DEPARTMENT OF HEALTH AND SOCIAL SERVICES

PROPOSED CHANGES TO REGULATIONS

7 AAC 18 - Radiation Sources and Radiation Protection
7 AAC 80 - Fees for Department Services

♦

In a Joint Project with the Alaska Department of Environmental Conservation (Amending 18 AAC 85—Radiation Protection)

♦

PUBLIC REVIEW DRAFT

November 20, 2013

Public hearing: December 16, 2013

COMMENT PERIOD ENDS: January 15, 2014

Please see the public notice for details about how to comment on these proposed changes.

Notes to reader:

1. Except as discussed in note 2, new text that amends an existing regulation is **bolded and underlined**.

2. If the lead-in line above the text of the regulations states that a new section, subsection, paragraph, or subparagraph is being added, or that an existing section, subsection, paragraph, or subparagraph is being repealed and readopted (replaced), *the new or replaced text is not bolded or underlined*.

3. [ALL-CAPS TEXT WITHIN BRACKETS] indicates text that is to be deleted.

4. When the word "including" is used, Alaska Statutes provide that it means "including, but not limited to."

5. Only the text that is being changed within a section of the current regulations is included in this draft. Refer to the text of that whole section, published in the current Alaska Administrative Code, to determine how a proposed change relates within the context of the whole section and the whole chapter.

Title 7. Health and Social Services.
Part 2. Public Health.
Chapter 18. Radiation Sources and Radiation Protection.

Article

Article 1. Radioactive materials.

Section

7 AAC 18.010(a) is amended to read:

7 AAC 18.010. Production of radioactive materials. (a) To operate in this state a device, machine, or process that produces a radioactive material, directly or as a byproduct, a person must obtain the approval of the department under **(b) – (e) of** this section **and is subject to the provisions of (h) of this section**.

7 AAC 18.010(b)(6) is amended to read:

(b) A person seeking an approval under this section must submit a written application that

. . . .

(6) includes **a copy** [COPIES] of any permit required under federal, state, or municipal law;

. . . .

7 AAC 18.010(f) is repealed:

(f) Repealed ___/___/2014.

. . . .

7 AAC 18.010 is amended by adding a new subsection to read:

(h) The discharge and disposal of radioactive materials are regulated by the Alaska Department of Environmental Conservation (DEC) under 18 AAC 85, and by the United States Nuclear Regulatory Commission (USNRC) under regulations established under 42 U.S.C. and P.L. 109-58 (Energy Policy Act of 2005). A person who intends to discharge or dispose of a radioactive material, other than a discharge or disposal authorized by the USNRC, shall contact DEC and the USNRC regarding applicable requirements. (Eff. 11/22/2005, Register 176; am 3/30/2006, Register 177; am ____/____/2014, Register ____)

Authority: AS 18.05.010 AS 18.05.040 AS 18.60.475

The editor's note for 7 AAC 18.010 is changed to read:

Editor's note: For purposes of 7 AAC 18.010(h), the Alaska Department of Environmental Conservation may be contacted at P.O. Box 111800, Juneau, AK 99811-1800; and the United States Nuclear Regulatory Commission, Region IV, may be contacted at 612 E. Lamar Boulevard, Suite 400, Arlington, Texas 76011-4125; telephone (817) 860-8100; Website: www.nrc.gov.

As of Register 190, July 2009, the regulations contained in 7 AAC 18.105 – 7 AAC 18.990 became effective simultaneously with the repeal of regulations of the Department of Environmental Conservation that contained the basic substance of 7 AAC 18.105 – 7 AAC 18.990 and appeared in 18 AAC 85.010 – 18 AAC 85.200, 18 AAC 85.220 – 18 AAC 85.270, 18 AAC 85.330 – 18 AAC 85.660, and 18 AAC 85.740 – 18 AAC 85.78018 AAC 85.010 – 18 AAC 85.200, 18 AAC 85.220 – 18 AAC 85.270, 18 AAC 85.330 – 18 AAC 85.660, and 18 AAC 85.740 – 18 AAC 85.780. During the relocation of the regulations to 7 AAC 18, the Department of Health and Social Services made necessary technical and substantive changes to the regulations.

