

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

**THE MATTER OF PROPOSED
MINNESOTA RULES RELATING TO
EXAMINATION REQUIREMENTS FOR
X-RAY EQUIPMENT OPERATORS
PARTS 4730.5000 TO 4730.5500
GOVERNING EXAMINATION REQUIREMENTS
FOR X-RAY EQUIPMENT OPERATORS**

**STATEMENT OF NEED
AND
REASONABLENESS**

Minnesota Rules, parts 4730.5000 to 4730.5500 are proposed to implement the requirements of Laws of Minnesota, 1995, Chapter 146, related to examination for x-ray machine operators.

STATUTORY AUTHORITY TO ADOPT RULES

The authority for the commissioner of health to adopt rules regulating examinations for x-ray equipment operators is contained in Laws of Minnesota, 1995, Chapter 146, which is to be codified as M.S., section 144.121, subdivisions 5, 6 and 7.

NEED FOR REVISION OF RULES

The Minnesota Department of Health (MDH) proposes to add parts 4730.5000 to 4730.5500 to Minnesota Rules, Chapter 4730 related to ionizing radiation. The new rules govern examination requirements for x-ray equipment operators. The proposed rules are needed to implement the provisions of Laws of Minnesota, 1995, Chapter 146. This law requires that:

"after January 1, 1997 an individual in a facility with x-ray equipment for use on humans that is registered under subdivision 1 may not operate, nor may the facility allow the individual to operate, x-ray equipment unless the individual has passed an examination approved by the commissioner of health, or an examination determined to the satisfaction of the commissioner of health to be an equivalent national, state or regional examination that demonstrates the individual's knowledge of basic radiation safety, proper use of x-ray equipment, darkroom and film processing and quality assurance procedures. The commissioner shall establish by rule criteria for the approval of examinations required for an individual operating an x-ray machine in Minnesota."

The proposed rule parts 4730.5000 to 4730.5500 are necessary to clarify applicability of Laws of Minnesota 1995, Chapter 146, and to clarify responsibilities for individuals who must take the examination mandated by Laws of Minnesota 1995, Chapter 146, examination requirements that apply to any organization providing the examination, requirements for facilities using x-ray equipment and the applicability of equivalent examinations.

Several groups of individuals who operate x-ray equipment in Minnesota will be affected by the proposed rules. In predominantly medical settings such as offices, clinics and hospitals, some registered nurses and licensed practical nurses, medical assistants, chiropractic assistants, physicians' assistants, podiatric assistants, and laboratory technicians take x-rays and process x-rays. None of these professions require formal training related to the operation of x-ray equipment and x-ray film processing for their licenses, certifications or registrations. In addition, there are many medical facilities that employ other individuals to take x-ray who have not passed any examination related to the operation of x-ray equipment to take x-rays. The consequence of untrained individuals taking and processing x-rays is that patients and operators may be exposed to unnecessary radiation. Because untrained operators do not know how to use the x-ray equipment properly, they may be setting the x-ray machines so that patients are exposed to unnecessary radiation and in turn the operator may also be exposed. Additionally when untrained individuals take or improperly process radiographs, they may have to retake the x-ray thus exposing the patient to unnecessary radiation. Also, poor quality radiographs may result in medical misdiagnoses.

SMALL BUSINESS IMPACT

Minnesota Statutes, section 14.115 excludes certain businesses from the application of section 14.115 in subdivision 7, clause (3).

(3) service businesses regulated by government bodies, for standards and costs, such as nursing homes, long-term care facilities, hospitals, providers of medical care, day care centers, group homes, and residential care facilities, but not including businesses regulated under chapter 216B or 237....

The proposed rules may impact small businesses such as single or small group physician practices, dental practices, chiropractic, and podiatric practices. While the department believes that many of the potentially impacted small businesses are excluded under section 14.115, the department has considered the factors specified in section 14.115 during the development of the proposed rules.

