

May 11, 2007

State of Minnesota
Minnesota Department of Health
Environmental Health Division
Indoor Environments and Radiation Section

Draft Statement of Need and Reasonableness

In the Matter of the Proposed Permanent Rules Governing Sources of Ionizing Radiation,
Minnesota Rules, Chapter 4732.

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MINNESOTA DEPARTMENT OF HEALTH

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MINNESOTA DEPARTMENT OF HEALTH

STATEMENT OF NEED AND REASONABLENESS

Possible Repeal of Rules Governing Ionizing Radiation, Minnesota Rules, Chapter 4730 and Replacement with Proposed Rules Governing Ionizing Radiation, Minnesota Rules, Chapter 4732.

INTRODUCTION

The Minnesota Department of Health (MDH) regulates sources of ionizing radiation to reduce radiation exposure. Since there are both benefits and consequences to radiation exposure, it is essential that steps be taken to limit the exposure of the human body to unnecessary radiation exposure. Even when precautions are taken, radiation can have a negative impact on a human body. For example, radiation can cause cellular mutations that could result in cancer, cataracts, or other health related problems. When exposed to radiation, the human body may be able to repair some of the damage, but since damage may also occur at a cellular level (e.g. affecting the DNA), not all of the damage may be repaired. Additionally, although certain health problems may develop quickly, sometimes, effects may not be seen for years. Generally, development of some cancers may take 20 years or more.

Accordingly, it is critical that safety precautions be used to protect against unnecessary ionizing radiation. These proposed rules set out procedures to protect workers who operate radiation-producing equipment, patients receiving "controlled" exposures of ionizing radiation for either diagnostic or therapeutic purposes, and people indirectly exposed to sources of ionizing radiation. For example, unnecessary exposure may result when individuals who assist in holding patients while taking radiographs or others (e.g., family members, other staff) come in to close proximity of ionizing radiation.

There are approximately 12,000 registered radiation-producing pieces of equipment in 4291 registered facilities throughout Minnesota. Of this number, 194 facilities have industrial applications. Industrial pieces of radiation-producing equipment are located in bottling plants, paper mills, and manufacturing facilities of all types. The remainder of the radiation-producing equipment is used for various medical applications. The radiation-producing equipment is located in hospitals, clinics, dental, veterinary, chiropractic and podiatric offices.

The MDH has been regulating sources of ionizing radiation since Minnesota Rules Chapter 4730 was first adopted in 1971. The current rules relating to x-ray equipment were implemented in 1990. MDH has updated Chapter 4730 several times with the latest update in 1999. These changes were made to address evolving technology and associated health and safety concerns. Unfortunately, this has resulted in a disorganized rule that is difficult for the regulated community to follow. Moreover, Chapter 4730 has now become inconsistent with radiation

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protection standards found in Minnesota Rules Chapter 4731, regulations in neighboring states and nationally recognized standards. For example, Chapter 4730 requires monitoring for occupational workers if they reach 25% of their occupational dose limit. Chapter 4731, however, indicates the workers must be monitored if they are at 10% of their occupational dose limit. The conflicting rules from the MDH have resulted in confusion for those facilities that have both ionizing radiation equipment and radioactive materials. Equally as important, Chapter 4730 needs to be modified to be consistent with federal regulations and to address newer technological changes that have occurred since 1999.

In view of the effort required to change Chapter 4730, the radiation program consulted with the Minnesota Office of Revisor of Statutes (Revisor) to try and determine the best approach. These numerous changes to Chapter 4730 have resulted in a disorganized rule that is difficult for the regulated community to follow. Accordingly, the Revisor agreed that the best approach was to repeal Chapter 4730 and replace it with a new Chapter 4732. This would allow the MDH to address federal equipment standards, emerging technology, and operation of radiation-producing equipment.

In 2004, the MDH established an Advisory Group consisting of both regulated as well as other interested parties to review the proposed rules. Participants of the Advisory Group included representatives of the medical, chiropractic, dental, podiatry, veterinary, and research communities; members of various licensing boards and associations; x-ray service providers; and interested persons who operate x-ray equipment. The two main concerns identified by the Advisory Group were that Chapter 4730 had become disorganized and difficult to follow, and that it needed to be consistent with the radiation standards found in Chapter 4731. The MDH worked closely with the Advisory Group to address these concerns and develop proposed Chapter 4732.

The proposed Chapter 4732 includes federal performance standards for radiation-producing equipment. Chapter 4732 also includes requirements for shielding in facilities for radiation protection of employees and the public, new levels for personnel monitoring, and a retake or reject analysis to encourage users to keep radiation doses as low as is reasonably achievable and ensure diagnostic images.

The proposed rules that relate to equipment performance incorporate language from the Code of Federal Regulations, Title 21. Other portions of the proposed rules were developed using "The Suggested State Regulations for Control of Radiation," (SSRCR) Volume 1, Ionizing Radiation, from the Conference of Radiation Control Program Directors (CRCPD). The SSRCR is designed to provide guidance for the development of state rules. The MDH, also relied on other sources to develop rules in areas for which the SSRCR standards have lagged behind the changes in technology or use.

Other parts of the proposed rules are based on or refer to guidelines for protection against ionizing radiation that are based on reports developed by the National Council on Radiation Protection and Measurements (NCRP). The NCRP is a nonprofit corporation chartered by Congress in 1964 to serve the public interest by facilitating and stimulating cooperation among national and international organizations concerned with scientific and related aspects of radiation

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in protection and measurement. The NCRP regularly prepares and updates reports related to development of rules for specific applications. The reports used in the development of the proposed rules are cited in the attached bibliography.

Parts of the proposed rules are based on the American Association of Physicists in Medicine (AAPM), 1994, Report 13 "Physical Aspects of Quality Assurance in Radiation Therapy," and American Institute of Physics, 1994, Report 40 "Comprehensive QA for Radiation Oncology."

Finally, some of the rules are based on regulations found in neighboring states. These were used to provide consistency within our geographical region and benefit facilities that also conduct business in neighboring states. These proposed amendments are designed to enhance the health and safety of the public.

ALTERNATIVE FORMAT

Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, Braille, or cassette tape. To make such a request, please contact:

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TTY users: (651) 201-5797

STATUTORY AUTHORITY

All sources of statutory authority were adopted and effective prior to January 1, 1996, so Minnesota Statutes, section 14.125, does not apply. The MDH is proposing to repeal Minnesota Rules, Chapter 4730 and replace it with proposed Chapter 4732.

Generally, Minnesota Statute § 14.06 is an agency's standing grant of authority to adopt procedural rules. Specifically, however, the MDH's authority to adopt rules governing "sources of radiation" is set forth in Minnesota Statutes § 144.12, subdivision 1, which provides that:

[t]he commissioner may adopt reasonable rules pursuant to chapter 14 for the preservation of the public health. The rules shall not conflict with the charter or ordinance of a city for the first class upon the same subject. The commissioner may control, by rule, by requiring the taking out of licenses or permits, or by other appropriate means any of the following matters...Clause (15)
"Sources of radiation, and the handling, storage, transportation, use

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and disposal of radioactive isotopes and fissionable materials;
and....

Under the above-cited statutes, the MDH has the necessary statutory authority to adopt the proposed rules.

REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out seven factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (7) below quote these facts and then give the agency's response.

(1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule

The classes of persons affected by this proposed rule would be:

- 4291 registered facilities that currently own radiation-producing equipment. The types of facilities are broken down as follows:

Chiropractic	748
Dental	1910
Educational	46
Government	32
Hospitals	144
Industrial	194
Medical	680
Podiatry	65
Portable x-ray service	11
Radiation therapy	12
Research	5
Veterinary	439
Other	5
Total	4291

- Service providers are defined as people engaged in the business of assembling, installing, repairing, or replacing, one or more components into a diagnostic or industrial radiation-producing equipment system or subsystem or conducting equipment performance evaluations on diagnostic or industrial equipment. This class includes physicists and consultants. Registrants contract with this class to perform various tasks such as training of staff, calibration of equipment upon installation of equipment, performance evaluations, or conducting required quality control tests. Under the proposed rules, service providers must register with MDH. This is a new requirement that is not in the current Chapter 4730.

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- Healthcare recipients in Minnesota would benefit by the reduction of radiation exposure.

The costs of the proposed rule:

- Current registrants, service providers, physicists, and consultants will not incur any additional costs.
- Fees for registration of radiation-producing equipment have not been increased, and there is no registration fee for the service providers, physicists, or consultants.

The three classes of affected persons will benefit from the proposed rule in the following ways:

- The registered community will benefit financially when the time frame for some of the quality control tests is changed to coincide with the equipment performance evaluations. The new testing will be conducted at intervals not to exceed 24 months instead of performing tests at intervals not to exceed 12 months.
- The registered community will also benefit from the registration of service providers, physicists, and consultants. Service Provider registration will assist the regulated community in complying with the proposed rule by ensuring that this class has appropriate qualifications.
- Service providers benefit by gaining assurance that they are properly qualified to assist the regulated community.
- Citizens of Minnesota will benefit from a safer environment in the area of radiation-producing equipment through operators' compliance with Minnesota laws.

(2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues

- There are no costs to MDH or to any other agency of the implementation and enforcement of the proposed rule.
- Since there are no fee increases for current registrants or service providers, MDH does not anticipate that these proposed rules would have any effect on state revenues.

(3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule

The proposed rule decreases the costs for the regulated community by relaxing certain timing of requirements.

- The proposed rules do require training for new technology. The new technologies and training for those technologies are essential for the protection of the health and safety of the public as well as operators of the radiation-producing equipment. Accordingly, there

are no less costly methods or less intrusive methods for achieving the purpose of the proposed rules.

(4) a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule

- The Department considered amending the current ionizing radiation rule, *Minnesota Rules*, Chapter 4730. After a discussion with the Revisor, a decision was made to repeal the current chapter and replace Chapter 4730 with the proposed ionizing radiation rule, Chapter 4732. This will eliminate confusion for the regulated community.
- Additionally, the proposed rules implement specialty-specific grouping that will make it easier for the regulated community to navigate the proposed rules. The new format eliminates duplicative requirements, regroups the rules into a more usable format, removes obsolete language, and incorporates nationally recognized standards.

(5) the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals

- There are no probable costs of complying with the proposed rule for the regulated community, other governmental units, businesses, or individuals (i.e., service providers, physicists or consultants).
- The proposed registration of service providers, physicists and consultants has no associated registration fee.
- There are no probable costs to the citizens of Minnesota. There is no increase in costs to the regulated community or service providers. Health care costs should not increase as a result of these proposed rules.

(6) the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals

- If the proposed rule is not adopted, the consequences are that health and safety of the public is jeopardized by an out-dated, inconsistent, and extremely difficult to follow rule in Chapter 4730.
- Moreover, the financial burden born by registrants is greater under the current Chapter 4730. Without the adoption of the proposed rules, registrants do not benefit from the changes in the timing of some of the quality control tests, adjustment in training frequency, establishment of rules for animal research apart from other veterinary medicine requirements, and recognition of advance practice nurses, registered physician

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assistants and radiologic assistants. All of these changes are designed to ease the burden of this regulated industry while still assuring the health and safety of the public.

(7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference

- The proposed rules incorporate essential portions of the Code of Federal Regulations, Title 21 in an attempt to make Minnesota laws more consistent with federal regulations and national standards. At the same time, these proposed rules also assure that the current rules are updated to reflect emerging trends in technology and education. The expectation is that there will be a reduction in radiation exposure when equipment is required to comply with the national standards. The Advisory Group and MDH discussed this at length and determined that this was the most responsible approach for assuring that the citizens of Minnesota were protected from unnecessary ionizing radiation.

PERFORMANCE-BASED RULES

Minnesota law (Minnesota Statutes, sections 14.002 and 14.131) requires that the SONAR describe how the MDH, in developing the rules, considered and implemented performance-based standards that emphasize superior achievement in meeting the MDH's regulatory objectives and maximum flexibility for the regulated party and the MDH in meeting those goals. MDH staff asked the Advisory Group representing the affected community for input on performance-based standards. Advisory Group members agreed that the proposed rule was needed to ensure that the public and occupational workers were protected from unnecessary radiation and that radiation-producing equipment met federal standards. They also agreed that this rule was the best method to achieve these goals. The MDH drafted the proposed rules to reflect the Advisory Group members and regulated communities input throughout the rule writing process.

By including information from the Code of Federal Regulations, Title 21, for example the equipment performance evaluations, calibrations, and the ALARA program, the MDH has included performance-based standards for the regulated community to recognize possible equipment performance issues. The different quality control tests give the registrant an indication of their equipment's performance. The quality control testing is done on various schedules; daily, monthly, at intervals not to exceed six months, and finally not to exceed 24 months. Many of these quality control tests can be done by the registrant or their employees thereby saving costs.

ADDITIONAL NOTICE

Minnesota Statutes, sections 14.131 and 14.23, require that the SONAR contain a description of the MDH's efforts to provide additional notice to persons who may be affected by the proposed rules or explain why these efforts were not made.

The proposed rules were developed by MDH staff in close cooperation with many interested and affected parties. In 2004, the MDH formed an Advisory Group, which consisted of members

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from all the major radiation-producing equipment user groups and other interested parties. Specifically, the Advisory Group was made up of the following:

- Minnesota Medical Association
- Minnesota Dental Association
- Minnesota Veterinary Medical Association
- Minnesota Nursing Association
- Minnesota Board of Medical Practice
- Minnesota Board of Dentistry
- Minnesota Board of Chiropractic Examiners
- Minnesota Board of Veterinary Medicine
- Minnesota Board of Nursing
- Minnesota Radiological Society
- Vendors of x-ray equipment associated components
- Medical and dental consultants for the registered facilities
- Physicists servicing Minnesota registrants
- In-house service people (i.e., people employed by a registered facility)

The Request for Comments was published in the State Register on October 18, 2004. Additionally, on October 27, 2004, the MDH mailed a postcard notice to all of the members of the Advisory Group and the 4291 facilities that have registered x-ray equipment to notify them of public forums that were being held to discuss the Request for Comments, the proposed rules, and to provide the regulated community with an opportunity to comment and express any concerns that they had. The MDH held five public forums in five separate locations throughout Minnesota as follows:

- St. Paul – April 5, 2005, MDH Snelling Office Park, 1645 Energy Park Drive, St. Paul, MN
- Mankato – May 11, 2005, Holiday Inn, 121 East Main Street, Mankato, MN
- Fergus Falls – June 23, 2005, Bigwoods Event Center, 925 Western Avenue, Fergus Falls, MN
- Bemidji – July 13, 2005, Holiday Inn Express, 2422 Ridgeway Ave. N.W., Bemidji, MN
- Duluth – August 11, 2005, Black Woods Banquet Center, 195 Highway 2, Duluth, MN

Moreover, the Request for Comments, proposed Chapter 4732, and information on submitting comments were also posted on the MDH web sites, including a direct link to the X-ray Unit web site.

The Certificate of Distribution of the Request for Comments and Proposed Rule, which was signed by George F. Johns, Jr., Supervisor of the Radiation Control Section of MDH, is part of the official rulemaking record.

On January 30, 2007, the MDH submitted a proposed Additional Notice Plan for the Notice of Intent to Adopt Rules as a separate document to the Office of Administrative Hearings (OAH) for approval. The proposed Additional Notice Plan consists of the following elements:

1. Publishing the Notice of Intent to Adopt A Rule Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing If 25 or More Requests For Hearing Are Received (Notice).
2. Mailing a postcard notice (postcard) with information about the proposed rule and publication of the Notice. The postcard will also identify an MDH contact for the proposed rule, provide a website where copies of the Notice, proposed rule, SONAR, and additional information may be found, and set a deadline for submitting comments. This postcard notice will be mailed to the 4291 facilities that register radiation-producing (x-ray) equipment with MDH. The types of facilities are broken down as follows:

Chiropractic	748
Dental	1910
Educational	46
Government	32
Hospitals	144
Industrial	194
Medical	680
Podiatry	65
Portable x-ray service	11
Radiation therapy	12
Research	5
Veterinary	439
<u>Other</u>	<u>5</u>
Total	4291

3. Posting the Notice, proposed Chapter 4732, SONAR, and information on submitting comments on the MDH websites. The MDH web sites, specifically, the Indoor Environments and Radiation Section web site and X-ray web page, serve as valuable sources of current information about the Environmental Health (EH) division's rulemaking activities. Stakeholders who are required to register with the MDH and other interested parties use these web sites to obtain information about the MDH's rulemaking activities. The EH web site may be found at www.health.state.mn.us/divs/eh. It includes a link to the X-ray web page that will include the Notice and the proposed rule. The X-ray web page may be accessed directly at: www.health.state.mn.us/divs/eh/radiation/xray.
4. Mailing a letter and the Notice to Advisory Group participants. In 2004, the MDH established an Advisory Group consisting of both regulated as well as other interested parties to review the proposed rules. Participants of the Advisory Group included representatives of the medical, chiropractic, dental, podiatry, veterinary,

and research communities; members of various licensing boards and associations; x-ray service providers; physicists, consultants and interested persons who operate x-ray equipment. The MDH worked closely with the Advisory Group to develop the proposed rules.

5. Mailing the postcard, identified above, to service providers and vendors of x-ray equipment. This class of persons is not currently required to register with the MDH, but will be required to register with the MDH if the proposed rules are adopted. Since publication of the Request for Comments in October of 2004, the MDH has met with representatives of this class to develop the proposed rule and representatives of this class also participated in the Advisory Group described in item 4.
6. Mailing a letter and the Notice to physicists that assist registrants in regulatory compliance issues related to x-ray equipment and facilities. This class is hired by registered facilities to consult on quality assurance programs and radiation safety issues. Since publication of the Request for Comments in October of 2004, the MDH has met with representatives of this class to develop the proposed rules, and representatives of this class also participated in the Advisory Group described in item 4.
7. Mailing a letter and the Notice to consultants (other than physicists identified above) who provide consultation regarding quality assurance and assist facilities with employee training needs, including quality control testing of x-ray equipment. Since publication of the Request for Comments in October of 2004, the MDH has met with representatives of this class to develop the proposed rules, and representatives of this class also participated in the Advisory Group described in item 4.
8. Mailing a letter and the Notice to medical, dental, and veterinary licensing boards, professional associations, and professional societies. Representatives from this class were active participants on the Advisory Group described above. The letter will request that information regarding the MDH's proposed rule and the Notice be included in newsletters and/or web sites of these entities.
9. Mailing a letter and the Notice to professional associations and societies. Representatives from this class were active participants on the Advisory Group described above. The letter will request that information regarding the MDH's proposed rules and the Notice be included in newsletters and/or web sites of these entities.
10. Mailing a letter and the Notice to persons on the MDH's rulemaking mailing list established by Minnesota Statutes, section 143.14, subdivision 1a.
11. Mailing a letter and the Notice to chairs and ranking minority party members of the health policy and budget committees of both the House and Senate as required by

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Minnesota Statutes, section 14.116. These are the committees with jurisdiction over the subject matter of the proposed rules.

This notice plan constitutes the MDH's good faith efforts to seek information by other methods designed to reach persons or classes of persons who might be significantly affected by the proposed rules.

Current registrants would be the most affected by the proposed rules. Accordingly, the persons or classes of person significantly impacted by the proposed rules are already aware of and in compliance with many of the provisions set out in the proposed rules as many of the items were carried over from current Chapter 4730. Persons or classes of person who are not required to register with the MDH will be only minimally impacted by the proposed rules.

CONSULT WITH FINANCE ON LOCAL GOVERNMENT IMPACT

As required by Minnesota Statutes, section 14.131, the Department has consulted with the Commissioner of Finance. We did this on March 9, 2007 by sending to the Commissioner of Finance copies of the documents sent to the Governor's Office for review and approval prior to the Department publishing the Notice of Intent to Adopt. The documents included: The Governor's Office Proposed Rule and SONAR form; preliminary draft rules; and preliminary SONAR.

COST OF COMPLYING FOR SMALL BUSINESS OR CITY

As required by Minnesota Statutes, section 14.127, the Department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect will exceed \$25,000 for any small business or small city. The Department has determined that the cost of complying with the proposed rules in the first year after the rules take effect will not exceed \$25,000 for any small business or small city.

MDH has made this determination based on the probable costs of complying with the proposed rule, as described in the Regulatory Analysis section of this SONAR. As stated in the Regulatory Analysis section, there is no increase in fees for this proposed rule; the costs would not exceed \$25,000. MDH discussed with the Advisory Group whether these costs would exceed \$25,000 during the first year for any small business. The Advisory Group, which included representatives from small businesses, stated that the costs would not exceed \$25,000.

LIST OF WITNESSES

If these rules go to a public hearing, the Department anticipates having the following witnesses testify in support of the need for and reasonableness of the rules.

1. Susan McClanahan, R.T., MDH
2. Kimberly Pappas, R.T., MDH
3. American Registry of Radiologic Technologists representative

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STATEMENT OF NEED AND REASONABLENESS JUSTIFICATION BY RULE PART

The proposed Chapter 4732 is new and will replace current Chapter 4730. The language in the proposed chapter allows for consistency with federal requirements; encompasses revision of current requirements to meet current and emerging technology requirements and reorganizes the rule parts for clarity, consistency and ease of use for the regulated community. At the recommendation of the Advisory Group and the MDH Radiation Control staff, many rule parts in Chapter 4730 were deemed valid and are included in the proposed chapter,

4732.0100. PURPOSE AND SCOPE

Subpart 1. Purpose. This subpart establishes the rationale for Chapter 4732 to protect the public from unnecessary radiation exposure. At the recommendation of the Advisory Group and the MDH Radiation Control staff, this language is carried from the current Chapter 4730, Ionizing Radiation Rules. The language is still appropriate and necessary to explain the purpose of the radiation rules.

Subpart 2. Scope. This subpart identifies the persons required to comply with this proposed chapter. The proposed language is recommended by the Conference of Radiation Control Program Director's (CRCPD) Suggested State Regulations for Control of Radiation (SSRCR).

Subpart 3. Additional requirements. This subpart establishes the commissioner's ability to impose additional requirements when necessary to protect the health of the public in Minnesota. The proposed language is taken from the Conference of Radiation Control Program Director's (CRCPD) Suggested State Regulations for Control of Radiation (SSRCR).