Article 2. Registration and Use of Ionizing Radiation Sources.

Section

The heading for 7 AAC 18.105 is changed, and 7 AAC 18.105(a) is amended to read:

7 AAC 18.105. Applicability of 7 AAC 18.105 – 7 AAC 18.690 and 7 AAC 18.900 – 7 AAC 18.990 [7 AAC 18.110 – 7 AAC 18.990]**.** (a) Except as otherwise specified in AS 18.60.525, the provisions of **7 AAC 18.105 – 7 AAC 18.690 and 7 AAC 18.900 – 7 AAC 18.990** [7 AAC 18.110 – 7 AAC 18.990] apply to a person in this state who receives, possesses, uses, transfers, owns, or acquires a radiation source. **A person who fails to comply with an applicable requirement of this chapter is subject to the penalty provisions of AS 18.60.535.**

The lead-in language of 7 AAC 18.105(b) is amended to read:

(b) The provisions of **7 AAC 18.105 – 7 AAC 18.690 and 7 AAC 18.900 – 7 AAC 18.990** [7 AAC 18.110 – 7 AAC 18.990] may not be construed to limit the dose of radiation that is intentionally applied to a patient for healthcare purposes by, or under the direction of, a **licensed** practitioner of the healing arts [LICENSED IN THIS STATE], except that

• • •

7 AAC 18.105(c) is amended to read:

(c) Notwithstanding the minimum requirements and the permissible levels of ionizing radiation exposures established in **7 AAC 18.105 – 7 AAC 18.690 and 7 AAC 18.900 – 7 AAC 18.990** [7 AAC 18.110 – 7 AAC 18.990], registrants and operators shall apply the principles of ALARA to ensure that registrants, operators, and the general public are exposed only to the lowest amount of ionizing radiation necessary to accomplish an intended purpose.

7 AAC 18.105(d) is amended to read:

(d) For the purposes of **7 AAC 18.105 – 7 AAC 18.690 and 7 AAC 18.900 – 7 AAC 18.990** [7 AAC 18.110 – 7 AAC 18.990], the principles of ALARA means making every reasonable effort to maintain exposures to radiation as low as reasonably practical, consistent with the purpose for which the exposure is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations. **The ALARA principle requires that patient exposures for specific procedures, as based upon a current and appropriate technique chart, do not exceed the following:**

RADIOGRAPHIC ENTRANCE EXPOSURE LIMITS			
	Patient Thickness (cm)	**Exposure Limit (mR)**	**Exposure Limit (mSv)**
Chest (PA)			
(Non-Grid)	23	20	0.2
(Grid)	23	20	0.2
Abdomen (KUB)	23	450	4.5
Lumbo-Sacral Vertabrae (AP)	23	550	5.5
Cervical Vertebra (AP)	13	120	1.2
Thoracic Vertebra (AP)	23	325	3.25
Full Vertebral Column	23	300	3.0
Skull (lateral)	15	150	1.5
Foot (AP)	8	50	0.5

7 AAC 18.105 is amended by adding a new subsection to read:

(e) Definitions applicable to terms used in this chapter are set out in 7 AAC 18.990. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.525 **AS 18.60.535**
AS 18.60.485

7 AAC 18.110(a) is amended to read:

7 AAC 18.110. Registration requirement. (a) A person **who** [THAT] receives, possesses, uses, transfers, owns, or acquires an ionizing radiation source [OR RADIOACTIVE MATERIAL], except **a source regulated by the United States Nuclear Regulatory Commission or a source** [THOSE] specifically exempted in AS 18.60.525 and 7 AAC 18.125, shall register by submitting to the department an application, including **each applicable fee required under 7 AAC 80.030(c)** [ALL APPLICABLE FEES], on a registration form prescribed and provided by the department.

