Table of Contents

16.02.27 - Idaho Radiation Control Rules

000. Legal Authority. 3
001. Title And Scope. 3
002. Definitions. 3
003. -- 005. (Reserved). 11
006. Exemptions. 12
007. Records. 12
008. Inspections. 12
009. Tests. 12
010. Additional Requirements. 12
011. Violations. 12
012. Impounding. 12
013. Prohibited Radiation Uses. 12
014. Communications. 12
015. -- 049. (Reserved). 13
050. Registration. 13
051. Scope. 13
052. (Reserved). 13
053. Exemptions For Registration Purposes. 13
054. -- 089. (Reserved). 13
090. Registration. 13
091. Administrative Appeal Of Final Registration Decisions. 16
092. Modified Revocation Of Registration. 16
093. -- 099. (Reserved). 17
100. Standards For Protection Against Radiation. 17
101. -- 109. (Reserved). 17
110. Occupational Exposures. 17
111. -- 119. (Reserved). 19
120. Precautionary Procedures. 19
121. -- 139. (Reserved). 21
140. Records, Reports, And Notifications. 21
141. -- 149. (Reserved). 24
150. Radiation Safety Requirements For Industrial Radiographic Operations. 24
151. -- 152. (Reserved). 24
153. Equipment Control. 24
154. Personal Radiation Safety Requirements For Radiographers And Radiographers' Assistants. 25
155. Precautionary Procedures In Radiographic Operation. 28
156. -- 199. (Reserved). 29
200. Use Of X-Rays In The Healing Arts. 29
201. -- 202. (Reserved). 29
203. General Requirements. 29
204. General Requirements For All Diagnostic X-Ray Systems. 33
205. Fluoroscopic X-Ray Systems. 35
206. Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Or Veterinarian Systems. 39

207. Intraoral Dental Radiographic Systems. 43
208. Veterinary Medicine Radiographic Installations. 45
209. Therapeutic X-Ray Installations. 46
210. X-Ray And Electron Therapy Systems With Energies Of One MeV And Above. 51
211. Radiographic Machines Used For Mammography. 59
212. -- 299. (Reserved). 63
300. Radiation Safety Requirements For Analytical X-Ray Operations. 63
301. -- 319. (Reserved). 63
320. Equipment. 64
321. -- 329. (Reserved). 65
330. Administrative Responsibilities. 65
331. Area Requirements. 65
332. -- 339. (Reserved). 66
340. Operating Procedures. 66
341. -- 349. (Reserved). 67
350. Radiation Safety Requirements For Particle Accelerator Operations. 67
351. -- 352. (Reserved). 67
353. Registration Procedure. 67
354. Radiation Safety Requirements For The Use Of Particle Accelerators. 68
355. -- 439. (Reserved). 70
440. Public And Confidential Information. 70
441. -- 449. (Reserved). 71
450. Notices, Instructions And Reports To Workers -- Inspections. 71
451. -- 995. (Reserved). 75
996. Administrative Provisions. 75
997. Confidentiality Of Records. 75
998. -- 999. (Reserved). 75

16.02.27 - IDAHO RADIATION CONTROL RULES

000. LEGAL AUTHORITY.
The Idaho Legislature in Title 39, Chapters 1 and 30, Idaho Code, has granted to the Board of Health and Welfare the authority to adopt rules governing the control of radiation to protect the health of the citizens of the state. The Idaho Legislature in Title 39, Chapters 1 and 30, Idaho Code, has granted the Director of the Department of Health and Welfare the authority to enforce rules adopted by the Idaho State Board of Health and Welfare. (7-1-98)

001. TITLE AND SCOPE.
These rules shall be cited, in full, as Idaho Department of Health and Welfare Rules, IDAPA 16.02.27, "Idaho Radiation Control Rules". Except as otherwise specifically provided, these rules apply to all persons who possess, use, transfer, own or acquire any radiation machine. (7-1-98)

002. DEFINITIONS.
As used in these rules, the following terms have the definitions set forth below: (7-1-98)

01. Accessible Surface. The external surface of the enclosure or housing provided by the manufacturer. (7-1-98)

02. Act. The "Radiation and Nuclear Material Act," Sections 39-3001 through 39-3024, Idaho Code. (7-1-98)

03. Added Filtration. Any filtration added to the inherent filtration. (7-1-98)

04. Aluminum Equivalent. The thickness of aluminum (Type 1100) affording the same attenuation, under specified conditions, as the material in question. (7-1-98)

05. Analytical X-Ray Equipment. Equipment used for x-ray diffraction or fluorescence analysis. (7-1-98)

06. Analytical X-Ray System. A group of components utilizing x-rays or gamma rays to determine the elemental composition or to examine the microstructure of material. (7-1-98)

07. Assembler. Any person engaged in the business of assembling, replacing, or installing one (1) or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services. (7-1-98)

08. Attenuation Block. A block or stack, having dimensions twenty (20) centimeters by twenty (20) centimeters by three and eight-tenths (3.8) centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation. (7-1-98)

09. Automatic Exposure Control. A device which automatically controls one (1) or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (see also "Phototimer"). (7-1-98)

10. Beam Limiting Device. A device which provides a means to restrict the dimensions of the x-ray field, such as but not limited to collimator, diaphragm, or cone. (7-1-98)

11. Cabinet Radiography. Industrial radiography using radiation machines, which is conducted in an enclosed, interlocked cabinet, such that the radiation machine will not operate unless all openings are securely closed, and the cabinet is so shielded that every location on the exterior meets conditions for an unrestricted area as specified in Subsection 110.04. (7-1-98)

12. Cabinet X-Ray System. An x-ray system with the x-ray tube installed in an enclosure (hereinafter

termed cabinet) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system. (7-1-98)

13. **Calendar Quarter**. Not less than twelve (12) consecutive weeks nor more than fourteen (14) consecutive weeks. The first calendar quarter of each year will begin in January and subsequent calendar quarters will be arranged so that no day is included in more than one (1) calendar quarter and no day in any one (1) year is omitted from inclusion within a calendar quarter. (7-1-98)

14. **Calibration**. The determination of: (7-1-98)

a. The response or reading of an instrument relative to a series of known radiation values over the range of the instrument; or (7-1-98)

b. The strength of a source of radiation relative to a standard. (7-1-98)

15. **Certified Cabinet X-Ray System**. A cabinet x-ray system which has been certified in accordance with 21 CFR 1010.2 as having been manufactured, assembled and maintained pursuant to the provisions of 21 CFR 1020.40. (7-1-98)

16. **Certified Components**. Components of x-ray systems which are subject to regulations promulgated under P.L. 90-602 which is available at all county law libraries. (7-1-98)

17. **Certified System**. Any x-ray system which has one (1) or more certified components. (7-1-98)

18. **CFR**. Code of Federal Regulations. (7-1-98)

19. **Collimator**. A device or mechanism by which the x-ray beam is restricted in size. (7-1-98)

20. **Control Panel**. That part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors. (7-1-98)

21. **Dead-Man Switch**. A switch so constructed that a circuit-closing contact can be maintained only by continuous pressure on the switch by the operator. (7-1-98)

22. **Diagnostic Source Assembly**. The tube housing assembly with a beam-limiting device attached. (7-1-98)

23. **Diagnostic X-Ray System**. An x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization. (7-1-98)

24. **Dose**. Absorbed dose or dose equivalent as appropriate. (7-1-98)

a. Absorbed dose is the energy imparted to matter by ionizing radiation per unit mass of irradiated material at the place of interest. The special unit of absorbed dose is the rad (see “Rad”). (7-1-98)

b. Dose equivalent is a quantity that expresses on a common scale for all radiation a measure of the postulated effect on a given organ. It is defined as the absorbed dose in rads times certain modifying factors. The unit of dose equivalent is the rem (see “Rem”). (7-1-98)

25. **Entrance Exposure Rate**. The exposure per unit time at the point where the center of the useful beam enters the patient. (7-1-98)

26. **Exposure**. The quotient of dQ by dm where “dQ” is the absolute value of the total charge of the

ions of one (1) sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air (the special unit of exposure is the roentgen (R)). (7-1-98)

27. **Exposure Rate**. The exposure per unit of time, such as roentgen per minute and milliroentgen per hour. (7-1-98)

28. **Facility**. The location at which one (1) or more radiation machines are installed and/or located within one (1) building, vehicle, or under one (1) roof and are under the same administrative control. (7-1-98)

29. **Fail-Safe Characteristics**. A design feature which causes beam port shutters to close, or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device. (7-1-98)

30. **Filter**. Material placed in the useful beam to absorb preferentially the less penetrating radiations. (7-1-98)

31. **Fluoroscopic Imaging Assembly**. A component which comprises a reception system in which x-ray photons produce a fluoroscopic image, including equipment housings, electrical interlocks if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly. (7-1-98)

32. **General Purpose Radiographic X-Ray System**. Any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions. (7-1-98)

33. **Gonadal Shield**. A protective barrier for the testes or ovaries. (7-1-98)

34. **Half-Value Layer (HVL)**. The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the exposure rate by one-half (1/2). (7-1-98)

35. **Healing Arts**. Medicine, dentistry, chiropractic, podiatry, osteopathy, and veterinary medicine. (7-1-98)

36. **Healing Arts Screening**. The testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment. (7-1-98)

37. **High Radiation Area**. Any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one (1) hour a dose in excess of one hundred (100) millirems. (7-1-98)

38. **Human Use**. The internal or external administration of radiation to human beings. (7-1-98)

39. **Image Intensifier**. A device, including housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density. (7-1-98)

40. **Image Receptor**. Any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. (7-1-98)

41. **Individual**. Any human being. (7-1-98)

42. **Industrial Radiography**. The examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation. (7-1-98)

43. **Inherent Filtration**. The filtration permanently in the useful beam, including the window of the x-ray tube and any permanent tube or source enclosure. (7-1-98)

44. **Inspection**. An official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Radiation Control Agency. (7-1-98)

45. **Interlock**. A device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur. (7-1-98)

46. **Kilovolts Peak (kVp)**. See "Peak Tube Potential". (7-1-98)

47. **Lead Equivalent**. The thickness of lead affording the same attenuation, under specified conditions, as the material in question. (7-1-98)

48. **Leakage Radiation**. Radiation emanating from the diagnostic or therapeutic source assembly except for: (7-1-98)

a. The useful beam; and (7-1-98)

b. Radiation produced when the exposure switch or timer is not activated. (7-1-98)

49. **Leakage Technique Factors**. The technique factors associated with the diagnostic or therapeutic source assembly which are used in measuring leakage radiation. They are defined as follows: (7-1-98)

a. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten (10) millicoulombs, i.e., ten (10) milliampere seconds, or the minimum obtainable from the unit, whichever is larger. (7-1-98)

b. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum- rated peak tube potential. (7-1-98)

50. **Light Field**. That area of the intersection of the light beam from the beam-limiting device and one (1) of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth (1/4) of the maximum in the intersection. (7-1-98)

51. **Local Components**. Part of an analytical x-ray system including areas that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but not including power supplies, transformers, amplifiers, readout devices, and control panels. (7-1-98)

52. **Normal Operating Procedures**. Step-by-step instruction necessary to accomplish the analysis. These procedures must include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant and data recording procedures, which are related to radiation safety. (7-1-98)

53. **Occupational Dose**. Exposure of an individual to radiation in a restricted area or exposure in the course of employment in which the individual's duties involve exposure to radiation, provided, that occupational dose will not be deemed to include any exposure of an individual to radiation for the purpose of diagnosis or therapy of such individual. (7-1-98)

54. **Open Beam Configuration**. An analytical x-ray system in which an individual could accidently place some part of his body in the primary beam path during normal operation. (7-1-98)

55. **Particle Accelerator**. The term "particle accelerator" is very broad and covers many types of devices. It is generally defined as a device used to impart kinetic energy to electrically charged particles such as electrons, protons, deuterons, and helium ions, and is referred to herein to designate devices that accelerate particles to energies greater than approximately one (1) MeV, or to neutron generators which operate with a potential of about

one hundred fifty (150) kv. Such accelerators as cyclotrons, betatrons, linear accelerators, Van de Graaff accelerators, Cockcroft- Walton type neutron generators, and resonant transformers are included. (7-1-98)

56. **Peak Tube Potential**. The maximum value of the potential difference across the x-ray tube during an exposure. (7-1-98)

57. **Permanent Radiographic Installation**. An installation or structure designed or intended for radiography and in which radiography is regularly performed. (7-1-98)

58. **Person**. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other state, or political subdivision or agency thereof, any legal successor, representative, agent or agency of the foregoing. (7-1-98)

59. **Personal Supervision**. Supervision in which the authorized operator of an x-ray unit or radioisotopic device is physically present at the site where sources of radiation and associated equipment are being used, watching the performance of the assistant or trainee and in such proximity that immediate assistance can be given if required. (7-1-98)

60. **Personnel Monitoring**. The determination of exposure to a person. (7-1-98)

61. **Personnel Monitoring Equipment**. Devices designed to be worn or carried by an individual for the purpose of estimating the dose received, such as film or thermoluminescent dosimetry badges, pocket chambers, pocket dosimeters, or film and thermoluminecsent dosimetry rings. (7-1-98)

62. **Phototimer**. A method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device. The radiation monitoring device is part of an electronic circuit which controls the duration of time the tube is activated. (7-1-98)

63. **Physician**. An individual licensed by the Idaho State Board of Medicine to practice medicine. (7-1-98)

64. **Position Indicating Device (PID)**. A device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device. (7-1-98)

65. **Primary Beam**. Radiation which passes through an aperture of the source housing by a direct path from the x-ray tube or a radioactive source located in the radiation source housing. (7-1-98)

66. **Protective Apron**. Apron made of radiation absorbing materials, used to reduce radiation exposure. (7-1-98)

67. **Protective Barrier**. A barrier of radiation attenuating materials used to reduce radiation exposure. (7-1-98)

a. Primary Protective Barrier. A barrier sufficient to attenuate the useful beam to the required degree to assure compliance with Subsections 110.01, 110.03, and 110.04. (7-1-98)

b. Secondary Protective Barrier. A barrier sufficient to attenuate stray radiation to the required degree to assure compliance with Subsections 110.01, 110.03, and 110.04. (7-1-98)

68. **Protective Glove**. Glove made of radiation absorbing materials used to reduce radiation exposure. (7-1-98)

69. **Qualified Expert**. An individual who has demonstrated to the satisfaction of the Radiation Control Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs. (7-1-98)

70. **Rad**. The special unit of absorbed dose. One (1) rad equals one one-hundredth (.01) of a joule per kilogram of material. For example, if tissue is the material of interest, then one (1) rad equals one hundred (100) ergs per gram of tissue. (7-1-98)

71. **Radiation**. Ionizing radiation, that is, gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons, protons, and other atomic particles. (7-1-98)

72. **Radiation Area**. Any area, accessible to individuals, in which there exists radiation at such levels that a major portion of the body could receive in any one (1) hour a dose in excess of five (5) millirem, or in any five (5) consecutive days a dose in excess of one hundred (100) millirem. (7-1-98)

73. **Radiation Control Agency**. The Idaho Department of Health and Welfare. (7-1-98)

74. **Radiation Machine**. Any device capable of producing radiation except devices which produce radiation only from radioactive material. (7-1-98)

75. **Radiation Safety Officer**. An individual who has the knowledge and responsibility to apply appropriate radiation protection principles and rules. (7-1-98)

76. **Radiograph**. An image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record. (7-1-98)

77. **Radiographer**. Any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these rules and all conditions of licensure. (7-1-98)

78. **Radiographer's Assistant**. Any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools, or survey instruments in industrial radiography. (7-1-98)

79. **Radiographic Imaging System**. Any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation. (7-1-98)

80. **Radiological Physicist**. An individual who: (7-1-98)

a. Is certified by the American Board of Radiology in therapeutic radiological physics, radiological physics, or x- and gamma-ray physics; or (7-1-98)

b. Has a bachelor's degree in one of the physical sciences or engineering and three (3) years full-time experience working in therapeutic radiological physics under the direction of a physicist certified by the American Board of Radiology. The work duties must include duties involving the calibration and spot-checks of a medical accelerator or a sealed source teletherapy unit; or (7-1-98)

c. Has a Master's or a Doctor's degree in physics, biophysics, radiological physics, health physics, or engineering; has had one (1) year's full-time training in therapeutic radiological physics; and has had one (1) year's full-time work experience in a radiotherapy facility where the individual's duties involve calibration and spot-checks of a medical accelerator or a sealed source teletherapy unit. (7-1-98)

81. **Rating**. The operating limits as specified by the component manufacturer. (7-1-98)

82. **Registrant**. Any person who owns or possesses any device capable of emitting radiation which is registered with the Radiation Control Agency. (7-1-98)

83. **Registration**. The filing with the Radiation Control Agency of all devices capable of emitting radiation in accordance with these rules. (7-1-98)

84. **Rem**. A measure of dose equivalent. One (1) millirem (mrem) equals one one-thousandth (.001)

rem. For the purpose of these rules, any of the following is considered to be equivalent to a dose of one (1) rem: (7-1-98)

a. An exposure of one (1) R of x-, or gamma radiation; or (7-1-98)

b. An absorbed dose of one (1) rad due to x-, gamma, or beta radiation; or (7-1-98)

c. An absorbed dose of one-tenth (0.1) rad due to neutrons or high energy protons. (7-1-98)

d. If it is more convenient to measure the neutron flux, or equivalent, than to determine the neutron dose in rads, one (1) rem of neutron radiation can, for purposes of these rules, be assumed to be equivalent to fourteen million (14,000,000) neutrons per square centimeter incident upon the body; or, if there exists sufficient information to estimate with reasonable accuracy the approximate distribution in energy of the neutrons, the incident number of neutrons per square centimeter equivalent to one (1) rem can be estimated from the following table.

NEUTRON FLUX DOSE EQUIVALENTS TABLE		
Neutron Energy (MeV)	**Number of Neutrons per Square Centimeter Equivalent to a Dose of 1 Rem (Neutron/cm^2)**	**Average Flux to Deliver 100 Millirem in 40 Hours (Neutrons/ cm^2 per Second)**
Thermal	970×10^6	670
0.001	720×10^6	500
0.005	820×10^6	570
0.02	400×10^6	280
0.1	120×10^6	80
0.5	43×10^6	30
1.0	26×10^6	18
2.5	29×10^6	20
5.0	26×10^6	18
7.5	24×10^6	17
10.0	24×10^6	17
10 to 30	14×10^6	10

(7-1-98)

e. An absorbed dose of five one-hundredths (0.05) rad due to particles heavier than protons and with sufficient energy to reach the lens of the eye. (7-1-98)

85. **Restricted Area**. Any area access to which is controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and/or radioactive material. Restricted area does not include any areas used for residential quarters, although a separate room or rooms in a residential building can be set apart as a restricted area. (7-1-98)

86. **Roentgen**. A measure of the exposure of x- or gamma radiation in terms in the electric charge produced in air. One (1) Roentgen (R) is defined as the amount of x- or gamma radiation required to produce by ionization 2.58×10^4 coulomb of ions per kilogram of dry air. (7-1-98)

87. **Scattered Radiation**. Radiation that, during passage through matter, has been deviated or deflected in direction. (7-1-98)

88. **Shielded Room Radiography**. Industrial radiography conducted in an enclosed room so shielded that every location on the exterior meets the conditions as specified in Subsection 110.04. (7-1-98)

89. **Shutter**. A device, attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly. (7-1-98)

90. **Source-Image Receptor Distance (SID)**. The distance from the source to the center of the input surface of the image receptor. (7-1-98)

91. **Source of Radiation**. Any radioactive material, or any device or equipment emitting or capable of producing radiation. (7-1-98)

92. **Spot Film**. A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure. (7-1-98)

93. **Spot Film Device**. A device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor, including clip-on cassette holders. (7-1-98)

94. **SSD (Source Skin Distance)**. The distance between the source of radiation and the skin of the patient. (7-1-98)

95. **Stray Radiation**. The sum of leakage and scattered radiation. (7-1-98)

96. **Survey**. An evaluation of the production, use, release, disposal, and/or presence of sources of radiation under a specific set of conditions to determine actual or potential radiation hazards. When appropriate, such evaluation includes, but is not limited to tests, physical examination, and measurements of levels of radiation or concentration of radioactive material present. (7-1-98)

97. **Technique Factors**. The conditions of operation are specified as follows: (7-1-98)

a. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs; and (7-1-98)

b. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses; and (7-1-98)

c. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs. (7-1-98)

98. **Temporary Job Site**. Any location where industrial radiography is performed other than the location(s) listed in a certificate of registration. (7-1-98)

99. **Termination of Irradiation**. The stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel. (7-1-98)

100. **Test**. The process of certifying compliance with an applicable rules. (7-1-98)

101. **These Rules**. Idaho Department of Health and Welfare Rules, IDAPA 16, Title 02, Chapter 27, Sections 000 through 999, “Idaho Radiation Control Rules”. (7-1-98)

102. **Traceable to a National Standard**. When a quantity or a measurement has been compared to a national standard directly or indirectly through one (1) or more intermediate steps and when all comparisons have been documented. (7-1-98)

103. **Tube**. An x-ray tube, unless otherwise specified. (7-1-98)

104. Tube Housing Assembly. The tube housing with tube installed, including high-voltage and/or filament transformers and other appropriate elements when contained within the tube housing. (7-1-98)

105. Tube Rating Chart. The set of curves which specify the rated limits of operation of the tube in terms of the technique factors. (7-1-98)

106. Unrestricted Area. Any area access to which is not controlled by the licensee or registrant for purposes of protection of individuals from exposure to radiation and radioactive materials, and any area used for residential quarters. (7-1-98)

107. Useful Beam. The radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation. (7-1-98)

108. Variable-Aperture Beam-Limiting Device. A beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given source to image distance (SID). (7-1-98)

109. Visible Area. That portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image. (7-1-98)

110. Worker. An individual engaged in work under a registration issued by the Radiation Control Agency and controlled by a registrant, not including the registrant. (7-1-98)

111. X-Ray Control. A device which controls input power to the x-ray high-voltage generator and/or the x-ray tube, including equipment such as timers, phototimers, automatic brightness stabilizers and similar devices which control the technique factors of an x-ray exposure. (7-1-98)

112. X-Ray Equipment. An x-ray system, subsystem or component thereof. (7-1-98)

a. Mobile. X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled. (7-1-98)

b. Portable. X-ray equipment designed to be hand-carried. (7-1-98)

c. Stationary. X-ray equipment installed in a fixed location. (7-1-98)

113. X-Ray Field. That area of the intersection of the useful beam and any one (1) of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth (1/4) of the maximum in the intersection. (7-1-98)

114. X-Ray High-Voltage Generator. A device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential, including but not limited to a means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements. (7-1-98)

115. X-Ray Source. The focal spot of the x-ray tube. (7-1-98)

116. X-Ray System. An assemblage of components for the controlled production of x-rays, including an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures; additional components which function with the system are considered integral parts of the system. (7-1-98)

117. X-Ray Tube. Any electron tube which is designed for the conversion of electrical energy into x-ray energy. (7-1-98)

003. -- 005. (RESERVED).

