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State of Minnesota

Minnesota Department of Health

Statement of Need and Reasonableness

In the Matter of the Proposed Permanent Rules Governing Sources of Ionizing Radiation, Minnesota Rules, Chapter 4730.

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STATE OF MINNESOTA
MINNESOTA DEPARTMENT OF HEALTH

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Statement of Need and Reasonableness

The amendments to and new rule parts contained in Minnesota Rules, Chapter 4730 are proposed by the Department of Health (MDH) to revise adopted rules governing sources of ionizing radiation contained in adopted Minnesota Rules, parts 4730.0100 to 4730.3600.

Legal Authority

The authority for the proposed rules is found in Minnesota Statutes, sections 144.05, paragraph (c); 144.12, subdivision 1, clause (15); and 144.121.

Need for Revision of Rules

The purpose of state regulation of sources of ionizing radiation is to reduce unnecessary radiation exposure when and where possible, by whatever means practical. Ionizing radiation exposure has a cumulative effect on the human body, therefore, it is critical that steps be taken to limit the exposure of the human body to unnecessary ionizing radiation. The body does repair some of the "injury" done by ionizing radiation received, but does not always return to its original condition. Excessive ionizing radiation may shorten life, cause cancer, genetic defects, cataracts or other health problems in humans. Some health problems may develop quickly if the radiation dose is massive. With lower radiation doses, effects may not be seen for years or generations. Development of cancer in the human body may take 20 years or more; genetic effects may not show up in one generation but may show up in the next or succeeding generations. To protect against unnecessary exposure to ionizing radiation sources, procedures must be in place to protect workers operating x-ray equipment, patients receiving controlled doses of ionizing radiation for either diagnostic or therapeutic purposes, and any other persons in areas where ionizing radiation is used.

Major rules (Chapter 4730) governing sources of ionizing radiation were first promulgated in Minnesota on September 29, 1971. In 1978 a rule part on healing arts screening was added. Amendments to Chapter 4730 also occurred in 1986, 1988 and 1990 in the area of registration fees.

Since 1971 there have been several substantial amendments to the federal Radiation Control and Health and Safety Act of 1968 (Public Law 90-602), which governs the administration and enforcement of sources of ionizing radiation, and to federal regulations governing the manufacture of equipment. Standards governing the manufacture of diagnostic x-ray systems and their major components, radiographic equipment, fluoroscopic equipment, and computed tomography equipment have been added to federal code (21 CFR, sections 1020.30, 1020.31, 1020.32 and 1020.33) and subsequently amended 14 different times between 1973 and 1985. Public law 90.602 requires that x-ray equipment used for human diagnostic purposes manufactured after August 1, 1974, to meet the federal Food and Drug Administration performance standards specified in the code of federal regulations, title 21, sections 1020.30 to 1020.33. Equipment meeting these standards is referred to as certified equipment. Equipment manufactured prior to 1974 is referred to as uncertified equipment.

Since 1971 ionizing radiation equipment has become more complex, sophisticated and powerful and the use of that equipment has changed dramatically. Ionizing radiation is now used widely in therapeutic as well as in diagnostic procedures. More comprehensive regulation is thus necessary to adequately protect public health. Much of Chapter 4730 applies to diagnostic x-ray equipment. State administrative rules need to address current therapeutic as well as diagnostic use. Therapeutic technology was new when Chapter 4730 was first promulgated. The adopted rules thus contain few requirements governing the use of therapeutic equipment. Twenty years ago typical cancer therapy treatment was often performed using radioactive cobalt teletherapy - a time consuming and inexact procedure. Now the same treatment is done with linear or particle accelerators which are more precise and give a more exact therapy dose to the patient because the whole treatment is computer controlled.

There are approximately 11,400 registered diagnostic and therapeutic x-ray machines in use in Minnesota. Of this number, approximately 50 are therapeutic x-ray machines; 600 are industrial; the rest are diagnostic machines. They are found in hospitals, clinics, medical, dental, veterinary, chiropractic and podiatric offices. Among diagnostic x-ray machines in use today are those manufactured during the 1930's. Although the numbers of x-ray machines of this age are diminishing slowly they still are in use and must be regulated.

Both the federal and state government have authority over different aspects of ionizing radiation equipment and its use. Public Law 90-602 enacted in 1968 required certification of certain electronic products emitting ionizing radiation and set performance standards to control the amount of ionizing radiation emitted. The law was enacted as a public health measure to standardize the performance of x-ray equipment because there was

no guarantee at the time that qualified operators would be available in all states. In 1968 only a few states had licensing or registration requirements for x-ray equipment operators. In Minnesota there are no requirements that x-ray equipment operators be licensed or certified. Federal performance standards for all electronic products emitting ionizing radiation, contained in federal code, went into effect in August 1974.

Federal law and codes apply to the manufacturers and installers of diagnostic x-ray equipment. They do not apply to the user of the equipment. Federal law and codes apply to equipment manufactured in the United States or imported into this country. States may regulate the user of x-ray equipment whether it be a facility or licensed practitioner of the healing arts. Each state may write rules for the user of equipment which emits ionizing radiation that may or may not be as strict as rules of another state.

Although the federal government does not require states to adopt equipment standards, if a state does adopt equipment standards, it may reference federal performance standards. A state rule on x-ray equipment performance may not be more stringent than the federal standard for certified equipment. Where federal standards are silent a state may adopt its own standards. Federal performance standards apply only to diagnostic x-ray equipment, not to therapeutic x-ray equipment. In view of changing technology and the fact that older equipment is still in use, it is necessary for the state to revise Chapter 4730 to protect public health by addressing both equipment standards and the operation of the equipment.

The proposed amendments to and new rule parts contained in Chapter 4730 not only include federal performance standards for diagnostic radiographic equipment but also include requirements for increased shielding of facilities for radiation protection, new reporting requirements to verify that equipment is operating safely, and quality assurance requirements to enable users to keep x-ray doses as low as reasonably achievable for diagnostic x-rays and enable therapeutic x-ray doses to be precise and accurate to avoid over exposure.

Parts of the proposed rules which relate to equipment requirements for diagnostic radiographic systems incorporate language from performance standards in federal code. Parts of the proposed rules which relate to administrative requirements for the operation of equipment and the performance of therapeutic x-ray systems are based on "The Suggested State Regulations for Control of Radiation", (SSRCR) Volume I, Ionizing Radiation, developed by the Conference of Radiation Control Program Directors (CRCPD). These model standards were developed by a task force of radiation control program staff from various states

and federal agencies which regulate radiation sources. They are designed to provide guidance to states in developing state rules. The CRCPD's SSRCR standards are updated regularly to reflect developments in x-ray technology.

Parts of the proposed rules are based on or refer to guidelines for protection against ionizing radiation developed as "reports" 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 the scientific and related aspects of radiation protection and measurement. The NCRP regularly prepares and updates reports on a wide range of topics related to radiation protection and measurement. The reports used in the development of the proposed rules or incorporated within the rules are cited in the attached bibliography.

A third body of standards on which parts of the rules are based is Report 13 "Physical Aspects of Quality Assurance in Radiation Therapy" of the American Association of Physicists in Medicine (AAPM).

Notice of Solicitation; Advisory Work Group

Notices of Intent to Solicit Outside Opinion were published in the State Register on February 13, 1989, at 13 S.R.2000; August 7, 1989 at 14 S.R. 292; and February 12, 1990 at 14 S.R. 2014. The proposed rules were developed with the assistance of an advisory work group consisting of members from all the major x-ray user groups (Exhibit A). The Department held seven meetings between April and August of 1989 with the advisory work group to discuss rule provisions.

Advisory group members included representatives from the American Association of Physicists in Medicine, Minnesota Chiropractic Association, Minnesota Dental Association, Minnesota Dental Hygienists, Minnesota Hospital Association, Minnesota Podiatric Medical Association, Minnesota Radiological Society, Minnesota Society of Radiological Technologists, Minnesota Veterinary Medicine Association and the Health Physics Society.

Among those members of the work group whose opinions are noted in the statement of need and reasonableness are Dr. Joel Gray, Chairperson of the advisory work group. Dr. Gray received his doctorate in medical physics from the University of Toronto Institute of Medical Sciences. He is a consultant in diagnostic radiology and a professor of radiologic physics at the Mayo Medical School and Mayo Clinic and Foundation, Rochester, Minnesota. He is a member of the National Council on Radiation Protection and Measurement (NCRP); the International Commission on Radiological Protection; the American Association of

Physicists in Medicine (AAPM); the Radiological Society of North America; and the American Roentgen Ray Society.

The department also notes the advice provided by Edwin C. McCullough, Ph.D., who is a medical radiation physicist and therapeutic radiologist with the Mayo Clinic, Rochester, Minnesota.

Fiscal impact: Cost of implementation to state and local government

Pursuant to Minnesota Statutes, sections 3.982, 14.11 and 15.065, the Minnesota Department of Health has prepared a fiscal note estimating the annual cost of the proposed rule to local agencies, school districts and state public agencies. The fiscal note is available from the department.

If the adoption of a rule requires expenditure of public monies by public bodies, Minnesota Statutes, section 14.11, subdivision 1 requires that the agency give a reasonable estimate of total cost to all local public bodies in the state to implement the rule for the two years immediately following adoption of the rule if the estimated cost exceeds $100,000 in either of the two years.

Adoption of the proposed rule would require expenditure of public monies by local public bodies such as public health clinics and public schools with their own radiographic equipment, and local public hospitals with their own radiographic or therapeutic x-ray equipment. The proposed rules related to quality assurance would result in additional costs for the 65 publicly-funded hospitals and clinics operated by local governments around the state. However, approximately 35 percent of the publicly-owned hospitals are accredited by the Joint Commission for the Accreditation of Health Care Organizations which currently requires all of the proposed quality assurance procedures. Accredited hospitals would not be incurring any new costs related to the implementation of the proposed quality assurance requirements. The total cost to local bodies associated with implementation of the proposed quality assurance requirements will be $148,441 for each of the two years immediately following adoption of the proposed rules. Although there may be costs associated with the proposed additional shielding requirements for all facilities using any type of x-ray equipment, it is difficult to estimate when a hospital or clinic may add new equipment or remodel its x-ray facilities.

Pursuant to Minnesota Statutes, section 15.065, a rule cannot be put into effect without first providing the House Appropriations and Senate Finance Committees with a copy of the fiscal note. A copy of the fiscal note prepared by the department was sent to the legislative committees when the rules were submitted to the

State Register. The fiscal note identifies staff and equipment costs to the Department of Health of $124,469 and $104,617 respectively for the first two years following implementation of the proposed rule. The costs to other state agencies not accredited by the JCAHCO as specified in the fiscal note total $154,412 for each of the two years following implementation of the proposed rule.

Small Business Considerations

Minnesota Statutes, section 14.115, requires that an agency consider five factors for reducing the impact of proposed rules on small business. The proposed amendments will have an impact on small businesses such as single or small group physician practices, dental practices, chiropractic, podiatric and veterinary practices. The methods identified in statute for reducing the impact of the rule on small business include the:

a) establishment of less stringent compliance reporting requirements;

b) establishment of less stringent schedules or deadlines for compliance or reporting requirements;

c) consolidation or simplification of compliance with reporting requirements;

d) establishment of design standards for small business; and

e) exemption of small business from the rules.

The major purpose of these rules is to protect public health by preventing unnecessary exposure of individuals to ionizing radiation from diagnostic and therapeutic x-ray systems and medical particle accelerators.

a) The rules governing the use of ionizing radiation equipment in the healing arts are designed to ensure that individuals are at all times protected to the greatest extent possible from unnecessary exposure to ionizing radiation. Proposed reporting requirements enable the Commissioner of Health to ensure that radiographic or therapeutic x-ray equipment is used so public health is protected.

b) Rules governing the establishment of schedules or deadlines for reporting requirements are adopted and proposed to protect the health of individuals and the public.

c) Further simplification or consolidation of requirements is not reasonable since all the proposed requirements are necessary to protect public health.

d) Design standards for diagnostic x-ray systems are established by the federal government. They require equipment manufacturers to meet federal performance standards; require certification of all electronic products emitting ionizing radiation; and set performance standards to control the amount of ionizing radiation emitted (Public Law 90-602). The state must acknowledge applicable federal law. Although there are no federal design standards for therapeutic x-ray equipment, it would be unreasonable to have separate design standards for therapeutic x-ray equipment used only by small business. Most small businesses do not have expensive, highly technical or therapeutic equipment. The proposed standards are necessary to protect public health regardless of the size of the business.

e) Since the proposed rules are designed to protect the public from unnecessary exposure to ionizing radiation, it would be unreasonable to exempt small businesses from the proposed rules. The consumers and employees of small business services must also be protected.

Submission to LCRAR

In accordance with Minnesota Statutes, sections 14.131 and 14.23, the department sent a copy of the statement of need and reasonableness to the legislative commission to review administrative rules when the document became available for public review.

Statement of Need and Reasonableness Justification by Rule Part

Proposed Chapter 4730 includes amendments to adopted rules and new rule parts. Amendments are proposed to: delete language that is inconsistent with federal requirements; add new requirements; revise current requirements; and reorganize adopted rules for clarity and consistency.

4730.0100 DEFINITIONS

Subpart 1. Scope. This subpart establishes definitions of terms used in chapter 4730. It is necessary to establish definitions to ensure the consistent and intended interpretation of the proposed rules. The definitions proposed are necessary to give a common understanding to the defined term as used in chapter 4730.

Subpart 2. Absorbed dose. This definition is based on the same term as defined in the Glossary of NCRP Report No. 102, Appendix A. This definition is recommended in the CRCPD's SSRCR Section A.2 under "dose."

Subpart 4. Accelerator. This definition is based on the term as defined in the Glossary of NCRP Report No. 51, Appendix A.1 and

the term "particle accelerator" recommended in the CRCPD's SSRCR Section A.2.

Subpart 5. Accelerator-produced material. There is no definition in NCRP reports or Federal Performance Standards of this term. This definition, however, is recommended in the CRCPD's SSRCR Section A.2 under "accelerator-produced material."

Subpart 6. Added filtration. There is no definition of this term in NCRP reports or Federal Performance Standards. This definition, however, is recommended in the CRCPD's SSRCR Section F.2 under "added filtration."

Subpart 7. Aluminum equivalent. This definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. This definition is recommended in the CRCPD's SSRCR Section F.2 under "aluminum equivalent."

Subpart 8. Applicator. There is no definition of this term in NCRP reports. This definition is recommended in the CRCPD's SSRCR Section F.9 (a), however, under "applicator."

Subpart 9. Appropriate limit. The amendment to this subpart is technical. It removes the reference to other definition subparts. Those definitions that are referred to remain in these rules.

Subpart 10. Arc therapy. There is no definition of this term in NCRP reports, Federal Performance Standards, or the CRCPD's SSRCR. This term was defined by the staff and the Rule Advisory Work Group as a replacement for "moving beam therapy" as that phrase is defined in the CRCPD's SSRCR Section F.9(a). This term is now being used rather than the term "moving beam therapy."

Subpart 11. Filter-filtration. This subpart is proposed for repeal because the terms "filter or filtration," as defined in this part, are used throughout chapter 4730.

Subpart 12. Assembler. There is no definition of this term in NCRP reports. The definition proposed is based on the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(3) and this definition is also recommended in the CRCPD's SSRCR Section F.2 under "assembler."

Subpart 13. Attenuation. This definition was previously subpart 2.

Subpart 14. Attenuation block. The definition proposed is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A, and Federal Performance Standard 21 CFR 1020.30(b)(4). This definition is recommended in the CRCPD's SSRCR Section F.2 under "attenuation block."

Subpart 15. Automatic exposure control (AEC). There is no definition of this term in NCRP reports. The proposed definition is based on the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(5). The proposed definition is the same as that recommended in the CRCPD's SSRCR Section F.2 under "automatic exposure control."

Subpart 16. Beam axis. The proposed definition is based on the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(6). The proposed definition is recommended in the CRCPD's SSRCR Section F.2 under "beam axis."

Subpart 17. Inherent filter. This subpart is proposed for repeal because it has been replaced by "inherent filtration" as defined in this part.

Subpart 18. Beam-limiting device (BLD). The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. The proposed definition is the same as the term as defined in the Federal Performance Standard 21 CFR 1020.30(b)(7) and as recommended for definition in the CRCPD's SSRCR Section F.2 under "beam-limiting device."

Subpart 19. Beam monitoring system. There is no definition of this term in NCRP reports or Federal Performance Standards. However, the proposed definition is recommended in the CRCPD's SSRCR Section F.2 under "beam monitoring system."

Subpart 20. Beam scattering filter. There is no definition of this term in NCRP reports or Federal Performance Standards. This definition is recommended, however, in the CRCPD's SSRCR Section F.2 under "beam scattering filter."

Subpart 21. Kilovolt peak (kVp). This subpart is proposed for repeal. The term is proposed for amendment elsewhere in this part and renumbered.

Subpart 22. Becquerel (Bq). The proposed definition is similar to the definition in the Glossary of NCRP Report No. 102, Appendix A. This proposed definition is the same as the term as defined in the CRCPD's SSRCR Section A.12(d) under "radioactivity."

Subpart 23. Bucky. There is no definition of this term in NCRP reports, Federal Performance Standards or CRCPD's SSRCR. The proposed definition was arrived at through a consensus of radiation section staff and members of the Rule Advisory Work Group. It is a simplified version of a term commonly used in the profession. Taber's Cyclopedic Medical Dictionary, 16th Edition, defines "bucky diaphragm" (Gustav P. Bucky, German born, U.S. roentgenologist, 1880 to 1963) as "a grid that is suspended

immediately beneath the radiologist's table. It is constructed so that the effects of backscatter and secondary radiation are eliminated when radiographs of dense structures are taken."

Subpart 24. By-product material. There is no definition of this term in NCRP reports or Federal Performance Standards. Item A is the term as defined by the U.S. Nuclear Regulatory Commission in Title 10, Chapter 1, Code of Federal Regulations, Part 20.3(a)(3). Proposed items A and B are recommended in the CRCPD's SSRCR Section A.2 under "by-product material."

Subpart 25. C-arm. There is no definition of this term in NCRP reports, Federal Performance Standards, or the CRCPD's SSRCR. This is the proposed definition for "c-arm" that is currently under review by the CRCPD for inclusion in the next revision of the SSRCRs.

Subpart 26. Calibration. There is no definition of this term in NCRP reports or Federal Performance Standards. Items A and B are the definition as recommended in the CRCPD's SSRCR Section F.2 under "calibration." Item C is an added definition that was developed by consensus with radiation control section staff and the Rule Advisory Work Group from several work group member's experience calibrating equipment. The units of calibration listed for therapeutic systems are consistent with the accepted protocol of the American Association of Physicists in Medicine (AAPM) in Report No. 13, Table VII.

Subpart 27. Central axis of the beam. This definition is necessary to give a common understanding to the term as used in chapter 4730. There is no definition in NCRP reports. This definition is recommended in the CRCPD's SSRCR Section F.9(a) under "central axis of the beam."

Subpart 28. Cephalometric device. There is no definition of this term in NCRP reports. The proposed definition is based on the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(53). The proposed definition is the same as that recommended in the CRCPD's SSRCR Section F.2 under "cephalometric device."

Subpart 29. Personnel monitor. This subpart is proposed for repeal because the more inclusive term "personnel monitoring equipment" is proposed for definition in this part instead.

Subpart 30. Certified components. This definition is necessary because components of x-ray systems are subject to requirements of federal performance standards. There is no definition of this term in NCRP reports or Federal Performance Standards. There is a definition of the term in the CRCPD's SSRCR Section F.2 under "certified components" but is different than the term as proposed herein and is being reviewed by the CRCPD for accuracy. The

proposed definition in this part is the same as the definition of "certified components" currently under review by the CRCPD for inclusion in the next revision of the SSRCRs.

Subpart 31. Primary beam. This subpart is proposed for repeal because the term "useful beam" is proposed for use in chapter 4730 instead.

Subpart 32. Certified system. The proposed definition is necessary because x-ray systems are subject to requirements of federal equipment performance standards. There is no definition of this term in NCRP reports or Federal Performance Standards. There is a similar definition in the CRCPD's SSRCR Section F.2 under "certified system."

Subpart 33. Changeable filter. There is no definition of this term in NCRP reports or Federal Performance Standards. There is a similar definition in the CRCPD's SSRCR Section F.2 under "changeable filter."

Subpart 34. Clinical range. There is no definition of this term in NCRP reports, Federal Performance Standards, or the CRCPD's SSRCR. The proposed definition was the consensus of radiation control section staff and Rule Advisory Work Group members.

Subpart 35. Coefficient of variation or C. There is no definition of this term in NCRP reports. The proposed definition is the same as the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(8). The proposed definition is also the same as that recommended in the CRCPD's SSRCR Section F.2 under "coefficient of variation."

Subpart 36. Cold flow. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition was reviewed and approved of by radiation control section staff and members of the Rule Advisory Work Group. The proposed definition is taken from the "Dictionary of Scientific & Technical Terms," McGraw-Hill Book Co., New York, 1976.

Subpart 37. Collimation. This subpart was previously numbered subpart 4.

Subpart 38. Collimator. The proposed definition is based on the definition in the Glossary of NCRP Report No. 51, Appendix A, and the definition of "beam limiting device" in the Glossary of NCRP Report No. 102, Appendix A. There is no definition in Federal Performance Standards or the CRCPD's SSRCR.

Subpart 39. Commissioner. This subpart was previously numbered subpart 5.

Subpart 40. Computed tomography (CT). There is no definition of this term in NCRP reports. The proposed definition is the same as the term defined in Federal Performance Standard 21 CFR 1020.30(b)(58) and the term as defined in the CRCPD's SSRCR Section F.2 under "computed tomography."

Subpart 41. Radiation protection survey. This subpart is proposed for repeal because the term is proposed for incorporation into the definition of "survey or radiation safety survey" in this part.

Subpart 42. Contact therapy system. There is no definition of this term in Federal Performance Standards. The proposed definition is based on the definition of "contact therapy apparatus" in the Glossary of NCRP Report No. 102, Appendix A and the proposed definition is the same as the definition of the term in the CRCPD's SSRCR Section F.2 under "contact therapy system."

Subpart 43. Control panel. There is no definition of this proposed term in NCRP reports. The proposed definition is the same as the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(9). The proposed definition is the same as the definition of the term in the CRCPD's SSRCR Section F.2 under "control panel."

Subpart 44. Controlled area. This subpart, which is subpart 6 in the adopted rule, has been amended for consistency with the proposed definition of "radiation safety officer."

Subpart 45. Coulomb per kilogram (C/kg). The proposed definition is discussed in NCRP Report No. 82, Section 3.2. There is no definition of the proposed term in Federal Performance Standards. The term is discussed in the CRCPD's SSRCR Section A.12(c) under "exposure."

Subpart 46. CT conditions of operation. There is no definition of the proposed definition in NCRP reports. The proposed definition is the same as the term defined in Federal Performance Standard 21 CFR 1020.33(b)(3) and the term as defined in the CRCPD's SSRCR Section F.11(a) under "CT conditions of operation."

Subpart 47. CT dose index (CTDI). There is no definition of the proposed term in NCRP reports. The proposed definition is the same as that in Federal Performance Standard 21 CFR 1020.33(b)(1) and is the same as the definition in CRCPD's SSRCR Section F.11(a) under "computed tomography dose index."

Subpart 48. CT gantry. There is no definition of this term in NCRP reports or presently in Federal Performance Standards. The proposed definition is based on a proposed amendment to Federal Performance Standard 21 CFR 1020.30 as published in the Federal Register on page 42683, dated October 17, 1989. This definition

is recommended in the CRCPD's SSRCR Section F.11(a) under "CT gantry."

Subpart 49. CT number. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. The proposed definition is the same as the term defined in Federal Performance Standard 21 CFR 1020.33(b)(4) and the term as defined in CRCPD's SSRCR Section F.11 under "CT number."

Subpart 50. Curie (CI). This subpart is numbered as subpart 7 in the current adopted rule. It is proposed for amendment to make it consistent with the term as discussed in NCRP Report No. 82, Section 3.4. The proposed term as amended is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The term as proposed for amendment is the same as the term as defined in the CRCPD's SSRCR Section A.2 under "curie" and with the term as discussed in the CRCPD's SSRCR Section A.12(d) under "radioactivity."

Subpart 51. Dead-man switch. This subpart is numbered subpart 8 in the current adopted rule. It is proposed for amendment to clarify that the switch should be activated by the operator. The term as amended is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. It is the same as the term as defined in the CRCPD's SSRCR Section F.2 under "dead-man switch."

Subpart 52. Densitometer. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition was developed by consensus of the department's radiation control section staff and members of the Rule Advisory Work Group. It is based on the term as defined in the second college edition of the American Heritage Dictionary published by the Houghton Mifflin Company which defines the term as "an apparatus for measuring the optical density of a material, such as a negative."

Subpart 53. Diagnostic source assembly. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. It is the same as the term as defined in the Federal Performance Standard 21 CFR 1020.30(b)(11) and in the CRCPD's SSRCR Section F.2 under "diagnostic source assembly."

Subpart 54. Diagnostic-type protective tube housing. This subpart is currently numbered as subpart 9 in the adopted rule.

Subpart 55. Diagnostic radiographic imaging system. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition is the same as the definition of "diagnostic radiographic imaging

system" that is currently under review by the CRCPD for inclusion in the next revision of the SSRCRs.

Subpart 56. Diagnostic radiographic system. There is no definition of this term in NCRP reports. The term as proposed is similar to the definition in Federal Performance Standard 21 CFR 1020.30(b)(12) and is based on the definition recommended in the CRCPD's SSRCR Section F.2 under "diagnostic x-ray system." The proposed definition includes the phrase "or animal body" to include the systems used by veterinarians.

Subpart 57. Dose. The proposed definition references "absorbed dose" and "dose equivalent" which are defined in this part. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the proposed term in the Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section A.2 under "dose."

Subpart 58. Dose commitment. The proposed term is discussed in NCRP Report No. 91, Section 6.1 under "committed dose equivalent." There is no definition in Federal Performance Standards. The proposed term is the same as the definition of "dose commitment" in CRCPD SSRCR Section A.2.

Subpart 59. Dose equivalent (DE). This subpart, which is subpart 10 in the current adopted rule, is proposed for amendment to make the term consistent with the term as discussed in NCRP Report No. 82, Section 3.3. The term as proposed for amendment is based on the definition of "dose equivalent" in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The term as proposed for amendment is the same as the defined term "dose equivalent" in the CRCPD's SSRCR Section A.2. It is similar to the term as discussed in the CRCPD's SSRCR Section A.12(b) under "dose equivalent."

Subpart 60. Dose monitoring system. There is no definition of this proposed definition in NCRP reports or Federal Performance Standards. The proposed definition is based on the term as defined by the CRCPD's SSRCR Section F.9(a) under "dose monitoring system." The staff of the department's radiation control section and the Rule Advisory Work Group recommend adding the language "at a given location within a defined geometry" to clarify the applicability of the definition.

Subpart 61. Dose monitor unit. There is no definition of the proposed term in NCRP reports or Federal Performance Standards. The proposed term is based on the term "dose monitor unit" as defined in the CRCPD's SSRCR Section F.9 (a).

Subpart 62. Dose profile. There is no definition of this term in NCRP reports. The proposed term is the same as the definition in Federal Performance Standard 21 CFR 1020.33(b)(7) and the definition in the CRCPD's SSRCR Section F.11(a) under "dose profile."

Subpart 63. Effective dose equivalent. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in the Federal Performance Standards or the CRCPD's SSRCR.

Subpart 64. Electron-beam generator. The proposed definition is based on the definition in the Glossary of NCRP Report No. 51, Appendix A. There is no definition of the term in the Federal Performance Standards or the CRCPD's SSRCR.

Subpart 65. Elemental area. There is no definition of this term in NCRP reports or Federal Performance Standards. This definition is recommended in the CRCPD's SSRCR Section F.11(a) under "elemental area."

Subpart 66. Entrance exposure rate. There is no definition of this term in NCRP reports or Federal Performance Standards. This definition is recommended in the CRCPD's SSRCR Section F.2 under "entrance exposure rate."

Subpart 67. ESE. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. It was the consensus of the radiation control section staff and the Rule Advisory Work Group to add this definition. It is a term commonly used in the profession.

Subpart 68. Exposure. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. It is the same as the definition in the Federal Performance Standard 21 CFR 1020.30(b)(14) and in the CRCPD's SSRCR Section A.2 under "exposure."

Subpart 69. Exposure rate. The definition proposed is based on the term as defined in the Glossary of NCRP Report No. 49, Appendix A. There is no definition of this term in the Federal Performance Standards. The proposed definition is the same as the definition in the CRCPD's SSRCR Section A.2 under "exposure rate."

Subpart 70. Facility. There is no definition of this term in NCRP reports or Federal Performance Standards. It is the same as the definition in the CRCPD's SSRCR Section B.2 under "facility."

Subpart 71. Field emission equipment. There is no definition of this proposed term in NCRP reports. The proposed definition is the same as the term as defined in Federal Performance Standard

21 CFR 1020.30(b)(15) and in the CRCPD's SSRCR Section F.2 under "field emission equipment."

Subpart 72. Field-flattening filter. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same, however, as the definition in the CRCPD's SSRCR Section F.9 under "field-flattening filter."

Subpart 73. Filter or filtration. This subpart, which is subpart 11 in the current adopted rule, is proposed for amendment to make the definition consistent with the term as defined in the CRCPD's SSRCR.

Subpart 74. Fluoroscopic imaging assembly. There is no definition of this term in NCRP reports. However, the proposed definition is the same as the term defined in Federal Performance Standard 21 CFR 1020.30(b)(16) and in the CRCPD's SSRCR Section F.2 under "fluoroscopic imaging assembly."

Subpart 75. Focal spot. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section F.2 under "focal spot."

Subpart 76. Gantry. There is no definition of this proposed term in NCRP reports or presently in Federal Performance Standards. It is based on the definition proposed as part of amendments to Federal Performance Standard 21 CFR 1020.30 in the Federal Register on page 42683, dated October 17, 1989, and on the definition recommended in the CRCPD's SSRCR Section F.11(a) under "CT gantry."

Subpart 77. General purpose radiographic x-ray system. There is no definition of this term in NCRP reports. However, the proposed definition is the same as the definition in the Federal Performance Standard 21 CFR 1020.30(b)(17) and in the CRCPD's SSRCR Section F.2 under "general purpose radiographic x-ray system."

Subpart 78. Gonad shield. There is no definition of this term in NCRP reports or Federal Performance Standards. However, the proposed definition is the same as the definition in the CRCPD's SSRCR Section F.2 under "gonad shield."

Subpart 79. Gray (Gy). The proposed definition is based on the definition of this term in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of this term in Federal Performance Standards. The proposed definition is the same as the term as defined in the CRCPD's SSRCR Section A.12(a) under "absorbed dose."

Subpart 80. Half-value layer (HVL). This subpart, which is subpart 12 in the current adopted rule, is proposed for amendment to make the definition consistent with the term in other codes and guidelines. The proposed definition, as amended, is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A. The proposed definition is the same as the term defined in the Federal Performance Standard 21 CFR 1020.30(b)(18) and in the CRCPD's SSRCR Section F.2 under "half-value layer."

Subpart 81. Healing arts. This subpart, which is subpart 13 in the current adopted rule, is proposed for amendment to clarify that healing arts includes all branches of medicine.

Subpart 82. Healing arts screening or screening. This subpart, which incorporates parts of subpart 34, item B of the current rule, is proposed for amendment to make it consistent with the term as defined in CRCPDs SSRCR guidelines. There is no definition of the term in NCRP reports or Federal Performance Standards. As proposed, it is the same as the definition in the CRCPD's SSRCR Section F.2 under "healing arts screening."

Subpart 83. High radiation area. This subpart is subpart 14 in the current adopted rule and is proposed for renumbering.

Subpart 84. Human use. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the term as defined in the CRCPD's SSRCR Section A.2 under "human use."

Subpart 85. Image intensifier. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. The proposed definition is the same as the term defined in the Federal Performance Standard 21 CFR 1020.30(b)(52) and in the CRCPD's SSRCR Section F.2 under "image intensifier."

Subpart 86. Image receptor. The proposed definition is based on the defined term in the Glossary of NCRP Report No. 102, Appendix A. The proposed definition is the same as the term defined in the Federal Performance Standard 21 CFR 1020.30(b)(19) and in the CRCPD's SSRCR Section F.2 under "image receptor."

Subpart 87. Image receptor support. There is no definition of this term in NCRP Reports. The proposed definition is based on the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(54) and in the CRCPD's SSRCR Section F.2 under "image receptor support." The proposed definition removes the words "in a horizontal plane" because mammography image receptor supports may be used in any orientation, not just horizontal.

Subpart 88. Individual. This definition is necessary to distinguish a human being from the term "person" as defined in

this part and used throughout chapter 4730. The term "person" includes other entities in addition to human beings.

Subpart 89. Industrial radiographer. This subpart is numbered as subpart 15 in the current adopted rule.

Subpart 90. Industrial radiography. This subpart is numbered as subpart 16 in the current adopted rule.

Subpart 91. Inherent filtration. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The proposed definition is the same as the term as defined in the CRCPD's SSRCR Section F.2 under "inherent filtration."

Subpart 92. Inspection. This definition is needed to describe the limit of the commissioner's authority for determining compliance with the law and rules.

Subpart 93. Interlock. This subpart is numbered as subpart 18 in the current rule and is proposed for amendment to make it consistent with the term as used in other codes and industry guidelines. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 49 and Report 102, Appendix A. There is no definition of the term in Federal Performance Standards. The additional language proposed is the same as that contained in the CRCPD's SSRCR Section A.2 under "interlock."

Subpart 94. Ionizing radiation. This subpart is numbered as subpart 19 in the current rule and referred to in adopted subpart 37. It has been amended to simplify format and make the definition consistent with the term as used in other codes and standards. The definition is recommended in the CRCPD's SSRCR Section A.2 under "radiation."

Subpart 95. Irradiation. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 51, Appendix A. There is no definition of the term in Federal Performance Standards. Definition of this term is contained in the CRCPD's SSRCR Section F.2 under "irradiation."

Subpart 96. Isocenter. There is no definition of this proposed term in NCRP reports or Federal Performance Standards. The proposed term is the same as that defined in the CRCPD's SSRCR Section F.9 under "isocenter."

Subpart 97. Iso-line. This subpart is proposed for renumbering and is currently subpart 20 in the adopted rule.

Subpart 98. Kilovolt peak (kVp). This subpart, which is subpart 21 in the current adopted rule, is proposed for amendment to include the word "or" before the acronym for clarification and to correct terminology. The definition, as proposed for amendment, is based on the term as defined in NCRP Report No. 49, Appendix A; and the definition of "peak tube potential" in the Federal Performance Standard 21 CFR 1020.30(b)(25) and in the CRCPD's SSRCR Section F.2.

Subpart 99. Kilowatt second (kWs). There is no definition of this term in NCRP Reports or Federal Performance Standards. The proposed definition is the same as the term as defined in the CRCPD's SSRCR Section F.2 under "kWs."

Subpart 100. Lead equivalence or lead equivalent. This subpart is proposed for amendment to add the term "lead equivalent." This subpart is numbered as subpart 22 in adopted part 4730.0100.

Subpart 101. Leakage radiation. This proposed definition is currently included as part of the adopted definition of "radiation." It is proposed as a separate definition for format purposes and clarity.

Subpart 102. Leakage technique factors. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. The term is the same as the definition in Federal Performance Standard 21 CFR 1020.30(b)(21) and in the CRCPD's SSRCR Section F.2 under "leakage technique factors" except that the phrase "peak tube potential" has been modified to "kVp" and "current" to "milliamperage" for clear drafting.

Subpart 103. Licensed practitioner of the healing arts. This definition is necessary to clarify that the term only includes those practitioners who, as part of their license from the appropriate licensing or examining board, are authorized to prescribe or take x-rays. The intent is to exclude those licensed practitioners who have no training or experience in x-rays and are not legally authorized to prescribe or take x-rays.

Subpart 104. Light field. There is no definition of this term in NCRP reports. The proposed definition is the same as the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(22) and in the CRCPD's SSRCR Section F.2 under "light field."

Subpart 105. Line-voltage regulation. There is no definition of this term in NCRP reports. The proposed term is the same as the definition in Federal Performance Standard 21 CFR 1020.30(b)(23) and in the CRCPD's SSRCR Section F.2 under "line-voltage regulation."

Subpart 106. Linear attenuation coefficient or u. There is no definition of this term in NCRP reports or Federal Performance

Standards. The proposed definition is the same, however, as the term as defined in the CRCPD's SSRCR Section F.2 under "linear attenuation coefficient or u."

Subpart 107. mA. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition, however, is the same as the definition in the CRCPD's SSRCR Section F.2 under "mA."
Subpart 108. mAs. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition, however, is the same as the definition in the CRCPD's SSRCR Section F.2 under "mAs."