4732.0110. DEFINITIONS

Part 4732.0110 is a compendium of the definitions used throughout Chapter 4732. It is both necessary and reasonable to have extensive and detailed definitions for something as complex and potentially dangerous as radiation-producing equipment. A large percentage of the definitions are very specific to radiation-producing equipment, shielding, uses, and the health effects of radiation that were found in Chapter 4730 and included in Chapter 4732. The remaining definitions are added because of a need to define an emerging technology or use of that emerging technology. These definitions were taken from a variety of sources and noted in the respective definitions.

Subpart 1. Scope. This subpart establishes definitions of terms used in Chapter 4732. It is necessary to establish definitions to ensure the consistency and understanding for the intended interpretation of the proposed rules. The proposed definitions therefore are necessary to assist the registrant in the understanding of Chapter 4732 for consistency in compliance.

Subpart 2. Absorbed dose. This definition was carried over from Chapter 4730, subpart 2, and should be carried forward into proposed Chapter 4732. The definition in 1990 was based on the same term as defined in the Glossary of NCRP Report No. 102, Appendix A. This definition is also found in the CRCPD's SSRCR, Section A. 2 and is used in the Iowa Department of Public

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Health Rules, Public Health # 641. The Advisory Group and the MDH Radiation Control staff recommended that this definition be retained.

Subpart 3. Absorbed dose rate. This proposed definition is found in the CRCPD's SSRCR, Section A. 2 and used in the Iowa Department of Public Health Rules, Public Health # 641. The Advisory Group and the MDH Radiation Control staff recommended that this definition be included.

Subpart 4. Accelerator. This definition is carried over from Chapter 4730, subpart 4, and was based on the Glossary of NCRP Report No. 51, Appendix A.1 and on the recommendations found in CRCPD's SSRCR, Section A. 2. This definition is also used in the Iowa Department of Public Health Rules, Public Health # 641. The Advisory Group and the MDH Radiation Control staff recommended that this definition be retained.

Subpart 5. Added filtration. This definition is carried forward from Chapter 4730, subpart 6, as it is still a valid definition and this language is recommended by the Conference of Radiation Control Program Director's Suggested State Regulations for Control of Radiation. The Advisory Group and the MDH Radiation Control staff recommended that this definition be retained.

Subpart 6. Adult. This definition is carried forward from Chapter 4730, subpart 6a, as it is still a valid definition and this language is also found in the Health Physic Society's Handbook of Health Physics and Radiological Health, G-1, published 1998.

Subpart 7. Air kerma. The proposed definition was not in Chapter 4730. However, it is needed for the newer technologies. The proposed language is taken from the CRCPD's SSRCR, Part X and recommended for inclusion by the Advisory Group and the MDH Radiation Control staff.

Subpart 8. Aluminum equivalent. This definition is carried forward from Chapter 4730, subpart 7, as it is still valid and allows for continued consistency for compliance with the proposed chapter.

Subpart 9. Annual. The proposed definition is put in place to allow consistency in compliance with the Radioactive Materials, Chapter 4731. The inclusion of this definition was a consensus of members of the Advisory Group and the MDH Radiation Control staff.

Subpart 10. Appropriate limit. This definition is carried forward from Chapter 4730, subpart 9, as it is still valid and allows for consistency in compliance with this proposed chapter.

Subpart 11. As low as reasonably achievable or ALARA. The proposed definition was not in Chapter 4730, but is being added for consistency with the *Minnesota Rules*, Chapter 4731, Radioactive Materials. The language is also recommended by the CRCPD's SSRCR, Section A.2 and used in surrounding states to ensure that exposure to radiation is kept as low as reasonable.

Subpart 12. Attenuation. This definition is carried forward from Chapter 4730, subpart 13 at the recommendation of members of the Advisory Group. It is still valid and allows for consistency in compliance with this proposed chapter.

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Subpart 13. Attenuation block. This definition is carried forward from Chapter 4730, subpart 14. This definition is still valid and allows for consistency in compliance with this proposed chapter.

Subpart 14. Audit. The proposed definition has been added for consistency with *Minnesota Rules*, Chapter 4731, Radioactive Materials. The proposed language is also found in the Health Physics Society's Handbook of Health Physics and Radiological Health, G-29, published in 1998.

Subpart 15. Automatic exposure control (AEC). This definition is carried from Chapter 4730, subpart 15, as it is still valid allowing for consistency in compliance with this proposed chapter. This language is also found in the CRCPD's SSRCR, Part F.

Subpart 16. Base plus fog density. The proposed term was developed by the members of the Advisory Group and the MDH Radiation Control staff for clarification and to promote consistency in compliance with this proposed chapter. The decision was made for inclusion in the proposed rule.

Subpart 17. Beam axis. This definition is carried forward from Chapter 4730, subpart 16 it is still valid and allows for consistency in compliance with this proposed chapter. This language is also consistent with language recommended by the CRCPD's SSRCR Part X.

Subpart 18. Beam-limiting device (BLD). This definition is carried forward from Chapter 4730, subpart 18, as it is still valid. This language is consistent with the CRCPD's SSRCR, Part F.

Subpart 19. Beam-monitoring system. This definition is carried forward from Chapter 4730 as it is still valid. This language is consistent with the CRCPD's SSRCR.

Subpart 20. Beam-scattering filter or foil. This definition is proposed language found in the CRCPD's SSRCR, Part X and allows for consistency in compliance with this proposed chapter.

Subpart 21. Bent beam linear accelerator. The proposed definition defines newer technology geometry that was not defined in Chapter 4730. This language is used in the Iowa Department of Public Health Rules, Public Health # 641. The Advisory Group and the MDH Radiation Control staff agreed to the inclusion of this definition.

Subpart 22. Bone densitometry system. The proposed definition is based on the definition in the CRCPD's SSRCR, Part F. It defines a new technology and new equipment.

Subpart 23. C-arm system. This definition is carried forward from Chapter 4730, subpart 25, as it is still valid and allows for consistency in compliance with the proposed chapter.

Subpart 24. Cabinet x-ray system. The proposed definition is language found in the CRCPD's SSRCR, Part E and recommended for use by members of the Advisory Group and the MDH Radiation Control staff to assist in the definition of a type of x-ray system.

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Subpart 25. Calibration. This definition is carried forward from Chapter 4730, subpart 26, as it is still valid and allows for consistency in compliance with the proposed radiation chapter. One section was added for further clarification using language from the CRCPD's SSRCCR.

Subpart 26. Cephalometric device. This definition is carried forward from Chapter 4730, subpart 28, as it is still valid. It allows for consistency in compliance with this proposed radiation chapter.

Subpart 27. Certified cabinet x-ray system. This definition is carried forward from Chapter 4730, subpart 28a, as it is still valid. It further defines a type of cabinet x-ray system for consistency in compliance with the radiation chapter.

Subpart 28. Certified components. This definition is carried forward from Chapter 4730, subpart 30, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 29. Certified system. This definition is carried forward from Chapter 4730, subpart 32, as it is still valid and allows for consistency in compliance with the proposed radiation chapter.

Subpart 30. Changeable filter(s). This definition is carried forward from Chapter 4730, subpart 33, as it is still valid and allows for consistency in compliance with the proposed radiation chapter.

Subpart 31. Clinical range. This definition is carried forward from Chapter 4730, subpart 34, as it is still valid and allows for consistency in compliance with the proposed radiation chapter.

Subpart 32. Coefficient of variation or C. The proposed definition is partially carried from Chapter 4730, subpart 35. A portion has been added to from the Iowa Department of Public Health Rules, Public Health # 641, to update it to include the new technologies. This was discussed by the Advisory Group and the MDH Radiation Control staff and the decision was made to include this language in the proposed chapter.

Subpart 33. Collimation. This definition is carried forward from Chapter 4730, subpart 37, as it is still valid and allows for understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 34. Collimator. The proposed definition is a partial carry over from Chapter 4730, subpart 38, as it is still valid. A portion from the CRCPD's SSRCCR, Part F has been added to include the new technologies.

Subpart 35. Commissioner. This definition is carried from Chapter 4730, subpart 39, as it is still valid and allows for understanding of the responsibilities of this program.

Subpart 36. Computed radiography. The proposed definition is necessary as a definition of a new technology. The Advisory Group and the MDH Radiation Control staff recommended the

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proposed language be taken from the Health Physics Society's Handbook of Health Physics and Radiological Health and the American Association of Physicists in Medicine.

Subpart 37. Computed tomography. This definition is carried forward from Chapter 4730, subpart 40, as it is still valid and allows for understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 38. Control panel. This definition is carried forward from Chapter 4730, subpart 43, as it is still valid and allows for understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 39. CT conditions of operation. This definition is carried forward from Chapter 4730, subpart 46, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 40. CT dose index (CTDI). This definition is carried forward from Chapter 4730, subpart 47, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 41. CT Gantry. This definition is carried forward from Chapter 4730, subpart 48, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 42. CT number. This definition is carried forward from Chapter 4730, subpart 49, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 43. CT scan. This definition is carried forward from Chapter 4730, subpart 165, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 44. CT scan increment. This definition is carried forward from Chapter 4730, subpart 166, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 45. CT Scan time. This definition is carried forward from Chapter 4730, subpart 168, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance the proposed radiation chapter.

Subpart 46. Dead-man switch. This definition is carried forward from Chapter 4730, subpart 51, as it is still valid. This is part of the FDA Code of Federal Regulations, Title 21 for equipment. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 47. Declared pregnant woman. The proposed definition is based on consistency with the *Minnesota Rules*, Chapter 4731, Radioactive Materials, and the language is found in the

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CRCPD's SSRCR. The Advisory Group and the MDH Radiation Control staff agreed on this proposed language.

Subpart 48. Densitometer. This definition is carried forward from Chapter 4730, subpart 52, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter. Some of the language proposed is found in the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 49. Diagnostic radiologic physicist. The proposed definition is based on language taken from the Health Physics Society Handbook of Health Physics and Radiological Health and from members of the Advisory Group.

Subpart 50. Diagnostic x-ray imaging system. This definition is carried forward from Chapter 4730, subpart 55, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter. Some of the language proposed is found in the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 51. Digital radiography. The Advisory Group and the MDH Radiation Control staff proposed this definition based on language found in the radiology textbook, Radiologic Science for Technologists by Steward C. Bushong, published 2001. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 52. Direct supervision. The proposed definition is based on language recommended in the Iowa Department of Public Health Rules, Public Health # 641. It is added for understanding and to promote consistency in compliance with the proposed radiation chapter.

Subpart 53. Dose. This definition is carried forward from Chapter 4730, subpart 57, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 54. Dose equivalent (DE). This definition is carried forward from Chapter 4730, subpart 59, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

Subpart 55. Dose limits or limits. The proposed definition is based on language recommended in the CRCPD's SSRCR, Section A.2. Members of the Advisory Group and the MDH Radiation Control staff recommended this be adopted for understanding and to promote consistency in compliance with the proposed radiation chapter.

Subpart 56. Dose-monitoring system. This definition is carried forward from Chapter 4730, subpart 60, as it is still valid. It allows for further understanding by the regulated parties and ensures consistency in compliance with the proposed radiation chapter.

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Subpart 57. Dose-monitor unit. This definition is carried forward from Chapter 4730, subpart 61, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 58. Effective dose equivalent (H_E). This definition is carried forward from Chapter 4730, subpart 63, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 59. Electron-beam generator. This definition is carried forward from Chapter 4730, subpart 64, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 60. Electronic signature. The proposed definition is language taken from Minnesota Statute, 325L. This is incorporated for understanding and consistency with the statute and compliance with the proposed radiation chapter.

Subpart 61. Exposure. This definition is carried forward from Chapter 4730, subpart 68, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter. The units of exposure were added for additional clarification.

Subpart 62. Exposure rate. This definition is carried forward from Chapter 4730, subpart 69, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. The units of exposure rate were added for additional clarification.

Subpart 63. External beam radiation therapy. The proposed definition is added for clarification of the technology. The language recommended by members of the Advisory Group and the MDH Radiation Control staff is taken from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 64. Facility. This definition is carried from Chapter 4730, subpart 70, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 65. Field emission equipment. This definition is carried forward from Chapter 4730, subpart 71, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 66. Field-flattening equipment. This definition is carried forward from Chapter 4730, subpart 72, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. Some addition language recommended by members of the Advisory Group was taken from the CRCPD's SSRCR and this was included in this definition.

Subpart 67. Filmless radiography or photostimulable storage phosphor (PSP) imaging. The proposed definition is recommended language from the Health Physics Society's Handbook of Health Physics and Radiological Health and the American Association of Physicists in Medicine.

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This provides a better understanding and promotes consistency in compliance with this proposed chapter. This definition was reviewed and recommended for inclusion by the Advisory Group and the MDH Radiation Control staff.

Subpart 68. Filter or filtration. This definition is carried forward from Chapter 4730, subpart 73, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 69. Fluoroscopic imaging assembly. This definition is carried forward from Chapter 4730, subpart 74, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter. New language from the Code of Federal Regulation Title 21, section 1020.30 was added for clarity.

Subpart 70. Focal spot. This definition is carried forward from Chapter 4730, subpart 75, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. There is new language added from the CRCPD's SSRCR, Part F for added clarity.

Subpart 71. Gantry. This definition is carried forward from Chapter 4730, subpart 76, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 72. General purpose radiographic x-ray system. This definition is carried forward from Chapter 4730, subpart 77, as it is still valid and provides an understanding and promotes consistency in compliance with this proposed chapter.

Subpart 73. Gonad shield. This definition is carried forward from Chapter 4730, subpart 78, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 74. Gray. This definition is carried forward from Chapter 4730, subpart 79, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 75. Half-value layer (HVL). This definition is carried forward from Chapter 4730, subpart 80, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 76. Healing arts. This definition is carried forward from Chapter 4730, subpart 81, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 77. Healing arts screening or screening. This definition is carried forward from Chapter 4730, subpart 82, as it is still valid and provides understanding and promotes consistency in continued compliance with this proposed chapter.

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Subpart 78. High radiation area. This definition is carried forward from Chapter 4730, subpart 83, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 79. Image intensifier. This definition is carried forward from Chapter 4730, subpart 85, as it is still valid and provides understanding and promotes consistency in compliance with the proposed radiation chapter.

Subpart 80. Image quality. The proposed definition relates to new technologies. It is needed for understanding, clarity and consistency in compliance with this proposed chapter. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641 at the advice of the Advisory Group and the MDH Radiation Control staff.

Subpart 81. Image Receptor. This definition is carried from Chapter 4730, subpart 86, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. The new language added for the new technologies. The recommended new language is taken from CRCPD's SSRCR, Part F.2.

Subpart 82. Individual. This definition is carried forward from Chapter 4730, subpart 88, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 83. Individual monitoring. The proposed language is added to be consistent with Radioactive Materials Rule, Chapter 4731. This is provides understanding and promotes consistency in continued compliance with the proposed radiation chapter.

Subpart 84. Individual monitoring devices. The proposed definition is added to be consistent with Radioactive Materials Rule, Chapter 4731. It replaces the definition in Chapter 4730 subpart 126, "Personnel monitoring device." The proposed language will allow for understanding and consistency with the proposed radiation chapter.

Subpart 85. Industrial cabinet baggage system. This definition is carried forward from Chapter 4730, subparts 88a and 88b. It is combined to provide enhanced understanding of the systems, which should improve compliance with the proposed radiation chapter.

Subpart 86. Industrial vault radiography. The proposed definition is carried forward from Chapter 4730, subpart 88b. Some new additional language suggested by the MDH Radiation Control staff has been added for clarity and consistency in compliance with this proposed chapter.

Subpart 87. Industrial radiographer. This definition is carried forward from Chapter 4730, subpart 89, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

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Subpart 88. Industrial radiographer's assistant. This definition is carried forward from Chapter 4730, subpart 89a, as it is still valid and provides understanding and promotes consistency in continued compliance with this proposed chapter.

Subpart 89. Industrial radiography. This definition is carried forward from Chapter 4730, subpart 90. The language was changed slightly using recommended language dealing with new technologies from CRCPD's SSRCR, Section E.3 to improve clarity and for consistency in compliance with this proposed chapter. The Advisory Group and the MDH Radiation Control staff agreed this was the language to deal with new technologies.

Subpart 90. Inherent filtration. This definition is carried forward from Chapter 4730, subpart 91, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 91. Inspection. This definition is carried forward from Chapter 4730, subpart 92, as it is still valid and provides understanding and promotes consistency in continued compliance with the proposed chapter.

Subpart 92. Instrument traceability. Using recommended language from the CRCPD's SSRCR, Section A.2, the proposed definition is added for clarity and consistency in compliance with this proposed chapter.

Subpart 93. Interlock. This definition is carried forward from Chapter 4730, subpart 93, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. Some language from the CRCPD's SSRCR has been added for clarity with the new technologies.

Subpart 94. Ionizing radiation. This definition was carried forward from Chapter 4730, subpart 94. It has been modified slightly to encompass new technologies and remove any reference to radioactive material. The language used is taken from the Iowa Department of Public Health Rules, Public Health # 641. Both the Advisory Group and the MDH Radiation Control staff agreed this was the language to be used in the proposed chapter.

Subpart 95. Irradiation. This definition is carried forward from Chapter 4730, subpart 95, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 96. Isocenter. This definition is carried forward from Chapter 4730, subpart 96, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 97. Kilovolt peak (kVp). This definition is carried forward from Chapter 4730, subpart 98. As in Chapter 4730, it is defined as peak tube potential.

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Subpart 98. Lead equivalence or lead equivalent. This definition is carried forward from Chapter 4730, subpart 100, as it is still valid and provides understanding and promotes consistency in compliance with the proposed chapter.

Subpart 99. Leakage radiation. This definition is carried forward from Chapter 4730, subpart 101. It has been modified slightly to encompass the new technologies, but it is still valid. Inclusion provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 100. Leakage technique factors. This definition is carried forward from Chapter 4730, subpart 102, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 101. Licensed practitioner of the healing arts. This definition is carried forward from Chapter 4730, subpart 103. It has been modified slightly to include the registered physician assistants, but it is still valid and provides understanding and promotes consistency in continued compliance with the proposed radiation chapter.

Subpart 102. Light field. This definition is carried forward from Chapter 4730, subpart 104, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 103. Line-voltage regulation. This definition is carried forward from Chapter 4730, subpart 105, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 104. mA. This definition is carried forward from Chapter 4730, subpart 107, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 105. mAs. This definition is carried forward from Chapter 4730, subpart 108, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 106. Maximum line current. This definition is carried forward from Chapter 4730, subpart 109, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 107. Medical event. The proposed definition is added to provide consistency and understanding for compliance with this proposed chapter. Members of the Advisory Group recommended the language from the CRCPD's SSRCR and Iowa Department of Public Health Rules, Public Health # 641 be used.

Subpart 108. Medical uses. The proposed definition is added to provide consistency and understanding for registrant compliance with this chapter. The proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641.

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Subpart 109. Medical particle accelerator. This definition is carried forward from Chapter 4730, subpart 110. It is subpart 4, titled "Accelerator" in this proposed chapter. This change was recommended by the MDH Radiation Control staff for clarity.

Subpart 110. Medical physicist. The proposed definition is incorporated to further define the physicist's role. The language is taken from the Health Physics Society's Handbook of Physics and Radiological Health. This definition was separated out for clarity, understanding and promotes consistency in compliance with this proposed chapter.

Subpart 111. Megavolt (MV) (mega electron volt (MeV)). The proposed definition is being added to address new technologies that have emerged since 1991. The proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641 at the recommendation of the MDH Radiation Control staff.

Subpart 112. Moving beam radiation therapy. The proposed definition is being added to address new technologies that have emerged since 1991. The proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 113. Nominal tomographic section thickness. This definition is carried forward from Chapter 4730, subpart 117, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 114. Non-stochastic effects. This definition is carried forward from Chapter 4730, subpart 118, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. There is additional proposed language to address new technologies.

Subpart 115. Nominal treatment distance. This definition was found in Chapter 4730, subpart 119. The proposed definition uses language from the CRCPD's SSRCR, Section X.2 to address newer technologies. This should provide a better understanding and promote consistency in compliance with this proposed chapter.

Subpart 116. Occupation dose. This term was found in Chapter 4730, subpart 120. However, the proposed definition provides a better understanding and promotes consistency in compliance with this proposed chapter for the newer technologies. The proposed language is taken from the CRCPD's SSRCR, Section A.2.

Subpart 117. Open-beam configuration. This definition is carried forward from Chapter 4730, subpart 120a, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 118. Optical density or O.D. This definition is carried forward from Chapter 4730, subpart 121, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

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Subpart 119. Patient. This definition is carried forward from Chapter 4730, subpart 122, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 120. Peak tube potential. This definition is carried forward from Chapter 4730, subpart 123, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 121. Permanent radiographic installation. This definition is carried forward from Chapter 4730, subpart 124, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. Additional language was proposed to be added as requested by the MDH Radiation Control staff to include industrial vaults for clarity.

Subpart 122. Person. This definition is carried forward from Chapter 4730, subpart 125, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 123. Personal protective garments. The proposed definition encompasses two definitions from Chapter 4730, subpart 135 and subpart 137. Language to encompass newer and a larger variety of protective garments put in use since 1991 has been added. This was a recommendation from the MDH Radiation Control staff and members of the Advisory Group.

Subpart 124. Personnel monitoring dosimeter. The proposed definition is carried forward from Chapter 4730. It is addressed in this proposed chapter as "Individual monitoring devices," subpart 83.

Subpart 125. Phantom. This definition is carried forward from Chapter 4730, subpart 127, as it is still valid and provides understanding and promotes consistency in continued compliance with the proposed chapter.

Subpart 126. Phototimer. This definition is carried forward from Chapter 4730, subpart 128, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 127. Pixel or picture element. This definition is carried forward from Chapter 4730, subpart 130, as it is still valid. It provides a better understanding and promotes consistency in compliance with this proposed chapter and the newer technologies.

Subpart 128. Port film or portal imaging. This definition is carried forward from Chapter 4730, subpart 131, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 129. Positive beam limiting (PBL). The proposed definition addresses newer technologies. This proposed language was taken from the CRCPD's SSRCR.