006. EXEMPTIONS.
The Radiation Control Agency can, upon application therefor or upon its own initiative, grant such exemptions or exceptions from the requirements of these rules as it determines are authorized by law and will not result in undue hazard to public health and safety and/or property. (7-1-98)

007. RECORDS.
Each registrant must keep records showing the receipt, transfer, and disposal of all radiation machines. Additional record requirements are specified elsewhere in these rules. (7-1-98)

008. INSPECTIONS.

01. Preregistration Inspections. The Agency has the right to conduct prelicensing inspections to verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a registration and whether any special conditions must be attached thereto by visiting the facility or location where radiation machines would be possessed or used. (7-1-98)

02. Inspections of Facilities. Each registrant must afford the Agency at all reasonable times opportunity to inspect radiation machines and the premises and facilities wherein such radiation machines are used or stored. (7-1-98)

03. Inspections of Records. Each registrant will make available to the Agency for inspection, upon reasonable notice, records maintained pursuant to these rules. (7-1-98)

009. TESTS.
Each registrant must perform or permit the Radiation Control Agency to perform such reasonable tests as the Radiation Control Agency deems appropriate or necessary including, but not limited to, tests of radiation machines, facilities wherein radiation machines are used or stored, radiation detection and monitoring instruments, and other equipment and devices used in connection with utilization or storage of registered radiation machines. (7-1-98)

010. ADDITIONAL REQUIREMENTS.
The Radiation Control Agency can, by registration condition, impose upon any registrant such requirements in addition to those established in these rules as it deems appropriate or necessary to minimize danger to public health and safety and/or property. (7-1-98)

011. VIOLATIONS.
An injunction or other court order can be obtained prohibiting any violations of any provision of the Act or any rule, regulation, or order issued thereunder. Any person who willfully violates any provision of the Act or any rule, regulation, or order issued thereunder could be guilty of a crime and, upon conviction, could be punished by fine or imprisonment or both, as provided by law. (7-1-98)

012. IMPOUNDING.
Radiation machines are subject to impoundment pursuant to Section 39-3014, Idaho Code. (7-1-98)

013. PROHIBITED RADIATION USES.

01. Radiation Sources Used for Shoe Sizing. It is unlawful to operate any device or machine using fluoroscopic x-ray or radiation principles for fitting or selling footwear. (7-1-98)

02. Unauthorized Use on Humans. It is unlawful to intentionally apply ionizing radiation to human beings except by or under direct supervision of persons, other than veterinarians, licensed to practice healing arts and authorized to use such radiation or as otherwise provided in these rules related to exposures. (7-1-98)

03. General Health and Safety. The Radiation Control Agency shall have the authority to prohibit the use of radiation machines when found to be detrimental to health and safety. (7-1-98)

014. COMMUNICATIONS.
All communications and reports concerning these rules, and applications filed thereunder, may be addressed to the

Radiation Control Section, Idaho Department of Health and Welfare, Bureau of Laboratories, 2220 Old Penitentiary Road, Boise, Idaho 83712-8299. (7-1-98)

015. -- 049. (RESERVED).

050. REGISTRATION.
Sections 050 through 099 provide for the registration of radiation machines. (7-1-98)

051. SCOPE.
Radiation machines, unless exempt under Section 006 and 053, must be registered with the Radiation Control Agency in accordance with the requirements of Section 090. (7-1-98)

052. (RESERVED).

053. EXEMPTIONS FOR REGISTRATION PURPOSES.
The following radiation machines are exempt from the registration requirements: (7-1-98)

01. Television Receivers. Domestic television receivers; and (7-1-98)

02. Radiation Producing Electrical Equipment. Other electrical equipment that produces radiation incidental to its operation for other purposes, providing the dose equivalent rate averaged over an area of ten (10) square centimeters does not exceed five-tenths (0.5) millirem per hour at five (5) centimeters from any accessible surface of such equipment. The production testing or factory servicing of such equipment is not exempt; and(7-1-98)

03. Machines in Transit or Storage. Radiation machines while in transit or storage incident thereto. (7-1-98)

054. -- 089. (RESERVED).

090. REGISTRATION.

01. Registration of Radiation Machine Facilities. The owner or person having possession of any radiation machine or facility shall apply for registration with the Radiation Control Agency within thirty (30) days of acquisition and prior to operation of such facility. (7-1-98)

a. Application for registration shall be on forms furnished by the Radiation Control Agency and shall contain: (7-1-98)

i. Name of the owner, organization or person having administrative control and responsibility for use; and (7-1-98)

ii. Address and telephone number where the machine is located and used except that a central headquarters can be used for a mobile machine used at various temporary field locations; and (7-1-98)

iii. A designation of the general category of use, such as dental, medical, industrial, veterinary, and research. (7-1-98)

iv. The manufacturer, model number, and type of each radiation machine located within the facility. (7-1-98)

v. If the facility is mobile, the geographic areas within the State where it will be used. (7-1-98)

vi. The signature of the individual designated under Subsection 090.01.b. (7-1-98)

vii. Name of the radiation machine supplier, installer, and service agent. (7-1-98)

viii. The date of application and signature of the individual responsible for the use of the facility.

(7-1-98)

b. Designate on the application form an individual to be responsible for radiation protection. (7-1-98)

c. Each registrant shall prohibit any person from furnishing radiation machine servicing or services as described in Subsection 090.02 to his radiation machine facility until such person provides evidence that such person has been registered with the Agency as a provider of services in accordance with Subsection 090.02. (7-1-98)

02. Application for Registration of Servicing and Services. (7-1-98)

a. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration with the Agency within thirty (30) days prior to furnishing or offering to furnish any such services. (7-1-98)

b. When required by the Radiation Control Agency an application for registration shall be completed on forms furnished by the Agency and contain: (7-1-98)

i. Name, address, and telephone number of the following: (7-1-98)

(1) The individual or the company to be registered. (7-1-98)

(2) The owner(s) of the company. (7-1-98)

ii. The services which are to be provided. (7-1-98)

iii. The area of the State and other states to be covered. (7-1-98)

iv. A list of the individuals or employees qualified to provide these services. (7-1-98)

v. The date of application and signature of the individual responsible for the company, beneath a statement of the items specified in Subsection 090.02. (7-1-98)

c. Each person listed under Subsection 090.02.b.i.(1) shall specify: (7-1-98)

i. That such person has read and understands the requirements of these rules; (7-1-98)

ii. The services for which such person is applying for registration; (7-1-98)

iii. The training and experience that qualify such person listed under Subsections 090.02.b.i.(1) and 090.02.b.ii. to discharge the services for which the registrant is applying for registration; (7-1-98)

iv. The type of measurement instrument to be used, frequency of calibration, and source of calibration; and (7-1-98)

v. The type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule. (7-1-98)

d. For the purpose of Subsection 090.02 services include but may not be limited to: (7-1-98)

i. Installation or servicing of radiation machines and associated radiation machine components; (7-1-98)

ii. Calibration of radiation machines or radiation measurement instruments or devices; (7-1-98)

iii. Radiation protection or health physics consultations or surveys; and (7-1-98)

iv. Personnel dosimetry services. (7-1-98)

e. No individual may perform services which are not specifically stated for that individual on the notice of registration issued by the Radiation Control Agency. (7-1-98)

03. Issuance of Notice of Registration. (7-1-98)

a. Upon a determination that an applicant meets the requirements of the rules and regulations, the Radiation Control Agency may issue a notice of registration. (7-1-98)

b. The Radiation Control Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary. (7-1-98)

04. Expiration of Notice of Registration. Except as provided by Subsection 090.05, each notice of registration will expire at the end of the day specified in the notice in the month and year stated therein. (7-1-98)

05. Renewal of Notice of Registration. (7-1-98)

a. Application for renewal of registration shall be filed in accordance with Subsection 090.01 or 090.02. (7-1-98)

b. In any case in which a registrant not less than thirty (30) days prior to the expiration of his existing notice of registration has filed an application in proper form for renewal, such existing notice of registration shall not expire until the application status has been finally determined by the Radiation Control Agency. (7-1-98)

06. Report of Changes. The registrant shall notify the Radiation Control Agency in writing before any change which would render the information contained in the application for registration or the notice of registration no longer accurate. (7-1-98)

07. Approval Not Implied. No person, in any advertisement, shall refer to the fact that a facility is registered with the Radiation Control Agency pursuant to the provisions of Section 090 and no person shall state or imply that any activity under such registration has been approved by the Radiation Control Agency. (7-1-98)

08. Seller, Vendor, Assembler or Transfer Obligation. (7-1-98)

a. Any person who sells, leases, transfers, or lends radiation machines in this State shall notify the Radiation Control Agency within fifteen (15) days of: (7-1-98)

i. The names and addresses of persons who have received these machines; and (7-1-98)

ii. The manufacturer and model of each machine transferred, sold, leased, or lent; and (7-1-98)

iii. The date of transfer, sale, lease, or lending of each radiation machine. (7-1-98)

b. No person shall make, sell, lease, transfer, lend or install x-ray equipment or the supplies used in connection with such equipment unless such supplies and equipment, when placed in operation and used, meets the requirements of these rules. This includes responsibility for the delivery of cones or collimators, filters, adequate timers, and fluoroscopic shutters where applicable. (7-1-98)

09. Out-of-State Radiation Machines. Whenever any radiation machine is to be brought into the State for use during a period not in excess of one hundred eighty (180) days, the person proposing to bring such machine into the State must give written notice to the Radiation Control Agency at least five (5) working days before such machine enters the State. The notice must include the type of radiation machine, the nature, duration, and scope of use, and the exact location where the radiation machine is to be used. If, for a specific case, the five (5) day period would impose an undue hardship on the person, he can, upon application to the Radiation Control Agency, obtain permission to proceed sooner. In addition, the person with an out-of-state machine must: (7-1-98)

a. Comply with all applicable rules and regulations of the Radiation Control Agency; and (7-1-98)

b. Supply the Radiation Control Agency with other information which the Radiation Control Agency reasonably requests. (7-1-98)

10. **Registrant Obligation**. The registrant will be subject to all applicable requirements of these rules. (7-1-98)

091. ADMINISTRATIVE APPEAL OF FINAL REGISTRATION DECISIONS.
Within thirty (30) days after a final registration decision has been issued pursuant to Sections 050 through 090 the applicant may petition the Radiation Control Agency to review the decision in accordance with this Section. The thirty (30) day period within which an applicant may request review under this Section begins with the service of notice of the Radiation Control Agency's decision unless a later date is specified in that notice. Any petition for administrative review shall be in writing and state the reasons supporting review. Within a reasonable time following filing of a petition for review, the Radiation Control Agency shall hold a hearing in accordance with Title 67, Chapter 52, Idaho Code, and issue a final decision. (7-1-98)

092. MODIFIED REVOCATION OF REGISTRATION.

01. **Modification, Revocation, and Termination of Registrants**. Pursuant to amendments to the Act, departmental rules or regulations, or orders issued by the Radiation Control Agency, the terms and conditions of all registrations are subject to amendment, revision, or modification, and are subject to suspension or revocation. (7-1-98)

a. Any registration can be revoked, suspended, modified, or denied, in whole or in part. (7-1-98)

i. For any materially false statement: (7-1-98)

(1) In the application; or (7-1-98)

(2) In any statement of fact required under provisions of the Act or under these rules; or (7-1-98)

ii. Because of the conditions revealed: (7-1-98)

(1) By the application; or (7-1-98)

(2) By statement of fact; or (7-1-98)

(3) By any report; or (7-1-98)

(4) By any record; or (7-1-98)

(5) By any inspection; or (7-1-98)

(6) By any other means which would warrant the Radiation Control Agency to refuse to grant a registration on an original application; or (7-1-98)

iii. For violations of or failure to observe any of the terms and conditions: (7-1-98)

(1) Of the Act; or (7-1-98)

(2) Of the license; or (7-1-98)

(3) Of any rule; or (7-1-98)

(4) Of any regulation; or (7-1-98)

(5) Of an order of the Radiation Control Agency. (7-1-98)

b. Except in cases of willful violation or in which the public health, interest or safety requires otherwise, no registration can be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, the facts or conduct which warrant such actions have been called to the attention of the registrant in writing and the registrant must have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements. (7-1-98)

02. Emergency Action. If the Director finds the public health, safety or welfare requires emergency action, the Director shall incorporate findings in support of such action in a written notice of emergency revocation issued to the registrant. Emergency revocation shall be effective upon receipt by the registrant. Thereafter, if requested by the registrant in writing, the Director shall provide the registrant a revocation hearing and prior notice thereof. Such hearings shall be conducted in accordance with Title 67, Chapter 52, Idaho Code. (7-1-98)

093. -- 099. (RESERVED).

100. STANDARDS FOR PROTECTION AGAINST RADIATION.
Section 100 establishes standards for protection against radiation hazards. Except as otherwise specifically provided, Section 100 applies to all registrants. Nothing in Section 100 can be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or therapy. In addition to complying with these requirements, every reasonable effort must be made to maintain radiation exposures, to unrestricted areas, as far below the limits specified in Section 100 as practicable. The phrase "as far below the limits specified in Section 100 as practicable" means as low as is practicably achievable taking into account the state of technology, and the economics of improvements in relation to benefits to the public health and safety and other socioeconomic considerations in relation to the utilization of ionizing radiation in the public interest. (7-1-98)

101. -- 109. (RESERVED).

110. OCCUPATIONAL EXPOSURES.

01. Exposure of Individuals to Radiation in Restricted Areas. Except as provided in Subsection 110.01.b., no registrant may possess, use, receive, or transfer radiation machines in such a manner as to cause any individual in a restricted area to receive in any period of one (1) calendar quarter from all radiation machines in the registrant's possession a dose in excess of the limits specified in Subsection 110.01.a.: (7-1-98)

a. Occupational Exposure Limits.

OCCUPATIONAL EXPOSURE LIMITS	
	Rem Per Calendar Quarter
Whole body, head and trunk, active blood-forming organs, lens of eyes, or gonads	1 1/4
Hands and forearms, feet and ankles	18 3/4
Skin of whole body	7 1/2

(7-1-98)

b. A registrant may permit an individual in a restricted area to receive a dose to the whole body greater than that permitted in the table in Subsection 110.01.a., provided: (7-1-98)

i. During any calendar quarter the dose to the whole body from radiation machines in the registrant's possession does not exceed three (3) rem; and (7-1-98)

ii. The dose to the whole body, when added to the accumulated occupational dose to the whole body,

does not exceed five (5) (N-18) rem where "N" equals the individual's age in years at his last birthday; and (7-1-98)

iii. The registrant has determined the individual's accumulated occupational dose to the whole body on a clear and legible record containing all the information required pursuant to Subsection 140.01.a. and has otherwise complied with the requirements of Subsection 110.02 as used in Subsection 110.01.b. "Dose to the whole body" includes any dose to the whole body, gonads, active blood-forming organs, head and trunk, or lens of the eye. (7-1-98)

c. For determining the doses specified in Section 110 a dose from x-rays or gamma rays up to ten (10) MeV can be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate. (7-1-98)

d. No registrant can change the method observed by him of determining calendar quarter for purposes of these rules except at the beginning of a calendar year from Subsection 002.14. (7-1-98)

02. Determination of Accumulated Dose. (7-1-98)

a. Each registrant shall require any individual, prior to first entry of the individual into the registrant's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one (1) calendar quarter an occupational dose in excess of twenty-five percent (25%) of the applicable standards specified in Subsections 110.01 and 110.04.a., to disclose in a written, signed statement: (7-1-98)

i. That the individual had no prior occupational dose during the current calendar quarter; or (7-1-98)

ii. The nature and amount of any occupational dose which the individual may have received during the specifically identified current calendar quarter, from radiation machines possessed or controlled by the other persons, and each registrant shall maintain records of such statements until the Agency authorizes disposition. (7-1-98)

b. Before permitting any individual in a restricted area to receive exposure to radiation in excess of the limits specified in Subsection 110.01, each registrant must: (7-1-98)

i. Obtain a signed certificate on a clear and legible record containing all the information required, showing each period of time after the individual attained the age of eighteen (18) in which the individual received an occupational dose of radiation (copies of certificates can be obtained from the Radiation Control Agency); and (7-1-98)

ii. Calculate, on a clear and legible record containing all the information required pursuant to Subsection 140.01.a., the previously accumulated occupational dose received by the individual and the additional dose allowed for that individual under Subsection 110.01.b. (7-1-98)

iii. In the preparation of a clear and visible record containing all the information required, make a reasonable effort to obtain reports of the individual's previously accumulated occupational dose. For each period for which the registrant obtains such report, he must use the dose shown in the report. In any case where a registrant is unable to obtain reports of the individual's occupational dose for a previous complete calendar quarter, it must be assumed that the individual has received the occupational dose specified in the following applicable columns:

ASSUMED OCCUPATIONAL DOSES		
Part of Body	**Column 1**	**Column 2**
	Assumed Dose in Rem for Calendar Quarters Prior to January 1, 1961	Assumed Dose in Rem for Calendar Quarters on or After January 1, 1961

ASSUMED OCCUPATIONAL DOSES		
Part of Body	**Column 1**	**Column 2**
Whole Body, gonads, active blood-forming organs, head and trunk, lens of eye	3 3/4	1 1/4

(7-1-98)

iv. The registrant shall retain and preserve all records used until the agency authorizes their disposition. If calculation of the individual's accumulated occupational dose for all periods prior to January 1, 1961, yields a result higher than the applicable accumulated dose value for the individual as of that date, as specified in Subsection 110.01.b., the excess can be disregarded. (7-1-98)

03. Exposure of Minors. Registrants must not possess, use or transfer radiation machines in such a manner as to cause any individual within a restricted area, who is under eighteen (18) years of age, to receive in any period of one (1) calendar quarter from all sources of radiation in such licensee's or registrant's possession a dose in excess of ten percent (10%) of the limits specified in the table in Subsection 110.01.a. For determining the doses specified in Subsection 110.04.a., a dose from x-rays or gamma rays up to ten (10) MeV can be assumed to be equivalent to the exposure measured by a properly calibrated appropriate instrument in air at or near the body surface in the region of the highest dose rate. (7-1-98)

04. Permissible Levels of Radiation from External Sources in Unrestricted Areas. (7-1-98)

a. Except as authorized by the Radiation Control Agency pursuant to Subsection 110.04.c., licensees or registrants must not possess, use, or transfer radiation machines in such a manner as to create in any unrestricted area from such sources of radiation in his possession: (7-1-98)

i. Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of two (2) millirem in any one (1) hour; or (7-1-98)

ii. Radiation levels which, if an individual were continuously present in the area, could result in his receiving a dose in excess of one hundred (100) millirem in any seven (7) consecutive days. (7-1-98)

b. It is the intent of Subsection 110.04 to limit radiation levels so that it is unlikely that individuals in unrestricted areas would receive a dose to the whole body in excess of five-tenths (0.5) rem in any one (1) year. If in specific instances, it is determined by the Radiation Control Agency that this intent is not being met, the Radiation Control Agency can, pursuant to Section 010 impose such additional requirements on the licensee or registrant as necessary. (7-1-98)

c. Any person can apply to the Radiation Control Agency for proposed limits upon levels of radiation in unrestricted areas in excess of those specified in Subsection 110.04.a. resulting from the applicant's possession or use of radiation machines. Such applications must include information as to anticipated average radiation levels and anticipated occupancy times for each unrestricted area involved. The Radiation Control Agency will approve the proposed limits if the applicant demonstrates to the satisfaction of the Radiation Control Agency that the proposed limits are not likely to cause any individual to receive a dose to the whole body in any period of one (1) calendar year in excess of five-tenths (0.5) rem. (7-1-98)

111. -- 119. (RESERVED).

120. PRECAUTIONARY PROCEDURES.

01. Surveys. Each registrant must make or cause to be made such surveys, as defined in Subsection 002.96, as necessary for him to establish compliance with these rules, and as reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. (7-1-98)

02. Personnel Monitoring. Each registrant must supply appropriate personnel monitoring equipment to, and must require the use of such equipment by: (7-1-98)

a. Each individual who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any one (1) calendar quarter in excess of twenty-five percent (25%) of the applicable value specified in Subsection 110.01.a.; and (7-1-98)

b. Each individual under eighteen (18) years of age who enters a restricted area under such circumstances that he receives, or is likely to receive, a dose in any one (1) calendar quarter in excess of five percent (5%) of the applicable value specified in Subsection 110.01.a.; and (7-1-98)

c. Each individual who enters a high radiation area. (7-1-98)

03. Caution Signs, Labels, and Signals. (7-1-98)

a. General: Except as otherwise authorized by the Radiation Control Agency, symbols prescribed by Subsection 120.03 must use the conventional radiation caution colors, magenta or purple on yellow background. The radiation symbol is the conventional three-bladed design as follows: (7-1-98)

i. Cross-hatched area must be magenta or purple; and (7-1-98)

ii. Background must be yellow. (7-1-98)

iii. Design must appear as indicated in Appendix A located at the end of this chapter. (7-1-98)

iv. In addition to the contents of signs and labels prescribed in this Section, a registrant can provide on or near such signs and labels any additional information which could be appropriate in aiding individuals to minimize exposure to radiation. (7-1-98)

b. Radiation Areas. Each radiation area must be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION" (or) "DANGER"
"RADIATION AREA"

(7-1-98)

c. High Radiation Areas. Each high radiation area must be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words:

"CAUTION" (or) "DANGER"
"HIGH RADIATION AREA"

(7-1-98)

i. Each entrance or access point to a high radiation area must be: (7-1-98)

(1) Equipped with a control device which will cause the level of radiation to be reduced below that at which an individual might receive a dose of one hundred (100) millirem in one (1) hour upon entry into the area; or (7-1-98)

(2) Equipped with a control device which will energize a conspicuous visible or audible alarm signal in such a manner that the individual entering the high radiation area and the registrant, or a supervisor of the activity are made aware of the entry; or (7-1-98)

(3) Maintained locked except during periods when access to the area is required, with positive control

over each individual entry. (7-1-98)

ii. The controls required by Subsection 120.03.c.ii. must be established in such a way that no individual will be prevented from leaving a high radiation area. (7-1-98)

iii. In the case of a high radiation area established for a period of thirty (30) days or less, direct surveillance to prevent unauthorized entry can be substituted for the controls required by Subsection 120.03.c.ii. (7-1-98)

iv. Any registrant can apply to the Radiation Control Agency for approval of methods not included in Subsections 120.03.c.ii. and 120.03.c.iv. for controlling access to high radiation area. The Radiation Control Agency will approve the proposed alternatives if the registrant demonstrates that the alternative method of control will prevent unauthorized entry into a high radiation area, and that the requirement of Subsection 120.03.c.iii. is met. (7-1-98)

121. -- 139. (RESERVED).