Subpart 109. Maximum line current. There is no definition of this term in NCRP reports. The proposed definition, however, is the same as the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(24) and in the CRCPD's SSRCR Section F.2 under "maximum line current."

Subpart 110. Medical particle accelerator. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same, however, as the term as defined in the CRCPD's SSRCR Section A.2 under "particle accelerator."

Subpart 111. Maximum permissible concentrations (MPC). This subpart, currently numbered as subpart 24 in adopted part 4730.0100, is proposed for amendment to add "or" before the acronym for clarification; to include reference to the Code of Federal Regulations; and to the availability of the incorporated materials.

Subpart 112. Maximum permissible dose or dose equivalent (MPD). This subpart, which is subpart 25 in the current adopted rule, is proposed for amendment to correct references in this chapter.

Subpart 113. Maximum permissible neutron radiation. This subpart is proposed for renumbering and is currently numbered subpart 26 in the adopted rule.

Subpart 114. NCRP. This term is necessary to define because many of the National Council on Radiation Protection and Measurements reports are incorporated by reference into chapter 4730.

Subpart 115. NARM. There is no similar definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the term as defined in the CRCPD's SSRCR Section A.2 under "NARM."

Subpart 116. Neutron generator. The proposed definition is based on the term as defined in the Glossary in NCRP Report No.

51, Appendix A. There is no definition of the term in Federal Performance Standards or the CRCPD's SSRCR.

Subpart 117. Nominal tomographic section thickness. There is no definition of this term in NCRP reports. However, the proposed definition is the same as the definition of the term in Federal Performance Standard 21 CFR 1020.33(b)(11) and in the CRCPD's SSRCR Section F.11(a) under "nominal tomographic section thickness."

Subpart 118. Nonstochastic effects. The proposed definition is based on the term as defined in the Glossary in NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards or the CRCPD's SSRCR.

Subpart 119. Nominal treatment distance. There is no definition of this term in NCRP reports or Federal Performance Standards. However, the proposed definition is the same as the term "normal treatment distance" as defined in the CRCPD's SSRCR Section A.2. The Rule Advisory Work Group and staff recommended changing "normal" - which means usual - to "nominal" - which means minimal.

Subpart 120. Occupational dose. The proposed definition is based on the definition of "occupational exposure" in the Glossary in NCRP Report No. 51, Appendix A. There is no definition of the term in the Federal Performance Standards. The proposed definition is the same as the definition in the CRCPD's SSRCR Section A.2 under "occupational dose."

Subpart 121. Optical density or O.D. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition was developed by discussion between radiation control section staff and members of the Rule Advisory Work Group.

Subpart 122. Patient. This subpart is necessary to expand the common use of the term that usually refers to humans to also include animal patients. The proposed definition is the same as the term as defined in the CRCPD's SSRCR Section F.2 under "patient."

Subpart 123. Peak tube potential. There is no definition of this term in NCRP reports. The proposed definition is the same as the definition in Federal Performance Standard 21 CFR 1020.33(b)(25) and in the CRCPD's SSRCR Section F.2 under "peak tube potential."

Subpart 124. Permanent radiographic installation. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition was

developed through discussion between radiation control section staff and members of the Rule Advisory Work Group.

Subpart 125. Person. This subpart is proposed for renumbering and is currently numbered as subpart 28 in adopted rule part 4730.0100.

Subpart 126. Personnel monitoring equipment. The proposed definition is based on the definition of "personnel monitor" in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of this proposed term in Federal Performance Standards. This definition is the same as the definition recommended in the CRCPD's SSRCR Section A.2 under "personnel monitoring equipment."

Subpart 127. Phantom. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The proposed definition is the same as the definition in CRCPD's SSRCR Section F.2 under "phantom."

Subpart 128. Phototimer. There is no definition of the proposed term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the definition of the term in the CRCPD's SSRCR Section F.2 under "phototimer."

Subpart 129. Picocurie. This subpart is proposed for renumbering and is currently numbered as subpart 30 in adopted part 4730.0100.

Subpart 130. Pixel. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A. The proposed definition is the same as the term as defined in Federal Performance Standard 21 CFR 1020.33(b)(12) and is the same as the term "picture element" as defined in the CRCPD's SSRCR Section F.11(a).

Subpart 131. Port film. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition was develop through discussion with department radiation control section staff and members of the Rule Advisory Work Group.

Subpart 132. Position indicating device (PID). There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition, however, is the same as the definition recommended in the CRCPD's SSRCR Section F.2 under "position indicating device."

Subpart 133. Primary dose monitoring system. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition, however, is the same as the

definition recommended in the CRCPD's SSRCR Section F.2 under "primary dose monitoring system."

Subpart 134. Primary protective barrier. This subpart, which is currently part of the definition of "protective barrier" in adopted part 4730.0100, subpart 34, is proposed as a separate definition for clarity and consistency with other adopted or recommended standards. The proposed definition is based on the defined term in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section F.2 under "primary protective barrier."

Subpart 135. Protective apron. This subpart is proposed for renumbering. It is currently numbered as subpart 33 in part 4730.0100.

Subpart 136. Protective barrier or barrier. This subpart, which is currently numbered as subpart 34 in adopted part 4730.0100, is proposed for amendment to include the term "barrier" in addition to "protective barrier". It is also proposed for amendment to distinguish between primary and secondary protective barriers which are proposed for separate definition in this part.

Subpart 137. Protective glove. This subpart is proposed for renumbering and is currently numbered subpart 35 in adopted rule part 4730.0100.

Subpart 138. Quality assurance program. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The definition was developed by radiation control section staff and reviewed by members of the Rule Advisory Work Group.

Subpart 139. Quality factor. This subpart is currently included as part of the definition of "dose equivalent" in adopted part 4730.0100. The subpart is proposed for amendment to make it consistent with terms defined in other standards. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 91, Appendix A. There is no definition of the term in Federal Performance Standards or the CRCPD's SSRCR.

Subpart 140. Rad. This proposed definition is currently included in adopted part 4730.0100, subpart 36 as part of the definition of "dose equivalent." The subpart has been amended to make it consistent with terms defined in other standards. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 91, Appendix A. There is no definition of the term in Federal Performance Standards or the CRCPD's SSRCR.

Subpart 141. Radiation. This definition is currently numbered as subpart 37 in adopted part 4730.0100. The subpart is proposed for renumbering and is proposed for amendment to delete the terms "ionizing radiation, leakage radiation, scattered radiation, secondary radiation, stray radiation and useful beam" which have been given separate definitions in this part, and to include the reference to ionizing radiation.

Subpart 142. Radiation area. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 51, Appendix A. There is no definition of the term in the Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section A.2 under "radiation area."

Subpart 143. Radiation detector or detector. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section F.2 under "radiation detector."

Subpart 144. Radiation hazard. This subpart is proposed for renumbering. It is currently numbered as subpart 38 in adopted rule part 4730.0100.

Subpart 145. Radiation head. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section F.9 under "radiation head."

Subpart 146. Radiation machine. This subpart is proposed for renumbering. It is currently numbered as subpart 39 in adopted rule part 4730.0100.

Subpart 147. Radiation protection. This subpart is proposed for renumbering. It is currently numbered as subpart 40 in adopted rule part 4730.0100.

Subpart 148. Radiation safety. This subpart is proposed for renumbering. It is currently numbered as subpart 42 in adopted rule part 4730.0100.

Subpart 149. Radiation safety officer. The proposed definition is based on the definition of "radiation protection (safety) officer" in the Glossary of NCRP Report No. 51, Appendix A. There is no definition of this term in Federal Performance Standards. The proposed definition is based on the definition recommended in the CRCPD's SSRCR Section A.2 under "radiation area." The additional language "who has been designated by the facility in compliance with part 4730.0400, item B" at the end of the definition refers to a part in this chapter where the qualifications and duties of this person are outlined.

Subpart 150. Radiation therapy simulation system. There is no definition of this term in NCRP Reports. The proposed definition is based on the definition in Federal Performance Standard 21 CFR 1020.30(b)(50) and to the recommended definition in the CRCPD's SSRCR Section F.2 under "radiation therapy simulation system."

Subpart 151. Radioactive material. This subpart is proposed for renumbering. It is currently subpart 43 in adopted part 4730.0100.

Subpart 152. Radioactivity. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section A.2 under "radioactivity."

Subpart 153. Radiograph. The proposed definition is based on the definition of this term in the Glossary of NCRP Report No. 102, Appendix A. The definition of "image receptor" in Federal Performance Standard 21 CFR 1020.30(b)(19); and the definition recommended in the CRCPD's SSRCR Section F.2 under "radiograph."

Subpart 154. Radiography. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards or the CRCPD's SSRCR. The proposed definition was developed by radiation control section staff and reviewed by members of the Rule Advisory Work Group.

Subpart 155. Radiographic exposure device. This subpart is proposed for renumbering. It is currently subpart 44 in adopted part 4730.0100.

Subpart 156. Rating. There is no definition of this term in NCRP Reports. The proposed definition is based on the definition in Federal Performance Standard 21 CFR 1020.30(b)(30) and the recommended definition in the CRCPD's SSRCR Section F.2 under "rating."

Subpart 157. Recording. There is no definition of this term in NCRP Reports. The is definition is based on the definition in Federal Performance Standard 21 CFR 1020.30(b)(31) and to the recommended definition in the CRCPD's SSRCR Section F.2 under "recording."

Subpart 158. Reference plane. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is recommended in the CRCPD's SSRCR Section F.11(a) under "reference plane."

Subpart 159. Registrant. This subpart is proposed for renumbering. It is currently numbered as subpart 45 in adopted rule part 4730.0100.

Subpart 160. Registration. The definition is necessary to make reference to the registration requirements in chapter 4730. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is based on the definition recommended in CRCPD's SSRCR Section A.2 under "registration."

Subpart 161. Rem. This subpart is currently numbered as subpart 46 in adopted rule part 4730.0100. This subpart is proposed for renumbering and amendment to make the defined term consistent with standards in other codes and guidelines. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition in Federal Performance Standards. The proposed definition is based on the definition recommended in CRCPD's SSRCR Section A.2 under "rem" including the footnote.

Subpart 162. Response time. There is no definition of this term in NCRP Reports. The definition is based on the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(32) and the recommended definition in CRCPD's SSRCR Section F.2 under "response time."

Subpart 163. Restricted area. This subpart is proposed for renumbering. It is currently numbered as subpart 47 in adopted rule part 4730.0100.

Subpart 164. Roentgen. This subpart is proposed for renumbering. It is currently numbered as subpart 48 in adopted rule part 4730.0100.

Subpart 165. Scan. There is no definition of this term in NCRP reports. The proposed definition is the same as the definition of the term in Federal Performance Standard 21 CFR 1020.30(b)(59) and in the CRCPD's SSRCR Section F.11(a) under "scan."

Subpart 166. Scan increment. There is no definition of this term in NCRP reports. The proposed definition is the same as the defined term in Federal Performance Standard 21 CFR 1020.33(b)(14) and in CRCPD's SSRCR Section F.11(a) under "scan increment."

Subpart 167. Scan sequence. There is no definition of this term in NCRP reports. The proposed definition is the same as the term as defined in Federal Performance Standard 21 CFR 1020.33(b)(15) and in the CRCPD's SSRCR Section F.11(a) under "scan sequence."

Subpart 168. Scan time. There is no definition of this term in NCRP reports. The proposed definition is the same as the defined term in Federal Performance Standard 21 CFR 1020.30(b)(60) and in CRCPD's SSRCR Section F.11(a) under "scan time."

Subpart 169. Scattered radiation. The proposed definition is currently numbered as subpart, subpart 49 in adopted part 4730.0100. Subpart 49, in turn references to subpart 37 which is the current adopted definition of "radiation". It is proposed that the defined term "scattered radiation" be moved from the current definition of "radiation" in subpart 37 to ease reading of the rule.

Subpart 170. Secondary dose monitoring system. There is no definition of the proposed term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the recommended defined term in the CRCPD's SSRCR Section F.2 under "secondary dose monitoring system."

Subpart 171. Secondary protective barrier. The defined term in this subpart is currently included in adopted part 4730.0100, subpart 34. It is proposed for amendment to ease reading of the rule and reduce indirect cross referencing.

Subpart 172. Secondary radiation. This subpart, which is numbered as subpart 51 in adopted part 4730.0100, then references the definition of "radiation" in adopted subpart 37. A separate definition for "secondary radiation" is proposed to ease reading of the rule and reduce indirect cross referencing.

Subpart 173. Sensitometer. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition was developed by department radiation control section staff and reviewed by the Rule Advisory Work Group. The Second College Edition of <u>The American Heritage Dictionary</u> published by the Houghton Mifflin Company defines this equipment as "1. A device used for measuring the sensitivity of photographic film to light. 2. A device similar to a sensitometer for measuring the sensitivity of eyes to light." The term as proposed for definition here is more precise as to its use in testing radiographic equipment.

Subpart 174. Shadow tray. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section F.9 under "shadow tray."

Subpart 175. Shutter. The proposed definition is based on the definition of the term in the Glossary of NCRP Reports No. 49 and 102, Appendix A. There is no definition of the term in Federal Performance Standards. The proposed definition is the same as

the term defined in the CRCPD's SSRCR Section F.2 under "shutter."

Subpart 176. SI equivalent. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The definition was developed by radiation control section staff and reviewed by Rule Advisory Work group members. It is necessary to generate a definition for clarification.

Subpart 177. Sievert (Sv). The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards, however, the proposed definition is recommended in the CRCPD's SSRCR Section A.12(b) under "dose equivalent."

Subpart 178. Source. This subpart is proposed for renumbering. It is currently numbered as subpart 52.

Subpart 179. Source of radiation. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is recommended, however, in the CRCPD's SSRCR Section A.2 under "source of radiation."

Subpart 180. Source-to-image distance (SID). The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A. The proposed definition is the same as the definition of "source-image receptor distance (SID)" in Federal Performance Standard 21 CFR 1020.30(b)(34) and the same as the definition of the term recommended in the CRCPD's SSRCR Section F.2 under "source-image receptor distance."

Subpart 181. Source-to-skin distance (SSD). The proposed definition is based on the definition of "source-surface distance (source-skin distance)(SSD)" in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The proposed definition is recommended in the CRCPD's SSRCR Section F.2 under "SSD."

Subpart 182. Spot check. There is no definition of this term in NCRP reports or Federal Performance Standards. It is the same, however, as the definition of the term in the CRCPD's SSRCR Section F.2 under "spot check."

Subpart 183. Spot film. The proposed definition is based on the term as defined in the Glossary of NCRP Report No. 102, Appendix A. There is no definition in Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section F.2 under "spot film."

Subpart 184. Spot-film device. There is no definition of this term in NCRP reports. The proposed definition is based on the

definition of the term in Federal Performance Standard 21 CFR 1020.30(b)(51) and in the CRCPD's SSRCR Section F.2 under "spot-film device."

Subpart 185. Stationary beam therapy. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the term recommended in the CRCPD's SSRCR Section F.9 under "stationary beam therapy."

Subpart 186. Stepless adjustment. There is no definition of this term in NCRP reports, Federal Performance Standards or the CRCPD's SSRCR. The proposed definition is necessary to provide a common meaning of its use in chapter 4730. The definition was developed by radiation control section staff and reviewed by the Rule Advisory Work Group.

Subpart 187. Stochastic effects. The proposed definition is the same as the definition in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards or CRCPD's SSRCR.

Subpart 188. Storage container. This subpart is proposed for renumbering. It is currently subpart 53 in part 4730.0100.

Subpart 189. Stray radiation. This term is currently numbered as subpart 54 in adopted part 4730.0100. It then references to adopted subpart 37 which is the current definition of "radiation." A separate subpart for the definition of "stray radiation" is proposed to ease reading of the rule and reduce indirect cross referencing.

Subpart 190. Survey or radiation safety survey. The term "radiation safety survey" has been added to this subpart for clarification. The term facility has replaced "installation" for consistency with subpart 70.

Subpart 191. Target. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A. There is no definition of the term in Federal Performance Standards. The proposed definition is the same, however, as the term recommended in the CRCPD's SSRCR Section F.9 under "target."

Subpart 192. Technique factors. The proposed definition, items A to D, as based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A and Federal Performance Standard 21 CFR 1020.30(b)(36). The proposed definition, items A to D, is the same as the term recommended in the CRCPD's SSRCR Section F.2 under "technique factors" except that the phrase "peak tube potential" has been changed to "kVp" for clear drafting. Item E is proposed for addition to the definition after discussion between radiation control section staff and members of the Rule

Advisory Work Group to provide another set of conditions under which leakage technique factors could be employed.

Subpart 193. Television receiver. This subpart is proposed for renumbering. It is currently subpart 56 in adopted part 4730.0100.

Subpart 194. Teratogenic effects. The proposed definition is the same as the term as defined in the Glossary of NCRP Report No. 91, Appendix A. There is no definition of the proposed term in Federal Performance Standards or the CRCPD's SSRCR.

Subpart 195. Termination of irradiation. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is the same as the definition recommended in the CRCPD's SSRCR Section F.2 under "termination of irradiation."

Subpart 196. Therapeutic field size. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is recommended in the CRCPD's SSRCR Section F.9 under "field size."

Subpart 197. Therapeutic-type protective tube housing. This subpart is proposed for renumbering. It is currently subpart 57 in adopted part 4730.0100.

Subpart 198. Tomogram. There is no definition of this term in NCRP reports. The proposed definition is based on the term as defined in Federal Performance Standard 21 CFR 1020.30(b)(61) and in the CRCPD's SSRCR Section F.2 under "tomogram." The proposed definition was revised by radiation control section staff and reviewed by the Rule Advisory Work Group to further clarify the meaning as it is commonly used in the industry.

Subpart 199. Tomographic plane. There is no definition of the proposed term in NCRP reports. The proposed definition is based on the definition of the term in Federal Performance Standard 21 CFR 1020.33(b)(18) and is the same as the definition in the CRCPD's SSRCR Section F.11(a) under "tomographic plane."

Subpart 200. Tomographic section. There is no definition of this term in NCRP reports. However, the proposed definition is the same as the definition in Federal Performance Standard 21 CFR 1020.33(b)(19) and in the CRCPD's SSRCR Section F.11(a) under "tomographic section."

Subpart 201. Traceable to a standard. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is based on the definition recommended in the CRCPD's SSRCR Section F.2 under "traceable to a national standard." The proposed definition was revised by radiation

control section staff and reviewed by members of the Rule Advisory Work Group to clarify that the standard is maintained at the National Institute of Standards and Technology rather than leaving the definition ambiguous as to which national standard.

Subpart 202. Tube housing assembly. There is no definition of this term in NCRP reports. The proposed term is based on the definition of the term in Federal Performance Standard 21 CFR 1020.30(b)(38) and the definition in the CRCPD's SSRCR Section F.2 under "tube housing assembly." The proposed definition was revised by radiation control section staff and reviewed by members of the Rule Advisory Work Group to delete extraneous verbiage.

Subpart 203. Tube rating chart. This subpart has been added to give a common understanding to this term as it is used in Chapter 4730. There is no definition in the NCRP reports. This is the definition in Federal Performance Standard 21 CFR 1020.30(b)(39) and this definition is recommended in the CRCPD's SSRCR Section F.2 under "tube housing assembly."

Subpart 204. Type 1100 aluminum alloy. There is no definition of this term in NCRP reports. This specific aluminum alloy is defined by the Aluminum Association in its "Aluminum Standards and Data" which is referenced in Federal Performance Standard 21 CFR 1020.30(b)(2), footnote 1. The same type of aluminum alloy is referenced in the CRCPD's SSRCR Section F.2 under footnote 1 for "aluminum equivalent."

Subpart 205. Unit of exposure. This subpart, which is currently numbered as subpart 58 in adopted part 4730.0100, is proposed for amendment to reflect the addition of references to the international system of units in addition to the conventional system of measurement.

Subpart 206. Unit of radioactivity. This subpart, which is currently subpart 59 in adopted part 4730.0100, is proposed for amendment to reflect the addition of references to the international system of units in addition to the conventional system of measurement.

Subpart 207. Units of radiation dose. This subpart, which is currently subpart 60 in adopted part 4730.0100, is proposed for amendment to reflect the addition of references to the international system of units in addition to the conventional system of measurement.

Subpart 208. Unrestricted area. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is based on the definition recommended in the CRCPD's SSRCR Section A.2 under "unrestricted area."

Subpart 209. Useful beam. This subpart is currently numbered as subpart 61 in adopted part 4730.0100. Subpart 61 then referenced to the term "useful" as included in the definition of radiation in currently adopted subpart 37 of part 4730.0100. A separate definition and subpart is proposed to ease reading of the rule and reduce indirect cross referencing. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 102, Appendix A; Federal Performance Standard 21 CFR 1020.30(b)(61); and the CRCPD's SSRCR Section F.2 under "useful beam." The proposed definition was revised by radiation control section staff and reviewed by members of the Rule Advisory Work Group to clarify that the useful beam may emanate from an x-ray tube or radioactive source and pass by a direct path through a window, aperture, cone, or other collimating device.

Subpart 210. Variable-aperture beam-limiting device. There is no definition of this term in NCRP reports. The proposed definition is the same as the term in Federal Performance Standard 21 CFR 1020.30(b)(41) and the CRCPD's SSRCR Section F.2 under "variable-aperture beam-limiting device."

Subpart 211. Virtual source. There is no definition of this term in NCRP reports or Federal Performance Standards. The definition is the same as the term recommended in the CRCPD's SSRCR Section F.9 under "virtual source."

Subpart 212. Visible area. There is no definition of this term in NCRP reports. The proposed definition is the same as the defined term in Federal Performance Standard 21 CFR 1020.30(b)(42) and the CRCPD's SSRCR Section F.2 under "visible area."

Subpart 213. Wedge filter. There is no definition of this term in NCRP reports or Federal Performance Standards. The proposed definition is recommended in the CRCPD's SSRCR Section F.2 under "wedge filter."

Subpart 214. X-ray control. There is no definition of this term in NCRP reports. The proposed definition is the same as the term in Federal Performance Standard 21 CFR 1020.30(b)(43) and the CRCPD's SSRCR Section F.2 under "x-ray control."

Subpart 215. X-ray equipment. There is no definition of this term in NCRP reports. The first sentence of the proposed definition is the same as the definition in Federal Performance Standard 21 CFR 1020.30(b)(44) and is based on the definition recommended in the CRCPD's SSRCR Section F.2 under "x-ray equipment." Additional language is proposed by the radiation control section staff and has been reviewed by members of the Rule Advisory Work Group to address the use of mobile and portable x-ray equipment.

Subpart 216. X-ray field. There is no definition of this term in NCRP reports. The proposed definition is the same as the defined term in Federal Performance Standard 21 CFR 1020.30(b)(45) and the CRCPD's SSRCR Section F.2 under "x-ray field."

Subpart 217. X-ray generator. The proposed definition is based on the definition of the term in the Glossary of NCRP Report No. 51, Appendix A. There is no definition in Federal Performance Standards or the CRCPD's SSRCR.

Subpart 218. X-ray high-voltage generator. There is no definition of this term in NCRP reports. The proposed definition is the same as the defined term in Federal Performance Standard 21 CFR 1020.30(b)(46) and the CRCPD's SSRCR Section F.2 under "x-ray high-voltage generator."

Subpart 219. X-ray subsystem. There is no definition of this term in NCRP reports. There is a definition of the term in Federal Performance Standard 21 CFR 1020.30(b)(48). The proposed definition is the same as the term recommended in the CRCPD's SSRCR Section F.2 under "x-ray subsystem."

Subpart 220. X-ray system. There is no definition of this term in NCRP reports. The proposed definition is the same as the definition in Federal Performance Standard 21 CFR 1020.30(b)(47) and in the CRCPD's SSRCR Section F.2 under "x-ray system."

Subpart 221. X-ray tube or tube. There is no definition of this term in NCRP reports. There is a definition of the term in Federal Performance Standard 21 CFR 1020.30(b)(49). The proposed definition is the same as the defined term recommended in the CRCPD's SSRCR Section F.2 under "x-ray tube."

4730.0200 PURPOSE AND SCOPE.

The proposed amendments to this part are clean up amendments to provide for clearer drafting, ease future internal reference and ensure consistent use of terms. The term "used" is preferred to "utilized" by the Revisor. The range of rule parts "4730.0100 to 4730.3600" are amended to "this chapter" throughout the proposed rules to ease future reference to rules pertaining to the ionization of radiation. Reference to "this chapter" means all the parts contained within the chapter. The phrase "ionizing radiation" is proposed for use because that is the specific phrase that is defined in part 4730.0100.

4730.0300 PRECAUTIONARY PROCEDURES.

The proposed changes to this part are technical clean up amendments. Part 4730.3600 is proposed for repeal and

replacement with part 4730.3605. Change in the internal reference to the new standard is needed.

4730.0310 PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS.

The purpose of part 4730.0310 is to change the exposure limits previously specified in currently adopted part 4730.3300 which is now proposed for repeal. The standards in part 4730.0310 are proposed in response to changes in section 22 of NCRP Report No. 91.

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

Subpart 2. Radiation dose standards for individual workers in restricted areas. This subpart is necessary to ensure that radiation dose measurements are accurately determined. Accurate exposure measurement is necessary so an individual worker exposed to radiation is not exposed unnecessarily. The provisions in this subpart are included in 10 CFR 20, part 20.4 (d).

Item A. The permissible doses allowed by this item are specified in 10 CFR 20.101 (a) and supported by the NCRP in Report No. 91, Section 22, table 22.1.

Item B. The registrant may permit an individual worker in a restricted area to receive a planned special occupational exposure provided certain conditions occur. The conditions specified in item B are consistent with those in NCRP Report No. 91, Section 15.

Item C. No registrant shall possess, use, receive, or transfer sources of radiation in such a manner as to cause any woman working in a restricted area to receive a total dose equivalent limit, excluding medical exposure, of 0.5 rem to the woman's embryo and fetus. Once a pregnancy becomes known, the exposure of the embryo and fetus shall be no greater than 0.05 rem in any month excluding medical exposure. The provisions of this item are specified in NCRP Report No. 91, Section 11.

4730.0340 DETERMINATION OF ACCUMULATED OCCUPATIONAL DOSE.

Subpart 1. Disclosure before first entry into registrant's restricted area. The registrant is required to have an individual worker disclose, in writing, before first entry into a restricted area, any prior occupational dose during the current calendar quarter or the nature and amount of any occupational dose the individual worker received from sources of radiation possessed or controlled by another person. This requirement is necessary so an individual worker does not exceed the limits specified in part 4730.0310. The provisions in this subpart are

consistent with those specified in 10 CFR 20, part 20.102 (a) and CRCPD's SSRCR Section D.102(a)(1).

The registrant is required to maintain a record of the individual worker's disclosure for the lifetime of the individual worker or a minimum of 20 years after termination of employment with the facility, whichever is less. This time of retention was determined by radiation control section staff to be an adequate length of time to determine if health effects would occur in the individual. Most radiation health effects do not show up immediately but some as many as 20 years later. A registrant is currently required to keep exposure records indefinitely in accordance with adopted part 4730.0300, subpart 4 which is proposed for repeal. Indefinite recordkeeping in this case is not necessary, particularly beyond the lifetime of the worker. It is reasonable to keep individual worker dose records 20 years or for the lifetime of the worker so an employee or potential new employer can check back and determine the level of previous dosages.

Subpart 2. Disclosure before entry into registrant's area exceeding occupational limits. Before allowing an individual worker to be exposed in a restricted area to radiation levels which exceed the limits set in part 4730.0310, this subpart requires the registrant to calculate the amount of accumulated dose to the individual worker who will be entering the restricted area and the amount of additional dose the worker will receive in excess of part 4730.0310, subpart 2, item C. This standard is based on provisions in 10 CFR 20, part 20.102 (b) and the CRCPD's SSRCR Section D.102(b)(1).

Subpart 3. Preparation of accumulated dose records. This subpart requires the registrant to make a reasonable effort to determine the individual worker's previously accumulated occupational history. In any case where a registrant is unable to obtain reports of the individual worker's occupational dose for a previous complete calendar quarter, the proposed rule provides for an alternative method to calculate a maximum amount of previous dose. The estimated doses are conservative and are proposed to prevent the individual worker from receiving accumulated doses that exceed the amounts specified in part 4730.0310. The conservative limits specified assume previous dosage estimates to prevent overexposure of an individual. There are similar provisions for calculating the presumed accumulated doses contained in 10 CFR 20, part 20.102 (c)(1) and the CRCPD's SSRCR Section D.102(c)(1).

Subpart 3 also requires the retention and preservation of records used in preparing the accumulated dose record for the lifetime of the individual worker or a minimum of 20 years after the individual worker's termination of employment with the facility, whichever is less. This retention time is determined by

radiation section staff to be an adequate length of time to determine if radiation related effects will occur in the individual. Radiation effects typically do not show up in the short term. An employee or potential employer may want to check back and determine previous dosages.

4730.0360 EXPOSURE OF MINORS.

This part restricts the registrant from possessing, using or transferring sources of radiation in such a manner as to cause any occupational exposure to an individual within a restricted area who is under 18 years of age except for training purposes.

The proposed part sets the occupational limit for training purposes at 0.1 rem. This proposed limit is consistent with standards in NCRP Report No. 91 and within the limits for occupational exposure set in part 4730.0310 and public exposure set in part 4730.0380. This provision is necessary to prevent anyone under the age of 18 years from being occupationally exposed to radiation except for training. Adopted part 4730.3300 prohibits any occupational exposure of an individual under the age of 18. The human body continues to grow until approximately age 18. By restricting the occupational exposure of persons below this age, developmental harm to the individual is reduced. The proposed provisions specified in this part are based on those now specified in 10 CFR 20, part 20.104 and the CRCPD's SSRCR Section D.104.
They are reasonable in that they allow some flexibility for the employment and training of minors, but at the same time provide some protection and restrictions within established limits to address the continued growth of minors.

4730.0380 PUBLIC PERMISSIBLE LEVELS OF RADIATION FROM EXTERNAL SOURCES IN UNRESTRICTED AREAS.

The restrictions specified in this part are necessary to prevent exposure in unrestricted areas of a facility. The general public in unrestricted areas should not be exposed to radiation beyond the limits specified in this part. The exposure limits specified account for whether the individual is continuously present, or only periodically present. In either case, some maximum limits are set in item B for exposure dosages. The department has interpreted continuously present to mean that an individual is occupying the space at least 40 hours a week. There is a difference in exposure if the individual is continuously present versus periodically present. Because of this difference the exposure limits are adjusted accordingly. The limits under item B are larger just as they are in part 4730.0310 because the lens of the eye, skin and extremities are not routinely included in the calculation of effective dose equivalent, so a separate limit applies to these parts of the body. The standards specified in items A and B are specified in NCRP Report No. 91, Section 17.

The department has chosen to use the limits specified in the NCRP Report rather than limits contained in 10 CFR Part 20 and the CRCPD's SSRCR because NCRP Report No. 91 is more current. It was published in June of 1987.

4730.0400 REGISTRATION REQUIREMENTS.

The proposed amendments to this part are clean up amendments to provide for clearer drafting, ease future internal reference, and ensure consistent use of terms throughout the proposed rule parts. The phrase "according to the" is preferred to "in accordance with" by the Revisor.

Item B. The word "the" is preferred to "such" by the Revisor and the responsible individual is now defined in part 4730.0100 as the "safety" rather than "protection" officer. Consistent use of defined terms is necessary.

(1) and (3). The amendments to these subitems is necessary for clear drafting and to avoid the use of sexist language.

(2), (4) and item F. The range of rule parts "4730.0100 to 4730.3600" are amended to "this chapter" to ease future reference to rules pertaining to sources of ionizing radiation. Reference to "this chapter" means all the parts contained within the chapter. Further changes to language in item (4) are necessary for clear drafting.

Item G. Reference to the specific rule parts pertaining to registration is necessary for clear drafting. The amendment of "U.S." to "United States" is necessary to meet Revisor drafting standards. Part 4730.3600 is proposed for repeal and replacement by part 4730.3605. Change in the internal reference to the new reference is needed.

4730.0500 RENEWAL OF REGISTRATION.

The proposed changes to this part are clean up amendments. The range of rule parts "4730.0100 to 4730.3600" are amended to "this chapter" to ease future reference to rules pertaining to sources of ionizing radiation. Reference to "this chapter" means to all the parts contained within chapter 4730. The word "the" is preferred to "such" by the Revisor.

4730.0700 PERIODIC TESTING REQUIREMENTS.

Subpart 1. It is necessary to repeal the general requirements for record keeping in subpart 1 because more specific provisions are proposed in parts 4730.0340, 4730.1520 and 4730.1690.

Subpart 2. The provision in subpart 2 for inspection by the commissioner is proposed for repeal for formatting purposes. It

has been replaced with a similar provision and renumbered as part 4730.1450.

Subpart 3. The proposed amendments to this subpart are necessary for consistency with the Revisor's drafting guidelines.

4730.0800 EXEMPTIONS.

The proposed amendment to this part is for technical clean up purposes. The range of rule parts "4730.0100 to 4730.3600" are amended to "this chapter" to ease future reference to rules pertaining to sources of ionizing radiation. Reference to "this chapter" means all the parts contained within chapter 4730. The word "the" is preferred to "such" by the Revisor.

4730.0900 VENDOR RESPONSIBILITY.

Subpart 1. The proposed amendments to this part are for technical clean up purposes. The phrase "imaging assembly" is necessary to make the terminology used throughout chapter 4730 consistent with the terms defined in part 4730.0100. The range of rule parts "4730.0100 to 4730.3600" are amended to "this chapter" to ease future reference to rules pertaining to sources of ionizing radiation. Reference to "this chapter" means all the parts contained within chapter 4730. The word "the" is preferred to "such" by the Revisor and "will" is deleted to provide an active verb for current rather than future compliance.

4730.1100 NOTIFICATION OF INCIDENTS AND LOST SOURCES.

This part is proposed for repeal because proposed parts 4730.1110 and 4730.1120 include these requirements.

4730.1110 REPORTS OF THEFT OR LOSS OF RADIATION SOURCES.

This proposed part contains the requirements currently included in adopted part 4730.1100, subpart 3. The requirements for notifying the commissioner of the theft or loss of any radiation source have been modified, however, to ensure that the commissioner receives all the necessary information about the theft or loss immediately after the incident occurs rather than after a period of time. Immediate notification allows the commissioner to take appropriate action as soon as possible. The provision for making reports after normal business hours or weekends through the Minnesota Department of Public Safety's duty officer is included because the Department of Public Safety is responsible for public emergencies involving hazardous materials. Executive Order No. 90-2: Assigning Emergency Responsibilities to State Agencies: Rescinding Executive Order 88-2, was published in the State Register June 18, 1990, at 14 S.R. 2940 to 2949. Part XVII, section 1724 specifies that within the

Department of Public Safety and in compliance with the Superfund Amendment and Reauthorization Act (SARA):

> The Division of Emergency Management shall maintain a 24-hour duty officer system for the purpose of ensuring the proper receipt and dissemination of disaster notifications to appropriate state and local government officials. This is to include, among the types of emergencies, reports of hazardous materials spills in compliance with SARA Title III, and notifications of pipeline emergency releases and reportable incidents in compliance with federal and state statutes and rules.

4730.1120 REPORTS OF INCIDENTS INVOLVING RADIATION SOURCES

Subpart 1. Immediate notification. Items A, B, and C of this part are contained in currently adopted part 4730.1100, subpart 1. Items D, E, and F are consistent with the recommended requirements in Part D 403 (a) of the CRCPD'S SSRCR model rules that are based on federal notification requirements for radioactive materials regulated by the Nuclear Regulatory Commission. The provisions in items D, E, and F provide greater public health protection by affording the commissioner more opportunity to be informed about incidents.

Subpart 2. Notification within 24 hours. Items A, B, and C of this part are contained in adopted part 4730.1100, subpart 2. Items D, E, and F are based on Part D 403 (b) of the CRCPD's SSRCR model rules developed in response to federal notification requirements for radioactive materials regulated by the Nuclear Regulatory Commission. As is the case in subpart 1, these items provide greater public health protection by affording the commissioner more opportunity to be informed about incidents.

4730.1130 MANDATORY REPORTS OF OVEREXPOSURES AND EXCESSIVE LEVELS AND CONCENTRATIONS.

Subpart 1. Additional reports. The requirement in this subpart for written notification after incidents or conditions in items A, B, and C is based on Part D 405 (a) of the CRCPD's SSRCR standards developed in response to federal regulations on the control of exposures within a facility to radioactive material. The requirement for a written report gives the commissioner the opportunity to review and evaluate the situation and take corrective action, as necessary.

Subpart 2. Reports on individuals. Items A through D are based on requirements in Part D 405 (b) of the CRCPD's SSRCR model rules. The report provides the commissioner with necessary information to ensure that the incident will be properly corrected.

Subpart 3. Report of individual dose. This subpart is based on requirements in Part D 405 (c) of the CRCPD's SSRCR model rules. The report provides the commissioner with necessary information to ensure that the individual exposed is properly identified and a record made of the dose level.