7 AAC 18.110(b) is amended to read:

(b) An applicant **who seeks** to become a registrant, or who is renewing a registration, of an ionizing radiation source shall identify on the registration form the

(1) name, address, [AND] telephone number**, facsimile number, and electronic mail address** of the owner [OR FACILITY];

(2) **facility** name, **if any, and the** address, [AND] telephone **number,** [AND] facsimile **number, and electronic mail address at** [NUMBERS OF] the site of operation;

(3) name, title, **telephone number, facsimile number,** and electronic mail address of the individual responsible for radiation protection;

(4) ionizing radiation source type; and

(5) total number of x-ray tubes **or ionizing radiation sources**.

7 AAC 18.110(c) is amended to read:

(c) An applicant **who seeks** to become a registrant, or who is renewing a registration, of radioactive materials shall **contact the United States Nuclear Regulatory Commission as provided in 7 AAC 18.010(h)** [IDENTIFY ON THE REGISTRATION FORM (1) THE NAME, ADDRESS, AND TELEPHONE NUMBER OF THE OWNER OR FACILITY; (2) THE NAME, ADDRESS, TELEPHONE NUMBER, AND ELECTRONIC MAIL ADDRESS OF THE INDIVIDUAL RESPONSIBLE FOR RADIATION SAFETY; (3) A DESCRIPTION OF THE SOURCE MATERIAL, INCLUDING ACTIVITY AND PHYSICAL FORM; (4) THE MANUFACTURER, MODEL NAME, AND SERIAL NUMBER, IF PART OF EQUIPMENT; AND (5) THE LOCATION, IF NOT AT THE ADDRESS OF THE OWNER]. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The editor's note for 7 AAC 18.110 is changed to read:

Editor's note: For the purposes of submitting a registration form under 7 AAC 18.110, the department's contact information is the Department of Health and Social Services, Division of Public Health, Radiological Health Program, **5455 Dr. Martin Luther King Jr Avenue, Suite 168** [4500 S. BONIFACE PKWY.], Anchorage, AK 99507-1270; telephone: (907) 334-2100;

7 AAC 18.115(a) is amended to read:

7 AAC 18.115. Registration procedure. (a) No later than 30 days after a person, subject to the provisions of 18 AAC 85.110, acquires an ionizing radiation source [OR RADIOACTIVE MATERIAL], the person shall register the ionizing radiation source [OR RADIOACTIVE MATERIAL] with the department.

7 AAC 18.115(b) is amended to read:

(b) An application for an initial registration and renewal of registration must be submitted on a form **supplied** [PRESCRIBED AND PROVIDED] by the department, and **must** include **each applicable fee required under 7 AAC 80.030(c)** [ALL APPLICABLE FEES]. The applicant shall provide all information necessary to complete the form and any other applicable information that the department may request.

. . . .

7 AAC 18.115(e) is amended to read:

(e) Before a registrant's registration expires under this section, the registrant shall renew the registration with the department by submitting an application for renewal on a form prescribed and provided by the department, including **each applicable fee required under 7 AAC 80.030(c)** [ALL APPLICABLE FEES].

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.120(a) is amended to read:

7 AAC 18.120. Authorization to operate. (a) Before the initial operation of a device or source capable of producing radioactive material or radiation fields in excess of 200 millisieverts or 20 rems per minute, a registrant shall apply **to the department for an authorization to operate** [,] by submitting an application prescribed and provided by the department, **and** including **each applicable fee required under 7 AAC 80.030(c)** [ALL APPLICABLE FEES, FOR AN AUTHORIZATION TO OPERATE]. The department will issue an authorization to operate only after inspecting the device or radiation source in the location of operation and **only if** the department determines that the device or radiation source and the environment meet the requirements necessary for safe operation as specified in 7 AAC 18.110 – **7 AAC 18.180** [7 AAC 18.990]. **Each operator shall also apply for the permit required under 7 AAC 18.900.**
. . . .