140. RECORDS, REPORTS, AND NOTIFICATIONS.

01. Records of Surveys and Radiation Monitoring. (7-1-98)

a. Each registrant shall maintain records showing the radiation exposures of all individuals for whom personnel monitoring is required under Subsection 120.02. Such records must be kept on clear and legible records containing all the information required below: (7-1-98)

i. Name; and (7-1-98)

ii. Social Security Number; and (7-1-98)

iii. Date of Birth; and (7-1-98)

iv. Name of Registrant; and (7-1-98)

v. Dose Records for the whole body, skin, or hands and forearms, feet and ankles; and (7-1-98)

vi. Whole Body Dose Status; and (7-1-98)

vii. Method of Monitoring; and (7-1-98)

viii. Period of Exposure; and (7-1-98)

ix. X-Ray or Gamma Dose for Period; and (7-1-98)

x. Neutron Dose for Period; and (7-1-98)

xi. Total Dose for Period; and (7-1-98)

xii. Running Dose for Calendar Quarter; and (7-1-98)

xiii. Total Lifetime Accumulated Dose. (7-1-98)

b. The doses entered in the forms or records required above must be for periods of time not exceeding one (1) calendar quarter. (7-1-98)

c. Each registrant shall maintain records in the same units used in Section 100 showing the results of surveys required by Subsection 120.01. (7-1-98)

d. Records of individual exposure to radiation which must be maintained pursuant to Subsection 140.01.a. must be preserved indefinitely or until the Radiation Control Agency authorizes their disposal. (7-1-98)

e. The discontinuance of or curtailment of activities, does not relieve the registrant of responsibility for retaining all records required by this Section. A registrant can, however, request the Radiation Control Agency to accept such records. Acceptance of the records by the Radiation Control Agency relieves the or registrant of subsequent responsibility only in respect to their preservation as required by this Section. (7-1-98)

f. Records of the results of surveys and monitoring which must be maintained pursuant to Subsection 140.01.c. must be preserved for two (2) years after completion of the survey except that the following records may be maintained until the Agency authorized their disposition: (7-1-98)

i. Records of the results of surveys to determine compliance with Subsection 110.03; and (7-1-98)

ii. In the absence of personnel monitoring data, records of the results of surveys to determine external radiation dose; and (7-1-98)

g. Records which must be maintained pursuant to this part may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Agency rules. (7-1-98)

h. If there is a conflict between the Agency's rules in this part, registration, or other written Agency approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this part for such records will apply unless the Agency, pursuant to Section 006 of this chapter, has granted a specific exemption from the record retention requirements specified in the rules in this part. (7-1-98)

02. Report of Theft or Loss of Sources of Radiation. Each licensee or registrant must report by telephone to the Radiation Control Agency the theft or loss of any source of radiation immediately after such occurrence becomes known. (7-1-98)

03. Notification of Incidents. (7-1-98)

a. Each registrant must immediately notify the Radiation Control Agency by telephone of any incident involving any radiation machine possessed by him and which may have caused or threatens to cause: (7-1-98)

i. A dose to the whole body of any individual of twenty-five (25) rems or more of radiation; a dose to the skin of the whole body of any individual of one hundred fifty (150) rem or more of radiation; or a dose to the feet, ankles, hands, or forearms of any individual of three hundred seventy-five (375) rems or more of radiation; or (7-1-98)

b. Each registrant must, within twenty-four (24) hours, notify the Radiation Control Agency by telephone of any incident involving any source of radiation possessed by him and which may have caused or threatens to cause: (7-1-98)

i. A dose to the whole body of any individual of five (5) rem or more of radiation; a dose to the skin of the whole body of any individual of thirty (30) rem or more of radiation; or a dose to the feet, ankles, hands, or forearms of seventy-five (75) rems or more of radiation; or (7-1-98)

c. Any report filed with the Radiation Control Agency pursuant to this Section must be prepared in such a manner that names of individuals who have received exposure to radiation will be stated in a separate part of the report. (7-1-98)

d. Details of any report filed with the Radiation Control Agency pursuant to this Section will be held confidential except as necessary for protection of the public health and to prevent accidental overexposure of individuals. (7-1-98)

04. Reports of Overexposure and Excessive Levels and Concentration. (7-1-98)

a. In addition to any notification required by Subsection 140.03, each registrant must make a report in writing within thirty (30) days to the Radiation Control Agency of: (7-1-98)

i. Each exposure of an individual to radiation in excess of any applicable limit as set forth in Section 100 or as otherwise approved by the Radiation Control Agency; and (7-1-98)

ii. Any incident for which notification is required by Subsection 140.03; and (7-1-98)

iii. Levels of radiation whether or not involving excessive exposure of any individual, in an unrestricted area in excess of ten (10) times any applicable limit as set forth in Section 100 or as otherwise approved by the Radiation Control Agency. Each report required under Subsection 140.04 must describe the extent of exposure of individuals to radiation, including estimates of each individual's exposure as required by Subsection 140.01.b.; levels of radiation; the cause of the exposure, and corrective steps taken or planned to assure against a recurrence. (7-1-98)

b. Any report filed with the Radiation Control Agency pursuant to this Section must include, for each individual exposed, the name, social security number, date of birth, and an estimate of the individual's exposure. The report must be prepared so that this information is stated in a separate part of the report. (7-1-98)

c. In any case where a registrant is required pursuant to the provisions of this Section to report to the Radiation Control Agency any exposure of an individual to radiation, the registrant must, not later than the making of such report to the Radiation Control Agency, also notify such individual of the nature and extent of exposure. Such notice must be in writing and must contain the following statement:

"This report is furnished to you under the provisions of the Radiation Control Agency rules entitled 'Idaho Radiation Control Rules,' IDAPA 16, Title 02, Chapter 27, Rules of the Department of Health and Welfare. You should preserve this report for future reference." (7-1-98)

d. Each report required under Subsection 140.04.d. shall describe the extent of exposures of individuals to radiation, levels of radiation involved, the cause of exposure, levels, and corrective steps taken or planned to assure against a recurrence. (7-1-98)

05. Notifications and Reports to Individuals. (7-1-98)

a. Requirements for notification and reports to individuals of exposure to radiation are specified in Subsection 450.04. (7-1-98)

b. When a registrant is required pursuant to Subsection 140.04 to report to the Radiation Control Agency any exposure of an individual to radiation, the registrant must also notify the individual. Such notice must be transmitted at a time not later than the transmittal to the Radiation Control Agency, and must comply with the provisions of Subsection 450.04.a. (7-1-98)

06. Records and Reports of Misadministrations. (7-1-98)

a. When a misadministration involves any therapy procedure, the registrant shall notify by telephone the Radiation Control Agency. The registrant shall also notify the referring physician of the affected patient and the patient or a responsible relative (or guardian). These notifications must be made within twenty-four (24) hours after the licensee discovers the misadministration. If the referring physician, patient, or the patient's responsible relative or guardian cannot be reached within twenty-four (24) hours, the registrant shall notify them as soon as practicable. The registrant is not required to notify the patient or the patient's responsible relative or guardian without first consulting the referring physician; however, the licensee shall not delay medical care for the patient because of this. (7-1-98)

b. Within fifteen (15) days after an initial therapy misadministration report to the Radiation Control Agency, the registrant shall report, in writing to the Radiation Control Agency and to the referring physician, and furnish a copy of the report to the patient or the patient's responsible relative (or guardian) if either was previously

notified by the licensee under the provisions of Subsection 140.07.a. The written report must include the registrant's name; the referring physician's name; a brief description of the event; the effect on the patient; the action taken to prevent recurrence; whether the registrant informed the patient or the patient's responsible relative (or guardian), and if not, why not. The report must not include the patient's name or other information that could lead to identification of the patient. (7-1-98)

c. When a misadministration involves a diagnostic procedure, the Radiation Safety Officer shall promptly investigate its cause, make a record for review, and retain the record as directed in Subsection 140.07. The registrant shall also notify the referring physician within fifteen (15) days if the misadministration involved the administration of a dosage five (5) fold different from the intended dosage. (7-1-98)

d. Each registrant shall retain a record of each misadministration for ten (10) years. The record must contain the names of all individuals involved in the event (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence. (7-1-98)

e. Aside from the notification requirement, nothing in this section affects any rights or duties of registrants and physicians in relation to each other, patients, or responsible relatives (or guardians). (7-1-98)

141. -- 149. (RESERVED).

150. RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS. The rules in Section 150 apply to all registrants who use radiation machines for industrial radiography; provided, however, that nothing in Section 150 will apply to the use of radiation machines in the healing arts. The requirements of Section 150 are in addition to and not in substitution for the other requirements of this chapter. (7-1-98)

151. -- 152. (RESERVED).

153. EQUIPMENT CONTROL.

01. Storage Precautions. Radiation machines must be physically secured to prevent tampering or removal by unauthorized personnel. (7-1-98)

02. Radiation Survey Instruments. (7-1-98)

a. The registrant must maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by Section 153 and Subsection 120.01. (7-1-98)

b. Each radiation survey instrument must be calibrated at intervals not to exceed three (3) months and after each instrument servicing and a record maintained of the latest date of calibration. Instrumentation required under this Section must have a range such that two (2) milliroentgens per hour through one (1) roentgen per hour can be measured; (7-1-98)

i. At energies appropriate for use and at intervals not to exceed three (3) months and after each instrument servicing; (7-1-98)

ii. Such that accuracy within plus or minus twenty percent (20%) can be demonstrated; and (7-1-98)

iii. At two (2) or more widely separated points, other than zero (0), on each scale. (7-1-98)

c. Records of these calibrations must be maintained for two (2) years after the calibration date for inspection by the Radiation Control Agency. (7-1-98)

03. Utilization Logs. Each registrant must maintain current logs, which must be kept available for inspection by the Radiation Control Agency, showing for each radiation machine the following information: (7-1-98)

a. A description, or make and model number, of each radiation machine; and (7-1-98)

b. The identity of the radiographer to whom assigned; and (7-1-98)

c. Locations where used and dates of use; and (7-1-98)

d. The voltage and current, where applicable, and exposure time for each radiographic exposure employing a radiation machine. (7-1-98)

04. Inspection and Maintenance. (7-1-98)

a. Each registrant must ensure that checks for obvious defects in radiation machines are performed prior to each day of use. (7-1-98)

b. Each registrant must conduct a program of at least quarterly inspection and maintenance of radiation machines to assure proper functioning of components important to safety. All appropriate parts must be maintained in accordance with manufacturer's specifications. Records of inspection and maintenance must be maintained for inspection by the Radiation Control Agency until their disposal is authorized by the Radiation Control Agency. (7-1-98)

c. If any inspection conducted pursuant to Subsections 153.04.a. and 153.04.b. reveals damage to components critical to radiation safety, the device must be removed from service until repairs have been made. (7-1-98)

05. Permanent Radiographic Installation. Permanent radiographic installations having high radiation area entrance controls of the type described in Subsections 120.03.c.ii.(2), 120.03.c.ii.(3), and 120.03.c.iv. must also meet the following requirements: (7-1-98)

a. Each entrance that is used for personnel access to the high radiation area must have both visible and audible warning signals to warn of the presence of radiation. The visible signal must be activated by radiation. The audible signal must be activated when an attempt is made to enter the installation while the source is exposed. (7-1-98)

b. The control device or alarm system must be tested for proper operation at the beginning of each period of use. Records of these tests must be maintained for inspection by the Agency until their disposal is authorized. (7-1-98)

154. PERSONAL RADIATION SAFETY REQUIREMENTS FOR RADIOGRAPHERS AND RADIOGRAPHERS' ASSISTANTS.

01. Limitations. On personnel operating radiation machines. (7-1-98)

a. Registrants must not permit any individuals to act as radiographers as defined in these rules until such individuals: (7-1-98)

i. Have been instructed in the subjects outlined in Subsection 154.04, and have demonstrated understanding thereof; and (7-1-98)

ii. Have received copies of and instruction in the rules contained in Section 150 and the applicable Sections of Section 100 and Section 450 Radiation Control Agency registrant's operating and emergency procedures; and have demonstrated understanding thereof; and (7-1-98)

iii. Have demonstrated competence to use the source of radiation, related handling tools, and survey instruments which will be employed in their assignment. (7-1-98)

iv. Have demonstrated an understanding of the instructions in Subsection 154.01.a. by successful completion of a written test and a field examination on the subjects covered. (7-1-98)

b. Registrants must not permit any individuals to act as a radiographer's assistant as defined in these rules until such individuals: (7-1-98)

i. Have received copies of and instructions in the registrant's operating and emergency procedures; and have demonstrated understanding thereof; and (7-1-98)

ii. Have demonstrated competence to use under the personal supervision of the radiographer the radiation machine and radiation survey instruments which will be employed in their assignment. (7-1-98)

iii. Have demonstrated an understanding of the instructions in Section 154.01.b. by successfully completing a written or oral test and a field examination on the subjects covered. (7-1-98)

c. Records of the above training, including copies of written tests and dates of oral tests and field examinations, must be maintained for inspection by the Radiation Control Agency for three (3) years following termination of employment. (7-1-98)

d. Each registrant must conduct an internal audit program to ensure that the Radiation Control Agency's conditions and the registrant's operating and emergency procedures are followed by each radiographer and radiographer's assistant. These internal audits must be performed at least quarterly, and each radiographer must be audited at least annually. Records of internal audits must be maintained for inspection by the Agency for two (2) years from the date of the audit. (7-1-98)

02. Operating and Emergency Procedures. The registrant's operating and emergency procedures must include instructions in at least the following: (7-1-98)

a. The handling and use of radiation machines to be employed such that no individual is likely to be exposed to radiation doses in excess of the limits established in Section 100, "Standards for Protection Against Radiation"; and (7-1-98)

b. Methods and occasions for conducting radiation surveys; and (7-1-98)

c. Methods for controlling access to radiographic areas; and (7-1-98)

d. Methods and occasions for locking and securing radiation machines; and (7-1-98)

e. Personnel monitoring and the use of personnel monitoring equipment including steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale; and (7-1-98)

f. Transportation to field locations, including packing of radiation machines in the vehicles, posting of vehicles, and control of radiation machines during transportation; and (7-1-98)

g. Minimizing exposure of individuals in the event of an accident; and (7-1-98)

h. The procedure for notifying proper personnel in the event of an accident; and (7-1-98)

i. Maintenance of records; and (7-1-98)

j. The inspection and maintenance of radiation machines. (7-1-98)

03. Personnel Monitoring Control. (7-1-98)

a. Registrants must not permit any individual to act as a radiographer or as a radiographer's assistant unless, at all times during the radiographic operations, each such individual will wear a film badge or thermoluminescent dosimeter (TLD) and either a pocket dosimeter or pocket chamber. Pocket dosimeters and pocket chambers will be capable of measuring doses from zero (0) to at least two hundred (200) milliroentgens and must be recharged daily or at the beginning of each shift. A film badge or TLD will be assigned to and worn by only one (1)

individual. (7-1-98)

b. Pocket dosimeters and pocket chambers must be read and doses recorded daily. A film badge or TLD must be immediately processed if a pocket chamber or pocket dosimeter is discharged beyond its range. The film badge or TLD reports received from the processor and records of pocket dosimeter and pocket chamber readings must be maintained for inspection by the Radiation Control Agency. (7-1-98)

c. Pocket dosimeters and chambers must be checked for correct response to radiation at periods not to exceed one (1) year. Acceptable dosimeters must read within plus or minus thirty percent (30%) of the true radiation exposure. (7-1-98)

04. Subjects to Be Covered During the Instruction of Radiographers. (7-1-98)

a. Fundamentals of Radiation Safety, to include at least: (7-1-98)

i. Characteristics of gamma and x-radiation; and (7-1-98)

ii. Units of radiation dose (millirem); and (7-1-98)

iii. Bioeffects of excessive exposure of radiation; and (7-1-98)

iv. Levels of radiation from radiation machines; and (7-1-98)

v. Methods of controlling radiation dose, including: (7-1-98)

(1) Working time; and (7-1-98)

(2) Working distances; and (7-1-98)

(3) Shielding; and (7-1-98)

vi. Radiation Protection Standards; and (7-1-98)

b. Radiation Detection Instrumentation, to include at least: (7-1-98)

i. Use of radiation surveys instruments, including: (7-1-98)

(1) Operation; and (7-1-98)

(2) Calibration; and (7-1-98)

(3) Limitations; and (7-1-98)

ii. Survey techniques; and (7-1-98)

iii. Use of Personnel Monitoring Equipment, including: (7-1-98)

(1) Film badges, TLDs; and (7-1-98)

(2) Pocket dosimeters; and (7-1-98)

(3) Pocket chambers; and (7-1-98)

c. Radiographic Equipment, to include at least: (7-1-98)

i. Operation and control of x-ray equipment; and (7-1-98)

d. The Requirements of Pertinent Federal regulations and State rules; and (7-1-98)

e. The Registrant's Written Operating and Emergency Procedures; and (7-1-98)

f. Case histories of radiography accidents. (7-1-98)

155. PRECAUTIONARY PROCEDURES IN RADIOGRAPHIC OPERATION.

01. Documents Required at Field Radiography Sites. Each registrant conducting industrial radiography at a temporary jobsite must have the following records available at that site for inspection by the Agency: (7-1-98)

a. Appropriate certificate of registration. (7-1-98)

b. Operating and emergency procedures; (7-1-98)

c. Applicable rules and regulations; (7-1-98)

d. Survey records required pursuant to Section 155 for the period of operation at the site; (7-1-98)

e. Daily pocket dosimeter records for the period of operation at the site; and (7-1-98)

f. The latest instrument calibration and leak test records for specific devices in use at the site. Acceptable records include tags or labels which are affixed to the device or survey meter. (7-1-98)

02. Security. During each radiographic operation, the radiographer or radiographer's assistant must maintain a direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Section 002, except: (7-1-98)

a. Where the high radiation area is equipped with a control device or alarm system as described in Subsection 120.03; or (7-1-98)

b. Where the high radiation area is locked to protect against unauthorized or accidental entry. (7-1-98)

03. Posting. Notwithstanding any provisions in Subsection 120.04.c., areas in which radiography is being performed must be conspicuously posted as required by Subsections 120.03.b. and 120.02.c.i. (7-1-98)

04. Radiation Surveys and Survey Records. (7-1-98)

a. No radiographic operation will be conducted unless calibrated and operable radiation survey instrumentation, as described in Subsection 153.04, is available and used at each site where radiographic exposures are made. (7-1-98)

b. Records must be kept of the surveys required by Subsection 155.04.c. and maintained for inspection by the Radiation Control Agency for two (2) years after completion of the surveys. (7-1-98)

c. A physical radiation survey must be made after each radiographic exposure using radiation machines to determine that the machine is "off". (7-1-98)

05. Special Requirements and Exemptions for Enclosed Radiography. (7-1-98)

a. Systems for enclosed radiography designed to allow admittance of individuals must: (7-1-98)

i. Comply with all applicable requirements of this part and Subsection 110.04. If such a system is a certified cabinet x-ray system, it must comply with all applicable requirements of this part and 21 CFR 1020.40. (7-1-98)

ii. Be evaluated at intervals not to exceed one (1) year to assure compliance with the applicable requirements as specified in Subsection 155.05.a. Records of these evaluations must be maintained for inspection by the Radiation Control Agency for a period of two (2) years after the evaluation. (7-1-98)

b. Certified cabinet x-ray systems designed to exclude individuals are exempt from the requirements of this part except that: (7-1-98)

i. Operating personnel must be provided with either a film badge or a thermoluminescent dosimeter, and reports of the results must be maintained for inspection by the Radiation Control Agency. (7-1-98)

ii. No registrant may permit any individual to operate a cabinet x-ray system until such individual has received a copy of and instruction in the operating procedures for the unit and has demonstrated competence in its use. Records which demonstrate compliance with this Subsection must be maintained for inspection by the Radiation Control Agency until disposition is authorized by the Radiation Control Agency. (7-1-98)

iii. Tests for proper operation of high radiation area control devices or alarm systems, where applicable, must be conducted, recorded, and maintained in accordance with Subsection 153.09. (7-1-98)

iv. The registrant must perform an evaluation, at intervals not to exceed one (1) year, to determine conformance with Subsection 110.04. If such a system is a certified cabinet x-ray system, it must be evaluated at intervals not to exceed one (1) year to determine conformance with 21 CFR 1020.40. Records of these evaluations must be maintained for inspection by the Radiation Control Agency for a period of two (2) years after the evaluation. (7-1-98)

c. Certified cabinet x-ray systems must be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Radiation Control Agency pursuant to Section 006. (7-1-98)

156. -- 199. (RESERVED).

200. USE OF X-RAYS IN THE HEALING ARTS.
Section 200 establishes requirements, for which a registrant is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of Section 200 are in addition to, and not in lieu of, other applicable provisions of these rules. (7-1-98)

201. -- 202. (RESERVED).

