

STATE OF MINNESOTA
COUNTY OF HENNEPIN

BEFORE THE MINNESOTA
COMMISSIONER OF HEALTH

IN THE MATTER OF PROPOSED PERMANENT
RULES RELATING TO GENERAL ACCREDITATION
REQUIREMENTS FOR LABORATORIES

STATEMENT OF NEED
AND REASONABLENESS

The Minnesota Commissioner of Health, (hereinafter "commissioner"), pursuant to Minnesota Statutes, sections 14.05 to 14.12 and 14.22 to 14.28, presents facts establishing the need for and the reasonableness of the above captioned proposed permanent rules.

This statement of need and reasonableness demonstrates that the commissioner:

- . has statutory authority to adopt the rule,
- . has taken necessary procedural actions,
- . has determined that the rule is needed,
- . has determined that the rule is reasonable, and
- . has satisfied any other requirements imposed by law.

The commissioner will be granted increasing authority to certify and license laboratories. In anticipation of this trend, rules pertaining to licensure of laboratories performing drug and alcohol testing in the workplace will be in two sets. The first set will contain general administrative rules. The second set will consist of the technical standards which pertain specifically to drug and alcohol testing. As new accreditation programs are implemented, the standards which pertain to the specific type of laboratory test to be covered by licensure or certification may be added to Chapter 4740.

I. STATUTORY AUTHORITY

The statutory authority of the commissioner to adopt these rules is briefly noted below. The specific statutory authority for each rule is discussed in detail as part of the rule-by-rule justification.

Minnesota Statutes, section 181.953, subdivision 1, requires the commissioner to license laboratories which test samples from Minnesota employees for alcohol, drugs and drug metabolites. Authority is granted to the commissioner to:

- . set standards for licensing, suspending and revoking a license,
- . define appropriate component samples for testing,
- . set threshold detection levels for drugs, drug metabolites and alcohol,
- . list criteria for chain-of-custody procedures,
- . set annual license fees, and
- . grant licenses to laboratories licensed by a state or federal agency if that agencies standards meet or exceed those of the State of Minnesota.

II. COMPLIANCE WITH RULEMAKING PROCEDURAL REQUIREMENTS

Minnesota Statutes, sections 14.05 - 14.12 and 14.22 - 14.28, specify certain procedures which must be followed when an agency adopts or amends rules. Procedures applicable to all rules (Minnesota Statutes, sections 14.05 - 14.15) have been complied with by the commissioner. The commissioner has determined that the adoption of proposed parts 4740.0100 to 4740.0170 is non-controversial and has elected to follow procedures set forth in Minnesota Statutes, sections 14.22 - 14.28, which provide for an expedited process for the adoption of non-controversial administrative rules without holding a public hearing.

Minnesota Statutes, section 14.10, requires an agency that seeks information or opinions from persons outside the agency for adoption of rules to publish notice of such action in the State Register. This will serve to notify interested persons in the community of the opportunity to submit comments or data on the subject of the rules. A notice of solicitation of outside information or opinions appeared in the State Register, on August 17, 1987, at Volume 12, Number 7, page 294.

The adoption of these rules will not require expenditure of public money by local public bodies of greater than \$100,000.00 in either of the two years following promulgation, nor do these rules have any impact on agricultural land. (Minnesota Statutes, section 14.11, 1986.)

Pursuant to Minnesota Statutes, section 14.23, the commissioner has prepared this statement of need and reasonableness which is available to the public.

The commissioner will publish a notice of intent to adopt the rules without public hearing in the State Register and mail copies of the notice and proposed rules to persons registered with the Minnesota Department of Health pursuant to Minnesota Statutes, section 14.14, subdivision 1(a). The notice will include the following statements:

- a) that the public have 30 days in which to submit comments on the proposed rules;
- b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;
- c) giving information pertaining to the manner in which persons shall request a hearing; and
- d) that the rule may be modified if modifications are supported by data and the views submitted.
- e) other information required by Minnesota Statutes, section 14.22.

If 25 or more persons submit to the Minnesota Department of Health a written request for a hearing of the proposed rules, the agency shall proceed under the provisions of Minnesota Statutes, sections 14.131 - 14.20, and notice of hearing shall be published in the State Register.

If no hearing is required, the commissioner will submit the proposed rules and notice as published, the rules as proposed for adoption, any written comments which have been received, and this statement of need and reasonableness to the Attorney General for approval of the rules.

These rules shall become effective five working days after publication of a notice of adoption in the State Register.

III. SMALL BUSINESS CONSIDERATIONS

The impact of rules on small businesses was examined as required by Minnesota Statutes, chapter 14.115. The affect was considered by the following methods:

- . at least one of the members of the technical advisory group owns and operates a small business,
- . The Minnesota Association of Commerce and Industry reviewed preliminary drafts of the rules,
- . over thirty laboratories which have applied for transitional laboratory approval to perform drug and alcohol testing will receive copies of the rules, as they appear in the State Register, for comment,
- . and the administrative requirements for application and renewal of a license were established to simplify or consolidate application and reporting requirements.

