1/12/93

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of Proposed Rules of the Minnesota Department of Health Relating to Ionizing Radiation, parts 4730.1475, 4730.1510, 4730.1655, 4730.1691, 4730.1750, 4730.1950, 4730.2050 and 4730.2150.

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Department of Health is proposing amendments to the above captioned rule parts contained in chapter 4730. Minnesota Rules Chapter 4730 relating to sources of ionizing radiation was extensively revised by the department in 1991 to address changes in federal standards for equipment and to add reporting, shielding and quality assurance provisions.

Provisions relating to x-ray equipment became effective September 10, 1991. Provisions relating to imaging quality assurance became effective December 10, 1991. Subsequently the department received complaints from representatives of the regulated community primarily about the adopted quality assurance rules. Some portions of the adopted quality assurance rules were then delayed by the 1992 legislature. Chapter 444 of Laws of Minnesota 1992 was adopted in April 1992 and delayed implementation of quality assurance rule parts, except those for mammography, fluoroscopy, therapy, tomography, computed tomography, cinefluorography and cardiac catheterization. Chapter 444 mandated that the commissioner undertake a review of portions of the adopted quality assurance rules as well as consult with various interested parties. Chapter 444 specified:

> Subdivision 1. [DELAY OF APPLICATION OF PARTS OF EXISTING RULES.] Except as they relate to mammographic procedures, Minnesota Rules, parts 4730.1655; 4730.1670; 4730.1675, subpart 1; 4730.1688; 4730.1690, subpart 1; and 4730.1691, subparts 1 to 3, 4, items A to I and K, subparts 7, 9, and 11, items A to D and F, and subpart 12 are not effective before July 1, 1993. Unless amended pursuant to subdivision 2, all of the rules cited in this subdivision are effective July 1, 1993.
>
> Subd. 2. [RULEMAKING.] The commissioner of health shall review the rules listed in subdivision 1 in order to determine their appropriateness for and application to medical, dental, chiropractic, podiatric, osteopathic, and veterinary medicine facilities. As part of this

review the commissioner shall consult with those health-related licensing boards defined in section 214.01 which are subject to the provisions of the ionizing radiation rules, and the commissioner shall also consult with representatives of the affected health care professions.

As a result of consultation with the interested parties specified in chapter 444, as well as other parties who have commented on or expressed interest in the rules, the department is proposing amendments to the adopted rules. In addition to amendments to the delayed quality assurance provisions, the department is also proposing technical amendments to adopted chapter 4730 that were generated by department staff. In the course of implementation of chapter 4730 department staff identified rule provisions necessary for clear administration or to correct technical errors.

Statutory authority to adopt rules.

In addition to the authority to undertake rulemaking specified in Laws of Minnesota 1992, chapter 444, section 1 (subdivision 2), authority for the proposed rules is found in Minnesota Statutes, section 144.05, paragraph (c); section 144.12, subdivision 1, clause (15); and section 144.121.

Notice of Solicitation.

A notice of intent to solicit outside opinion on revisions to the adopted rules was published in the January 4, 1993 State Register (Volume 17, Number 27) at 17 S.R. 1717.

As required by Laws of Minnesota Chapter 444, subdivision 2, prior to initiating rulemaking, the department consulted with medical, dental, chiropractic, podiatric, and veterinary medicine facilities as well as representatives of the health-related licensing boards defined in Minnesota Statutes, section 214.01. During the summer and fall of 1992, the department queried, and when requested, met with representatives of the following groups to ascertain their concerns about the adopted quality assurance rules. Staff either received letters from, or made telephone contact with all the parties. Those parties indicated with an asterisk had one or more meetings with department staff.

Board of Medical Examiners
Board of Nursing
Board of Podiatry
* Board of Dentistry
Board of Veterinary Medicine
* Minnesota Radiological Society
* Minnesota Medical Association
Minnesota Academy of Family Physicians
* Minnesota Dental Association
Minnesota Dental Hygiene Association
Minnesota Academy of Physician Assistants

* Minnesota Society of Radiologic Technologists
Minnesota Board of Chiropractic Examiners
* Minnesota Chiropractic Association
* Minnesota Veterinary Medicine Association
Minnesota Hospital Association
* Minnesota Podiatric Association

Effect on agricultural land

The adoption of these rules will not have a direct adverse impact on agricultural land (Minnesota Statutes, section 14.111).