7 AAC 18.120(c) is amended to read:

(c) **A registrant must submit to the department a decommissioning plan approved by the United States Nuclear Regulatory Commission under 10 C.F.R. 20, Subpart E, and Consolidated Decommissioning Guidance (NUREG-1757, Volume 1, Section 5.1) before the installation or operation of a device or before the receipt of radioactive material if the** [IF A] registrant installs, intends to install, operates**, or intends to operate**

(1) a device containing radioactive material with a half-life greater than **120** [65] days, other than imaging device calibration sources or clinical markers**;** [,] or

(2) [OPERATES] a device capable of inducing nuclear instability of portions of the building structure [, THE REGISTRANT MUST SUBMIT A DECOMMISSIONING PLAN TO THE DEPARTMENT BEFORE THE INSTALLATION OR OPERATION OF THE DEVICE OR RECEIPT OF THE MATERIAL].

7 AAC 18.120 is amended by adding a new subsection to read:

(d) A registrant who operates a device that requires authorization under this section shall ensure that the device is operated in accordance with the guidance of an in-house radiation management committee that includes a designated radiation protection officer, an individual involved in the administration of the registrant's facility, and an individual qualified to operate the device. The registrant shall ensure that the committee meets at least once each year. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The editor's note for 7 AAC 18.120 is changed to read:

Editor's note: For the purposes of submitting an application under 7 AAC 18.120, the department's contact information is the Department of Health and Social Services, Radiological Health Program, **5455 Dr. Martin Luther King Jr Avenue, Suite 168** [4500 S. BONIFACE PKWY.], Anchorage, AK 99507-1270; telephone: (907) 334-2100; fax: (907) 334-2161.

7 AAC 18.125(b)(3) is repealed:

7 AAC 18.125. Exemptions.

. . . .

(b) In addition to the ionizing radiation sources described in (a) of this section, the following sources of ionizing radiation are exempt from the requirements of this chapter:

. . . .

(3) repealed ___/___/2014;

7 AAC 18.125(b)(4) is amended to read:

(4) hands or dials of timepieces and other instruments containing luminous radioactive material [, EXCEPT THAT A PERSON WHO POSSESSES OR USES THE MATERIAL TO APPLY LUMINOUS RADIOACTIVE MATERIAL TO HANDS OR DIALS OF TIMEPIECES AND INSTRUMENTS IS REQUIRED TO MEET THE REQUIREMENTS OF THIS CHAPTER];

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485 AS 18.60.525

7 AAC 18.130(a) is amended to read:

7 AAC 18.130. Vendor registration; notice of transfer. (a) Before a distributor, retailer, qualified expert, or other agent sells, leases, services, calibrates, installs, repairs, or in any other manner transfers or verifies accurate functioning of an ionizing radiation source requiring registration under 7 AAC 18.110, that person shall register with the department by submitting a form prescribed and provided by the department, including **each applicable fee required under 7 AAC 80.030(c)** [ALL APPLICABLE FEES].

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

7 AAC 18.150 is amended to read:

7 AAC 18.150. Maintenance of records. A registrant of an ionizing radiation source [OR RADIOACTIVE MATERIAL] shall keep records of

(1) the receipt, **possession, use,** transfer, or disposal of each ionizing radiation source for at least three years following the event; and

(2) exposure incidents **involving** [OR EXCESSIVE CONCENTRATIONS OF] ionizing radiation for at least three years from the date of occurrence. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

7 AAC 18.170 is amended to read:

7 AAC 18.170. Inspections. (a) A registrant shall allow the department, or the department's designee, upon request, an opportunity to inspect

(1) all ionizing radiation sources in the **registrant's** possession**;** [OF THE REGISTRANT] and

(2) the facility where the sources are used or stored.

(b) A registrant shall make available, upon request, for inspection by the department, or the department's designee, all records pertaining to receipt, possession, use, transfer, or disposal of **each** [RADIOACTIVE MATERIALS OR] ionizing radiation **source** [SOURCES].

(c) During an inspection, the department, or the department's designee, may consult privately with an individual who maintains the records specified in (b) of this section, [HANDLES RADIOACTIVE MATERIALS,] operates an ionizing radiation source, or is otherwise employed at the facility.

(d) For **at least** [THE] 90 days **after the registrant receives the results of an inspection under this section, the** [FOLLOWING AN INSPECTION, A] registrant shall post in a conspicuous location in the facility, or make available for viewing upon request, the results of the inspection. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

Article 3. Ionizing Radiation Protection Requirements.