4730.1140 NOTIFICATIONS AND REPORTS TO INDIVIDUAL WORKERS.

Subpart 1. Report to individual. This subpart is based on the requirement in Part J.13 (a) of the CRCPD's SSRCR standards which in turn are based on federal requirements in 10 CFR Part 19. It is necessary to provide this information to an individual worker exposed to radiation so the individual worker can estimate the level of radiation he or she can be safely exposed to in the future.

Subpart 2. Quarterly exposure report. This subpart is based on a requirement in Part J.13 (b) of the CRCPD's SSRCR standards which in turn are based on federal requirements in 10 CFR Part 19. It provides information to an individual worker exposed to radiation that is necessary to estimate the level of radiation he or she can safely be exposed to in the future. The consensus of the radiation control section staff and members of the Rule Advisory Work Group is that quarterly reporting to the individual worker is a more reasonable reporting time rather than annually as suggested in J.13 (b). Too much exposure could accumulate in a year's time. During such a prolonged period the individual's work habits could have been corrected to prevent additional exposure.

Subpart 3. Report at end of employment. This subpart is based on a requirement in Part J.13 (c) of the CRCPD's SSRCR standards which in turn is based on the federal requirements contained in 10 CFR Part 19. It provides information to an individual worker exposed to radiation necessary to estimate the level of radiation he or she can safely be exposed to in the future.

Subpart 4. Report to worker of exposure. This subpart is based on a requirement in Part J.13 (d) of the CRCPD's SSRCR standards which in turn is based on federal requirements in 10 CFR Part 19. It provides information to an individual exposed to radiation necessary to estimate the level of radiation he or she can safely be exposed to in the future. It is necessary to keep the employee informed of any exposure that exceeds the permissible limits set in part 4730.0310.

4730.1200 PROHIBITED USES OF RADIATION.

This part is proposed for repeal because the requirements are included in proposed part 4730.1210.

4730.1210 PROHIBITED USES OF RADIATION.

Subpart 1. General provision. This subpart is necessary to protect individuals from exposure to radiation that has not been authorized by a licensed practitioner of the healing arts for healing arts purposes. The practitioner of the healing arts must balance the risk versus benefit to the patient and determine that exposure to radiation is necessary to assist in the determination of the patient's condition. This restriction is recommended in the CRCPD's SSRCR Section F.3(a)(vii).

Exposure of an individual for nonhealing arts training, instruction, or demonstration, or other purposes is prohibited except as specified for the training of minors in part 4730.0360 and within the occupational exposures as specified in part 4730.0310. If there is no healing arts purpose behind the exposure, the individual is receiving unnecessary radiation which can be prevented. This provision is similar to adopted part 4730.1200, subpart 2 but has been expanded to include other known nonhealing-arts purposes where the department has seen unnecessary radiation exposure. This prohibition is recommended in the CRCPD's SSRCR Section F.3(a)(vii)(a).

Exposure of an individual for the purposes of healing arts screening except as authorized by parts 4730.1310 and 4730.0360 is prohibited. Healing arts screening is another area where the commissioner must decide if the risk of exposure of an individual to radiation outweighs the potential benefit of the screening. This provision is similar to adopted part 4730.1200, subpart 4, which is proposed for repeal, except that the wording has been changed for clearer drafting, to ease internal reference and ensure consistent use of terms. These provisions are recommended in the CRCPD's SSRCR Section F.3(a)(vii)(b).

Subpart 2. Prohibited radiation producing equipment and procedures. This subpart is necessary to protect an individual from exposure to radiation producing equipment and procedures that produce unnecessary radiation, unproductive radiation, or higher levels of radiation than is available with current state-of-the-art equipment and procedures.

Item A prohibits the use of fluoroscopic devices for fitting shoes. This prohibition is necessary because there is no diagnostic or therapeutic healing arts purpose to this type of fluoroscopic x-ray equipment. These devices have been regulatorily prohibited in this state since December 4, 1958, and are currently prohibited by part 4730.1200, subpart 1.

Item B prohibits the use of photofluorographic equipment. This type of diagnostic equipment is no longer widely used because it requires more radiation than a conventional radiograph to illuminate a photofluorographic screen so that a small non-x-ray film can be taken. This film produces a very poor diagnostic

image and is difficult for the physician to interpret. This item is necessary because the extra radiation required to produce this non-x-ray film is unnecessary for the patient.

Item C prohibits the use of dental fluoroscopic imaging assemblies. This type of diagnostic equipment presents unnecessary radiation exposure to the patient. It requires more radiation than a diagnostic intraoral exposure device and there is no permanent record of the exposure for later review. Prohibition of this equipment is supported by NCRP Report No. 102, Section 2.2(e); NCRP Report No. 35, Section 4.6; and the CRCPD's SSRCR in Section F.7(f)(4).

Item D prohibits the use of hand-held radiographic or fluoroscopic imaging devices. This type of diagnostic equipment gives unnecessary radiation exposure to the patient. Hand-held radiographic or fluoroscopic imaging requires more radiation than conventional diagnostic radiographic and fluoroscopic exposures because of the short source-to-image receptor distance. There also is no permanent record of the exposure for later review. Prohibition of this equipment is supported by NCRP Report No. 102, Section 3.3.2(d) and Section 3.4.1(d), and the CRCPD's SSRCR in Sections F.6(c) and Section F.5(f) which restrict any radiographic or fluoroscopic imaging devices to a minimum SID.

Item E prohibits the use of fluoroscopy for positioning a patient for general radiographic imaging. This is necessary because this procedure gives unnecessary radiation to the patient and there is no diagnostic or therapeutic purpose for the use of the radiation. This prohibition is supported by NCRP Report No. 102, Section 2.2(e) and the CRCPD's SSRCR in Section F.3(a)(vii)(a).

Item F prohibits the use of fluoroscopy and c-arm fluoroscopes by a person other than a licensed practitioner of the healing arts. It is necessary to preclude untrained personnel from using this type of equipment. Untrained personnel may expose patients to unnecessary radiation. This prohibition is supported by NCRP Report No. 102, Section 3.3.4(o) and the CRCPD's SSRCR in Section F.3(a)(vii)(a).

Item G prohibits the use of direct exposure film for all procedures other than intraoral dental radiography, therapeutic portal imaging, and industrial radiography. This prohibition is necessary because direct exposure film requires more radiation than exposure using an intensifying screen to produce an image on the film. The intensifying screen enhances the exposure created by the x-ray beam within the film holder. The exception to this prohibition for dental radiography is reasonable because a cassette containing intensifying screens would be very difficult if not impossible to place in the patient's mouth. In the case of therapeutic portal imaging, the exposure from the therapy equipment uses such high energy that to use an intensifying

screen would be impossible due to the short time of the exposure. Industrial radiography is excluded from the prohibition because of the high energy used and because the equipment is enclosed and is used in specially controlled areas. This prohibition was supported by the Rule's Advisory Work Group based on its knowledge of potential radiation exposure to the public.

Item H prohibits nonimage intensified fluoroscopic x-ray equipment. Nonimaged intensified systems require more radiation dose to produce a diagnostic image than image intensified systems and thus expose the patient to more radiation than necessary. This prohibition is supported by NCRP Report No. 102, Section 3.3.4(r) and is included in Part F.7.(h) of the CRCPD's SSRCR.

Item I prohibits dental intraoral radiography with kilovoltages less than 50 kVp. The penetration of kVp at less than 50 is inadequate to produce a good diagnostic image. Consequently exposure is unnecessarily higher from these machines. This prohibition is included in Part F.7 (h) of the CRCPD's SSRCR.

Item J prohibits the use of x-ray equipment not specifically designed by the manufacturer for imaging of the breast. Specially designed equipment is necessary to adequately image breast tissue for subtle lesions. The prohibition is supported by the NCRP in Report #85, "Mammography, A User's Guide," Sections 2.2.2-2.2.6 and 2.4.

Subpart 3. Unauthorized exposure of a personnel monitoring equipment. This subpart is necessary to protect workers from being unnecessarily exposed to radiation as a consequence of exposure of personnel monitoring equipment. This requirement is included in Part F.3 (a)(x)(b) of the CRCPD's SSRCR.

4730.1300 COMMISSIONER APPROVAL OF SCREENING.

This part is proposed for repeal. The requirements contained in this part have been included in proposed part 4730.1310.

4730.1310 HEALING ARTS SCREENING.

Subpart 1. General. This subpart is necessary to ensure that the commissioner reviews screening program plans and that screening does not proceed until the commissioner approves any x-ray screening program. Currently the most common x-ray screening programs are for mammography. However, the requirements in this part apply to all x-ray screening programs. The requirement for commissioner approval is included in Part F3.(a)(xi) of the CRCPD's SSRCR. This subpart also ensures that all applicants meet the same requirements as a permanent x-ray facility.

Item A. Registration of applicants who seek to undertake an x-ray screening program ensures that the commissioner is aware that an x-ray screening program is proposed.

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. This requirement is in current part 4730.1300, subpart 1, and Part F3.(a)(xi) of the CRCPD's SSRCR.

Subpart 2. Content of application.

Item A. This information is necessary for registration, inspection and proposal review. It is required in adopted rule 4730.1300, subpart 2, item A.

Item B. This information is required for inspection purposes. It is required in adopted part 4730.1300, subpart 2, item B.

Item C. Since an individual chooses to be screened by a program rather than being directed to participate by a practitioner of the healing arts, it is particularly important to make every effort to protect individuals and the general public from exposure to unnecessary radiation from x-ray 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. This requirement is in adopted part 4730.1300, subpart 2, item F.

Item D. This item is necessary because it is important that every effort is made to avoid public exposure to unnecessary radiation. This requirement is in adopted part 4730.1300, subpart 2, item K.

Item E. This item is necessary so the commissioner can verify that a practitioner of the healing arts is the individual who will interpret the screening images. The requirement in this item is included in Part F, Appendix C of the CRCPD's SSRCR.

Item F. This item is necessary to ensure that the commissioner is able to inspect the program.

Item G. This subpart is necessary to ensure that an appropriate number of radiological projections are used in an examination so exposure is minimized and a clear image is obtained for accurate diagnosis. For example, it is acknowledged practice to take at least two views of the breast in a mammographic procedure.

Item H. This item is necessary to ensure that appropriate equipment is used for screening procedures. In the case of mammographic screening, only equipment specifically designed by the manufacturer for imaging of the breast may be used. This is

recommended by the NCRP in Report #85, pages 3 and 34 and is supported by the American Radiological Society. Part 4730.1850, subpart 5 is specific as to the use of mammography equipment.

Item I. Although x-ray screening may be a one time occurrence performed in mobile x-ray units, it will be required that the applicant follow the record retention requirements specified in proposed part 4730.1520. In the case of mammographic records, for example, images must be maintained for seven years to provide for a comparative baseline.

Item J. This item is necessary because the commissioner should be aware of the type of population proposed for examination by the screening program. Currently the only screening programs operating in Minnesota are for mammography (imaging of the breast). This item requires that selection of the population for mammographic screening should be made using criteria specified by the Conference of Radiation Control Program Directors, Inc. in "Mammography Screening Guide," Publication 87-4, February 1987. These criteria are widely used by organizations that regularly perform screening programs, including the American Cancer Society as noted in the brochure "Now Breast Cancer Has Virtually Nowhere to Hide."

Item K. 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 a screening program which might be used at some time in the future for which no exposure measurements are currently established.

Item L. This item is necessary to ensure that quality assurance procedures as specified in other parts of the proposed rule have been met. With regard to mammography screening, NCRP Report #85 page 3 recommends that quality assurance procedures be used.

Item M. This item is necessary because x-ray screening procedures are unlike x-rays performed in a permanent facility for diagnostic purposes at the direction of a practitioner of the healing arts. The procedures for interpreting x-ray findings to the individual screened, sending the results to the individual and recommending follow-up treatment, if necessary, must be specified for the individual's benefit. This requirement is currently in adopted part 4730.1300, subpart 2, item J.

Subpart 3. Additional information. This subpart is necessary to allow the commissioner to request additional information to ensure that the screening program is conducted in a manner which protects the individuals screened. This requirement is in current rule part 4730.1300, subpart 2, item O.

Subpart 4. Notification of commissioner's decision. This subpart is necessary to provide the applicant with verification that the program has been approved for a specific period of time.

Subpart 5. Changes in screening program. This subpart is necessary to allow the commissioner to inspect a program if any changes are to be made to ensure that the changes will not result in unnecessary radiation exposure. This requirement is in current rule part 4730.1300, subpart 3.

Subpart 6. Denial of approval. This subpart is necessary because the commissioner may have to deny or revoke approval of a program if an applicant fails to comply with the proposed requirements in chapter 4730.
Subpart 7. 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.

Subpart 8. Renewal of screening application. This subpart is necessary to provide the commissioner with 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 commissioner can make an informed decision as would be the case on an initial application.

4730.1400 VIOLATIONS.

Subpart 1. Prohibition of violation. The proposed amendments to this part are necessary to provide for cleaner drafting, ease future internal reference and ensure consistent use of terms. The amendment of the term "persons" to "any individual" is necessary for clear drafting. The rules apply not just to a group of people but are designed to protect each and every individual from radiation hazard. Similarly singularizing the phrase "hazards of" to "a radiation hazard" is necessary to ensure that any single radiation hazard in and of itself shall be governed by these rules.

Subpart 2. Commissioner approved healing arts screening. The phrase "healing arts" is necessary to add to this subpart to ensure consistent use of terms throughout the proposed rules and ensure that terms and phrases used are the same as those defined. The phrase "or his representative" is necessary to delete to avoid the use of sexist language. The reference to part 4730.1310 is necessary to clarify what is meant by the application process, and deletion of the reference to the range of rule part numbers and use of the phrase "this chapter" is proposed to ease future reference to rules pertaining to the ionization of radiation. Reference to "this chapter" means all the parts contained within chapter 4730.

Subpart 4. Withdrawal of approval for noncompliance with application. The addition of the phrase "for healing arts screening" and reference to the specific rule part number is necessary for clear drafting. Reference to the range of rule part numbers and use of the phrase "this chapter" is proposed to ease future reference and amendment.

4730.1450 OPPORTUNITY TO INSPECT.

The provisions of this part are not new. The provision has been moved from part 4730.0700, subpart 2 to a separate rule part for formatting purposes and clearer drafting. The amendments made to this part have been to clarify that the requirement applies to all registrants and that the commissioner rather than agent of the board shall have the opportunity to inspect.

4730.1475 VARIANCES.

This part is necessary to provide parties governed by chapter 4730 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 variances 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. The Department is then asked if the standard can be varied so the project or procedure can take place legally. In some cases there may be alternative means which accomplish the same purpose as the original standard. If alternatives exist they should be considered and perhaps substituted for the standard prescribed.

The Department proposes that all provisions of Chapter 4730 are subject to variance except those which govern the registration of sources of radiation (part 4730.0400) which directly implements statute, and part 4730.0600, which governs fees.

The environmental health division general variance procedures and criteria for rules it enforces provide that a request for a variance contain:

A. the specific language of the rule from which the variance is requested;
B. the reasons why the rule cannot be met;
C. the alternative measures that will be taken to assure a comparable degree of protection to health or the environment if a variance is granted;
D. the length of time for which the variance is requested;
E. a statement that the party applying for the variance will comply with the terms of the variance, if granted; and

F. other relevant information necessary to properly evaluate the request for the variance.

The decision to grant or deny a variance will be based on an evaluation by the commissioner of whether:

A. the variance was requested in the manner prescribed;
B. the variance will have no potential adverse effect on public health, safety or the environment;
C. the alternative measures to be taken, if any, are equivalent to or superior to that prescribed in the adopted rule;
D. strict compliance with the rule will impose an undue burden on the applicant; and
E. the variance does not vary a statutory standard.

The applicant is notified in writing of the commissioner's decision and if a variance is granted, the notice specifies the period of time for which the variance is effective and the alternative measures or conditions, if any, that the applicant must meet.

The alternative measure or conditions attached to the variance have the force and effect of the applicable rule. If the registrant violates the alternative measures or conditions the registrant is subject to the enforcement actions or penalties specified by chapter 4730 which are injunctive relief or misdemeanor. A variance may be renewed. Denial, revocation or refusal to renew a variance is subject to a contested case hearing under Minnesota Statutes, chapter 14.

The general information requirements specified to request a variance are reasonable to assure that the Department has sufficient information to make a well-founded determination and make it without having to make further inquiries. A written request is reasonable to assure that there is a hard copy record of the request and no error occurs because terms are not heard correctly. All of the information is requested at once so the amount of time required to prepare a response is as short as possible. Further information is necessary so the Department can determine whether the need for the variance has been sufficiently documented. The information requested is necessary so the Department can be assured that the public health purpose underlying the original standard can still be met, that the requestor understands how the variance will work, and that the requestor bears the responsibility for complying with the terms of the variance, if granted. The requestor is encouraged to provide any additional information if such information would help the Department arrive at a decision.

Specifying the criteria to be used by the Department to make a variance decision is necessary so the parties involved know what

the standard is that will be used to determine whether a project or procedure can continue or proceed. Specifying the criteria commits the Department to weighing each request according to a set of minimum criteria, all of which underlie the public health protection goals of the variance standards. Specifying the criteria makes the process visible and helps assure that every request is reviewed fairly while assuring that protection of the public health remains as the ultimate goal in applying certain standards.

Whether the variance was requested in the manner prescribed is a reasonable criterion to ensure that the Department receives the information needed to weigh the request. The variance cannot adversely effect public health, safety or the environment. The adopted standard to which a variance is requested is justified on the basis of its need to protect public health, or the environment. These protection should not be compromised once established. The alternative measures proposed, thus, must provide equivalent or superior means to protect public health, safety or the environment and should not conflict with the adopted standard. In some cases strict compliance may pose an undue burden on the applicant. While it is sometimes difficult to weigh public health, safety and environmental costs against the costs of an individual party, it is reasonable that no one party's burden be unduly excessive. Minnesota Statutes, section 14.05, subdivision 4 prohibits an agency from granting a variance to statutory standards.

It is necessary that the applicant be notified in writing of the commissioner's decision so all parties have a clear understanding of what is expected of each and to specify with certainty what the terms and conditions of the variance are. Part 4717.7030 also makes it clear that the effect of a variance is that it is as binding on the grantee as was the original adopted standard.

Proposed parts 4717.7000 to 4717.7050 were approved December 20, 1990 by the Office of the Attorney as they were proposed, were filed with the Secretary of State. The adopted rules were published in the State Register January 14, 1991, and were effective January 22, 1991.

4730.1500 REGISTRANT'S SAFETY REQUIREMENTS.

This part is proposed for repeal because the requirements are included in part 4730.1510.

4730.1510 REGISTRANT'S SAFETY REQUIREMENTS.

Subpart 1. Registrant's responsibility. This subpart is needed to assure that it is the registrant who is responsible for the operation of ionizing radiation equipment in accordance with the requirements of this chapter. This is necessary to protect the

public health. This subpart is based on part F.3 (a)(1) of the CRCPD's SSRCR.

Subpart 2. X-ray system compliance. This subpart is necessary so a registrant only operates an x-ray system that is in compliance with the provisions of this chapter and public health is consequently protected. This subpart is based on part F.3 (a)(1)(i) of the CRCPD's SSRCR.

Subpart 3. Individuals who may apply radiation. This subpart addresses the question of having qualified persons operate x-ray equipment. Since the state has no licensing or certification program for the operators of x-ray equipment, such persons must be under the supervision of a licensed practitioner of the healing arts to protect patients and operators and other individuals who may be exposed to ionizing radiation. This subpart is based on part F.3 (a)(1)(ii) of the CRCPD's SSRCR.

Subpart 4. Procedure and safety instruction. This subpart assures that initial training and annual retraining for x-ray system operators is provided to protect patients, operators and others from exposure to radiation. Adopted part 4730.0400, item B (3) currently requires instruction in hazards and safety practices. Subpart 4 further clarifies what the department seeks in the way of instruction. Registrants are provided some flexibility in training operators because, depending on the size and nature of the x-ray equipment and facility, registrants may not need to provide the same training to all operators. Written safety procedures are required so operators will have easy access to them at any time. The particular reference to human exposure to radiation, embryo fetus exposure to radiation, restrictions on operating techniques and projections for when holding devices cannot be used is the most critical information for any operator to be familiar with to protect against unnecessary exposure to radiation. NCRP Report No. 102 part 2.2.c, recommends special protection for the embryo fetus during radiological examination. A general requirement for training x-ray operators and providing written procedures is included in part F.3 (a)(1)(ii) and (iv) of the CRCPD's SSRCR.

Subpart 5. Radiographic technique chart. This subpart is necessary to ensure that the operator has all the information necessary in an easily accessible place for safe operation of the diagnostic x-ray system. This subpart is based on part F.3. (a)(1)(iii) of the CRCPD's SSRCR.

Subpart 6. Exposure of individuals other than the patient. Item A is necessary to ensure that individuals who are not involved with an x-ray procedure are protected against any unnecessary exposure to radiation. This subpart is based on Part F.3. (a)(1)(v) of the CRCPD's SSRCR.

Item B is required so individuals who must be closely involved with a patient during an x-ray procedure, such as during surgery, and are in the radius of the x-ray beam, are protected from radiation exposure. The 0.5 millimeter lead equivalent protection is recommended in part F.3. (a)(1)(v)(a) of the CRCPD's SSRCR.

Item C is required to protect workers who may be exposed to scatter radiation. The 0.5 millimeter lead equivalent protection which is recommended in part F.3.(a)(1)(v)(b) of the CRCPD's SSRCR is consistent with the required protection in item B. The Rule Advisory Work Group agreed that 0.5 protection is necessary for worker protection against scattered radiation.

Item D is required to protect persons in the room, other than the patient and staff, during radiological procedures. The amount of protection required in this situation can be less because these persons are likely to be further away from the x-ray source and not exposed to scattered radiation regularly. This requirement is based on Part F.3. (a)(1)(v)(c) of the CRCPD's SSRCR.

Item E is a protective mechanism for preventing any individual other than the patient in the vicinity of an x-ray or fluoroscopic machine from being exposed to radiation. This provision was recommended by the Rule Advisory Work Group.

Item F is necessary to ensure that individuals not involved with a therapeutic x-ray procedure are protected against unnecessary exposure to radiation. This requirement is supported by NCRP Report No. 102, Section 2.2.i. and j.

Subpart 7. Gonad protection. This subpart is necessary because gonads are sensitive organs that must be protected from exposure to radiation. The 0.25 millimeter lead equivalence protection is recommended in Part F.3. (a)(1)(vi) of the CRCPD's SSRCR. These model rules, which applied to pregnant women only, were expanded to apply to men also because their reproductive organs are also sensitive to radiation exposure.

Subpart 8. Holding. Item A is necessary to address conditions that require that a patient, x-ray film or film cassette be held during a radiation exposure. This requirement is based on Part F.3 (a)(1)(viii)(a) of the CRCPD's SSRCR and is supported by NCRP Report No. 102, Section 2.2.h.

The written safety procedures required by item B on holding patients during radiation exposure or holding film are necessary to protect the operator. The requirement is based on Part 3.F (a)(1)(viii)(b) of the CRCPD's SSRCR.

Item C is necessary to provide protection to the human holder. The requirement is based on Part 3.F. (a)(1)(viii)(c) of the CRCPD's SSRCR and NCRP Report No. 102, Section 2.2.h.

Item D is necessary to protect individuals when holding patients or film. This requirement is based on Part 3.F. (a)(1)(viii)(d) and (e) of the CRCPD's SSRCR and NCRP Report No. 102, Section 2.2.h.

Item E is necessary to specify that patients receiving therapeutic radiation not be held by a person. This requirement is based on Part F.9. (d)(4) of the CRCPD's SSRCR.

Subpart 9. Prevention of unauthorized use. This subpart is necessary to protect against unauthorized use of any therapeutic x-ray system. Such a system can be hazardous if an untrained individual operates it.

Subpart 10. Radiological practice standards. This subpart is necessary to ensure that all x-ray equipment and procedures provide the most possible protection of public health by minimizing exposure to radiation. Procedures that provide for the clearest x-ray images possible in the shortest time provide the most protection against unnecessary radiation exposure. This requirement is supported by the NCRP in Report No. 102, Section 2.2.

Item A further specifies equipment use to support the general principle in this subpart. The requirement in item A is included in Part 3F, (a)(ix)(a) of the CRCPD's SSRCR.

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 part 4730.1210, subpart 2, item G.

Item C is necessary to reiterate the principle that a patient should only be exposed to enough radiation to produce a good image of diagnostic quality. This requirement is included in Part F3, (a)(ix)(b) of the CRCPD's SSRCR.

Items D, E and F are necessary to ensure that procedures are used which minimize conditions that result in radiographic images of poor quality and thus could compromise accurate diagnosis. Fog is the cloudy haze produced on film exposed to extraneous light. Too much fog makes for a poor image of the item being x-rayed. These items have been reviewed and were supported by the Rule Advisory Work Group.

Item G is necessary because portable x-ray equipment is not as accurate as stationary equipment and should only be used when a patient cannot be moved to a stationary installation. This

requirement is included in Part F3, (A)(ix)(c) of the CRCPD's SSRCR.

Item H is necessary to ensure that the risks from radiation exposure are minimized when radiographic devices other than fluoroscopic, dental intraoral, veterinary or computed tomographic devices are used. This requirement is included in Part F3, (A)(ix)(d) of the CRCPD's SSRCR.

Item I is necessary to insure that protective aprons and gloves are monitored for protection integrity. The annual monitoring and record of monitoring was supported by the Rule Advisory Work Group.

Subpart 11. Personnel monitoring. This subpart addresses the need to know levels of exposure to radiation for persons working with ionizing radiation. The required use of personnel monitoring equipment allows accurate measurement of safe levels of radiation. This is important for people working in high radiation areas. It is critical that the equipment is worn in a place on the body where the most accurate measurement can be made. This must be outside any protective clothing. Personnel monitoring is supported by the NCRP in Report No. 102, section 8.3.1.

Item A is necessary to ensure that individuals in restricted areas likely to receive radiation doses in excess of the limits in proposed part 4730.0310 wear personnel monitoring equipment. This requirement is in current rule part 4730.0300, subpart 4, item A.

Item B is necessary to ensure that individuals working in a high radiation area wear personnel monitoring equipment. This requirement is currently in adopted part 4730.0300, subpart 4, item B.

Subpart 12. Placement of personnel monitoring equipment. This subpart is necessary to ensure that when protective clothing is worn, radiation exposure is monitored by personnel monitoring equipment.

Item A ensures that when a protective apron is worn the personnel monitoring equipment is worn outside the apron. This requirement ensures an accurate reading of radiation doses to the head and neck.

Item B requires a record of the doses measured by the personnel monitoring equipment. It is necessary to maintain a record because of the need to measure accumulated radiation exposure over time. This requirement is included in Part F.3. (a)(x)(a)(2) of the CRCPD's SSRCR.

Item C ensures that when personnel monitoring equipment is not being worn it is maintained in a nonradiation area to assure accurate readings when it is worn in radiation areas.

Subpart 13. Facility design requirements. This subpart is a general requirement for shielding x-ray facilities. It is necessary to provide the commissioner with the opportunity to require modifications to a structure to protect the public and workers from unnecessary radiation.

4730.1520 RECORDS TO BE MAINTAINED BY THE REGISTRANT.

Subpart 1. Individual x-ray systems. Item A is necessary so the commissioner knows the maximum rating of the x-ray tube and generator, and the operating techniques used do not overheat the tube.

Item B allows the commissioner to check with the equipment manufacturer on equipment specifications.

Item C allows the commissioner to check for scattered radiation readings at the worst case scenario.

All the records required in item D provide the commissioner with information necessary to establish that individuals are being protected from unnecessary exposure to radiation.

The information required by item E is necessary for the commissioner to establish that adequate protection and shielding is being provided for the operators and persons not involved in the radiographic procedures.
The half-value layer of the x-ray beam and the kVp at which the half-value layer was determined (Item F) is necessary information so the commissioner can establish that the x-ray equipment has sufficient filtration in the main beam to prevent soft x-rays from causing unnecessary exposure to the patient. Soft x-rays do not have the power to penetrate the whole body and expose an imaging device. They just cause unnecessary exposure to the patient.

All the records required in item G provide the commissioner with information necessary to determine that radiation safety surveys, radiation leakage measurements, calibrations, quality control measurements, maintenance, and equipment modifications are performed as required by these rules and by whom.

The floor plan required in item H allows the commissioner to determine that individuals are protected from unnecessary exposure to radiation because the stationary therapeutic or diagnostic x-ray system room is adequately shielded.

Subpart 2. Mammographic image retention. This subpart is necessary to ensure that baseline data, the first mammogram taken, will be available when an individual has a second mammogram taken. The American Radiological Society and the American Cancer Society recommend that after a first mammogram is taken at 35 years of age, the second should be taken five to seven years later (American Cancer Society "Now, Breast Cancer Has Virtually Nowhere to Hide" and "Cancer Facts for Women" and American College of Radiology "Standards for the Performance of Screening Mammography"). It is especially critical for soft tissue imaging, such as mammography, to determine if lumps, calcifications or other structures in the breast have changed and by how much. Mammographic image retention is recommended in Section F 3(2) of the CRCPD's SSRCR, Volume I, Ionizing Radiation. This provision is consistent with the standards used by the American Cancer Society and the American College of Radiology to certify mammography programs.

Subpart 3. Facilities. The retention of personnel monitoring records, radiation safety surveys and quality control measurement records is required so the commissioner can keep track of when persons involved with ionizing radiation equipment are exposed to ionizing radiation and how the equipment is functioning.

Item A is required to ensure consistency in measurements.

Item B allows for some flexibility in how records should be kept, but ensures that the records are authenticated by the registrant.

Item C is required so an individual or the commissioner may have access to their exposure records even if the facility ceases operation for any reason. This may be critical information in evaluating a future health problem for the individual.

Subpart 4. Personnel monitoring records. This item is required so an individual may obtain exposure records at some time in the future. Such information may be needed so the individual can evaluate a health condition or employment position.

Item A requires a retention time that is recommended by the radiation control unit staff to be an adequate length of time to determine if health effects would occur in the individual. This recommendation is made after a review of literature which shows that radiation effects show up within 20 years after exposure. Radiation effects typically occur over longer periods of time. This retention provision is reasonable because it provides an opportunity for an employee or potential employer to check previous dosage amounts.

Item B requires that if exposure records are unavailable, the results of incident exposure surveys must be maintained to

provide the individual with occupational exposure data at some time in the future.

Item C requires the registrant to notify the worker at least quarterly about the worker's exposure so the worker may keep the exposure as low as reasonably achievable.

Item D is necessary so the commissioner can evaluate if individuals are being protected from unnecessary exposure to radiation.

4730.1530 ORDERING OF RADIOGRAPHIC EXAMINATIONS.

This part is necessary to protect the patient from unnecessary radiation. The individual practitioner must weigh the risk of the x-ray examination against the benefit to the patient. This precludes the registrant who is not a practitioner of the healing arts from requiring certain routine x-ray examinations without a licensed practitioner having evaluated the patient and made the risk versus benefit analysis.

Item A requires the licensed practitioner to physically witness that he/she ordered the radiographic examination.

Item B requires a stated clinical indication for the examination so the person taking the radiograph has a clear indication of the reason for the exam and may set-up the x-ray system properly based on that clinical indication.

4730.1610 GENERAL SHIELDING REQUIREMENTS FOR MEDICAL, CHIROPRACTIC, PODIATRIC, OSTEOPATHIC AND VETERINARY MEDICINE FACILITIES.

Subpart 1. Applicability. This part is necessary to clarify that shielding requirements apply to new or remodelled facilities used for particular types of x-rays.

Subpart 2. General shielding requirements for diagnostic radiographic facilities constructed or remodelled six months after the effective date of the chapter. This subpart is necessary to ensure that the public and workers in and around a diagnostic x-ray facility are protected from radiation. The criteria established by the NCRP in the reports listed in items A through D represent state-of-the-art guidelines for protection from radiation for the public and facility workers. This subpart updates adopted part 4730.1600, subpart A which is proposed for repeal. Six months provides time to inform affected parties and contractors of the new shielding provisions and give them some lead time to plan for compliance.

Subpart 3. Requirements for lead or lead equivalent shielding for a diagnostic radiographic facility, constructed or remodelled

six months after the effective date of this chapter. Six months provides time to inform affected parties and contractors of the new shielding provisions and give them some lead time to plan for compliance.

Item A is necessary to ensure proper lead protection. With age, lead runs or cold flows thus becoming thinner at the top than the bottom. This causes less lead protection in the top of the lead wall than was originally designed and intended. A serious overexposure could occur if the lead were to cold flow. This item is similar to the provisions currently in adopted part 4730.1600, item B which is proposed for repeal.

Item B is necessary to ensure that individuals are protected from unnecessary exposure to radiation. Seven feet high is a standard height required in the industry and is specified in NCRP Report No. 49, Section 4.3. This item is similar to adopted part 4730.1800, subpart 2, item A which is proposed for repeal.

Item C is necessary to ensure that individuals are protected from unnecessary exposure to radiation. This item does not allow a door of lesser lead equivalency than the lead equivalency of the adjacent wall thus maintaining the amount of lead protection to anyone outside the door. This item is similar to what is stated in NCRP Report No. 49, Section 4.3 and the requirement in adopted rule part 4730.1600, item E which is proposed for repeal.

Item D is necessary to ensure that individuals are protected from unnecessary exposure to radiation. This item is similar to NCRP Report No. 49, Sections 4.2 and 4.3 and in adopted rule part 4730.1600, items C and D which are proposed for repeal.

Item E is necessary to ensure that individuals are protected from unnecessary exposure to radiation. The area behind a chest cassette holder or upright bucky, if not protected as a primary barrier, could allow serious overexposure to occur. This item is similar to adopted rule part 4730.1800, subpart 2, item A which is proposed for repeal.

Subpart 4. Design requirements for a diagnostic radiographic facility. For a diagnostic radiographic facility, constructed or remodelled six months after the effective date of this chapter, the requirements in subparts 5 to 8 apply. Six months provides time to inform affected parties and contractors of the new shielding provisions and give them some lead time to plan for compliance.

Subpart 5. Space requirements for an operator's booth in a diagnostic radiographic facility. The requirements in items A to D are required for an operator's booth in a diagnostic radiographic facility.

Item A is necessary to ensure that the operator has enough unobstructed floor space in the operator's booth to position himself or herself properly so the operator gets the full protection of the shielded booth. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 1.(a).

Item B is necessary to ensure that the operator has enough space in one dimension to have a shielded barrier to stand behind. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 1.(b).

Item C is necessary to ensure that the design of the control panel, including any overhang, cables or other encroachments, do not interfere with the operator's ability to stand totally behind the protective barrier. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 1.(c).

Item D is necessary to ensure that the operator's booth provides adequate protection so the operator is not exposed to radiation in excess of the exposure limits set in part 4730.0310. This provision is similar to the CRCPD's SSRCR Part F, Appendix B, 1.(d) with the addition of specifying which limits cannot be exceeded.

Subpart 6. Structural requirements for an operator's booth in a diagnostic radiographic facility. The requirements in items A to D are required for an operator's booth in a diagnostic radiographic facility.

Item A is necessary to ensure that scattered radiation does not come over the booth walls at a level where it will directly strike an individual. This height is specified because the height of the x-ray source and of most individuals is less than seven feet according to NCRP Report No. 49, Section 4.3. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 2.(a).

Item B is necessary to ensure that the operator is not exposed to primary beam radiation. The intent of this provision is to preclude a facility from installing a chest cassette holder, upright bucky or other similar device on the wall outside of the operator's booth.

Item C is necessary to ensure that the operator is not inadvertently exposed to radiation because a door or movable panel was not closed and interlocked. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 2.(b).

Item D is necessary to ensure that the operator is not exposed to ionizing radiation in excess of the exposure limits specified in part 4730.0310. In addition, if a facility's workload does not exceed 100 milliampere-minutes per week and all walls in the

diagnostic exposure room are shielded with a minimum of 1.6 millimeter lead, including the protective barrier, then it is not necessary to estimate the shielding requirements to meet the requirements of part 4730.0310. The intent of this provision is that 1.6 millimeter lead is substantially more lead than is necessary to shield for 100 milliampere-minutes of exposure per week and meet the exposure limits in part 4730.0310.

Subpart 7. X-ray control placement for an operator's booth in a diagnostic radiographic facility.

Item A is necessary to ensure that the operator cannot activate the exposure button unless he or she is in the operator's booth; not outside the booth. If the exposure button were located closer to the open edge of the control booth, the operator could conceivably stand outside the operator's booth and reach in to make an exposure thus defeating the purpose of the operator's booth. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 3.(a).

Item B is necessary to ensure that the operator is able to view the patient easily through the viewing window while making an exposure. If the viewing window is blocked with notes, technique charts, etc., the actual viewing space would be restricted and possibly cause the operator to try and observe the patient around the outside edge of the operator's booth or not observe the patient at all. In the first case the operator would receive unnecessary radiation exposure and in the second case there is a possibility that the patient may have a problem but the exposure is made anyway thus necessitating an additional exposure because the first film was unusable. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 3.(b).