Fiscal impact

The adoption of the proposed rule amendments will not require the expenditure of public money by local public bodies of greater than $100,000 in the two years following promulgation. In conjunction with the overall proposed revision of chapter 4730 in 1991, the Minnesota Department of Health prepared a fiscal note estimating the annual cost of the proposed rules to state and local public bodies, pursuant to Minnesota Statutes, sections 3.982, 14.11 and 15.065.

The net impact of these proceedings is primarily to clarify existing requirements, provide additional options for compliance or in some cases, reduce fiscal impact via reduced test frequencies.

Small business considerations

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, podiatric and veterinary 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 amendments.

Minnesota Statutes, section 14.115 requires that an agency consider five factors for reducing the impact of proposed rules on small business. According to Minnesota Statutes, section 14.115, a small business is an entity, including its affiliates, that (a) is independently owned and operated; (b) is not dominant in its field;

and (c) employs fewer than 50 full-time employees or has gross annual sales of less than $4 million.

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

A. the establishment of less stringent compliance or reporting requirements for small businesses;

B. the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

C. the consolidation or simplification of compliance or reporting requirements;

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 the requirements of the proposed rules.

The proposed amendments to the rules must balance the proposed amendments as necessary and reasonable to protect public health against the benefits of reducing costs to small businesses.

A. These proceedings do not open existing reporting provisions. They remain necessary and reasonable as adopted.

B. The department has proposed reducing the schedule for dental and radiographic equipment calibration from annual to biennial. The calibration schedule is the same for all dental and radiographic facilities. However, regardless of size patients and employees must be protected from unnecessary ionizing radiation exposure.

C. These proceedings do not open existing reporting provisions for consolidation or simplification. The existing provisions remain necessary and reasonable as adopted.

D. Whenever possible the department establishes performance standards and provides flexibility to regulated parties to develop methods or procedures to achieve them. The proposed amendments provide additional options for compliance with quality assurance testing devices and safety and training documents. Flexibility for facility and system specific training is provided.

E. The proposed rules are necessary to protect the public from unnecessary exposure to ionizing radiation. It would not be reasonable to protect only the patients, employees or public from exposure at large businesses. The consumers and employees of small business services must also be protected.

Submission to LCRAR

In accordance with Minnesota Statutes, section 14.131 and 14.23, the department sent a copy of the statement of need and reasonableness to the legislative commission to review administrative rules before the rule was published in the State Register.

Statement of need and reasonableness; justification of rule part.

4730.1510 REGISTRANT'S SAFETY REQUIREMENTS.

Subp. 4. **Procedures and safety instruction.** Regulated facility registrants expressed concern that the instruction on safety and procedures specified in subpart 4 were not necessary and employees were already trained through educational, certification or registration programs. While the department recognizes the general training and instruction many employees receive for licensure, registration or certification, such training and instruction is not specific to the facility or specific system being operated. The purpose of subpart 4 is to ensure that employees are instructed on safe operating procedures, emergency procedures for malfunctioning equipment, and quality assurance procedures specific to a facility and particular x-ray system. The registrant of the system is responsible for ensuring that the initial training takes place and that at least annually consideration is made to retrain in areas that may have changed or where deficient performance is noted. The subpart, while specific in requiring that the instruction take place, is broadly written to allow for individual facility discretion. The proposed amendments are necessary to clarify that the training provided is to be specific to the individual facility and to the specific x-ray system being operated. It is reasonable that staff be familiar with procedures developed by a registrant in the facility. This provision is also reasonable in that it applies to all personnel operating x-ray systems. While some practices require licensed, registered, or certified operators or technicians, that is not the case for all facilities or practices. There is no state education requirements for x-ray machine operators. This provision ensures that those persons hired to operate an x-ray machine receive training from the registrant of that facility, in safe operating procedures.