Section

The lead-in language of 7 AAC 18.200(a) is amended to read:

7 AAC 18.200. Prohibited uses. (a) A person may not direct or order the application of radiation to an individual, except that a **licensed** practitioner of the healing arts [LICENSED BY THIS STATE], or a person working under the direction or order of a **licensed** practitioner of the healing arts [LICENSED BY THIS STATE], may apply radiation to an individual. Any direction or order to apply, or application of, radiation to an individual must

. . .

7 AAC 18.200(c)(1) is amended to read:

(c) The use of a medical fluoroscope

(1) without image **amplification** [INTENSIFICATION] for the application of ionizing radiation to an individual is prohibited;

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

7 AAC 18.210(a) is amended to read:

7 AAC 18.210. External radiation limits in controlled area. (a) A registrant shall possess, use, receive, and transfer sources of ionizing radiation in a controlled area with adequate safeguards to assure that an individual worker's total occupational exposure to all sources of ionizing radiation in the registrant's possession during any span of a calendar year, from both external and internal exposures, does not exceed the following dose limits:

(1) an annual **whole body** limit which is the lesser of the

(A) total effective dose equivalent of **two** [FIVE] rems **(0.02 Sv)** [(0.05 SV)]; or

(B) sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye of 50 rems (0.5 Sv); and

(2) the annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities are a

(A) lens dose equivalent of **five** [15] rems **(0.05 Sv)** [(0.15 SV)]; and

(B) shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

. . . .

7 AAC 18.210(c) is amended to read:

(c) If an individual works for more than one registrant and is exposed, or likely to be exposed, to ionizing radiation from multiple sources, the total combined exposures from all registrants may not exceed the limits specified in (a) of this section. A registrant shall maintain a record for each individual worker that incorporates the annual exposure information for all registrants **for whom** [THAT] the individual works [FOR]. **Records required under this subsection are subject to the requirements of 7 AAC 18.340.** (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

7 AAC 18.230 is repealed:

7 AAC 18.230. Airborne radioactive material in controlled area. Repealed. (Eff. 4/9/2009, Register 190; repealed ____/____/2014)

The lead-in language of 7 AAC 18.240(a) is amended to read:

7 AAC 18.240. External radiation limits in uncontrolled area. (a) Except as authorized by the department under (b) of this section, a registrant may not **receive,** possess, use, or transfer sources of ionizing radiation in a manner that creates, in any uncontrolled area from the sources in the registrant's possession, ionizing radiation levels which

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7 AAC 18.240(a)(2)(B) is amended to read:

(2) cause or are likely to cause an

. . . .

(B) unborn fetus to receive a dose during the entire period of gestation in excess of **0.1 rem (1 milliseivert)** [FIVE MILLISIEVERTS OR 0.5 REMS].

. . . .
(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.250(a) is amended to read:

7 AAC 18.250. Dose limits for a minor. (a) A registrant may not **receive,** possess, use, or transfer sources of ionizing radiation in a manner that causes a minor within a controlled area to receive from all sources of ionizing radiation in the registrant's possession a dose in excess of 10 percent of the limits specified in 7 AAC 18.210.

7 AAC 18.250(b) and (c) are repealed:

(b) Repealed ____/____/2014.

(c) Repealed ____/____/2014. (Eff. 4/9/2009, Register 190; am ____/____/2012, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

7 AAC 18.252 is amended by adding a new subsection to read:

7 AAC 18.252. Dose limits for a student.

. . . .

(d) Notwithstanding the limits set in (a) and (b) of this section, a student who is 18 years of age or older, and who conducts a medical imaging activity in a healthcare setting, may receive no more than the applicable limit specified for occupational exposure in a controlled area, as set out in 7 AAC 18.210. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.255(d) is amended to read:

7 AAC 18.255. Dose limits for a declared pregnant woman.

. . . .