Subpart 8. Viewing system requirements for an operator's booth in a diagnostic radiographic facility.

Item A is necessary to ensure that the operator can observe the patient during the exposure, any occupant other than the patient in the room, and any entry into the room.

Item B is necessary to ensure that the operator has an adequate viewing system which, if it is a window, meets several additional requirements.

Subitem (1) is necessary to provide the operator with the same degree of shielding protection as the adjacent barrier so the exposure limits in part 4730.0310 are not exceeded. This provision is based on the recommendation in the CRCPD's SSRCR Part F, Appendix B, 4.(b)(3).

Subitem (2) is necessary to provide the operator with a minimum viewing area through which the operator may observe the patient,

other occupants of the room, and any entry doors. This item specifies that for existing diagnostic radiographic facilities at least an eight inch by ten inch viewing area in the window be provided. This is an area which is about 55% of the size recommended in the CRCPD's SSRCR Part F, Appendix B, 4.(b)(1). The consensus of radiation control unit staff and the Rule Advisory Work Group was that an eight inch by ten inch viewing area would be adequate for existing facilities.

Subitem (3) is necessary to ensure that the operator stands behind the protective barrier while viewing the patient during the exposure, any occupant other than the patient in the room, and any entry into the room. If the operator's viewing position were at any other location, the operator may be inclined to view the patient, others and the entry door by looking around the barrier itself. This provision is recommended in the CRCPD's SSRCR Part F, Appendix B, 4.(b)(2).

Subitem (4) is necessary for diagnostic radiographic facilities constructed or structurally remodelled after the effective date of this chapter to ensure that the operator has a viewing area which is at least the area specified in subitem (2). By requiring a larger window size the facility is better able to ensure that the operator has enough viewing area to properly view the patient, others and the entry door through the window. The size specified is necessary to accommodate the range in heights between staff persons, male and female, tall and short, who use the viewing window.

4730.1620 GENERAL SHIELDING REQUIREMENTS FOR DENTAL RADIOGRAPHIC FACILITIES.

Item A is necessary to ensure that intraoral dental radiographic facilities constructed or structurally remodelled six months after the effective date of this chapter meet national shielding criteria for protecting the operators, patients and general public from either direct or scattered radiation.

Item B is necessary to ensure that facilities that perform extraoral dental radiography meet the additional requirements specified in part 4730.1610, subpart 2 and the criteria presented in NCRP Report Number 49. This additional protection is necessary because dental extraoral radiography is similar to medical radiography in the size of x-ray field and image receptors, the distance between focal spot and image receptor, and the possibility that individuals other than the patient may be exposed to direct or scattered radiation similar to the direct or scattered radiation from a chest or skull radiograph.

4730.1630 GENERAL REQUIREMENTS FOR A THERAPEUTIC X-RAY FACILITY.

Subpart 1 is necessary to ensure that the public and workers in and around a therapeutic x-ray facility are protected from radiation. The criteria established by the NCRP in the reports listed in items A through G represent state-of-the-art guidelines to protect the public and facility workers from radiation. This subpart updates part 4730.1600, subpart A which is proposed for repeal.

Subpart 2. Shielding requirements for therapeutic x-ray systems and medical particle accelerators. This subpart is necessary to remind registrants that there are exposure limits that must not be exceeded when the primary and secondary barriers are installed for a therapeutic x-ray system or medical particle accelerator.

Subpart 3. Facility design requirements for therapeutic x-ray systems with energies of 50 kVp and above.

Item A is necessary to ensure that the operator stays in constant verbal contact with the patient and any other individual in the treatment room before, during, and after treatment. This is necessary to ensure that if the patient is having a problem, this can be communicated to the operator and the operator can prevent or interrupt a treatment. This provision is recommended in NCRP Report No. 102, Section 5.1.2 (c) and in the CRCPD's SSRCR Section F.8(b)(1).

Items B and C are necessary to ensure that the operator can constantly view the patient, any other individual in the treatment room before, during and after treatment and any doorways into the room. This is necessary to ensure that if the patient or other individual in the room is having a problem, or someone inadvertently enters the room the operator may observe it and may prevent or interrupt a treatment. This provision is recommended in NCRP Report No. 102, Section 5.1.2 (b) and in the CRCPD's SSRCR Section F.8(b)(2).

Item D is necessary to ensure that the patient is observed during treatment. This requirement says that the facility <u>may</u> have a closed-circuit television as a means of observing the patient. The intent of the radiation control unit staff and the Rule Advisory Work Group is that this should not be the primary viewing system but could act as a back-up viewing system. This type of system is one of those recommended in the CRCPD's SSRCR Section F.8(b)(2)(i).

Subpart 4. Additional requirements for therapeutic x-ray systems with energies of 150 kVp and above, and medical particle accelerators. This subpart is necessary to ensure that the operator is outside the treatment room at a control console located behind a fixed barrier to keep the exposure of the operator below the exposure limits in part 4730.0310. This provision is recommended in NCRP Report No. 49, Sections 6.1, 6.2

and 6.3; NCRP Report Number 102, Section 5.1.2(a); and in the CRCPD's SSRCR Section F.8(b)(3)(i) and (ii), and Section F.9(c)(1) and (2).

Subpart 5. Additional requirements for medical particle accelerators.

Item A is necessary to ensure that the operator can constantly view the patient before, during and after treatment through a closed-circuit television system or an equivalent system so the exposure limits in part 4730.0310 are not exceeded. This is necessary to ensure that if the patient is having a problem, or someone inadvertently enters the room the operator may observe it and may prevent or interrupt a treatment. This provision is recommended in NCRP Report No. 102, Section 5.1.2 (b) and is based on the recommendation in the CRCPD's SSRCR Section F.9(c)(3). The proposed provision differs from the CRCPD's recommendation in that the radiation control unit staff and the Rule Advisory Work Group concluded that windows and mirrors were not acceptable methods of viewing the patient in this situation. This is because a window with enough lead equivalency to protect the operator from the rays produced by a medical particle accelerator would be too thick to see the patient clearly through. Likewise to view a mirror in the same situation would be impossible.

Item B is 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 necessary 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. This provision is recommended in NCRP Report No. 102, Section 5.1.2 (c) and in the CRCPD's SSRCR Section F.9(c)(4).

Item C is necessary to ensure that any individual near a treatment room entrance will know when the useful beam is in the "on" position. This will warn the individual that staying in the area could expose the person to low levels of radiation below the limits set in part 4730.0310 but still measurable and unnecessary unless the person is occupationally exposed. This provision is recommended in NCRP Report No. 102, Section 5.1.2 (d) and in the CRCPD's SSRCR Section F.9(c)(5).

Item D is necessary to prevent a misadministration of radiation to the patient and a possible accidental occupational overexposure to an employee who may inadvertently get caught in the treatment room. By requiring the safety interlock to be reset first by closing the door and thereby resetting the interlock that has been tripped and then re-initiating irradiation by manual action at the main control panel, it is ensured that irradiation cannot continue without the operator checking the control panel before re-initiating the irradiation.

This provision is recommended in NCRP Report No. 102, Section 5.1.1 (n) and in the CRCPD's SSRCR Section F.9(c)(6).

4730.1655 REQUIRED QUALITY ASSURANCE PROGRAM PROCEDURES.

Quality assurance program procedures are necessary because such procedures ensure that radiographic x-ray images are of consistently high quality. Good quality images are those which provide diagnostic information with the least possible radiation exposure and cost to the patient. In the case of therapeutic x-rays, quality assurance procedures are required to ensure that the equipment is maintained and operated so patients and operators are not exposed to unnecessary radiation. The need for quality assurance has been recognized by the federal government. Quality assurance is required for facilities accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHCO), recommended by the NCRP and by the Conference of Radiation Control Directors (CRCPD) in the Suggested State Regulations for the Control of Radiation (SSRCR).

A report published in 1979 by the federal Department of Health, Education and Welfare, Bureau of Radiological Health titled, "Quality Assurance for Radiographic X-ray Units and Associated Equipment," HEW Publication (FDA) 79-8094, encourages all diagnostic facilities to develop quality assurance programs according to facility type, size and needs. The report points out that implementation of quality assurance procedures result in a reduction in patient radiation exposure because fewer radiographs have to be taken.

Subpart 1. General. The quality assurance program specified is designed to ensure that every imaging procedure is necessary and appropriate to the clinical problem at hand; the images generated contain information critical to the solution of the problem; the recorded information is correctly interpreted and made available in a timely fashion to the patient and physician; and the examination results in the lowest radiation exposure, cost and inconvenience to the patient. Supporting arguments for quality assurance programs are found in NCRP Report No. 99, Section 1.2., and in the Bureau of Radiological Health Publication, FDA 80-8110, "Quality Assurance Programs for Diagnostic Radiology Facilities". A three month period for compliance with quality assurance program provisions is specified to give registrants time to develop and implement the program while at the same time ensuring that such a program is in place in a timely manner to further protect the public from radiation exposure.

Items A to E and the additional statement following item E list the required components of a quality assurance program. The rationale for requiring each of the components is discussed individually in the subparts listed for each component.

Subpart 2. General quality assurance program procedures. This subpart itemizes the required procedures which are supported by the NCRP in Report No. 99, Section 2.1. "Quality control is a series of distinct technical procedures which ensure the production of a satisfactory product. Its aim is to provide quality that is not only satisfactory and diagnostic, but also dependable and economic. Quality assurance is an all encompassing program, including quality control that extends to administrative, educational and preventive maintenance methods."

Item A. A quality assurance manual is necessary to ensure test consistency and knowledge of procedures for persons involved in equipment operation. Suggested contents of a quality assurance manual are included in the regulations governing the administration of the radiation control for Health and Safety Act of 1968 (Public Law 90-602), and Code of Federal Regulations, title 21, part 1000.55 (c)(7).

Item B. A list of all tests conducted and what action was taken to correct any deficiencies is important so this information is collected in one place for inspection review. This provision is consistent with the requirements in Code of Federal Regulations, title 21, part 1000.55 (c)(7) which specifies parameters to be monitored and procedures to be followed when difficulties are detected.

Item C. The calibration of testing equipment falls within the parameters of quality assurance. If the calibration of test equipment is not as frequent as within the past two years, then the accuracy of the quality assurance test may be questioned. As equipment is used and ages, it tends to "wander;" its measurement accuracy becomes less consistent and precise.

Subpart 3. Quality assurance measurements for all diagnostic x-ray facilities. Quality assurance measurements for diagnostic x-ray facilities are an integral part of a quality assurance program. Inclusion of the required tests and minimum performance criteria in part 4730.1691 and specification of the minimum frequency for performing the quality assurance tests, as well as after any change in the facility or equipment, are consistent with the requirements stated in Code of Federal Regulations, title 21, part 1000.55 (c)(7)(ii, iii, iv and viii). It is reasonable that the registrant and the registrant's employees be familiar with NCRP Report No. 99 "Quality Assurance of Diagnostic Imaging Equipment" because this comprehensive handbook is widely accepted in the industry as a quality assurance standard.

4730.1665 COMPUTED TOMOGRAPHY QUALITY ASSURANCE MEASUREMENTS.

Subpart 1. Applicability. Quality assurance measurements for computed tomography facilities beyond the general requirements specified in part 4730.1655 are necessary because of the

complexity of these devices. This position is supported by the NCRP in Report No. 99, section 14.

Subpart 2. General quality assurance measurements. NCRP Report No. 99, section 14 states:

> In equipment as complex as a computed tomographic unit, routine quality control procedures are essential to the maintenance of optimal image quality. This requirement is due in part to the multitude of components involved in image formation, and in part to the extensive data processing that occurs between data accumulation and production of the final image presented to the viewer for interpretation. These tests should be performed on a regular basis in time set aside for quality control measurements. Appropriate quality control tests should also be performed following major maintenance on a computed tomographic unit.

Item A. The quality assurance measurements and calibration procedures specified in this subpart are based on those specified in the regulations governing the administration of radiation control for Health and Safety Act of 1968, Code of Federal Regulations, title 21, part 1000.55 (c)(3)(iii)(f)(2). The quality assurance measurements and calibration procedures specified in this subpart are directly from NCRP Report No. 99, Section 14 and Table A.9.

Item B. The computed tomography dose index must be measured in two positions to ensure that the CT unit is uniform in the processing of data to produce the final image. The computed tomography dose index is discussed in NCRP Report No. 99, Section 14 and the wording used for this item is based on that specified in the CRCPD's SSRCR Section F.11(d)(2)(vi)(b).

Item C. This item is necessary to ensure that routine quality assurance checks as specified in part 4730.1691 are performed and reviewed by the registrant. These parameters are consistent with the regulations governing the administration of the radiation control for the Health and Safety Act of 1968, Code of Federal Regulations, title 21, part 1000.55 (c)(3) and by NCRP Report No. 99, Section 14. Because computed tomography x-ray machines are so complex, the quality control that must be followed for these units is very specific and specialized.

Item D. This item is necessary to ensure that the radiation output check of the computed tomography x-ray system is performed according to the schedule listed in part 4730.1691 and after any change or replacement of components which could cause a change in the radiation output. It is essential that the radiation output of this type of system be performed with a calibrated dosimetry

system. This is necessary because of the multitude of components involved in image formation, and in part to the extensive data processing that occurs between data accumulation and production of the final image presented to the viewer for interpretation. If the radiation output is not calibrated correctly the usefulness of the clinical information is decreased. Two years between dosimetry calibration system calibrations against a national calibration standard is routine in the industry. The computed tomography output is discussed in NCRP Report No. 99, Section 14 and a similar requirement is included in the CRCPD's SSRCR Section F.11(d)(2)(i to iii).

It is necessary that computed tomography dosimetry phantoms which comply with Code of Federal Regulations, title 21, section 1020.33 (b)(6) be used to ensure uniform calibration of the computed tomography x-ray system. The computed tomography phantom is discussed in NCRP Report No. 99, Section 14. A similar requirement is included in the CRCPD's SSRCR Section F.11(d)(2)(iv). The definition of the computed tomography dosimetry phantom in the Code of Federal Regulations, title 21, section 1020.33 (b)(6) has the same provisions as item D, (3), (b) and (c) of this subpart.

The radiation control unit staff and the Rule Advisory Work Group concluded it is necessary to require dose measurements for head and body technique using typical clinical techniques used at the facility so the facility would have a base line set of data for these types of examinations to reference. This provision is based on the recommendation in the CRCPD's SSRCR Section F.11(d)(2)(v).

Subpart 3. Additional operator quality assurance measurements. This subpart is necessary to ensure that quality assurance measurements are performed by an individual at the facility who is familiar with the computed tomography x-ray system.

Item A is necessary to ensure that quality assurance measurements with either daily or monthly frequencies, including those specified for processing, are carried out. A computed tomography x-ray system is a very complex x-ray system which requires constant operator observation of parameters critical to the operation of the equipment. This ensures day-to-day integrity of the computed tomography data being acquired and processed. The intent of this item is to require constant checking of this complex equipment by personnel familiar with the unit to find small problems with the equipment and correct them before they become large problems. This procedure is supported throughout NCRP Report No. 99, and especially in Section 14 which deals exclusively with computed tomography x-ray systems.

Item B is necessary to ensure that the operator's quality assurance methods and results are monitored by either the

registrant or the radiation safety officer. This is in the interest of both the registrant and the patient. The acquisition of images is another way of monitoring the methods, results, and consistency of the operator and his or her quality assurance procedures. This item is based on the CRCPD's SSRCR Section F.11(d)(3)(iv) and NCRP Report No. 99, in Section 14 and Table A.9.

4730.1670 RADIATION SAFETY SURVEYS.

Subpart 1. Applicability. This subpart is necessary to ensure that each registrant performing diagnostic or therapeutic x-ray procedures ensures that radiation safety surveys are performed in accordance with this part. This is listed as a responsibility of the registrant in part 4730.0400 and is emphasized in this part in more detail.

Subpart 2. General radiation safety survey requirements for all diagnostic radiography systems. This subpart is necessary to ensure that the registrant makes or has made the radiation safety surveys necessary for establishing compliance with these rules. It is reasonable to perform a safety survey at the time of initial installation to ensure that there is not an equipment hazard or malfunction. Annual surveys are necessary because of the power and complexity of these systems. The registrant must also make a survey after any change in the facility or x-ray system that might cause a significant increase in radiation hazard. The intent of this provision is when there is a change in a major component of the x-ray system, i.e., x-ray tube, collimator, image intensifier, etc., a radiation safety survey be performed to ensure safe output levels and compliance with this chapter. Records must be prepared and maintained as specified in part 4730.1520. This is a responsibility listed for an individual designated by the owner or person having possession of any source of ionizing radiation as the radiation safety officer listed in part 4730.0400, Item B, (4) and is recommended in the CRCPD's SSRCR Section D.201 and is similar to that recommended in NCRP Report No. 102 in Section 3.1.

Subpart 3. Radiation safety survey requirements for computed tomography systems. This subpart is necessary to ensure that the registrant makes or has made a radiation safety survey on the computed tomography system at the time of installation and at least annually after an initial safety survey. An initial safety survey is necessary to ensure that the very powerful and complex equipment operates properly prior to use. Annual surveys are necessary to ensure continued safe operation. In addition, the registrant must make a survey after any change in the facility or x-ray system that might cause a significant increase in radiation hazard. The intent of this is when there is a change in a major component of the x-ray system, i.e., x-ray tube, collimator, etc., a radiation safety survey be performed. Records must be

prepared and maintained as specified in part 4730.1520. This is a responsibility listed for an individual designated by the owner or person possessing any source of ionizing radiation as the radiation safety officer listed in part 4730.0400, Item B, (4) and is recommended in the CRCPD's SSRCR Section F.11(d)(1) and is based on NCRP Report No. 102, in Section 3.1.

Subpart 4. Radiation safety survey requirements for therapeutic x-ray systems. This subpart is necessary to ensure that the registrant makes or has made a radiation safety survey on all therapeutic x-ray systems at the time of initial installation and at least once annually after. An initial safety survey is necessary to ensure that the very powerful and complex equipment operates properly prior to use. Annual surveys are necessary to ensure continued safe operation at the facility. In addition, the registrant must make a survey after any change in the facility or x-ray system that might cause a significant increase in radiation hazard. The intent of this provision is when there is a change in a major component of the x-ray system, i.e., x-ray tube, collimator, etc., a radiation safety survey is performed. Records must be prepared and maintained as specified in part 4730.1520. This is a responsibility listed for an individual designated by the owner or person having possession of any source of ionizing radiation as the radiation safety officer listed in part 4730.0400, Item B, (4) and is recommended in the CRCPD's SSRCR Section F.8(c)(1) and F.9(d)(1), and is based on NCRP Report No. 102, Section 5.1.4 (b).

4730.1675 CALIBRATIONS.

Subpart 1. Diagnostic radiographic system calibrations. This subpart is necessary to ensure that a diagnostic radiographic system is maintained so the quality of images are at an optimum level. The Joint Commission on the Accreditation of Health Care Organizations (JCAHCO) requires that every x-ray generator and imaging system be calibrated and thoroughly checked at least once a year. Dr. Joel Gray, medical physicist and chair of the Rule Advisory Work Group, in "Quality Control in Diagnostic Imaging" states that quality control checks should be carried out immediately following annual calibration and preventative maintenance as well as at six month intervals between annual invasive servicing. In addition, quality control checks should be made immediately after any servicing that may affect the quality of images or the radiation output of the equipment.

The consensus of the radiation control unit staff and the Rule Advisory Work Group was that this was a necessary requirement to ensure that patients are not exposed to incorrect or unnecessary amounts of radiation. Incorrect amounts of radiation would be given if the machine is not calibrated and too much radiation was used to expose the image receptor. Unnecessary amounts of radiation would be given if not enough radiation was used to

expose a patient and it was necessary to re-expose a patient for the same purpose because the first image was not diagnostic. This provision is supported by NCRP Report No. 102, Section 3.4.3 (n) which recommends the measurement of the air kerma per 100 milliampere seconds at a given kVp at least annually.

Subpart 2. Therapeutic x-ray system calibrations for systems of less than one MeV. This subpart 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, reasons for additional calibrations, and what type of dosimetry system must be used. The potential harm to the patient is much greater with a therapeutic x-ray system than it is for a diagnostic x-ray system. It is imperative that a therapeutic x-ray system be properly calibrated. An improperly calibrated therapeutic system could cause a serious misadministration of radiation to a patient causing serious health problems or death. The frequency of calibration and the reasons for additional calibrations are identical in intent with adopted rule part 4730.2200, subpart 3, item D which is being proposed for repeal because it is being replaced by this more specific rule. The sub-items under Item A are based on NCRP Report No. 102, Sections 6.3.1 and 6.3.2. In addition, calibration frequency and reasons for additional calibrations are identical with the recommendations in the CRCPD's SSRCR Section F.8(c)(2)(i). The type of dosimetry system is identical with the recommendations in the CRCPD's SSRCR Section F.8(c)(2)(iii) with the national standard actually specified in this item.

Item B is necessary to ensure that the calibration of the therapeutic x-ray system is operating within parameters in compliance with the manufacturer's design specifications and measure parameters that can quickly ascertain if the system is out of calibration. This item is identical to the recommendations of the CRCPD's SSRCR in Section F.8(c)(2)(v) and is based on NCRP Report No. 102, Section 6.2.

Item C is necessary to ensure that any operator has ready access to the calibration data to verify the treatment parameters for a patient. This item is identical to the recommendations of the CRCPD's SSRCR in Section F.8(c)(2)(vii). This only makes good sense as the calibration report needs to be readily available to those who work in the area of the control panel.

Subpart 3. Calibrations for therapeutic x-ray systems greater than one MeV. This subpart 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 to ensure that the latest calibration protocol is followed for therapeutic x-ray systems greater than one MeV. This item is similar to the recommendations by the CRCPD's SSRCR in Section F.9(d)(2)(i) with the difference being that the actual protocol is specified by name. Sub-item (1) is recommended in NCRP Report No. 102, Section 6.2.

Item B is necessary because it specifies that the dosimetry system must also be calibrated. This item specifies the frequency of calibration, reasons for additional calibrations of the dosimetry system, and what the dosimetry system must be calibrated against. The potential harm to the patient is much greater with a therapeutic x-ray system than it is for a diagnostic x-ray system. It is imperative that a therapeutic x-ray system be properly calibrated. An improperly calibrated therapeutic system could cause a serious misadministration of radiation to a patient causing serious health problems or death. This item is similar to the recommendations in the CRCPD's SSRCR Section F.9(d)(2)(iii). The proposed item specifies verification of calibration every two years, while the CRCPD recommends annually. The Rule Advisory Work Group recommended the less stringent standard because the equipment in question does not "drift" much.

Item C is necessary to ensure that the therapy dose in soft tissue is accurate. Soft tissue is that part of the body which is the hardest to treat because of the variability and make-up of the tissue. Therefore it is necessary to be able to treat this tissue accurately. This item is based on the recommendation in the CRCPD's SSRCR Section F.9(d)(2)(iv). However, the radiation control staff and the Rule Advisory Work Group agreed that the state-of-the-art in this field can accomplish a two percent accuracy.

Item D is necessary to ensure that the calibration, as a minimum, include the measurements listed in this item. These tests are determined by the radiation control unit staff and the Rule Advisory Work Group as the minimum that anyone calibrating a therapy system of this power should minimally perform to ensure that the radiation beam is properly calibrated. These measurements are recommended in the CRCPD's SSRCR Section F.9(d)(2)(v).

Item E is necessary to ensure that any operator has ready access to the calibration data to verify the treatment parameters for a patient. This item is identical to the recommendations of the CRCPD's SSRCR in Section F.9(d)(2)(vii). This provision makes good sense because the calibration report needs to be readily available to those who work in the area of the control panel.

4730.1680 THERAPEUTIC X-RAY SYSTEM SPOT CHECKS.

Subpart 1. Spot checks for therapeutic x-ray systems of less than one MeV. This subpart is necessary to specify the minimum frequency of spot checks and which requirements must be met. This subpart is based on the recommendations in the CRCPD's SSRCR in Section F.8(c)(3). The NCRP Report No. 102, Section 6.4 also recommends spot checks.

Item A is necessary to ensure that the procedures are available for review and to ensure that they are consistently performed. They must be maintained according to the record keeping rules proposed in part 4730.1520 and must be made available to the commissioner on request. The provision differs from the CRCPD's SSRCR in Section F.8(c)(3)(i) in that the radiation control unit staff and the Rule Advisory Work Group think the procedures must be in writing and available for inspection at the facility.

Item B is necessary to ensure that parameters exceeding the tolerances set in part 4730.1695 are corrected so a patient is not irradiated by a therapy system that is not within its operating tolerances. If a system is operated outside its operating tolerances the patient could receive a therapy dose which may be inaccurate. The parameters in part 4730.1695 are derived from the American Association of Physicists in Medicine (AAPM) report No. 13, Table II, page 29 which is the currently accepted quality assurance document in the industry. The proposed provision is based on the CRCPD's SSRCR Section F.8(c)(3)(iv) with the difference being that the proposed rule specifies where the tolerance levels are located within the proposed rules.

Item C is necessary to ensure that if there is a change in the operating level of a therapy system, the system is not used until it has been recalibrated. This ensures that the patient receives the correct dose at treatment. This provision is based on the CRCPD's SSRCR Section F.8(c)(3)(v). The proposed rule specifies spot check tolerances rather than using a "qualified expert's" spot check procedures.

Subpart 2. Spot checks for therapeutic x-ray systems greater than one MeV. It is necessary to specify the minimum frequency for spot checks and the spot check requirements that must be met. This provision is based on the recommendations in the CRCPD's SSRCR in Section F.9(d)(3). The NCRP Report No. 102, Section 6.4 also recommends spot checks.

Item A is necessary to ensure that the procedures are available for review and that they are consistently and correctly performed. This provision is identical to the wording in the first part of the first sentence in the CRCPD's SSRCR in Section F.9(d)(3)(i).

Item B is necessary to ensure that the frequency of the spot checks is specified as well as the acceptable tolerance for each parameter tested. In this way the person performing the spot check has knowledge of what is acceptable and how often the tests must be performed. This provision is identical to the CRCPD's SSRCR in Section F.9(d)(3)(iii).

Item C is necessary to ensure that the absorbed dose in a phantom are not changing. This is critical since if the absorbed dose is changing in a phantom, a patient could be receiving the wrong therapeutic dose. This provision is based on the CRCPD's SSRCR Section F.9(d)(3)(iv). The Radiation Control Unit staff and Rule Advisory Work Group agreed that this type of equipment is stable enough that monthly spot checks are adequate.

Item D is necessary to ensure that a built-in device is not used to test a spot check parameter. It is critical to have an outside measuring device, not dependent on any part of the circuitry being tested, to make this type of measurement. This ensures independent verification of the parameters. This provision is identical to the requirements in the CRCPD's SSRCR in Section F.9(d)(3)(v).

Item E is necessary to ensure that parameters exceeding the tolerances set in part 4730.1695 are corrected so a patient is not irradiated by a therapy system not within its operating tolerances. If it were to be operated outside its operating tolerances the patient could receive a therapy dose which may be inaccurate. The parameters in part 4730.1695 are derived from the American Association of Physicists in Medicine Report No. 13, Table II, page 29 which is the currently accepted quality assurance document in the industry. This provision is based on the requirement in the CRCPD's SSRCR Section F.9(d)(3)(vi) with the difference being that the CRCPD standards refer to the AAPM protocol in a footnote and the proposed rule incorporates the AAPM protocol and table by reference.

Item F is necessary to ensure that if there is a change in the operating level of a therapy system, the system is not used until it is recalibrated. This ensures that the patient receives the correct dose at treatment. This provision is based on the CRCPD's SSRCR Section F.9(d)(3)(vii). Spot check tolerances are specified rather than using a "qualified expert's" spot check procedures.

Item G is necessary to ensure that a calibrated dosimetry system is used for all radiation measurements. The qualities of such a dosimetry system are established in part 4730.1675, subpart 3, item B to ensure that a reliable and accurate dosimetry system is available. This provision is identical to the wording in the CRCPD's SSRCR in Section F.9(d)(3)(ix).

4730.1685 MEDICAL PARTICLE ACCELERATOR QUALITY ASSURANCE.

Subpart 1. Radiation monitoring equipment. This subpart is necessary to ensure that the proper type of calibrated, portable monitoring equipment is available for the types of radiation produced at this type of facility. Without this type of portable monitoring equipment the facility could not monitor for all types of potentially harmful levels of radiation being produced and a patient may receive a radiation dose that is not within his/her treatment protocol. This provision is based on the requirement in the CRCPD's SSRCR Section I.11(a).

Subpart 2. Radiation safety survey. This subpart is necessary to ensure the safety of both the patient and the operators. The NCRP Report No. 102, Section 7.1 recommends that these surveys be made. This is similar to the requirement in the CRCPD's SSRCR Section I.11(b) with the exception that the registrant must ensure that the radiation survey be performed.

Subpart 3. Written procedures. This subpart is necessary to ensure that the procedures, established by the radiation safety officer, are available so they may be reviewed and performed correctly. This provision is based on the requirement in the CRCPD's SSRCR in Section I.11(g) except that the radiation safety officer is specified to establish the written procedures.

4730.1688 IN-SERVICE EDUCATION IN QUALITY ASSURANCE.

This part is necessary to emphasize the need for training in quality assurance. Instruction of workers is already required in adopted part 4730.0400. This rule part further clarifies the nature of the instruction required. As specified in part 4730.1510, subpart 4, quality assurance education is essential to ensure that proper quality assurance tests are performed so the radiation dose to the patient and operators, if applicable, are kept to the amount minimally necessary to provide the diagnosis or treatment of the patient. The NCRP Report No. 99, Section 2.6.8 states, "Human factors are of utmost importance in quality assurance, and therefore personnel education should be continuous. Training should be directed at all facility personnel."

4730.1690 QUALITY ASSURANCE RECORDS.

Subpart 1. Diagnostic radiographic facility records. This subpart is necessary to ensure that specified records are retained for each diagnostic imaging system as required in part 4730.1520. There are two reasons for this. First, the registrant or user will know when quality assurance tests were performed and the results of the quality assurance tests. Second, the registrant or user would know if needed repairs or recalibrations had been completed. The federal Food and Drug

Administration in HHS publication FDA 83-3218, section 3.2.2 states, "The purpose of record keeping is ... to provide the basic information for problem detection and solving."

Subpart 2. Computed tomography x-ray facility records. This subpart is necessary to ensure that computed tomography calibrations and quality assurance measurements are recorded, plotted and maintained until the next inspection by the commissioner. The reasons for this are stated above in support of subpart 1. There is a similar requirement in the CRCPD's SSRCR Sections F.11(d)(2)(vii) and F.11(d)(3)(v).

Subpart 3. Therapeutic x-ray facility records. This subpart is necessary to ensure that records for calibrations of therapy systems, dosimetry systems, spot check measurements and any necessary corrective actions for therapeutic x-ray systems are available for inspection by the commissioner. The reasons for this are stated above in support of subpart 1. There is a similar requirement in the CRCPD's SSRCR in Sections F.8(c)(2)(vii), F.8(c)(3)(vi), F.9(d)(2)(vi) and F.9(d)(3)(viii).

Subpart 4. Medical particle accelerator facility records. This subpart is necessary to ensure that records for radiation safety surveys, calibrations, and instrumentation tests for a medical particle accelerator are available for inspection by the commissioner. The reasons for this are stated above in support of subpart 1. There is a similar requirement in the CRCPD's SSRCR in Sections I.11(h).

4730.1691 MINIMUM DIAGNOSTIC QUALITY ASSURANCE TESTS FOR ALL FACILITIES.

The listing of these minimum quality assurance tests for diagnostic facilities is derived from NCRP Report Number 99, Tables A.1 to A.10. The tests listed in these proposed rules were agreed upon by the radiation control unit staff and the Rule Advisory Work Group as those which are feasible to accomplish in facilities using ionizing radiation for diagnostic purposes without putting an unreasonable burden on the facility. This is the minimum necessary to provide diagnostic images of good quality and keep exposure of the patient to a minimum.

Subpart 1. Image receptors. Item A is necessary to ensure that there is good contact between the film and screen in a cassette so a diagnostic image is recorded. This is recommended in NCRP Report No. 99, Table A.2 and is discussed in detail in Section 7.4.3 of the same report.

Item B is necessary to ensure that the screens, the film being used, and the cassettes are matched to provide optimum diagnostic quality without overexposing the patient. This provision is

similar to the listing in NCRP Report No. 99, Table A.2 and is discussed in detail in Section 7.4.2 of the same report. The difference is that ± 0.10 O.D. is proposed while the NCRP lists ± 0.05 O.D. The consensus of the staff and the Rule Advisory Work Group was that the NCRP number was too rigid and ± 0.10 gives adequate protection for this test.

Subpart 2. Automatic processing. Item A is necessary to ensure that unnecessary darkroom fog, which is cloudy distortion that forms on a film image from extraneous light, is not allowed on diagnostic films. Darkroom fog can obscure a physical malady on a diagnostic image making a clinical diagnosis difficult or impossible. The minimum test interval and minimum performance criteria proposed varies from that specified in NCRP Report No. 99, Table A.1 and discussed in Section 6.1.3 in that quarterly versus semi-annually frequency are specified and a 0.08 O.D. for routine diagnostic images and 0.04 O.D. for mammographic images are specified. The proposed item varies from the 0.05 O.D. listed in the NCRP report because mammography needs to be tighter and routine diagnostic images can have more leeway and still produce adequate images. The frequency of testing difference was dictated by a concern that six months was too long a period of time to not check something that can have a profound effect on image quality.

Item B is necessary to ensure that the film processing and chemicals are not producing poor diagnostic images. This provision is based on the listing in NCRP Report No. 99, Table A.1 and is discussed in detail in Section 6.2.4 of the same report. The proposed rules, however, specify ± 0.15 O.D. and the NCRP report lists ± 0.10. When the department staff reviewed the recommendations on chemicals the NCRP listed ± 0.15. The department thinks the combination of the chemicals and the processor must be the same.

Item C is necessary to ensure that the proper temperature is used to process diagnostic images. Variations of more than 0.5 degrees Fahrenheit can have a significant effect on image quality. The department chose to follow the manufacturer's recommendations rather than a fixed number because of the wide variations in temperatures at which processors effectively operate.

Subpart 3. Manual processing. Item A. See justification in subpart 2, item A above.

Item B. See justification in subpart 2, item B above.

Item C. See justification in subpart 2, item C above.

Subpart 4. All diagnostic radiographic tubes; required when applicable.

The intent of the "required when applicable" part of the above is that if an x-ray system has a particular feature, e.g., phototimer, than the particular test that addresses that feature must be a parameter tested. Also, the tests in this subpart have all been listed as an annual frequency so a facility will not have the burden of having someone test certain parameters semiannually and other tests annually. All will be annual tests so a service person or physicist only has to come into a facility once each year.

The items listed below are deemed essential by the NCRP Report No. 99. The tests listed in this subpart were agreed upon by the radiation control unit staff and the Rule Advisory Work Group as those which are feasible to accomplish in facilities using ionizing radiation for diagnostic purposes without putting an unreasonable burden on the facility. This is the minimum necessary to provide diagnostic images of good quality and keep exposure of the patient to a minimum.

Item A is directly from NCRP Report No. 99, Table A.2.

Item B is directly from NCRP Report No. 99, Table A.2. with the addition of the $\pm$ 3% of the source-to-image distance, both directions (total) from Federal Performance Standards, 21 CFR 1020.31(e).

Item C is directly from NCRP Report No. 99, Table A.2.

Item D is directly from NCRP Report No. 99, Table A.2.

Item E is directly from NCRP Report No. 99, Table A.2.

Item F is directly from NCRP Report No. 99, Table A.2.

Item G is directly from NCRP Report No. 99, Table A.2.

Item H is directly from NCRP Report No. 99, Table A.2.

Item I is directly from NCRP Report No. 99, Table A.2.

Item J is directly from NCRP Report No. 99, Table A.2.

Item K is directly from NCRP Report No. 99, Table A.2.

Subpart 5. For facilities with fluoroscopes and C-arm fluoroscopes. The tests in this subpart have all been listed as an annual frequency so a facility need not have someone test certain parameters semiannually and others annually. All will be annual tests so a service person or physicist has to come to a facility once each year.

The items listed below are deemed essential in NCRP Report No. 99 and the tests listed in this subpart were agreed upon by the radiation control unit staff and the Rule Advisory Work Group as those which are feasible to accomplish in facilities using ionizing radiation for diagnostic purposes without putting an unreasonable burden on the facility. This is the minimum necessary to provide diagnostic images of good quality and keep exposure of the patient to a minimum.

Item A is directly from NCRP Report No. 99, Table A.3.

Item B is added to the proposed rules to have a routine method of checking the high level control maximum output at tabletop or equivalent which is a requirement in part 4730.2150, subpart 5, item A.