Compliance with the "umbrella" standards for accreditation are necessary whether the laboratory is a small business or a large concern.

Impact of rules relating to technical standards and fee requirements are discussed in the statement of need and reasonableness specific to the particular laboratory test category.

IV. GENERAL STATEMENT OF REASONABLENESS

The Commissioner of Health is being granted increasing authority to regulate laboratories through licensure and certification. The purpose of this rule is to promote consistency in the accreditation of all laboratories performing tests or analyses for a purpose defined by rule or statute or pursuant to a Federal environmental regulatory program which requires certification by a state agency. Other rules will apply to laboratories according to the specific tests performed pursuant to the pertinent regulatory or federal program purposes.

The "umbrella" rule will help assure administrative consistency among various laboratory accreditation programs and will promote simplicity and efficiency internally and for our clientele.

A technical advisory group consisting of seven prominent toxicologists and scientists reviewed the rules. Members of the group included:

- . Fred Apple, Ph.D., Hennepin County Medical Center;
- . Kingsley LaBrosse, Ph.D., Medtox, New Brighton;
- . Thomas P. Moyer, Ph.D., Mayo Clinic;
- . David Ehresman, MT(ASCP), St. Paul-Ramsey Medical Center;
- . John H. Eckfeldt, M.D., University of Minnesota Hospitals;
- . Larry Bowers, Ph.D., University of Minnesota Hospitals;
and
- . S. G. Jejurikar, Ph.D., Forensic Toxicology, Bureau of Criminal Apprehension, State of Minnesota.

Preliminary drafts of the rules were sent for comment to a group made up of the Minnesota State Bar Association, Minnesota Association of Commerce and Industry, Minnesota Department of Labor and Industry, Minnesota Department of Employee Relations, American Civil Liberties Union, Employers Association, the AFL-CIO and AFSME and the principal authors of the bill.

V. RULE-BY-RULE JUSTIFICATION

4740.0100 **Purpose and Scope**

The purpose is simply that Chapter 4740 contains accreditation and licensing standards for laboratories that perform tests or analyses covered by state law.

4740.0110 **Definitions**

Terms used for these rules are defined to make the provisions of the rules clear and understandable.

4740.1020 **Application Procedures**

Subpart 1. Standards This rule is based upon Minnesota Statutes, section 181.953, subdivision 1. The commissioner must adopt rules which address standards for licensure, suspension and revocation of a license.

Subpart 2. Contents The commissioner needs identifying information including name of the laboratory, address of the laboratory, and other items in order to carry out the provisions of Minnesota Statutes, section 181.953, subdivision 1. The application form will be consistent for all accreditation programs covered in Chapter 4740.

Subpart 3. Documentation In order to confirm compliance with technical standards, the laboratory must have available for inspection the items covered in 4740.0120, Subpart 3. Certain items, such as proficiency testing results, may be required as part of the license or certificate application. The other items will be available for inspection by a person representing the commissioner.

Subpart 4. Fee The commissioner must set the fee at an amount so that total fees collected will recover the costs of administering the program, see Minnesota Statutes, section 181.95, subdivision 1(d).

Subpart 5. Inspection An on-site inspection of a laboratory is necessary to confirm statements and information received in the application process. Compliance with specific technical standards may be confirmed by examination of documents named in 4740.0120, Subpart 3.

4740.0130 **Provisional Accreditation**

Provisional certification is especially necessary in the early implementation of an accreditation program. Information submitted with the application for accreditation will indicate probable compliance. Compliance will be confirmed by on-site observations.

4740.0140 **Term of Accreditation**

The burden of application and renewal of a license or certificate is placed on the laboratory. This will clearly place the responsibility for renewal with the laboratory. We will be better able to direct our energies towards efforts directly related to inspections rather than spending disproportionate time in the renewal process.

4740.0150 **Compliance**

The laboratory is accredited based on information pertaining to test methodology, laboratory procedures and practices, instrumentation and laboratory management. Changes in these areas will require communications to determine if these changes affect laboratory data quality and accreditation status.

4740.0160 **Licensing and Certification; Renewal**

The accreditation program must be conducted using funds from license and certificate fees. A deadline for receipt of application for renewal, with fees, will help assure that adequate funds are available to administer the program at any given point in time. Automatic suspension of accreditation due to failure to submit a timely application for renewal will enable limited program resources to be channeled to the survey, compliance and review functions.

4740.0170 **Licensing and Certification;**
Suspension and Revocation

Laboratories which will not or cannot comply with accreditation standards may face suspension or revocation of the applicable accreditation. The contested case procedures required by Minnesota Statutes, chapter 14, will be followed in such instances.

9-2-88

Date

Sister Mary Madonna Ashton

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Commissioner of Health

Minnesota Department of Health

JAI:RS 5-24-88

Rev. 8/16/88:rs