Subp. 8. Holding. The existing rule provides that no human routinely hold a film cassette, intraoral film, or the patient without benefit of lead protection. The proposed clarification is necessary to ensure that in those nonroutine cases where the patient must hold a film cassette, protection is provided for the patient in the area that is not of clinical interest. In the case of intraoral film, there may be the the occasional, nonroutine situation where the patient may have to assist in holding the film. Mechanical holding devices such as bite blocks, film holders or

tongue depressors with film taped to it, may be used. As specified in part 4730.1950, the film must not routinely be held by hand.

Subp. 10. Radiological practice standards.

Item F. The proposed amendments specified in subitems (1) to (3) are necessary to clarify film processing procedures. A performance standard for film processing is specified in subitem (1). Subitems (2) and (3) clarify what the department believes is a common sense issue. When processing film, it is necessary that the instructions of the manufacturer of the film be followed for the film processing time and temperature for the film. The chemical manufacturer's instructions for mixing the chemicals used to process film must be followed. It is reasonable to mandate that the processor follow the instuctions of the manufacturer in either case to ensure consistency throughout the processing procedure.

Item H. This amendment is necessary to provide an exception for systems that routinely are used at a distance from the skin of less than 30 centimeters. Failure to provide an exception was an oversight. The excepted systems include fluoroscopes, dental intraoral, dental panoramic and computed tomography systems. This exception is reasonable in that it reflects current practice and is consistent with the designed use of the specific systems.

4730.1655 REQUIRED QUALITY ASSURANCE PROGRAM PROCEDURES.

Subp. 3. Quality control measurements for all diagnostic x-ray facilities. Two additional documents that could be used as information sources on quality assurance programming are proposed. The dental community requested that the additional publications be permitted for the dental community as a quality assurance program reference. It is reasonable whenever possible to provide the regulated community with a variety of options for compliance with rule provisions. The quality assurance publications recommended by the dental community and developed by Roger L. Burkhart for the United States Department of Health, Education and Welfare, Public Health Service, Food and Drug Administration are comparable to that developed by the National Council on Radiation Protection and Measurements in Report #99. Dr. Burkhart's publications are specifically oriented to the diagnostic radiology facility and to the small radiology facility.

4730.1691 DIAGNOSTIC QUALITY CONTROL TESTS FOR A QUALITY ASSURANCE PROGRAM.

Subp. 2. Automatic processing. Items A and B.
Subp. 3. Manual processing. Items A and B.

The proposed clarification to subpart 2, items A and B and Subpart 3, items A and B on darkroom fog and sensitometry and densitometry with the addition of the words "exposed on-site at the time of

test" is necessary to ensure that any preexposed film used in testing film is exposed at the facility just prior to the test. There have been instances where preexposed film has been used that was exposed in quantity outside of the facility weeks prior to use. Undeveloped exposed film images have a short shelf life before image quality begins to deteriorate. To ensure an accurate and consistent exposure comparison, the film must be exposed on-site at the time the test is performed.

Subp. 4. All diagnostic radiographic tubes; required when applicable. Application of this rule part was delayed by Laws of Minnesota, chapter 444. Subsequent consultation with the parties specified in Laws of Minnesota, Chapter 444, indicated concern with the frequency for the performance of the calibration tests in this subpart. Report #99 of the National Council on Radiation Protection and Measurements was the basis for the adopted quality assurance tests and frequencies. Report #99 recommends testing annually or semi annually. The department, in 1991, proposed an annual test frequency. Though annual and semi-annual testing would have been consistent with NCRP recommendations, annual testing was proposed to reduce the number of times an equipment representative or physicist would have to be called in to perform tests. Consultation on the delayed rule provisions with industry representatives prompted recommendations to change the testing frequency from "annually" to "biennially". The chiropractor's association representive suggested "every three years" but the representative indicated biennially would be acceptable. In response to comment received on the delayed rules, the department is therefore, proposing to revise the adopted rules, to require testing biennially as requested by the regulated industry representatives.

In item J, the department proposes to add clarifying language to make this item consistent with the modification proposed in part 4730.1750, subpart 15, item C. The calibration test measures kVp accuracy. For federally certified equipment, the variation must be within the limits specified by the manufacturer. For noncertified equipment, it is within five percent of the indicated kVp as the adopted rule specifies. The adopted five percent provision was consistent with NCRP recommendations in Report #99, Appendix A, Table A.2 (page 195).