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Subpart 130. Position indicating device (PID). This definition is carried forward from Chapter 4730, subpart 132, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 131. Prescribed dose. The proposed definition represents newer technologies. This proposed language was taken from the CRCPD's SSRCR, Appendix B.

Subpart 132. Primary beam. This definition is carried forward from Chapter 4730, subpart 132a, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 133. Primary dose-monitoring system. This definition is carried forward from Chapter 4730, subpart 133, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 134. Primary protective barrier. This definition is carried forward from Chapter 4730, subpart 134, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 135. Protective apron. This definition was found in Chapter 4730, subpart 135 and for purposes of this proposed chapter was included in "Personnel protective garments," subpart 122.

Subpart 136. Protective barrier or barrier. This definition is carried forward from Chapter 4730, subpart 136, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 137. Protective glove. This definition was found in Chapter 4730, subpart 135 and for purposes of this proposed chapter is included in "Personnel protective garments," subpart 122. This was done for the sake of clarity.

Subpart 138. Pulsed mode. This definition is carried forward from Chapter 4730, subpart 137a, as it is still valid and provides understanding and promotes consistency in continued compliance with this proposed chapter as more of the newer technologies have equipment with this pulsed mode option.

Subpart 139. Quality assurance program. This definition is in Chapter 4730 however the proposed definition provides a more definitive description of the program. The proposed language is taken from two sources: the National Council on Radiation Protection and Measurements (NCRP) Report No. 99, "Quality Assurance for Diagnostic Imaging" and CRCPD's SSRCR.

Subpart 140. Quality control. The proposed definition is taken from the NCRP Report No. 99. It addresses parts of a quality assurance program. Defining this aspect of the program should provide understanding within the regulated community and promote consistency in compliance with this proposed chapter.

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Subpart 141. Quarter. The proposed definition was recommended by the MDH Radiation Control staff and members of the Advisory Group for clarity. The language is taken from CRCPD's SSRCR, Part D.2.

Subpart 142. Rad. This definition is carried forward from Chapter 4730, subpart 140, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 143. Radiation. This definition is carried forward from Chapter 4730, subpart 141, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 144. Radiation area. This definition is carried forward from Chapter 4730, subpart 142, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 145. Radiation detector or detector. This definition is carried forward from Chapter 4730, subpart 143, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter

Subpart 146. Radiation head. This definition is carried forward from Chapter 4730, subpart 145, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 147. Radiation-producing equipment. This definition is carried forward from Chapter 4730, subpart 146, as it is still valid and provides understanding and promotes consistency in continued compliance with this proposed chapter.

Subpart 148. Radiation protection. This definition is carried forward from Chapter 4730, subpart 147, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 149. Radiation safety officer. This definition is carried forward from Chapter 4730, subpart 149, as it is still valid and provides understanding for the regulated community and promotes consistency in compliance with this proposed chapter. There was a slight modification in proposed language using the CRCPD's SSRCR, Section A.2. This was a recommendation by members of the Advisory Group. The MDH Radiation Control staff agreed with that recommendation.

Subpart 150. Radiation therapy simulation system. This definition is carried forward from Chapter 4730, subpart 150, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 151. Radiograph. This definition is carried forward from Chapter 4730, subpart 153, as it is still valid and provides understanding and promotes consistency in compliance with this

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proposed chapter. There was a slight modification in the proposed language using the CRCPD's SSRCR, Part F for the newer technologies for clarification purposes.

Subpart 152. Radiographic imaging system. This definition is carried forward from Chapter 4730, subpart 154, radiography, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. There was a slight modification in the proposed language as recommended by the MDH Radiation Control staff for clarification purposes based on newer technologies.

Subpart 153. Rated line voltage. The proposed definition is taken the CRCPD's SSRCR, Part F to encompass the newer technologies for a better understanding, clarification and consistency in compliance with this proposed chapter.

Subpart 154. Rating. This definition is carried forward from Chapter 4730, subpart 156, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 155. Recording. This definition is carried forward from Chapter 4730, subpart 157, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 156. Reference man. This definition is carried forward from Chapter 4730, subpart 157a, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. A slight modification in the proposed language using the Iowa Department of Public Health Rules, Public Health # 641 language for clarification for the newer technologies.

Subpart 157. Reference plane. This definition is carried forward from Chapter 4730, subpart 158, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 158. Registered physician assistant. The proposed definition has been added to encompass this practitioner of the healing arts in coordination with Minnesota Statutes, Chapter 147A.

Subpart 159. Registered radiological assistant. The proposed definition has been added to encompass a new category of occupational workers in a radiology setting. The proposed language is taken from the American Registry of Radiologic Technologists and is recommended for inclusion by the Advisory Group and the MDH Radiation Control staff.

Subpart 160. Registrant. This definition is carried forward from Chapter 4730, subpart 159, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. This definition describes who is required to register with the Department.

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Subpart 161. Registration. This definition is carried forward from Chapter 4730, subpart 160, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 162. Rem. This definition is carried from Chapter 4730, subpart 161, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. This definition has been modified to remove the references to radioactive materials.

Subpart 163. Restricted area. This definition is carried forward from Chapter 4730, subpart 163, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 164. Retake or reject. The proposed definition is recommended by the MDH Radiation Control staff and the Advisory Group. The proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 165. Retake or reject analysis program. The proposed definition defines the program that would track additional patient exposures. It is recommended by the MDH Radiation Control staff and the Advisory Group. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 166. Roentgen. This definition is carried forward from Chapter 4730, subpart 164, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 167. Scattered radiation or secondary radiation. This definition is carried forward from Chapter 4730, subparts 169 and subpart 172 and still is valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 168. Secondary dose-monitoring system. This definition is carried forward from Chapter 4730, subpart 170, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 169. Secondary protective barrier. This definition is carried forward from Chapter 4730, subpart 171, as it is still valid and provides understanding and promotes consistency in continued compliance with this proposed chapter.

Subpart 170. Sensitometer. The proposed definition is recommended by the MDH Radiation Control staff for clarification for better compliance with this proposed chapter. The members of the Advisory Group agreed with the recommendation to use the language from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 170. Sensitometric strip. The proposed definition is recommended by the MDH Radiation Control staff for clarification for better compliance with this proposed chapter. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641.

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Subpart 171. Sensitometry. The proposed definition is recommended by the MDH Radiation Control staff for clarification for better compliance with this proposed chapter. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 172. Service provider. The proposed definition is recommended by the MDH Radiation Control staff for clarification for better compliance with this proposed chapter. The definition for assembler is in the CRCPCD's SSRCCR, Part F and is equivalent and was recommendation for inclusion as a "service provider" to be more encompassing of these individuals by the MDH Radiation Control staff.

Subpart 173. Shadow tray. This definition is carried forward from Chapter 4730, subpart 174, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 174. Shutter. This definition is carried forward from Chapter 4730, subpart 175, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 175. SI equivalent. This definition is carried forward from Chapter 4730, subpart 176, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 176. Sievert (Sv). This definition is carried forward from Chapter 4730, subpart 177, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 177. Source. This definition is in Chapter 4730, subpart 178 but was modified using proposed language from CRCPCD's SSRCCR Part F and by removing the references to radioactive material sources. It now becomes specific to ionizing radiation-producing equipment.

Subpart 178. Source of radiation. This definition is carried over from Chapter 4730, subpart 179, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. The proposed definition has been modified to remove the reference to radioactive materials.

Subpart 179. Source-to-image distance (SID). This definition is carried over from Chapter 4730, subpart 180, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 180. Source-to-skin distance (SSD). This definition is carried over from Chapter 4730, subpart 181, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

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Subpart 181. Spot check. This definition is carried over from Chapter 4730, subpart 182, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 182. Spot film. This definition is carried over from Chapter 4730, subpart 183, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 183. Spot-film device. This definition is carried forward from Chapter 4730, subpart 184, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 184. Stationary beam therapy. This definition is carried forward from Chapter 4730, subpart 185, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 185. Step wedge. The proposed definition is recommended by the MDH Radiation Control staff and members of the Advisory Group. The proposed language was recommended for clarification for consistency in compliance with this proposed chapter.

Subpart 186. Stepless adjustment. This definition is carried forward from Chapter 4730, subpart 186, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 187. Stochastic effects. While this definition was in Chapter 4730, subpart 187, the proposed definition includes language taken from CRCPD's SSRCR, Part D that addresses concerns associated with the newer technologies.

Subpart 188. Storage. The proposed definition is taken from the CRCPD's SSRCR Part B to represent the storage issue for radiation-producing equipment not radioactive materials.

Subpart 189. Storage area. Chapter 4730, subpart 187a, has a definition for storage area that refers to radioactive material. The proposed language is recommended by the MDH Radiation Control staff to reflect the storage of radiation-producing equipment for clarification of compliance with this proposed chapter.

Subpart 190. Stray radiation. The definition was carried forward from Chapter 4730, subpart 189, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 191. Supervising physician. The proposed definition was recommended by the Advisory Group to be in agreement with the *Minnesota Statutes*, Chapter 147A.20.

Subpart 192. Survey or radiation safety survey. While Chapter 4730, subpart 190, has a definition for survey, the proposed definition was modified to remove reference to radioactive materials. The language was taken from the CRCPD's SSRCR.

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Subpart 193. Target. The definition was carried from Chapter 4730, subpart 191, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 194. Technique factors. The definition was carried from Chapter 4730, subpart 192. With modifications to remove reference to radioactive materials, it is still valid. The definition provides understanding and promotes consistency in continued compliance with this proposed chapter.

Subpart 195. Television receiver. The definition was carried from Chapter 4730, subpart 193, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 196. Temporary jobsite. The proposed definition varies from the definition in Chapter 4730, subpart 193a, because the proposed definition's language is specific to radiation-producing equipment. Reference to radioactive materials has been removed. The proposed language was recommended by the MDH Radiation Control staff.

Subpart 197. Termination of irradiation. The definition was carried from Chapter 4730, subpart 195, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 198. Therapeutic radiation machine. The proposed definition was recommended by the members of the Advisory Group and the language was taken from the CRCPD's SSRCR to address newer technologies.

Subpart 199. Therapeutic radiological physicist. The proposed definition was recommended by the MDH Radiation Control staff and members of the Advisory Group. The language is found in the Health Physics Society's Handbook of Physics and Radiological Health.

Subpart 200. Therapeutic-type protective tube housing. The definition was carried over from Chapter 4730, subpart 197, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 201. Tomogram. The definition was carried over from Chapter 4730, subpart 198, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 202. Tomographic plane. The definition was carried over from Chapter 4730, subpart 199, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 203. Tomographic section. The definition was carried over from Chapter 4730, subpart 200, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

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Subpart 204. Traceable to a standard. The definition was carried over from Chapter 4730, subpart 201, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 205. Tube housing assembly. The definition was carried over from Chapter 4730, subpart 202. Basically, it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. However, it was modified to address the newer technologies. The proposed change in language was taken from the CRCPD's SSRCR.

Subpart 206. Type rating chart. The definition was carried over from Chapter 4730, subpart 203, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 207. Type 1100 aluminum alloy. The definition was carried over from Chapter 4730, subpart 204, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 208. Useful beam. While this definition is in Chapter 4730, subpart 209, the proposed definition has been modified using language from the CRCPD's SSRCR to address the newer technologies.

Subpart 209. Utilization log. The proposed definition was by the MDH Radiation Control staff and members of the Advisory Group. The proposed language was taken from the CRCPD's SSRCR to specifically address registrants having radiation-producing equipment. Reference to radioactive materials has been deleted.

Subpart 210. Variable-aperture beam-limiting device. The definition was carried over from Chapter 4730, subpart 210, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 211. Very high radiation area. The definition was carried over from Chapter 4730, subpart 210a, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter. The language recommended by the MDH Radiation Control staff specific to radiation-producing equipment was taken from the CRCPD's SSRCR.

Subpart 212. Virtual source. The definition was carried over from Chapter 4730, subpart 211, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 213. Visible area. The definition was carried over from Chapter 4730, subpart 212, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 214. Wedge filter. The definition was carried over from Chapter 4730, subpart 213, as it is still valid and provides understanding and promotes consistency in compliance with this

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proposed chapter. There was a slight modification to address the newer technologies using language from the CRCPD's SSRCR.

Subpart 215. Worker. The definition was carried over from Chapter 4730, subpart 213b, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 216. Written directive. The proposed definition has been added to eliminate confusion in the understanding and compliance with this proposed chapter. The proposed language was taken from the CRCPD's SSRCR. Members of the Advisory Group and the MDH Radiation Control staff agreed that it was appropriate to add to this proposed chapter.

Subpart 217. X-ray control. While there is a definition for this in Chapter 4730, subpart 214, the proposed definition has been modified using language from the CRCPD's SSRCR to be specific for those registrants using radiation-producing equipment. This will allow for better understanding by the regulated community and promote consistency in compliance with this proposed chapter.

Subpart 218. X-ray equipment. The definition was carried over from Chapter 4730, subpart 215, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 219. X-ray field. The definition was carried over from Chapter 4730, subpart 216, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 220. X-ray generator. The definition was carried over from Chapter 4730, subpart 217, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 221. X-ray high-voltage generator. The definition was carried over from Chapter 4730, subpart 218, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 222. X-ray system. The definition was carried over from Chapter 4730, subpart 220, as it is still valid and provides understanding and promotes consistency in compliance with this proposed chapter.

Subpart 223. X-ray tube or tube. The definition was carried over from Chapter 4730, subpart 221, as it is still valid and provides understanding and consistency in compliance with this proposed chapter.

Subpart 224. Year. The proposed definition was recommended by the MDH Radiation Control staff and members of the Advisory Group to eliminate confusion, to provide better understanding of the requirements, and to promote consistency in compliance with this proposed chapter. The

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proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641.

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4732.0200. REGISTRATION REQUIREMENTS FOR RADIATION-PRODUCING EQUIPMENT AND OTHER ELECTRONIC MACHINES THAT PRODUCE RADIATION.

This proposed part and subparts are included to update the registration process to assist in the understanding of the required registration information needed.

Subpart 1. Applicability. This subpart is necessary because it identifies the parties required to register, when that needs to take place and what information is required. This has changed from Chapter 4730. The proposed language changes have been taken from the Iowa Department of Public Health Rules, Public Health # 641 and the CRCPD's SSRCR. The MDH Radiation Control staff and Advisory Group reviewed this rule part and did not find any problems with the applicability subpart.

Items A, B and C will facilitate registration for the registrant and make their understanding of compliance issues easier by implementing a list like approach for requirements. Items D and E will assist in further understanding for the registrant of compliance issues.

Subpart 2. Issuance of notice of registration. This proposed subpart is new. Chapter 4730 does not require an issuance of any type of notice of registration. At one time, the Radiation Control Section of the Minnesota Department of Health issued a receipt of registration. This practice was abandoned in the early 1990's. The regulated community has indicated they would like documentation of their registration reinstated. Therefore, the Advisory Group recommended that this rule be added. The proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 3. Renewal of registration is carried over from Chapter 4730.0500 and is still viable. Proposed item B permits electronic signatures or equivalent procedures in compliance with Minnesota Statutes 135L.

Subpart 4. Staggered schedule for renewal of registration is carried over from Chapter 4730.0500, subpart 1 and is still viable for collecting registration fees.

Subpart 5. Renewals affected by change of location is carried over from Chapter 4730.0500 and is still viable. The proposed subparts have modifications to address the changes in newer technologies.

Subpart 6. Change of ownership was proposed to eliminate confusion associated with changes in ownership of the facility. The proposed language was recommended by the MHD Radiation Control staff and reviewed and approved by the Advisory Group.

4732.0210. REGISTRATION FEES.

This part was modified from the part in Chapter 4730.0600, where the fees were listed by machine type in reference the *Minnesota Statutes*, Section 144.121, subdivision 1a. This was done by reference to facilitate future rulemaking pertaining to the registration fees. The decision

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was agreed upon by both the Advisory Group and the MDH Radiation Control staff to not list the fees in this part of the proposed chapter to eliminate confusion for the regulated community.

4732.0220. GENERAL REQUIREMENTS FOR ALL FACILITIES.

Subpart 1. Responsibilities of the registrant. This language was carried over from Chapter 4730.0400. It has been modified to address the newer technologies and the changing responsibilities the registrant would have for compliance with this proposed chapter.

Item A, the proposed language was taken from Iowa Department of Public Health Rules, Public Health # 641.

Items B and C are carried from Chapter 4730.0400, item B and Chapter 4730.0400, item D as they are still valid for this proposed chapter.

Subpart 2. Submission. The proposed language is recommended for inclusion to be compatible with *Minnesota Rules*, Chapter 4731, Radioactive Materials Rules. Chapter 4731 is also enforced by the MDH Radiation Control, radioactive materials unit. Consistency between the two rules will eliminate confusion for the regulated community that is regulated under both of these chapters.

Subpart 3. Shielding requirements. The proposed language is recommended for inclusion by the MDH Radiation Control staff and members of the Advisory Group to address the newer technologies and to promote an understanding of the rule. The shielding plan is considered a primary step for the protection of the public and occupational workers from unnecessary radiation.

Subpart 4. Exemption. The proposed language to exempt dental intraoral facilities from subpart 3 requirements was a recommendation from the MDH Radiation Control staff and members of the Advisory Group. This was based on the radiation output of the intraoral equipment.

4732.0250. RECIPROCITY FOR OUT OF STATE RADIATION-PRODUCING EQUIPMENT.

This proposed rule part is recommended for inclusion by the MDH Radiation Control staff and members of the Advisory Group to provide consistency with *Minnesota Rules*, Chapter 4731, Radioactive Materials. This rule will require the identification of locations where radiation-producing equipment is used by individuals who are not required to register in Minnesota. The proposed language for this part was taken from the CRCPD's SSRCR, Part B.

Subpart 1. Applicability. The applicability is defined in this subpart. This is a new requirement for companies outside Minnesota that bring radiation-producing equipment into Minnesota for temporary use. To have this listed will be a benefit to them and assist with their understanding of their responsibilities for public health and safety while in Minnesota.

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Subpart 2. Compliance. This subpart allows companies from outside Minnesota to have information concerning the requirements for use in a form that is easy to understand. The proposed language was taken from the CRCPD's SSRCR, Part B.

Subpart 3. Inspections. The proposed inspection portion of this part provides notification to the companies bringing equipment into Minnesota that they are subject to inspection.

4732.0275. REGISTRATION OF SERVICE PROVIDERS.

This proposed rule part is recommended for inclusion by the MDH Radiation Control staff and members of the Advisory Group. In addition, the responsibilities of vendors are covered under this rule, Chapter 4732.0280, and Chapter 4730.0900. The proposed language for this proposed rule part was taken from the CRCPD's SSRCR, Part B.

Subpart 1. Application. The general requirements subpart provides t service providers the information concerning the registration process.

Subpart 2. Services covered. The services listed are to assist the service providers by more easily identifying how, when and why they must register with the commissioner. This is information that will help the service providers in complying with the requirements.

Subpart 3. Application requirements. The proposed application requirements listed in this subpart will make it easier for the service providers to complete the application. This was recommended by service providers that would be affected by this rule part. The MDH Radiation Control staff and members of the Advisory Group agreed this was a worthwhile addition.

Subpart 4. Issuance of notice of registration. The proposed language resulted from a discussion with the service providers as to when and how they would be informed of their registration as well as what they could present to prospective clients to verify completion of registration.

4732.0280. SERVICE PROVIDER'S RESPONSIBILITY.

Subpart 1. General requirements. The proposed language for this rule part was taken from the CRCPD's SSRCR Part B. This was also reviewed and approved by the MDH Radiation Control staff, the members of the Advisory Group and service providers. The intent is to ensure there is consistency and compliance with this rule.

Subpart 2. Notification requirements. The proposed language in this subpart is from Chapter 4730.0900 and modified using language taken from the CRCPD's SSRCR, Part B to promote consistency, foster compliance, and to address the newer technologies. Notification is necessary for the commissioner to be informed of newer technologies.

Subpart 3. Calibrations. The proposed language in this subpart is from Chapter 4730.0900 and modified using language taken from CRCPD's SSRCR, Part B. Calibrations must be done at the time of installation so that the registrant knows that the equipment installed by the service provider meets the proposed specifications. While this requirement is carried over from Chapter

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4730, the requirements for calibration reports are further clarified. The service provider's responsibility is defined in this subpart for clarity and understanding.

Subpart 4. Equipment performance tests. Equipment performance evaluation requirements are carried from Chapter 4730. This rule clearly states the requirement for the registrant to have their radiation-producing equipment tested at intervals not to exceed 24 months to be in compliance. The service provider's responsibility is also clearly defined in this subpart.

Subpart 5. Individual monitoring. The proposed language regarding the monitoring of individual service providers to comply with Chapter 4732.0220 is also carried over from Chapter 4730. This subpart is proposed for clarification of individual monitoring.

Subpart 6. Phantom use. The use of phantoms for maintenance, demonstration, and training by the service providers is a public health and safety issue that needs to be clearly addressed. This proposed subpart is carried over from Chapter 4730.

4732.0300. EXEMPTIONS.

This part is carried over from Chapter 4730 for consistency in compliance with this proposed chapter. The references to radioactive materials have been removed.

4732.0305. PROHIBITED USES.

Subpart 1. General provision. This subpart has been carried from Chapter 4730.1210, as it is still valid. There were some modifications in subpart 3 made for clarification due to the newer technologies and the radiation exposures that are associated with those technologies. The modifications were recommended by the MDH Radiation Control staff and members of the Advisory Group. The licensed practitioners of the healing arts consider the risk versus benefit to the patient and determine the necessity of exposure to radiation.

Item A. This proposed language carried from Chapter 4730.1210 and indicates that exposure of individuals for training, instruction, demonstration, or research. Research is prohibited except when approved by the Code of Federal Regulations, Title 21 or via a variance approved by the commissioner.

Item B. This proposed language is necessary and is carried over from Chapter 4730. This allows the exposure of individuals for purposes of healing arts screening only when done in accordance with 4732.0565.