203. GENERAL REQUIREMENTS.
The following general requirements must be followed in the use of x-rays in the healing arts. (7-1-98)

01. Administrative Controls. (7-1-98)

a. The registrant will be responsible for directing the operation of the x-ray machines which have been registered with the Radiation Control Agency under Subsection 090.01. Such persons or designated agents will assure that the following provisions are met in the operation of the x-ray machine(s): (7-1-98)

i. An x-ray machine which does not meet the provisions of these rules must not be operated for diagnostic or therapeutic purposes, if so directed by the Radiation Control Agency; and (7-1-98)

ii. Individuals who will be operating the x-ray equipment must be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment. (7-1-98)

b. In the vicinity of each x-ray system's control panel a chart must be provided which specifies, for all examinations which are performed by that system, a listing of current information, including but not limited to the following, for each projection within that examination: (7-1-98)

i. Patient's anatomical size versus technique factors to be utilized; (7-1-98)

ii. Type and size of the film or film-screen combination to be used; (7-1-98)

iii. Type of grid to be used if any, and focal distance; (7-1-98)

iv. Source to image receptor distance to be used; and (7-1-98)

v. Type and location of placement of gonadal shielding to be used. (7-1-98)

c. Written safety procedures and rules will be provided to each individual operating x-ray equipment under the registrant's control; such procedures and rules will include any restrictions of the operating technique required for the safe operating of the particular x-ray system. The operator must be able to demonstrate familiarity with these rules. (7-1-98)

d. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training can be in the room during the radiographic exposure. For all persons other than the patient being examined, the following must be observed: (7-1-98)

i. All individuals will be positioned such that no part of the body, including the extremities not protected by five tenths (0.5) mm lead equivalent, will be struck by the useful beam; (7-1-98)

ii. Staff and ancillary personnel must be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than twenty-five hundredths (0.25) mm lead equivalent; (7-1-98)

iii. Patients who cannot be removed from the room will be protected from the direct scatter radiation by whole body protective barriers of twenty-five hundredths (0.25) mm lead equivalent or will be positioned such that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor; and (7-1-98)

iv. When a portion of the body of any staff or ancillary personnel is potentially subjected to stray radiation which could result in that individual receiving one-quarter (1/4) of the maximum permissible dose, as defined in Section 100 additional protective devices can be required by the Radiation Control Agency. (7-1-98)

e. Gonadal shielding of not less than five-tenths (0.5) mm lead equivalent must be used for patients who have not passed the productive age of eighteen (18) to forty five (45) during radiographic procedures in which the gonads are in the direct (useful) beam, except for cases where this would interfere with the diagnostic procedure. (7-1-98)

f. Persons must not be exposed to the useful beam except for healing arts purposes, each exposure of which has been authorized by a licensed practitioner of the healing arts. Deliberate exposure for the following purposes is specifically prohibited: (7-1-98)

i. Exposure of an individual for training, demonstration or other purposes, unless there are also healing arts requirements and proper prescription has been provided; and (7-1-98)

ii. Exposure of an individual for the purpose of healing arts screening without prior written approval of the Radiation Control Agency. Screening for this purpose will mean an exposure of a person without a prior examination by a licensed practitioner. (7-1-98)

g. When a patient or film must be provided with auxiliary support during a radiation exposure: (7-1-98)

i. Mechanical holding devices will be used when the technique permits. The safety rules required by Subsection 203.01.c. will list individual projections where holding devices cannot be utilized; (7-1-98)

ii. Written safety procedures, as required by Subsection 203.01.c., will indicate the requirements for selecting a human holder and the procedure the holder will follow; (7-1-98)

iii. The human holder will be protected as required by Subsection 203.01.d.; (7-1-98)

iv. No person can be used routinely to hold film or patients; (7-1-98)

v. A record must be made of the examination and must include the name of the human holder, date of the examination, number of exposures and technique factors utilized for the exposure(s); and (7-1-98)

vi. In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam must be protected by not less than five-tenths (0.5) mm lead equivalent material. (7-1-98)

h. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information must be utilized. This includes but is not limited to: (7-1-98)

i. The speed of film or screen and film combinations, using the fastest speed consistent with the diagnostic objective of the examinations; (7-1-98)

ii. Using the minimum radiation exposure to the patient required to produce images of good diagnostic quality; and (7-1-98)

iii. Portable or mobile equipment only for examinations where it is impractical to transfer patients to a stationary radiographic installation. (7-1-98)

i. Regarding personnel monitoring, all persons who are associated with the operation of an x-ray system are subject to the occupational exposure limits and the requirements for the determination of the doses as stated in Section 100. In addition, the following requirements apply: (7-1-98)

i. When protective clothing or other devices are worn on portions of the body and when a monitoring device is required, at least one (1) such device must be worn at the collar outside of the protective clothing. The dose to the whole body based on the maximum dose attributed to any one (1) critical organ, which includes the gonads, blood forming organs, head and trunk, or lens of the eye, must be recorded in the reports required by Subsection 140.01. If more than one (1) device is used and a record is made of the data, each dose must be identified with the area where the device was worn on the body; and (7-1-98)

ii. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited. (7-1-98)

j. Any person proposing to conduct a healing arts screening program must not initiate such a program without prior approval of the Radiation Control Agency. When requesting such approval, that person must submit the information outlined in the following Subsections. If any information submitted to the Radiation Control Agency becomes invalid or outdated, the Agency must be immediately notified. Persons requesting that the Radiation Control Agency approve a healing arts screening program must submit the following information and evaluations: (7-1-98)

i. Name and address of the applicant and, where applicable, the names and addresses of agents within this State. (7-1-98)

ii. Diseases or conditions for which the x-ray examinations are to be used in diagnoses. (7-1-98)

iii. A detailed description of the x-ray examinations proposed in the screening program. (7-1-98)

iv. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information. (7-1-98)

v. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations. (7-1-98)

vi. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert must show that such system(s) do satisfy all requirements of these rules. (7-1-98)

vii. A description of the diagnostic film quality control program. (7-1-98)

viii. A copy of the technique chart for the x-ray examination procedures to be used. (7-1-98)

ix. The qualifications of each individual who will be operating the x-ray system(s). (7-1-98)

x. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation must be specified. (7-1-98)

xi. The name and address of the individual who will interpret the radiograph(s). (7-1-98)

xii. A description of the procedures to be used in advising the individuals screened and their private practitioners of the healing arts of the results of the screening procedure and any further medical needs indicated. (7-1-98)

xiii. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations. (7-1-98)

02. Exemptions. The Radiation Control Agency can waive compliance with the specific requirements of Section 203 for an existing machine or installation if: (7-1-98)

a. Such compliance would require replacement or substantial modification of the machine or installation; and (7-1-98)

b. The registrant demonstrates to the Radiation Control Agency's satisfaction, achievement through other means of radiation protection equivalent to that required by these rules. (7-1-98)

03. Structural Shielding. Each installation must be provided with primary barriers and/or secondary barriers as necessary to assure compliance with Subsections 110.01 and 110.04. This requirement will be deemed to be met if the thicknesses of such barriers are equivalent to those as computed in accordance with National Council of Radiation Protection Report No. 49, (or it's successor) "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to Ten (10) MeV", which may be obtained from NCRP Publications, 7910 Woodmont, Bethesda, MD 20814. (7-1-98)

04. Minimum Design Requirements for an X-ray Machine Operator's Booth. (7-1-98)

a. The operator will be allotted not less than seven and five-tenths (7.5) square feet of unobstructed floor space in the booth. The booth must protect the operator from the useful beam and from any radiation which has been scattered only once. (7-1-98)

i. The minimum space, as indicated above, can be any geometric configuration but with no dimension less than two (2) feet. (7-1-98)

ii. The space allotted will not include any encumbrance by the console, such as overhang, cable, or other similar encroachments. (7-1-98)

iii. The booth must be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette does not reach the operator's station in the booth. (7-1-98)

iv. The booth walls must be at least seven (7) feet high and must be permanently fixed to the floor or other structure. (7-1-98)

v. When a door or movable panel is used as an integral part of the booth structure, it must have a

permissive device which prevents an exposure when the door or panel is not closed. (7-1-98)

b. The operator's switch for the radiographic machine will be fixed within the booth and: (7-1-98)

i. Must be at least forty (40) inches from any open edge of the booth wall which is proximal to the examining table; and (7-1-98)

ii. Must allow the operator to use the majority of the available viewing window. (7-1-98)

c. Viewing system requirements: (7-1-98)

i. Each booth must have at least one (1) viewing device which will: (7-1-98)

(1) Be so placed that the operator can view the patient during any exposure; and (7-1-98)

(2) Be so placed that the operator can have full view of any occupant of the room and can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then that door must have a permissive device controlling the exposure which will prevent exposure if the door is not closed. (7-1-98)

ii. If the viewing system is a window, the following requirements also apply: (7-1-98)

(1) The window must have a visible area of at least one (1) square foot, the center of which is five (5) feet above the floor; and (7-1-98)

(2) The window materials must have at least the same lead equivalence as that required in the booth's wall in which it is to be mounted. (7-1-98)

iii. When the viewing system utilizes one (1) or more mirrors, the mirrors must be so located as to accomplish the general requirements as in Subsection 203.04.c.i. (7-1-98)

iv. When the viewing system utilizes electronic means, such as a television: (7-1-98)

(1) The camera must be so located as to accomplish the general requirements in Subsection 203.04.c.i.; and (7-1-98)

(2) There must be an alternate viewing system to serve as a back-up in case of electronic failure. (7-1-98)

204. GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS.
In addition to other requirements of Section 200, all diagnostic x-ray systems must meet the following requirements: (7-1-98)

01. Battery Charge Indicator. On battery-powered generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation. (7-1-98)

02. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source must not exceed one hundred (100) milliroentgens in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance will be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters. (7-1-98)

03. Beam Quality. (7-1-98)

a. The half-value layer (HVL) of the useful beam for a given x-ray tube potential must not be less than the values shown in the following table. If it is necessary to determine such HVL at an x-ray tube potential which is

not listed in the table, linear interpolation or extrapolation can be made.

Design Operating Range (kilovolts peak)	Measured Potential (kilovolts peak)	Half-Value Layers (millimeters of aluminum)
Below 50	30	0.3
	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

(7-1-98)

b. The above HVL criteria will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table:

FILTRATION REQUIRED vs OPERATING VOLTAGE	
Operating Voltage (kVp)	**Total Filtration (inherent plus added)**
	(Millimeters aluminum equivalent)
Below 50	0.5 Millimeters
50 -- 70	1.5 Millimeters
Above 70	2.5 Millimeters

(7-1-98)

c. In addition to the requirements of Subsection 204.03.a., all intraoral dental radiographic systems manufactured on and after December 1, 1980, must have a minimum half-value layer not less than one point five (1.5) millimeters aluminum equivalent filtration permanently installed in the useful beam. (7-1-98)

d. Beryllium window tubes must have a minimum of zero point five (0.5) millimeter aluminum equivalent filtration permanently installed in the useful beam. (7-1-98)

e. For capacitor energy storage equipment, compliance with the requirements of Subsection 204.03

must be determined with the maximum quantity of charge per exposure. (7-1-98)

f. The required minimal aluminum equivalent filtration must include the filtration contributed by all materials which are always present between the source and the patient. (7-1-98)

g. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device must link the kVp selector with the filter(s) and must prevent an exposure unless the minimum amount of filtration required by Subsection 204.03 is in the useful beam for the given kVp which has been selected. (7-1-98)

04. Multiple Tubes. Where two (2) or more radiographic tubes are controlled by one (1) exposure switch, the tube or tubes which have been selected must be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected. (7-1-98)

05. Mechanical Support of Tube Head. The tube housing assembly supports must be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system. (7-1-98)

06. Technique Indicators. (7-1-98)

a. The technique factors to be used during an exposure must be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure must be indicated. (7-1-98)

b. The requirement of Subsection 204.06.a. may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors must be visible from the operator's position except in the case of spot films made by the fluoroscopist. (7-1-98)

07. Warning Label. The control panel containing the main power switch must bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed." (7-1-98)

08. Radiation From Components Other Than the Diagnostic Source Assembly. The radiation emitted by a component other than the diagnostic source assembly must not exceed two (2) milliroentgens in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance must be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters. (7-1-98)

205. FLUOROSCOPIC X-RAY SYSTEMS.
All fluoroscopic x-ray systems must meet the following requirements: (7-1-98)

01. Limitation of Useful Beam. (7-1-98)

a. The fluoroscopic tube must not produce x-rays unless the primary protective barrier is in position to intercept the useful beam at all times. (7-1-98)

b. The entire cross section of the useful beam must be intercepted by the primary protective barrier of the fluoroscopic image assembly at any Source to Image Distance (SID). (7-1-98)

c. Radiation therapy simulation systems will be exempt from all the requirements of Subsections 205.01.a., 205.03, 205.04, and 205.07, provided that: (7-1-98)

i. Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and (7-1-98)

ii. Systems which do not meet the requirements of Subsection 205.07 are provided with a means of

indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures must require in such cases that the timer be reset between examinations. (7-1-98)

d. The x-ray field produced by fluoroscopic equipment without image intensification must not extend beyond the entire visible area of the image receptor. This requirement applies to field size for both fluoroscopic procedures and spot filming procedures. In addition: (7-1-98)

i. Means must be provided for stepless adjustment of the field size; (7-1-98)

ii. The minimum field size at the greatest SID must be equal to or less than five (5) by five (5) centimeters. (7-1-98)

e. For image-intensified fluoroscopic equipment, neither the length nor the width of the x-ray field in the plane of the image receptor can exceed the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width must be no greater than four percent (4%) of the SID. (7-1-98)

i. Means must be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or a visible area of greater than three hundred (300) square centimeters must be provided with means for stepless adjustment of the x-ray field; (7-1-98)

ii. All equipment with a fixed SID and a visible area of three hundred (300) square centimeters or less must be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to one hundred twenty-five (125) square centimeters or less. Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size of five (5) by five (5) centimeters or less. (7-1-98)

iii. For rectangular x-ray fields used with circular image reception, the error in alignment must be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. (7-1-98)

f. Spot-film devices which are certified components must meet the following additional requirements: (7-1-98)

i. Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film selector. Such adjustment must be automatically accomplished 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 manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size must be only at the operator's option; (7-1-98)

ii. It must be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID must be equal to, or less than, five (5) by five (5) centimeters; (7-1-98)

iii. The center of the x-ray field in the plane of the film must be aligned with the center of the selected portion of the film to within two percent (2%) of the SID; and (7-1-98)

iv. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor. (7-1-98)

02. Activation of the Fluoroscopic Tube. X-ray production in the fluoroscopic mode must be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist must be able to terminate the x-ray exposures at any

time; however, means can be provided to permit completion of any single exposure of the series in process. (7-1-98)

03. Exposure Rate Limits. (7-1-98)

a. Entrance exposure rate - allowable limits: (7-1-98)

i. Except as provided below in Subsections 205.03.a.ii. and 205.03.a.iii., the exposure measured at the point where the center of the useful beam enters the patient must not exceed ten (10) roentgens per minute. (7-1-98)

ii. When provided with optional high level control, the equipment must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens per minute at the points where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, will be required to avoid accidental use. (7-1-98)

iii. In addition to the other requirements of Section 205, any new equipment installed after the effective date of these rules which does not incorporate an automatic exposure control, such as automatic brightness control or ionization chamber control, must not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens per minute at the point where the center of beam enters the patient except during recording of fluoroscopic images. (7-1-98)

iv. Compliance with Subsection 205.03 will be determined as follows: (7-1-98)

(1) If the source is below the tabletop, exposure rate will be measured one (1) centimeter above the tabletop or cradle; (7-1-98)

(2) If the source is above the tabletop, the exposure rate will be measured at thirty (30) centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement; (7-1-98)

(3) In a C-arm type of fluoroscope, the exposure rate will be measured thirty (30) centimeters from the input surface of the fluoroscopic imaging assembly; (7-1-98)

(4) Movable grids and compression devices must be removed from the useful beam during the measurement. (7-1-98)

b. Periodic measurement of entrance exposure rate will be performed as follows: (7-1-98)

i. Measurements must be made annually or after any maintenance of the system which might affect the exposure rate; (7-1-98)

ii. Results of these measurements must be posted where any fluoroscopist may have ready access to such results while using the fluoroscope. The measurement results must be stated in roentgens per minute and include the technique factors used in determining such results. The name of the person performing the measurements and the date the measurements were performed must be included in the results; (7-1-98)

iii. Personnel monitoring devices may be used to perform the measurements required by Subsection 205.03.b.i., provided the measurements are made as described below. (7-1-98)

iv. Conditions of periodic measurement of entrance exposure rate are as follows: (7-1-98)

(1) The measurement must be made under the conditions that satisfy the requirements of Subsection 205.03.a.iv.; (7-1-98)

(2) The kVp must be the kVp typical of clinical use of the x-ray system; (7-1-98)

(3) The x-ray system(s) that incorporates automatic exposure control must have sufficient material placed in the useful beam to produce a milliamperage typical of the use of the x-ray system; and (7-1-98)

(4) X-ray system(s) that do not incorporate an automatic exposure control must utilize a milliamperage typical of the clinical use of the x-ray system. Materials should be placed in the useful beam when conducting these periodic measurements to protect the imaging system. (7-1-98)

04. Radiation Transmitted Through Barrier. (7-1-98)

a. The exposure rate resulting from transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, must not exceed two (2) milliroentgens per hour at ten (10) centimeters 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. (7-1-98)

b. For measuring compliance of barrier transmission, the following will apply: (7-1-98)

i. The exposure rate resulting from transmission through the primary protective barrier combined with the radiation from the image intensifier will be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters; (7-1-98)

ii. If the source is below the tabletop, the measurement will be made with the input surface of the fluoroscopic imaging assembly, positioned thirty (30) centimeters above the tabletop; (7-1-98)

iii. If the source is above the tabletop and the SID is variable, the measurement will be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it will not be closer than thirty (30) centimeters; (7-1-98)

iv. The attenuation block will be positioned between the point of entrance exposure rate measurement and the input surface of the fluoroscopic imaging assembly, and the block will be ten (10) centimeters from the point of entrance exposure rate measurement; (7-1-98)

v. Movable grids and compression devices must be removed from the useful beam during the measurement. (7-1-98)

05. Indication of Potential and Current. During fluoroscopy and cinefluorography, x-ray tube potential and current will be continuously indicated; and (7-1-98)

06. Source-to-Skin Distance. The source-to-skin distance must not be less than: (7-1-98)

a. Thirty-eight (38) centimeters on stationary fluoroscopes installed after May 8, 1968; (7-1-98)

b. Thirty-five and one-half (35.5) centimeters on stationary fluoroscopes which were in operation prior to May 8, l968; (7-1-98)

c. Thirty (30) centimeters on all mobile fluoroscopes; and (7-1-98)

d. Twenty (20) centimeters for image intensified fluoroscopes used for specific surgical application. The user's operating manual must provide precautionary measures to be adhered to during the use of this device; (7-1-98)

07. Fluoroscopic Timer. (7-1-98)

a. Means must be provided to preset the cumulative on-time of the fluoroscopic tube. (7-1-98)

b. The maximum cumulative time of the timing device must not exceed five (5) minutes without resetting. (7-1-98)

c. A signal audible to the fluoroscopist, or the appropriate operator, must indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. (7-1-98)

08. Mobile Fluoroscopes. (7-1-98)

a. In addition to the other requirements of Section 205, mobile fluoroscopes must provide image intensification. (7-1-98)

09. Control of Scattered Radiation. (7-1-98)

a. Fluoroscopic table designs, when combined with procedures utilized, must be such that no unprotected part of any staff or ancillary person's body will be exposed to unattenuated scattered radiation which originated from under the table. The attenuation required must be not less than twenty-five hundredths (0.25) mm equivalent. (7-1-98)

b. Equipment configuration, when combined with procedures utilized, must be such that no portion of any staff or ancillary person's body, except the extremities, will be exposed to the unattenuated scattered radiation emanating from above the tabletop unless: (7-1-98)

i. That individual is at least one hundred twenty (120) cm from the center of the useful beam; (7-1-98)

ii. The radiation has passed through not less than twenty-five hundredths (0.25) mm lead equivalent material, such as drapes, Bucky-slot cover, sliding or folding panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in Subsection 203.01.d.; (7-1-98)

iii. Upon application to the Radiation Control Agency with adequate justification, exceptions to Subsection 205.09 may be made in some special procedures where a sterile field will not permit the use of the normal protective barriers or where the protective barriers would interfere with the procedures. (7-1-98)

206. RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, DENTAL INTRAORAL, OR VETERINARIAN SYSTEMS.
For those radiographic systems, other than fluoroscopic, dental intraoral or veterinarian systems, the following requirements must be met: (7-1-98)

01. Beam Limitation. The useful beam must be limited to the area of clinical interest. (7-1-98)

a. General Purpose Stationary and Mobile X-ray Systems: (7-1-98)

i. In regard to variable x-ray field limitations, there must be provided a means for stepless adjustment of the size of the x-ray field. (7-1-98)

ii. Means must be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field must not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam. (7-1-98)

iii. The Radiation Control Agency may grant an exemption on noncertified x-ray systems to Subsections 206.01.a.i. and 206.01.a.ii. provided the registrant makes a written application for such exemption and in that application: (7-1-98)

(1) Demonstrate it is impractical to comply with Subsections 206.01.a.i. and 206.01.a.ii.; and (7-1-98)

(2) The purpose of Subsections 206.01.a.i. and 206.01.a.ii. will be met by other methods. (7-1-98)

b. In addition to the requirements of Subsection 206.01.a., all stationary general purpose x-ray systems must meet the following requirements: (7-1-98)

i. Means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%); (7-1-98)

ii. The beam-limiting device must numerically indicate the field size in the plane of the image receptor to which it is adjusted; (7-1-98)

iii. Indication of field size dimensions and SID's must be specified in inches and/or centimeters, and must be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within two percent (2%) of the SID when the beam axis is perpendicular to the plane of the image receptor. (7-1-98)

c. Radiographic equipment designed for only one (1) image receptor size at a fixed SID must be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID or must be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. (7-1-98)

d. Special purpose x-ray systems will be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. (7-1-98)

e. Additionally, special purpose x-ray systems will be provided with means to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID or means must be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. (7-1-98)

f. Requirements of Subsections 206.01.d. and 206.01.e. can be met with a system that meets the requirements for a general purpose x-ray system as specified in Subsection 206.01.a. or, when alignment means are also provided, can be met by compliance with either of the following two (2) provisions: (7-1-98)

i. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed; each such device must have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or (7-1-98)

ii. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings must indicate the image receptor size and SID for which each aperture is designed and must indicate which aperture is in position for use. (7-1-98)

02. Radiation Exposure Control Devices. (7-1-98)

a. A means, such as a timer, must be provided to terminate the exposure at a preset time interval, at a preset product of current and time, at a preset number of pulses, or at a preset radiation exposure to the image receptor. In addition: (7-1-98)

i. Termination of exposure must cause automatic resetting of the timer to its initial setting or to zero (0); (7-1-98)

ii. It must be impossible to make an exposure when the timer is set to a zero (0) or "off" position, if either position is provided. (7-1-98)

b. X-ray Control (Exposure Switch): (7-1-98)

i. A control must be incorporated into each x-ray system such that an exposure can be terminated at any time except for: (7-1-98)

(1) Exposure of one-half (1/2) second or less; or (7-1-98)

(2) During serial radiography when means must be provided to permit completion of any single exposure of the series in process. (7-1-98)

ii. Each x-ray control must be located for stationary x-ray systems in such a way as to be permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure. (7-1-98)

iii. X-ray controls for mobile and portable x-ray systems: (7-1-98)

(1) If used for greater than one (1) week in one (1) location, such as one (1) room or suite, must meet the requirements of Subsections 206.02.a. and 206.02.b.; (7-1-98)

(2) If used for more than one (1) hour and less than one (1) week at one (1) location, such as one (1) room, or suite, must meet the requirement of Subsection 206.02.b.iii.(1) or be provided with a six and one-half (6.5) foot high protective barrier which is placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient; (7-1-98)

(3) If used to make an exposure of only one (1) patient at the use location, must meet the requirement of Subsections 206.02.b.iii.(1) or 206.02.b., or be provided with a method of control which will permit the operator to be at least twelve (12) feet from the tube head assembly during an exposure. (7-1-98)

iv. The x-ray control must provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the esposure has terminated. (7-1-98)

c. When an automatic exposure control, such as a phototimer, is provided: (7-1-98)

i. Indication must be made on the control panel when this mode of operation is selected; (7-1-98)

ii. When the x-ray tube potential is equal to or greater than fifty (50) kVp, the minimum exposure time for field emission equipment rated for pulsed operation must be equal to or less than a time interval equivalent to two (2) pulses; (7-1-98)

iii. The minimum exposure time for all equipment, other than that specified in Subsection 206.02.c.ii., must be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five (5) mAs, whichever is greater; (7-1-98)

iv. Either the product or peak x-ray tube potential, current and exposure time must be limited to not more than sixty (60) kWs per exposure or the product of x-ray tube current and exposure time must be limited to not more than six hundred (600) mAs per exposure, except when the x-ray tube potential is less than fifty (50) kVp, in which case the product of x-ray tube current and exposure time must be limited to not more than two thousand (2000) mAs per exposure; (7-1-98)

v. A visible signal must indicate when an exposure has been terminated at the limits described in Subsection 206.02.c.iv., and manual resetting must be required before further automatically timed exposures can be made. (7-1-98)

d. When four (4) timer tests are performed, at identical timer settings, the average time period (T) will be greater than five (5) times the maximum period (Tmax) less the minimum period (Tmin). T must be equal to or less than five-tenths (0.5) seconds. (7-1-98)