Subp. 5. For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators. Consultation with regulated industry representatives prompted recommendations for a change in the test frequency for fluoroscopic system calibration from annually to biennially. In response to comment received on the delayed rule parts, the department proposes to revise the adopted standard to require biennial testing. This testing frequency would be consistent for the frequency for other diagnostic radiography systems which have a similar dose output. The addition of the high contrast test in item G is necessary to

make the testing protocol consistent with NCRP test procedures for fluoroscopic equipment. NCRP Report #99 (page 208, table A.8) recommends high contrast tests as "essential" for fluoroscopic systems. In Table 8.3 of NCRP Report #99, it is further recommended that the test performance criteria be center 40 and edge 35 (copper mesh wires per inch) for a 15 centimeter (six inch) intensifier and center 35 and edge 30 (copper mesh wires per inch) for a 23 centimeter (nine inch) intensifier. The minimum test performance criteria specified in item G is reasonable because it is consistent with performance criteria of a nationally recognized organization.

Subp. 6. For facilities with mammography systems. Item D. The modifications proposed for subpart 6, item D are necessary to clarify the existing standard and make it consistent with the performance standard specified by the American College of Radiology (ACR) for the accreditation of mammography programs. The ACR has adopted criteria for a phantom image for testing mammography systems. The phantom is designed to simulate a 4.5 centimeter compressed breast. Various artifacts, fibrils, specks and masses are immersed in a wax insert. The wax insert is encased in a lucite block. An exposure is made of the block and the resulting image is evaluated to determine how capable the x-ray system is able to record information. Mammography systems must be capable of picking up very small abnormalities in breast tissue. Early detection of small abnormalities is essential to ensure prompt diagnosis of cancerous tissue. Specifications titled "Technical Specifications for Mammography Accreditation" are for breast phantom devices and are contained in the ACR's "Mammography Accreditation Program." The phantom specifications are proposed for incorporation into the proposed rules. Incorporation of the ACR criteria for a phantom image is reasonable because it provides a consistent testing mechanism that is nationally recognized. The minimum performance criteria specified is consistent with the recommendations of the ARC. Phantom image evaluation is now required by the states of Utah, Michigan, Arkansas, Maine, New York, Oklahoma and Rhode Island.

Subp. 10. For facilities with interventional study and vascular imaging systems. The department is proposing to modify the heading of subpart 10 to clarify applicability to all interventional and vascular imaging systems, not just those relating to cardiac catheterization. This is a reasonable modification since similar systems are used to visualize other parts of the body and the same kind of tests are employed to ensure proper imaging results. Interventional studies and vascular imaging tests must continue to be performed semi-annually. The tests specified in subparts 4 and 5 (item I) are proposed for consistency with current practice. An annual test frequency for these systems is necessary to specify in item I because the radiation exposure is of a higher dose and more lengthy than from conventional fluoroscopy.

Subp. 11. For facilities with dental intraoral systems. The testing frequency is proposed for revision from annual to biennial for the same reasons as indicated for subpart 4. Item E is proposed for modification to make this item consistent with the modification proposed in part 4730.1750, subpart 15, item C. The calibration test measures kVp accuracy. For federally certified equipment, the variation must be within the limits specified by the manufacturer. For noncertified equipment, it is within five percent of the indicated kVp as the adopted rule specifies. A new item G is proposed for addition to subpart 11 to clarify what the department expects in the way of a fog test for dental intraoral systems. The test proposed, test interval and minimum performance criteria are the same as that use for automatic processing and manual processing for all diagnostic systems.

Subp. 12. For facilities with dental extraoral systems including panoramic systems. Item A is proposed for modification to include alternatives to the sensitometry and densitometry devices specified in subparts 2, item B and subpart 3, item B. The dental industry recognizes and uses other devices called step wedges or dose normalizing and monitoring devices, that may be used to consistently test image quality. These devices are dental system specific are currently acceptable to the department for dental systems. It is reasonable, where alternative options are available and recognized that they also be specified. A new item C is proposed for addition to subpart 12 to clarify what the department expects in the way of a fog test for dental extraoral systems. The test proposed, test interval and minimum performance criteria are the same as that used for automatic processing and manual processing for all diagnostic systems.