Item C. The MDH Radiation Control staff recommended this proposed language to allow the exposure of individuals for bone densitometry precision testing procedures. It is used for training of x-ray operators only when each training exposure on a patient is ordered by a licensed practitioner of the healing arts. A licensed practitioner of the healing arts is best qualified to make the decision concerning the additional patient exposures used for the training of staff. The decision should be based on the review of the benefit the patient would receive during extra radiation exposure. This would be based on the patient's condition (including the physical

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characteristics, physical condition, ethnic background, and life style), diet, which includes consideration of calcium and vitamin D intake and not the need for staff training as phantoms are available for training purposes.

Subpart 2. Other prohibited radiation doses. This subpart was carried over from Chapter 4730.1210, and is still valid. Doses for occupational workers for any training must not exceed dose limits in other parts of this proposed chapter.

Subpart 3. Prohibited radiation-producing equipment and procedures. This subpart was carried over from Chapter 4730. This subpart is necessary to protect an individual from unintended exposure to radiation-producing equipment. It is necessary to eliminate procedures that result in unnecessary or unproductive radiation exposures for the patient, occupational worker or the public.

Item A is a carry over from Chapter 4730 and is still valid. This prohibition is necessary because there is no diagnostic or therapeutic benefit from this type of fluoroscopic x-ray equipment for shoe fitting.

Item B is also a carry over from Chapter 4730 and is still valid. This type of diagnostic equipment is no longer used routinely because it requires more radiation than conventional radiography. In addition, the radiographic film produced is of very poor diagnostic quality. This item is necessary because the extra radiation required to produce this non-diagnostic film represents unnecessary exposure to the patient.

Item C is carried over from Chapter 4730. Since Chapter 4730 was initiated in 1991, other hand-held equipment has been developed. The newer equipment makes this requirement more valid because diagnostic equipment of this type has a greater potential for unnecessary radiation exposure to the patient. This is due to possible motion because of the equipment holder's inability to hold the unit still for the exposure because of the weight; the design of the equipment which allows radiation back scatter shielding to be removed by the operator, and the occupational worker would be exposed to unnecessary radiation.

Item D is carried over from Chapter 4730. It prohibits the use of direct exposure film for all procedures except for the following:

- intraoral dental radiography because a cassette containing intensifying screens would be difficult if not impossible to place inside a patient's mouth;

- therapeutic portal imaging because the exposure from therapy equipment uses such high energy, using an intensifying screen would make it impossible to acquire an appropriate image to define the area of the patient to be treated;

- industrial radiography which is not used on patients. It uses a very high energy level, and is used in an enclosed and specially controlled area; and

- finally, radiographic absorptiometry because of the short exposure time and the image is only the middle finger of the predominant hand.

Item E is carried from Chapter 4730.1210. It prohibits non-image intensified fluoroscopic x-ray equipment. Non-imaged intensified fluoroscopic systems require more radiation dose to produce

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a diagnostic image than imaged intensified systems; therefore, they expose the patient to more radiation than necessary.

Item F is carried over from Chapter 4730 prohibiting the use of dental intraoral radiographic units operating less than 50 kVp because the penetration of kVp at less than 50 is inadequate to produce a good diagnostic dental image. Consequently, the exposure from these devices is unnecessarily higher for the patient.

Item G is carried over from Chapter 4730.1210. Specially designed equipment is necessary to adequately image breast tissue for subtle lesions. The Food and Drug Administration's Mammography Quality Standards Act govern this equipment for the safety of the patient.

Subpart 4. Unauthorized exposure of individual monitoring devices is carried from Chapter 4730 because it is still valid. This subpart is necessary to protect against from deceptive exposure to personnel monitoring equipment, resulting in an inaccurate exposure record for the individual. Ultimately, inaccurate exposure records could have a significant adverse impact upon a registrant's liability. Additionally, it can increase the stress level in an individual whose individual monitoring device was exposed in a deceptive practice.

4732.0306. UNAUTHORIZED USES.

This proposed language is recommended by the MDH Radiation Control staff and members of the Advisory Group to enable the commissioner to review an unauthorized or prohibited use in a timely manner should an emergency arise or a new technology emerge, and that require the uses of radiation producing equipment or procedures

Item A is proposed to address new technology of hand held radiation-producing equipment that was employed after hurricane Katrina and can be available for emergencies when electrical power is not readily available. To ensure radiation safety for the operator in these situations, the manufacturer's radiation shielding devices must be in place.

Item B is proposed to allow the commissioner to evaluate situations where positioning of the patient by fluoroscopy would be of benefit to the patient and be able to review the radiation dose to the patient that is attributed to the positioning under fluoroscopy.

Item C is proposed in this part to address situations where fluoroscopy equipment is used and a licensed practitioner of the healing arts is not available for supervision because the diagnosis is made during the fluoroscopic procedure. The commissioner can decide if the risk of radiation exposure to both the operator and the patient when used by a non-licensed practitioner outweighs the potential benefit in the situation.

Item D is proposed to accommodate any future technology. It provides the commissioner the opportunity to decide if the risk of radiation exposure of an individual outweighs the potential benefit of the use of fluoroscopy equipment in a dental office.

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Item E is proposed to address situations where the use of phantoms could not be used or personnel protective garments or shielding are not used appropriately. The commissioner can decide if the risk of exposure to an individual or member of the public outweighs the potential benefit in the situation of concern.

4732.0308. VARIANCE TO RULES RELATING TO IONIZING RADIATION.

The proposed rule part is carried from Chapter 4730.0850 and is still valid. It is necessary to provide parties governed by Chapter 4732 with procedures and criteria for the consideration of a variance to adopted standards. Minnesota Statutes, Section 14.05, subdivision 4 requires that an agency "adopt rules setting forth procedures and standards by which variance shall be granted and denied." In the course of enforcing existing standards, there may be an occasion or instance where not all applicable standards can be met. This gives the commissioner a method to review and make a decision to allow a variance to a rule part in appropriate situations.

Registrants can ask the commissioner to consider if the standard can be varied so the project or procedure can take place. If there are alternative means that accomplish the same purpose as the original standard, they should be considered and perhaps substituted for the standard prescribed.

The commissioner submits that all provisions of Chapter 4732 are subject to variance except those that govern the registration of sources of radiation (part 4732.0200), registration of service providers (part 4732.0275), x-ray operators (parts 4732.0570 through 4732.0590) and part 4732.0210 registration fees. The registration fees are governed by Minnesota Statutes. The criterion for the variance is set out in *Minnesota Rules*, Chapter 4717.7000 to 4714.7050.

4732.0310. DATA PRIVACY.

This proposed rule part is to ensure compatibility with *Minnesota Statutes*, Chapter 13 and *Minnesota Rules*, Chapter 4731, Radioactive Material. The members of the Advisory Group and the MDH Radiation Control staff recommended that the proposed language be taken from Radioactive Materials Rules, Chapter 4731 for ease of compliance with those registrants that are regulated by both Chapter 4731 and the proposed rule, Chapter 4732.

4732.0315. DELIBERATE MISCONDUCT.

This proposed rule part is included to be consistent with understanding and compliance with this proposed chapter. The members of the Advisory Group and the MDH Radiation Control staff recommended that the proposed language be taken from *Minnesota Rules*, Chapter 4731, Radioactive Materials, for ease of compliance with those registrants that are regulated by both Chapter 4731 and the proposed rule, Chapter 4732.

4732.0320. EMPLOYEE PROTECTION.

This proposed rule part is included for consistency and compliance with *Minnesota Statute*, Sections 181.931 to 181.935 plus the *Minnesota Rules*, Chapter 4731, Radioactive Materials. The members of the Advisory Group and the MDH Radiation Control staff recommended that the proposed language be taken from *Minnesota Rules*, Chapter 4731, Radioactive Materials, for

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ease of compliance with those registrants that are regulated by both Chapter 4731 and the proposed rule, Chapter 4732.

4732.0330. RECORDS.

This proposed rule part is included to be consistent with understanding and continued compliance with the proposed chapter.

Subpart 1. Applicability. This will clarify which records are required to be kept for inspection by the commissioner. The proposed language was taken from *Minnesota Rules*, Chapter 4731, Radioactive Materials, to facilitate compatibility between the two rules and to ensure compliance by the registrants that would be regulated by both the *Minnesota Rules*, Chapter 4731, Radioactive Materials, and the proposed rule, Chapter 4732.

Items A through D provide the commissioner with information necessary to verify that individuals are being protected from unnecessary exposure to radiation. These items were carried over in part from Chapter 4730.1520, as they are still valid.

Subpart 2. Format and safeguarding records. This proposed subpart language was taken from the *Minnesota Rules*, Chapter 4731, Radioactive Materials, for consistency and ease of compliance with those registrants that are regulated by both Chapter 4731 and the proposed rule, Chapter 4732. The members of the Advisory Group and the MDH Radiation Control staff recommended that the proposed language be used.

Subpart 3. Reporting units. The proposed language was taken in part from Chapter 4730.1520 and the *Minnesota Rules*, Chapter 4731, Radioactive Materials. It is important that reporting units are consistent in both programs. The members of the Advisory Group and the MDH Radiation Control staff recommended that the proposed language be used for ease of compliance with those registrants that are regulated by both Chapter 4731 and the proposed rule, Chapter 4732.

Subpart 4. Retention schedule for records. The proposed language was recommended by the members of the Advisory Group, registrants, and the MDH Radiation Control staff. The records provide the commissioner with information necessary to determine that the radiation safety surveys, calibrations, quality control measurements, training, maintenance and any equipment modifications are performed as required by the proposed chapter.

4732.0335. INSPECTIONS AND TESTING.

Subpart 1. Inspections. The language in this subpart is in part carried over from Chapter 4730. This provision has been included to clarify that the requirement applies to all registrants. It indicates to the registrant that the commissioner has the responsibility to inspect for compliance with this proposed chapter and requires that documentation of factors protecting occupationally exposed workers and members of the public be provided to the commissioner.

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Subpart 2. Testing. The proposed language is recommended by the MDH Radiation Control staff and members of the Advisory Group to ensure that the registrant has an understanding of their responsibilities in ensuring radiation safety in their facilities.

4732.0340. VIOLATIONS AND ENFORCEMENT REQUIREMENTS.

The proposed language was taken from the Iowa Department of Public Health Rules, Public Health #641. The MDH Radiation Control staff and members of the Advisory Group reviewed the proposed language and recommended the language be included. This was included so the registrants have an understanding of their responsibilities following an inspection by the commissioner. It also addresses the penalties that can be imposed in accordance with *Minnesota Statutes*, sections 144.989 to 144.993.

4732.0355. GENERAL REQUIREMENTS FOR SHIELDING AGAINST IONIZING RADIATION.

Subpart 1. Applicability. This proposed part clarifies shielding requirements that apply to new or remodeled facilities used for particular types of radiation-producing equipment. The general requirement language is carried over in part from Chapter 4730. This rule requires shielding based on national standards, doses to the occupational worker, and on doses to members of the public. The proposed time frame provides opportunity to inform affected parties and contractors of the new shielding provisions and gives them time to plan for compliance.

Subpart 2. Shielding details. The shielding details concept was carried from 4730.1610, but the proposed language was taken from the CRCPD's SSRCR. The MDH Radiation Control staff and members of the Advisory Group reviewed and agreed with the language as appropriate.

Subpart 3. Operator's booth design requirements. With the one exception, the language included in this subpart was taken from Chapter 4730.1610. In item E (2) (b) the window size was changed from 24 inches high x 18 inches wide to the proposed 350 square inches. The Advisory Group recommended this language as it offers more choices based on the facility type of use and represents a potential savings to the regulated community. The MDH Radiation Control staff agreed with this recommendation.

Subpart 4. Records. This was included to ensure that the facilities know that shielding plans and results of the radiation surveys must be maintained in according to the records portion of the proposed rule.

4732.0360. SHIELDING PLAN.

The proposed language for this part was taken from the CRCPD's SSRCR. The proposed time frame provides an opportunity to inform affected parties and contractors of the new shielding provisions and give them time to plan for compliance.

Subpart 1. Shielding plan requirements. The proposed language was taken from the CRCPD's SSRCR. The NCRP report #147, "Structural Shielding Design for Medical X-ray Imaging Facilities" recommends that the plan include all the assumptions made in the design concerning workload and occupancy factors for the adjacent areas as well as other pertinent assumptions that

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may restrict the present or future use of the x-ray room. This would be consistent with the proposed language from the CRCPD's SSRCR.

Subpart 2. Modifications. The proposed language is recommended to ensure that modifications will protect the occupational worker and members of the public from unnecessary radiation following any facility modifications.

Subpart 3. Radiation survey. The proposed language will provide the commissioner with the information necessary to ensure the new construction or modification of existing facilities will protect the occupational worker and members of the public from unnecessary radiation.

Subpart 4. Shielding plan submittal. The proposed language requiring submission of a shielding plan will provide the commissioner with the information necessary to ensure that new construction or modification of facilities will protect the occupational worker and the members of the public from unnecessary radiation.

Subpart 5. Exemptions. The proposed language exempting the items A through F was recommended by the MDH Radiation Control staff and members of the Advisory Group. The exemptions are based on control of radiation by equipment design or that a replacement does not increase the radiation doses beyond the limits indicated in other parts of this rule.

Subpart 6. Records. This part was included to ensure that the facilities know that the shielding plans and results of the radiation surveys must be maintained in according to the records portion of this rule.

Subpart 7. Permanent placard. The proposed language ensures that the registrant and the employees of the registrant know what lead equivalent shielding is contained in the x-ray room and where it is located in that room. This is vital information for the registrant to maintain. It documents current conditions and ensures availability of this knowledge in the case of remodeling or sale of the facility.

4732.0365. ADDITIONAL SHIELDING REQUIREMENTS FOR DENTAL FACILITIES.

This part was taken from Chapter 4730 with some slight modification to address dose limits for occupational workers, patients, as well as members of the public. The recommended changes came from the MDH Radiation Control staff and members of the Advisory Group. The proposed language is inclusive for dental facilities with intraoral or extraoral equipment.

732.0370. ADDITIONAL SHIELDING REQUIREMENTS FOR INDUSTRIAL FACILITIES USING RADIATION-PRODUCING EQUIPMENT.

Subpart 1, Industrial facilities; Subpart 2, Applicability and Subpart 3, General shielding and design requirements for industrial radiography include the language that requires providing the commissioner with the information that ensures industrial facilities using the radiation-producing equipment are designed to minimize the doses for occupational workers and members of the

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public so that the limits are not exceeded. The MDH Radiation Control staff recommended the proposed language. Some of the proposed language was carried over from Chapter 4730.1640.

Subpart 4. Exception. The proposed language exempts the industrial x-ray systems that by design do not increase the radiation risk beyond the dose limits established in other areas of the proposed rule.

4732.0380. ADDITIONAL SHIELDING REQUIREMENTS FOR ACCELERATORS.

The proposed rule language is in part taken from Chapter 4730.1630 and from the Iowa Department of Public Health Rules, Public Health # 641. The members of the Radiation Advisory Group and the MDH Radiation Control staff have reviewed and agreed with this language.

Subpart 1. Design requirements for accelerator facilities. Because of the high exposures used with accelerators, the shielding requirements in items A through J are to remind registrants that there are exposure limits that must not be exceeded. The design requirements from barriers, interlocks or safety devices, cutoff switches, instrumentation, controls, entrances all must be addressed in each design for accelerator facilities. Each of these should be addressed and maintained though out the lifetime of the accelerator.

Subpart 2. Additional design requirements for medical use accelerators. The additional design requirements for medical use accelerators are designed for the registrant to be in communication with the patient both by audio means and be able to see the patient.

Item A in the proposed language is included to ensure that the operator is outside the treatment room at a control console. It also requires the operator to have a constant view of the patient before, during, and after treatment through a closed-circuit television system (or equivalent system). This is necessary to ensure patient safety and that no one inadvertently enters the room. The treatment must be interrupted if the operator observes a patient condition that warrants termination of radiation or if the operator cannot prevent inadvertent entry.

Item B is the proposed language necessary to ensure that the operator stays in constant verbal contact with the patient in the treatment room before, during and after treatment. This is to ensure that if the patient is having a problem, it can be communicated to the operator and the operator can prevent or interrupt a treatment.

Subpart 3. Modification of an accelerator or room before use. The proposed language ensures that any modification of either the accelerator, therapeutic equipment, or the structure of the accelerator or treatment room is provided to the commissioner. This action is to ensure that the dose limits for occupational worker, patients, or members of the public are reviewed and are not exceeded.

Subpart 4. Radiation surveys. The proposed language ensures that the commissioner is provided with information to verify radiation levels in restricted areas are not likely to cause personnel exposures in excess of the dose limits in other portions of this rule.

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Subpart 5. Corrective actions. This is necessary to ensure that if any change in radiation levels are identified by radiation surveys they are corrected and the commissioner is notified. The registrant must lock the control in the "OFF" position and not use the unit.

4732.0385. CAUTION SIGNS.

The proposed language was carried from Chapter 4730.0300 with recommendations for slight modifications taken from CRCPD's SSRCR and *Minnesota Rules*, Chapter 4731, Radioactive Materials. The modifications were taken to address new technologies. The MDH Radiation Control staff and the Advisory Group reviewed the recommendations and agreed to their inclusion in the proposed rule.

Subpart 1. Standard radiation symbol and labeling. This language is from Chapter 4730.0300 with updated information concerning the coloring taken from the CRCPD's SSRCR.

Subpart 2. Additional information on signs and labels. The proposed language is taken from the CRCPD's SSRCR.

Subpart 3. Prohibitions on use of the symbol. This language is taken from Chapter 4730.0300 as still valid for use in this rule.

Subpart 4. Posting and labeling requirements. The language is taken from Chapter 4730.0300 as is still valid for use in this rule.

Subpart 5. Exceptions to posting requirements. The proposed language is taken from CRCPD's SSRCR. It clarifies that registrants are not required to post an area or room if they have control of the area. The registrants and members of the Advisory Group recommended the inclusion of this exception.

4732.0400. DETERMINATION OF ACCUMULATED OCCUPATIONAL DOSE.

This proposed language was taken from CRCPD's SSRCR. Part of the proposed language was also carried over from Chapter 4730.0340. The proposed and carry over language was reviewed by the MDH Radiation Control staff and members of the Advisory Group prior to inclusion and agreed to include it in the proposed chapter.

Subpart 1. Determination of prior occupational dose. This requirement is necessary to ensure that an individual worker does not exceed the dose limits in this proposed chapter. The registrant has the responsibility to know the previous dose received by an occupational worker if possible and to maintain the record of that exposure.

Subpart 2. Complying with the determination of prior occupational dose. The proposed language for this subpart was taken from the CRCPD's SSRCR. The MDH Radiation Control staff and members of the Advisory Group reviewed this language prior to inclusion and agreed to include it in the proposed chapter.

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4732.0410. OCCUPATIONAL DOSE LIMITS FOR ADULTS.

Subpart 1. Applicability. This subpart is necessary to ensure that all registrants understand that the standards specified in this part are applicable to all.

Subpart 2. Occupational dose control. This subpart is necessary to ensure that the radiation doses for the individual workers are accurately measured and determined. Accurate exposure measurement is necessary so an individual worker exposed to radiation is not exposed unnecessarily. This proposed language is taken from the CRCPD's SSRCR.

Subpart 3. Doses in excess of limits. This subpart is necessary to ensure that the registrant is aware of dose limits when planned special exposure activities are being implemented. This proposed language is taken from the CRCPD's SSRCR.

Subpart 4. Dose equivalent. The proposed language is taken from the CRCPD's SSRCR to clarify the requirements for dose determination and monitoring of individual workers.

Subpart 5. Reduction of dose. This subpart is necessary because of the potential additional dose received by individuals employed at different facilities during the current year. This proposed language is taken from the CRCPD's SSRCR.

Subpart 6. Dose information. This subpart is necessary for the registrant's information on individual workers to ensure the dose limits are not exceeded. This proposed language was taken from the CRCPD's SSRCR.

4732.0415. DOSE EQUIVALENT TO AN EMBRYO/FETUS.

The proposed language for this part was carried over from Chapter 4730.0310 for continued compliance and is still valid for this rule. The registrants need to be aware of their responsibilities to an employee that declares her pregnancy in writing.

4732.0420. EXPOSURE OF MINORS.

The proposed language for this part was taken from Chapter 4730.0360. It was slightly modified using the CRCPD's SSRCR to address the newer technologies. This proposed rule part is necessary to prevent individuals under the age of 18 years from being occupationally exposed to radiation greater than 10 percent of the annual occupational dose limits for adult workers. By restricting the occupational exposure of persons below this age, developmental harm to the individual is reduced.

4732.0425. PLANNED SPECIAL EXPOSURES.

While planned special exposures are a part of Chapter 4730.0310, the proposed rule part was updated to address the newer technologies and concerns of the MDH Radiation Control staff and members of the Advisory Group. The registrant may permit a worker to receive a planned special

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occupational exposure under specific circumstances as indicated in this part. The proposed language is taken from the CRCPD's SSRCR.

4732.0430. DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC.

The proposed rule part is necessary to prevent exposure in unrestricted areas of a facility. In unrestricted areas, the general public should not be exposed to radiation beyond the limits specified in this part. The exposure limits specified address whether the individual is continuously present or only periodically present. (The Department has interpreted continuously present to mean that an individual is occupying the space at least 40 hours a week.) In either case, some maximum limits are set in items A and B for exposure dosages. The proposed language is taken from the CRCPD's SSRCR. The Advisory Group and the MDH Radiation Control staff agreed this language should be included in the proposed chapter.

4732.0440. INDIVIDUAL MONITORING.

This proposed rule part addresses the need to be informed of radiation exposure levels for persons working with ionizing radiation. The required use of personnel monitoring equipment allows accurate measurement of radiation doses. This is especially important for people working in high radiation areas.

Subpart 1. Applicability. This identifies who needs to be monitored and under what circumstances. The proposed language in this part was taken from the CRCPD's SSRCR, Chapter 4730, and the *Minnesota Rules*, Chapter 4731, Radioactive Materials. The Advisory Group and the MDH Radiation Control staff agreed this language should be used for inclusion in the proposed chapter.