Minnesota Statutes, section 14.115 requires that an agency consider five factors for reducing the impact of proposed rules on small business. The proposed rules will have an impact on a number of establishments that meet the definition of small business in 14.115. Many members of the advisory work group represented small business interests and participated in the drafting of the proposed rules.

The methods delineated in Minnesota Statutes, section 14.115 for reducing the impact of the rule on small business include:

- a) The establishment of less stringent compliance or reporting requirement for small businesses;
- b) the establishment of less stringent schedules or deadlines for compliance or reporting requirement for small businesses;
- c) the consolidation or simplification of compliance or reporting for small businesses;
- d) the establishment of performance standards for small businesses to replace design or operational standards required in rule; and
- e) the exemption of small businesses from any or all of the requirements of the rule.

The major purpose of these rules is to protect public health by preventing unnecessary exposure of individuals to ionizing radiation.

- a) The establishment of less stringent compliance or reporting requirement for small business is not reasonable because the proposed rules are designed to ensure that public exposure to ionizing radiation is minimized. The work group and department did consider alternatives and recognized various equivalent means as specified in part 4730.5400 to meet the requirements of law.
- b) The establishment of less stringent schedules or deadlines for compliance would be contrary to the specificity of the law that requires all persons who operate an x-ray machine on a human being to have passed an examination by January 1, 1997.
- c) Further consolidation or simplification of compliance or reporting requirements has been proposed to the extent that the department recognized in part 4730.5400 equivalent alternatives to compliance.
- d) The establishment of performance standards is the basis of the examination process. An individual, whether employed by a large or small business, must pass the examination as required by law.
- e) The exemption of small businesses from any or all of the requirement of the proposed rules would not be reasonable because no exceptions are provided for in the law with respect to the size of a business.

FISCAL IMPACT

Under Minnesota Statutes, section 14.11, subdivision 1, if a rule

will require the expenditure of over \$100,000 in either of the two following years by local public bodies, the agency adopting the rule must prepare a written statement estimating the total cost of the rule to all local public bodies.

It is very difficult to estimate how many individuals will have to take the examination mandated by Laws of Minnesota 1995, Chapter 146, and the proposed rules. The department estimates that approximately 1,600 medical facilities including chiropractic and podiatric facilities, employ individuals to take x-rays. In December 1994, 2,900 radiologic technologists were registered in Minnesota by the American Registry of Radiologic Technologists and were employed as radiological technologists. If it is assumed that statewide approximately 5,500 individuals operate x-ray equipment, given the number of medical x-ray machines registered by the MDH, and 2,900 are already qualified to operate x-ray equipment, it is estimated that approximately 2,600 persons will be affected by the proposed rules.

The estimates are very uncertain at this time because no formal survey of the number of individuals who are employed to take x-rays has been done.

It is also unclear at this time how many small businesses, i.e. facilities with fewer than 50 employees will be affected or the extent to which employees of local public bodies will be impacted by the proposed rules. Since the rules do not mandate any fees that an organization providing the examination required by the proposed rules should charge, it is difficult to estimate what the fiscal impact will be. A clinic or solo practitioner, whether a public or private entity, can choose to have their employee take responsibility for taking the examination and paying the applicable examination fee. However, they could also choose to pay for any training that their employee may need to prepare for the examination and also pay the examination fee. It is the choice of the small business or public entity whether or not to pay the fee for an employee to take the required examination. Currently the examination fee for a limited radiographic technologist license in some states is \$20-\$25.

Although the rules do not address training for x-ray machine operators, some operators may need to take some formal training in order to prepare for the examination. It is estimated that in order for an individual with no knowledge or experience with x-ray equipment to be able to pass the proposed examination, approximately 30 to 40 hours of formal classroom training may be needed. This is based on the formal training required in other states to prepare for the limited radiologic technologist license. However, that type of limited license includes more subject areas than those required under this proposed rule. The cost of approximately 30 to 40 hours of formal education through the community college system in Minnesota is approximately \$15.00 to

20.00 per hour. The individual could choose to take other types or forms of training offered in conjunction with other course work or through professional associations. The cost then could be much less.