Item C is directly from NCRP Report No. 99, Table A.3.

Item D is directly from NCRP Report No. 99, Table A.3.

Item E is the same as a radiographic reproducibility as listed in Subpart 4, item E.

Item F is the same as a radiographic phototimer reproducibility as listed in Subpart 4, item K.

Subpart 6. For facilities with mammography systems. The tests in this subpart have all been listed as an annual frequency except item D so a facility need not have someone test certain parameters semiannually and other tests annually. All, except item D, are annual tests so a service person or physicist will only have to come into a facility once each year. Item D is a test that can be performed by the facility quarterly and is necessary to ensure excellent mammographic imaging because soft tissue is so hard to visualize. Waiting a year between tests could mean several cancers could be missed because of poor imaging.

The items listed are deemed essential by the NCRP in Report Number 99 and the tests listed in this subpart were agreed upon by the radiation control unit staff and the Rule Advisory Work Group as those which are feasible to accomplish in facilities using ionizing radiation for diagnostic purposes without putting an unreasonable burden on the facility. This is the minimum necessary to provide diagnostic images of good quality and keep exposure of the patient to a minimum.

Item A. Same as tests listed above in subpart 4 for the same reasons.

Item B is directly from NCRP Report No. 99, Table A.6 except that radiation control unit staff and the Rule Advisory Work Group

recommend strongly that kVp for mammographic x-ray systems need to have tighter kVp limits because of the need to visualize soft tissue which is very difficult.

Item C is necessary to ensure that the absorbed dose to the breast is as low as reasonably achievable without mammographic image degradation because not enough radiation was used. These values are directly from NCRP Report No. 85, Section 8.2, Conclusion 5.

Item D is directly from NCRP Report No. 99, Table A.6 except for the frequency which is discussed above.

Item E is the same as a radiographic phototimer reproducibility as listed in Subpart 4, item K.

Subpart 7. For facilities with tomography systems other than computed tomography. Item A is directly from NCRP Report No. 99, Table A.5.

Item B is directly from NCRP Report No. 99, Table A.5.

Item C is directly from NCRP Report No. 99, Table A.5 except that the manufacturer's specifications are specified as the criteria to follow.

Subpart 8. For facilities with computed tomography scanners.

Item A is directly from NCRP Report No. 99, Table A.9.

Item B is directly from NCRP Report No. 99, Table A.9.

Item C is directly from NCRP Report No. 99, Table A.9.

Item D is directly from NCRP Report No. 99, Table A.9.

Item E is directly from NCRP Report No. 99, Table A.9.

Item F is directly from NCRP Report No. 99, Table A.9.

Item G is directly from NCRP Report No. 99, Table A.9.

Item H is directly from NCRP Report No. 99, Table A.9.

Subpart 9. For facilities with cinefluorographic systems.

Item A is directly from NCRP Report No. 99, Table A.8.

Item B is directly from NCRP Report No. 99, Table A.3.

Item C is directly from NCRP Report No. 99, Table A.3.

Subpart 10. For facilities with cardiac catherization systems.

Item A is the same as tests listed above in subpart 4 for the same reasons.

Item B is the same as tests listed above in subpart 5 for the same reasons.

Item C is directly from NCRP Report No. 99, Table A.8.

Item D is directly from NCRP Report No. 99, Table A.8.

Item E is directly from NCRP Report No. 99, Table A.8.

Item F is the same as tests listed above in subpart 9, item A for the same reasons.

Item G is directly from NCRP Report No. 99, Table A.8.

Item H is directly from NCRP Report No. 99, Table A.8.

Subpart 11. For facilities with dental intraoral systems.

Item A is the same as tests listed above in subparts 2 and 3 for the same reasons.

Item B is directly from NCRP Report No. 99, Table A.7 with the referenced minimum performance criteria listed in part 4730.1750, subpart 6, item A.

Item C is directly from NCRP Report No. 99, Table A.7 with the referenced minimum performance criteria listed in part 4730.1950, subpart 4, item F.

Item D is directly from NCRP Report No. 99, Table A.7.

Subpart 12. For facilities with dental extraoral systems including panoramic systems.

Item A is the same as tests listed above in subparts 2 and 3 for the same reasons.

Item B is the same as tests listed above in subpart 4 for the same reasons.

4730.1692 EXPOSURE TIME CONTROL LIMITS FOR SINGLE PHASE FULL-WAVE RECTIFIED GENERATORS.

This part is directly from NCRP Report No. 99, Table 7.3.

4730.1693 THERAPY QUALITY ASSURANCE. PARTIAL LISTING OF MINIMUM QUALITY ASSURANCE TESTS AND LIMITS FOR MEASUREMENT EQUIPMENT.

This part is directly from the American Association of Physicists in Medicine (AAPM) Report Number 13, Table I, pages 21-22. This table is accepted in the industry as the minimum criteria for quality assurance of therapy systems. In subpart 1, item (1) the acronym for the AAPM was inserted since they are the organization under whom this table was drafted and approved. The minimum test interval was changed for this same item from four years to two years to coincide with the calibration requirements in other parts of this rule where two years is the maximum time interval between times that dosimetry systems must be recalibrated. Second, in subpart 7, item (2), aneroid barometers are no longer used and mercury barometers are now the barometers in use.

4730.1695 QUALITY ASSURANCE CRITERIA FOR EXTERNAL BEAM TELETHERAPY AND SIMULATION SYSTEMS.

This part is directly from AAPM Report Number 13, Table I, pages 29. The AAPM table is accepted in the industry as the minimum criteria for quality assurance of external beam teletherapy and simulation equipment. There is one change proposed to this table. In subpart 1, item B, subitem (1) the minimum test interval is changed from daily to weekly based on the advice of the medical physicists on the Rule Advisory Work Group who stated that current state of the art in this type of therapy the dose per monitor unit along the central axis is stable enough that weekly testing is sufficient.

4730.1750 GENERAL EQUIPMENT REQUIREMENTS FOR ALL DIAGNOSTIC RADIOGRAPHIC SYSTEMS.

Subpart 1. Applicability. This part applies to all diagnostic radiographic systems including intraoral dental radiographic systems, veterinary medicine radiographic systems, fluoroscopic x-ray systems, and computed tomography systems. These diagnostic radiographic systems all have common attributes that are best addressed at one time in this part. This part applies to all equipment including that manufactured after August 1974 and certified as meeting federal standards specified in Code of Federal Regulators, title 21, sections 1020.30 to 1020.33 as well as uncertified diagnostic x-ray equipment.

Subpart 2. Warning label. This subpart requires that all diagnostic x-ray control consoles have a warning label to remind the equipment operator of danger to a patient and the operator unless safe exposure factors and operating instructions are observed. This warning is a safety message to remind the operator how dangerous this equipment could be if not properly used. This warning label is required by Federal Performance Standard 21 CFR 1020.30(j) and is recommended in the CRCPD's SSRCR Section F.4(a).

Subpart 3. Battery charge indicator. This subpart requires all battery-powered diagnostic x-ray generators to have a visual means on the control console to indicate whether the battery is charged for proper operation. If the battery is not properly charged when an x-ray exposure is attempted, the x-ray machine may not properly expose the film being taken thus potentially requiring more exposures to be made and causing unnecessary radiation to the patient. This standard is required by the Federal Performance Standard 21 CFR 1020.30(o) and is the standard recommended in the CRCPD's SSRCR Section F.4(b).

Subpart 4. Leakage radiation from the diagnostic source assembly. This subpart requires that leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source to not exceed 100 milliroentgens in one hour when the x-ray tube is operated at the leakage technique factors. This amount of leakage is the same as that stated in currently adopted part 4730.0100, subpart 9 (which is proposed for renumbering as subpart 54) for a diagnostic-type protective tube housing.
This is the upper limit of acceptable leakage from the diagnostic source assembly (tubehead), where all of the x-rays are produced in an x-ray machine. This requirement is consistent with Federal Performance Standard 21 CFR 1020.30(k) and is the standard recommended in the CRCPD's SSRCR Section F.4(c).

Subpart 5. Radiation from components other than the diagnostic source assembly. This subpart requires that leakage radiation from the diagnostic source assembly be within two milliroentgens in one hour in any direction at five centimeters from any accessible surface of the component. This requirement is necessary to prevent radiation leakage into the environment through components that are necessary to make the x-ray exposure. Properly designed components can prevent unnecessary radiation from getting into the environment. This requirement is consistent with Federal Performance Standard 21 CFR 1020.30(l) and is the standard recommended in the CRCPD's SSRCR Section F.4(d).

Subpart 6. Beam quality, half-value layer. This subpart requires that diagnostic x-ray machines have a minimum amount of filtration in the main x-ray beam of the x-ray machine dependent upon the maximum kVp rating of the machine. The amount of filtration is specified in the table in item A. The table is broken down into four categories: design operating range (kVp), measured (kVp), half-value layer - other x-ray systems, and specified dental systems. The first category lists the ranges of kVp because there are distinct break points. The second category lists the measured (kVp) which is a very specific kVp number. As the kVp increases, the amount of filtration (half-value layer specified in millimeters of aluminum) specified in the third category increases to provide adequate filtration of

the x-ray beam. The fourth category is similar to the third category except it is for dental systems only. Filtration is added to an x-ray machine to prevent soft x-rays (those not strong enough to penetrate the body and produce an image) from getting out of an x-ray machine. Only the hard x-rays which can penetrate the human body and get through to make an image on the x-ray film can penetrate the filtration and get out of the x-ray machine. Soft x-rays do not have the energy to do this and only cause unnecessary x-ray exposure to the patient and others. This requirement is consistent with Federal Performance Standard 21 CFR 1020.30(m)(1). This requirement is similar to the one recommended in the CRCPD's SSRCR Section F.4(e) in that categories one, two and three are identical. The fourth category, however, is undergoing revision at this time and has not been published in final form. If it is adopted as proposed for revision, the CRCPD standard will be the same as the Federal Performance Standard.

Item B states that all intraoral dental radiographic systems installed on or after December 1, 1980 must have a minimum half-value layer of 1.5 millimeters aluminum. This date is specified in federal performance standards. This requirement is necessary to prevent soft x-rays from getting out of a dental intraoral radiographic machine. Soft x-rays are x-rays with low kVp, usually between 30 and 50 kVp, that don't have the power to penetrate the human body and expose a film at the same time. Soft x-rays thus have no useful purpose and only cause unnecessary radiation exposure to the patient. This requirement is consistent with Federal Performance Standard 21 CFR 1020.30(m)(1) and is the standard recommended in the CRCPD's SSRCR Section F.4(e)(1)(iii).

Item C specifies a compliance testing procedure for properly testing capacitor energy storage equipment. The procedure requires the capacitor to be fully charged and a technique which discharges at least half of the energy stored in the capacitor. It is necessary to test the equipment this way to get true and reproducible readings because of the nature of the capacitor energy storage equipment. This requirement is consistent with Federal Performance Standard 21 CFR 1020.30(m)(2) and is the standard recommended in the CRCPD's SSRCR Section F.4(e)(1)(v).

Item D states that the half-value layer must always be measured with all the materials ordinarily present in the x-ray beam. The test is thus performed the same way that the patient is usually exposed to the x-ray beam. This is the standard recommended in the CRCPD's SSRCR Section F.4(e)(1)(vi).

Subpart 7. Beam quality, filtration controls. This subpart requires that x-ray systems with variable kVp and variable filtration must prevent an exposure unless adequate filtration is present in the x-ray beam to meet the half-value layer specified

in subpart 6, item A for the kVp selected. This requirement is consistent with Federal Performance Standard 21 CFR 1020.30(m) and is recommended in the CRCPD's SSRCR Section F.4(e).

Subpart 8. Multiple tubes. When two or more x-ray tubes are operated off the same control console, this subpart requires that there be a positive means to indicate which tube is activated - both at the control console and at the selected tube. Positive indication lets the operator know which x-ray tube is energized for exposure. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(j) and is recommended in the CRCPD's SSRCR Section F.4(f).

Subpart 9. Mechanical support of the tube head. This subpart requires that an x-ray tube be stable during an exposure unless movement is a designed function of the system. This requirement is necessary to prevent repeated exposure due to tube head movement exposure blur. This requirement is consistent with the recommendations in the CRCPD's SSRCR Section F.4(g).

Subpart 10. Technique factors. This subpart requires that the technique factors (the kilovoltage, milliamperage and exposure time or milliampere-seconds) used in making a diagnostic x-ray exposure be indicated prior to exposure so the operator knows what settings are being used for that patient's x-ray film. Prior knowledge of the settings are necessary to prevent an x-ray from being retaken. For automatic exposure control (AEC) devices installed after the effective date of this chapter an additional requirement is added so the operator knows after the exposure how much milliamperage, exposure time or milliampere-seconds were given in the last exposure. Item C is a convenient way for fixed x-ray machines to be marked without requiring additional indicators or dials. Items A and C of this subpart are consistent with Federal Performance Standard 21 CFR 1020.31(a)(1) and recommended in the CRCPD's SSRCR Section F.4(h). Item B is needed so the operator knows whether the previous exposure was accurate and correct. On automatic exposure control devices, only the kilovoltage and the milliamperage or only the kilovoltage can be preset. All other technique factors are automatically controlled by a sensor in the bucky, wall bucky or spot film device measuring the amount of ionizing radiation penetrating through to the sensor.

Subpart 11. Timers. This subpart requires all radiographic, dental intraoral and veterinary medicine radiographic x-ray units to have a timer that terminates the exposure according to a preset indication. The x-ray equipment must have a device that electronically terminates the exposure rather than the operator manually terminating the exposure. Manually terminating exposure is an inaccurate and not easily reproducible way of making an x-ray exposure. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(a)(2) and (i); and is

recommended in the CRCPD's SSRCR Sections F.6(f)(7), F.7(c), F.7(g)(4), and F.10(a)(4).

Subpart 12. Reproducibility. This requirement states that each diagnostic x-ray machine must have a timer that makes the same exposure each time within certain limits. These limits, the difference between the maximum and the minimum, must be less than or equal to twenty percent of the average of four timer tests run consecutively. This requirement is mathematically equal to the equation used in Federal Performance Standards and the SSRCR. This requirement is recommended in CRCPD's SSRCR Sections F.6(b)(4) and F.7(c)(2).

Subpart 13. X-ray control. The requirements in this subpart are needed for safety reasons. A dead-man type switch requires continuous pressure on the switch for the exposure to be completed. If for any reason 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 to completion thus giving the patient unnecessary radiation. Specifying where the x-ray control must be located for stationary and portable x-ray systems other than dental intraoral systems is necessary to protect the operator who is taking x-rays. In the case of portable x-ray systems, a conservative estimate of an x-ray machine's workload in milliampere-minutes per week is used as the cutoff point where a fixed or portable protective barrier is required. For dental intraoral system the protected position is one which meets the requirements in part 4730.1950, subpart 4, item E. Finally, the operator must be able to observe dials or indicators to determine when an exposure is completed. This is necessary to prevent the operator from direct exposure to the beam or scattered radiation prior to the termination of an exposure. Likewise, the audible signal requirement is an additional requirement to actually indicate the end of the exposure for the same safety reason as the visual indication. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(a) and is recommended in CRCPD's SSRCR Sections F.6(b)(2), F.7(d) and F.10(a)(5).

Subpart 14. Exposure reproducibility. This requirement states that each diagnostic x-ray machine must have exposure reproducibility when all exposure technique factors are held constant. This limit is the difference between the maximum and the minimum exposure and must be less than or equal to twenty percent of the average exposure when four exposure tests are run consecutively. This requirement is mathematically equal to the equation used in the Federal Performance Standard and the CRCPD's SSRCR. This requirement is recommended in the CRCPD's SSRCR Sections F.6(d) and F.7(e).

Subpart 15. Additional requirements applicable only to certified x-ray systems. This requirement states that certified x-ray systems must meet certain additional criteria. Items A to E require that: A) the radiographic system be on an adequate power supply as specified by the manufacturer and the coefficient of variation be no greater than 0.05; B) when the radiographic system allows a choice of x-ray milliamperage settings and meets item A, the average exposure ratios not differ by more than one-tenth times their sum; C) the radiographic system's technique factors not exceed the limits specified by the manufacturer; D) the x-ray control console have a signal audible to the operator to indicate the exposure has terminated; and E) a diagnostic radiographic system and its certified components be maintained in compliance with applicable requirements of federal performance standards.

These requirements are needed to protect health and safety. First, the radiographic system must be on an adequate power supply as specified by the manufacturer. Without an adequate power supply, a diagnostic radiographic system may not have the power to make the correct exposure thus necessitating additional unnecessary exposure to the patient. The coefficient of variation is a mathematical evaluation of a series of exposures to determine the variation between all exposures in the series. Again, if the exposure is not consistent enough at the same settings, unnecessary exposures to the patient may result. This requirement is consistent with the Federal Performance Standard 21 CFR 1020.31(b) and (b)(1) and is recommended in the CRCPD's SSRCR Sections F.6(f)(1) and F.7(g)(1).

Second, the average ratio of exposures checks the linearity of exposures from one milliampere station to the next to assure that exposures are within limits if the operator has to choose a higher or lower milliampere station to make another exposure on the same patient. This requirement reduces the risk that an unnecessary exposure may be needed because the milliampere stations were not linear. This requirement is consistent with the Federal Performance Standard 21 CFR 1020.31(c) and (c)(1) and is recommended in the CRCPD's SSRCR Sections F.6(f)(2) and F.7(g)(2).

Third, the technique factors must be within the ranges specified by the manufacturer thus reducing the need for possible unnecessary exposures. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(a)(4) and is recommended in the CRCPD's SSRCR Sections F.6(f)(3) and F.7(g)(3).

Fourth, the x-ray control console must make an audible signal at the termination of the exposure so the operator may watch the patient and know when the exposure is over. In this way the patient is watched for movement rather than the operator having

to watch the indicators. If the latter were true and the patient moved, an unnecessary x-ray exposure might be necessary to retake the x-ray film because of a blurred image on the first film. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(h) and is recommended in the CRCPD's SSRCR Sections F.6(b)(2)(ii)(c) and F.7(d)(3).

Last, certified diagnostic radiographic systems must be maintained in compliance with Federal Performance Standards that were in effect when that system or component was manufactured. In this manner, a certified system or component should never go out of compliance with the Federal Performance Standard that was in effect at the time of manufacture. At present there is no comparable Federal Performance Standard for this provision although this requirement is in final draft form for the CRCPD's SSRCR. Without this requirement, the registrant does not have to maintain a certified system or component in any manner thus invalidating the reason the Federal Performance Standards were promulgated in the first place.

4730.1850 DIAGNOSTIC RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, VETERINARY MEDICINE, OR COMPUTED TOMOGRAPHY SYSTEMS.

Subpart 1. Applicability. This part applies to all certified and uncertified diagnostic x-ray systems except fluoroscopic, dental intraoral, veterinary medicine, or computed tomography x-ray systems for which there are separate regulations in this chapter. These requirements apply to medical radiographic x-ray systems whether they are currently under state jurisdiction (uncertified) or whether the equipment meets federal performance standards (certified equipment). Through the revision of chapter 4730, the state is incorporating federal performance standards.

The requirements in this part are in addition to the general requirements specified in parts 4730.0100 to 4730.1750. All registrants of x-ray equipment must meet the provisions of parts 4730.0100 to 4730.1750 regardless of the type of x-ray equipment a registrant owns or uses.

Subpart 2. Beam limitation. The useful beam must be limited to the patient's area of clinical interest. This requirement states that the beam size shall only be that which is necessary for diagnostic purposes and not a larger beam size. This requirement is similar to the requirement in adopted part 4730.1500, item C. This requirement is recommended in the CRCPD's SSRCR Section F.6(a).

Subpart 3. General purpose stationary x-ray systems. Subpart 3 specifies requirements for: the alignment of the x-ray field size; visually defining the edges of the x-ray field; indicating the perpendicularity with the image receptor field; alignment of

the center of the x-ray field and the center of the image receptor field; beam-limiting device numerical indicators; and the accuracy of all the above. These 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. These requirements are consistent with Federal Performance Standard 21 CFR 1020.31(d)(1) and (2), 1020.31(e)(1)(i) to (iii) and are recommended in the CRCPD's SSRCR Section F.6(a)(1) and (2).

Subpart 4. Diagnostic radiographic systems designed for one image receptor size. This requirement states that if only one image receptor size is used at a fixed distance, then the useful beam must not exceed the size of the image receptor and the center of the useful beam cannot be misaligned more than two percent of the indicated distance. Since only one image receptor size is being used, the requirement is stricter than if multiple image receptors are used because there is no need to be adjustable. These requirements are consistent with Federal Performance Standard 21 CFR 1020.31(f)(2) and is recommended in the CRCPD's SSRCR Section F.6(a)(3).

Subpart 5. Diagnostic radiographic systems designed only for mammography. This subpart specifies how accurate the dimensions of an x-ray field must be for mammography. When x-rays of soft tissue such as the breast are taken it is critical that only the area of clinical interest be exposed. It is necessary to reduce the possibility of inducing cancer because of too much radiation to soft tissue. Thus this requirement is as strict as subpart 4 for a one image receptor while also maintaining the center misalignment requirements specified in subpart 4. These requirements are consistent with the Federal Performance Standard 21 CFR 1020.31(f)(3) and are recommended in the CRCPD's SSRCR Section F.6(a)(4).

Item A of this subpart specifies that the radiographic equipment used for imaging the breast be designed specifically for mammographic imaging. Mammography is a specialized imaging process. Use of only a specifically designed machine for mammography optimizes the quality of the diagnostic image.

Item B specifies the type of x-ray tube target material that must be used for mammography; item C states the minimum half-value layer for each system; the kilovoltage for each type of system is specified in item D; item E states that only a screen-film system may be used for screen-film imaging; and items F and G indicate the mean glandular dose for either system. These requirements are consistent with the recommendations of NCRP Report No. 85 on mammography.

Subpart 6. Other noncertified general purpose x-ray systems. This subpart is intended to address noncertified general purpose x-ray systems that: 1) were in existence prior to the date Federal Performance Standards went into effect; and 2) have been routinely inspected by the state in accordance with adopted state regulations. Proposed item A changes the existing regulation in part 4730.1800, subpart 1, item C to two percent of the indicated distance rather than a fixed accuracy of one inch for a source-film distance of 72 inches. Items B and C are taken from adopted part 4730.1800, subpart 1, items B, C, and D. The requirements in this subpart are consistent with Federal Performance Standard 21 CFR 1020.31(e)(1)(i) to (iii) and are recommended in the CRCPD's SSRCR Section F.6(a)(5).

Subpart 7. Radiation exposure, x-ray controls. This subpart requires that an x-ray control console provide for the termination of an exposure greater than one-half second and completion of a single exposure in a series of exposures. These requirements are consistent with Federal Performance Standard 21 CFR 1020.31(a)(2)(i) to (ii) and are recommended in the CRCPD's SSRCR Section F.6(b)(2)(i).

Subpart 8. Radiation exposure, automatic exposure controls. This subpart establishes limits on an automatic exposure control system. Limits for minimum exposure as well as an indicator are necessary to indicate this mode is selected or that an exposure has been completed. These requirements are consistent with Federal Performance Standard 21 CFR 1020.31(a)(3)(i) to (iv) and recommended in the CRCPD's SSRCR Section F.6(b)(3)(i) to (v).

Subpart 9. Source-to-skin distance. This subpart establishes a minimum source-to-skin distance of 30 centimeters for all portable x-ray systems. This provision is necessary so exposures are not made at lesser distances which greatly increases the dose to the patient but does not usually provide a readable diagnostic image. This requirement is consistent with the Federal Performance Standard 21 CFR 1020.31(h)(2) and is recommended in the CRCPD's SSRCR Section F.6(c).

Subpart 10. Radiation from capacitor energy storage equipment in standby status. This subpart sets the maximum amount of leakage radiation that may be emitted from the x-ray tube of a capacitor energy storage equipment unit when the exposure switch or timer is not activated. Radiation may be emitted by the capacitor energy storage equipment when it is charged to its full potential for an exposure and the exposure is not made. As the equipment stands there the capacitors slowly lose their electrical charge and give off radiation. This subpart limits the amount of leakage radiation from this type of system that is allowed. The limits specified in this subpart are consistent with Federal Performance Standard 21 CFR 1020.31(k) and are recommended in the CRCPD's SSRCR Section F.6(e).

Subpart 11. Additional requirements for certified systems only. These additional requirements apply only to certified systems. The additional requirements are: [Item A, subitem (1)] stepless adjustment of the size of the x-ray field with a minimum field size equal to or less than five by five centimeters at a source-to-image distance of 100 centimeters; [subitem (2)] the light localizer must have an average illuminance of not less than 160 lux at 100 centimeters or maximum source-to-image distance, whichever is less. Subitem (3) is the measurement protocol used to measure the illuminance specified in subitem (2).

(Item B) portable x-ray systems must meet the requirements in item A, subpart 3; (Item C) positive beam limitation; and (Item D) limits transmission of the x-ray beam through any mammography image receptor support.

Stepless adjustment of the size of the x-ray field is needed to limit unnecessary radiation by requiring a system where both sides of the collimator blades function independently. This allows the field size to be restricted either horizontally or vertically. The minimum size requirement at a source-to-image distance is necessary to specify so if a minimum size is needed on one or the other side it may be attained by either of the sets of collimator blades thus restricting the amount of radiation a patient receives. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(d) and (d)(1), and is recommended in the CRCPD's SSRCR Section F.6(f)(4)(i).

Light localizers [Item A, subitem (2)] used to define the x-ray field must have at least 160 lux illuminance at 100 centimeters source-to-image distance or the maximum source-to-image distance, whichever is less. This requirement is needed so the x-ray operator can see the light field and adjust the beam limiting device to only expose that portion of the patient's anatomy which is required to be x-rayed. By specifying the illuminance above ambient conditions this requirement allows the x-ray operator to properly do his or her job. This provision is consistent with Federal Performance Standard 21 CFR section 1020.31(d)(2)(ii) and recommended in the CRCPD's SSRCR Section F.6(f)(4)(ii). The existing limit in both federal and CRCPD documents is 160 lux.

Portable x-ray systems must meet the same requirements for stepless adjustment of the size of the x-ray field and illuminance from the light localizer as stated in item A. This requirement in item B emphasizes that because an x-ray system is portable is not a reason to require less safety standards. The requirements are the same as for a stationary x-ray system. This requirement is consistent with Federal Performance Standard 21 CFR section 1020.31(d) and (d)(1) to (d)(2), and is recommended in the CRCPD's SSRCR Section F.6(f)(5). There is a slight difference in that Federal Performance Standards define a mobile

general purpose x-ray system the way a portable x-ray system is defined in these rules.

Positive beam limitation systems are required for those combinations of components in a general purpose x-ray system that include a tube housing assembly, an x-ray control, and a table (if so equipped) and meet the standards in item C, subitems (1) to (6).

Subitem (1) specifies that: (a) the image receptor be placed in a permanently mounted cassette holder; (b) the image receptor length and width be less than 50 centimeters; (c) the x-ray beam axis be within plus or minus three degrees of vertical and the source-to-image distance be between 90 and 130 centimeters or the x-ray beam axis must be within plus or minus three degrees of horizontal and the source-to-image distance must be between 90 and 205 centimeters; (d) the x-ray beam axis be perpendicular to the plane of the image receptor within plus or minus three degrees; (e) and neither tomographic nor stereoscopic radiography be performed. The federal performance standard on this point has five qualifying requirements. Positive beam limitation systems are required only for "general purpose" x-ray systems. When operating general purpose systems, the x-ray operator is more prone to make mistakes because of the constantly changing image receptor sizes and diagnostic results needed. The federal standards exclude several categories of diagnostic x-ray equipment that, because of their common use of the same techniques or image receptors, could use a manually adjusted beam limitation system. If any one of these qualifying requirements is rule, the omission would reduce the number of systems required to have positive beam limitation, thus possibly increasing the amount of exposure patients may receive. Item C, subitem (1), (a) to (e) are consistent with Federal Performance Standard 21 CFR 1020.31(e)(3), and this standard is recommended in the CRCPD's SSRCR Section F.6(f)(6)(i)(a) to (e).

Positive beam limitation equipment has additional requirements for how it is to work. The positive beam limitation equipment must prevent exposures when the length or width of the x-ray field size is more than three percent of the source-to-image distance unless the system is being overridden, or the sum of the length and width differences without regard to sign cannot exceed four percent of the source-to-image distance. The intent of the positive beam limitation system requirement is to automatically or semi-automatically adjust the beam limiting devices collimator blades so the maximum x-ray field size possible is no larger than the image receptor size being used within limits. Those limits are that the width or length of the positive beam limitation system cannot be more than three percent off in any one direction and a total of four percent off in both directions without regard to sign. The positive beam limitation system must prevent exposures if this criteria is not met so long as the x-ray beam

axis is perpendicular to the plane of the image receptor and the conditions requiring positive beam limitation are met. The limits three percent of the source-to-image distance in any one direction and four percent of the source-to-image distance total misalignment is a reasonable limit which installers and service personnel have been adhering to since the Federal Performance Standard went into effect in August 1974. Item C, subitem (2) a and b are consistent with the Federal Performance Standard 21 CFR 1020.31(e)(2)(i) to (ii), and this standard is recommended in the CRCPD's SSRCR Section F.6(f)(6)(ii).

If the positive beam limitation system has an override possibility there are specific requirements for the override system to operate correctly. First, the override possibility must be designed so it works only in the event of a positive beam limitation system failure or system servicing [Item C, subitem (3)]. If the positive beam limitation system is installed where the operator considers it part of the operational control or the operator has manuals which describe the system, a key must be used to override the system and be present while the system is being overridden, and the key or key switch must be clearly and durably labeled "For x-ray field limitation system failure." The override system requirement was worded this way so an operator could not just turn off the positive beam limitation system and leave it that way, defeating the intended purpose of positive beam limitation. This is another safety check on the positive beam limitation system so it is kept operational as much as possible rather than allowing an operator to override the system, open the collimator blades wide open on the beam limiting device, and expose a patient to a large x-ray beam. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(e)(6) and this standard is also recommended in the CRCPD's SSRCR Section F.6(f)(6)(iii).

There are specific conditions under which positive beam limitation equipment must be tested [Item C, subitem (4)]. These conditions state that the positive beam limitation equipment must indicate the beam axis is perpendicular to the plane of the image receptor, the provisions of item C, subitem (1) are met, and compliance is determined no sooner than five seconds after insertion of the image receptor into a permanently mounted cassette holder in order for the testing to be properly performed. If the positive beam limitation system is not within plus or minus three degrees of vertical or horizontal, positive beam limitation is not required to be functional and would invalidate the testing. Certain image receptors less than 50 centimeters in length or width must be used. These are the most common sizes of image receptors used. Image receptors exceeding this size are used for specialized work only. The x-ray beam axis must be within plus or minus three degrees of vertical and the source-to-image distance must be between 90 and 130 centimeters for vertical work and the x-ray beam axis must be

within plus or minus three degrees of horizontal and the source-to-image distance must be between 90 to 205 centimeters for horizontal work. Most routine general purpose machines operate between these parameters. Specialized x-ray systems usually operate outside one or more of these parameters. The five second insertion rule allows the positive beam limitation system time to work. Otherwise positive beam limitation is not required to be functional outside these parameters and would invalidate the testing. This requirement is consistent with Federal Performance Standard 21 CFR 1020.31(e)(4) and this standard is recommended in the CRCPD's SSRCR Section F.6(f)(6)(iv).

The positive beam limitation system must be able to produce a field size which is smaller than either of the dimensions of the image receptor [Subitem (5)]. This allows the operator to collimate down to just the area of clinical interest rather than leaving the beam limiting device at the maximum for the image receptor being used. This requirement reduces the amount of unnecessary radiation the patient will receive. In addition, the system must be able to produce a minimum size x-ray field of five by five centimeters or less. The minimum size requirement is necessary so that if only a minimum size is needed on one or the other side it may be attained by either of the sets of collimator blades thus restricting the amount of radiation a patient receives. This requirement is consistent with Federal Performance Standard 21 CFR section 1020.31(e)(5), and is the standard recommended in the CRCPD's SSRCR Section F.6(f)(6)(v).

The positive beam limitation system must be designed so that when an image receptor is changed the system must either prevent an exposure until the beam limiting device is manually adjusted for the new image receptor size or the system automatically senses the new image receptor and adjusts itself [Subitem (6)]. The system must be designed so that if an image receptor is changed, either the system prevents an exposure until the beam limiting device is manually adjusted to the image receptor size or smaller, or the positive beam limitation system automatically senses the new image receptor and adjusts the beam limiting device automatically to the new image receptor size. In this way the operator cannot make a mistake on adjustment of the beam size. Either the operator adjusts it manually or the positive beam limitation system adjusts the beam limiting device automatically. This should prevent unnecessary x-ray retakes and thus unnecessary radiation from occurring because the operator forgot to change the beam limiting device's collimator blades and made an exposure with either too large or too small an x-ray field size. This requirement is consistent with Federal Performance Standard 21 CFR section 1020.31(e)(5) and is the standard recommended in the CRCPD's SSRCR Section F.6(f)(6)(vi).

Item D states the maximum amount of radiation that is allowed to be transmitted through a mammography image receptor support

installed after September 5, 1978 and the protocol on how to properly test for this transmission of radiation. This standard was adopted in federal code in 1977, effective September 5, 1978. It is necessary to have this regulation so the patient's reproductive area is protected from unnecessary radiation transmitted through the mammography image receptor support device. The testing protocol is specified so the transmission is measured at the correct location using the maximum settings possible from the particular mammography unit. This requirement is consistent with Federal Performance Standard 21 CFR section 1020.31(l) and is recommended in the CRCPD's SSRCR Section F.6(f)(8).

4730.1950 INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS.

Subpart 1. Applicability. This part applies to x-ray systems used for intraoral dental radiography. Requirements for extraoral dental radiography are covered in part 4730.1850. Intraoral dental radiography uses a dental x-ray machine intended primarily for intraoral dental radiography. The machine is used with fixed beam size, filtration, and technique settings. This is a special type of diagnostic x-ray machine and special provisions are necessary to properly regulate this machine. In some instances the machine may be fitted into another apparatus for extraoral dental radiography, but those uses are regulated by part 4730.1850.

Subpart 2. Source-to-skin distance. This subpart sets the minimum source-to-skin distance for intraoral dental radiographic machines at 7.1 inches. This is necessary to reduce the exposure to the patient. The closer the source-to-skin distance the larger the amount of radiation to the patient. By setting a minimum source-to-skin distance this reduces unnecessary radiation to the patient. This requirement is consistent with Federal Performance Standard 21 CFR section 1020.31(h)(1)(i) and is the standard recommended in the CRCPD's SSRCR Section F.7(a).

Subpart 3. Field limitation. This subpart sets the maximum field size for radiographic systems using an intraoral image receptor at 2.76 inches at a minimum source-to-skin distance of 7.1 inches. With rectangular position-indicating-devices, the longer side must not exceed two inches. This limits the amount of radiation the patient receives by restricting the beam size. This requirement is consistent with Federal Performance Standard 21 CFR Section 1020.31(f)(1)(i) and is the standard recommended in the CRCPD's SSRCR Section F.7(b). The rectangular beam size restriction is not discussed in either of the documents listed above but is consistent in size based on rectangular image receptors available in the industry.

Subpart 4. Safety controls. Item A requires that intraoral film holders and bite blocks be used and film not be hand held. This

requirement is necessary to prevent the operator of a intraoral dental radiographic machine from requiring someone (including the operator) from holding film. Hand holding film is a dangerous practice that in time may lead to the loss of fingers as has been evidenced by practitioners who have lost fingers and extremities because they have held film in the past. This requirement is not listed in Federal Performance Standards because this is under user control and not manufacturer control. This requirement, however, is the same as the standard recommended in the CRCPD's SSRCR Section F.7(f)(1).

Item B requires that the tube housing and position-indicating-device not be hand held during an exposure and be stable before and during exposure. The hand held prohibition is necessary to protect the operator from being too close to the actual source of radiation. A stable tubehead is necessary to protect the patient. If the tubehead is not stable, the x-ray may need to be repeated because the tubehead drifted away from the original position and the film was not struck correctly by the x-rays. This requirement is not listed in Federal Performance Standards because it is a user control and not manufacturer control. This standard, however, is recommended in the CRCPD's SSRCR Section F.7(f)(2).

Item C states that adults of reproductive age and children must be provided with gonadal protection when a full mouth series of exposures are made with intraoral radiography. A full mouth series of exposures is 14 to 18 intraoral film exposures all taken at the same time. Although rarely done, this still presents a large amount of scattered radiation to a patient's gonad area if a full mouth series of exposures are taken. This regulation is carried over from adopted part 4730.2100, subpart 3, item G.