4730.1750 GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIOGRAPHIC SYSTEMS.

Subp. 15. Additional requirements applicable only to certified X-ray systems. It is necessary to amend the wording in item C to clarify the nature of the technique factor deviation. In some cases the manufacturer has specified limits. Where that occurs, those should be the standard. However, where none are specified then the deviation must have a coefficient of variation of no more than five percent. A variation of no more than five percent is consistent with the minimum performance criteria for kVp accuracy specified in adopted part 4730.1691, subpart 4, item J, and item A of this subpart 15.

4730.1950 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS.

Subp. 4. Safety controls. Item A is proposed for amendment to clarify that the provision prohibits the routine holding of film. There may be individual or exceptional instances where intraoral film, as in the case of endodontics where rubber dams are used, where the patient may need to hold film. In most cases the film is

held with a holder or bite block.

Item C is proposed for repeal. The output from dental intraoral systems does not mandate lead apron shielding of the gonadal area of patients because the direct exposure area is not near the gonads. Some dentists provide shielding during exposures because their patients expect it, but this is not necessary.

4730.2050 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS.

Subpart 1. Applicability. Item C is proposed for addition to this subpart to clarify that when exposures are made using dental intraoral equipment, the equipment and safety standards applicable to the use of dental intraoral equipment shall apply. This is a reasonable clarification because the same equipment is used, whether it be used on a human patient, or a animal subject. In both cases the equipment must be used and function properly and safely to prevent unnecessary exposure to both employees, the public and pet owners who may be asked to assist with radiographic procedures.

Subp. 2. Beam limitation. The modification to item A is necessary for clarification. As adopted, the item could be construed to mean that the collimator must merely be available. That is not the intent. The intent is to apply to use.

Because x-ray systems used by veterinarians are similar to those of general purpose stationary x-ray systems used for medical diagnostic purposes (part 4730.1850, subpart 3, item B) it is necessary to ensure that methods are in place to provide for the visual definition of the x-ray field. The method in proposed Item B and the proposed modification to item C, subitem (4) provide for the determination of the accuracy of the x-ray dimensions and other components in the beam limiting system prior to exposure. The method and indicators are needed to limit exposure to employees and the public and confine exposure to the area of clinical interest.

4730.2150 FLUOROSCOPIC X-RAY SYSTEMS.

Subp. 11. Control of scattered radiation. Item A prescribes the use of shielding to control scattered radiation. The proposed modification is intended to allow for various means to attenuate the scattered radiation and provide for a performance standard. Attenuation by at least 70 percent falls within the attenuation provided by various devices. The department has tested for scattered radiation and found that the materials routinely used by registrants in facilities provides for attenuation in the range of 80 to 90 percent. The threshold proposed by the department provides for some fluctuation in dose. The department believes that most facilities will easily be able to comply with a 70 percent attenuation.

REPEALER.

Part 4730.1475 is proposed for repeal. The existing provision is identical to existing part 4730.0850. Repeal is necessary and reasonable to reduce redundancy and duplication.

References

The following referenced material is available at the Minnesota Department of Health, Barr Reference Library, or through the Minitex Interlibrary Loan System.

Roger L. Burkhart, Ph. D. United States Department of Health, Education and Welfare, Public Health Service.

"Quality Assurance Program for Diagnostic Radiology Facilities" HEW Publication (FDA) 80-8110, February 1980.

"A Basic Quality Assurance Program for Small Radiology Facilities," HEW Publication (FDA) 83-8218, 1983.

Code of Federal Regulations, title 21, section 1020.31.

National Council on Radiation Protection and Measurements. Report No. 99. "Quality Assurance for Diagnostic Imaging Equipment," December 30, 1988. 7910 Woodmont Avenue, Bethesda, Md. 20814.

STATE OF MINNESOTA

MINNESOTA DEPARTMENT OF HEALTH

In the Matter of Proposed Rules of the Minnesota Department of Health Relating to Ionizing Radiation, parts 4730.1475, 4730.1510, 4730.1655, 4730.1691, 4730.1750, 4730.1950, 4730.2050 and 4730.2150.

STATEMENT OF NEED AND REASONABLENESS

Date: January 12, 1993

Marlene E. Marschall
Commissioner of Health