03. Source-to-Skin Distance. All radiographic systems must be provided with a durable, securely fastened means to limit the source-to-skin distance to not less than thirty (30) centimeters. This can be met when the collimator or cone provides the required limits. (7-1-98)

04. Exposure Reproducibility. The coefficient of variation of exposure must not exceed one-twentieth (0.05) when all technique factors are held constant. This requirement will be deemed to have been met if, when four (4) exposures are made at identical technique factors, the value of the average exposure (E) is greater than or equal to five (5) times the maximum exposure (Emax) minus the minimum exposure (Emin): E >5 (Emax-Emin). (7-1-98)

05. Standby Radiation from Capacitor Energy Storage Equipment. Radiation emitted from the x-ray tube when the exposure switch or timer is not activated must not exceed a rate of two (2) milliroentgens per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open. (7-1-98)

06. Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one (1) or more certified components will be required to comply with the following requirements which relate to that certified component in addition to other applicable requirements of these rules. (7-1-98)

a. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, the estimated coefficient of variation of radiation exposures must be no greater than five one-hundredths (0.05). (7-1-98)

b. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray to be potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product, mR/mAs, obtained at any two (2) consecutive tube current settings must not differ by more than $[X_1 - X_2]<0.10(X_1 \text{ Plus } X_2)$, where X_1 and X_2 are the average mR/mAs (microcoulomb/kilogram per mAs) one-tenth (0.10) times their sum. (7-1-98)

c. Deviation of technique factors from indicated values must not exceed the limits provided for that system by its manufacturer. (7-1-98)

d. Beam Limitation for Stationary and Mobile General Purpose X-ray Systems. (7-1-98)

i. There must be provided a means of stepless adjustment of the size of the x-ray field. The minimum field size at an SID of one hundred (100) centimeters must be equal to or less than five (5) by five (5) centimeters. (7-1-98)

ii. When a light localizer is used to define the x-ray field, it must provide an average illumination of not less than one hundred sixty (160) lux, that is, fifteen (15) footcandles, at one hundred (100) centimeters or at the maximum SID, whichever is less. The average illumination will be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on or after May 27, 1980, are exempt from this requirement. (7-1-98)

iii. The edge of the light field at one hundred (100) centimeters or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined in I_1 I_2 where I_1 is the illumination three (3) millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination three (3) millimeters from the edge of the light field away from the center of the field. Compliance will be determined with a measuring instrument-aperture of one (1) millimeter in diameter. (7-1-98)

e. Beam limitation for portable x-ray systems must meet the field limitation requirements of Subsection 206.01.a. and 206.06.f. (7-1-98)

f. Field Limitation and Alignment on Stationary General Purpose X-ray Systems. For stationary,

general purpose x-ray systems which contain a tube housing assembly, an x-ray control and, for those systems so equipped, a table, all certified in accordance with 21 CFR 1020.30(c): (7-1-98)

i. Means must be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within five (5) seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than five (5) seconds or is manual, will prevent production of x-rays until such adjustment is completed. At SID's at which the device is not intended to operate, the device will prevent the production of x-rays. (7-1-98)

ii. The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, will be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than three percent (3%) of the SID and that the sum of the length and width differences without regard to sign be no greater than four percent (4%) of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. (7-1-98)

iii. The radiographic system must be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of one hundred (100) centimeters must be equal to or less than five (5) by five (5) centimeters. Return to positive beam limitation as defined in Subsections 206.06.f.i. and 206.06.f.ii. will occur upon a change in image receptor. (7-1-98)

iv. Positive beam limitation can be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not within ten (10) degrees of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation will be automatic. (7-1-98)

v. A capability can be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key will be required to override the positive mode. It must be impossible to remove the key while the positive mode is overridden. (7-1-98)

g. Timers. Except for dental panoramic systems, termination of exposure must cause automatic resetting of the timer to its initial setting or to "zero" (0). (7-1-98)

207. INTRAORAL DENTAL RADIOGRAPHIC SYSTEMS.
In addition to the provisions of Sections 203 and 204 the requirements of Section 207 apply to x-ray equipment and associated facilities used for dental radiography. (See Section 206 for criteria for extraoral dental radiographic systems.) (7-1-98)

01. Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor must be provided with means to limit source-to-skin distance to not less than: (7-1-98)

a. Eighteen (18) centimeters if operable above fifty (50) kilovolts peak; (7-1-98)

b. Ten (10) centimeters if not operable above fifty (50) kilovolts peak. (7-1-98)

02. Field Limitation. (7-1-98)

a. Radiographic systems designed for use with an intraoral image receptor must be provided with means to limit the x-ray beam such that: (7-1-98)

i. If the minimum source-to-skin distance (SSD) is eighteen (18) centimeters or more, the x-ray field, at the minimum SSD, must be containable in a circle having a diameter of no more than seven (7) centimeters; and (7-1-98)

ii. If the minimum SSD is less than eighteen (18) centimeters, the x-ray field, at the minimum SSD,

must be containable in a circle having a diameter of no more than six (6) centimeters. (7-1-98)

b. An open ended shielded position indicating device must be used. The shielding must be equivalent to that required for the diagnostic source assembly in Subsection 204.03. (7-1-98)

c. Units installed previous to the effective date of these rules will be exempted from Subsection 207.02.b. (7-1-98)

03. **Timers**. A means, such as a timer, must be provided to terminate the exposure at a preset time interval, at a preset product of current and time, at a preset number of pulses, or at a preset radiation exposure to the image receptor. In addition: (7-1-98)

a. Termination of exposure must cause automatic resetting of the timer to its initial setting or to zero (0); and (7-1-98)

b. It must not be possible to make an exposure when the timer is set to a zero (0) or "off" position, if either position is provided; and (7-1-98)

c. When four (4) timer tests taken at identical timer settings are performed, the average time period (T) must be greater than five (5) times the maximum period (Tmax) less the minimum period (Tmin). T must be less than or equal to five (5) seconds. (7-1-98)

04. **X-ray Control (Exposure Switch)**. (7-1-98)

a. A control must be incorporated into each x-ray system such that an exposure can be terminated at any time, except for exposures of one-half (1/2) second or less. (7-1-98)

b. Each x-ray control must be located in such a way as to meet the following criteria: (7-1-98)

i. Stationary x-ray systems must have the control switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and (7-1-98)

ii. Mobile and portable x-ray systems which are: (7-1-98)

(1) Used for greater than one (1) week in one (1) location must meet the requirements of Subsection 207.04.b.i.; or (7-1-98)

(2) Used for more than one (1) hour and less than one (1) week at one (1) location must meet the requirements of Subsection 207.04.b.ii.(1) or be provided with a six and one-half (6.5) foot high protective barrier which is placed at least six (6) feet from the tube housing assembly and at least six (6) feet from the patient; or (7-1-98)

(3) Used to make an exposure(s) of only one (1) patient at the use location must meet the requirement of Subsections 207.04.b.ii.(1) or 207.04.b.ii.(2), or be provided with a method of control which will permit the operator to be at least twelve (12) feet from the tube head assembly during an exposure. (7-1-98)

c. The x-ray control must provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated. (7-1-98)

d. When dental units are installed in adjacent rooms or areas, protective barriers must be provided between the rooms or areas. (7-1-98)

05. **Exposure Reproducibility**. The exposure produced must be reproducible to within the following criteria: When all technique factors are held constant, the coefficient of variation must not exceed one-tenth (0.10). This will be deemed to have been met when four (4) exposures at identical technique factors are made and the value of the average exposure (E) is equal to or greater than five (5) times the maximum exposure (Emax) minus the

minimum exposure (Emin) E >5 (Emax-Emin). (7-1-98)

06. Operating Controls. (7-1-98)

a. Patient and film holding devices must be used when the techniques permit. The safety rules, required by Subsection 203.01, must list individual projections where holding devices cannot be utilized. (7-1-98)

b. Neither the tube housing nor the position indicating device can be hand held during an exposure. (7-1-98)

c. The x-ray system must be arranged and operated in such a manner that the useful beam at the patient's skin does not exceed the dimensions specified in Subsection 207.02.a. (7-1-98)

d. Dental fluoroscopy without image intensification is prohibited. (7-1-98)

07. Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one (1) or more certified components will be required to comply with the following requirements which relate to that certified component in addition to other applicable requirements of these rules. (7-1-98)

a. Regarding reproducibility, Subsection 207.07.b. will apply when the equipment is operated on an adequate power supply as specified by the manufacturer. (7-1-98)

b. For any specific combination of selected technique factors, the estimated coefficient of variation or radiation exposures must be no greater than five one-hundredths (0.05). (7-1-98)

c. Regarding linearity, Subsection 207.07.d. applies when the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of 21 CFR 1000 for any fixed x-ray tube potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rated. (7-1-98)

d. The average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) obtained at any two (2) consecutive tube current settings must not differ by more than one-tenth (0.10) times their sum. (7-1-98)

e. To insure accuracy, deviation of technique factors from indicated values must not exceed the limits provided for that system by its manufacturer. (7-1-98)

f. All certified dental x-ray systems manufactured on and after December 1, 1980, must have a minimum half-value layer not less than one and one-half (1.5) millimeters aluminum equivalent. Systems operating above, seventy (70) kVp are subject to the filtration requirements of Subsection 204.03.a. (7-1-98)

208. VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS.

01. Equipment. (7-1-98)

a. The protective tube housing must be of diagnostic type. (7-1-98)

b. Diaphragms or cones must be provided for collimating the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the housing. (7-1-98)

c. The total filtration permanently in the useful beam must not be less than five-tenths (0.5) millimeters aluminum equivalent for machines operating up to fifty (50) kVp, one and one-half (1.5) millimeters aluminum equivalent for machines operating between fifty (50) to seventy (70) kVp, and two and one-half (2.5) millimeters aluminum equivalent for machines operating above seventy (70) kVp. (7-1-98)

d. A device must be provided to terminate the exposure after a preset time or exposure. (7-1-98)

e. A dead-man type of exposure switch must be provided, together with an electrical cord of sufficient

length, so that the operator can stand out of the useful beam and at least six (6) feet from the animal during all x-ray exposures. (7-1-98)

02. Structural Shielding. All wall, ceiling, and floor areas will be equivalent to or provided with applicable protective barriers as required in Subsections 110.01, 110.03, and 110.04. (7-1-98)

03. Operating Procedures. (7-1-98)

a. The operator must stand well away from the useful beam and the animal during radiographic exposures. (7-1-98)

b. No individual other than the operator can be in the x-ray room while exposures are being made unless such individual's assistance is required. (7-1-98)

c. When an animal must be held in position during radiography, mechanical supporting or restraining devices can be used. If the animal must be held by an individual, that individual must be protected with appropriate shielding devices, such as protective gloves and apron, and he must be so positioned that no part of his body will be struck by the useful beam. The exposure of any individual used for this purpose must be monitored. (7-1-98)

04. Veterinary Medicine Therapeutic X-Ray Installations. All of the requirements for equipment, installation, construction and operation contained in Sections 209 and 210 are effective as applicable to veterinary practice. (7-1-98)

209. THERAPEUTIC X-RAY INSTALLATIONS.

01. Therapeutic X-Ray Systems of Less Than One MeV. (7-1-98)

a. Equipment requirements are as follows: (7-1-98)

i. When the tube is operated at its leakage technique factors, the leakage radiation must not exceed the value specified at the distance specified for the classification of that x-ray system. (7-1-98)

(1) In contact therapy systems leakage radiation shall not exceed one hundred (100) milliroentgens per hour at five (5) centimeters from the surface of the tube housing assembly. (7-1-98)

(2) In zero (0) to one hundred fifty (150) kVp systems which were manufactured or installed prior to the effective date of these rules must have a leakage radiation which does not exceed one (1) roentgen in one (1) hour at one (1) meter from the source. (7-1-98)

(3) In zero (0) to one hundred fifty (150) kVp systems which are manufactured on or after the effective date of these rules must have a leakage radiation which does not exceed one hundred (100) milliroentgens in one (1) hour at one (1) meter from the source. (7-1-98)

(4) In one hundred fifty one (151) to nine hundred ninety nine (999) kVp systems the leakage radiation must not exceed one (1) roentgen in one (1) hour at one (1) meter from the source except systems that operate in excess of five hundred (500) kVp may have a leakage radiation at one (1) meter from the source not to exceed one-tenth of one percent (0.1%) of the useful beam one (1) meter from the source. (7-1-98)

ii. Permanent fixed diaphragms or cones used for limiting the useful beam must provide the same or a higher degree of protection as required for the tube housing assembly. (7-1-98)

iii. Removable and adjustable beam limiting devices are as follows: (7-1-98)

(1) Removable beam limiting devices must, for the portion of the useful beam to be blocked by these devices, transmit not more than one percent (1%) 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. (7-1-98)

(2) Adjustable beam limiting devices installed after the effective date of these rules must meet the requirements of Subsection 209.01.a.iii.(1). (7-1-98)

(3) Adjustable beam limiting devices installed before the effective date of these rules must, for the portion of the x-ray beam to be blocked by these devices, transmit not more than five percent (5%) of the useful beam at the maximum kilovoltage and maximum treatment filter. (7-1-98)

iv. The filter system must be so designed that: (7-1-98)

(1) The filters cannot be accidentally displaced at any possible tube orientation; (7-1-98)

(2) The radiation at five (5) centimeters from the filter insertion slot opening does not exceed thirty (30) roentgens per hour under any operating conditions; and (7-1-98)

(3) 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. (7-1-98)

v. The tube housing assembly must be capable of being immobilized for stationary treatments. (7-1-98)

vi. The tube housing assembly must be so marked that it is possible to determine the location of the focal spot to within five (5) millimeters, and such markings must be readily accessible for use during calibration procedures. (7-1-98)

vii. Contact therapy tube housing assemblies must have a removable shield of at least five-tenths (0.5) millimeter lead equivalency at one hundred (100) kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use. (7-1-98)

viii. Systems of greater than one hundred fifty (150) kVp manufactured after the effective date of these rules must be provided with a beam monitor system which: (7-1-98)

(1) Has the detector of the monitor system interlocked to prevent incorrect positioning; (7-1-98)

(2) Does not allow irradiation until a preselected value of exposure has been made at the treatment control panel; (7-1-98)

(3) Independently terminates irradiation when the preselected exposure has been reached; (7-1-98)

(4) Is so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined; (7-1-98)

(5) Has a display at the control panel from which the dose at a reference point in soft tissue can be calculated; (7-1-98)

(6) Has a control panel display which maintains the administered dose reading until intentionally reset to zero (0); and (7-1-98)

(7) Has a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers. (7-1-98)

ix. The requirements for a timer are: (7-1-98)

(1) A timer which has a display must be provided at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator. (7-1-98)

(2) The timer must be a cumulative timer which activates with the production of radiation and retains

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 (0). (7-1-98)

(3) The timer must terminate irradiation when a preselected time has elapsed if any dose monitoring system present has not previously terminated irradiation. (7-1-98)

(4) The timer must permit accurate presetting and determination of exposure times as short as one (1) second. (7-1-98)

(5) The timer must not permit an exposure if set at zero (0). (7-1-98)

(6) The timer must not activate until the shutter is opened when irradiation is controlled by a shutter mechanism. (7-1-98)

x. The control panel, in addition to the displays required in other provisions of Section 209 must have: (7-1-98)

(1) An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible; (7-1-98)

(2) An indication of whether x-rays are being produced; (7-1-98)

(3) Means for indicating x-ray tube potential and current; (7-1-98)

(4) Means for terminating an exposure at any time; (7-1-98)

(5) A locking device which will prevent unauthorized use of the x-ray system; and (7-1-98)

(6) For x-ray systems manufactured after the effective date of these rules, a positive display of specific filter(s) in the beam. (7-1-98)

xi. When a control panel may energize more than one (1) x-ray tube: (7-1-98)

(1) It must be possible to activate only one (1) x-ray tube at any time. (7-1-98)

(2) There must be an indication at the control panel identifying which x-ray tube is energized. (7-1-98)

(3) There must be an indication at the tube housing assembly when that tube is energized. (7-1-98)

xii. There must be means of determining the source-to-skin distance (SSD) to within one (1) centimeter. (7-1-98)

xiii. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five (5) seconds, the beam must be automatically attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition: (7-1-98)

(1) After the unit is at operating parameters, the shutter must be controlled electrically by the operator from the control panel; and (7-1-98)

(2) An indication of shutter position must appear at the control panel. (7-1-98)

xiv. Each x-ray system equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and at the control panel. (7-1-98)

02. Facility Design Requirement for X-Ray Systems Capable of Operating Above Fifty kVp. (7-1-98)

a. Provision must be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication must be used. (7-1-98)

b. The requirements for viewing systems are as follows: (7-1-98)

i. Windows, mirrors, closed-circuit television, or an equivalent system must be provided to permit continuous observation of the patient during irradiation and must be so located that the operator can observe the patient from the control panel. (7-1-98)

ii. When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, must be available for use in the event of failure of the primary viewing system. (7-1-98)

c. Additional requirements for X-ray systems capable of operation above one hundred fifty (150) kVp. (7-1-98)

i. All protective barriers must be fixed except for entrance door or beam interceptors. (7-1-98)

ii. The control panel must be located outside the treatment room. (7-1-98)

iii. Entrance interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel. (7-1-98)

iv. When any door referred to in Subsection 209.02.c.iii. is opened while the x-ray tube is activated, the exposure at a distance of one (1) meter from the source shall be reduced to less than one hundred (100) milliroentgens per hour. (7-1-98)

03. Operating Procedures. (7-1-98)

a. X-ray systems must not be left unattended unless the system is secured against unauthorized use. (7-1-98)

b. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used. (7-1-98)

c. The tube housing assembly must not be held by hand during operation unless the system is designed to require such holding and the peak tube potential of the system does not exceed fifty (50) kVp. In such cases, the holder must wear protective gloves and apron of not less than five-tenths (0.5) mm lead equivalency at one hundred (100) kVp. (7-1-98)

d. No individual other than the patient may be in the treatment room unless such individual is protected by a barrier sufficient to meet the requirements of Section 110. No individual other than the patient may be in the treatment room during exposures from x-ray systems operating above one hundred fifty (150) kVp. (7-1-98)

e. The x-ray system must not be used in the administration of radiation therapy unless the requirements of Subsections 209.03 and 209.05.e. have been met. (7-1-98)

04. Surveys. (7-1-98)

a. All new facilities, and existing facilities not previously surveyed, must have a survey made by, or under the direction of a qualified expert. In addition, such surveys must be done after any change in the facility or equipment which might produce a significant increase in radiation hazard. (7-1-98)

b. The registrant must obtain a written report of the survey from the qualified expert and a copy of the report must be transmitted by the registrant to the Radiation Control Agency within thirty (30) days of receipt of the

report. (7-1-98)

c. The survey and report must indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules. (7-1-98)

05. Calibrations. (7-1-98)

a. The calibration of an x-ray system must be performed at intervals not to exceed one (1) year and after any change or replacement of components which could cause a change in the radiation output. (7-1-98)

b. The calibration of the radiation output of the x-ray system must be performed by or under the direction of a qualified expert who is physically present at the facility during such calibration. (7-1-98)

c. Calibration of the radiation output of an x-ray system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The system must have been calibrated within the preceding two (2) years. (7-1-98)

d. The calibration must be such that the dose at a reference point in soft tissue can be calculated to within an uncertainty of five percent (5%). (7-1-98)

e. The calibration of the x-ray system may include, but not be limited to, the following determinations: (7-1-98)

i. Verification that the x-ray system is operating in compliance with the design specifications; (7-1-98)

ii. The exposure rates as a function of field size, technique factors, filter, and treatment distance used; (7-1-98)

iii. The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present; and (7-1-98)

iv. An evaluation of the uniformity of the largest radiation field used. (7-1-98)

f. Records of calibration must be maintained by the registrant for five (5) years after completion of the calibration. (7-1-98)

g. A copy of the most recent x-ray system calibration must be available at or in the area of the control panel. (7-1-98)

06. Spot Checks. Spot checks must be performed on x-ray systems capable of operation at greater than one hundred fifty (150) kVp. Such spot-checks must meet the following requirements: (7-1-98)

a. The spot-check procedures must be in writing and shall have been developed by a qualified expert. A copy of the procedures must be submitted to the Radiation Control Agency prior to its implementation. (7-1-98)

b. If a qualified expert does not perform the spot-check measurement, the results of the spot-check measurements must be reviewed by a qualified expert within fifteen (15) days. (7-1-98)

c. The spot-check procedures must specify the frequency at which tests or measurements are to be performed. The spot-check procedures must specify that the spot-checks shall be performed during the calibration specified in Subsection 209.05. The acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration specified in Subsection 209.05 must be stated. (7-1-98)

d. The cause for a parameter exceeding a tolerance set by the qualified expert must be investigated and corrected before the system is used for patient irradiation. (7-1-98)

e. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the qualified expert's spot-check procedures, the system must be recalibrated as required in Subsection 209.05. (7-1-98)

f. Records of spot-check measurements must be maintained by the registrant for two (2) years after completion of the spot-check measurements and any necessary corrective actions. (7-1-98)

g. Where a spot-check involves a radiation measurement, such measurement must be obtained using a system satisfying the requirements of Subsection 209.05 or which has been intercompared with a system meeting those requirements within the previous year. (7-1-98)

210. X-RAY AND ELECTRON THERAPY SYSTEMS WITH ENERGIES OF ONE MEV AND ABOVE. Section 350, except Subsections 354.06.c. and 354.06.d., shall apply to medical facilities using therapy systems with energies one (1) MeV and above. (7-1-98)

01. Requirements for Equipment. (7-1-98)

a. Leakage radiation to the patient area. (7-1-98)

i. Equipment built after the effective date of these rules shall meet the following requirements: (7-1-98)

(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads due to leakage radiation, including x-rays, electrons, and neutrons, at any point in a circular plane of two (2) meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size must not exceed one-tenth of one percent (0.1%) of the maximum absorbed dose in rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the plane surface. Measurements excluding those for neutrons may be averaged over an area up to but not exceeding one hundred (100) square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons may be averaged over an area up to but not exceeding two hundred (200) square centimeters. (7-1-98)

(2) For each system, the registrant must determine or obtain documentation from the manufacturer the leakage radiation existing at the positions specified in Subsection 210.01.a.i.(1) for the specified operating conditions. Records on leakage radiation measurements must be maintained for inspection by the Radiation Control Agency. (7-1-98)

ii. Equipment installed before the effective date of these rules shall meet the following requirements: (7-1-98)