(d) If the dose equivalent to the embryo or fetus exceeds 0.5 rem or five millisieverts, or is within 0.05 rem or 0.5 millisieverts of the dose **limit**, at the time the woman becomes a declared pregnant woman, the registrant is in compliance with (a) of this section if the additional dose equivalent to the embryo or fetus does not exceed 0.05 rem or 0.5 millisieverts during the remainder of the pregnancy.

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.260 is amended to read:

7 AAC 18.260. Limitation on electrical equipment used for teaching purposes. Electrical equipment **that is** used for teaching purposes, and that may emit x-rays incidental to the intended purpose of the equipment, may not be operated in a manner that the external exposure exceeds 10 milliroentgens per hour at 30 centimeters from any accessible surface of the equipment. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.270(b)(2) is amended to read:

7 AAC 18.270. Surveys.

. . . .

(b) If applicable, a survey must include

. . . .

(2) measurements of levels of ionizing radiation [OR CONCENTRATIONS OF RADIOACTIVE MATERIAL] present; and

7 AAC 18.270(b)(3) is amended to read:

(3) an annual calibration of radiation survey meters and personnel monitoring devices by a

(A) [NVLAP ACCREDITED] laboratory **accredited by the National Voluntary Laboratory Accreditation Program; a subdepartment of the National Institute of Standards and Technology, Standard Services Division;** or

(B) qualified expert.

7 AAC 18.270(c) is amended to read:

(c) For the purpose of this section, "survey" includes an evaluation of all ionizing radiation hazards incident to the production, use, release, disposal, transfer, or presence of [RADIOACTIVE MATERIALS OR OTHER] sources of ionizing radiation under a specific set of conditions. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.270 is amended by adding an editor's note to read:

Editor's note: More information about the National Voluntary Laboratory Accreditation Program referred to in 7 AAC 18.270(b)(3)(A) may be obtained by contacting the National Institute of Standards and Technology at Building 101, Room A800, 100 Bureau Drive, Stop 1624, Gaithersburg, Maryland 20899-1624.

7 AAC 18.280(a) is amended by adding new paragraphs to read:

7 AAC 18.280. Personnel monitoring. (a) A registrant shall supply the appropriate individual monitoring device to, and require the use of the device in accordance with, the manufacturer's instructions for use by

. . . .

(4) a declared pregnant woman likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 1 millisievert (0.1 rem); and

(5) an individual working in the vicinity of medical fluoroscopic equipment.

. . . .

7 AAC 18.280 is amended by adding new subsections to read:

(c) An individual monitoring device used for the dose to an embryo or fetus of a declared pregnant woman under (a)(3) of this section must be located under the protective apron at the waist.

(d) An individual monitoring device used for eye dose equivalent must be located at the neck or collar, or an unshielded location closer to the eye, outside the protective apron.

(e) If only one individual monitoring device is used to determine the effective dose equivalent for external radiation under 7 AAC 18.210, the device must be located at the neck or collar outside the protective apron.

(f) If a second individual monitoring device is used for the same purpose, the device must be located under the protective apron at the waist.

(g) A second individual monitoring device is required for a declared pregnant woman. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.290(g) is repealed:

7 AAC 18.290. Posting, labeling, and caution signs.

. . . .

(g) Repealed ____/____/2014.

7 AAC 18.290(h) is repealed:

(h) Repealed ____/____/2014.

7 AAC 18.290(i) is repealed:

(i) Repealed ____/____/2014.

7 AAC 18.290(j) is repealed:

(j) Repealed ____/____/2014.

7 AAC 18.290(k) is repealed:

(k) Repealed ____/____/2014.

7 AAC 18.290(*l*) is repealed:

(*l*) Repealed ____/____/2014.

7 AAC 18.290(m) is repealed:

(m) Repealed ____/____/2014.

7 AAC 18.290(n) is repealed:

(n) Repealed ____/____/2014.

Table II set out at the end of 7 AAC 18.290 is repealed.

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.300 is amended to read:

7 AAC 18.300. Instruction of personnel. [(a)] A registrant shall assure that a qualified expert informs **and instructs** each individual working in or frequenting any portion of a controlled area

(1) of the occurrence of ionizing radiation or sources of ionizing radiation in that portion of the controlled area**;** [.]