Subpart 2. Assignment. The MDH Radiation Control staff and members of the Advisory Group proposed language to clarify and discourage the practice of sharing an individual monitoring device. When this practice is allowed, the registrant cannot differentiate the results between those sharing the device and who might have received a dose in excess of the limits in the proposed rule.

Subpart 3. Placement of individual monitoring device. It is critical that the equipment is worn in a place on the body where the most accurate measurement can be made. This location must also be outside any protective clothing.

Items A, B, and C are necessary to ensure that radiation exposure is monitored appropriately so the results are accurate when protective clothing is worn. Devices worn outside the protective clothing ensures an accurate reading of radiation doses to the head and neck. The proposed language was taken from both Chapter 4730.1510 and the CRCPD's SSRCR.

Item D indicates the placement of the monitoring device when worn by a declared pregnant woman to monitor the exposure to the embryo/fetus accurately.

Subpart 4. Individual monitoring control devices. The proposed language is necessary for clarification. The registrant must have a control device to monitor any background radiation assigned devices receive. This exposure is then subtracted from the individual workers exposure

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record to provide the occupational dose. The language was carried over from Chapter 4730.1510.

Subpart 5. Veterinary facilities. The subpart is to ensure that veterinary facilities comply with *Minnesota Statutes*, section 144.121, subdivision 4. The language was taken from Chapter 4730.1510.

Subpart 6. Industrial facilities. The proposed language is necessary to ensure that any industrial facility has an understanding of the requirements for their occupational workers. The proposed language was taken from the CRCPD's SSRCR.

Subpart 7. Exception for permanent industrial radiographic installations. The members of the Advisory Group recommended the proposed language for clarification.

Subpart 8. Exception for industrial pulsed mode devices. The members of the Advisory Group recommended the proposed language for clarification.

Subpart 9. Direct reading pocket dosimeters. The proposed language for this subpart was taken from the CRCPD's SSRCR, Chapter 4730.1510, and the *Minnesota Rules*, Chapter 4731, Radioactive Materials. It is necessary for the registrant to understand when direct reading pocket dosimeters are required.

Subpart 10. Off-scale dosimeters. The proposed language for this subpart was taken from the Chapter 4730.1510 and the CRCPD's SSRCR. This is necessary for an individual to understand the requirements when their monitoring device it is found to be off-scale.

Subpart 11. Lost or damaged direct reading pocket dosimeters. The proposed language for this subpart was taken from Chapter 4730.1510 for the registrants to understand the requirements for an individual monitoring device when it is discovered to be lost or damaged.

Subpart 12. Alarming ratemeters. The MDH Radiation Control staff and members of the Advisory Group recommended that the language from 4730 be included in this rule as it was still valid.

Subpart 13. Individual monitoring dosimetry records. This subpart is necessary as it provides information to the registrant on the radiation doses of all individuals for whom individual monitoring is required.

Subpart 14. Individual monitoring reports. The proposed language for this subpart is based on the CRCPD's SSRCRs and was taken from Chapter 4730.1140 as well as the *Minnesota Rules*, Chapter 4731, Radioactive Materials.

Item A is necessary to provide this information to workers exposed to radiation so the workers can assume responsibility for their exposure. It is necessary to keep the employee informed of any exposure to ensure that the exposure does not exceed any dose limit in this rule. The language was taken from Chapter 4730.1140. The requirement for individual quarterly reports

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was modified to be an annual report, which is consistent with the Radioactive Materials Rules. The members of the Advisory Group recommend this change. The MDH Radiation Control staff agreed with this change.

Items B and C are necessary to ensure that the report is in writing and follows the requirements in item C for consistency. This language was taken from Chapter 4730.1140.

Item D is necessary to ensure that the individual worker exposed to radiation can estimate the level of radiation he or she can safely be exposed to in the future. This language was taken from Chapter 4730.

4732.0500. REGISTRANT'S SAFETY RESPONSIBILITIES.

Subpart 1. Applicability. This subpart is needed to assert that the registrant is responsible for the operation of ionizing radiation-producing equipment in accordance with the requirements of this proposed chapter. This is necessary to protect the public health. This subpart was taken from Chapter 4730.1510.

Subpart 2. Designation of radiation safety officer. This subpart is needed to assure that there is a qualified individual involved in the operation of the radiation-producing equipment and that the individual is knowledgeable of radiation hazards and precautions.

Items A and B further define the qualifications and knowledge that the radiation safety officer must have to function in that role. The oversight of the radiation safety officer is essential to provide the registrant with information needed to maintain the safe operation of the radiation-producing equipment in the facility. The members of the Advisory Group and the MDH Radiation Control staff recommend this language be included in the proposed rule.

Items C, D, and E are necessary to complete the information to ensure that the radiation safety officer is qualified and willing to fulfill the duties. The proposed language was taken from the Radioactive Materials Rules, Chapter 4731.

Subpart 3. Commissioner option. This language was carried from Chapter 4730.0500 and is still valid.

Subpart 4. Individuals who may apply radiation to humans. This subpart requires the operation of radiation-producing equipment by persons that meet the x-ray operator requirements. It is necessary to protect patients, operators, and other individuals who may be exposed to ionizing radiation. This is language carried from Chapter 4730.1510.

Subpart 5. Records. This subpart serves as a reminder that records must be kept for all aspects of this rule.

4732.0505. Radiation Safety Officer Responsibilities. The MDH Radiation Control staff and members of the Advisory Group requested that the expected responsibilities of the radiation safety officer be outlined in this rule. This was to for clarification and to promote compliance

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with this rule. The proposed language was taken in part from *Minnesota Rules*, Chapter 4731, Radioactive Materials, and the CRCPD's SSRCR.

4732.0510. OPERATING AND EMERGENCY PROCEDURES AND SAFETY INSTRUCTIONS FOR ALL MEDICAL AND DENTAL FACILITIES.

This part assures that each registrant understands that operating and emergency procedures and safety instructions are required for each facility. Training for operators is essential to protect patients, operators, and others from exposure to unnecessary radiation. Registrants are provided some flexibility in training depending on the size and nature of the equipment. Not all registrants may need to provide the same training to operators.

Subpart 1. Safety procedures for the facility. Written safety procedures are required so that operators of the equipment will have easy access to the procedures at all times. The proposed language for this was taken in part from Chapter 4730.1510, the CRCPD's SSRCR and the *Minnesota Rules*, Chapter 4731, Radioactive Materials.

Item A indicates who is responsible for the creation and maintenance of the safety procedures. The language for this was taken from CRCPD's SSRCR.

Item B identifies which individual workers require training and what topics need to be covered. The language was taken from the *Minnesota Rules*, Chapter 4731, Radioactive Materials, for consistency within the two programs in the Radiation Control unit.

Item C is a reminder that documentation or record of any training must be maintained in accordance with this proposed chapter.

Subpart 2. Exposure of individuals other than the patient. This subpart is necessary to ensure that individuals who are not involved with an x-ray procedure are protected against any unnecessary exposure. This is based on language from Chapter 4730.1510.

Items A through C are specific areas of concern to the members of the Advisory Group and the MDH Radiation Control staff. The language was carried over from chapter 4730.1510 and language from the CRCPD's SSRCR. These areas of concern are necessary to protect the occupational worker, the patient, and the public from unnecessary exposure to radiation.

Subpart 3. Gonad protection. This subpart was carried over from Chapter 4730 and is still valid. The gonads are radiosensitive organs that must be protected from exposure to radiation.

Subpart 4. Holding. Item A is necessary to address conditions that required a patient to hold an x-ray film or film cassette during a radiation exposure. The language was carried over from Chapter 4730. The language was originally taken from the CRCPD's SSRCR.

Item B contains the requirement for safety procedures for holding patients during radiation exposure. It also addresses holding of film to protect the operator.

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Subpart 5. Records. This is a reminder that records on these items must be maintained in accordance with this proposed chapter.

4732.0520. QUALITY ASSURANCE PROGRAM.

The specified quality assurance program is designed to ensure that imaging procedures are necessary and appropriate. It is also established to ensure that the images contain information critical to the solution of the problem; that the recorded information is correctly interpreted and made available to the patient and physicians in a timely manner; and that the examination results in the lowest radiation exposure, lowest cost, and least inconvenience to the patient.

Subpart 1. General requirements. This subpart provides information about the required contents of a quality assurance program to the registrant and radiation safety officer. The language proposed in items A through C is taken from Chapter 4730.1655.

Item D language is necessary to ensure that the registrant understands that equipment must not be used on patients if an operating parameter is exceeded. This is to ensure that unnecessary exposure to radiation does not take place. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 3. Records. This is a reminder that records on these items must be maintained in accordance with this proposed chapter.

4732.0530. ALARA PROGRAM.

ALARA stands for as low as reasonably achievable. This part is necessary to ensure that each facility is utilizing procedures that minimize the exposure to patients and occupational workers to unnecessary radiation, and yet produce a diagnostic radiography or image. Procedures that provide for the most diagnostic image possible in the shortest time provide the most protection against unnecessary radiation exposure. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641. This requirement is supported by the CRCPD's SSRCR.

4732.0535. RETAKE OR REJECT ANALYSIS PROGRAM.

A retake or reject analysis program will provide the registrant information to assure that the patients, public, and occupational workers are not being exposed to unnecessary radiation because of unknowledgeable or unqualified operators. The proposed language for this entire part was taken from the CRCPD's SSRCR.

Subpart 1. Applicability. This subpart is to ensure that the registrants understand that they are responsible for implementing this program. Items A through D are the parts to promote an understanding of this rule.

Subpart 2. Corrective actions. This is necessary to ensure that the retake or reject analysis is completed and any corrective actions must be taken to continue the viability of this program.

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4732.0540. RADIATION PROGRAM AUDITS.

The proposed language for this entire part is taken from the Iowa Department of Public Health Rules, Public Health # 641, and the CRCPD's SSRCR. This is a necessary part to provide the registrant the information concerning the radiation program audit.

Subpart 1. Applicability. This proposed language is necessary because it explains that each registrant or radiation safety officer is responsible for the annual review of the quality assurance program.

Subpart 2. Procedures. Site-specific procedures must be implemented for compliance with this proposed chapter.

Subpart 3. Corrective actions. This subpart is necessary to ensure that the audit is conducted and corrective actions are taken.

Subpart 4. Records. This is a reminder that records on these items must be maintained in accordance with this proposed chapter.

4732.0545. UTILIZATION LOG.

Items A through C are necessary to provide the registrants with the information needed to complete the utilization log. This utilization log is a method that allows the registrant or radiation safety officer to review the radiation exposures on a routine basis; to monitor any problems in the operation of the equipment; or to identify any operator problems. This proposed language was taken from the CRCPD's SSRCR, recommendations from the Advisory Group, and from the MDH Radiation Control staff.

Item D covers the exemptions for radiation-producing equipment that would not expose occupational workers to unnecessary radiation during use.

4732.0550. RADIOLOGICAL PRACTICE STANDARDS.

This part is necessary to ensure that all radiation-producing equipment and procedures protect public health and safety by minimizing exposure to radiation.

Items A through F specify equipment used to support the general principle in this part.

Item B is necessary to protect the patient from unnecessary radiation exposure. This item complements the prohibition against the use of direct exposure film in 4732.0305.

Item C is necessary to reiterate the principle that a patient should only be exposed to enough radiation to produce a good quality diagnostic image. Item D is necessary because portable radiation-producing equipment is not as accurate as stationary equipment; therefore, it should only be used when a patient cannot be moved to a stationary installation. This language was taken from the CRCPD's SSRCR.

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Item E is necessary as it is a compliance issue with the Code of Federal Regulations, Title 21, 1030.

Item F is language taken from Chapter 4730.1510 and remains valid as a part of a quality assurance program. Inclusion of protective garments other than aprons and gloves was made based on a recommendation of the Advisory Group. Based on this recommendation, "personnel protective garments" is the proposed term that is used.

Subpart 1. Radiographic technique chart. This subpart is necessary to ensure that the operator has information for the safe operation of the diagnostic x-ray systems in an easily accessible place. This proposed language was taken from Chapter 4730.

Items A through C are used to define the requirements for compliance with this proposed chapter.

Subpart 2. Exceptions. Newer diagnostic radiation-producing equipment has the anatomical programs for exposures internally set at the time of manufacture. To make the facility reproduce this in the form of a technique chart is not necessary. For industrial facilities a technique chart is not a necessity because radiation exposure is not to a patient; therefore, there is an exception for industrial facilities.

4732.0555. X-RAY FILM PROCESSING REQUIREMENTS.

The proposed language for this part was reviewed by the Advisory Group and the MDH Radiation Control staff and recommended for inclusion in this proposed chapter.

Subpart 1. Processing equipment. The proposed language for this subpart was taken directly from the CRCPD's SSRCR. The purpose of this subpart is to ensure that each facility understands the film processing requirements necessary to achieve quality images.

Items A and B define requirements for the two main types of processing. This is done to ensure compliance with this proposed chapter.

Subpart 2. Processing quality control. The proposed language was taken from Chapter 4730.1510, recommendations from the Advisory Group, and the MDH Radiation Control staff. The supporting positions also come from the NCRP Report # 99, Quality Assurance for Diagnostic Imaging, CRCPD's SSRCR and Iowa Department of Public Health Rules, Public Health # 641.

Subpart 3. Darkroom or glove box fog tests. This subpart is necessary to ensure that procedures used minimize conditions that result in radiographic images of poor quality that could compromise accurate diagnosis. Fog is the cloudy haze produced on a film exposed to extraneous light. Too much fog makes for a poor image of the anatomy or item being x-rayed.

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Subpart 4. Outdated film. This subpart is necessary because film that is outdated and not tested for viability could result in unreadable images. Consequently, repeat films could be required which would result in additional patient or occupational worker exposures. The Advisory Group and the MDH Radiation Control staff recommended this language for inclusion in the chapter.

4732.0560. ORDERING OF DIAGNOSTIC RADIOGRAPHIC OR THERAPEUTIC PROCEDURES.

This part is necessary to ensure that the correct patient receives the correct diagnostic or therapeutic procedures. This is carried from Chapter 4730.1530 with some additional modifications to address newer technologies.

Subpart 1. Applicability. This part is necessary to identify the individuals responsible for the ordering of diagnostic or therapeutic procedures. The Advisory Group and the MDH Radiation Control staff proposed and reviewed the language for this part for inclusion in this proposed chapter.

Subpart 2. Diagnostic radiographic procedure orders. The proposed language is taken from Chapter 4730.1530 and the Iowa Department of Public Health Rules, Public Health # 641. The Advisory Group and the MDH Radiation Control staff recommended slight modifications to encompass changes required to be consistent with Minnesota Statutes.

Items A through D prevent unnecessary radiation to the patient and occupational worker.

Item E addresses a change in the Minnesota Statutes concerning dental practices. The scope of practice is added for clarification.

Subpart 3. Exception for dental facilities. This proposed language was recommended to be compatible with Minnesota Statutes concerning dental practices and the scope of practice for dentistry. Recall x-rays must be designated by the dentist in charge and included in procedures for all dental employees to follow.

Subpart 4. Therapeutic procedure orders. This proposed language is necessary to ensure that the correct patient, dose and overall treatment time is identified. It also requires follow-up to ensure that no unnecessary radiation is received by the patient or the worker.

Items A through D are proposed to ensure that no unnecessary radiation is administered.

Subpart 5. Identification prior to administration of treatment. The proposed language is necessary to ensure that the correct patient is receiving the therapeutic radiation dose. This proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641.

4732.0565. HEALING ARTS SCREENING.

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Subpart 1. General requirements. This language was carried over from Chapter 4730. It is still necessary to review and approve diagnostic screening programs. The requirements in this part apply to all screen programs except mammography, which is governed by the U.S. Food and Drug Administration.

Item A. Registration of the applicants who seek to undertake an x-ray screening program ensures that the commissioner is aware of the x-ray screening program and has approved its application.

Item B. Requesting permission to perform x-ray screening ensures that the commissioner has the opportunity to inspect the equipment, review and approve procedures prior to program initiation.

Subpart 2. Content of application. This subpart's proposed language is necessary to ensure that all applicants meet the same requirements. Items A through Q further define those requirements. This language is taken from Chapter 4730.1310 and the CRCPD's SSRCR.

Items A and B identify the applicant's name and address of where the screening program will be held.

Item C. Because an individual chooses to be screened without consulting a licensed practitioner of the healing arts, it is particularly important to protect individuals and the general public from unnecessary radiation exposure resulting from this self-referral screening programs. That is why the applicant for the screening program is requested to specify the compelling health reason (or health emergency) for the screening program.

Item D. This subpart is necessary to ensure that an appropriate number of radiological projections are used in an examination so that a clear image is obtained for accurate diagnosis and the exposure is minimized.

Item E is necessary to identify the demographics of population proposed for examination by the screening program.

Item F. This item is necessary because it is important that every effort is made to avoid public exposure to unnecessary radiation

Item G. This item is necessary to ensure that appropriate exposure measurements are used for a screening program. Peer review for exposure measurements can be used for future screening programs for which no exposure measurements are currently established.

Item H. This item is necessary to ensure that unnecessary radiation is not an issue in the screening program. This would be an addition to item G.

Item I. This item is necessary to ensure that quality assurance procedures as specified in other parts of the proposed rule have been met.

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Item J. The technique chart mentioned in this item is essential to ensure that patient radiation exposure is as low as reasonable achievable and that a diagnostic image is obtained for accurate diagnosis.

Items K, L and M, deal with some aspect of the qualifications of the individuals who will be taking the x-ray, supervising the operator, or interpreting the images. This is vital information to ensure that those involved in the screening program are qualified, that the radiation exposure will be as low as reasonable achievable, and the images will be interpreted by a licensed practitioner of the healing arts.

Items N and O define the notification of the results to the patient and the retention of the images and records relating to the screening procedure. This is necessary because x-ray screening procedures are unlike other x-ray procedures performed at the direction of a licensed practitioner of the healing arts. The procedures for interpreting x-ray findings to the individual screened, sending the results to the individual, and recommending necessary follow-up treatment, must be specified for the individual's benefit.

Items P and Q are necessary for the registrant to understand the restrictions in frequency and the duration of the screening application.

Subpart 3. Notification of commissioner's decision. This proposed language is essential to provide the applicant with verification that the program has been approved for a specific period. The language was taken from Chapter 4730.1310.

Subpart 4. Changes in screening program. This proposed language is necessary to allow inspection of a program if any changes are to be made. Inspections will ensure that the changes do not result in unnecessary radiation exposure. This was taken from Chapter 4730.1310 and the CRCPD's SSRCR.

Subpart 5. Appeal procedure. This subpart is necessary to provide the applicant with the opportunity to appeal a decision made by the commissioner regarding the denial, revocation, or refusal to approve an application or renewal. This also gives the applicant the time line in which to renew the screening program if necessary. The proposed language was taken from Chapter 4730.1310 and the CRCPD's SSRCR.

Subpart 6. Renewal of screening application. This subpart is necessary to provide the opportunity to review continuation of an x-ray screening program. It is necessary for the applicant to provide all the information required under subpart 2 so the Department can make an informed decision regarding the renewal of the screening program.

4732.0570. OPERATOR REQUIREMENTS.

This part is necessary to ensure the registrant adheres to *Minnesota Statute*, Section 144.131.

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4732.0575. EXAMINATION REQUIREMENTS.

The proposed language is carried over from Chapter 4730.5100 and is still valid. The MDH Radiation Control staff recommended that this language be maintained for consistency of knowledge of the examination requirements for the regulated community.

Subpart 1. General. The subpart is necessary to describe the scope of the examinations. Items A through D are the areas listed in *Minnesota Statutes*, Section 144.121, subdivision 5.

Subpart 2. Examination approval. This subpart is necessary and ensures 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.

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

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 are required to take an examination in order to take x-rays will to have the opportunity to do so.

Subpart 4. Proctors. This subpart is new and necessary to ensure that individuals can remain objective in the proctoring of the examinations. The MDH Radiation Control staff recommended that this language be included after discussions with the regulated community.

Subpart 5. 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. This language was taken from Chapter 4730.5100.

Subpart 6. Notice to individual. This subpart is necessary and was taken from Chapter 4730.5100. It is essential to ensure that an individual who has taken an examination is notified of the results in a timely fashion.

Subpart 7. Examination security. This subpart is necessary to ensure that an individual cannot have someone else take the examination for him or her.

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Subpart 8. Passing level. This part is taken from Chapter 4730.5100 and is still valid with respect to the passing level that must be met. The seventy percent is generally accepted among testing organizations.

Subpart 9. Closed book examination. This subpart is taken from Chapter 4730.5100, as it is still valid.

Subpart 10. Validity standards. This subpart is taken from Chapter 4730.5100 and is still valid 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. These standards are easily available at the state law library and can also be purchased.

Subpart 11. 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.

Item B is necessary to ensure that the examination provider includes the highest percent of questions on radiation safety. The language was taken from Chapter 4730.5100 and is still valid.

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 12. Examination content. This subpart was taken from Chapter 4730.5100 and is still valid and necessary to ensure that the examination required by *Minnesota Statutes*, Section 144.121. The statute addresses the topic information required to test an individual's knowledge of those topic areas.

4732.0580. REGISTRANT REQUIREMENTS FOR OPERATORS IN 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. This language was taken from Chapter 4730.5200.

4732.0585. EQUIVALENT EXAMINATIONS.

Subpart 1. General. This part is necessary to address the requirement of *Minnesota Statutes*, 144.121 that provides for an equivalent examination. All the examination in subparts 2 through 7 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 4732.0570 through 4732.0585.

Subpart 2. Radiologic technologist registration examination. This subpart specifies that the radiologic technologist registration examination for radiologic technologist qualifies as an equivalent examination to that required part in parts 4732.0585 through 4732.0590.

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Subpart 3. 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 4732.0570 through 4732.0590.

Subpart 4. Radiologic technologist with a 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 a jurisdiction outside Minnesota may request the commissioner to determine if the license examination meets the requirements of part 4732.0570.

Subpart 5. Other professional registrations. This subpart is necessary and taken from Chapter 4730.5200 as still valid to clarify that an individual who has passed a registration examination, may request a determination of equivalency according to the procedures and criteria in the Minnesota Department of Health variance procedures referenced in this proposed chapter.