Item D specifies that in addition to the structural shielding requirements in part 4730.1620 there are additional shielding requirements that must be provided. These requirements state that dental rooms containing intraoral dental radiography systems must be provided with barriers at all areas struck by the useful beam. Usually the attenuation of ordinary wall materials is sufficient to act as a protective barrier without any special shielding material being needed. In addition, if there are dental intraoral radiographic units in adjacent rooms or areas there must be protective barriers between the rooms or areas. This is to protect the patient as well as the adjacent occupationally-exposed person and keep their exposure to unnecessary radiation as low as practicable.

Item E states that each installation must be provided with a protective barrier for the operator or the installation must be arranged so the operator can stand at least six feet from the patient and the tubehead and not be in the useful beam. The

intent is to protect the operator from a continuous occupational exposure by having the operator stand behind a protective barrier or at least six feet from the patient and tubehead. For intraoral dental radiographic installations the protective barrier can be the hallway wall or a similar structure. If no protective barrier is available there must be at least six feet between where the operator stands and the patient and tubehead. The operator must not be in the useful beam. Using the inverse square rule, the operator would be receiving less than or equal to 36 times less radiation than if the operator stood right next to the patient and tubehead and in the useful beam. This requirement is not listed in Federal Performance Standards because it is under user control and not manufacturer control. This standard, however, is recommended in the CRCPD's SSRCR Section F.7(d)(2).

Item F states that the exposure at the end of the cone must not exceed the values listed in table 4730.1950 which is kVp and film speed dependent. The exposures are specified as free-in-air without backscatter and the kVp is the actual kVp tested at the time of inspection. The reasons for this item is to ensure that the correct exposure at skin entrance (ESE) for the film speed being used is the value selected. Frequently the indicated kVp is significantly different from the actual kVp. This table is taken from the CRCPD's Publication No. 88-5 "Average Patient Exposure Guides 1988" which states guidelines for several types of x-ray projections including dental intraoral radiography. The MDH in its current adopted state regulations has an intraoral maximum limit of 0.8 roentgen per film regardless of the kVp used (part 4730.2100, subpart 3, item A). Table 4730.1950 refines the current requirement by taking into account the actual kVp and film speed used. In this way the proposed requirement should reduce the amount of radiation being received by the patient. This requirement is not listed in Federal Performance Standards because it is under user control and not manufacturer control. The CRCPD's SSRCR has not discussed this proposed guideline and has not adopted a similar rule.

4730.2050 VETERINARY MEDICINE RADIOGRAPHIC SYSTEMS.

Federal Performance Standards apply to diagnostic x-ray systems being used on human patients. No part of federal standards apply to veterinary medicine x-ray systems. The CRCPD's SSRCR addresses several concerns which are proposed in this chapter.

Subpart 1. Applicability. This subpart is necessary to make it clear to whom the rules apply. Application of the standards in parts 4730.0100 to 4730.1750 to veterinary services as well as services to humans is consistent with the National Council on Radiation Protection and Measurement (NCRP) Report No. 36 titled "Radiation Protection in Veterinary Medicine" which states that:

> The objective of veterinary use of radiation is to obtain optimum diagnostic information or therapeutic effect with minimum exposure of the radiological personnel concerned and the general public, and to reduce to the minimum, all unnecessary irradiation of the animal patient. To the extent that the animal patient exposure is reduced, so is there a proportional decrease in the exposure of persons. (NCRP Report No. 36, 1. Introduction;1.1 Scope; page 1)

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 the radiographic and fluoroscopic procedures. These persons must be safeguarded.

Subpart 2. Beam limitation. This subpart is necessary to prevent and reduce unwanted and unneeded ionized radiation exposure to workers and the public. The standard specified is consistent with NCRP Report No. 36 which states that:

> The useful beam shall be collimated to the size of the cassette used, which, in turn, should be the smallest size needed to obtain the clinical objective. Rectangular collimators which conform more closely to the shape of the cassette are preferred to cones. Diaphragms, cones or collimators shall provide the same degree of protective shielding as that required of the tube housing.

Item A. Restriction of the projected light and x-ray field to no more than two percent of the distance of the x-ray tube to the film source-to-image distance in any direction is necessary to prevent unneeded and unwanted exposure to ionized radiation. This restriction is specified in current adopted rule part 4730, subpart 1, item C which states that, "the field size indication on adjustable collimators shall be accurate to within two inches for a source-film distance of 72 inches." NCRP Report No. 33 titled "Medical X-Ray and Gamma-Ray protection for Energies up to 10 MEV" also specifies that, "the field size indication on adjustable collimators shall be accurate to within two inches for a source-film distance of 72 inches." (Page 13, section 3.2, part a).

Item B. Labeling the fixed dimension beam limiting collimator is necessary to ensure proper use. Adopted part 4730.1800, subpart 1, item B now specifies that "such devices (diaphragms, cones, adjustable collimators) shall be calibrated in terms of the size of the projected useful beam at all utilized focal-spot-to-film distances." NCRP Report No. 33 titled "Medical X-Ray and Gamma-Ray Protection for Energies up to 10 MEV" states: "such devices shall be calibrated in terms of the size of the projected useful

beam at specified source-film distances." (Page 12, section 3.2, part b). The labeling is the indication that the device has been properly calibrated for the size of the projected useful beam.

Item C. The use of mechanical cassette holding devices to steady the cassette when horizontal beam x-rays are used is necessary to prevent unwanted and unneeded exposure. This provision is consistent with national standards. NCRP Report No. 36 (page 17, section 5.2) states: "the cassette itself shall not be held by hand....Persons holding shall stand so as not to place any part of their bodies in the useful beam." NCRP Report No. 33 (page 16, section 3.2, part c) states:

> When a patient must be held in position for radiography, mechanical supporting or restraining devices should be used. If the patient must be held by an individual, that individual shall be protected with appropriate shielding devices such as protective gloves and apron and he should be so positioned that no part of his body will be struck by the useful beam and that his body is as far as possible from the edge of the useful beam.

Item D. Use of a foot switch with appropriate protective clothing is permitted. This provision is consistent with the standard in NCRP Report No. 36, (page 15, section 4.3) which states: "If an animal patient must be held or positioned manually, the individual holding the animal shall wear protective clothing.... and shall keep all parts of his body out of the useful beam." To accomplish this, a foot switch activated by one of the holders would be applicable.

Subpart 3. Operating procedures. The registrant is ultimately responsible for the tube and its use. Therefore, it is reasonable that the registrant have the responsibility of ensuring the application of the operating procedures of the equipment registered to the applicant. This provision is consistent with NCRP Report No. 36, section 2.1.1.

Item A. Prohibiting the operator from standing in the path of the useful beam is consistent with both NCRP Report No. 36, section 5.2 and Report No. 33, section 3.2, part c, referenced in subpart 2, item C above. The provision is also consistent with Wisconsin rule HSS 157.07, subpart 3 which states: "The operator shall stand well away from the tube housing and the animal during radiographic exposures. The operator shall not stand in the useful beam."

Item B. Prohibiting nonessential persons from being in the radiographic room is consistent with NCRP Report #33 (page 16, section 3, subpart 3D) and NCRP Report #36 (page 14, section 4.3) which both state: "Only persons whose presence is necessary

shall be in the radiographic area during exposures." Wisconsin rule HSS 446.30, subpart 3 specifies that "No individual other than the operator shall be in the x-ray room while exposures are being made unless such person's assistance is required."

Item C. Wisconsin rule HSS 446.30 states: "Any individual holding or supporting an animal or the film during radiation exposure shall wear protective gloves and apron having a lead equivalent of not less than 0.5mm lead..." This requirement is consistent with federal standards previously cited for protective aprons and gloves.

4730.2150 FLUOROSCOPIC X-RAY SYSTEMS.

Subpart 1. Applicability. This part applies to all fluoroscopic x-ray systems whether certified or uncertified.

Subpart 2. Limitation of useful beam, primary barrier. This subpart states that the useful beam must be limited by the primary barrier and without the primary barrier in place the fluoroscope must not work. This provision is necessary to restrict the useful beam so only a fluoroscopic beam which has been attenuated by the primary barrier will cause scattered radiation in the room. The fluoroscope must not operate when the primary barrier is not in place. An unattenuated fluoroscopic beam must not be shot into the room thus increasing the exposure of everyone in the room. This requirement is consistent with Federal Performance Standard 21 CFR section 1020.32(a)(1) (first two sentences) and is the standard recommended in the CRCPD's SSRCR Section F.5(a)(1).

Subpart 3. Limitation of useful beam, x-ray field. This subpart specifies that only image intensified fluoroscopes are permitted to view fluoroscopic images. This provision is needed to reduce radiation exposure to the patient. An image intensified fluoroscope needs far less radiation to do a fluoroscopic study than a non-image intensified fluoroscope which are rarely, if ever, used anymore. The staff of the radiation control unit and members of the Rule Advisory Work Group think that because of the large difference in the amount of radiation received by the patient this provision is reasonable to implement. There is no similar provision in Federal Performance Standards or the CRCPD's SSRCR.

Item A specifies the collimation requirements for image-intensified fluoroscopic equipment. They are similar to the radiographic misalignment criteria. Neither the length nor the width of the x-ray field in the plane of the image receptor must exceed the visible area of the image receptor by more than three percent of the source-to-image distance and the sum of the excess length and width must be no greater than four percent of the source-to-image distance. In addition means must be provided to

further limit the field size. The provisions in this item are needed so only that which the radiologist or physician can see in the image receptor (mirror system or on television monitor) is what is being irradiated on the patient. The patient radiation exposure is limited because the field size is limited. The requirement for further limitation on the field size is necessary so the doctor may cone down just to the area of clinical interest and not have to use a wide open beam. This also reduces the amount of radiation that the patient receives. This requirement is consistent with Federal Performance Standard 21 CFR Section 1020.32(b)(2)(i) and (iv), and is recommended in the CRCPD's SSRCR Section F.5(a)(2)(ii) and (a).

Subitem (1) states that beam-limiting devices installed after May 22, 1979, as specified in federal code, and incorporated in equipment with either a variable source-to-image distance or a visible area of greater than 46.5 square inches, must be provided with stepless adjustment of the x-ray field. Subitem (2) states that all fluoroscopic equipment with a fixed source-to-image distance and a visible area of 46.5 square inches or less must be provided with stepless adjustment of the x-ray field or with means to further limit the x-ray field at the plane of the image receptor. At the greatest source-to-image distance, stepless adjustment must provide continuous field sizes from the maximum attainable to a field size 1.97 by 1.97 inches or smaller. These requirements are directly from Federal Performance Standard 21 CFR Section 1020.32(b)(2)(iv) and are recommended in the CRCPD's SSRCR Section F.5(a)(2)(ii)(a) and (b).

Subitems (3) and (4) are the same as the requirements for non-image intensified fluoroscopic equipment item A, subitems (3) and (4). In addition, subitem (4) puts restrictions on how to determine misalignment for rectangular x-ray fields. These restrictions emphasize the need to center on the visible area of the image receptor when determining misalignment. This requirement is necessary to reduce the exposure to the patient. If the x-ray beam is misaligned the patient is receiving radiation in an unwanted area of the body. This requirement is consistent with Federal Performance Standard 21 CFR Section 1020.32(b)(2)(ii) and (iii), and is recommended in the CRCPD's SSRCR Section F.5(a)(2)(ii)(c) and (d).

Item B specifies additional requirements for spot film devices which are certified components. Subitem (1) requires that means be provided to select the proper size and portion of the film which has been selected at the spot-film selector. The selection and positioning must be automatic except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices installed after June 21, 1979, if the x-ray field size is smaller than that of the selected portion of the film, the means of adjustment must only be at the operator's option. This requirement is directly

from Federal Performance Standard 21 CFR Section 1020.31(g)(1) and is recommended in the CRCPD's SSRCR Section F.5(a)(2)(iii)(a).

Subitem (2) states that it must be possible to adjust the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the film. Minimum field size must be 1.97 by 1.97 inches or less. This requirement is directly from Federal Performance Standard 21 CFR Section 1020.31(g)(3) and is recommended in the CRCPD's SSRCR Section F.5(a)(2)(iii)(b).

Subitem (3) specifies that the center of the x-ray field in the plane of the film be aligned with the center of the selected portion of the film to within two percent of the SID. This requirement is directly from Federal Performance Standard 21 CFR Section 1020.31(g)(4) and is recommended in the CRCPD's SSRCR Section F.5(a)(2)(iii)(c).

Subitem (4) specifies that on spot-film devices installed after February 25, 1978 (which is the date specified in the federal performance standards), if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis is perpendicular to the plane of the image receptor. Compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. This requirement is directly from Federal Performance Standard 21 CFR Section 1020.31(g)(2) and is recommended in the CRCPD's SSRCR Section F.5(a)(2)(iii)(d).

Item C states that if a means exists to override any of the automatic x-ray field size adjustments required in this subpart, there are certain conditions which must be met. The conditions specified in subitems (1) to (3) are: (1) it must be designed for system failure only; (2) it must incorporate a visible signal at the fluoroscopist's position which indicates when the system is overridden; and (3) it must be clearly and durably labeled as follows: "For x-ray field limitation system failure." This requirement is directly from Federal Performance Standard 21 CFR Section 1020.31(g)(5) and is recommended in the CRCPD's SSRCR Section F.5(a)(2)(iv).

Subpart 4. Activation of the fluoroscopic tube. In fluoro mode, x-ray production must be controlled by continuous pressure by the fluoroscopist for the entire time of the exposure. When recording serial fluoroscopic images, the fluoroscopist must be able to terminate the exposure at any time but means may be provided to complete any single exposure of the series in process. This requirement is directly from Federal Performance Standard 21 CFR Section 1020.32(c) and is recommended in the CRCPD's SSRCR Section F.5(b).

Subpart 5. Entrance exposure rate allowable limits. This subpart states that the registrant is responsible for ensuring that the entrance exposure rate allowable limits in this subpart are applied to a fluoroscopic x-ray system. The consensus of the radiation control unit staff and the Rule Advisory Work Group was that the registrant is responsible for ensuring that fluoroscopes under the registrant's control meet all applicable entrance exposure rate allowable limits. There is no comparable standard in either Federal Performance Standards or the CRCPD's SSRCR because the federal standards address equipment and not users of that equipment.

Item A states that the exposure rate measured at the point where the center of the useful beam enters the patient must not exceed ten roentgens per minute except during recording of fluoroscopic images or when optional high level control is provided. This applies to all fluoroscopic equipment, except as noted later, and includes non-certified fluoroscopes and certified fluoroscopes with automatic exposure rate control. This requirement is consistent with adopted part 4730.1700 subpart 3, item A, and is specified in Federal Performance Standard 21 CFR Section 1020.32(d)(1) and is recommended in the CRCPD's SSRCR Section F.5(c)(1)(i). Item A also specifies that the maximum entrance exposure rate must not exceed 20 roentgens per minute except during the recording of fluoroscopic images. This requirement was developed through discussion between radiation control unit staff and members of the Rule Advisory Work Group. There is no Federal Performance Standard limit nor is there a CRCPD's SSRCR recommendation for this type of limit. The staff and work group members thought that twice the limit in Item A gives the fluoroscopist more than enough radiation to do any fluoroscopic examination. Fluoroscopic machines have the capacity for adjustment for this limitation.

Item B specifies that certified systems which do not incorporate an automatic exposure rate control must not be operable at any combination of kVp and milliamperage, except during recording of fluoroscopic images or when optional high level control is activated. The exposure rate measured at the point where the center of the useful beam enters the patient must not exceed five roentgens per minute. This requirement is directly from Federal Performance Standard 21 CFR Sections 1020.32(d)(2), 1020.32(d)(2)(i) and (ii), and is recommended in the CRCPD's SSRCR Section F.5(c)(1)(iii).

Item C states that when provided with optional high level control, the fluoroscopic x-ray system must not be operable at any combination of kVp or milliamperage which results in an exposure rate in excess of five roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. There are additional requirements that specify that the fluoroscopist must provide

continuous manual activation of the high level control and a continuous signal, audible to the fluoroscopist, must indicate that the high level control is activated. This requirement is directly from Federal Performance Standard 21 CFR Section 1020.32(d)(1)(ii) and is recommended in the CRCPD's SSRCR Section F.5(c)(1)(ii).

Item D specifies how compliance with Subpart 5 must be determined. Subitem (1) states that the one-eighth inch thick sheet of lead that covers the entire cross section of the primary beam must be placed at a minimum distance of 5.9 inches from the point of measurement on the image receptor side of the patient. This requirement is the result of discussion between radiation control unit staff and members of the Rule Advisory Work Group. There is no Federal Performance Standard compliance procedure nor is there a CRCPD's SSRCR recommendation for this type of procedure. This additional procedural step will specify for whomever is testing a fluoroscope in Minnesota what the standard amount of lead that is acceptable for "driving" a fluoroscope to its maximum output and its position relative to the measurement point. In this manner there will not be a controversy of one method being better than another method.

Subitem (2) specifies that if the x-ray source is below the tabletop or cradle, the exposure must be measured at 0.4 inches above the tabletop or cradle. This requirement is needed so all persons testing the output of a fluoroscope in this configuration are actually testing at the skin entrance of the patient. This requirement is directly from Federal Performance Standard 21 CFR Section 1020.32(d)(3)(i) and is recommended in the CRCPD's SSRCR Section F.5(c)(1)(iv)(b).

Subitem (3) specifies that if the x-ray source is above the tabletop or cradle, the exposure rate must be measured at 11.8 inches above the tabletop or cradle with the end of the beam-limiting device or spacer positioned as close as possible to the point of measurement. This requirement is needed for the same reason as subitem (2) with the additional comment that in specifying that the beam-limiting device or spacer be as close as possible to the point of measurement. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(d)(3)(ii) and is recommended in the CRCPD's SSRCR Section F.5(c)(1)(iv)(c).

Subitem (4) states that C-arm fluoroscopes must meet the entrance exposure rate limits specified in subpart 5, items A and B. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(d)(1), and is recommended in the CRCPD's SSRCR Section F.5(c)(1)(i) and (ii). In addition, the C-arms must be tested at 11.8 inches from the input surface of the fluoroscopic imaging assembly, with the x-ray source positioned at any SID and the beam-limiting device or spacer is not closer than 11.8 inches

from the input surface of the fluoroscopic imaging assembly. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(d)(3)(iii) and is recommended in the CRCPD's SSRCR Section F.5(c)(1)(iv)(d).

Item E states that periodic measurement of the maximum and clinical exposure rate must be performed as specified in this item. This requirement specifies that the fluoroscope's maximum exposure rate under any combination of kVp and mA must be tested. This is a machine maximum. The clinical exposure rate is the common setting that a fluoroscopist would use typically for specific fluoroscopic exams. The consensus of the radiation control unit staff and the Rule Advisory Work Group was that since there is no Federal Performance Standard limit and the CRCPD's SSRCR recommendation is only that the entrance exposure rate limit be tested, which entrance exposure limits shall be performed must be specified. In this manner, the fluoroscopist will know before he or she fluoroscopes a patient what the typical and maximum exposure rate is to a patient. The reference in the CRCPD's SSRCR is Section F.5(c)(1)(v).

Subitem (1) states that the above mentioned exposure rates must be made annually or after any maintenance of the system which might effect the exposure rate. This is the recommendation in the CRCPD's SSRCR Section F.5(c)(1)(v)(a).

Subitem (2) states that the results of these measurements must be posted where any fluoroscopist may have ready access to them while using the fluoroscope and must be kept as part of the record required in part 4730.1520, subpart 1, item D. The requirement further states how the results must be listed including units, technique factors used, person doing the measurements and the date that the measurements occurred. These items are all needed so the fluoroscopist will have accurate knowledge of the exposure rate he or she is using and how current the information is. This is another way of informing the fluoroscopist so he or she may adjust the fluoro technique so the patient only receives the amount of radiation necessary to perform the fluoroscopic examination. This is the recommendation in the CRCPD's SSRCR Section F.5(c)(1)(v)(b).

Subitem (3) states the conditions of periodic measurement of the clinical entrance exposure rate. These conditions are as follows:

> (a) the measurements must be made under the conditions specified in item D, subitems (2), (3), and (4). This is specifying where the measurement is taken in relation to the tabletop, cradle, source or image intensifier depending on which type of equipment is being tested. This is the recommendation in the CRCPD's SSRCR Section F.5(c)(1)(v)(d)(1);

(b) specifies that the kVp must be the kVp typically used for clinical use of the x-ray system. This is necessary so the fluoroscopist knows the radiation dose rate that is possible for common exams that he or she performs daily and not exams done infrequently. This is necessary so the fluoroscopist is able to keep the dose to the patient as low as practicable. This is the recommendation in the CRCPD's SSRCR Section F.5(c)(1)(v)(d)(2);

(c) specifies that for x-ray systems that incorporate an automatic exposure rate control, there is sufficient material in the useful beam to produce kilovoltage and milliamperage typical of the use of this x-ray system. If insufficient material is in the useful beam, an incorrect exposure rate would be measured. This is necessary so the fluoroscopist knows the radiation dose rate that is possible for common exams using the automatic exposure rate control mode that is performed daily and not exams done infrequently. This is necessary so the fluoroscopist may be able to keep the dose to the patient as low as practicable. This is the recommendation in the CRCPD's SSRCR Section F.5(c)(1)(v)(d)(3);

(d) specifies that for x-ray systems that do not incorporate an automatic exposure rate control, the kilovoltage and milliamperage used for the test must be typical of the use of this x-ray system. This is necessary so the fluoroscopist knows the radiation dose rate that is possible for common exams performed daily and not exams done infrequently. This is necessary so the fluoroscopist can keep the dose to the patient as low as practicable. This is the recommendation in the CRCPD's SSRCR Section F.5(c)(1)(v)(d)(3).

(e) specifies that materials be placed in the useful beam when conducting these measurements to protect the imaging system. These materials are necessary because it is very easy to "burn" an image of the testing equipment into the imaging system. This is a very expensive and sensitive imaging system that magnifies and amplifies the image that is being transmitted to the imaging system. If an image is "burned" into the system the fluoroscopist would lose use of this part of the imaging system thus requiring more radiation to the patient as the fluoroscopist does his or her job and has to maneuver around the "burned" image to do the same work. More time would be spent doing the examination thus requiring more radiation to the patient. The alternative is to replace the imaging system components which is extremely expensive. This is the recommendation in the CRCPD's SSRCR Section F.5(c)(1)(v)(d)(4) footnote 2.

Subitem (4) states the conditions of periodic measurement of the maximum entrance exposure rate. The conditions in subitems (2) and (3) are the same as for subitem (4) for the same reasons. Condition (1) is necessary to "drive" the fluoroscopic x-ray machines with automatic exposure rate control to their maximum kilovoltage and milliamperage and to protect the imaging system from getting an image "burned" into the imaging system as explained above in (e). For x-ray systems that do not incorporate an automatic exposure rate control, the x-ray system must be adjusted to a combination of kilovoltage and milliamperage which will produce the maximum entrance exposure rate from this x-ray system. This may not be at the maximum kilovoltage and maximum milliamperage setting for this x-ray system. There is no comparable Federal Performance Standard which sets these conditions of measurement. Nor is there any comparable CRCPD SSRCR recommendation that states these conditions of measurement. Since the user is permitted to make the measurement, conditions of measurements are stated within this subpart. The consensus of the radiation control unit staff and the Rule Advisory Work Group was that this requirement was necessary so anyone testing for the maximum entrance exposure rate would use the same material to "drive" and to protect the x-ray system that was being tested. In this way also the results could be compared without correcting for differences in materials used to "drive" and to protect the x-ray system. The conditions are similar to the clinical entrance exposure rate conditions in that the readings are taken at the same locations. The difference is that rather than using typical clinical kilovoltage and milliamperage settings, the x-ray system is being tested at its maximum. To safely do this, it is necessary to put a sheet of lead (1/16th inch thick) in the beam to "drive" an automatic entrance rate control system to its maximum entrance exposure rate or to manually adjust the kilovoltage and milliamperage to produce the maximum entrance exposure rate that the x-ray system is capable of producing.

Subpart 6. Barrier transmitted radiation rate limits. This subpart specifies that the exposure rate due to transmission of x-rays through the primary protective barrier with the attenuation block in the useful beam, combined with the radiation emitted from the image intensifier, must not exceed two milliroentgens (0.5 uC/kg) per hour at ten centimeters (3.9 inches) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate. This is necessary to provide protection to the fluoroscopist and the assisting personnel in the room during the fluoroscopy exam. This radiation is part of their occupational exposure because they are in the fluoroscopy room doing the examination. If the limit were higher they could be exposed to higher radiation levels than is permitted by this chapter as an occupational worker. This requirement is directly from Federal Performance Standard 21 CFR

1020.32(a)(1) (third sentence) and is the recommendation in the CRCPD's SSRCR Section F.5(d)(1).

Subpart 7. Measuring compliance of barrier transmission. This subpart states the conditions under which compliance with subpart 6 shall be determined. Since the user is permitted to make the measurement, conditions of measurements are stated within this subpart.

Item A states the size of the area over which the measurements shall be averaged. This is for the exposure rate due to transmission of x-rays through the primary protective barrier combined with radiation from the image intensifier. By stating a uniform area over which the measurement must be taken, there can be no question as to how the readings were taken. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(a)(2) and is recommended in the CRCPD's SSRCR Section F.5(d)(2)(i).

Item B states that the measurement must be made at 30 centimeters (11.8 inches) above the tabletop or cradle with the source below the tabletop or cradle. By stating an exact point where the measurement is to be made, anyone with the right equipment may make the measurement and compare it with the regulation. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(a)(2) and is recommended in the CRCPD's SSRCR Section F.5(d)(2)(ii).

Item C states that the measurement must be made no closer than 30 centimeters (11.8 inches) from the beam-limiting device or spacer to the point of measurement, when the source is above the tabletop or cradle and the source-to-image distance is variable. By stating an exact point where the measurement is to be made, anyone with the right equipment may make the measurement and compare it with the regulation. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(a)(2) and is recommended in the CRCPD's SSRCR Section F.5(d)(2)(iii).

Item D states that for all barrier transmission measurements the attenuation block must be positioned in the useful beam ten centimeters (3.9 inches) from the point of measurement of the entrance exposure rate and between that point and the input surface of the fluoroscopic imaging assembly. By stating an exact point where the measurement is to be made, anyone with the right equipment may make the measurement and compare it with the regulation. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(a)(2) and is recommended in the CRCPD's SSRCR Section F.5(d)(2)(v).

Subpart 8. Indication of potential and current. This subpart states that for fluoroscopic x-ray systems manufactured and installed after February 25, 1978, (which is the date specified

in federal code) during fluoroscopy and cinefluorography, the kilovoltage and milliamperage must be continuously indicated. This is needed so the fluoroscopist can always know at what settings the x-ray system is operating. The fluoroscopist thus knows from the posted last entrance exposure rate check how much radiation the patient is receiving. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(e) and is recommended in the CRCPD's SSRCR Section F.5(e).

Subpart 9. Source-to-skin distances. In this subpart, items A to D state the minimum source-to-skin distance for fluoroscopes, depending on when the w-ray system is installed or based on the specific application (portable or surgical) for which the x-ray system is used. For fluoroscopic systems the minimum source-to-skin distance is 38 centimeters (15 inches). The minimum source-to-skin distance is 35.5 centimeters (14 inches) for stationary fluoroscopes manufactured prior to August 1, 1974, which is the date specified in federal regulations. For portable fluoroscopes including c-arm type fluoroscopes, the minimum source-to-skin distance is 30 centimeters (11.8 inches). For image intensified fluoroscopes used for specific surgical applications, the minimum source-to-skin distance allowed is 20 centimeters (7.9 inches). This has the added requirement that for these special surgical applications, there are written safety procedures to provide precautionary measures to protect the patient, operators and support staff to reduce the amount of radiation they receive. These requirements are directly from Federal Performance Standard 21 CFR 1020.32(f) and are recommended in the CRCPD's SSRCR Section F.5(f)(1) to (4).

In addition, the consensus of the radiation control section staff and the Rule Advisory Work Group was that an additional requirement was necessary to protect the next operators and patients from unnecessary radiation. Therefore the last paragraph in item D is proposed. It states that the 20 centimeter (7.9 inch) spacer cone must be replaced with the 30 centimeter (11.8 inch) spacer cone immediately after the end of the fluoroscopic surgical procedure. In this way the image intensified fluoroscope will not be inadvertently used with the wrong spacer in place for ordinary fluoroscopic procedures. If left in place this smaller spacer cone could lead to serious overexposures to both the patient and operators because the fluoroscope is being used at a closer source-to-image distance than ordinarily used and the output at this source-to-image distance may not have been measured. There is no comparable Federal Performance Standard or CRCPD SSRCR recommendation for this provision.

Subpart 10. Fluoroscopic timer. This subpart states that the fluoroscope must have a cumulative timer that must be preset and cannot exceed five minutes without resetting. In addition, a signal audible to the fluoroscopist must indicate the completion

of the preset cumulative on time. This signal must continue to sound while x-rays are being produced and until the timing device is reset. A timing device is needed on a fluoroscope to remind the fluoroscopist how long the patient is being irradiated. Five minutes is a length of time which is reasonable and in most cases a good fluoroscopist may get several patients done within this time frame. The need for the audible signal to continue to emit a sound is a constant reminder to the fluoroscopist to finish the procedure as soon as possible because the patient is continuing to be irradiated while a sound is emitted. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(g) and is recommended in the CRCPD's SSRCR Section F.5(g).

Subpart 11. Control of scattered radiation. This subpart outlines procedures to be used in conjunction with the x-ray system equipment requirements to control the amount of scattered radiation from all fluoroscopes. These are procedures for the registrant to administer for all users of fluoroscopic equipment within the facility. Since these procedures are user oriented, there are no comparable federal performance standards which are in place for the manufacture and installation of x-ray equipment.

Item A specifies that fluoroscopic tables with undertable x-ray tubes must protect the operators by having two protective devices that are at least 0.25 millimeter lead equivalent. These devices are a bucky opening cover and lead drapes which must be attached to the intensifier tower to attenuate the scattered radiation which is either coming from the bucky opening or is scattered off the patient on the table. These devices are reasonable to require on a fluoroscopic table with an undertable tube because other than the primary beam, these devices protect the fluoroscopist and attending staff from the next largest source of scattered radiation. The primary beam from the undertable tube is aimed at the patient on the tabletop. Either in striking the fluoroscopic collimator blades or in striking the bottom side of the tabletop there can be a lot of scattered radiation. By putting a bucky slot cover of at least 0.25 mm lead equivalence over the bucky opening, the fluoroscopist is protected from this scattered radiation. Likewise, by requiring the attachment of lead drapes from the intensifier tower, this is protecting the fluoroscopist from scattered radiation coming off the patient. This requirement is recommended in general terms in the CRCPD's SSRCR Section F.5(i)(1) and (2). The consensus of the radiation control unit staff and members of the Rule Advisory Work Group is that it is necessary to be specific about the protective devices that must be available to protect anyone that would be operating or assisting in the fluoroscopic room so the exposure from scattered radiation does not exceed the allowable dose limits listed in part 4730.0310.

Item B specifies that for other equipment configurations, provision must be made through equipment design or radiation protection measures to assure that individuals do not exceed the allowable limits listed in part 4730.0310. This requirement was meant to assist the Department with any other configurations they might encounter in fluoroscopic equipment inspections in the field. The radiation control unit staff and members of the Rule Advisory Work Group recommend the proposed provision rather than listing all the different combinations of equipment and design that may be possible now and in the future. There is no similar recommendation in the CRCPD's SSRCR.

Subitem (1) further lists that any individual in a room during a fluoroscopic procedure must wear a protective apron of at least 0.5 mm lead equivalence. This procedure is stating that no one shall be in a fluoroscopic room during a fluoroscopic examination that is not protected by an apron of at least 0.5 mm lead equivalence. The rules in this way protect every occupationally exposed individual from radiation. This reinforces part 4730.1510, subpart 6, item D, which states that anyone in a diagnostic radiographic room must be wearing at least a 0.5 mm lead equivalent protective apron. There is no similar recommendation in the CRCPD's SSRCR section on fluoroscopic equipment and procedures. The radiation control unit staff and members of the Rule Advisory Work Group decided this additional procedure was needed to reinforce the registrant's radiation safety procedures in part 4730.1510.

Subitem (2) states that all fluoroscopic x-ray systems must be provided with drapes, bucky-slot cover panels, and self-supporting curtains that are made of not less than 0.25 mm lead equivalent material. This requirement is needed so all fluoroscopes have similar protective devices. See the justification for item A above. Even though a fluoroscope may have a different design, the protective devices for the fluoroscopist and others in the room must not be decreased. The object of these regulations is to protect the patient and occupationally exposed personnel as much as possible and this is a good way of ensuring protection for the fluoroscopist and other personnel in the room. There is no similar recommendation in the CRCPD's SSRCR section on fluoroscopic equipment and procedures.

Item C states that for single-tube above table combination radiographic and fluoroscopic x-ray systems used in the fluoroscopic mode, protective aprons of not less than 0.5 mm lead equivalence must be worn by any individual in the room during a fluoroscopic procedure. This is necessary so the individual does not exceed the allowable dose limits in part 4730.0310. This is a fluoroscope of a different configuration but the same protection should be afforded the fluoroscopist or any other individual required to be in the room during a fluoroscopic examination. It is good radiation practice to provide any

individual with a lead apron, portable lead shield, or lead barrier to protect the person from scattered radiation. This provision is consistent with the registrant safety practices in part 4730.1510. There is no similar recommendation in the CRCPD's SSRCR section on fluoroscopic equipment and procedures.

Item D states similar procedures for C-arm fluoroscopes. Because of their design and frequent use in surgical applications, C-arm fluoroscopes cannot be designed with a protective bucky-slot cover or lead drapes. Any individual in a room where a C-arm fluoroscope is used must be protected by a lead apron of at least 0.5 mm lead equivalence material. This is necessary to maintain the occupational exposure of any individual below the allowable limits set in part 4730.0310. This is the most logical radiation practice that can be administered with the design and use of this type of machine. There is no similar recommendation in the CRCPD's SSRCR section on fluoroscopic equipment and procedures.

Subpart 12. Radiation therapy simulation systems. This subpart exempts radiation therapy simulation systems from subpart 5, entrance exposure rate allowable limits, provided that two additional requirements are met. The patient being treated on a therapy simulation system is going through this diagnostic procedure to ascertain that the therapy protocol that has been chosen will effectively treat a cancerous condition. The amount of radiation from such a procedure may be large in terms of comparing it to a typical fluoroscopic procedure but minor compared to the total dose that will be delivered in a therapy treatment. It is critical that the treatment protocol be accurate. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(d)(4) and is recommended in the CRCPD's SSRCR Section F.5(j).

The additional requirements contained in this subpart do two things. First, item A specifies that only the patient may be in the therapy simulation room when x-rays are produced. This protects any other individual from receiving an occupational dose from a therapeutic simulation procedure. The radiation doses could be much larger than diagnostic fluoroscopic procedures thus an individual could exceed the allowable dose limit permitted in part 4730.0310 much sooner than with typical fluoroscopic examinations. There is no similar federal performance standard since this is a user procedure but this item is recommended in the CRCPD's SSRCR Section F.5(j)(1).

Item B states that for therapy simulation systems that do not meet the requirement of subpart 10, fluoroscopic timers, there must be a means to indicate the cumulative time a patient has been exposed to x-rays. In addition, the timer must be reset between examinations. Although a timer as specified in subpart 10 is not required with its five minute limit and audible signal, a timer nonetheless must be in place to accurately time the

cumulative exposure time of the patient. It is necessary that all radiation exposure to a patient is recorded so the attending physician knows how much radiation the patient has been exposed to. This could effect the radiation therapy treatment protocol or follow-up treatment. This requirement is directly from Federal Performance Standard 21 CFR 1020.32(g) last sentence and is recommended in the CRCPD's SSRCR Section F.5(j)(2). In Federal Performance Standard this item is listed as an alternative to subpart 10 that "may" be provided. The consensus of the radiation control unit staff and members of the Rule Advisory Work Group that this additional procedure is needed to reinforce the timer requirement in subpart 10.

4730.2250 COMPUTED TOMOGRAPHY SYSTEMS.

Subpart 1. Applicability. These requirements apply to all computed tomography (CT) systems which meet Federal Performance Standards for certified equipment. There are no non-certified computed tomography systems in the state.

The requirements in this part are in addition to the general requirements specified in parts 4730.0100 to 4730.1750. All types of x-ray equipment must meet provisions of parts 4730.0100 to 4730.1750 regardless of the type of x-ray equipment that a registrant owns or uses.