EFFECT ON AGRICULTURAL LAND; FARMING OPERATIONS

The proposed rules will have no direct or substantial adverse impact on agricultural land. The proposed rules are not specifically designed to affect farming operations. No regulatory controls are directed at or triggered by farming operations per se -thus no additional action was taken by the MDH under Minnesota statutes 14.111.

NOTICE OF INTENT TO SOLICIT OUTSIDE OPINION: ADVISORY WORK GROUP

A Notice of Intent to Solicit Outside Opinion was published in the State Register on August 7, 1995 at 20, S.R. 239. In addition to the notice being mailed to persons on the certified agency rule list, the notices were mailed to the organizations listed in Laws of Minnesota 1995, Chapter 146. The organizations listed in the law are those which will be directly affected by the proposed rules. These organizations were also requested to publish copies of the notice in any newsletters of their organization.

The MDH, as required by Laws of Minnesota 1995, Chapter 146, convened an advisory committee with representation from all the organizations listed in the law. A list of advisory group members is attached to this Statement of Need and Reasonableness (Appendix A). The advisory committee met initially in August 1995, and subsequently in September and October 1995. The advisory committee provided advice on developing the proposed rule not only as organizations whose members will be affected by the proposed rule, but also as professionals familiar with the use of x-ray equipment.

Part 4730.5000 Applicability. This part is needed to provide a general requirement to implement Laws of Minnesota, 1995, Chapter 146, which amends Minnesota Statutes, Section 144.121, by adding subdivisions 5 to 7.

Part 4730.5050. Definition. This part is needed to clearly define who must meet the requirements of parts 4730.5000 through 4730.5500. Because several different professions require that x-rays be taken and processed, there are often several different individuals involved in the x-ray procedures. For example, a licensed professional may position a patient and actually operate x-ray equipment, but a different individual may process the film. The definition is needed to clarify that an individual involved in any aspect of taking and processing x-rays must meet the requirements of parts 4730.5000 to 4730.5500. The definition is reasonable because both the operation of the x-ray equipment and the processing of the x-ray film have the potential for exposing

patients and operators to unnecessary radiation if either the x-ray equipment or film processing is performed improperly. The intention of the rules is to assure that individuals operating x-ray equipment and processing x-ray film will be tested on their proficiency so that they can practice radiation safety and minimize unnecessary radiation exposure to themselves and patients.

Part 4730.5100. Examination requirements. This part is necessary to describe specific requirements for parties providing an examination required in Laws of Minnesota, 1995, Chapter 146.

Subpart 1. General. This subpart is necessary to describe what the examination must test and that it is the Commissioner of Health who must approve the examination. Items A through D are the areas listed in Laws of Minnesota, 1995, Chapter 146, section 1, which is codified as Minnesota Statutes, section 144.121, subdivision 5.

Subpart 2. Examination approval. This subpart is necessary to ensure that the commissioner will actually review examination questions before an examination is held.

Item A is necessary to ensure that the commissioner will have adequate time to review an examination and can determine if the examination meets the criteria established in this part. At this time it is not known how many examinations will be submitted to the commissioner for approval during 1996. However, it is expected that there may be several because individuals will have to pass an approved examination before January 1, 1997 (the date on which the law takes effect) to continue taking x-rays.

Item B is necessary to ensure that an initial examination cannot be held until it has been approved by the commissioner.

Item C is necessary to provide the commissioner with some flexibility about approving an examination that will be changed minimally after it has been approved initially. There is no intent to impose an unnecessary burden on an examination provider to have an examination approved every time it is held. However it is important for the commissioner to have the opportunity to review new questions when they are to be used in an examination after it has been initially approved.

Subpart 3. Availability of examinations. This subpart is necessary to ensure that all individuals who will have to take an examination in order to take x-rays after January 1, 1997 will be able to have the opportunity to take an examination. If an individual fails an examination he or she may be able to take the examination again and still be able to meet the January 1, 1997 requirement.