Subpart 6. Registered physician assistants. This proposed language was recommended by the members of the Advisory Group and the MDH Radiation Control staff based on *Minnesota Statute* 147A. This is necessary due to the change in the above statute.

Subpart 7. Individuals having passed an examination for dual modality studies. The Advisory Group and the MDH Radiation Control staff recommended the proposed language. This has been included because of the national examinations for nuclear medicine technologists and because of newer technologies.

4732.0590. INDIVIDUALS OPERATING X-RAY EQUIPMENT DURING TRAINING.

Subpart 1. Exemptions from x-ray machine operator's exam. This subpart 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 in 4732.0570. The exemption language was taken from Chapter 4732.5500. The exemption is only for those individuals taking or processing x-rays within the scope of the training course.

Subpart 2. Externships. The members of the Advisory Group and the MDH Radiation Control staff recommended this language be included for clarity for the registrants. This will provide information for the commissioner to ensure that radiation doses to the patients and individuals in the training courses are as low as reasonable achievable.

Subpart 3. Utilization logs. The Advisory Group and the MDH Radiation Control staff recommended this language be included for continued clarity for the registrants.

4732.0600. REPORTS OF THEFT OR LOSS OF RADIATION-PRODUCING EQUIPMENT.

Subpart 1. Telephone reports. This subpart contains the requirements for notifying the commissioner of the theft or loss of any radiation-producing equipment. To ensure that the commissioner receives all the necessary information immediately after the incident occurs rather than much later. Immediate notification allows the commissioner to promptly take any appropriate action. This language was taken in part from Chapter 4730.1110.

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Subpart 2. Written follow-up reports. The language proposed in this subpart was taken from the CRCPD's SSRCR. The members of the Advisory Group and the MDH Radiation Control staff recommended the inclusion of this language to be similar to the responsibilities for the registrant as the licensee in the *Minnesota Rules*, Chapter 4731, Radioactive Materials.

4732.0610. REPORTS OF MEDICAL EVENTS OR INCIDENTS INVOLVING RADIATION-PRODUCING EQUIPMENT.

Subpart 1. Medical event. The proposed language is taken from the *Minnesota Rules*, Chapter 4731. The Advisory Group and the MDH Radiation Control staff recommended the inclusion of this language to be similar to the responsibilities for the registrant as the licensee in the *Minnesota Rules*, Chapter 4731. This provides the commissioner with information on any medical therapy event or incident involving diagnostic equipment or unnecessary radiation dose that exceeds the limits in this proposed chapter.

Subpart 2. Fluoroscopic event. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641, and recommended for inclusion by members of the Advisory Group and the MDH Radiation Control staff.

Subpart 3. Notification within 24 hours. The proposed language is taken in part from Chapter 4730.1120. The members of the Advisory Group and the MDH Radiation Control staff recommended the inclusion of this proposed language. This will provide prompt information on any medical event or incident and be consistent with the *Minnesota Rules*, Chapter 4731.

Subpart 4. Additional reports. Having the ability for additional written reports provides the Department with an opportunity to review and evaluate the situation and take corrective action, as necessary. The proposed language is taken in part from Chapter 4730.1130. The members of the Advisory Group and the MDH Radiation Control staff recommended the inclusion of this language.

Subpart 5. Reports on individuals. The proposed language requiring the report to individuals was taken in part from Chapter 4730.1130. The report provides the commissioner with necessary information to ensure that the incident will be properly corrected.

Subpart 6. Report to individual worker exposed beyond occupational levels. The proposed language in this subpart is to provide the commissioner with necessary information to ensure that the individual exposed is properly identified and a record made of the dose level.

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4732.0620. WARNING AND CONTROL DEVICES FOR HIGH AND VERY HIGH RADIATION AREAS.

The proposed language for this entire part was taken from the CRCPD's SSRCR. The members of the Advisory Group and the MDH Radiation Control staff recommended this proposed language for inclusion in the chapter as valid for the newer technologies.

4732.0630. BYPASSING A SAFETY DEVICE.

The proposed language for this was taken from the Iowa Department of Public Health Rules, Public Health # 641. The members of the Advisory Group and the MDH Radiation Control staff recommended this language for inclusion in the chapter for consistency and additional radiation safety.

4732.0700. CALIBRATIONS.

Subpart 1. Diagnostic radiographic system calibrations. The proposed language was taken from Chapter 4730.1675 and is still valid. There were slight modifications made to address newer technologies. The members of the Advisory Group and the MDH Radiation Control staff recommended the language for inclusion.

Subpart 2. Therapeutic system calibrations. The proposed language was taken from Chapter 4730.1675. The members of the Advisory Group and the MDH Radiation Control staff recommended the slight modifications to encompass the newer technologies.

Subpart 3. Tests after change or replacement. The MDH Radiation Control staff recommended this proposed language to ensure compliance and consistency with the rule. This would provide assurance for the Department that the equipment was functioning as the manufacturer intended.

4732.0710. RADIATION SURVEY OR MEASUREMENT INSTRUMENTS.

Subpart 1. Radiation survey or measurement instrument requirements. The proposed language was taken from Chapter 4730.0300, as it is still valid. This information will provide the commissioner with the knowledge that instruments used to calibrate or test the radiation-producing equipment used is within a National Institute of Standards and Technology (NIST) standard.

Subpart 2. Records. This is necessary to ensure records are available at the time of an inspection by the commissioner.

4732.0800. GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIATION-PRODUCING SYSTEMS.

Subpart 1. Applicability. This part applies to all diagnostic radiographic systems. These systems all have common attributes that are best addressed at one time in this part. The compliance for this equipment can be met in the proposed language taken from the Iowa Department of Public

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Health Rules, Public Health # 641. The members of the Advisory Group and the MDH Radiation Control staff recommend this proposed language for inclusion in the chapter.

Subpart 2. Radiation exposure x-ray control. The requirements in this subpart are needed for safety reasons. The dead-man type switch requires continuous pressure on the switch for the exposure to be completed. If the pressure is not maintained, the exposure terminates thereby reducing the exposure to the patient. This usually occurs because the patient has a problem; the patient has moved; or the x-ray film will not be usable. Without this requirement, the exposure could continue resulting in an unnecessary radiation exposure.

For dental intraoral system, the protected position protects the operator from unnecessary radiation during an exposure. Specifying where the x-ray control must be located is necessary to protect the operator who is taking x-rays and anyone who might inadvertently come into the room during an exposure. This rule is necessary to prevent the operator or member of the public from direct exposure to the beam or scattered radiation prior to the termination of an exposure. Finally, the operator must be able to observe dials and indicators to determine when an exposure is completed. The audible signal requirement is an additional requirement intended to indicate the end of the exposure. This proposed language is taken from Chapter 4730.1750 as still valid.

Subpart 3. Radiation exposure automatic exposure controls. This subpart was carried over from Chapter 4730.1750 and is still valid. The members of the Advisory Group and the MDH Radiation Control staff recommended that the language from Chapter 4730 be included in this proposed chapter.

Subpart 4. Radiation from capacitor energy storage equipment. This subpart was carried over from Chapter 4730.1750 as it is still valid. The members of the Advisory Group and the MDH Radiation Control staff recommended that the language from Chapter 4730 be included in this proposed chapter.

Subpart 5. Diagnostic radiographic systems designed for one image receptor size. This subpart carried over from Chapter 4730.1750 as it is still valid. The members of the Advisory Group and the MDH Radiation Control staff recommended that the language from Chapter 4730 be included in this proposed chapter.

Subpart 6. Beam quality half-value layer. The proposed language was taken in part from Chapter 4730.1750. The members of the Advisory Group recommended the modifications for inclusion to meet the new beam quality half-value layer requirements in the Code of Federal Regulations, Title 21 changed in 2006. The MDH Radiation Control staff agreed with this recommendation.

4732.0820. GENERAL PURPOSE DIAGNOSTIC RADIATION-PRODUCING EQUIPMENT MANUFACTURED IN VETERINARY FACILITIES OR PRIOR TO 1973.

Subpart 1. Applicability. These requirements apply to systems manufactured before 1973 and to equipment used in veterinary applications. These systems are not required to meet the federal performance standards in Code of Federal Regulations, Title 21. By implementing the proposed

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language, the Department has established requirements consistent with those associated with equipment manufactured after 1973 or used by veterinarians. This consistency is essential to eliminate the confusion created by the different standards.

Subpart 2. Beam limitation. The proposed language was taken from Chapter 4730.1850 and is still valid. The requirement states that the beam must be sized for diagnostic purposes and larger. The requirements present a logical way of visually defining an x-ray field and determining the accuracy of the dimensions and other components in the beam-limiting system so the patient is not exposed to unnecessary radiation.

Subpart 3. X-ray control console. The requirements in this subpart are needed for safety reasons. The dead-man type switch required the continuous pressure on the switch for the exposure to be completed. If the pressure is not maintained, the exposure terminates reducing the exposure to the patient. This usually occurs because the patient has a problem or has moved. The x-ray film will not be usable. If not for this requirement, the exposure could continue thereby giving the patient unnecessary radiation exposure.

For dental intraoral system, a protected position is necessary to protect the operator from unnecessary radiation during an exposure. Specifying where the x-ray control must be located is necessary to protect the operator who is taking x-rays and anyone who might inadvertently come into the room during an exposure. This is necessary to prevent the operator or member of the public from direct exposure to the beam or scattered radiation prior to the termination of an exposure. Finally, the operator must be able to observe dials, or indicators to determine when an exposure is completed. The audible signal requirement is an additional requirement to indicate the end of the exposure for the same safety reason as the visual indication. This proposed language is taken from Chapter 4730.1750 the language is still valid for the newer technologies.

Subpart 4. Beam quality half-value layer. This subpart is repeated in this part to ensure compliance and consistency within the imaging community and to provide assurance that the equipment is operating safely for the patient and operator.

4732.0825. FLUOROSCOPIC X-RAY SYSTEMS

Subpart 1. Applicability. The proposed language for this subpart was taken in part from Chapter 4730.2150 and taken from CRCPD's SSRCR for inclusion in the chapter to address the newer technologies.

Subpart 2. Fluoroscopic training requirements. A training program was recommended by the registrants. The members of the Advisory Group and the MDH Radiation Control staff recommended the proposed language be taken from North Dakota's Radiation Rules. The documentation of the training will provide the commissioner with the expectation that the patient, public and operators are not being exposed to unnecessary radiation due to lack of training.

Subpart 3. Registrant requirements. The proposed language addresses the registrant responsibilities for the use of fluoroscopic equipment. Some of the language was taken from

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Chapter 4730.2150, as it was still valid. Members of the Advisory Group and the MDH Radiation Control staff recommended that the language for inclusion in the chapter.

Subpart 4. Limitation of useful beam x-ray field. The language was taken from Chapter 4730.2150.

Item A specifies that only image-intensified fluoroscopes be permitted to view fluoroscopic images. This provision is needed to reduce radiation exposure to the patient.

Item B specified additional requirements for spot film devices to meet the requirements in Code of Federal Regulations, Title 21. Members of the Advisory Group requested that this be included in the proposed language to ensure consistency in an area of potential overexposures to the patient, public and the operators.

Subpart 5. Entrance exposure rate allowable limits. The proposed language for this subpart was taken from Chapter 4730.2150 and the CRCPD's SSRCR. The language is still valid.

Subpart 6. Indication of kilovoltage and milliamperage. This language was taken from Chapter 4730.2150 and from the CRCPD's SSRCR. Members of the Advisory Group and the MDH Radiation Control staff recommended this language be carried over, as it is still valid.

Subpart 7. Source-to-skin distance. In this subpart, items A through D state the minimum source-to-skin distance for fluoroscopes, depending on the specific application for which the system is used. These are safety requirements to provide precautionary measure to protect the patients, operators and support staff to reduce the amount of radiation they receive during a procedure. This proposed language is taken from Chapter 4730.2150, as it is still valid.

Subpart 8. Control of scattered radiation. The proposed language was taken from Chapter 4730.2150 and recommended by the MDH Radiation Control staff as still valid and should be included in chapter 4732.

Subpart 9. Radiation therapy simulation systems. The exemption for radiation therapy simulation systems was carried from Chapter 4730.2150 as still valid. The patient being treated on a therapy simulation system must undergo this diagnostic procedure to ascertain that the therapy protocol chosen will effectively treat a cancerous condition. The amount of radiation from such a procedure may be large in comparison to a typical fluoroscopic procedure, but minor when compared to the total dose that will be delivered in a therapy treatment protocol. It is critical that the treatment protocol be accurate. Members of the Advisory Group and the MDH Radiation Control staff recommend that this language be included in chapter 4732.

Subpart 10. Real-time cabinet fluoroscopic systems. The proposed language is recommended by members of the Advisory Group and the MDH Radiation Control staff as being essential to include in chapter 4732 used in a research situation to ensure that the operator, patient and public members are protected from unnecessary radiation.

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4732.0830. FLUOROSCOPIC DOSE-AREA-PRODUCT MONITOR.

The proposed language is recommended for inclusion by members of the Advisory Group and the MDH Radiation Control staff to equate to the new requirements in the Code of Federal Regulations, Title 21. This would provide the commissioner with the assurance the fluoroscopic equipment is not producing unnecessary radiation to the patient, operator, or members of the public.

4732.0835. REQUIREMENTS FOR COMPUTED RADIOGRAPHY, DIGITAL RADIOGRAPHY OR PHOTO-STIMULATABLE STORAGE PHOSPHOR RADIATION-PRODUCING EQUIPMENT.

Subpart 1. Applicability. The members of the Advisory Group and the MDH Radiation Control staff recommended the proposed language as essential to address all the registrants that operate this newer technology.

Subpart 2. Registrant requirements. The proposed language is recommended by members of the Advisory Group and the MDH Radiation Control staff as essential to provide the registrant with the requirements for compliance with this new chapter and for the new technologies. This information will provide to the commissioner assurance that the registrants understand the requirements in the rule and compliance with the dose levels in this proposed chapter.

Subpart 3. Quality assurance or quality control procedures. The proposed language is recommended for inclusion by members of the Advisory Group and the MDH Radiation Control staff as essential to provide the commissioner the information that quality control tests are being performed to ensure that unnecessary exposure to radiation is not occurring. These tests being conducted in accordance with the manufacturer's specifications will provide the information that training and understanding of the use of the equipment was complete.

4732.0850. BONE DENSITOMETRY SYSTEMS.

Subpart 1. Applicability. The MDH Radiation Control staff recommended the proposed language with some modifications taken from the Iowa Department of Public Health Rules, Public Health # 641. This is a newer technology and was not addressed in Chapter 4730. This rule part will apply to all facilities that have this technology and that the equipment must be maintained to the requirements of this proposed chapter.

Subpart 2. General requirements for bone densitometry systems. The proposed language is included for clarity because the technology is new. Registrants need to be aware of the requirements to properly maintain this equipment to reduce the potential of unnecessary radiation exposure to the patient, operator, or other members of the public.

Subpart 3. Quality assurance or quality control procedures. The proposed language is recommended for inclusion by members of the Advisory Group and the MDH Radiation Control staff. It is essential to ensure that quality control tests are being performed to prevent

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unnecessary exposure to radiation. Tests being conducted in accordance with the manufacturer's specifications will provide the necessary training and understanding of the equipment and its use.

Subpart 4. Bone density system operators. The proposed language is recommended by the MDH Radiation Control staff to ensure that the registrants and operators of this newer technology understand that they must comply with 4732.0570 through 4732.0590.

Subpart 5. Records. This is necessary to ensure the registrant has records to review and their availability at the time of an inspection by the commissioner.

4732.0860. COMPUTED TOMOGRAPHY REQUIREMENTS.

Subpart 1. Applicability. These requirements apply to all computed tomography (CT) systems that meet Federal Performance Standards for certified equipment. The requirements in this part are in addition to other general requirements for radiation-producing equipment specified in this proposed chapter.

Subpart 2. Facility design requirements. The proposed language on shielding design is recommended by members of the Advisory Group and the MDH Radiation Control staff. This is to ensure that a room where computed tomography equipment is installed affords the operator, patient, and members of the public protection from unnecessary radiation. The language was taken in part from Chapter 4730.1610 and the CRCPD's SSRCR. The shielding design requires that the control panel and x-ray control must be mounted in a permanently protected area outside the CT room. In addition, the rules require that the operator to remain in a protected area during the entire exposure. One is a design criteria and the other is a procedural control. Both provisions serve to reduce the amount of radiation that the operator may receive.

Subpart 3. CT Fluoroscopic procedures. The proposed language is recommended by members of the Advisory Group and the MDH Radiation Control staff. The inclusion of this language will provide the commissioner with the assurance that the operators are trained and know that unnecessary radiation is being controlled appropriately.

Subpart 4. Viewing systems. The proposed language was taken from Chapter 4730.1610 and 4730.2250, as it is still valid. This requirement states that the operator must be able to observe the patient, any other individual in the CT room, and any doorways into the CT room via a shielded window containing the same lead equivalent as the adjoining walls. An alternate viewing system may be employed. The main emphasis of these rules is to keep the amount of radiation that anyone receives as low as reasonably achievable.

Subpart 5. Audio communication. The proposed language was taken from Chapter 4730.2250 and recommended by the MDH Radiation Control staff to be included in this proposed chapter. This allows the CT operator at the control console to communicate with the patient during the procedure.

Subpart 6. Radiation surveys. Members of the Advisory Group and the MDH Radiation Control staff agree and recommend the proposed language to require verification of any shielding plan

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created for new construction. This would be done to ensure that the shielding for the CT room was done appropriately and the operator and public are protected from unnecessary radiation exposure. This survey is necessary at installation to ensure that the equipment operates properly prior to use on patients.

Subpart 7. Equipment performance measurements. The equipment performance measurements are necessary because of the complexity of these devices. These performance measurements must be performed on a regular basis to ensure that this equipment is functioning at the manufacturer's specifications and that the radiation output has not changed. This information provides assurance that the operator, patient, and members of the public are not receiving unnecessary radiation exposure.

Items A through K are necessary requirements to ensure that these devices are tested correctly to ensure they are in compliance with the rule and for protection of staff and patient.

Subpart 8. Spot checks. The proposed language was taken in part from Chapter 4730.2250 and from CRCPD's SSRCR. This was reviewed by the members of the Advisory Group and recommended for inclusion.

Subpart 9. Quality Assurance measurements performed by the CT operator. The proposed language in this subpart is necessary because of the complexity of the device. Performance of spot checks of equipment and image quality of the device can identify abnormalities and permit correction.

Subpart 10. Program review. The proposed language was taken from the CRCPD's SSRCR and recommended by the MDH Radiation Control staff for inclusion to provide assurance that the CT equipment is being operated without problems.

Subpart 11. Maximum surface CTDI identification. This requirement states the angular position where the maximum surface CTDI occurs must be identified. This is needed so the registrant doing quality assurance checks on the system has a reference position, which is identified so that a dosimetry chamber can be positioned for the checks. The CT system uses a computer to analyze the x-ray beams. A slight misalignment could cause significant problems in properly setting up the CT system. The proposed language was taken from Chapter 4730.2150

Subpart 12. Operating procedures. This subpart required that information about the operations, operators, radiation surveys, and equipment performance measurements of the system available at the time of inspection.

Item A addresses the qualifications of the operators and the training for the use of the equipment. Specifically, the training in anatomy and for the appropriate positioning is required to ensure that the patient will get a proper diagnostic examination without receiving unnecessary exposure.

Item B provides the information on the CT system; the use of the CT phantoms; schedule of quality control checks; allowable variations for the indicated measurements in the technique charts; and other operational information. By making this information available at the control

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console the operator can evaluate the daily quality control data to see if the CT system is set up correctly. This requirement is needed to ensure that the operator has sufficient knowledge of CT system operations and the changes necessary to correctly capture the diagnostic information for each patient. In part, the proposed language is taken from Chapter 4730 and from CRCPD's SSR, Section F. The MDH Radiation Control staff and the Advisory Group agree that it is necessary to specify what should be available for the operator. In this way, the operator does not have to seek the information elsewhere to compare the daily quality control checks with previous results.

Subpart 13. Corrective action. This subpart requires all conditions identified in the equipment performance evaluations or quality control tests that exceed established parameters must be corrected. If a parameter has been exceeded, the unit cannot be used on patients until the condition has been corrected and verified with further tests. The consensus of the MDH Radiation Control staff and the Advisory Group is that this is a reasonable requirement for state of the art equipment of this type. This language was recommended for use from the CRCPD's SSR, section F.

Subpart 14. CT fluoroscopic procedures. This part was recommended by members of the Advisory Group and agreed to by the MDH Radiation Control staff as necessary for the radiation safety for the patient, occupational worker, and the public.

Subpart 15. Records. This is required to ensure that the records are available for inspection by the commissioner.

4732.0865. COMPUTERIZED TOMOGRAPHY DESIGNED FOR VISUALIZATION OF HEAD AND SOFT TISSUES OF THE NECK.

Subpart 1. Applicability. This computerized tomography application is a new technology for facilities specializing in head and soft tissues of the neck. The MDH Radiation Control staff recommended that this separate section be promulgated for understanding and compliance with the radiation rules. The Advisory Group agreed with that recommendation.

Subpart 2. Facility design requirements. Because this is new for computed tomography facilities, it is imperative to address the design information and the radiation safety concerns.

Subpart 3. Radiation surveys. The facilities using this technology must be aware of the radiation hazards and the radiation surveys necessary to safely maintain the unit and to protect patients, occupational workers, and the public.

Subpart 4. Equipment performance measurements. The Advisory Group and the MDH Radiation Control staff recommended that the information for the equipment performance measurements be outlined for these facilities.

Item A gives the information concerning the standards the equipment must meet to comply with this rule.

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Item B indicates who would be qualified to perform these measurements.

Items C, D, E, F and G contain information on necessary equipment measurements and the requirements for equipment performance measurements.

Subpart 5. Spot checks. This subpart provides the information for the head and neck computed tomography spot checks and the parameters to ensure that the equipment meets specifications of the Code of Federal Regulations, the manufacturer or Chapter 4732. This will ensure that the patient is receiving a diagnostic examination with minimal dose.

Subpart 6. Equipment performance measurements performed by the CT operator. This subpart provides the requirements for the CT operator to ensure that the equipment is functioning as designed between the 24 months equipment performance evaluations. This proposed language was recommended by the MDH Radiation Control staff and agreed to by the Advisory Group.