Subpart 2. Termination of exposure. This subpart states that a visible signal must indicate when the x-ray exposure has terminated. In addition, the operator must be able to terminate any scan that is longer than one-half second in duration. This subpart is needed to give the operator more control over the CT unit. The operator is usually working from a computer console not a conventional control panel and as such does not have the usual dial readings or other signals to indicate the termination of the exposure. This is an additional positive step so that the operator knows when the exposure is actually over. This is similar to the additional requirement for certified equipment only in part 4730.1750 subpart 15, item D. These requirements are consistent with Federal Performance Standard 21 CFR 1020.33(f)(2)(i) third sentence and is recommended in the CRCPD's SSRCR Section F.11(b)(1)(ii). The consensus of the radiation control unit staff and members of the Rule Advisory Work Group is that it is not necessary to include the additional wording in the Federal Performance Standard 21 CFR 1020.33(f)(2)(i) and in the recommendation in the CRCPD's SSRCR Section F.11(b)(1)(i) because this rarely occurs and the amount of additional radiation to the patient is minimal. The second portion of this requirement about terminating any scan greater than one-half second in duration is similar to the requirement in part 4730.1850, subpart 7. These requirements are consistent with Federal Performance Standard 21 CFR 1020.33(f)(2)(iii) first sentence and is recommended in the CRCPD's SSRCR Section F.11(b)(1)(iii).

Subpart 3. Tomographic plane indication and alignment. This subpart states that the provisions in items A to C apply.

Item A states that means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane. This is necessary so the operator can assess where the scan will be bisecting the patient to determine if the scan is in the right area of that portion of the anatomy. Similarly, it is necessary to know where the reference plane is relative to the tomographic plane. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(g)(1) and is recommended in the CRCPD's SSRCR Section F.11(b)(2)(i).

Item B is a similar requirement for any multiple slice tomogram system. It requires that means must be provided to permit visual determination of the location of a reference plane. The operator needs to know where the reference plane is to determine if the scans will be taken in the correct part of the anatomy. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(g)(2) sentences one and three, and is recommended in the CRCPD's SSRCR Section F.11(b)(2)(ii).

Item C requires that if a light source is used to satisfy either item A or B (as opposed to a laser light source), the light source must be bright enough to be seen above the ambient light in the tomographic room. This is similar to the requirement in part 4730.1850, subpart 11, item A, subitem (2). The justification for the light source is identical. Light sources used to define the x-ray field must have at least 160 lux illuminance. This requirement is needed so the operator has a visible light field and the operator can properly adjust the beam limiting device to only expose that portion of the patient's anatomy which is required to be x-rayed. By specifying the illuminance above ambient conditions this requirement allows the x-ray operator to properly do his or her job. In the past light localizers had no limits and the light illuminance often was not bright enough to be seen by the x-ray operator thus often causing too large an x-ray field to be used. This requirement is found in Federal Performance Standard 21 CFR 1020.33(f)(5) and the CRCPD's SSRCR Section F.11(b)(2)(iii).

Subpart 4. Beam-on and shutter status indicators. This subpart states that the x-ray control and gantry must visually indicate whenever x-rays are produced, and, if applicable, whether the shutter is open or closed. All emergency buttons or switches must clearly be marked as to function. This requirement is necessary so the operator at the control console or any individual in the tomographic room knows when x-rays are being produced and the function of any emergency buttons or switches. In this way the operator may shut down the CT system in the event

of either a problem with the patient or if the operator is inadvertently caught in the CT room during a scan, thereby reducing exposure to the patient and/or the operator. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(h)(1) first sentence and is recommended in the CRCPD's SSRCR Section F.11(b)(3). Federal Performance Standard differs slightly in that it speaks about the "housing of the scanning mechanism" which the rule refers to as the gantry. These terms describe the same part of the CT system. Federal Performance Standard also does not have the second sentence of this subpart as part of its standard. The consensus of the radiation control unit staff and the Rule Advisory Work Group was that it was necessary to have this additional requirement in writing to make sure every operator is clearly aware what the function of each button or switch is in the event of an emergency.

Subpart 5. Indication of computed tomography conditions of operation. This subpart requires that a CT x-ray system be designed so the CT conditions of operation are indicated prior to initiation of the scan or scan sequence. If one or more of these conditions are at fixed values, this requirement may be met by permanent markings. The indication of these CT conditions of operation must be visible at any position from which the scan or scan sequence may be initiated. This is a reasonable requirement so the operator knows what the x-ray machine conditions are and proper settings are used for the exam being performed. If these are not available prior to initiation of the exposure, the patient may have to be irradiated again at the proper settings thus increasing the patient's total dose from the examination. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(f)(1) and is recommended in the CRCPD's SSRCR Section F.11(b)(3).

Subpart 6. Extraneous radiation. This subpart states that when the CT system is not being used to collect data for image production, the radiation adjacent to the tube port must not exceed the leakage radiation from the diagnostic source assembly when measured at one meter (39.4 inches) from the source in any direction. It further states the leakage limit is 100 milliroentgens (26 uC/kg) per hour when the x-ray tube is operated at its leakage technique factors. The measurements must averaged over an area of 100 square centimeters (15.5 square inches) with no linear dimension greater than 20 centimeters (7.9 inches). This requirement is necessary so the patient who may be laying on the CT system couch within the gantry is not being exposed to an excessive amount of extraneous radiation between scans. This requirement is also to protect the operator who is in close proximity to the gantry while positioning each and every patient. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(f)(2)(ii) and is recommended in the CRCPD's SSRCR Section F.11(b)(5).

Subpart 7. Maximum surface computed tomography dose index identification. This requirement states that the angular position where the maximum surface computed tomography dose index occurs must be identified. This requirement is needed so the registrant, in doing quality assurance checks on the system, has a reference position which is identified so a computed tomography dosimetry chamber may be positioned in the system for the checks. The CT system uses a computer to analyze the x-ray beams and a slight misalignment could cause significant problems in properly setting up the CT system to do its diagnostic work. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(g)(2) second and third sentences and is recommended in the CRCPD's SSRCR Section F.11(b)(6).

Subpart 8. Additional requirements. This subpart requires that the following items A to D apply to CT x-ray systems containing a gantry manufactured after September 3, 1985, which is a date specified in federal code. This requirement is directly from the Federal Performance Standard 21 CFR 1020.33(a) and is recommended in the CRCPD's SSRCR Section F.11(b)(7).

Item A states that the total error in the indicated location of the tomographic plane or reference plane must not exceed five millimeters (0.2 inches). The CT x-ray system is a state of the art diagnostic tool for the physician. For the physician to properly use the information obtained with the CT system the initial data acquisition must be extremely accurate. That is the reason this requirement is so exacting on the total error in the location of the tomographic or reference plane of the CT system. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(g)(3) and is recommended in the CRCPD's SSRCR Section F.11(b)(7)(i).

Item B states that the indication of an x-ray exposure of less than one-half second in duration must be actuated for at least one-half second. Indicators at or near the patient side of the gantry must be discernible to the operator. This requirement is needed so short duration x-ray exposures are discernible to the operator especially when the operator is in the CT room with the patient. A one-half second indication is set as the minimum discernible indication of an x-ray exposure by Federal Performance Standards. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(h)(1) second and third sentences and is recommended in the CRCPD's SSRCR Section F.11(b)(7)(ii). Federal Performance Standards differ slightly in that it speaks about the "housing of the scanning mechanism" while the rule refers to the gantry. The department believes this is the same part of the CT system. Both the Federal Performance Standard and the CRCPD's SSRCR further state that the indication must be discernible "from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible" rather than "to the operator"

as the proposed requirement states. The consensus of radiation control unit staff and members of the Rule Advisory Work Group is that the operator is the person who needs to discern the indicator, thus it is necessary to state it that way.

Item C states the amount of deviation that is allowed for the indicated scan increment versus the actual increment must not exceed one millimeter (0.04 inches) with a mass of 100 kilograms (220 pounds) on the support device. The support device must be incremented from its starting position to the maximum position or 30 centimeters (11.8 inches), whichever is less, and then returned to the starting position. The measurement may be taken anywhere along the incremented distance. As noted, the CT x-ray system is a state of the art diagnostic tool for the physician. For the physician to properly use the information obtained with the CT system, the initial data acquisition must be extremely accurate. That is the reason this requirement must be so precise. This indicated scan increment is just one of many variables that must be accurate to properly use the CT x-ray system as a diagnostic tool. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(i) and is recommended in the CRCPD's SSRCR Section F.11(b)(7)(iii).

Item D states that if the CT system is terminated prematurely by the operator the CT conditions of operation must be reset before the initiation of another scan. This requirement is necessary so the CT system will not start in the middle of the scan and expose the patient to unnecessary radiation. The scan would have to be completely redone because the full scan was not completed, thus irradiating the patient a second time in the same area of the anatomy. This requirement is directly from Federal Performance Standard 21 CFR 1020.33(f)(2)(iii) second sentence and is recommended in the CRCPD's SSRCR Section F.11(b)(7)(iv).

Subpart 9. Audio communication. This requirement states that within the CT area there must be two-way audio communication between the patient and operator at the control console. Since this requirement is user or registrant oriented because it involves the facility where the CT x-ray system is located, there is no comparable Federal Performance Standard. This requirement is recommended in the CRCPD's SSRCR Section F.11(c)(1).

Subpart 10. Patient observation. This requirement states that the operator at the control console must be able to directly observe the patient, any other individual in the CT room, and any doorways into the CT room through a shielded window containing the same lead equivalence as the adjoining walls. A closed circuit television system may be used as a secondary means of observing the patient. The main emphasis of these rules is to keep the amount of radiation that anyone receives as low as reasonably achievable. The shielded window must be of the same lead equivalence as the adjacent walls to protect the operator.

The window is necessary for the operator to view the patient, anyone else in the room or the doorways in case someone inadvertently enters the CT room. In this way all involved are protected in some manner. This requirement is recommended in the CRCPD's SSRCR Section F.11(c)(2), however, radiation control unit staff and the Rule Advisory Work Group propose more specificity. It is preferable to have the primary viewing of the CT room be direct observation rather than allowing an electronic system that could fail. An electronic system may be used as a backup to direct observation.

Subpart 11. Location of control panel and x-ray control. This requirement states that the control panel and x-ray control must be mounted in a permanently protected area outside the CT room. The operator is required to remain in that protected area during the entire exposure. This requirement protects the operator in two ways. First, the control panel and x-ray control are outside the CT room rather than as part of the same room. Second, it requires the operator to remain in the protected area during the entire exposure. Both provisions serve to reduce the amount of radiation that the operator may receive. The first is a design criteria and the second is a procedural control on the operator. The radiation control unit staff and members of the Rule Advisory Work Group think the location of the control panel and x-ray control should be similar to that of a therapy system for patient and the operator safety.

Subpart 12. Operating procedure information. This subpart requires that information about the operation, radiation safety surveys and quality control measurements be available at the control console. These include (item A) dates of the last radiation safety survey and quality control measurements; (item B) written results of the most recent radiation safety survey and quality control measurements; (item C) instructions on the use of CT phantoms, schedule of quality control checks, allowable variations for the indicated measurements, results of the last two years' quality control measurements, original quality control and acceptance test measurements, images, and digital data; and (item D) the distance in millimeters between the tomographic plane and the reference plane if a reference plane is used. By having all of this information available at the control console the operator can compare the daily quality control data with the information listed above 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 or not any changes are necessary so correct diagnostic information is recorded for each patient. This requirement is recommended in the CRCPD's SSRCR Section F.11(d)(4)(ii)(a) to (c). The radiation control unit staff and the Rule Advisory Work Group think it necessary to specify what exactly should be available at the control console. In this way the operator does not have to

go to another location or find someone else to compare results of the daily quality assurance checks with previous results.

Subpart 13. Corrective action. This subpart states that if a quality assurance measurement, as specified in part 4730.1665, subparts 2 and 3, exceeds a tolerance specified in part 4730.1691, the registrant must correct the problem to within the specified tolerance within five working days and verify the correction by performing the quality assurance measurements again. This requirement sets a reasonable length of time to correct problems that have been found with quality assurance measurements. In addition, it requires that the correction be verified by re-doing the quality control measurements that detected the problem initially. The consensus of the radiation control unit staff and the Rule Advisory Work Group is that this is a reasonable requirement for this type of state of the art equipment.

4730.2350 THERAPEUTIC X-RAY SYSTEMS OF LESS THAN ONE MeV.

Subpart 1. Applicability. This part specifies that in addition to those requirements in parts 4730.0100 to 4730.1695, the requirements in this part apply to therapeutic x-ray systems of less than one MeV output. It is necessary to have separate and distinct requirements for therapeutic x-ray systems of different outputs because of the design of the x-ray equipment, the shielded room where it is located, and the different operating procedures for each type of therapeutic x-ray equipment. There are no federal performance standards for therapeutic x-ray systems. There are, however, recommended guidelines in various National Council on Radiation Protection and Measurements (NCRP) reports from which the CRCPD's SSRCR recommendations were first adopted.

Subpart 2. Leakage radiation. This subpart specifies that when the tube is operated at its leakage technique factors, the instantaneous exposure rate leakage radiation must not exceed the value specified at the distance specified for the classification of that x-ray system listed below in items A to D. This subpart specifies what settings the x-ray system must be operated at to measure leakage radiation. It further specifies that the amount of leakage must not exceed the value specified at a specific distance from the x-ray tube. This requirement is necessary because each classification of therapy x-ray systems below one MeV has different leakage radiation values at a specified distance. This requirement is recommended in the CRCPD's SSRCR Section F.8(a)(1).

Item A specifies that the leakage radiation for contact therapeutic x-ray systems must not exceed 100 milliroentgens (25.8 uC/kg) per hour at five centimeters (1.97 inches) from the surface of the tube housing assembly. This requirement is needed

to limit the amount of leakage radiation that the patient receives in addition to the radiation received as part of treatment. This requirement is directly from the recommendations in NCRP Report No. 102, Section 5.2.2.1, paragraph (a)(1) and is recommended in the CRCPD's SSRCR Section F.8(a)(1)(i).

Item B specifies that the leakage radiation for zero to 150 kVp therapeutic x-ray systems installed prior to the effective date of this chapter not exceeding one roentgen in one hour at 39.4 inches from the source. This requirement is needed to limit the amount of leakage radiation that the patient receives in addition to the radiation that is received as part of treatment. This requirement is directly from the recommendations in NCRP Report No. 102, Section 5.2.2.1, paragraph (a)(2) and definitions in Appendix A; and is recommended in the CRCPD's SSRCR Section F.8(a)(1)(ii).

Item C specifies that the leakage radiation for zero to 150 kVp therapeutic x-ray systems installed after the effective date of this chapter not exceeding 100 milliroentgens (25.8 uC/kg) in one hour at one meter (39.4 inches) from the source. This requirement is needed to limit the amount of leakage radiation that the patient receives in addition to radiation received as part of treatment. The CRCPD in its rationale for this item stated that in the case of new x-ray therapy systems having a kVp of 150 or less, it appears practical that machines in this kVp range meet the diagnostic x-ray tube housing standard. Copies of the proposed SSRCR were furnished to known manufacturers of this type of machine at the time the recommended regulations were developed and no comments were received. This requirement is recommended in the CRCPD's SSRCR Section F.8(a)(1)(iii).

Item D specifies that leakage radiation for 151 to 999 kVp therapeutic x-ray systems must not exceed one roentgen in one hour at one meter (39.4 inches) from the source. However, systems that operate in excess of 500 kVp may have a leakage radiation at one meter (39.4 inches) from the source not to exceed 0.1 percent of the useful beam 39.4 inches from the source. This requirement is needed to limit the amount of leakage radiation that the patient receives in addition to the radiation received as part of treatment. This requirement is directly from the recommendations in NCRP Report No. 33, Section 3.4.1, paragraph (a) and definitions in Appendix A; and is recommended in the CRCPD's SSRCR Section F.8(a)(1)(iv).

Subpart 3. Leakage from permanent beam limiting devices. This subpart states that leakage from permanent fixed diaphragms or cones used for limiting the useful beam must provide the same or higher degree of protection as required for the tube housing assembly in subpart 2 above. This requirement is needed to limit the amount of leakage radiation the patient receives in addition to the radiation received as part of treatment. This requirement

is directly from the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (b) and is recommended in the CRCPD's SSRCR Section F.8(a)(2).

Subpart 4. Removable beam limiting devices. This subpart states that removable beam limiting devices must, for the portion of the useful beam to be blocked by these devices, transmit not more than five percent of the useful beam at the maximum kilovoltage and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient. This requirement is needed to limit the amount of leakage radiation the patient receives in addition to the radiation received as part of treatment. This requirement is directly from the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (c) and is recommended in the CRCPD's SSRCR Section F.8(a)(3)(i). The CRCPD's SSRCR states that the transmission value not be more than one percent as opposed to the proposed five percent value. The consensus of the radiation control unit staff and the Rule Advisory Work Group is that the proposed regulation should be uniform with adjustable beam limiting devices where the value is five percent and with NCRP Report No. 102, Section 5.1.1, paragraph (c) where the value is five percent.

Subpart 5. Adjustable beam limiting devices. This subpart states adjustable beam limiting devices installed after the effective date of this chapter must meet the requirements of subpart 4 above. Adjustable beam limiting devices installed before the revised rules are effective must, for the portion of the x-ray beam to be blocked by these devices, not transmit more than five percent of the useful beam at the maximum kilovoltage and the maximum treatment filter. This requirement is needed to limit the amount of leakage radiation the patient receives in addition to the radiation received as part of treatment. This requirement is directly from the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (c) and is recommended in the CRCPD's SSRCR Section F.8(a)(3)(ii) and (iii).

Subpart 6. Filter system. This subpart states three components that a filter system must be designed for:

Item A states that the filters cannot be accidentally displaced at any possible tube orientation;

Item B states that the radiation at five centimeters (1.97 inches) from the filter insertion slot opening must not exceed 30 roentgens (7.74 mC/kg) per hour under any operating conditions; and

Item C states that each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle must appear on the wedge or wedge tray.

This requirement is needed so: 1) the proper filter is in place for a treatment; 2) it does not fall out of the filter slot if the tube housing is rotated to another position; 3) the amount of leakage is not exceeding a predetermined limit; and 4) the operator can quickly identify what the filter is made of from the markings on the filter. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (e) and is recommended in the CRCPD's SSRCR Section F.8(a)(4).

Subpart 7. Tube immobilization. This subpart states that the tube housing assembly must be capable of being immobilized for stationary treatments. This requirement is needed so the tube does not shift during treatment thus exposing an area of the body not intended to be exposed. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (h) and is recommended in the CRCPD's SSRCR Section F.8(a)(5).

Subpart 8. Focal spot marking. This subpart states that the tube housing assembly must be marked so it is possible to determine the focal spot within five millimeters (0.2 inches) and such marking must be readily accessible for use during calibration procedures. This requirement is needed so any person who performs a calibration on this piece of equipment can quickly ascertain where the focal spot is on the machine since this is the point from which all radiation is produced and from which all other are dependent. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (f) second sentence and is recommended in the CRCPD's SSRCR Section F.8(a)(6).

Subpart 9. Beam block. This subpart states that if the x-ray tube of a contact therapy system is hand-held during irradiation, the operator must wear protective gloves and aprons. When practical, a cap of at least 0.5 millimeters lead equivalence must cover the aperture window of the tube housing of such apparatus when the apparatus is not being used. This requirement is necessary to protect the operator during treatments when the tube housing is hand-held. This requirement is directly from NCRP Report No. 102, Section 5.1.4, paragraph (e) and is recommended in the CRCPD's SSRCR Section F.8(a)(7). NCRP Report No. 102 further states in a comment after the aforementioned paragraph that 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.

Subpart 10. Timer. This subpart states what a timer which has a display must be provided at the control panel.

Item A states the timer must have a preset time selector and an elapsed time indicator;

Item B states the timer must be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated;

Item C states the timer must terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation;

Item D states the timer must permit accurate presetting and determination of exposure times within an accuracy of one second;

Item D states the timer must not permit an exposure is set at zero; and

Item E states the timer must not activate until the shutter is opened when irradiation is controlled by a shutter mechanism.

This subpart and the accompanying items are necessary so the therapeutic x-ray machine is accurately preset, timed, and terminated; and 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 mandatory items necessary to prevent accidental overexposure of the patient and operators, if applicable. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (k) and is recommended in the CRCPD's SSRCR Section F.8(a)(9)(i) to (vi). The only difference in the CRCPD's SSRCR is that sentence two of (ii) has been deleted because the therapeutic advisors to the Rule Advisory Work Group stated that this was the way that all timers, new or old, operate, therefore the statement is unnecessary.

Subpart 11. Control panel functions. This subpart states what the control panel must have.

Item A states the control panel must have an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

Item B states the control panel must have an indication of whether x-rays are being produced;

Item C states the control panel must have meters that indicate kVp and mA;

Item D states the control panel must have means for terminating an exposure at any time;

Item E states the control panel must have a locking device which will prevent unauthorized use of the x-ray system; and

Item F states the control panel must have a positive display of all specific filters in the beam if installed after the effective date of the proposed rules.

This subpart and items A to D are necessary so the therapeutic x-ray machine has an accurate indication for the operator of all control panel functions needed to evaluate the status of the machine before, during and after every treatment. Without these features the operator would not know when the therapeutic x-ray system was operating. Item E is necessary so unauthorized personnel cannot come in and activate an unattended x-ray system, whether during business hours or after business hours, and operate the equipment possibly causing tremendous overexposures to themselves or others. Item F is necessary so that the operator clearly knows which filter is in place. If the wrong filter were in place, the amount of radiation given to the patient could be significantly different. These are all mandatory items necessary to prevent accidental overexposure of the patient, operators, and others, if applicable. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.1.1, paragraphs (e), (i), (k), and (o); Section 5.2.2.1, paragraph (d) and is recommended in the CRCPD's SSRCR Section F.8(a)(10)(i) to (vi).

Subpart 12. Multiple tubes. This subpart states that if a control panel may energize more than one x-ray tube there are three conditions that must apply. Only one x-ray tube may be energized at any one time and there must be indication at the x-ray tube energized and on the control console of which tube is energized. There is no similar recommendation in the therapy sections of NCRP Report No. 102, however, this is based on a recommendation in 3.4.1 of the diagnostic design recommendations in the same report. This is recommended in the CRCPD's SSRCR Section F.8(a)(11)(i) to (iii).

Subpart 13. Source-to-skin distance. This subpart states that there must be means of determining the source-to-skin distance to within two millimeters (0.08 inches). This requirement is necessary because if the source-to-skin 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. This could result in the patient being improperly undertreated thus allowing a cancer to spread or conversely a serious overexposure could kill the cancer as well as the patient. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (g), and is recommended in the CRCPD's SSRCR Section F.8(a)(12). There are two notable differences. In the NCRP report there is no recommendation on how accurate the source-to-skin distance should be. In the CRCPD's SSRCR it specifies the accuracy to within 0.39 inches. The consensus of the radiation control unit

staff and members of the Rule Advisory Work Group is that the proposed regulation should be strict and coincide with the quality assurance tolerances in part 4730.1695 which state a tolerance of two millimeters (0.08 inches). Equipment is currently capable of achieving this tolerance and many operators follow this recommendation as better practice. Part 4730.1695 is derived from the American Association of Physicists in Medicine (AAPM) Report No. 13, May, 1984.

Subpart 14. Shutters. This subpart states that unless it is possible to bring the x-ray output up to the prescribed exposure parameters within five seconds, the beam must be automatically attenuated by a shutter having a lead equivalence of not less than that of the tube housing assembly. 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. This could result in the patient being improperly under treated thus allowing a cancer to spread. This provision is consistent with the recommendation in NCRP Report No. 102, Section 5.2.2.1, paragraph (e), and in the CRCPD's SSRCR Section F.8(a)(13).

In addition, Item A states that after the system is at its operating parameters, the shutter must be controlled electrically by the operator from the control panel. Item B states that an 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 underexposure of the patient. This could result in the patient being improperly under treated thus allowing a cancer to spread. This provision is consistent with the recommendation in NCRP Report No. 102, Section 5.2.2.1, paragraph (e), and in the CRCPD's SSRCR Section F.8(a)(13)(i) and (ii).

Subpart 15. Low-filtration x-ray tubes. This subpart 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 further states in a comment 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. This provision is consistent with the recommendation in NCRP Report No. 102, Section 5.2.2.1, paragraph (c), and is in the CRCPD's SSRCR Section F.8(a)(14).

Subpart 16. Entrance interlocks. This subpart states that for any therapeutic x-ray system capable of operating above 150 kVp,

interlocks must be provided so all entrance doors to the radiation therapy room are closed before treatment can be initiated or continued. In addition, this subpart states that if the radiation beam is interrupted by any door opening, it must not be possible to restore the system to operation without closing the door and manually reinitiating irradiation at the control panel. This subpart further states that if any entrance door is opened while the x-ray tube is activated, the exposure at one meter (39.4 inches) from the source must be reduced to less than 100 milliroentgens (0.001 sieverts or one millisievert) per hour. There are several reasons this requirement is needed. First, the amount of radiation produced by this type of machine is large. By interlocking the door so it must be closed before initiating a treatment, it is providing an extra safety step so radiation will not be sprayed out into the hallway. It provides a positive step so the operator is definitely out of the room when the treatment starts. By requiring that the door be closed and manual reactivation of the system is necessary to re-start a treatment once an entrance door has been opened, the operator and anyone else assisting the operator is protected from being trapped in a therapy room making adjustments to the patient or equipment and having the machine re-start simply by closing the door again. This subpart requires a manual activation, a positive sequence of steps to reactivate the system. Requiring the radiation exposure rate to be reduced to less than 100 milliroentgens per hour if an entrance door is opened while a treatment is in process reduces the radiation dose that anyone accidentally walking into a treatment room will receive. This requirement is based on recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (n), and is recommended in the CRCPD's SSRCR Section F.8(b)(3)(iii) and (iv). The NCRP report does not have the additional requirement about reducing the radiation exposure rate to less than 100 milliroentgens per hour when the entrance door is opened.

Subpart 17. Operating procedures. This subpart states that the tube housing must not be hand held during operation unless the system is designed to require such holding and the kVp does not exceed 50 kVp. In such cases, the holder must wear protective gloves and apron of not less than 0.5 millimeter lead equivalence at 100 kVp. This requirement is necessary to protect the person that may be hand holding the tube housing during treatment. By restricting this to the type of system that can be hand held and requiring it to operate below 50 kVp, the person wearing a lead apron as specified will not be exposed to excessive amounts of radiation. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.1.4, paragraph (e) first sentence, which was adopted in 1989 by the NCRP, and is recommended in the CRCPD's SSRCR Section F.8(c)(4)(iii). The NCRP report does not specify the lead equivalence of the protective gloves and apron that the CRCPD's SSRCR does. The consensus of the radiation control unit staff and members of the Rule Advisory Work Group is

that the proposed regulation should specify 0.5 lead equivalency because there are lead aprons available that have less lead equivalency in them that do not provide the protection needed for the holder.

Subpart 18. Additional requirements. This subpart states that the x-ray system must not be used in the administration of radiation therapy unless the requirements of part 4730.1675, subpart 2, and part 4730.1680, subpart 1, item C, have been met. The referenced parts are referring to calibration and recalibration of the therapy machine. This requirement is needed so the patient receives a radiation dose that is what the treating physician ordered. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.4, paragraph (a), Section 5.2.2.3, paragraph (a), Section 6.2, Section 6.3.1 and Section 6.3.2, and is recommended in the CRCPD's SSRCR Section F.8(c)(4)(v).

4730.2450 X-RAY AND ELECTRON THERAPY SYSTEMS WITH ENERGIES OF ONE MV AND ABOVE.

Subpart 1. Applicability. This subpart states that in addition to the requirements in parts 4730.0100 to 4730.1695, the requirements in this part apply to therapeutic x-ray systems with energies of one MV and above. It is necessary to have separate and distinct requirements for therapeutic x-ray systems of greater than one MV because of the design of the x-ray equipment, the shielded room where it is located, and the different operating procedures for this type of therapeutic x-ray equipment. There are no federal performance standards for therapeutic x-ray systems. There are, however, recommended guidelines in various National Council on Radiation Protection and Measurements (NCRP) reports from which the CRCPD's SSRCR recommendations were first adopted.

Subpart 2. System requirements; leakage radiation to the patient area. This subpart states that all x-ray and electron therapy systems or any part of a system must meet the requirements in this subpart. Item A specifies the leakage radiation to the patient area for systems installed after the effective date of these rules and item B specifies the leakage radiation to the patient area for systems installed before the effective date of these rules.

Under operating conditions producing maximum leakage radiation, 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 the leakage radiation must not exceed 0.1 percent of the maximum absorbed dose in rads of the unattenuated useful beam measured at the central axis of the beam and the patient plane. Item B further states that the measurements, excluding those for neutrons, must be averaged over up to 100

square centimeters (15.5 square inches) at the positions specified. Measurements for neutrons must be averaged over up to 200 square centimeters (31 square inches). This requirement is necessary to keep the leakage radiation to the patient 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. The measurement area is specified so there is no misunderstanding over which area the measurements were taken. Because neutrons are unlikely to exist in narrow intense beams under these conditions, the area of measurement is twice as large. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (a)(1), and is recommended in the CRCPD's SSRCR Section F.9(b)(1)(i)(a). The NCRP report states the leakage radiation must not exceed 0.2 percent. However, 0.1 percent is achievable with current technology from the three major vendors selling this type of equipment in Minnesota.

Item B 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 operating conditions specified in that item. This requirement is needed so the registrant has available the information necessary to meet item A. Either the registrant must determine it or be able to get the information from the manufacturer. There is no recommendation in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(1)(i)(b).

Subpart 3. Leakage of radiation outside the patient area. This subpart states that systems or any part of a system installed after the effective date of the proposed rules must meet the requirements in this subpart.

Item A specifies that the absorbed dose due to leakage radiation, except in the area specified in subpart 2, item A when measured at any point one meter (39.4 inches) from the path of the charged particle, before the charged particle strikes the target or window, must not exceed 0.1 percent of the maximum absorbed dose in rads of the neutrons and must not exceed 0.1 percent of the maximum absorbed dose in rads of the photons of the unattenuated useful beam measured at the intersection of the central axis of the beam and the circular plane specified in subpart 2, item A. This requirement is necessary to keep the leakage radiation to the patient 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. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (a)(2), and is based on the CRCPD's SSRCR Section F.9(b)(2)(i). The NCRP report states the leakage radiation from photons must not exceed 0.5 percent, excluding the leakage from neutrons. However, the consensus of the radiation control unit staff and the Rule Advisory Work Group is that the proposed

leakage radiation regulation should be 0.1 percent for photons to keep the leakage radiation to the patient area as low as reasonably achievable. This is a tighter limit for photon leakage. In the CRCPD's SSRCR the amount of leakage from neutrons is listed as 0.05 percent. The proposed standard is twice the
limit in the CRCPD's SSRCR. However due to the low contribution of neutrons to the therapeutic effect, raising the neutron limit to 0.1 percent will not seriously alter the therapy dose. In a comment after the NCRP reference it implies that the neutron absorbed dose rate is never greater than about 0.1 percent of the photon absorbed dose rate at the same point and makes a minimal contribution to the therapeutic effect.

Item B 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 specified operating conditions. This requirement is needed so the registrant has available the information necessary to meet item A. Either the registrant must determine it or should be able to get the information from the manufacturer since this is a new system. There is no recommendation in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(2)(ii).

Subpart 4. Beam limiting devices. This subpart states that adjustable or interchangeable beam limiting devices must be provided, and the devices must transmit no more than five percent of the useful beam at the nominal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient. In addition, this subpart states that the neutron component of the useful beam must be excluded from the five percent calculation limit. This subpart 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. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (c), and is recommended in the CRCPD's SSRCR Section F.9(b)(3). The second sentence was added by the radiation control unit staff and the Rule Advisory Work Group to clarify that auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient do not have to meet this requirement. These are not standard beam limiting devices and as such because they are specially made for each patient they can not be made uniformly enough to meet this criteria. The CRCPD's SSRCR recommends two percent of the useful beam be the limit but the radiation control unit staff and the Rule Advisory Work Group decided the NCRP value was more appropriate because it had just been recently reviewed and accepted.

Subpart 5. Filters. This subpart states that all x-ray and electron therapy systems must have filters that meet the requirements in this subpart.

Item A states that all compensating removable filters must be clearly identified. A description of the filter must be available in documentation at the control panel. For wedge filters, the wedge angle must appear on the wedge or wedge tray. This requirement is necessary so the correct filter is used for a particular treatment on a patient. 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 as their treatment. This could have serious consequences either in patient treatment or health. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (e), and is recommended in the CRCPD's SSRCR Section F.9(b)(4)(i).

Item B states that if the absorbed dose rate data required by subpart 17 relates exclusively to operation with a field flattening or beam scattering filter in place, the filter must be removable only with the use of tools. This requirement is necessary because equipment of this type typically only operates with field flattening or beam scattering filters in place. If these filters were easily removable by hand a serious misadministration of radiation could accidentally occur. By making the filters only removable with tools this mistake can not occur as easily. There is no similar recommendation in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(4)(ii).

Item C states that for systems or parts of systems installed after the effective date of the proposed rules which use a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters, there are a set of conditions that must be met:

Subitem (1) states that irradiation must not be possible until a selection of a filter has been made at the treatment control panel;

Subitem (2) states that an interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;

Subitem (3) states that a display must be provided at the treatment control panel showing the filters in use; and

Subitem (4) states that an interlock must be provided to prevent irradiation if any filter selection operation

carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

This set of requirements is necessary to prevent treatment of a patient until the correct filters are selected and in correct position, the operator at the control panel can see a display indicating which filter is in place and prevent a treatment if the filters selected in the treatment room differ from those selected at the control panel. This is a set of safety steps necessary to prevent a serious misadministration of radiation to a patient. If any of these could occur, this could have serious consequences to the patient either in treatment or health. There is no similar recommendation in NCRP reports. This is recommended in the CRCPD's SSRCR Section F.9(b)(4)(iii).

Subpart 6. Beam quality. This subpart states that the registrant must determine or obtain from the manufacturer, data sufficient to assure the beam quality requirements specified in this subpart. This requirement is needed so the registrant has available information to assure the beam quality requirements are met. Either the registrant must determine compliance or should be able to get the information from the manufacturer. There is no similar recommendation in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(5).

Item A states that the absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten centimeters (3.94 inches) greater than the practical range of the electrons must not exceed the values stated in Table 4730.2450. Linear interpolation must be used for values not listed. This requirement is necessary so x-rays are not a major contribution to an electron beam therapy treatment. X-rays and electrons are at different energy levels thus causing different absorbed doses to the patient being treated. If x-rays were allowed at a larger fraction of the maximum absorbed dose, this could cause a serious misadministration of radiation. This could have serious consequences to patient treatment or health. There is no similar recommendation in NCRP reports. This is recommended in the CRCPD's SSRCR Section F.9(b)(5)(i).

Item B states that compliance with item A must be determined using:

Subitem (1) states that a measurement within a phantom with the incident surface of the phantom at the nominal treatment distance and normal to the central axis of the beam;

Subitem (2) states that the largest field size available which does not exceed 15 by 15 centimeters (5.9 by 5.9 inches);

Subitem (3) states that all clinically relevant collimation systems must be used; and

Subitem (4) states that a phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five centimeters (1.97 inches) and whose depth is sufficient to perform the required measurements.

These requirements are necessary so everyone measures this parameter in the same manner and different methods of measurement are not being compared. There is no similar recommendation in NCRP reports. This provision is recommended in the CRCPD's SSRCR Section F.9(b)(5)(ii).

Item C states that the registrant must determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutrons, for specified operating conditions. This requirement is necessary because as the energy level of a therapy machine increases above approximately ten MeV, the possibility of neutrons being produced increases dramatically. This could contribute significantly to the absorbed dose to the patient during treatment. If a registrant does not have this information available, a serious misadministration of radiation to a patient could occur. This could have serious consequences to the patient either in treatment or health. There is no similar recommendation in NCRP reports. This is recommended in the CRCPD's SSRCR Section F.9(b)(5)(v).

Subpart 7. Radiation detectors. This subpart states that all therapeutic x-ray systems must be provided with radiation detectors in the radiation head. This requirement is needed so the radiation dose to the patient can be accurately monitored as it is delivered. This is recommended in the CRCPD's SSRCR Section F.9(b)(6).

Item A states that systems or any part of a system installed after the effective date of the proposed rules must measure all therapeutic radiation beams with at least two detectors. These detectors must be incorporated into two separate 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 there is a second system to accurately monitor the radiation dose and terminate the exposure at the end of the predetermined dose. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (f) first sentence, and is recommended in the CRCPD's SSRCR Section F.9(b)(6)(i).

Item B states that systems installed prior to the effective date of the proposed rules must be provided with 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. This is recommended in the CRCPD's SSRCR Section F.9(b)(6)(ii).

Item C states that the radiation detector and dose monitoring system into which that radiation detector is incorporated must meet the following requirements:

> Subitem (1) states that each radiation detector must be removable only with tools and must be interlocked to prevent incorrect positioning.

This requirement is necessary because the radiation detector must be removable only with the use of tools. 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 this mistake cannot occur as easily. Likewise if the radiation detector were not interlocked to prevent incorrect positioning, the radiation dose would not be properly monitored thus possibly causing a serious misadministration of radiation. There is no recommendation in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(a).

