 obtained from a human for the detection of a chemical, etiologic
2 agent, or histologic abnormality.

3 4740.0120 APPLICATION PROCEDURES.

4 Subpart 1. Standards. To obtain accreditation, the
5 laboratory must comply with subparts 2 to 5 and with the
6 technical standards that apply to the specific laboratory test
7 for which accreditation is sought, as specified in rule.

8 Subp. 2. Contents. The application shall include:

9 A. the address of the principal place of business or
10 headquarters;

11 B. the address and phone number of the laboratory
12 that seeks accreditation, if different than in item A;

13 C. the names of officers and the laboratory director;

14 D. written assurance that the laboratory meets the
15 standards of parts 4740.0100 to 4740.0170 and the standards that
16 apply to the specific test for which laboratory accreditation is
17 sought, as specified in rule;

18 E. the signatures of two officers or managing agents
19 of the laboratory and proof of the signatories' authority to
20 bind the laboratory; and

21 F. other reasonable information necessary to
22 determine compliance with accreditation requirements.

23 Subp. 3. Documentation. At the time of application, the
24 laboratory shall submit or have available for inspection the
25 following documents:

26 A. a current laboratory manual;

27 B. criteria for accepting and rejecting samples for
28 testing;

29 C. proficiency testing results;

30 D. internal quality assurance records;

31 E. corrective action for out-of-control quality
32 control results;

33 F. sample receipt and storage records;

34 G. equipment calibration and standardization records;

35 H. equipment repair and preventive maintenance

1 records;

2 I. personnel education and training requirements;

3 J. laboratory safety policies; and

4 K. written chain-of-custody procedures.

5 Subp. 4. Fee. The laboratory shall submit with its
6 application a nonrefundable fee, in the amount established by
7 the specific rule for the purpose or type of test for which
8 accreditation is sought.

9 Subp. 5. Inspection. The laboratory must demonstrate
10 compliance with accreditation requirements through an inspection
11 conducted by persons designated by the commissioner.
12 Inspections shall be unannounced and at a frequency established
13 by the rule specific to the purpose or type of test for which
14 accreditation is sought.

15 4740.0130 PROVISIONAL ACCREDITATION.

16 A laboratory that meets accreditation application
17 requirements shall receive provisional accreditation until an
18 on-site inspection is completed. Upon demonstration, through
19 inspections, of compliance with standards specific to the
20 purpose or type of testing for which accreditation is sought,
21 full accreditation shall be granted.

22 4740.0140 TERM OF ACCREDITATION.

23 Laboratories shall be accredited for a term of one year,
24 which shall include any period of provisional accreditation.
25 Unless a laboratory submits a timely application for renewal of
26 the accreditation, the accreditation expires without notice at
27 the end of the term.

28 4740.0150 COMPLIANCE.

29 All accredited laboratories shall immediately inform the
30 commissioner of any changes to the information required by part
31 4740.0120 and the rules specific to the laboratory test for
32 which accreditation is sought. The laboratory director must
33 inform the commissioner in writing of any changes in test
34 methodology, instrumentation, key personnel, or laboratory

1 ownership and submit revisions to the documents listed in part
2 4740.0120, subpart 3, within 14 calendar days of the change.

3 4740.0160 ACCREDITATION RENEWAL.

4 A laboratory shall submit an application for renewal of
5 accreditation with the applicable renewal fee, no later than 30
6 days before the expiration date of the current accreditation.
7 The renewal application shall contain the same information
8 required for an initial application in part 4740.0120, subpart
9 2. At the time of application for a renewal of its
10 accreditation, the laboratory shall also submit or have
11 available for inspection the documents listed in part 4740.0120,
12 subpart 3. Unless a laboratory submits a timely application for
13 accreditation renewal, the accreditation expires without further
14 notice at the end of the term.

15 4740.0170 ACCREDITATION; SUSPENSION AND REVOCATION.

16 The commissioner may, pursuant to Minnesota Statutes,
17 chapter 14, suspend, revoke, refuse to renew, condition, or
18 limit the accreditation of a laboratory upon finding that the
19 laboratory has repeatedly violated provisions of parts 4740.0100
20 to 4740.0160 or has repeatedly failed to meet standards defined
21 under the rule applicable to the specific laboratory test for
22 which the laboratory is accredited.