Subpart 4. Reporting examination results. This subpart is necessary to ensure that an organization holding an examination will have a reasonable time to report the results to the

commissioner. It also ensures that the commissioner will be informed about which individuals passed or failed the examination. This is necessary because the Commissioner is responsible at the time of an x-ray facility inspection for checking that all individuals taking x-rays have met the requirements in parts 4730.5000 to 4730.5200 or part 4370.5400.

Subpart 5. Notice to individual. This subpart is necessary to ensure that an individual who has taken an examination is notified of the result within a reasonable time.

Item A is necessary to ensure that the individual knows that he or she has passed or failed the examination so that he or she may if necessary, make arrangements to retake the examination.

Item B is necessary to ensure that if an individual has failed an examination that the individual can address the areas which the individual failed in the examination so that he or she can prepare adequately for retaking the examination.

Subpart 6. Examination security. This subpart is necessary to ensure that an individual cannot have someone else take the examination for him or her.

Subpart 7. Passing level. This part is necessary to notify an examination provider that the passing level must be seventy percent. This is a passing level generally accepted among testing organizations.

Subpart 8. Closed book examination. This subpart is needed to ensure that the examination will be a closed book test. It is reasonable to require this examination method because closed book tests are a well established and accepted form of testing.

Subpart 9. Validity standards. This subpart is necessary to ensure that an examination meets nationally accepted validity standards. The American Psychological Association Standards for Educational and Psychological Testing are widely used for all kinds of professional licensing, certification and registration examinations. The American Psychological Association Standards for Educational and Psychological Testing are easily available at the state Law Library and can also be purchased.

Subpart 10. Examination questions. This subpart is necessary because it provides in Item A guidance to a test provider on the acceptable number and type of questions. At least 75 multiple choice questions is reasonable for this type of examination. Several limited license examinations for x-ray operators in other states use between 75 to 100 multiple choice questions.

Item B is necessary to ensure that the examination provider includes the highest percent of questions on radiation safety. This

topic area is the most important area for an individual to be familiar with. There was general agreement among members of the advisory work group that the main emphasis of the examination should be on radiation safety.

Item C is necessary to ensure that an examination provider will not use the same questions each time an examination is held. Varying and reordering questions on each examination provides for examination security.

Subpart 11. Examination content. This subpart is necessary to ensure that the examination required by Minnesota Statutes, Section 144.121 includes information to address the topic areas listed in part 4730.5100 and to test an individual's knowledge of those topic areas. The work group carefully reviewed examination content from other states' x-ray operators limited license examinations. These included the states of Oregon, Florida, Montana, Arizona, Washington and Delaware. The list of topics were found in the other states' examinations and were agreed to by all representatives on the advisory work group.

Item A is necessary because it is critical that an examination include an adequate list of topics that test the fundamental knowledge of radiation safety. The list of subjects in this item was discussed at great length by the advisory work group. It was the most difficult list to compile, since the work group represented different professions who perform different types of x-rays. It was critical that consensus be reached about topics that are acknowledged as necessary to test an individual's basic knowledge about radiation safety that would apply in all settings where x-rays are performed. The work group carefully reviewed examination content on radiation safety from other states' x-ray operator limited license examinations. The list of topics in Item A were agreed to by all representatives on the advisory work group.

Item B is necessary to ensure an adequate list of topics to test an individual's knowledge of the proper use of x-ray equipment. When an individual does not understand how to properly use x-ray equipment, a patient and operator may be unnecessarily exposed to radiation.

Item C is necessary to ensure an adequate list of topics to test an individual's knowledge of darkroom and film processing. If an individual does not understand how to process x-ray film it is likely that x-rays may have to be retaken which means that both patient and operator may be exposed to unnecessary radiation.

Item D is necessary to ensure an adequate list of topics to test an individual's knowledge of quality assurance procedures for operating x-ray equipment and processing x-rays. If an individual does not understand quality assurance procedures, an individual will not be able to identify problems with x-ray equipment or film

processing. This means that a patient and operator may be exposed to unnecessary radiation because the operator is unable to identify problems, and it is likely that x-rays may have to be retaken which also means that both patient and operator may be exposed to unnecessary radiation.