(2) [(b) A REGISTRANT SHALL ASSURE THAT A QUALIFIED EXPERT INSTRUCTS EACH INDIVIDUAL WORKING IN OR FREQUENTING ANY PORTION OF A CONTROLLED AREA] about the safety problems associated with exposure to the sources of ionizing radiation and the precautions or procedures to minimize exposure**; and** [.]

(3) [(c) A REGISTRANT SHALL ASSURE THAT A QUALIFIED EXPERT INSTRUCTS EACH INDIVIDUAL WORKING IN OR FREQUENTING ANY PORTION OF A CONTROLLED AREA] in the applicable provisions of department regulations for the protection of personnel from exposure to ionizing radiation [OR RADIOACTIVE MATERIALS]. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.310 is repealed:

7 AAC 18.310. Storage of sources. Repealed. (Eff. 4/9/2009, Register 190; repealed ____/____/2014, Register _____)

7 AAC 18.320, including its editor's note, is repealed:

7 AAC 18.320. General requirements for disposal of radioactive material. Repealed. (Eff. 4/9/2009, Register 190; repealed ____/____/2014, Register _____)

7 AAC 18.330 is repealed:

7 AAC 18.330. Intrastate transportation of radioactive material. Repealed. (Eff. 4/9/2009, Register 190; repealed ____/____/2014, Register _____)

The lead-in language of 7 AAC 18.340(a) is amended to read:

7 AAC 18.340. Records. (a) A registrant shall maintain a record of the occupational radiation exposure history for each individual **for whom** [THAT] personnel monitoring is required under 7 AAC 18.280**,** on a form prescribed and provided by the department, or on a clear and legible record containing all the information specified in this subsection. The form must document each period of time after the individual attained the age of 18 in which the individual received an occupational dose of radiation, and **must** be signed by both the individual and the registrant, or the radiation **protection** [SAFETY] officer, when updated on an annual basis. The form must contain the following information regarding the individual:

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7 AAC 18.340(e) is repealed:

(e) Repealed ____/____/2014.

. . . .
(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The editor's note for 7 AAC 18.340 is changed to read:

Editor's note: For the purpose of transferring records under 7 AAC 18.340, the department's contact information is Department of Health and Social Services, Radiological Health Program, **5455 Dr. Martin Luther King Jr Avenue, Suite 168** [4500 S. BONIFACE PKWY.], Anchorage, AK 99507-1270; telephone: (907) 334-2100; fax: (907) 334-2161.

7 AAC 18.350 is amended to read:

7 AAC 18.350. Report to employees or individuals associated with registrant. A registrant, at the request of an individual employed **by** or associated with the registrant, shall advise the individual annually of the individual's exposure to ionizing radiation as shown in records maintained by the registrant under 7 AAC 18.220 and 7 AAC 18.340. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The heading for 7 AAC 18.355 is changed and 7 AAC 18.355(a) is amended to read:

7 AAC 18.355. Report to former employees <u>or individuals formerly associated with registrant</u>. (a) A registrant, at the request of an individual formerly employed **<u>by</u>** or associated with the registrant, shall furnish to the individual a report of the individual's exposure to ionizing radiation as shown in records maintained under 7 AAC 18.340. The registrant shall provide the report to the individual requesting the report within 30 days from the date the request is received by the registrant. The report must cover each calendar year of the individual's employment or association involving exposure to ionizing radiation, or a shorter period requested by the individual. The report must be in writing and contain the following statement: "This report is furnished to you under the regulations of the Department of Health and Social Services [REGULATIONS]. You should preserve this report for future reference."

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

The editor's note for 7 AAC 18.360 is changed to read:

Editor's note: For the purpose of reporting a theft or loss under 7 AAC 18.360, the department's contact information is Department of Health and Social Services, Division of Public Health, Radiological Health Program, **<u>5455 Dr. Martin Luther King Jr Avenue, Suite 168</u>** [4500 S. BONIFACE PKWY.], Anchorage, AK 99507-1270; telephone: (907) 334-2100; fax: (907) 334-2161.