Subpart 7. Program review. This proposed language was recommended by the radiation staff to ensure that the radiation safety officer was aware of any potential equipment problems.

Subpart 8. Operating procedures. This subpart requires that information about the operations, operators, radiation surveys, and equipment performance measurements is available at the time of inspection.

Item A addresses the qualifications of the operators and the necessary training in the equipment operations, CT positioning, and anatomy to ensure that the patient gets a diagnostic examination;

Item B provides information on the CT system, the use of the CT phantoms, schedule of quality control checks, allowable variations for the indicated measurements in the technique charts and other operation information. By having all of this information available at the control console the operator can evaluate the daily quality control data to see if the CT system is set up correctly. This requirement is needed so the operator has complete knowledge of how the CT system is working and whether any changes are necessary. The proposed language is partially taken from Chapter 4730 and language found in the CRCPD's SSR, Section F. The MDH Radiation Control staff and the Advisory Group agree that it necessary to specify what exactly should be available for the operator. This was necessary in this part to be consistent with 4732.0860.

Subpart 9. Corrective action. This subpart states that if a parameter of the equipment performance evaluations or quality control tests have been exceeded that parameter must be corrected and brought back into specifications. If a parameter has exceeded the CT system equipment manufacturer's specifications, the unit cannot be used on patients or limited to the uses permitted by written instructions until the unit has been brought back into specifications and verified with further tests. The consensus of the radiation control unit staff and the Advisory Group is that this is a reasonable requirement for this type of state of the art equipment. This will ensure the result is a diagnostic quality image for a correct diagnosis. This proposed language was recommended for use from the CRCPD's SSR, section F.

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Subpart 10. CT fluoroscopic procedures. This part was recommended by members of the Advisory Group and agreed to by the MDH Radiation Control staff as needed for consistency and radiation safety for the patient, occupational worker and the public.

Subpart 11. Records. This part ensures that records are available for review and inspection by the commissioner.

4732.0870. REQUIREMENTS FOR STEREOTACTIC MAMMOGRAPHIC EQUIPMENT.

Subpart 1. Equipment requirements. This entire rule part was recommended by members of the MDH Radiation Control staff and agreed to by members of the Advisory Group. The proposed language was taken from Iowa Department of Public Health Rules, Public Health # 641. Equipment requirements are necessary to ensure consistency. Listing items A, B and C gives the registrant and service provider options as to the standards for the equipment.

Subpart 2. Registrant requirements. Items A, B and C are the requirements for the operators of the equipment to ensure that the examination completed by the knowledgeable operator. Item D requires the registrant to have the equipment performance, procedures and records to be evaluated annually to ensure that nothing has changed and all items are compliant with the chapter.

Subpart 3. Records. This part ensures that records are available for review and inspection by the commissioner.

4732.0875. VETERINARY MEDICAL RADIOGRAPHIC SYSTEMS.

Federal Performance Standards apply to diagnostic or therapy systems being used on human patients. The federal equipment standards do not apply to veterinary medicine radiation-producing systems. The Advisory Group, the MDH Radiation Control staff and the CRCPD's SSRCCR addresses several concerns that are proposed in this proposed chapter and are included in the proposed language.

Subpart 1. Applicability. This subpart is necessary to make it clear to whom the rules apply. Application of the standards in this proposed chapter to veterinary services as well as service to humans is consistent with the National Council on Radiation Protection and Measurement (NCRP) Report No. 148 titled "Radiation Protection in Veterinary Medicine" which states that:

“The reasons for using radiation in veterinary medicine are to either obtain optimum diagnostic information or to achieve a specific therapeutic effect while maintaining the radiation dose to the radiological personnel and the general public as low as achievable (the ALARA principle). Similarly, it is also important to avoid all unnecessary irradiation to the animal patient.

To the extent that the animal patient exposure is reduced, there is usually a proportional decrease in the occupational exposures to personnel.” (NCRP Report No. 148, 2. Introduction; 2.1 Scope; page 6)

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Veterinary medicine radiographic and therapeutic installations must adhere to the requirements for general use radiography, fluoroscopy and therapy because workers, veterinarians and the general public are involved in radiographic and fluoroscopic procedures.

Subpart 2. Beam limitation. This subpart is necessary to prevent and reduce unwanted and unneeded ionized radiation exposure to workers and the public. This proposed language was taken from Chapter 4730, as it is still viable.

Item A addresses the limiting of the x-ray field. The standard specified is consistent with NCRP Report No. 148 that states that:

“The useful beam shall be limited to the smallest area compatible with the requirements of the examination. This minimizes radiation exposure to the patient and the operators of the equipment and improves image quality. Rectangular mechanical beam-limiting devices that conform more closely to the shape of the cassette are preferred to cones.”
(NCRP Report No. 148, 5.Radiography; 5.1.3 Operation, page 37)

Item B. Restriction of the projected light and x-ray field to no more than two percent of the distance to the film source-to-image distance in any direction is necessary to prevent unneeded and unwanted exposure to ionized radiation. This language was taken from Chapter 4730.

Item C. This item is for clarification for the beam-limiting devices and compliance with the requirements.

Subpart 3. X-ray control console. This subpart is necessary for consistency with x-ray control console items that come as manufactured and that the items must be kept in functional order. This is to ensure the operator or veterinarian know what parameters are set on the console, that they can see the animal patient and while they are observing the animal patient they are aware of the end of the exposure.

Subpart 4. Beam quality half-value layer. This subpart gives the registrant the place in the chapter to find the requirements of the beam quality half-value layer. This beam quality is the inherent filtration to remove the low energy x-rays that are easily scattered and also not useful for imaging.

Subpart 5. Operating procedures. The registrant is ultimately responsible for the tube and its use. Therefore, it is reasonable that the registrant have the responsibility to ensure the application of the operating procedures of the equipment.

Items A, B, C and D are included from Chapter 4730 and found in NCRP Report 148; 5.Radiography, 5.1.3 operation, page 37 and included for radiation safety of the operator and the public. Members of the MDH Radiation Control staff of the Advisory Group agree with these issues as needed for radiation safety in a veterinary facility. This proposed language is part from Chapter 4730, CRCPD's SSRCR, section F and part from Iowa Department of Public Health Rules, Public Health # 641.

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Subpart 6. Additional requirements for fluoroscopic systems in veterinary facilities. Members of the MDH Radiation Control staff and of the Advisory Group agreed that this subpart was necessary because of the potential exposure issues as fluoroscopy is added to the veterinary facilities options for services offered. Fluoroscopy should not be used as a substitute for radiography. It is appropriately reserved for study of dynamics or for guidance with spatial relationships. The proposed language is taken from the Iowa Department of Public Health Rules, Public Health #641 and the CRCPD's SSRCCR, Section F.

Subpart 7. Additional requirements for therapeutic systems in veterinary medical facilities. This subpart was recommended by members of the Advisory Group and agreed to by the MDH Radiation Control staff as being necessary to include in the area specific for veterinary facilities to ensure the registrant is aware of the requirements. The proposed language is taken from CRCPD's SSRCCR, Section F.

Subpart 8. Additional requirements for dental intraoral systems in veterinary medical facilities. This subpart is necessary to ensure that the registrant is operating the dental intraoral systems in consistency with dose limits for the operator and public in addition to maintaining the ALARA principle. The proposed language is from the CRCPD's SSRCCR, Section F.

Subpart 9. Records. This subpart is included to ensure that the records are available for review by the registrant and the commissioner at the time of inspection.

4732.0880. INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS.

Subpart 1. Applicability. This subpart applies to radiation-producing systems used for intraoral dental radiography. The equipment is used with fixed beam size, filtration, and technique settings are limited. This is a special type of diagnostic radiation-producing equipment and special provisions are necessary to properly regulate this equipment. In some instances the equipment maybe fitted into another apparatus for extraoral dental radiography, but those uses are regulated in part 4732.0890.

Subpart 2. Safety controls. Items A through D were taken from Chapter 4730 and are still valid.

Item A requires that intraoral film holders and bite blocs be used.

Item B requires the film not be hand held. This requirement is necessary to prevent the operator of intraoral dental radiographic machine from requiring hand holding the film. This requirement is found in the CRCPD's SSRCCR.

Item C prohibits the tube housing and position-indicating device from being hand held during an exposure. In addition, the components must be stable before and during exposure. The hand held prohibition is necessary to protect the operator from being too close to the source of radiation. A stable tube head is necessary to protect the patient from equipment that could fall on them. In addition, if the tube head is not stable, the x-ray needs to be repeated, thus giving the patient more radiation than needed.

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Item D states that the exposure at the end of the cone must not exceed the values listed in the table in 4732.0880. The output (kVp) and film speed are interrelated. The exposures are specified as "free-in-air" without backscatter. The kVp is the actual kVp tested at the time of inspection. This rule is to ensure that the correct exposure at skin entrance (ESE) for the film speed being used is the value selected by the operator.

Item E states that each installation provides a protective barrier for the operator or the installation must be arranged such that the operator can stand at least six feet from the tube head as well as not be in the useful beam. This item also requires the operator be able to view the patient during the exposure to ensure that the patient does not move or have other problems that might cause the film to be repeated.

Subpart 3. Beam quality half value layer. This requirement is necessary for consistency with other parts of the proposed rule and to be consistent with the new half value specifications for those pieces of equipment manufactured after June of 2006. These additional values were mandated by the FDA. The members of the Advisory Group and the MDH Radiation Control staff agree to this rule.

Subpart 4. Digital radiography. This proposed subpart was suggested by members of the Advisory Group and agreed to by the MDH Radiation Control staff as being necessary to address exposure levels of this new technology. This also gives digital radiography registrants the same information used by those using other types of radiography equipment.

Subpart 5. Records. This is required to ensure availability for the registrant and review by the commissioner at the time of inspection.

4732.0890. EXTRAORAL DENTAL SYSTEMS.

In current Chapter 4730, extraoral dental requirements are encompassed in part 4730.1750, "Diagnostic Radiographic Systems." The dental community requested that it be relocated from that section to facilitate identifying the requirements. This was accepted by the Advisory Group and the MDH Radiation Control staff and included as a separate rule part.

Subpart 1. Requirements. This is necessary to provide the registrants the information on the requirements that must be met in this proposed chapter for extraoral systems.

Subpart 2. Safety controls. The dental community requested this proposed subpart be included. The MDH Radiation Control staff agreed this was a good place to put the information concerning beam limitation. Reference to the other rule parts for general diagnostic radiographic equipment has been included as needed. In addition, this part reminds the operator that they must be protected and yet able to view the patient and that the dose limits must not be exceeded.

Subpart 3. Quality assurance and quality control procedures. The Advisory Group and the MDH Radiation Control staff wanted to ensure the registrant knows that the requirements for quality assurance and quality control procedures are still necessary for the safety of the extraoral systems, the operator, and the patient.

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Subpart 4. Digital Radiography. Recommendations of the Advisory Group and the MDH Radiation Control staff incorporated into this proposed rule part to ensure that digital radiography systems are operated safely for the operator, the patient, and the public. The technique chart requirement is necessary to ensure the operator exposes the patient appropriate to patient size.

Subpart 5. Records. This rule assures that records are available for registrant review and review during an inspection.

4732.0895. DENTAL COMPUTED TOMOGRAPHY SYSTEMS.

This proposed rule part refers the dental registrant to the rule requirements that must be followed when using Computed tomography equipment designed for the head and soft tissue of the neck.

4732.0900. GENERAL REQUIREMENTS FOR FACILITIES USING ACCELERATORS.

Subpart 1. Applicability. This rule is necessary to address the requirements for the use of accelerators. This rule addresses the design of accelerators, the shielding requirements, and the operating procedures for this type of therapeutic radiation-producing equipment.

Subpart 2. Operations. Members of the Advisory Group and the MDH Radiation Control staff recommend the proposed language for inclusion. The proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641, and the CRCPD's SSRCR Part X. There are also recommended guidelines in various reports issued by the National Council on Radiation Protection and Measurements (NCRP) from which CRCPD's SSRCRs were adopted. This subpart is necessary to prevent a serious misadministration of radiation to a patient and to protect the operator from unnecessary radiation exposure.

Item A is required because it specifies the instructions and training necessary for the equipment operators.

Item B is included to ensure that the operator is periodically audited to ensure compliance with the rule.

Item C are the records required for the registrant to review and to be available for the commissioner at the time of an inspection.

Item D addresses the operators of industrial accelerators and directs them to the appropriate requirements for that application.

Subpart 3. Radiation Safety officer duties for accelerator facilities. The proposed language is taken from Iowa Department of Public Health Rules, Public Health #641. The members of the Advisory Group and the MDH Radiation Control staff recommended its inclusion. This subpart outlines the radiation safety officer's duties in regards to an accelerator operation to ensure that the accelerator is being used safely and that procedures are being followed.

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Subpart 4. Individual monitoring. This proposed subpart addresses the safety of the operator, the patient, and the public by requiring the monitoring of operator exposures or the performance of radiation surveys. This proposed rule requires to registrant to ensure that the radiation levels are less than 100 mR/hr; to require individual monitoring; or to ensure that the accelerated beam is limited to specific areas.

Subpart 5. Operating and emergency procedures. This subpart states that all accelerators must be operated according to the procedures in this subpart, which is necessary to prevent a misadministration of radiation to a patient and protect the operator from unnecessary radiation exposure.

Item A states that all accelerators must be secured to prevent unauthorized use when not in operation. This is necessary to protect against unauthorized use of the accelerator, which could cause a serious unplanned radiation exposure. This is based on Iowa Department of Public Health Rules, Public Health # 641, CRCPD's SSRCR and NCRP Report No. 102.

Item B states that all safety and warning devices (including interlocks) must be checked for proper operation at intervals not to exceed three months. Results of such tests must be recorded and available at the time of an inspection by the commissioner.

Item C specifies the contents of operating and emergency procedures to ensure that the operator has as necessary information about equipment operation and the actions necessary in the event of an emergency.

Item D requires that a copy of the operating and emergency procedures be available and maintained at the accelerator control panel. A delay caused by the lack of accessibility to the operating and emergency procedures could cause a misadministration or death. This requirement language is found in CRCPD's SSRCR Section X and in the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 6. Records. This is necessary to ensure the records are available for the registrant to review and available at the time of inspection by the commissioner.

4732.0925. GENERAL REQUIREMENTS FOR THERAPEUTIC EQUIPMENT.

The MDH Radiation Control staff recommended the proposed language for this part be taken from the Iowa Department of Public Health Rules, Public Health #641, and CRCPD's SSRCR Part X. Members of the Advisory Group agreed to this inclusion.

Subpart 1. Protection radiation survey measurements. The radiation survey covered in Item A and the equipment quality control measurements in Item B are intended to ensure that the therapeutic equipment is functioning correctly.

Subpart 2. Dosimetry equipment. This provides the information for the registrant concerning the requirements for the dosimetry systems that must be used for calibration of the equipment.

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Item A addresses the calibration laboratories that are acceptable for compliance with this proposed chapter.

Item B addresses the comparison aspect of the calibration within 12 months and after each servicing.

Item C addresses the record requirements for the calibrations so the registrant recognizes the evidence of compliance for the dosimetry equipment.

Subpart 3. Records of external beam radiation therapy surveys and measurements. This ensures that the records of the surveys and measurements are available at the time of inspection.

4732.0930. THERAPEUTIC RADIATION MACHINES OF LESS THAN 500 KV.

Subpart 1. Equipment requirements. The proposed language is taken from current Chapter 4730; the Iowa Department of Public Health Rules, Public Health # 641; the CRCPD's SSRCR Part X; and the recommendations in NCRP Report No. 102, "Medical X-ray, Electron Beam and Gamma-ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)."

Item A is a general statement to ensure that the equipment is not operated over the maximum rated tube current for the maximum kV and specific distance, so the leakage air kerma rate does not exceed the limits for the classification of the therapeutic radiation machine. This requirement is necessary because each classification of therapy x-ray systems has different leakage radiation values at a specific distance.

Item B denotes the leakage air kerma rate for 150 kV systems measured at five centimeters from tube housing and must not exceed 100 mrad in any one hour. This requirement is needed to limit the amount of leakage radiation that the patient receives in addition to the radiation received as part of the treatment.

Item C denotes the leakage air kerma rate for a therapeutic radiation machine over 150 kV but less than 500 kV. This measured at the distance of one meter must not exceed one rad in any one hour. This requirement is needed to limit the amount of leakage radiation that the patient receives in addition to the radiation received as part of the treatment.

Item D addresses the requirement for the registrant to determine the leakage radiation for the specified operating conditions supplied by the manufacturer. This requirement is needed so the registrant has the information necessary to meet the leakage requirements for the specific equipment.

Item E address the records that must be kept for the registrant to compare results and for an inspection.

Item F requires permanent fixed diaphragms or cones that limit the useful beam to have the same or a higher degree of protection as required for the tube housing. This requirement is needed to limit the amount of leakage radiation the patient receives.

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Item G. This subpart states that adjustable or removable beam-limiting devices, diaphragms, cones, or blocks must not transmit more than five percent of the useful beam, the maximum kilovoltage, and maximum treatment filter. The requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam. This requirement is needed to limit the amount of leakage radiation the patient receives during treatment.

Item H. The requirement is needed to prevent the use of incorrect filters; filters from falling out of place; leakage from exceeding a predetermined limit; and the prompt identification of the filter material from the markings on the filter. All of this is needed to ensure that the patient receives the correct radiation treatment. If the wrong filter were in place, the amount of radiation given to the patient could significantly vary from the intended dose.

Item I. The requirement in this item is needed to prevent tube movement during treatment, which could result in radiation exposure to an unintended area of the patient's body.

Item J. This item states the tube housing assembly must be marked so it is possible to determine the source of radiation because it is where radiation is produced and is the point used in treatment planning.

Item K. This item is necessary to protect the operator during treatments when the tube housing is hand held. This is also needed because the radiation dose rate in air at the beam output surface of a contact therapy machine may be more than 10,000 rads per minute. Extreme precautions are necessary to prevent accidental exposure to the beam.

Item L. This item is necessary to address timer issues for therapeutic machines to ensure the machine is accurately preset, timed, and terminated. The timer must not permit exposures at a zero setting or until a shutter mechanism is opened (when irradiation is controlled by a shutter mechanism). These are all items necessary to prevent accidental overexposure of the patient and operators, if applicable.

Item M. This item states that the control panel must provide an indication of radiation-producing equipment activation. There must also be meters that indicate kVp and mA; a means to terminate the exposure at any time; a locking device that will prevent unauthorized use of the x-ray system; and positive display of the filters in the beam. These are necessary to effectively evaluate the operation of the equipment from the control panel before, during, and after every treatment. Without these features, the operator would not know when the therapeutic x-ray system was operating properly. The locking of the equipment so unauthorized personnel cannot activate an unattended system thereby causing tremendous overexposures to them or others is essential.

These items are all necessary to prevent accidental overexposure of the patient, operators, and others.

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Item N. This item states that if a control panel can energize more than one x-ray tube, there are conditions that must apply. These are a must to ensure that the equipment is being operated in a safe manner.

Item O. This item states that there must be means of determining the distance and that the operator must be able to make that determination within two millimeters. This requirement is necessary because if the distance is off even slightly, the radiation dose delivered to a certain depth within the body will be off considerably. This could cause serious under or overexposure of the patient and could result in the patient being improperly treated.

Item P. This item states that unless it is possible to bring the x-ray output up to the prescribed exposure parameters within five seconds, a shutter having a lead equivalency of not less than of the tube housing assembly must automatically attenuate the beam. This requirement is necessary to prevent the x-ray system from delivering a dose to the patient that is below the prescribed exposure parameters. This could cause serious underexposure of the patient, resulting in the patient being improperly under treated thus allowing a cancer to spread.

Once the system is at its operating parameters, the operator must be able to electronically control the shutter from the control panel. In addition, the indication of the shutter position must appear at the control panel. These requirements are necessary to prevent the x-ray system from delivering a dose to the patient that is below the prescribed exposure parameters. This could occur if the operator was not able to view the condition of the shutter at all times throughout the treatment. This could cause in the patient being under treated thus allowing a cancer to spread.

Item Q. This item states that any beryllium or other low-filtration window must be clearly labeled as "beryllium window" or "low-filtration window" on the tube housing and at the control panel. This requirement is necessary because low-filtration windows have a very high dose rate output. NCRP Report No. 102 states that because the radiation dose rate in air at the beam output surface of a beryllium window machine may be more than 10,000 rads per minute, extreme precautions are necessary to prevent accidental exposure to the beam.

Subpart 2. Facility design requirements. The MDH Radiation Control staff recommended the proposed language for this subpart from the Iowa Department of Public Health Rules, Public Health #641, Chapter 4730.2350 and 4730.2450 and CRCPD's SSRCR Part X. The Advisory Group agreed.

The requirements in Item A (continuous two-way communication between the patient and the operator) and item B (continuous observation of the patient during irradiation) are necessary to assure that the patient is receiving the treatment to the correct location. Observation of the patient is essential to assess the patient's condition and to reassure the patient that someone is watching.

Item C states that the treatment rooms must have additional requirements to ensure that the operator can control the treatment room entrance. This includes, interlocks on the irradiation room door and observation of the area to protect against unauthorized entry. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to

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operation without closing the door and reinitiating irradiation by manual action at the control panel. In addition, when a door is opened, the air kerma rate at a distance of one meter from the source must be reduced to less than 100 millirad per hour. These precautions reduce the radiation dose that anyone accidentally walking into a treatment room could receive.

Subpart 3. Full calibration measurements. The proposed language was taken from current Chapter 4730.1675 and the Iowa Department of Public Health Rules, Public Health # 641. This language was recommended by the MDH Radiation Control staff and agreed to by members of the Advisory Group. This is necessary to ensure that the radiation therapy dose to the patient is accurate and correct. A misadministration of a therapeutic dose of radiation could cause serious health consequences or even death.

Item A is necessary because it specifies the frequency of calibration and reasons for additional calibrations. Because of the potential harm to the patient, it is imperative that a therapeutic x-ray system be properly calibrated. The frequency of calibration and the reasons for additional calibrations are identical in intent because it is necessary to ensure that the therapeutic system is operating within parameters established by the manufacturer. The measured parameters can quickly identify if the system is out of calibration.