(1) For operating conditions producing maximum leakage radiation, the absorbed dose in rads due to leakage radiation excluding neutrons at any point in a circular plane of two (2) meters radius centered on a perpendicular to the central axis of the beam one (1) meter from the virtual source, and outside the maximum size useful beam, shall not exceed one-tenth of one percent (0.1%) of the maximum absorbed dose in rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the surface of the circular plane. Measurements shall be averaged over an area up to but not exceeding one hundred (100) square centimeters at the positions specified. (7-1-98)

(2) For each system, the registrant shall determine or obtain documentation from the manufacturer the leakage radiation existing at the positions specified in Subsection 210.01.a.i.(1) for the specified operating conditions. Records on radiation leakage must be maintained for inspection by the Radiation Control Agency. (7-1-98)

b. Leakage radiation outside the patient area for equipment installed after the effective date of these rules: (7-1-98)

i. The absorbed dose in rads due to leakage radiation except in the area specified in Subsection 210.01.a.i.(1) when measured at any point one (1) meter from the path of the charged particle, before the charged particle strikes the target or window, must not exceed one-tenth of one percent (0.1%) for x-ray leakage nor five hundredths of one percent (0.05%) for neutron leakage of the maximum absorbed dose in rads of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and the circular plane specified in Subsection 210.01.a.i.(1). (7-1-98)

ii. The registrant must determine or obtain documentation from the manufacturer, the actual leakage radiation existing at the positions specified in Subsection 210.01.b.i. for specified operating conditions. Radiation measurements excluding neutrons must be averaged over an area up to but not exceeding one hundred (100) square centimeters. Neutron measurements may be averaged over an area up to but not exceeding two hundred (200) square centimeters. (7-1-98)

c. Adjustable or interchangeable beam limiting devices must be provided, and such devices must transmit no more than two percent (2%) of the useful beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam limiting device. The neutron component of the useful beam shall not be included in this requirement. (7-1-98)

d. The requirements for filters are as follows: (7-1-98)

i. Each filter which is removable from the system must be clearly marked with an identification number. Documentation available at the control panel must contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray. (7-1-98)

ii. If the absorbed dose rate data required by Subsection 210.01.p. relates exclusively to operation with a field flattening or beam scattering filter in place, such filter must be readily removable only by the use of tools. (7-1-98)

iii. For equipment installed after the effective date of these rules which utilizes a system of wedge filters, interchangeable field flattening filters, or interchangeable beam scattering filters: (7-1-98)

(1) Irradiation must not be possible until a selection of a filter has been made at the treatment control panel; (7-1-98)

(2) An interlock system must be provided to prevent irradiation if the filter selected is not in the correct position; (7-1-98)

(3) A display must be provided at the treatment control panel showing the filter(s) in use; and (7-1-98)

(4) 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. (7-1-98)

e. The registrant must determine, or obtain from the manufacturer, data sufficient to assure that the following beam quality requirements are met: (7-1-98)

i. The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam ten (10) centimeters greater than the practical range of the electrons must not exceed the values stated in the following table. Linear interpolation shall be used for values not stated. (7-1-98)

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05

Maximum Energy of Electron Beam in MeV	X-Ray Absorbed Dose as a Fraction of Maximum Absorbed Dose
35	0.10
50	0.20

ii. Compliance with Subsection 210.01.e.i. may be determined using: (7-1-98)

(1) A measurement within a phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam; (7-1-98)

(2) The largest field size available which does not exceed fifteen (15) by fifteen (15) centimeters; and (7-1-98)

(3) A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least five (5) centimeters and whose depth is sufficient to perform the required measurement. (7-1-98)

iii. The absorbed dose at a surface located at the normal treatment distance, at the point of intersection of that surface with the central axis of the useful beam during x-ray irradiation, must not exceed the limits stated in the following table. Linear interpolation shall be used for values not stated:

Maximum Photon Energy in MV	Absorbed Dose at the Surface as a Fraction of the Maximum Absorbed Dose
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

(7-1-98)

iv. Compliance with Subsection 210.01.e.ii. may be determined by measurements made: (7-1-98)

(1) With a phantom using an instrument which will allow extrapolation to the surface absorbed dose; (7-1-98)

(2) Using a phantom whose size and placement meet the requirements of Subsection 210.01.e.ii. (7-1-98)

(3) After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam flattening filters; and (7-1-98)

(4) Using the largest field size available which does not exceed fifteen (15) by fifteen (15) centimeters. (7-1-98)

v. The registrant must determine, or obtain from the manufacturer, the maximum percentage absorbed dose in the useful beam due to neutrons, excluding stray neutron radiation, for specified operating conditions. (7-1-98)

f. All therapy systems must be provided with radiation detectors in the radiation head. (7-1-98)

i. Equipment installed after the effective date of these rules must be provided with at least two (2) radiation detectors. The detectors must be incorporated into two (2) separate dose monitoring systems. (7-1-98)

ii. Equipment installed before the effective date of these rules must be provided with at least one (1) radiation detector. This detector must be incorporated into a primary dose monitoring system. (7-1-98)

iii. The detector and the system into which that detector is incorporated must meet the following requirements. (7-1-98)

(1) Each detector must be removable only with tools and shall be interlocked to prevent incorrect positioning. (7-1-98)

(2) Each 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. (7-1-98)

(3) Each dose monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation. (7-1-98)

(4) For equipment installed after the effective date of these rules, the design of the dose monitoring systems must assure that the malfunction of one system does not affect the correction functioning of the second system, and the failure of any element common to both systems which could affect the correct function of both systems terminates irradiation. (7-1-98)

(5) Each dose monitoring system must have a legible display at the treatment control panel. For equipment installed after the effective date of these rules, each display must maintain a reading until intentionally reset to zero (0); have only one scale and no scale multiplying factors, utilize a design such that increasing dose is displayed by increasing numbers, and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and in the event of power failure, the dose monitoring information required in Subsection 210.01.f.iii.(5) displayed at the control panel at the time of failure will be retrievable in at least one (1) system for a twenty (20) minute period of time. (7-1-98)

g. In equipment installed after the effective date of these rules inherently capable of producing useful beams with asymmetry exceeding five percent (5%), the asymmetry of the radiation beam in two (2) orthogonal directions must be monitored before the beam passes through the beam limiting device. Facilities must be provided so that, if the difference in dose rate between one (1) region and another region symmetrically displaced from the central axis of the beam exceeds five percent (5%) of the central axis dose rate, indication of this condition is made at the control panel, and if this difference exceeds ten percent (10%), the irradiation is terminated. (7-1-98)

h. Selection and display of dose monitor units. (7-1-98)

i. Irradiation must not be possible until a selection of a number of dose monitor units has been made at the treatment control panel. (7-1-98)

ii. The preselected number of dose monitor units must be displayed at the treatment control panel until reset manually for the next irradiation. (7-1-98)

iii. After termination of irradiation, it must be necessary to reset the dosimeter display to zero (0) before subsequent treatment can be initiated. (7-1-98)

iv. For equipment installed after the effective date of these rules after termination of irradiation, it must be necessary to manually reset the preselected dose monitor units before irradiation can be initiated. (7-1-98)

i. Termination of irradiation by the dose monitoring system or systems during stationary beam therapy. (7-1-98)

i. Each primary system must terminate irradiation when the preselected number of dose monitor units has been detected by the system. (7-1-98)

ii. If original design of the equipment included a second dose monitoring system, that system must be capable of terminating irradiation when not more than fifteen percent (15%) or forty (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. (7-1-98)

iii. For equipment installed after the effective date of these rules, a second dose monitoring system must be present. That system shall be capable of terminating irradiation when not more than ten percent (10%) or twenty-five (25) dose monitoring units above the preselected number of dose monitor units set at the control panel has been detected by the second dose monitoring system. (7-1-98)

iv. For equipment installed after the effective date of these rules, an indicator on the control panel must show which dose monitoring system has terminated irradiation. (7-1-98)

j. It must be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it must be possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements must be automatically terminated. (7-1-98)

k. It must be possible to terminate irradiation and equipment movements, or go from an interruption condition to termination conditions, at any time, from the operator's position at the treatment control panel. (7-1-98)

l. The requirements for timers are as follows: (7-1-98)

i. A timer which has a display must be provided at the treatment control panel. The timer must have a preset time selector and an elapsed time indicator. (7-1-98)

ii. The timer must be a cumulative timer which activates with the production of radiation and retains 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 (0). (7-1-98)

iii. For equipment installed after the effective date of these rules after termination of irradiation and before irradiation can be reinitiated, it must be necessary to manually reset the preset time selector. (7-1-98)

iv. The timer must terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation. (7-1-98)

m. Equipment capable of both x-ray therapy and electron therapy must meet the following additional requirements: (7-1-98)

i. Irradiation must not be possible until a selection of radiation type has been made at the treatment control panel. (7-1-98)

ii. An interlock system must be provided to insure that the equipment can emit only the radiation type which has been selected. (7-1-98)

iii. 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. (7-1-98)

iv. An interlock system must be provided to prevent irradiation with x-rays except to obtain a port film when electron applicators are fitted. (7-1-98)

v. An interlock system must be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted. (7-1-98)

vi. The radiation type selected must be displayed at the treatment control panel before and during irradiation. (7-1-98)

n. Equipment capable of generating radiation beams of different energies must meet the following requirements: (7-1-98)

i. Irradiation must not be possible until a selection of energy has been made at the treatment control panel. (7-1-98)

ii. 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. (7-1-98)

iii. The nominal energy value selected must be displayed at the treatment control panel before and during irradiation. (7-1-98)

iv. For equipment installed after the effective date of these rules, an interlock system must be provided to terminate irradiation if the energy of the electrons striking the x-ray target or electron window deviates by more than twenty percent (20%) or three (3) MeV, whichever is smaller, from the selected nominal energy. (7-1-98)

o. Equipment capable of both stationary beam therapy and moving beam therapy must meet the following requirements: (7-1-98)

i. Irradiation must not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel. (7-1-98)

ii. An interlock system must be provided to insure that the equipment can operate only in the mode which has been selected. (7-1-98)

iii. 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. (7-1-98)

iv. The mode of operation must be displayed at the treatment control panel. (7-1-98)

v. For equipment installed after the effective date of these rules, an interlock system must be provided to terminate irradiation if: (7-1-98)

(1) Movement of the gantry occurs during stationary beam therapy; or (7-1-98)

(2) Movement of the gantry stops during moving beam therapy unless such stoppage is a preplanned function. (7-1-98)

vi. Moving beam therapy must be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement. (7-1-98)

(1) For equipment installed after the effective date of these rules, an interlock system must be provided to terminate irradiation if the number of dose monitor units delivered in any ten degrees (10) of arc differs by more than twenty percent (20%) from the selected value. (7-1-98)

(2) For equipment installed after the effective date of these rules, where gantry angle terminates the irradiation in arc therapy, the dose monitor units must differ by less than five percent (5%) from the value calculated from the absorbed dose per unit angle relationship. (7-1-98)

vii. Where the dose monitor system terminates the irradiation in arc therapy, the termination of irradiation must be as required by Subsection 210.01.i. (7-1-98)

p. For equipment installed after the effective date of these rules, a system must be provided from which readings the absorbed dose rate at a reference point in the treatment volume may be calculated. Radiation

detectors specified in Subsection 210.01.f. may form part of this system. In addition: (7-1-98)

i. The dose monitor unit rate shall be displayed at the treatment control panel. (7-1-98)

ii. If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameters utilized, 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. (7-1-98)

q. The registrant must determine, or obtain from the manufacturer, the location, with reference to an accessible point on the radiation head, of: (7-1-98)

i. The x-ray target or the virtual source of x-rays; and (7-1-98)

ii. The electron window or the virtual source of electrons if the system has electron beam capabilities. (7-1-98)

r. Capabilities must be provided so that all radiation safety interlocks can be checked for correct operation. When preselection of any of the operating conditions requires action in the treatment room and at the treatment control panel, selection at one (1) location must not give a display at the other location until the requisite selected operations have been completed in both locations. (7-1-98)

02. Facility and Shielding Requirements. In addition to Section 100, the following design requirements shall apply: (7-1-98)

a. All protective barriers must be fixed except for entrance doors or beam interceptors. (7-1-98)

b. The control panel must be located outside the treatment room. (7-1-98)

c. The requirements of viewing systems are as follows: (7-1-98)

i. Windows, mirrors, closed-circuit television, or an equivalent system must be provided to permit continuous observation of the patient during irradiation and must be so located that the operator may observe the patient from the control panel. (7-1-98)

ii. When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, must be available for use in the event of failure of the primary viewing system. (7-1-98)

d. Provision must be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements makes aural communication impractical, other methods of communication must be used. (7-1-98)

e. Treatment room entrances must be provided with warning lights in readily observable positions near the outside of all access doors to indicate when the useful beam is “on”. (7-1-98)

f. Interlocks must be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it must not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel. (7-1-98)

03. Surveys. (7-1-98)

a. All facilities must have a survey made by, or under the direction of, a qualified expert. In addition, such surveys must be done after any change in the facility or equipment, which might cause a significant increase in radiation hazard such as shielding changes, or x-ray unit relocation. (7-1-98)

b. The registrant must obtain a written report of the survey from the qualified expert, and a copy of the report must be transmitted by the registrant to the Radiation Control Agency within thirty (30) days of receipt of the report. (7-1-98)

c. The survey and report must indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules and regulations. (7-1-98)

04. Calibrations. (7-1-98)

a. The calibration of systems subject to Section 210 must be performed in accordance with an established calibration protocol acceptable to the Radiation Control Agency before the system is first used for irradiation of a patient, and thereafter at time intervals which do not exceed twelve (12) months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The calibration protocol published by the American Association of Physicists in Medicine is accepted as an established protocol. For other protocols, the user must submit that protocol to the Radiation Control Agency for concurrence that the protocol is acceptable before any calibration. (7-1-98)

b. The calibration must be performed under the direct supervision of a radiological physicist who is physically present at the facility during the calibration. (7-1-98)

c. Calibration radiation measurements required by Subsection 210.04 must be performed using a dosimetry system: (7-1-98)

i. Having a calibration factor for cobalt-60 gamma rays traceable to a national standard; (7-1-98)

ii. Which has been calibrated within the previous two (2) years and after any servicing that may have affected its calibration; (7-1-98)

iii. Which has been calibrated in such a fashion that any uncertainty can be stated for the radiation quantities monitored by the system; and (7-1-98)

iv. Which has had constancy checks performed on the system as specified by a radiological physicist. (7-1-98)

d. Calibrations must be in sufficient detail that the dose at a reference point in soft tissue may be calculated to within an uncertainty of five percent (5%). (7-1-98)

e. The calibration of the therapy beam must include, but not be limited to, the following determinations: (7-1-98)

i. Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, side light, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and jaw system, and beam flatness and symmetry at the specified depth; (7-1-98)

ii. The absorbed dose rate at various depths of water for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam; (7-1-98)

iii. The uniformity of the radiation field and any dependency upon the direction of the useful beam; (7-1-98)

iv. Verification that existing depth-dose data and isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions; and (7-1-98)

v. Verification of transmission and electron buildup factors for all accessories such as wedges, shadow trays, and compensators. (7-1-98)

f. Records of calibration measurements under Subsection 210.04.a. and dosimetry system calibrations under Subsection 210.04.c. must be maintained for five (5) years after completion of the full calibration. (7-1-98)

g. A copy of the latest calibration performed pursuant to Subsection 210.04.a. must be available in the area of the control panel. (7-1-98)

05. Spot Checks. Spot checks must be performed on systems subject to Section 210 during calibrations, and thereafter at intervals not to exceed one (1) month. Such spot-checks must meet the following requirements: (7-1-98)

a. The spot-check procedures must be in writing and must have been developed by a radiological physicist. A copy of the procedure must be submitted to the Radiation Control Agency prior to its implementation. (7-1-98)

b. If a radiological physicist does not perform the spot-check measurements, then the results of the spot-check measurements must be reviewed by a radiological physicist within fifteen (15) days. (7-1-98)

c. The spot-check procedures must specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot-check when compared to the value for that parameter determined in the calibration. (7-1-98)

d. Spot-checks shall be made of absorbed dose measurements at a minimum of two (2) depths in a phantom at intervals not to exceed one (1) week. (7-1-98)

e. Where a system has built-in devices which provide a measurement of any parameters during irradiation, such measurement must not be utilized as a spot-check measurement. (7-1-98)

f. The cause for a parameter exceeding a tolerance set by the radiological physicist must be investigated and corrected before the system is used for patient irradiation. (7-1-98)

g. Whenever a spot-check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot-check procedures, the system must be recalibrated as required in Subsection 210.04. (7-1-98)

h. Records of spot-check measurements must be maintained by the registrant for a period of two (2) years after completion of the spot-check measurements or any necessary corrective actions, whichever is later. (7-1-98)

i. Where a spot-check involves a radiation measurement, such measurement must be obtained using a system satisfying the requirements of Subsection 210.04.c. or which has been calibrated with a system meeting those requirements within the previous year. (7-1-98)

06. Operating Procedures. (7-1-98)

a. No individual other than the patient may be in the treatment room during treatment of a patient. (7-1-98)

b. If a patient must be held in position during treatment, mechanical supporting or restraining devices must be used. (7-1-98)

c. The system must not be used in the administration of radiation therapy unless the requirements of Subsections 210.01, through 210.05 have been met. (7-1-98)

211. RADIOGRAPHIC MACHINES USED FOR MAMMOGRAPHY.
In addition to other applicable requirements of these rules, radiation machines used for mammography shall comply with these requirements: (7-1-98)

01. General Requirements. (7-1-98)

a. Only radiation machines specifically designed for mammography shall be used; (7-1-98)

b. Radiation machines used for mammography shall be evaluated to ensure conformance to the requirements of these rules at intervals not to exceed twelve (12) months, and upon installation prior to being used on human beings. (7-1-98)

c. The registrant shall record the results of all tests made to evaluate compliance with these rules, and shall maintain these records available for inspection by the agency for a minimum of three (3) years. (7-1-98)

02. Radiation Machine Standards. (7-1-98)

a. X-ray Beam Quality. (7-1-98)

i. When used with screen-film image receptors, the useful beam shall have a half-value layer (HVL) between the values of: measured kilovoltage/100 and measured kilovoltage/100 + 0.1 millimeters aluminum equivalent. (7-1-98)

ii. All other mammography imaging modalities shall meet the requirements for minimum half-value layer specified in Subsection 204.03.a. of these rules. (7-1-98)

iii. Determination of half-value layer for mammography systems shall include the contribution to useful beam equivalent aluminum filtration made by the compression device. (7-1-98)

iv. The actual kilovolts-peak (kVp) shall be within plus or minus five percent (5%) of the indicated kVp. (7-1-98)

b. Radiation Output. (7-1-98)

i. Radiation machines used for mammography shall be capable of producing five hundred (500) milliroentgens/ second (one hundred twenty nine (129) microCoulomb/kilogram/second) for at least three (3) seconds, and producing a minimum output of eight (8) milliroentgens (two point one (2.1) microCoulomb/kilogram) per milliAmpere-second. (7-1-98)

ii. The minimum radiation output requirements of this part shall be measured at a point four point five (4.5) centimeters from the surface of the patient support device with the source-to-image receptor distance (SID) at maximum and the output attenuation of the compression device included. (7-1-98)

c. X-ray Beam Alignment\Limitation\Transmission. (7-1-98)

i. The radiation machine used for mammography shall be provided with means to limit the useful x-ray beam so that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated source to image receptor distance except the edge of the image receptor adjacent to the chest wall, where the x-ray field may extend beyond this edge by no more than two percent (2%) of the SID.(7-1-98)

ii. The projected collimator light field shall extend beyond the projected radiation field along both the length or width of the radiation field, at any designated source to image receptor distance, by no more than two percent (2%) of the SID. (7-1-98)

d. Mammographic Exposure Control. (7-1-98)

i. Radiation machines used for mammography shall incorporate means to terminate the exposure at a preset time interval, a preset product of tube current and exposure duration, a preset number of pulses, or a preset radiation exposure at the plane of the image receptor. (7-1-98)

ii. Exposure shall only be possible by the use of an exposure switch of the "deadman" type as defined in Subsection 002.30 of these rules. (7-1-98)

iii. When both manual and automatic exposure control modes are available, the x-ray control panel shall clearly indicate which mode is selected. (7-1-98)

iv. The coefficient of variation between exposures for both automatic and manual exposure modes shall not exceed five one hundredth (0.05). This requirement is met when four (4) successive exposures are made at identical exposure factors, and the standard devation of the four (4) exposure values divided by the mean exposure value is less than or equal to five one hundredth (0.05). (7-1-98)

v. Exposure control in the automatic exposure mode shall provide the capability of maintaining constant film density to within plus or minus three tenths (0.3) optical density unit of the average optical density over the range of clinically used kilovoltage, for acrylic or BR-12 phantom thicknesses of two (2) centimeters to six (6) centimeters. (7-1-98)

vi. The mammography exposure control system(s) shall limit the mean glandular dose, for one craniocaudal view of a four point five (4.5) centimeter compressed breast composed of fifty percent (50%) adipose fifty percent (50%) glandular tissue, not to exceed these values: (7-1-98)

(1) One (1) milligray (one hundred (100) millirads) for non-grid screen-film imaging modes; (7-1-98)

(2) Three (3) milligray (three hundred (300) millirads) for screen-film systems with grid. (7-1-98)

(3) The technical exposure factors used to determine compliance with this part shall be those used by the facility for its clinical images of a fifty percent (50%) adipose fifty percent (50%) glandular tissue four point five (4.5) centimeter compressed breast, craniocaudal view. (7-1-98)

vii. Determination of mean glandular dose shall be made with a breast phantom in the useful beam. The breast phantom shall be equivalent in attenuation to the RMI 156 breast phantom. (7-1-98)

e. Integral Ancillary Equipment. (7-1-98)

i. Radiation machines used for mammography shall be provided with an integral anti-scatter grid available for use with all image receptor sizes. (7-1-98)

ii. The mammography radiation machine shall be provided with a compression device which is capable of compressing the breast with a force of at least twenty five (25) pounds and no more than forty (40) pounds for a period of at least fifteen (15) seconds. (7-1-98)

iii. The chest wall edge of the compression paddle must be aligned with the chest wall edge of the image receptor to within one percent (1%) of the SID when the compression paddle is placed four point five (4.5) centimeters above the patient support device. (7-1-98)

iv. Radiation machines used for mammography, and which are newly installed after the effective date of these rules shall incorporate a post-exposure milliampere-seconds indicator when used in automatic exposure control mode. (7-1-98)