Part 4730.5200 Requirements for facilities using x-ray equipment. This part is necessary to ensure that the registrant of a facility with x-ray equipment understands the registrant's responsibility with regard to who may operate x-ray equipment.

Item A is necessary to ensure that the registrant may not allow anyone who has not met the requirements in parts 4730.5000 to 4730.5200 or part 4730.5200, or part 4730.5400 to operate x-ray equipment.

Item B is necessary to ensure that the registrant is aware that documentation verifying that every individual operating x-ray equipment in the facility has met the applicable requirements is available for inspection.

Part 4730.5300 Exemptions. This rule part is necessary to delineate which individuals may operate x-ray equipment without meeting the requirements in part 4730.5000 or 4730.5500. The Minnesota Statutes that provide for licensure of physicians, chiropractors, podiatrists, osteopaths and dentists all provide general language that allows licensed individuals to take x-rays. There is no reason to duplicate examination requirements to test proficiency in taking x-rays when there are provisions already in place.

Part 4730.5400. Equivalent examinations.

Subpart 1. General. This part is necessary to address the requirement in Laws of Minnesota, 1995, Chapter 146, amending Minnesota Statutes 144.121 by adding subdivisions 5 through 7, that provides for equivalent examinations. All the examinations in subparts 2 through 8 require considerably more knowledge of radiation safety, proper use of x-ray equipment, darkroom and film processing procedures and quality assurance procedures than the examination required under parts 4730.5000 to 4730.5200.

Subpart 2. Licensed dental hygienist examination. This subpart is necessary to state that the licensure examination for dental hygienist qualifies as an equivalent examination to that required in parts 4730.5000 to 4730.5200.

Subpart 3. Registered dental assistant examination. This subpart is necessary to state that the registration examination for dental assistant qualifies as an equivalent examination to that required in parts 4730.5000 to 4730.5200.

Subpart 4. Limited dental radiographic examination. This subpart is necessary to state that the limited dental radiographic examination

for dental assistant qualifies as an equivalent examination to that required in parts 4730.5000 to 4730.5200.

Subpart 5. Radiologic technologist registration examination. This subpart is necessary to state that the radiologic technologist registration examination for radiologic technologist qualifies as an equivalent examination to that required in parts 4730.5000 to 4730.5200.

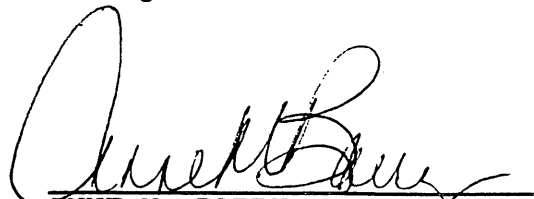
Subpart 6. Chiropractic radiologic technologist registration examination. This subpart is necessary to state that the chiropractic radiologic technologist examination qualifies as an equivalent examination to that required in parts 4730.5000 to 4730.5200.

Subpart 7. Radiologic technologist license from other United States jurisdictions. This subpart is necessary to clarify that an individual with a full or limited license as a radiologic technologist from another United States' jurisdiction may request the commissioner to determine if the license examination meets the requirements of part 4730.5000 to part 4730.5200.

Subpart 8. Other professional registrations. This subpart is necessary to clarify that an individual who has passed a registration examination that addresses the requirements in part 4730.5100, but which has not been deemed an equivalent examination under part 4730.5400, may request a determination of equivalency according to the procedures and criteria in the Minnesota Department of Health variance procedures, parts 4717.7000 to 4717.7050. It is reasonable for variance procedures to have to be followed for examinations not currently known to address radiologic information.

Part 4730.5500 Individuals operating x-ray equipment during training. This part is necessary to clarify that individuals participating in training courses for the professions listed in this part may operate x-ray equipment without having to take the examination required under part 4730.5000. When individuals are participating in training courses for the various professions listed in this part they only take or process x-rays under the supervision of a licensed or registered professional.

Date: *November 29, 1995*


ANNE M. BARRY
Commissioner of Health