Item B requires records be maintained and specifies the contents of those records. This is necessary to be able to review and compare the calibrations to ensure the equipment has not changed. The record must also be available for review at the time of an inspection.

Subpart 4. Periodic quality control checks. This subpart is necessary to specify the essentials needed to maintain the therapeutic equipment.

Items A through K identify:

- the type of therapeutic equipment that require periodic quality control checks;
- the requirements of the quality control checks;
- the written procedures provided by the therapeutic radiological physicist;
- the frequency at which the checks are to be performed;
- the acceptable tolerances for each parameter measured;
- the requirements for comparison of the calibration results to the quality control checks;
- the conditions requiring investigation and correction;
- the requirements for recalibration;
- the dosimetry systems to be used;
- the requirements for therapeutic radiological physicist's review and signature;
- the requirements for the safety quality control checks; and
- the records required to be maintained.

All these items are necessary to ensure that the therapeutic equipment is functioning according to manufacturer's specifications so that the patient does not receive unnecessary radiation during their treatment.

Subpart 5. Operating procedures.

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Item A states that the therapeutic radiation machine must not be unattended unless secured by the means in subpart 1.

Item B and Item C deal with the hand holding of the tube housing and the need to assist the patient during the treatment. This is necessary because there are times when the patient needs help. The rule outlines the protective garments or holding devices that must be used for radiation safety purposes.

Item D states where the operating and emergency procedures must be maintained so that the operator can refer to them quickly in the case of an emergency rather than having search for them elsewhere.

Item E is necessary as a reminder that only the patient should be in the treatment room.

Subpart 6. Records. All records must be kept and available at the time of an inspection by the commissioner.

4732.0940. THERAPEUTIC RADIATION MACHINES-PHOTON THERAPY SYSTEMS (500 KV AND ABOVE) AND ELECTRON THERAPY SYSTEMS (500 KEV AND ABOVE). Members of the Advisory Group and the MDH Radiation Control staff recommended the proposed language for this part be taken from the current Chapter 4730.2450, the Iowa Department of Public Health Rules, Public Health #641, and the CRCPD's SSRCR Part X. The CRCPD's SSRCR Part X is based on recommendations from guidelines in various reports by the National Council on Radiation Protection and Measurements (NCRP). One of the reports is NCRP Report No. 102, "Medical X-ray, Electron Beam and Gamma-ray Protection for Energies up to 50 MeV (Equipment Design, Performance and Use)"

Subpart 1. Equipment requirements.

Items A, B, and C address leakage radiation to the patient. Item A specifies a very specific set of physical locations and conditions with respect to the unattenuated central axis of the useful beam at which leakage radiation must not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at a nominal treatment distance. Item B states that leakage radiation through beam-limiting devices must meet the requirements in this item. This rule is needed to keep the leakage radiation from the beam-limiting devices to the patient area as low as reasonably achievable so other parts of the patient's body are not over irradiated when a specific area of the body is receiving treatment. Item C states how the measurement of the leakage radiation must be done.

Item D deals with filters and wedges that are used in the treatment. The filters must be identified by an identification number and the wedges must be marked with the wedge angle. Other interlocks and interlock systems must be in place. If a compensating removable filter or wedge filter were not properly marked, an operator could insert the wrong filter into the machine and an incorrect amount of radiation would be given to the patient. This could have serious patient health consequences.

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Item E states that for each system, the registrant must determine or obtain from the manufacturer the leakage radiation existing at positions specified in item A for the identified operating conditions. This requirement is needed to ensure that the registrant has available the information necessary to meet the requirements Item A.

Item F states that the therapeutic equipment must measure all radiation beams with at least two detectors. These detectors must be incorporated into two separate radiation dose-monitoring systems. This requirement is needed so the radiation dose to the patient can be accurately monitored as it is delivered. Two separate detectors are needed because of the complexity of the therapy equipment used. If one system fails, a second system is available to accurately monitor the radiation dose and terminate the exposure after a predetermined dose has been delivered. If the system was installed prior to July 1997, it must have at least one radiation detector. This radiation detector must be incorporated into a primary dose monitoring system. This requirement is needed so the radiation dose to the patient can be accurately monitored as it is delivered.

Item F subitem (2) (a) states that each radiation detector must be removable only with tools and must be interlocked to prevent incorrect position. This requirement is necessary because if the radiation detector were easily removable by hand, a serious misadministration of radiation could accidentally occur. By making the radiation detector only removable with tools, unintended removal is less likely to occur. Likewise, if the radiation detectors were not interlocked to prevent incorrect positioning, the radiation dose would not be properly monitored; thus possibly causing a serious misadministration of radiation.

Subitem (3) states that each dose monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation. This requirement is necessary to ensure that each dose monitoring system can monitor, interrupt, or terminate irradiation. If a system should fail, there could be a serious misadministration of radiation.

Subitem (4) states that the design of the dose monitoring system must assure that the malfunctioning of one dose monitoring system does not affect the correct functioning of the second dose monitoring; and that the failure of any element common to both dose monitoring systems which could affect the correct function of both dose monitoring systems terminates irradiation. This requirement is necessary so that each dose monitoring system is not dependent upon the other dose monitoring system. A failure of an element common to both dose monitoring systems causes the termination of irradiation. If the systems do not work in this manner, there could be a serious misadministration of radiation.

In subitem (5), the necessity for having each dose monitoring system have a legible display at the treatment control panel allowing the operator easy access to read the display before, during and after each treatment to ensure the operator clearly knows how much radiation the patient has received.

Item G addresses the issue of the selection and display of dose monitor units. This item requires all x-ray and therapy systems to provide for the selection and display of dose monitor units. This

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requirement is necessary so the operator has accurate information on how much radiation the patient has received.

Item I addresses the termination of irradiation by the beam-monitoring system (or systems) during stationary beam radiation therapy. This requirement is necessary so the patient does not receive more dose monitor units of radiation than intended. If the system did not terminate the irradiation at the end of the pre-selected number of dose monitor units, a serious misadministration of radiation could occur.

Item I, subitem (2) states that if the original design of the equipment included a secondary dose monitoring system, that system must be capable of terminating irradiation when not more than 15 percent or 40 dose monitoring units above the pre-selected number of dose monitor units has been detected. This requirement is necessary because it sets an upper limit to the amount of radiation that must be detected before termination of irradiation is initiated. If the secondary dose monitoring system did not terminate irradiation at this point, a serious misadministration of radiation could occur.

Subitem (3) requires that an indicator on the control panel for equipment manufactured after July 1997 must show which monitoring system has terminated irradiation. This requirement is necessary so the operator knows how much radiation was given to the patient and if a check for malfunction of the primary dose monitoring system is appropriate. This information is critical in determining the repairs that need to be completed.

Item J states that it must be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time. The operator must be able to interrupt treatment from the operator's position at the treatment control panel. This requirement is necessary so the operator can avoid any condition where the patient would receive an unwanted exposure to a therapy beam. If the operator could not terminate the irradiation or go from an interruption condition to termination, a serious misadministration of radiation could occur.

Item K states that if the equipment has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. Usually, interruption of treatment relates to patient safety (e.g., the patient is having a medical problem or the equipment has malfunctioned). Under those circumstances, if treatment is not interrupted, a serious misadministration of radiation could occur.

Item L addresses timers for the therapy equipment. This item requires that all x-ray and electron therapy systems have a timer that meets the requirements in this rule. The requirement is necessary so irradiation of a patient maybe accurately timed. The timer serves as a back-up device to protect against over-irradiation due to failure of preset integrating dose meters.

Subitem (1) states that a timer with a visual display must be provided at the treatment control panel. The timer must have a preset time selector and an elapsed time indicator. It is critical to visibly indicate the specific point in the therapy treatment cycle. If for any reason the treatment must be interrupted, it is critical that the operator can identify where the treatment was

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interrupted. The information ensures that after re-initiation and completion the operator can determine that the correct treatment was given.

Subitem (2) states that the timer must be a cumulative timer that activates with the production of radiation. After irradiation is terminated and before irradiation can be reinitiated, it must be necessary to reset the elapsed time indicator to zero. This requirement is necessary so that an accurate cumulative time is recorded on the treatment control panel. In this manner, the operator will know the actual time of exposure so that if the treatment has been interrupted, the correct time may be entered to complete the treatment. If the treatment is finished, this time is necessary to record how much radiation the patient has received.

Subitem (3) states the timer must terminate irradiation when a pre-selected time has elapsed if the dose monitoring systems have not previously terminated irradiation. This requirement is necessary to provide a back-up timing device that terminates the exposure if the dose monitoring systems do not terminate the exposure. This protects against over-irradiation due to failure of preset integrating dose meters.

Items M, N and O address the equipment where selection of beams of different energies is possible. Irradiation must not be possible until a selection of radiation type has been made at the treatment control panel. This requirement is necessary because of the energy level differences. If for any reason the treatment must be interrupted, it is critical that the operator know what the energy level was for the treatment when it was interrupted. The information ensures that when the treatment is resumed, the operator will be able to correctly re-establish the correct set the energy value.

Therapy with x-rays produces much different results from therapy with electrons, thus there is a need to differentiate between the two modalities. The discussion continues on the energy levels and the displays at the treatment control panel. The rule discusses the continuation of the appropriate filter or foil for the selected energy in its proper position.

Equipment is capable of both stationary and moving beam therapy must allow for the selection of the applicable therapy according to the requirement in this subpart. This is necessary because each type of therapy is intended for irradiation different parts of the patient's body. Incorrect selection of the type of therapy could cause a serious misadministration of radiation.

These items and sub-items are important to the level of therapy exposure necessary to ensure that the patient is treated appropriately and to avoid a serious misadministration of radiation. This proposed language was taken from current rule (4730.2450) and the Iowa Department of Public Health Rules, Public Health # 641.

Subpart 2. Facility design requirements for therapeutic radiation machines operating above 500 kV. Members of the MDH Radiation Control staff and of the Advisory Group requested this part in addition to the shielding requirements found in proposed 4732.0380. The proposed language was taken from the current rule (4730.2450) and the Iowa Department of Public Health Rules, Public Health # 641. This part is necessary because the protective barriers, safety

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interlock systems, and surveys in a therapy facility are significantly more important for the protection of the patients, the worker, and the public.

Subpart 3. Therapeutic radiological physicist support. The MDH Radiation Control staff and members of the Advisory Group believe that it is important to use the language from the Iowa Department of Public Health Rules, Public Health #641, as the proposed rule. This requirement is necessary to outline the education and responsibilities for the physicist in a therapeutic facility.

Subpart 4. Operating procedures. The MDH Radiation Control staff and members of the Advisory Group felt that it was important to use the language taken from the Iowa Department of Public Health Rules, Public Health #641, and CRCPD's SSRCR to identify the issues necessary for the registrants and the operators to know. It is essential to have a copy of the operating and emergency procedures at the treatment control console. In an emergency the operator does not have to look for the procedures, thereby delaying resolution of the issues.

Subpart 5. Full calibration measurements. This proposed language was taken from current rule (4730.1675), the Iowa Department of Public Health Rules, Public Health #641, and CRCPD's SSRCR. This was recommended for inclusion by the MDH Radiation Control staff and members of the Advisory Group. Full calibrations on therapy equipment is necessary to ensure that radiation therapy dose to the patient is accurate and correct. A misadministration of a therapeutic dose of radiation could cause serious health consequences or even death.

Item A is necessary because it specifies the frequency of calibration and reasons for additional calibrations. The potential harm to the patient is much greater with a therapeutic system than it is for a diagnostic radiation-producing system. It is imperative that a therapeutic x-ray system be properly calibrated. The frequency of calibration and the reasons for additional calibrations are identical in intent in this proposed rule because it is necessary to ensure that the therapeutic system is operating within the manufacturer's design specifications. Measured parameters can quickly ascertain if the system is out of calibration.

Item B refers the registrant to the proposed rule part that defines the dosimetry system to be used in the calibrations of the therapy equipment.

Item C states a record must be maintained and what the record must contain. This is necessary to be able to review and compare the calibrations to ensure the equipment has not changed. The record must also be available for review at the time of an inspection by the commissioner.

Subpart 6. Periodic quality control checks. This subpart is necessary to specify the essentials needed to maintain the therapeutic equipment operating at the manufacturer's specifications.

Items A through I identify:

- the type of therapeutic equipment that require periodic quality control checks;
- the requirements of the quality control checks;
- the written procedures provided by the therapeutic radiological physicist;
- the frequency at which the checks are to be performed;
- the acceptable tolerances for each parameter measured;

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- the requirements for comparison of the calibration results to the quality control checks;
- the conditions requiring investigation and correction;
- the requirements for recalibration;
- the dosimetry systems to be used;
- the requirements for therapeutic radiological physicist's review and signature;
- the requirements for the safety quality control checks; and
- the records required to be maintained.

All these items are necessary for the registrant to know what is required and what will be reviewed for compliance. These are also necessary to ensure that the therapeutic equipment is functioning according to manufacturer's specifications so that the patient does not receive unnecessary radiation during their treatment.

Subpart 7. Records. This is a requirement necessary for the registrant to maintain the records and what is essential to be in the records. These records need to be available during an inspection by the commissioner.

4732.1000. REQUIREMENTS FOR X-RAY FLUORESCENT VIEWERS AND BOMB DETECTION UNITS.

Members of the MDH Radiation Control staff and of the Advisor Group recommended that this part be added due to the special nature of this equipment. The proposed language was taken from the Iowa Department of Public Health Rules, Public Health # 641. This proposed rule addresses the issues important for public health and safety.

Subpart 1. Applicability. This subpart identifies the facilities that use this type of equipment and would be responsible for compliance with this proposed rule part.

Subpart 2. Operating and emergency procedures. It is essential that operators of this equipment know the registrant's procedures and where the copies of these procedures are kept. The operator should know their location in the event of an incident or accident, in order to react quickly.

Subpart 3. Instruction and training. This is necessary language to ensure that the operators have appropriate training on the equipment and the operating and emergency procedures required by subpart 2.

Subpart 4. Inspection and maintenance of equipment. This subpart is necessary to ensure that the equipment is operating in accordance with the manufacturer's specifications to ensure the safety of the operators and the public.

Subpart 5. Records. These records must be maintained and available at the time of the inspection by the commissioner.

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4732.1010. WARNING DEVICES FOR INDUSTRIAL RADIOGRAPHY FACILITIES.

This part is taken in part from current rule (4730.0300). The MDH Radiation Control staff and members of the Advisory Group recommended that this language be retained because it is still valid for technologies being employed.

4732.1020. POSTING REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHY.

This is necessary as a reminder for the industrial facilities using radiography that there are posting requirements in proposed rule part 4732.0385.

4732.1030. SURVEILLANCE FOR INDUSTRIAL RADIOGRAPHY.

The statement on surveillance was recommended for inclusion by the MDH Radiation Control staff. This proposed language is taken from the *Minnesota Rules*, Chapter 4731.4190, for consistency within Minnesota for safety of the operator and the public.

4732.1040. INDUSTRIAL FACILITY REQUIREMENTS FOR USING RADIATION-PRODUCING EQUIPMENT IN MANUFACTURING PROCESSES, GAUGES, AND CABINET.

The recommendation of the MDH Radiation Control staff was to carry over the language for these requirements from the current rule parts: 4730.2520, 4730.2540, 4730.2570, and 4730.2550, as they are still valid. The Advisory Group agreed with the recommendation.

4732.1050. REQUIREMENTS FOR PERMANENT INDUSTRIAL RADIOGRAPHIC INSTALLATIONS.

Members of the MDH Radiation Control staff and the Advisory Group agreed that this part was necessary because the equipment used in the permanent industrial radiographic installations has the potential to cause serious consequences if not operated properly. The proposed language is partially taken from current rule; 4730.2510 and 4730.2520, and from the Iowa Department of Public Health Rules, Public Health # 641. Each of the subparts addresses a requirement to ensure for the registrant that the equipment is being operated in a safe manner and is functioning in accordance with the equipment manufacturer's specifications.

4732.1060. INSTRUCTION AND TRAINING FOR INDUSTRIAL RADIOGRAPHY.

This requirement for training and instruction follows 4732.1050 to ensure that the operators know and understand the importance of operating this type of equipment safely to protect themselves and the public. This proposed language is taken from the Iowa Department of Public Health Rules, Public Health # 641, and *Minnesota Rules*, 4731.4140. Members of the MDH Radiation Control staff and the Advisory Group recommended the proposed language be included.

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4732.1070. RADIOGRAPHER CERTIFICATION.

Because of the potential safety hazards with permanent industrial radiography, members of the MDH Radiation Control staff and the Advisory Group recommended the proposed language be included. The proposed language was taken from the CRCPD's SSRCR. This is language that is recognized nationally as a requirement for radiographers in this type of industrial setting.

4732.1080. INDUSTRIAL RADIOGRAPHIC OPERATING AND EMERGENCY PROCEDURES.

To continue the assurance that permanent industrial radiography is performed in a safe manner, the MDH Radiation Control staff and the Advisory Group recommended the inclusion of the language from the CRCPD's SSRCR and the Iowa Regulation, Public Health #641. This requirement is necessary to ensure that the registrant has operating and emergency procedures for the operator, the procedures are maintained, and located where the radiographer can get to them quickly in the case of emergency.

4732.1090. INDUSTRIAL RADIOGRAPHY IN A TEMPORARY JOB SITE.

With the members of the Advisory Group and the MDH Radiation Control staff knowing that industrial radiography is done out of the facility, the proposed rule part is designed to ensure that it is done in a safe manner. This proposed language was taken from the Iowa Department of Public Health Rules, Public Health #641, and the CRCPD's SSRCR.

4732.1100. INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.

The members of the MDH Radiation Control staff and the Advisory Group recommended that these requirements be carried over from the current rule, 4730.1691, as it is still valid. There are a couple of changes also requested for ease of the registrant. Changes include going from annually to intervals not to exceed 24 months for some of the tests. This will coincide with the equipment performance testing. "Biennially" was changed to "at intervals not to exceed 24 months" for clarification. The listing of these minimum quality assurance tests for diagnostic facilities is derived from NCRP Report Number 99, "Quality Assurance for Diagnostic Imaging" Table A.2 to A.10. The tests listed in these proposed rules were determined to be feasible to accomplish in facilities using ionizing radiation for diagnostic purposes without imposing an unreasonable burden. This rule is necessary to provide diagnostic images of good quality and keep exposure of the patient as low as reasonable. For any parameter that is found to be out of adjustment, corrections must be made before re-using the equipment. This requirement is to ensure the equipment is operating as the manufacturer had intended.

Each subpart addresses a different type of equipment from Subpart 3 image receptors through subpart 12, facilities with dental extraoral systems including panoramic systems.

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4732.1120. THERAPEUTIC EQUIPMENT PERFORMANCE TESTS AND LIMITS FOR MEASUREMENT EQUIPMENT.

This part is directly from the American Association of Physicists in Medicine (AAPM) Report Number 13, Table 1. This table is accepted in the industry as the minimum criteria for quality assurance of therapy systems. The minimum tests interval was changed for this same item from four years to two years to coincide with the calibration requirements in other parts of the proposed rule. Members of the MDH Radiation Control staff and the Advisory Group agreed with carrying these requirements from current rule, 4730.1693, as still valid.

4732.1130. EQUIPMENT PERFORMANCE TESTS FOR EXTERNAL BEAM TELETHERAPY AND SIMULATION SYSTEMS.

This part is directly from AAPM Report Number 13, Table 1. The AAPM table is accepted in the industry as the minimum criteria for quality assurance of external beam teletherapy and simulation equipment. Members of the MDH Radiation Control staff and the Advisory Group agreed with carrying these requirements from current rule, 4730.1695, as still valid.

LIST OF EXHIBITS

In support of the need for and reasonableness of the proposed rules, the MDH anticipates that it will enter the following exhibits into the hearing record:

1. Sonar for 4732
2. Requests for Comments and comments during the comment period.
3. The Suggested State Regulations for Control of Radiation (SSRCR) Volume I
4. Iowa Department of Public Health Rules, Public Health #641, December 2002.
5. National Council on Radiation Protection and Measurements, Reports 39, 99,102, 145, 147,148
6. North Dakota Radiation Rule
7. Documents from the American Registry of Radiologic Technologists (ARRT)

CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

5/21/2007
Date

John Linc Stine
Division Director

May 11, 2007

BIBLIOGRAPHY

This material is available through the Minitex interlibrary system and is available for review at the Department.

American Association of Physicists in Medicine, Report No. 13, "Physical Aspects of Quality Assurance in Radiation Therapy," published by the American Institute of Physics, 335 East 45th Street, New York, New York, 1984.

"The Suggested State Regulations for Control of Radiation" (SSRCR), Volume I, "Ionizing Radiation" Parts A, B, D, E, F, H, I, J and X. Published by Conference of Radiation Program Directors, (CRCPD) 1999.

"Handbook of Health Physics and Radiological Health" Third Edition, 1998. Published by Williams and Wilkins.

Iowa Department of Public Health Rules, Public Health # 641. Published in December 2002.

National Council on Radiation Protection and Measurements, Reports:

Number 99, "Quality Assurance for Diagnostic Imaging";

Number 102 "Medical X-ray, Electron Beam and Gamma-ray Protection for Energies up to 50 MeV (equipment design, performance and use)";

Number 39 "Basic Radiation protection Criteria",

Number 147, "Structural Shielding Design for Medical X-ray Imaging Facilities";

Number 148, "Radiation Protection in Veterinary Medicine";

Number 145, "Radiation Protection in Dentistry";

Library of Congress Cataloging-in-Publication Data

"Quality Control in Diagnostic Imaging" by Joel E. Gray, Norlin T. Winkler, John Stears, and Eugene D. Frank, published by Aspen Publishers, Inc., Gaithersburg, Maryland, 1983.

"Radiologic Science for Technologists" by Steward C. Bushong, published by C.V. Mosby Company, St. Louis, Mo. In 2001.

"Textbook of Radiologic Technology" by Charles A. Jacobi and Don Q. Paris; published by C.V. Mosby Company, St. Louis, Mo.