03. Quality Assurance Program. (7-1-98)

a. QA Program Responsibilities. The registrant shall maintain, and have in place prior to the initiation of mammography imaging, a written quality assurance program for each mammography x-ray system. The registrant shall be responsible for providing qualified individuals whose duties include: (7-1-98)

i. Conducting equipment performance monitoring functions; (7-1-98)

ii. Analyzing the monitoring results to determine if there are problems requiring correction; (7-1-98)

iii. Carrying out or arranging for the necessary corrective actions when quality assurance testing indicates a standard in these rules is not met. (7-1-98)

b. Image Quality Standards/Processor Performance. (7-1-98)

i. Phantom Image Quality. The mammography x-ray system shall be capable of providing an image of a seventy five one hundredths (0.75) millimeter fiber, a thirty two one hundredths (0.32) millimeter speck group, and a seventy five one hundredths (0.75) millimeter mass. This standard will be met when a mammographic image of an RMI 156 breast phantom demonstrates four (4) fibers, three (3) speck groups and three (3) masses. (7-1-98)

ii. Mid-density (MD) density difference (DD). Deviations from established operating levels for measured values of mid-density (MD) and density difference (DD) on sensitometric control charts shall not exceed one tenth (0.10) Optical Density Units. (7-1-98)

iii. Base + Fog (B + F). The base + fog shall not exceed the established operating level by more than three one hundredths (0.03) Optical Density Units. (7-1-98)

iv. Darkroom Fog. Darkroom fog levels shall not exceed five one hundreths (0.05) Optical Density Units above base + fog. Darkroom fog tests shall be made with film presensitized by exposure to sufficient light from an intensifying screen so that after processing, an Optical Density of one and two tenths (1.2) to one and six tenths (1.6) is achieved. The presensitized film shall be exposed to darkroom safelight conditions for two (2) minutes. (7-1-98)

v. Image Receptor Systems. Image receptor systems and their individual components shall be specifically designed for, and appropriate to mammography imaging. (7-1-98)

vi. Intensifying Screens. Mammography image intensifying screens shall be removed from service and appropriate corrective action implemented if the following standards are not met: (7-1-98)

(1) Screen Speed Uniformity. Intercomparison of the measured optical density in the geometric center of a phantom image obtained with each intensifying screen in use shall be not exceed three tenths (.3) optical density unit between the minimum and maximum density. The technical exposure factors shall be the same for each screen, and the phantom used for these images shall be a four (4) centimeter thick cassette-sized phantom of acrylic or BR-12, or a breast phantom equivalent in attenuation to the RMI 156. (7-1-98)

(2) Screen-film Contact. Cassettes shall not be used for mammography if one or more large areas (> = one (1.0) centimeters) of poor film-screen contact is visualized on an image made with a forty (40) mesh mammography film- screen contact test tool. (7-1-98)

(3) Screen Identification. Each intensifying screen shall be legibly marked with a unique identification mark for that particular screen, visible on the film outside the area of clinical interest, with a corresponding mark on the outside of the cassette. (7-1-98)

vii. Film Processors. Film processors utilized for mammography shall be adjusted to, and operated at the specifications recommended by the mammographic film manufacturer. Alternative settings which are shown by documented test results to provide equivalent sensitometric performance are acceptable. (7-1-98)

viii. Reject Rate. Corrective action shall be taken if the film reject rate exceeds five percent (5%). The reject rate shall be based upon clinical images which must be repeated. (7-1-98)

c. Quality Assurance Tests/Intervals. The registrant shall ensure that the following quality control tests are performed when applicable equipment or components are initially installed, replaced or repaired, and at least at these specified intervals: (7-1-98)

i. Primary Secondary Barrier Transmission -- Upon initial installation and following each significant modification to the mammography system or the primary secondary barriers. (7-1-98)

ii. Processor performance by sensitometric means -- daily, or each day of use prior to the first patient exposure. For any mammography registrant using film processors at multiple locations, such as mobile mammography services, each processor shall be subject to this requirement. (7-1-98)

iii. Screen Cleanliness Artifacts -- weekly. (7-1-98)

iv. Image Quality -- monthly for stationary systems and prior to performing mammography at each location for mobile systems. (7-1-98)

v. Reject Rate Analysis -- three (3) months. (7-1-98)

vi. Compression Device -- six (6) months. (7-1-98)

vii. Darkroom Integrity (safelight condition, light leaks) -- six (6) months. (7-1-98)

viii. Screen-film Contac -- six (6) months. (7-1-98)

ix. Beam Alignment and Limitation -- twelve (12) months. (7-1-98)

x. Automatic Exposure Control Reproducibility -- twelve (12) months. (7-1-98)

xi. Collimator alignment -- twelve (12) months. (7-1-98)

xii. Focal Spot Size Resolution -- upon initiation installation and at each tube replacement, and at intervals not to exceed twelve (12) months. (7-1-98)

xiii. Half-value Layer -- twelve (12) months. (7-1-98)

xiv. kVp Accuracy -- twelve (12) months. (7-1-98)

xv. Radiation Output Reproducibility and Linearity -- twelve (12) months. (7-1-98)

d. QA Program Annual Review. In addition to the routine quality assurance testing required in these rules, the registrant shall effect a comprehensive review of the effectiveness of all elements of the quality assurance program for each mammography system at intervals not to exceed twelve (12) months. This review shall: (7-1-98)

i. Address all aspects of quality assurance in these rules for each mammography x-ray system; (7-1-98)

ii. Be documented in writing and the results maintained available for inspection by the agency for three (3) years; (7-1-98)

e. Corrective Action. When a mammography x-ray system fails one of the quality assurance tests required in these rules, unless otherwise specified herein, the mammography x-ray system shall be removed from service until appropriate corrective action is completed. The mammography x-ray system shall not be placed back into service until repeat test results verify adequacy of the corrective action. (7-1-98)

212. -- 299. (RESERVED).

300. RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY OPERATIONS.
The rules in Section 300 establish requirements for the use of analytical x-ray machines, as defined in Subsection 002.10 and 002.11 by persons registering such machines under the provisions of Section 090. The provisions of Section 300 are in addition to, and not in substitution for, other applicable provisions of these rules. (7-1-98)

301. -- 319. (RESERVED).

320. EQUIPMENT.

01. Labels. A label bearing essentially the words **"CAUTION RADIATION -- THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED"** must be placed near any switch which energizes a tube. All labels must use the conventional colors (magenta or purple on yellow background) and bear the conventional radiation symbol. (7-1-98)

02. Signs. A sign bearing the words **"CAUTION -- HIGH INTENSITY X-RAY BEAM"** must be placed in the area immediately adjacent to each tube housing. The sign must be so located that it is clearly visible to any person operating, aligning, or adjusting the unit or handling or changing a sample. (7-1-98)

03. Beam Alignment Apparatus. Any apparatus utilized in beam alignment procedures must be designed in such a way that excessive radiation will not strike the operator. Particular attention must be given to viewing devices, in order to ascertain that lenses and other transparent components attenuate the beam to an acceptable level. (7-1-98)

04. Warning Lights. (7-1-98)

a. An easily visible warning light labeled with the words **"X-RAY ON"**, or words having a similar intent, must be located: (7-1-98)

i. Near any switch that energizes an x-ray tube and must be illuminated only when the tube is energized; or (7-1-98)

ii. In the case of a radioactive source, near any switch that opens a housing shutter and must be illuminated only when the shutter is open. (7-1-98)

b. On equipment installed after the effective date of these rules, warning lights must have fail- safe characteristics. (7-1-98)

05. Safety Devices. A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path must be provided on all open-beam configurations. A registrant or licensee can apply to the Radiation Control Agency for an exemption from the requirement of a safety device. Such application will include: (7-1-98)

a. A description of the various safety devices that have been evaluated; and (7-1-98)

b. The reason each of these devices cannot be used; and (7-1-98)

c. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices. (7-1-98)

06. Shutter Mechanisms. If a shutter mechanism is used to control the primary beam, a shutter status (open or closed) indication must be provided in the area adjacent to the tube head so that the position of the shutter is readily discernible. (7-1-98)

07. Control Panel Interlock. If an interlock device turns off the x-ray beam, it must not be possible to resume operation without resetting the beam "ON" switch at the control panel. (7-1-98)

08. Leakage and Monitoring. The tube housing leakage radiation at any accessible point five (5) cm from the surface of the tube housing must not exceed two and one-half (2.5) mR per hour at each maximum specified tube rating. This measurement must be made with a monitoring instrument appropriate for the energy range generated by the x-ray equipment, and must be made with beam ports blocked off. (7-1-98)

09. Generator Cabinet. Each x-ray generator must be supplied with a protective cabinet which limits leakage radiation measured at a distance of five (5) cm from its surface such that it is not capable of producing a dose

in excess of twenty-five hundredths (0.25) mrem in one (1) hour. (7-1-98)

321. -- 329. (RESERVED).

330. ADMINISTRATIVE RESPONSIBILITIES.

01. Radiation Safety Officer. An individual at each facility must be designated to be responsible for maintaining radiation safety. This individual, designated the Radiation Protection Supervisor or Radiation Safety Officer, will be responsible for the following: (7-1-98)

a. Establishing and maintaining operational procedures so that the radiation exposure of each worker is kept as far below the maximum permissible dose as is practical; and (7-1-98)

b. Instructing all personnel who work with or near radiation producing machines in safety practices; and (7-1-98)

c. Maintaining a system of personnel monitoring; and (7-1-98)

d. Arranging for establishment of radiation control areas, including placement of appropriate radiation warning signs and/or devices; and (7-1-98)

e. Providing for radiation safety inspection of radiation producing machines on a routine basis; and (7-1-98)

f. Reviewing modifications to x-ray apparatus, including x-ray tube housing, cameras, diffractometers, shielding, and safety interlocks; and (7-1-98)

g. Investigating and reporting to proper authorities any case of excessive exposure to personnel and taking remedial action; and (7-1-98)

h. Being familiar with all applicable rules and regulations for control of ionizing radiation. (7-1-98)

02. Operator Qualifications. No individual will be permitted to act as an operator of a particular machine until such individual has received an acceptable amount of training in radiation safety as it applies to that machine and is approved by the Radiation Protection Supervisor or Radiation Safety Officer. Operators will be responsible for: (7-1-98)

a. Keeping radiation exposure to himself and to others as low as is practical; and (7-1-98)

b. Being familiar with safety procedures as they apply to each machine; and (7-1-98)

c. Wearing of personnel monitoring devices, if applicable; and (7-1-98)

d. Notifying the Radiation Protection Supervisor or Radiation Safety Officer of known or suspected excessive radiation exposures to himself or others. (7-1-98)

331. AREA REQUIREMENTS.

01. Radiation Levels. The local components of an analytical x-ray system must be located and arranged and must include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in Subsection 110.01. For systems utilizing x-ray tubes, these levels will be met at any specified tube rating. (7-1-98)

02. Surveys. Radiation surveys, as required by Subsection 120.01, of all analytical x-ray systems sufficient to show compliance with Subsection 331.01 must be performed: (7-1-98)

a. Upon installation of the equipment; and (7-1-98)

b. Following any change in the initial arrangement, number, or type of local components in the system; and (7-1-98)

c. Following any maintenance requiring the disassembly or removal of a local component in the system; and (7-1-98)

d. During the performance of maintenance and alignment procedures if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed; and (7-1-98)

e. Any time a visual inspection of the local components in the system reveals an abnormal condition; and (7-1-98)

f. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the Radiation Protection Guides, radiation dose limits, as set forth in Section 110. (7-1-98)

03. Exceptions to Surveying. Radiation survey measurements will not be required if a registrant or licensee can demonstrate compliance by some other means to the satisfaction of the Radiation Control Agency with Subsection 331.01. (7-1-98)

04. Posting. Each area or room containing analytical x-ray equipment must be conspicuously posted with a sign or signs bearing the radiation symbol and the words **"CAUTION - X-RAY EQUIPMENT"** or words having a substantially similar intent. (7-1-98)

332. -- 339. (RESERVED).

340. OPERATING PROCEDURES.

01. Normal Operating Procedures. Normal operating procedures must be written and available to all analytical x-ray equipment workers. No person will be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the Radiation Safety Officer. (7-1-98)

02. Emergency Procedures. Written emergency procedures pertaining to radiation safety must be established for each x-ray producing apparatus by the Radiation Protection Supervisor, and posted in a conspicuous location. These must list the telephone numbers of the Radiation Protection Supervisor and must include the following actions to be taken in case of a known, or suspected, accident involving radiation exposure: (7-1-98)

a. Notify Radiation Protection Supervisor; and (7-1-98)

b. Arrange for Medical Examination. Additionally, the examining physician must be notified that exposure to low energy x-rays may have occurred. (7-1-98)

03. Exposure. Personnel must not expose any part of their body to the primary beam. (7-1-98)

04. Installation, Repair, and Modification. Only properly trained maintenance personnel can be permitted to install, repair, or make other than routine modifications to the x-ray generating apparatus and the tube housing apparatus complex. (7-1-98)

05. X-Ray Diffraction and Spectrographic Equipment. Whenever possible, x-ray diffraction and spectrographic equipment must be placed in a room separate from other work areas. (7-1-98)

06. Alterations. If, for any reason, it is necessary to temporarily intentionally alter safety devices, such as bypassing interlocks or removing shielding, such action must be: (7-1-98)

a. Specified in writing and posted near the x-ray tube housing so that other persons will know the existing status of the machine; and (7-1-98)

b. Terminated as soon as possible. (7-1-98)

07. Unused Tube Head Ports. Tube head ports must be secured in the closed position in a manner which will prevent casual opening; these must be checked prior to use when the machine has been left unattended. (7-1-98)

08. Personnel Monitoring. Finger or wrist dosimetric devices must be provided to and must be used by: (7-1-98)

a. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and (7-1-98)

b. Personnel maintaining analytical x-ray equipment, if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed. (7-1-98)

09. Unattended Equipment. Analytical x-ray equipment must not be left unattended while the tube is energized unless: (7-1-98)

a. An interlock device is provided to prevent accidental entry into the primary beam; and (7-1-98)

b. The stray radiation at any accessible point at a distance of ten (10) inches, twenty-five (25) centimeters, from the tube housing or its containment, as measured with a monitoring instrument appropriate for the energy range generated, is no greater than two (2) mR per hour. (7-1-98)

10. Safety Devices. Safety devices should be tested at least once per week, and must be tested at intervals not to exceed one (1) month. (7-1-98)

11. Records. Records of personnel monitoring results and safety device tests must be maintained for inspection by the Radiation Control Agency. (7-1-98)

341. -- 349. (RESERVED).

350. RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATOR OPERATIONS.
The rules that follow comprise basic or minimum safety procedures for all accelerator facilities. The rules in Section 350 establish requirements for the use of particle accelerators by persons registering such machines under the provisions of Section 090. The provisions of Sections 350 through 399 are in addition to, and not in substitution for, other applicable provisions of these rules. (7-1-98)

351. -- 352. (RESERVED).

353. REGISTRATION PROCEDURE.

01. Registration Requirements. Persons must not receive, possess, use, transfer, own, or acquire a particle accelerator except as authorized in a registration issued pursuant to or otherwise provided for in these rules. The general procedures for registration of particle accelerator facilities are included in Section 090. (7-1-98)

02. General Requirements for the Issuance of a Registration for Particle Accelerators. In addition to the requirements of Section 090 a registration application for use of a particle accelerator will be approved only if the Radiation Control Agency determines that: (7-1-98)

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with Sections 353, 100, and 450 in such a manner as to minimize danger to public health and safety and/or property; and (7-1-98)

b. The applicant's proposed equipment, facilities, operating and emergency procedures are adequate to protect health and minimize danger to public health and safety and/or property; and (7-1-98)

c. The issuance of the registration will not be harmful or adverse to the health and/or safety of the public, and the applicant satisfies any applicable special requirement in Subsection 353.03; and (7-1-98)

d. The applicant has appointed a Radiation Safety Officer; and (7-1-98)

e. The applicant and/or his staff has substantial experience in the use of particle accelerators for the intended uses; and (7-1-98)

f. The applicant has established a radiation safety committee to approve, in advance, proposals for uses of particle accelerators, whenever deemed necessary by the Radiation Control Agency; and (7-1-98)

g. The applicant has an adequate training program for particle accelerator operators. (7-1-98)

03. Human Use of Particle Accelerators. In addition to the requirements set forth in Section 090 a registration for use of a particle accelerator in the healing arts will be issued only if: (7-1-98)

a. Whenever deemed necessary by the Radiation Control Agency, the applicant has appointed a medical committee of at least three (3) members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator. (Membership of the committee should include physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in depth dose calculations and protection against radiation); and (7-1-98)

b. The individuals designated on the application as the users have substantial training and experience in deep therapy techniques or in the use of particle accelerators to treat humans; and (7-1-98)

c. The individual designated on the application as the user is a physician. (7-1-98)

354. RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS. Section 354, establishes radiation safety requirements for the use of particle accelerators. The provisions are in addition to, and not in substitution for, other applicable provisions of these rules. The registrant will be responsible for assuring that all requirements of Section 350 are met. (7-1-98)

01. Limitations. (7-1-98)

a. No registrant will permit any person to act as a particle accelerator operator until such person: (7-1-98)

i. Has been instructed in radiation safety and has demonstrated an understanding thereof; and (7-1-98)

ii. Has received copies of and instruction in Section 350 and the applicable requirements of Sections 100 and 450 pertinent registration conditions and the registrant's operating and emergency procedures, and has demonstrated understanding thereof; and (7-1-98)

iii. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments which will be employed in that person's assignment. (7-1-98)

b. Either the radiation safety committee or the Radiation Safety Officer will have the authority to terminate the operations at a particle accelerator facility if such action is deemed necessary to protect health and/or minimize danger to public health and safety and/or property. (7-1-98)

02. Shielding and Safety Design Requirements. (7-1-98)

a. A qualified expert, acceptable to the Radiation Control Agency, must be consulted in the design of a particle accelerator installation and called upon to perform a radiation survey when the accelerator is first capable of producing radiation. (7-1-98)

b. Each particle accelerator installation must be provided with such primary and/or secondary barriers as are necessary to assure compliance with Subsections 110.01 and 110.04. (7-1-98)

03. Particle Accelerator Control and Interlock Systems. (7-1-98)

a. Instrumentation, readouts and controls on the particle accelerator control console must be clearly identified and easily discernible. (7-1-98)

b. All entrances into a target room or other high radiation area must be provided with interlocks that shut down the machine under conditions of barrier penetration. (7-1-98)

c. When an interlock system has been tripped, it must only be possible to resume operation of the accelerator by manually resetting controls at the position where the interlock has been tripped, and then at the main control console. (7-1-98)

d. Each safety interlock must be on a circuit which will allow its operation independently of all other safety interlocks. (7-1-98)

e. All safety interlocks must be designed so that any defect or component failure in the interlock system prevents operation of the accelerator. (7-1-98)

f. A scram button or other emergency power cutoff switch must be located and easily identifiable in all high radiation areas. This button or cutoff switch must include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cutoff switch. (7-1-98)

04. Warning Devices. (7-1-98)

a. All locations designated as high radiation areas, and entrances to such locations must be equipped with easily observable flashing or rotating warning lights that operate when, and only when, radiation is being produced. (7-1-98)

b. Except in facilities designed for human exposure, each high radiation area must have an audible warning device which will be activated for fifteen (15) seconds prior to the possible creation of such high radiation area. Such warning device will be clearly discernible in all high radiation areas and all radiation areas. (7-1-98)

c. Barriers, temporary or otherwise, and pathways leading to high radiation areas must be identified in accordance with Subsection 120.03. (7-1-98)

05. Operating Procedures. (7-1-98)

a. Particle accelerators, when not in operation, must be secured to prevent unauthorized use. (7-1-98)

b. Only a switch on the accelerator control console must be routinely used to turn the accelerator beam on and off. The safety interlock system will not be used to turn off the accelerator beam except in an emergency. (7-1-98)

c. All safety and warning devices, including interlocks, must be checked for proper operability at intervals not to exceed three (3) months. Results of such tests will be maintained for inspection at the accelerator facility. (7-1-98)

d. Electrical circuit diagrams of the accelerator and the associated interlock systems must be kept current and maintained for inspection by the Radiation Control Agency and available to the operator at each accelerator facility. (7-1-98)

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action will be: (7-1-98)

i. Authorized by the radiation safety committee and/or radiation safety officer; and (7-1-98)

ii. Recorded in a permanent log and a notice posted at the accelerator control console; and (7-1-98)

iii. Terminated as soon as possible. (7-1-98)

f. A copy of the current operating and the emergency procedures must be maintained at the accelerator control panel. (7-1-98)

g. Accelerators must not be left unattended while energized. (7-1-98)

06. Radiation Monitoring Requirements. (7-1-98)

a. There must be available at each particle accelerator facility, appropriate portable monitoring equipment which is operable and appropriately calibrated for the radiations being produced at the facility. This equipment must be tested for proper operation daily and calibrated at intervals not to exceed one (1) year, and after each servicing and repair. (7-1-98)

b. A radiation protection survey must be performed and documented by a qualified expert acceptable to the Radiation Control Agency when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas. (7-1-98)

c. Radiation levels in all high radiation areas must be continuously monitored. The monitoring devices must be electrically independent of the accelerator control and interlock systems and capable of providing local readout at both the control panel and at entrance to high radiation areas, and other appropriate locations, so that people entering or present become aware of the existence of the hazard. (7-1-98)

d. All area monitors will be calibrated at intervals not to exceed one (1) year and after each servicing and repair. (7-1-98)

e. Whenever applicable, periodic surveys must be made to determine the amount of airborne particulate radioactivity present in areas of airborne hazards. (7-1-98)

f. Whenever applicable, periodic smear surveys must be made to determine the degree of contamination in target and other pertinent areas. (7-1-98)

g. All area surveys must be made in accordance with the written procedures established by a qualified expert, or the Radiation Safety Officer of the particle accelerator facility. (7-1-98)

h. Records of all radiation protection surveys, calibration results, instrumentation tests, and smear results must be kept current and on file at each accelerator facility. (7-1-98)

355. -- 439. (RESERVED).

440. PUBLIC AND CONFIDENTIAL INFORMATION.

01. Accessibility. Except as provided in this section or other applicable law, information obtained or submitted pursuant to these rules will be available to the public for inspection and copying during normal working hours. Anyone requesting Radiation Control Agency assistance in collecting, copying or mailing public information must tender, in advance, the reasonable cost of those services. (7-1-98)

02. Confidentiality. Information concerning radiation sources submitted to the Radiation Control Agency pursuant to these rules which, as certified by the owner or operator of such source, relates to production or

sales figures or to processed or production unique to the owner or operator, or tends to adversely affect the competitive position of such owner or operator, may be disclosed only to the Board, the Radiation Control Agency or a hearing officer unless: (7-1-98)

a. The Board, after a hearing, determines that a claim of uniqueness or adverse effect is unwarranted; (7-1-98)

b. The owner or operator expressly consents to disclosure; or (7-1-98)

c. Disclosure is required for criminal prosecution of a violation of the Idaho Environmental Protection and Health Act. (7-1-98)

03. Department Discretion. The Radiation Control Agency may decline to release to the public: (7-1-98)

a. Inconclusive preliminary data or reports generated as part of ongoing studies; and (7-1-98)

b. Information obtained as part of ongoing investigations when release would: (7-1-98)

i. Interfere with enforcement proceedings; (7-1-98)

ii. Deprive a person of a fair or impartial adjudication; (7-1-98)

iii. Discourage informants from disclosing information to the Radiation Control Agency; (7-1-98)

iv. Disclose investigative techniques or proceedings; or (7-1-98)

v. Endanger the safety of Radiation Control Agency personnel. (7-1-98)

441. -- 449. (RESERVED).