> Subitem (2) states that each radiation detector must form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

This requirement is necessary so a correct absorbed dose may be calculated for each patient's treatment. If it is not possible to accurately use a dose monitoring system to calculate an absorbed dose at a reference point in a treatment volume, a serious misadministration of radiation could occur. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(b).

> Subitem (3) states that each dose monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation.

This requirement is necessary so each dose monitoring system can monitor, interrupt or terminate irradiation. If only one system has this capability and it should fail, there could be a serious misadministration of radiation. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(c).

> Subitem (4) states that the design of the dose monitoring system must assure that:

Sub-subitem (a) states that the malfunctioning of one dose monitoring system does not affect the correct functioning of the second dose monitoring system; and

Sub-subitem (b) states 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 each dose monitoring system is not dependent upon the correct functioning of the other dose monitoring system and if there is a failure of an element common to both dose monitoring systems, the failure causes the termination of irradiation. If the systems do not work in this manner, there could be a serious misadministration of radiation. There is no recommendation in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(d).

Subitem (5) states that each dose monitoring system must have a legible display at the treatment control panel. In addition, for dose monitoring systems installed after the effective date of the proposed rules, each display must:

This requirement is necessary so that the operator can easily read the display at the treatment control panel before, during and after each treatment. In this way the operator clearly knows how much radiation has been received by the patient. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(e).

Sub-subitem (a) states that the dose monitoring system must maintain a reading until it is intentionally reset to zero;

This requirement is necessary so the operator may record the actual dose given to the patient. In the event of a failure in any part of the system, it is critical to know how much radiation the patient has received, whether it was too much or not enough. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(e)(1).

Sub-subitem (b) states that the dose monitoring system must have only one scale and no scale multiplying factors;

This requirement is necessary so the operator may record the actual dose given to the patient. If there were more than one scale or scale multiplying factors are required there could be confusion for the operator when the reading is recorded. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(e)(2).

Sub-subitem (c) states that each dose monitoring system must use a design so any increased dose is displayed by increasing numbers and must be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined;

This requirement is necessary so the operator can keep track of the actual dose rate and actual dose given to the patient. In addition, if there is an overdose of radiation, it is very important to be able to accurately estimate how much radiation the patient actually receives. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(e)(3).

Sub-subitem (d) states that each dose monitoring system must display the dose monitoring information required by this subitem at the control panel and be retrievable in at least one dose monitoring system for a five-minute period of time in the event of a power failure.

This requirement is necessary so an accurate dose record can be maintained for the patient being treated when a power failure occurs. If this were not possible the actual dose the patient being treated received would not be accessible. This could cause serious problems in trying to plan the rest of the patient's treatment protocol. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(6)(iii)(e)(4). The CRCPD's SSRCR recommended requirement states that the dose monitoring information should be retrievable for a twenty-minute period of time instead of the five minute period proposed. The consensus of the radiation control unit staff and the Rule Advisory Work Group is that a five-minute time period is a long enough time period because procedures in most facilities are to take care of the patient and attend to the control panel readings immediately in the event of a power failure.

Subitem (6) states that the internal dose monitoring system must be capable of delivering a dose that varies by less than two percent over a 12-hour period.

This requirement is necessary so the actual dose being delivered to the patient does not vary by more than two percent over a 12-hour period. This is a requirement that ensures that the internal dose monitoring system is reproducible within acceptable limits. There is no recommendation in NCRP reports or recommended in the CRCPD's SSRCR. This requirement was proposed by radiation control unit staff and members of the Rule Advisory Work Group to fill a loophole.

Subpart 8. Beam symmetry. This subpart states that for system installed after the effective date of the proposed rules that has the capacity to produce useful beams with asymmetry exceeding five percent, the asymmetry of the radiation beam in two orthogonal directions must be monitored before the beam passes through the beam limiting device. The asymmetry must be measured for a 30 square centimeter (4.65 square inch) field at a depth of ten centimeters (3.9 inches) at the points that correspond to 80 percent of the full width half maximum of the central axis value. In addition, capabilities must be provided so that, if the difference in dose rate between one region of the body and another symmetrically displaced from the central axis of the beam exceeds five percent of the central axis dose rate, indication of the dose rate difference is made at the control panel and if the difference exceeds five percent the irradiation is terminated. This requirement is necessary to prevent uneven distribution of the dose rate across the treatment field. If the dose rate exceeds five percent, a serious misadministration of radiation could occur, therefore it is necessary that the machine terminate the irradiation at that time. This parameter is measured at a very specific location with respect to the radiation field, for a certain size field at points which correspond to 80 percent of the full width half maximum of the central axis value. By being this specific in the measurement protocol, there can be no comparison of other protocols to compare with. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (b), and is recommended in the CRCPD's SSRCR Section F.9(b)(7). There is a difference between the wording in both the NCRP reports and the CRCPD's SSRCR. The final version of the proposed rule was drafted with the assistance of the medical physicists such as Joel Gray, Mary Fox, and J. Thomas Payne on the Rule Advisory Work Group and other medical physicists in the state with known expertise in this field like Edwin McCullough. The portion they drafted was the second sentence in the first paragraph with respect to where this parameter is to be tested. They thought it was more precise to specify this measurement location up front rather than have to compare alternate methods after the fact. In addition, the CRCPD's SSRCR recommendation indicates the termination should take place at ten percent not five percent as proposed. The consensus of the radiation control unit staff and members of the Rule Advisory Work Group is that at more than five percent there already is enough of a difference that radiation should be terminated. Ten percent was deemed as too long to wait for the system to terminate irradiation. Serious misadministration of radiation could occur long before the ten percent difference is achieved.

Subpart 9. Selection and display of dose monitor units. This subpart specifies that all x-ray and electron therapy systems provide for the selection and display of dose monitor units according to this subpart. This requirement is necessary so the

operator has accurate information on how much radiation has been received by the patient.

Item A states that irradiation must not be possible until a selection of a number of dose monitor units has been made at the treatment control panel. This requirement is necessary so the system will not irradiate a patient with a "zero" setting at the control panel. If this type of irradiation were possible, a serious misadministration of radiation is possible. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (k), and is recommended in the CRCPD's SSRCR Section F.9(b)(8)(i).

Item B states that the preselected number of dose monitor units must be displayed at the treatment control panel until reset manually for the next irradiation. This requirement is necessary so the operator has knowledge of how many dose monitor units are given to the patient. This must be recorded in the patient's record to track the number of treatments the patient has received. If the reading was not maintained on the treatment control panel until reset for the next patient, the operator may not record the correct number of dose monitor units for the current patient. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(8)(ii).

Item C states that it must be necessary to manually reset the preselected dose monitor units after irradiation is terminated and before irradiation can be reinitiated on systems installed after the effective date of the proposed rules. This requirement is necessary so the operator is required to manually reset the number of preselected dose monitor units at the treatment control panel. In this manner the operator has to verify that the preselected dose monitor units are correct before the next patient may be treated. If this were not the case, the operator would not be checking the treatment control panel and all patients could receive the same preselected dose monitor units. This could lead to serious misadministrations of radiation. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(8)(iv).

Subpart 10. Termination of irradiation by the dose monitoring system or systems during stationary beam therapy. This subpart states that all x-ray and electron therapy systems must meet the requirements in this subpart regarding termination of irradiation by dose monitoring systems during stationary beam therapy. This requirement is necessary so the patient is not over irradiated during treatment.

Item A states that each primary system must terminate irradiation when the preselected number of dose monitor units has been detected by the system. 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 a preselected number of dose monitor units a serious misadministration of radiation could occur. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(9)(i).

Item B states that if the original design of the system included a second dose monitoring system, that system must be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system. This requirement is necessary because it sets an upper limit to the amount of radiation that must be detected before termination of irradiation is implemented. If this secondary dose monitoring system did not terminate irradiation at this point, a serious misadministration of radiation could occur. This requirement is recommended in the CRCPD's SSRCR section F.9(b)(9)(i).

Item C states that systems installed after the effective date of the proposed rules they must have a second dose monitoring system which terminates irradiation when not more than ten percent or 25 dose monitor units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system. This requirement is necessary because it sets an upper limit to the amount of radiation that must be detected before termination of irradiation is implemented. If this secondary dose monitoring system did not terminate irradiation at this point, a serious misadministration of radiation could occur. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (f), and this requirement is recommended in the CRCPD's SSRCR Section F.9(b)(9)(iii).

Item D states that systems installed after the effective date of the proposed rules must have an indicator on the control panel that shows which dose monitoring system has terminated irradiation. This requirement is necessary so the operator knows how much radiation was given to a particular patient and whether to check for misoperation of the primary dose monitoring system. It is critical to know these things so repairs can be made before a number of patients receive more than their prescribed dose during treatment. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(9)(iv).

Subpart 11. Interruption switches. This subpart states that all x-ray and electron therapy systems must meet the requirements in this subpart regarding switches that allow the interruption of irradiation. This requirement is necessary so irradiation of a patient may be interrupted during treatment. This may occur during treatment for a number of reasons but usually relating to patient safety.

Item A states that it must be possible to interrupt irradiation and equipment movement at any time from the operator's position at the treatment control panel. This requirement is necessary to protect the patient's safety. If this requirement was not present a treatment would have to go to completion before it could be terminated. If the patient is having a medical problem during treatment or if the therapy equipment itself has a malfunction, it is necessary to terminate the irradiation immediately. Otherwise a serious misadministration of radiation could occur. Examples of reasons are the following: the patient has moved and the therapy beam is no longer directed at the correct portion of the anatomy, or, the wedge tray may slip in its location thus allowing more radiation to a particular part of the body than was originally intended. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(10) first sentence.

Item B states that emergency off switches must be placed on the treatment console, on a wall outside the treatment room. Inside the treatment room, emergency off switches must be placed on the treatment couch, on walls to the right and left of the couch, in front of the primary beam, and in the gantry stand. This requirement is needed to protect the operator as well as the patient. With the emergency off switches located in so many locations, the operator may terminate the irradiation at the treatment control panel, or, if for any reason one of the operators or someone assisting the operator is caught in the room when a treatment begins, that person may push an emergency off switch at many places in the room to terminate the irradiation without having to cross through the radiation beam. This was an additional safety requirement that was the consensus of the radiation control unit staff and members of the Rule Advisory Work Group that is necessary to protect the persons that enter a treatment room, for any purpose. There is no similar recommendation in the CRCPD's SSRCR.

Subpart 12. Termination switches. This requirement states that all x-ray and electron therapy systems must have termination switches that make it possible to terminate irradiation and equipment movements, or go from an interruption condition to termination condition at any time 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. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(11).

Subpart 13. Timer. This subpart requires that all x-ray and electron therapy systems have a timer that meets the requirements

in this subpart. This requirement is necessary so irradiation of a patient may be accurately timed for each treatment and as a back-up device to protect against over-irradiation due to failure of preset integrating dose meters.

Item A states that a timer which has 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 necessary to visibly display where in the therapy cycle the treatment actually is for the operator. If for any reason the treatment must be interrupted, it is critical that the operator knows where the treatment was interrupted so when treatment is resumed the operator knows if the correct treatment was given. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (f), and is recommended in the CRCPD's SSRCR Section F.9(b)(12)(i).

Item B states that the timer must be a cumulative timer which activates with the production of radiation and returns its reading after irradiation is interrupted or terminated. 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 way the operator knows the actual time of exposure so that if the treatment has been interrupted, the correct time may be entered to finish the treatment. If the treatment is finished, this time is necessary to record in the patient's record to show much radiation the patient has received. The second sentence of this requirement is necessary so the operator has to manually reset the timer to zero, essentially clearing the timer, before resetting to the new treatment setting before irradiation may proceed. In this way there should be no carryover of the one patient's setting to the next patient. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (k), and is recommended in the CRCPD's SSRCR Section F.9(b)(12)(ii).

Item C states for systems installed after the effective date of the proposed rules that after termination of irradiation and before irradiation can be reinitiated, it must be necessary to manually reset the preset time selector. This requirement is necessary so the operator has to manually reset the timer to zero, essentially clearing the timer, before resetting to the new treatment setting before irradiation may proceed. In this way there should be no carryover of one patient's setting to the next. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (k), and is recommended in the CRCPD's SSRCR Section F.9(b)(12)(iii).

Item D states that the timer must terminate irradiation when a preselected time has elapsed if the dose monitoring systems have

not previously terminated irradiation. This requirement is necessary so the timer acts as 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. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (f), and is recommended in the CRCPD's SSRCR Section F.9(b)(12)(iv).

Item E states that for systems installed after the effective date of the proposed rules if the backup timer is automatically set by control circuitry, the additional time must not be more than ten percent above the time determined by dividing the number of monitor units by the monitor unit irradiation rate. This requirement is similar to subpart 10, item C in that it is setting an upper limit to the amount of over-irradiation that can occur. This requirement is necessary because it sets an upper limit to the amount of time that must be detected before termination of irradiation is implemented. If the dose monitoring systems did not terminate irradiation at this point, the timer will backup those systems, thus preventing a serious misadministration of radiation. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (f). There is no recommendation in the CRCPD's SSRCR.

Subpart 14. Selection of radiation type. This subpart states that therapy systems capable of emitting both x-rays and electrons must allow for the selection of the radiation type according to the requirements in this subpart. This requirement is necessary because of the energy level difference between x-rays and electrons. Therapy with x-rays produces much different results from therapy with electrons, thus there is a very critical need to be able to differentiate between the two. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(13).

Item A states that 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 difference between x-rays and electrons. Therapy with x-rays produces much different results from therapy with electrons, thus there is a very critical need to be able to differentiate between the two. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (c), and this requirement is recommended in the CRCPD's SSRCR Section F.9(b)(13)(i).

Item B states that an interlock system must be provided to ensure that the equipment can emit only the radiation type which has been selected. This requirement is necessary to prevent radiation of the wrong type being given to a patient for treatment. There is an energy level difference between x-rays

and electrons. Therapy with x-rays produces much different results from therapy with electrons, thus there is a very critical need to be able to differentiate between the two. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (c), and this requirement is recommended in the CRCPD's SSRCR Section F.9(b)(13)(ii).

Item C states that an interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel. This requirement is necessary to prevent a misadministration of radiation. If conditions in the treatment room are not the same as on the treatment control panel, it could happen that a patient received x-rays instead of electron beam therapy thus giving the patient the wrong energy level and amount of radiation than that which was prescribed. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (c), and is recommended in the CRCPD's SSRCR Section F.9(b)(13)(iii).

Item D states that an interlock system must be provided to prevent irradiation with x rays except to obtain a port film when electron applicators are fitted. This requirement is necessary to prevent x-ray irradiation of the patient when electron applicators are fitted except when a port film is being taken. This requirement could prevent a misadministration of radiation. This requirement is necessary to prevent radiation of the wrong type being given to a patient for treatment. There is an energy level difference between x-rays and electrons. Therapy with x-rays produces much different results from therapy with electrons. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(13)(iv).

Item E states that the radiation type selected must be displayed at the treatment control panel before and during irradiation. This requirement is necessary so the operator has knowledge of what radiation type is being given to the patient. This must be recorded in the patient's record in order to track the number of treatments of which energy level the patient has received. If the reading was not maintained on the treatment control panel until reset for the next patient, the operator may not record the radiation type for the current patient. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(13)(v).

Subpart 15. Selection of energy. This subpart states that systems capable of generating radiation beams of different energies must allow for the selection of the energy value according to the requirements in this subpart. This requirement is necessary because of the energy level difference between radiation beams of different energies. Therapy with four MeV electrons produces much different results from therapy with ten

MeV electrons, thus there is a very critical need to be able to differentiate between the two. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(14).

Item A states that irradiation must not be possible until a selection of energy has been made at the treatment control panel. This requirement is necessary to prevent irradiation of the patient with the wrong energy level radiation. This could be a very serious misadministration of radiation. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (c), and the CRCPD's SSRCR Section F.9(b)(14)(i).

Item B states that an interlock must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel. This requirement is necessary to prevent a misadministration of radiation. If conditions in the treatment room are not the same as on the treatment control panel, it could happen that a patient received four MeV electrons instead of ten MeV electrons thus giving the patient the wrong energy level and amount of radiation than that which was prescribed. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (c), and the CRCPD's SSRCR Section F.9(b)(14)(ii).

Item C states that the nominal energy value and photon or electron modality selected must be displayed at the treatment control panel before and during irradiation. This requirement is necessary to visibly display for the operator what energy value the patient is receiving. If for any reason the treatment must be interrupted, it is critical that the operator knows what the energy level was for the treatment when it was interrupted so that when the treatment is resumed the operator will be able to correctly set the energy value again. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (f), and in the CRCPD's SSRCR Section F.9(b)(14)(iii).

Subpart 16. Selection of stationary beam therapy or moving beam therapy. This subpart states that systems capable of both stationary and moving beam therapy must allow for the selection of stationary or moving beam therapy according to the requirements in this subpart. This requirement is necessary because each type of therapy is intended to irradiate different parts of the patient's body. Incorrect selection of the type of therapy could cause a serious misadministration of radiation. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(15).

Item A states that irradiation must not be possible until a selection of stationary or moving beam therapy has been made at the treatment control panel. This requirement is necessary

because each type of therapy is intended to irradiate different parts of the patient's body. Stationary beam therapy is intended to expose a specific part of the body and only that part. Moving beam therapy, as the name implies, is intended to be used with the therapy beam moving and covering a specified portion of the body but the portion may be spread around the curve of that body portion. Incorrect selection of the type of therapy could cause a serious misadministration of radiation. This requirement is similar to the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (e), and this requirement is recommended in the CRCPD's SSRCR Section F.9(b)(15)(i).

Item B states that an interlock system must be provided to ensure that the equipment can operate only in the mode which has been selected. This requirement is necessary because each type of therapy is intended to irradiate different parts of the patient's body. Stationary beam therapy is intended to expose a specific part of the body and only that part. Moving beam therapy, as the name implies, is intended to be used with the therapy beam moving and covering a specified portion of the body but the portion may be spread around the curve of that body portion. If the interlock were not in place and functioning this could cause a serious misadministration of radiation. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (e), and the CRCPD's SSRCR Section F.9(b)(15)(ii).

Item C states that an interlock system must be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel. This requirement is necessary to prevent a misadministration of radiation. If conditions in the treatment room are not the same as on the treatment control panel, it could happen that a patient could receive stationary beam therapy when the patient was supposed to receive moving beam therapy. This could change the amount of radiation than that which was prescribed. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (e), and this requirement is recommended in the CRCPD's SSRCR Section F.9(b)(15)(iii).

Item D states that the mode of operation must be displayed at the treatment control panel. This requirement is necessary so that the operator has knowledge of what therapy mode is being given to the patient. This must be recorded in the patient's record in order to track the number of treatments of which mode the patient has received. If the mode was not maintained on the treatment control panel until reset for the next patient, the operator may not record the therapy mode for the current patient. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(15)(iv).

Item E states that for systems installed after the effective date of the proposed rules an interlock system must be provided to terminate irradiation if:

> (1) movement of the gantry occurs during stationary beam therapy; or
>
> (2) movement of the gantry stops during moving beam therapy unless stoppage is a preplanned function.

This requirement is necessary because each type of therapy is intended to irradiate different parts of the patient's body. Stationary beam therapy is intended to expose a specific part of the body and only that part. Moving beam therapy as the name implies is intended to be used with the therapy beam moving and covering a specified portion of the body but the portion may be spread around the curve of that body portion. If the interlock were not in place and functioning, and one of the aforementioned movements of the gantry occurs, this could cause a serious misadministration of radiation. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.2.3.1, paragraph (e), and the CRCPD's SSRCR Section F.9(b)(15)(v).

Item F states that moving beam therapy must be controlled to provide accurate total dose and arc angle.

> (1) For systems installed after the effective date of the proposed rules where the angle of rotation terminates the radiation, the maximum difference between the delivered and expected monitor units (MU) must not exceed three percent or one MU, whichever is greater. This requirement goes on to specify the method of calculation of the expected MU, the observed terminal gantry angle must be within plus or minus two degrees of expected and states that this requirement applies for all arcs of 45 degrees or more at all MU/degree values specified by the manufacturer as "clinically usable."

This requirement is similar to subpart 10, item B and subpart 13, item E. It set an upper limit to the amount of over-irradiation that may occur. This requirement is necessary because it sets an upper limit to the amount of MU or arc angles that must be detected before termination of irradiation is implemented. If the arc angle or the MU dose monitoring systems did not terminate irradiation at this point, a serious misadministration of radiation could occur. There is no similar recommendation in the NCRP reports. This requirement is based on the CRCPD's SSRCR Section F.9(b)(15)(vi) and (vi)(a). The radiation control unit staff and members of the Rule Advisory Work Group proposed this language to present a requirement that is usable and understandable to all users of this equipment.

(2) For systems installed after the effective date of the proposed rules where the dose monitoring system terminates the irradiation, the maximum difference between the observed and expected angle of rotation of the gantry shall not exceed plus or minus two degrees. This requirement goes on to specify the method of calculation of the expected angle of rotation, the agreement of the expected MU to set MU must be three percent, or one MU, whichever is greater and states that this requirement applies for all arcs of 45 degrees or more at all MU/degree values specified by the manufacturer as "clinically usable."

This requirement is similar to subpart 10, item B, subpart 13, item E, and subpart 16, item F, subitem (1). It set an upper limit to the amount of over-irradiation that may occur. This requirement is necessary because it sets an upper limit to the amount of absorbed dose rate radiation that must be detected before termination of irradiation is implemented. If the component that monitors the absorbed dose rate did not terminate irradiation at this point, a serious misadministration of radiation could occur. There is no recommendation in the NCRP reports. This requirement is based on the CRCPD's SSRCR Section F.9(b)(16)(ii). The radiation control unit staff and the Rule Advisory Work Group propose the specified language to present a value at which termination of irradiation should occur.

Subpart 17. Absorbed dose rate. This subpart states that systems installed after the effective date of the proposed rules must have a component from which readings of the absorbed dose rate at a reference point in the treatment volume can be calculated. It states that the radiation detectors in subpart 7 may form a portion of this system. The requirements in items A and B also apply. This requirement is necessary so the radiation dose to the patient can be accurately monitored as it is being delivered. This is recommended in the CRCPD's SSRCR Section F.9(b)(16).

Item A states that the dose monitor unit rate must be displayed at the treatment control panel. This requirement is necessary so the operator can easily read the display at the treatment control panel. In this way the operator clearly knows how much radiation has been received by the patient. There is no recommendation in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(16)(i).

Item B states that if the system can deliver under any conditions an absorbed dose rate at the nominal treatment distance of more than ten percent above the value specified by the manufacturer for any equipment parameters used, a device must be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The value at which the irradiation will be terminated must be in a record maintained by

the registrant. This requirement is similar to subpart 10, item B, subpart 13, item E and subpart 16, item F, subitem (1). It set an upper limit to the amount of over-irradiation that may occur. This requirement is necessary because it sets an upper limit to the difference between the observed and expected angle of rotation that must be detected before termination of irradiation is implemented. If the angle of rotation or the MU dose monitoring systems did not terminate irradiation at this point, a serious misadministration of radiation could occur. There is no recommendation in NCRP reports. This requirement is based on the CRCPD's SSRCR Section F.9(b)(15)(vi) and (vi)(b). The record keeping required by this subpart is necessary so the operator has ready access to this information to determine if the maximum value has been attained. This could be critical in determining if there was a problem with the system.

Subpart 18. Location of virtual source and beam orientation. This subpart states that the registrant shall determine, or obtain from the manufacturer, the location, with reference to an accessible point on the radiation head, of:

A. the x-ray target or the virtual source of electrons; and

B. the electron window or the virtual source of electrons if the system has electron beam capabilities.

This requirement is necessary so any person who would perform a calibration on this type of equipment can quickly ascertain where the x-ray target or virtual source is on the machine. This is the point from which all radiation is produced and from which all other locations and calculations of many parameters are dependent. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1, paragraph (f) second sentence and is recommended in the CRCPD's SSRCR Section F.9(b)(17).

Subpart 19. System checking facilities. This subpart states that capabilities shall be provided so all radiation safety interlocks can be checked for correct operation. The subpart goes on to state that if preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one location shall not give a display at the other location until the requisite selected operations in both locations have been completed. This requirement is necessary to ensure that the safety interlocks can be tested for correct operation. If the facility were unable to test the interlocks, they could not determine if the interlocks were or were not working properly. Failure of any one of the radiation safety interlocks could cause a serious misadministration of radiation. The requirement that preselection of operating conditions requires action both in the treatment room and at the treatment control panel is a safety

feature to prevent an accidental over-exposure either of the patient or operator. If the wrong set of operating parameters are used because an action was not completed at one of the two locations, a serious misadministration of radiation could occur. There is no similar requirement in the NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section F.9(b)(18).

Subpart 20. Operating procedures. This subpart states that any therapy system with energies greater than one MV shall not be used in the administration of radiation therapy unless the requirements of parts 4730.1670, subpart 4, 4730.1675, subpart 3 and 4730.1680, subpart 2 have been met. The referenced parts refer to radiation safety surveys, spot checks, and calibration and recalibration of the therapy machine. This requirement is needed so the patient receives a radiation dose that is what the treating physician has ordered and the radiation therapy system operates correctly. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.4, paragraphs (a) and (b), Section 5.2.2.3, paragraphs (a) and (b), Section 6.2, Section 6.3.1 and Section 6.3.2, and is recommended in the CRCPD's SSRCR Section F.9(d)(4)(iii).

4730.2475 RADIATION SAFETY REQUIREMENTS FOR THE USE OF MEDICAL PARTICLE ACCELERATORS.

Subpart 1. Applicability. This subpart states that in addition to the requirements of parts 4730.0100 to 4730.1695, this part applies to medical particle accelerators used in the treatment of humans. This part is necessary
because of the design of a medical particle accelerator, the shielded room where it is located, and the different operating procedures for this type of therapeutic x-ray equipment. There are no federal performance standards for therapeutic x-ray systems including medical particle accelerators, however, there are recommended guidelines in various National Council on Radiation Protection and Measurements (NCRP) reports from which the CRCPD's SSRCR recommendations are adopted. This requirement is based on the CRCPD's SSRCR Section I.1(b).

Subpart 2. Medical committee to evaluate and approve medical particle accelerators. This subpart states that the registrant must appoint a medical committee of at least three members to evaluate and approve uses of a medical particle accelerator for diagnosis, research, and therapy on a person. Membership of the committee must include the radiation safety officer and a physician expert in therapeutic radiology. The subpart suggests that other members may include physicians who are experts in internal medicine and hematology. This subpart is necessary to ensure that the medical particle accelerator is used for purposes and according to procedures that protect patients, operators, auxiliary personnel and the general public. The required members

of the committee would have knowledge about radiation safety, the medical particle accelerator, and how large a dose could be given safely to a patient. The intended purpose of this committee is to prevent misadministration of radiation to a patient under the guise of diagnosis, research or therapy. There is no recommendation in NCRP reports. This requirement is based on the CRCPD's SSRCR Section I.4(a).

Subpart 3. Controls and interlock systems. This subpart states that all medical particle accelerators used in the treatment of humans must meet the requirements for controls and interlock systems in this subpart. This subpart is necessary to prevent a serious misadministration of radiation to a patient and protect the operator from radiation exposure.

Item A states that instrumentation, readouts, and controls on the medical particle accelerator control console must be clearly identified and easily discernible. This requirement is necessary so the operator at the control console knows when the medical particle accelerator is operating and the function of any emergency buttons or switches. In this way the operator may shut down the medical particle accelerator system in the event of either a problem with the patient or if someone were inadvertently caught in the medical particle accelerator room during a treatment. These requirements are necessary to reduce exposure to the patient and other persons. There is no recommendation in NCRP reports. This requirement is based on the CRCPD's SSRCR Section I.8(a).

Item B states that each entrance into a treatment room or other high radiation area must be provided with a safety interlock that shuts down the system under conditions of barrier penetration. This requirement is necessary to prevent anyone entering a medical particle accelerator room from receiving an accidental occupational radiation dose in excess of the occupational limits specified in part 4730.0310. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.1 (n), and is recommended in the CRCPD's SSRCR Section I.8(b).

Item C states that each safety interlock must be on a circuit which allows it to operate independently of all other safety interlocks. This requirement is necessary so that in the event of failure of one safety interlock, the other safety interlocks will still be operational thus preventing a possible misadministration of radiation because the safety interlocks were all non-operational. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section I.8(c).

Item D states that all safety interlocks must be designed so any defect or component failure in the safety interlock system prevents operation of the medical particle accelerator. This

requirement is necessary to prevent a misadministration of radiation to the patient and to prevent a possible accidental occupational overexposure to an operator who may inadvertently get caught in the treatment room. There is no recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section I.8(d).

Item E states that when a safety interlock system has been triggered, it must be possible to resume operation of the medical particle accelerator only by manually resetting controls at the position where the safety interlock has been tripped and, lastly, at the main control panel. This requirement is necessary to prevent a misadministration of radiation to the patient and prevent exposure of an operator who may inadvertently get caught in the treatment room by requiring the safety interlock to be reset first where the interlock has been tripped and then at the main control panel. This is recommended in NCRP Report Number 102, Section 5.1.1 (n) and the CRCPD's SSRCR Section I.8(e).

Item F states that emergency "off" switches must be placed on the treatment console and on a wall outside the treatment room. Inside the treatment room, emergency "off" switches must be placed on the treatment couch, on walls to the right and left of the couch, in front of the primary beam, and in the gantry stand. This requirement is necessary to protect the operator or anyone assisting the operator in positioning the patient. In the event that the medical particle accelerator is accidentally started before all personnel clear the treatment room, the staff and anyone assisting the patient can hit an emergency "off" switch to prevent the treatment from starting or going to completion. In this way they would be prevented from receiving an exposure of radiation. This requirement is based on NCRP Report No. 49, Section 6.3, paragraph 8 and the CRCPD's SSRCR Section I.8(f). The wording chosen was the consensus of radiation control unit staff and members of the Rule Advisory Work Group to protect persons that enter a treatment room, for any purpose. The CRCPD's SSRCR recommendation does not go far enough and give persons in the room enough options to stop the exposure from occurring.

Subpart 4. Warning devices. This subpart states that all medical particle accelerators used in the treatment of humans must meet the requirements for warning devices in this subpart. This subpart is necessary to prevent a serious misadministration of radiation to a patient and protect the operator from radiation exposure.

Item A states that each location designated as a high radiation area, and each entrance to such location, must be equipped with easily observable warning lights that operate when, and only when, radiation is produced. This requirement is necessary to warn the operator and anyone in the vicinity of a medical

particle accelerator, which is a high radiation area, that a medical particle accelerator treatment is occurring. This should prevent an accidental overdose of radiation. This requirement is based on the recommendations in NCRP Report No. 102, Section 5.1.2 (d), and the CRCPD's SSRCR Section I.9(a).

Item B states that barriers and pathways leading to high radiation areas must be posted according to part 4730.0300. This requirement is necessary to provide anyone entering a high radiation area with a visible indication that this a high radiation area. This requirement is based on the recommendations in NCRP Report No. 51, Section 2.2.3, and is recommended in the CRCPD's SSRCR Section I.9(c).

Subpart 5. Operating procedures. This subpart states that all medical particle accelerators used in the treatment of humans must be operated according to the procedures in this subpart. This subpart is necessary to prevent a serious misadministration of radiation to a patient and protect the operator from radiation exposure.

Item A states that medical particle accelerators, when not in operation, must be secured to prevent unauthorized use. This subpart is necessary to protect against unauthorized use of the medical particle accelerator system which could cause a serious misadministration of radiation. This requirement is based on NCRP Report No. 102, Section 5.1.1 (o), and is recommended in the CRCPD's SSRCR Section I.10(a).

Item B states that all safety and warning devices, including interlocks, must be checked for proper operation at intervals not to exceed one month. Results of such tests must be recorded in writing and be available at the medical particle accelerator facility for inspection by the commissioner. These records must be maintained until the next inspection by the commissioner. This requirement is based on NCRP Report No. 51, Section 2.2.3 paragraph 5, and this requirement is recommended in the CRCPD's SSRCR Section I.10(c). There is a difference of opinion between the NCRP report, the CRCPD's recommendation, and the proposed requirement. The difference is in the length of time between checking the safety and warning devices. The values range from one month to one year. The consensus of the radiation control unit staff and the Rule Advisory Work Group is that one month should be used because of the seriousness of the situation if a safety and warning device fails.

Item C states that electrical circuit diagrams of the medical particle accelerator and the associated safety interlock systems must be kept current and maintained for inspection by the commissioner and the operator at each medical particle accelerator facility. This requirement is necessary so if there is failure of any component in the system or if there is an

accidental overexposure, it would be necessary to use the electrical circuit diagrams to trace any problems or make changes. If the electrical circuit diagrams are not up to date this could cause considerable delay in correcting problem with the electrical circuitry. There is no similar recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section I.10(d).

Item D states that, if, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action must require:

(1) prior authorization by the radiation safety committee or radiation safety officer;

(2) a record in a permanent log and a notice posted at the medical particle accelerator control console; and

(3) termination as soon as possible.

This requirement is necessary to prevent a possible misadministration of radiation. With safety interlocks bypassed, the realm of the impossible becomes the realm of the possible. By requiring prior authorization of the radiation safety committee or radiation safety officer, this implies they have reviewed the work to be done, considered the benefit of such action, and approved of the bypass as the way to correct another problem. It is necessary to log and post the bypassing to give notice to the operator of the equipment that an abnormal occurrence is happening and preclude the operator from doing anything that might cause further degradation of the system. Lastly, termination shall be as soon as possible. The bypassing should be the exception to the operating conditions, not the normal operating procedure. The shorter the bypassing occurs the less chance that some other problem may occur. There is no similar recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section I.10(e).

Item E states that a copy of the current operating and emergency procedures must at all times be available at the medical particle accelerator control panel. This requirement is necessary so the operator has as much information about how the equipment is supposed to operate and what to do in the event of an emergency. If the operating and emergency procedures were not readily available at the medical particle accelerator there might be a time delay which could cause a more serious misadministration of radiation which for this type of equipment could mean the death of a patient. There is no similar recommendation in NCRP reports. This requirement is recommended in the CRCPD's SSRCR Section I.10(f).

4730.2500 INDUSTRIAL X-RAY INSTALLATIONS.

Subpart 3. The changes to this part are technical clean up amendments. Part 4730.3300 is proposed for repeal. The new proposed rule parts that set maximum permissible doses are parts 4730.0310 to 4730.0380.

4730.2600 RADIUM USE IN THE HEALING ARTS.

The proposed changes to this part are technical clean up amendments. They are necessary to ensure accurate internal reference. The range of rule parts "4730.0100 to 4730.3600" are amended to "this chapter" to ease future reference to rules pertaining to the ionization of radiation. Reference to "this chapter" means all the parts contained within chapter 4730. Part 4730.0300, subpart 4 is proposed for repeal. It would be replaced by the proposed safety requirements in part 4730.1510. If the repeal and new proposed rules are found to be necessary and reasonable, then internal reference to the new rule parts is required. Similarly it is proposed that part 4730.1100 be repealed and replaced with the reporting requirements in parts 4730.1110 to 4730.1140.

4730.2700 RADIUM USED FOR INDUSTRIAL PURPOSES.

The changes to this part are technical clean up amendments. They are necessary to ensure accurate internal reference. Part 4730.1100 is proposed for repeal. It would be replaced by the proposed reporting requirements in parts 4730.1110 to 4730.1140. If the repeal and new proposed rules are found to be necessary and reasonable, then internal reference to the new rule parts is required.

4730.2900 SPECIAL USES OF ELECTRIC EQUIPMENT.

The changes proposed to this part are technical clean up amendments. They are necessary to ensure accurate internal reference. Part 4730.0300 and part 4730.3300 are proposed for repeal. They would be replaced by the proposed requirements in parts 4730.0310 and 4730.0360. If the repeal and new proposed rules are found to be necessary and reasonable, then internal reference to the new rule parts is required.

4730.3600 EXEMPT CONCENTRATIONS.

This part is proposed for repeal because the requirements have been reformatted and included in part 4730.3605.

4730.3605 CONCENTRATIONS IN AIR AND WATER ABOVE NATURAL BACKGROUND.

The provisions of this part are not new. The provision had been previously adopted in part 4730.3600. The new proposed rule part

has been reformatting for clearer drafting. This part is directly from the U. S. Nuclear Regulatory Commission, Title 10, Chapter 1, Code of Federal Regulations, Part 20, Appendix B and from the CRCPD's SSRCR Section D, Appendix A. There have been changes from the word "isotope" to "radionuclide" and the addition of several radionuclides to the existing part 4730.3600. Additional changes were made to the Appendix and are documented in the Federal Register on June 24, 1974 (39 FR 22428) and the final rule was published in the Federal Register on October 31, 1975 (40 FR 50704).

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Exhibit A

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Minnesota Society of Radiologic Technologists
Sue McClanahan, R.T.(R)

Minnesota Veterinary Medicine Association
Daniel A. Feeney, D.V.M.

North Central Chapter, Health Physics Society
Kevin Nelson, M.S.
Jerome W. Staiger, M.S., Alternate