450. NOTICES, INSTRUCTIONS AND REPORTS TO WORKERS -- INSPECTIONS.

01. Purpose and Scope. Section 450 establishes requirements for notices, instructions and reports by registrants to individuals engaged in work under a registration and options available to such individuals in connection with the Radiation Control Agency compliance inspections of registrants regarding radiological working conditions. (7-1-98)

02. Posting of Notices to Workers. (7-1-98)

a. Each registrant must post current copies of the following documents: (7-1-98)

i. The rules in Sections 450 and 100; and (7-1-98)

ii. The certificate of registration; and (7-1-98)

iii. The operating procedures applicable to work under the registration; and (7-1-98)

iv. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Section 000 and any response from the registrant. (7-1-98)

b. If posting of a document specified in Subsections 450.02.a.i., 450.02.a.ii., or 450.02.a.iii. is not practicable, the registrant can post a notice which describes the document and states where it can be examined. (7-1-98)

c. Agency form “Notice to Employees” must be posted by each registrant wherever individuals work in or frequent any portion of a restricted area. This form must include the following wording:

"NOTICE TO EMPLOYEES"

STANDARDS FOR PROTECTION AGAINST RADIATION

In Idaho Radiation Control Rules, the Idaho State Board of Health has established standards for your protection against radiation hazards.

YOUR EMPLOYER'S RESPONSIBILITY

Your employer is required to....

1. Apply these rules to work involving sources of radiation.

2. Post or otherwise make available to you a copy of the Idaho Department of Health and Welfare Radiation Control Rules and operating procedures which apply to work you are engaged in, and explain their provisions to you.

YOUR RESPONSIBILITY AS A WORKER

You should familiarize yourself with those provisions of the Idaho Department of Health and Welfare Radiation Control Rules, and the operating procedures which apply to the work you are engaged in. You should observe its provisions for your own protection and protection of your co-workers.

WHAT IS COVERED BY THESE RULES

1. Limits on exposure to radiation in restricted and unrestricted areas;
2. Measures to be taken after accidental exposure;
3. Personnel monitoring, surveys and equipment;
4. Caution signs, labels, and safety interlock equipment;
5. Exposure records and reports; and
6. Related matters.

REPORTS ON YOUR RADIATION EXPOSURE HISTORY

1. The Idaho Department of Health and Welfare Radiation Control Rules require that your employer give you a written report if you receive an exposure in excess of any applicable limit as set forth in the rules. The basic limits for exposure to employees are set forth in Section 100. This section specifies limits on exposure to radiation.

2. If you work where personnel monitoring is required, and if you request information on your radiation exposures,

a. Your employer must give you a written report, upon termination of your employment, of your radiation exposures, and

b. Your employer must advise you annually of your exposure to radiation.

INSPECTIONS

All registered activities are subject to inspection by representatives of the Idaho Department of Health and Welfare.

INQUIRIES

Inquiries dealing with the matters outlined above can be sent to the Radiation Control Section, Idaho Department of Health and Welfare, 2220 Old Penitentiary Road, Boise, Idaho, 83712-8299, having inspection responsibility over your installation.

POSTING REQUIREMENT

"COPIES OF THIS NOTICE MUST BE POSTED IN A SUFFICIENT NUMBER OF PLACES IN EVERY ESTABLISHMENT WHERE EMPLOYEES ARE EMPLOYED IN ACTIVITIES REGISTERED, PURSUANT TO IDAHO DEPARTMENT OF HEALTH AND WELFARE RADIATION CONTROL RULES, TITLE 02, CHAPTER 27, SECTION 050, BY THE IDAHO DEPARTMENT OF HEALTH AND WELFARE, TO PERMIT EMPLOYEES WORKING IN OR FREQUENTING ANY PORTION OF A RESTRICTED AREA TO OBSERVE A COPY ON

THE WAY TO OR FROM THEIR PLACE OF EMPLOYMENT." (7-1-98)

d. Documents, notices or forms posted pursuant to this Section must appear in a sufficient number of places to permit individuals engaged in work under the registration to observe them on the way to or from any particular work location to which the document applies, must be conspicuous, and must be replaced if defaced or altered. (7-1-98)

e. Radiation Control Agency documents posted pursuant to Subsection 450.02.a.iv. must be posted within five (5) working days after receipt of the documents from the Radiation Control Agency; the registrant's response, if any, must be posted within five (5) working days after dispatch from the registrant. These documents must remain posted for a minimum of five (5) working days or until action correcting the violations has been completed, whichever is later. (7-1-98)

03. Instructions to Workers. All individuals working in or frequenting any portion of a restricted area must: (7-1-98)

a. Be instructed in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; (7-1-98)

b. Be instructed in and directed to observe, to the extent within the worker's control, the applicable provisions of Radiation Control Agency rules for the protection of personnel from exposures to radiation occurring in such areas; (7-1-98)

c. Be instructed of their responsibility to report promptly to the registrant any condition which can lead to or cause a violation of Radiation Control Agency rules or unnecessary exposure to radiation; (7-1-98)

d. Be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction which might involve exposure to radiation; and (7-1-98)

e. Be advised as to the radiation exposure reports which workers can request pursuant to Subsection 450.04. The extent of these instructions must be commensurate with potential radiological health protection problems in the restricted area. (7-1-98)

04. Notifications and Reports to Individuals. (7-1-98)

a. Each registrant must advise workers annually of their exposure to radiation as shown in records maintained by the registrant pursuant to Subsections 140.01.a. and 140.01.c. (7-1-98)

b. Each registrant must furnish to the workers a report of their exposure to radiation. Such report must be furnished within thirty (30) days from the time the request is made, or within thirty (30) days after the exposure of the individual has been determined by the registrant, whichever is later; must cover, within the period of time specified in the request, each calendar quarter in which the worker's activities involved exposure to radiation from radiation machines registered with the Radiation Control Agency; and must include the dates and locations of work under the registration in which the worker participated during this period. (7-1-98)

c. When a registrant is required pursuant to Subsection 140.04 to report to the Radiation Control Agency any exposure of an individual to radiation, the registrant must also provide the individual a report on his exposure data included therein. Such reports will be transmitted at a time not later than the transmittal to the Radiation Control Agency. (7-1-98)

d. At the request of a worker who is terminating employment in a given calendar quarter with the registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the registrant's facility in that calendar quarter, each registrant must provide to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the registrant during that specific identified calendar quarter or fraction thereof, or provide a written estimate of that dose if the finally determined personnel monitoring results are not

available at that time. Estimated doses must be clearly indicated as such. (7-1-98)

05. Presence of Representatives of Registrants and Workers During Inspection. (7-1-98)

a. Each registrant must afford to the Radiation Control Agency at all reasonable times opportunity to inspect machines, activities, facilities premises, and records pursuant to these rules. (7-1-98)

b. During an inspection, Radiation Control Agency inspectors can consult privately with workers as specified in Subsection 450.06. The registrant can accompany Radiation Control Agency inspectors during other phases of an inspection. (7-1-98)

c. If, at the time of inspection, an individual has been authorized by the workers to represent them during Radiation Control Agency inspections, the registrant must notify the inspectors of such authorization and give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions. (7-1-98)

d. Each workers' representative must be routinely engaged in work under control of the registrant and have received instructions as specified in Subsection 450.03. (7-1-98)

e. Different representatives of registrants and workers can accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one (1) worker's representative at a time can accompany the inspectors. (7-1-98)

f. With the approval of the registrant and the workers' representative, an individual who is not routinely engaged in work under control of the registrant, for example, a consultant to the registrant or to the workers' representative, must be afforded the opportunity to accompany Radiation Control Agency inspectors during the inspection of physical working conditions. (7-1-98)

g. Notwithstanding the other provisions of this Section, Radiation Control Agency inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area will be an individual previously authorized by the registrant to enter that area. With regard to areas containing information classified by an agency of the U.S. Government in the interest of national security, an individual who accompanies an inspector may have access to such information only if authorized to do so. (7-1-98)

06. Consultation with Workers During Inspections. (7-1-98)

a. Radiation Control Agency inspectors can consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Radiation Control Agency Rules to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection. (7-1-98)

b. During the course of an inspection any worker can bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe could have contributed to or caused any violations of the Act, these rules, or any unnecessary exposure of an individual to radiation from a registered radiation machine under the registrant's control. Any such notice in writing must comply with the requirements of Subsection 450.07.a. (7-1-98)

c. The provisions of Subsection 450.06 must not be interpreted as authorization to disregard instructions pursuant to Subsection 450.03. (7-1-98)

07. Requests by Workers for Inspections. (7-1-98)

a. Any worker or representative of workers who believes that a violation of the Act, these rules exists or has occurred in work under a registration with regard to radiological working conditions in which the worker is engaged, can request an inspection by giving notice of the alleged violation to the Idaho Radiation Control Agency. Any such notice must be in writing, must set forth the specific grounds for the notice, and must be signed by the worker or representative of the workers. A copy must be provided to the registrant by the Radiation Control Agency

no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein will not appear in such copy or on any record published, released, or made available by the Radiation Control Agency, except for good cause shown. (7-1-98)

b. If upon receipt of such notice, the state official determines that the complaint meets the requirements set forth in Subsection 450.07 and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he must cause an inspection to be made, as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this Section need not be limited to matters referred to in the complaint. (7-1-98)

c. No registrant can discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by Section 450. (7-1-98)

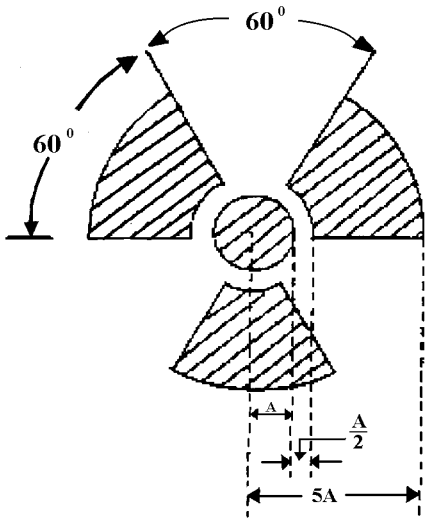
451. -- 995. (RESERVED).

996. ADMINISTRATIVE PROVISIONS.
Contested case appeals shall be governed by Idaho Department of Health and Welfare Rules, IDAPA 16.05.03, Sections 000., et seq., "Rules Governing Contested Case Proceedings and Declaratory Rulings". (7-1-98)

997. CONFIDENTIALITY OF RECORDS.
Any disclosure of information obtained by the Department is subject to the restrictions contained in Idaho Department of Health and Welfare Rules, IDAPA 16.05.01, "Use and Disclosure of Department Records". (7-1-98)

998. -- 999. (RESERVED).

APPENDIX A



Subject Index

A

Accessible Surface 3
Activation of the Fluoroscopic Tube 36
Added Filtration 3
Additional Requirements Applicable to Certified Systems Only 45
Additional Requirements Applicable to Certified Systems Only, Other Than Fluoroscopic 42
Additional Requirements, Registration Condition 12
Administrative Appeal Of Final Registration Decisions 16
Administrative Controls, Healing Arts 29
Administrative Responsibilities 65
Alterations, Safety Devices, Analytical X-Ray System 66
Aluminum Equivalent 3
Analytical X-Ray Equipment 3
Analytical X-Ray System 3
Application for Registration of Servicing & Services 14
Approval Not Implied, Registration 15
Area Requirements 65
Assembler 3
Attenuation Block 3
Automatic Exposure Control 3

B

Battery Charge Indicator, Diagnostic X-Ray Systems 33
Beam Alignment Apparatus 64
Beam Limitation, Clinical Interest 39
Beam Limiting Device 3
Beam Quality, Diagnostic X-Ray Systems 33

C

CFR, Code of Federal Regulations 4
Cabinet Radiography 3
Cabinet X-Ray System 3
Calendar Quarter 4
Calibration 4
Calibrations, Electron Therapy Systems 58
Calibrations, Therapeutic X-Ray Installations 50
Caution Signs, Labels, & Signals 20
Certified Cabinet X-Ray System 4
Certified Components 4
Certified System 4
Collimator 4
Communications 12
Consultation With Workers During Inspections 74
Control Panel Interlock 64
Control of Scattered Radiation, Fluoroscopic X-Ray Systems 39

D

Dead-Man Switch 4
Definitions, IDAPA 16.02.27, Idaho Radiation Control Rules 3
Design Requirements, X-Ray Machine Operators Booth, Healing Arts 32
Determination of Accumulated Dose, Occupational Exposures 18
Diagnostic Source Assembly 4
Diagnostic X-Ray System 4
Documents Required At Field Radiography Sites 28
Dose 4

E

Emergency Action, Revocation of Registration 17
Emergency Procedures 66
Entrance Exposure Rate 4
Equipment Control 24
Equipment, Safety 64
Equipment, Veterinary Radiographic Installations 45
Exceptions to Surveying, Analytical X-Ray System 66
Exemptions 12
Exemptions For Licensing & Registration Purposes 13
Exemptions, General Requirements, Healing Arts 32
Expiration of Notice of Registration 15
Exposure 4
Exposure Rate 5
Exposure Rate Limits, Fluoroscopic X-Ray Systems 37
Exposure Reproducibility 42, 44
Exposure of Individuals to Radiation in Restricted Areas 17
Exposure of Minors, Occupational Exposures 19
Exposure, Operating Procedures 66

F

Facility 5
Facility & Shielding Requirements, Electron Therapy Systems 57
Facility Design Requirement for X-Ray Systems Capable of Operating Above Fifty KVP 48
Fail-Safe Characteristics 5
Field Limitation, Dental 43
Filter 5
Fluoroscopic Imaging Assembly 5
Fluoroscopic Timer, Fluoroscopic X-Ray 38
Fluoroscopic X-Ray Systems 35

G

General Health & Safety, Prohibited Uses 12
General Purpose Radiographic X-Ray System 5
General Requirements, Healing Arts 29
General Requirements, Mammography 60
Generator Cabinet, Equipment 64
Gonadal Shield 5

H

Half-Value Layer (HVL) 5
Healing Arts 5
Healing Arts Screening 5
High Radiation Area 5
Human Use 5
Human Use of Particle Accelerators 68

I

Image Intensifier 5
Image Receptor 5
Impounding, Radiation Machines 12
Indication of Potential & Current, During Fluoroscopic & Cinefluorography 38
Industrial Radiography 5
Inherent Filtration 5
Inspection 6
Inspection & Maintenance, Equipment 25
Inspections 12
Inspections of Facilities 12
Inspections of Records 12
Installation, Repair, & Modification 66
Instructions to Workers, Restricted Area 73
Interlock 6
Intraoral Dental Radiographic Systems 43
Issuance of Notice of Registration 15

K

Kilovolts Peak (KVP) 6

L

Labels, Equipment Safety 64
Lead Equivalent 6
Leakage & Monitoring, Tube Housing 64
Leakage Radiation 6
Leakage Radiation From the Diagnostic

Source Assembly, Diagnostic X-Ray Systems 33
Leakage Technique Factors 6
Light Field 6
Limitation of Useful Beam, Fluoroscopic X-Ray Systems 35
Limitations 68
Limitations, Personnel Safety Requirements 25
Local Components 6

M

Machines in Transit or Storage, Exemptions 13
Mechanical Support of Tube Head, Diagnostic X-Ray Systems 35
Mobile Fluoroscopes, Fluoroscopic X-Ray 39
Modification, Revocation, & Termination of Registrants 16
Modified Revocation Of Registration 16
Multiple Tubes, Controlled by One Exposure Switch, Diagnostic X-Ray Systems 35

N

Normal Operating Procedures 66
Notices, Instructions & Reports To Workers -- Inspection 71
Notification of Incidents, Theft or Loss 22
Notifications & Reports to Individuals 23
Notifications & Reports to Individuals, Annually 73

O

Occupational Dose 6
Occupational Exposures 17
Open Beam Configuration 6
Operating & Emergency Procedures 26
Operating Controls, Dental 45
Operating Procedures, Analytical X-Ray System 66
Operating Procedures, Electron Therapy Systems 59
Operating Procedures, Particle Accelerators 69
Operating Procedures, Therapeutic X-Ray 49
Operating Procedures, Veterinary Radiographic Installations 46
Operator Qualifications 65
Out-of-State Radiation Machines, Registration 15

P

Particle Accelerator 6
Particle Accelerator Control & Interlock Systems 69
Peak Tube Potential 7
Permanent Radiographic Installation 7, 25
Permissible Levels of Radiation From External Sources in Unrestricted Areas, Occupational Exposures 19
Personal Radiation Safety Requirements For Radiographers & Radiographers Assistants' 25
Personal Supervision 7
Personnel Monitoring 7
Personnel Monitoring Control 26
Personnel Monitoring Equipment 7
Personnel Monitoring, Analytical X-Ray System 67
Personnel Monitoring, Precautionary Procedures 20
Phototimer 7
Position Indicating Device (PID) 7
Posting of Notices to Workers 71
Posting, Precautionary Procedures 28
Posting, Signs, Analytical X-Ray System 66
Precautionary Procedures 19
Precautionary Procedures In Radiographic Operation 28
Preregistration Inspections 12
Primary Beam 7
Prohibited Radiation Uses 12
Protective Apron 7
Protective Barrier 7
Protective Glove 7
Public & Confidential Information 70

Q

Qualified Expert 7
Quality Assurance Program, Mammography 61

R

Rad 8
Radiation 8
Radiation Area 8
Radiation Control Agency 8
Radiation Exposure Control Devices 40
Radiation From Components Other Than the Diagnostic Source Assembly, Diagnostic X-Ray Systems 35
Radiation Levels, Analytical X-Ray System 65
Radiation Machine 8
Radiation Machine Standards, Mammography 60
Radiation Monitoring Requirements, Particle Accelerator 70
Radiation Producing Electrical Equipment, Exemptions 13
Radiation Safety Officer 8
Radiation Safety Officer, Administrative Responsibilities 65
Radiation Safety Requirements For Analytical X-Ray Operations 63
Radiation Safety Requirements For Industrial Radiographic Operations 24
Radiation Safety Requirements For Particle Accelerator Operations 67
Radiation Safety Requirements For The Use Of Particle Accelerators 68
Radiation Sources Used for Shoe Sizing 12
Radiation Survey Instruments, Equipment 24
Radiation Surveys & Survey Records 28
Radiation Transmitted Through Barrier, Fluoroscopic X-Ray Systems 38
Radiograph 8
Radiographer 8
Radiographer's Assistant 8
Radiographic Imaging System 8
Radiographic Machines Used For Mammography 59
Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Or Veterinarian Systems 39
Radiological Physicist 8
Records & Reports of Misadministrations 23
Records of Surveys, Radiation Monitoring & Disposal 21
Records, Personnel Monitoring 67
Records, Receipt, Transfer 12
Records, Reports, & Notifications 21
Registrant 8
Registrant Obligation, Registration 16
Registration 13
Registration Procedure 67
Registration Requirements, Particle Accelerator 67
Registration of Radiation Machine Facilities 13
Registration, Machines 13
Rem 8
Renewal of Notice of Registration 15
Report of Changes, Registration 15
Report of Theft or Loss of Sources of Radiation 22
Reports of Overexposure & Excessive

Levels & Concentration 23
Representatives of Registrants & Workers During Inspection 74
Requests by Workers for Inspections 74
Requirements For All Diagnostic X-Ray Systems 33
Requirements for Equipment, Electron Therapy Systems 51
Requirements for Issuance of a Registration for Particle Accelerators 67
Restricted Area 9
Roentgen 9

S

SSD (Source Skin Distance) 10
Safety Devices 64
Safety Devices, Analytical X-Ray System 67
Scattered Radiation 9
Security, Radiographic Operations 28
Seller, Vendor, Assembler or Transfer Obligation, Registration 15
Shielded Room Radiography 10
Shielding & Safety Design Requirements, Particle Accelerator 68
Shutter 10
Shutter Mechanisms, Equipment 64
Signs, Equipment 64
Source of Radiation 10
Source-Image Receptor Distance (SID) 10
Source-to-Skin Distance, Dental 43
Source-to-Skin Distance, Fluoroscopic X-Ray 38
Source-to-Skin Distance, Other Than Fluoroscopic, Dental Intraoral, Veterinarian Systems 42
Special Requirements & Exemptions for Enclosed Radiography 28
Spot Checks, Electron Therapy Systems 59
Spot Checks, Systems Higher Than One Hundred Fifty kVp, Therapeutic X-Ray 50
Spot Film 10
Spot Film Device 10
Standards For Protection Against Radiation 17
Standby Radiation From Capacitor Energy Storage Equipment 42
Storage Precautions, Equipment 24
Stray Radiation 10
Structural Shielding, General Requirements, Healing Arts 32
Structural Shielding, Veterinary Radiographic Installations 46
Subjects to be Covered During the Instruction of Radiographers 27
Survey 10
Surveys, Analytical X-Ray System 65
Surveys, New Facilities, Therapeutic X-Ray 49

T

Technique Factors 10
Technique Indicators, Diagnostic X-Ray Systems 35
Television Receivers, Exemptions 13
Temporary Job Site 10
Termination of Irradiation 10
Tests 12
Therapeutic X-Ray Installations 46
Therapeutic X-Ray Systems of Less Than One MeV 46
Timers, Dental 44
Traceable to a National Standard 10
Tube 10
Tube Housing Assembly 11
Tube Rating Chart 11

U

Unattended Equipment, Analytical X-Ray 67
Unauthorized Use on Humans, Prohibited Uses 12
Unrestricted Area 11
Unused Tube Head Ports 67
Use Of X-Rays In The Healing Arts 29
Useful Beam 11
Utilization Logs, Maintained for Inspection 24

V

Variable-Aperture Beam-Limiting Device 11
Veterinary Medicine Radiographic Installations 45
Veterinary Medicine Therapeutic X-Ray Installations 46
Violations 12
Visible Area 11

W

Warning Devices, High Radiation Areas & Entrances 69
Warning Label, Control Panel, Diagnostic X-Ray Systems 35
Warning Lights, X-Ray On, Equipment 64
Worker 11

X

X-Ray & Electron Therapy Systems With Energies Of One MeV & Above 51
X-Ray Control 11
X-Ray Control (Exposure Switch), Dental 44
X-Ray Diffraction & Spectrographic Equipment 66
X-Ray Equipment 11
X-Ray Field 11
X-Ray High-Voltage Generator 11
X-Ray Source 11
X-Ray System 11
X-Ray Tube 11