The lead-in language of 7 AAC 18.370(a) is amended to read:

7 AAC 18.370. Notification of incident. (a) A registrant shall immediately notify the department by telephone or facsimile**<u>, followed by a confirming letter,</u>** of an incident involving a source of ionizing radiation possessed by the registrant that may have caused or threatens to cause

• • •

The lead-in language of 7 AAC 18.370(b) is amended to read:

(b) A registrant shall within 24 hours notify the department by telephone or facsimile**<u>, followed by a</u>** [AND] confirming letter**<u>,</u>** of an incident involving a source of radiation possessed by the registrant that may have caused or threatens to cause

• • •

7 AAC 18.370(c) is amended to read:

(c) **For purposes of confidentiality, a notification** [A REPORT] filed with the department under this section must be prepared in a manner that the name of an individual who has received exposure to ionizing radiation is stated in a separate part of the **notification** [REPORT].

7 AAC 18.370 is amended by adding a new subsection to read:

(d) Within 30 days of the determination by a physician of either actual or suspected acute or long-term functional damage to an organ or a physiological system of a patient exposed to therapeutic or diagnostic radiation from a radiation-producing machine, the registrant shall document the finding and provide a report to the department and shall provide a clinical summary to the prescribing physician and the patient. The report must be retained for at least five years. This reporting requirement does not apply to any event of any functional damage to a patient organ or a physiological system that was an expected outcome when the causative procedures were prescribed. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The editor's note for 7 AAC 18.370 is changed to read:

Editor's note: For the purpose of notifying the department of an incident under 7 AAC 18.370, the department's contact information is Department of Health and Social Services, Division of Public Health, Radiological Health Program, **5455 Dr. Martin Luther King Jr Avenue, Suite 168** [4500 S. BONIFACE PKWY.], Anchorage, AK 99507-1270; telephone: (907) 334-2100; fax: (907) 334-2161.

7 AAC 18.380(a) is amended to read:

7 AAC 18.380. Report of overexposures and excessive levels and concentrations. (a) In addition to the notification required under 7 AAC 18.370, a registrant shall submit a detailed report in writing to the department within 30 days of an incident [IN WHICH]

(1) **for which** notification is required under 7 AAC 18.370;

(2) **in which an** [EACH] exposure **occurred** of an individual to ionizing radiation [OR CONCENTRATIONS OF RADIOACTIVE MATERIAL] in excess of an applicable limit as set out in 7 AAC 18.200 – 7 AAC 18.390 or as otherwise approved by the department; and

(3) **in which** levels of ionizing radiation [OR CONCENTRATIONS OF RADIOACTIVE MATERIAL], not involving excessive ionizing radiation doses **occurred** to any individual, in an uncontrolled area in excess of 10 times any applicable limits as set out in 7 AAC 18.200 – 7 AAC 18.390 or as otherwise approved by the department.

7 AAC 18.380(b) is amended to read:

(b) A report required under this section must describe the

(1) extent of exposure of **each** [AN] individual to ionizing radiation [OR TO RADIOACTIVE MATERIAL];

(2) levels of ionizing radiation [AND CONCENTRATIONS OF THE RADIOACTIVE MATERIAL INVOLVED];

(3) cause of the exposure **or** [,] levels [, OR CONCENTRATIONS]; and

(4) corrective steps **that were** taken or planned to assure against a recurrence.

7 AAC 18.380(c) is amended to read:

(c) If a registrant is required under this section to report to the department any exposure of an individual to ionizing radiation [OR CONCENTRATIONS OF RADIOACTIVE MATERIAL], the registrant shall, not later than the delivery of the report to the department, also notify the individual of the nature and extent of exposure. The notice must be in writing and contain the following statement: "This report is furnished to you under the regulations of the Department of Health and Social Services [REGULATIONS]. You should preserve this report for future reference."

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The editor's note for 7 AAC 18.380 is changed to read:

Editor's note: For the purpose of submitting a written report under 7 AAC 18.380, the department's contact information is Department of Health and Social Services, Radiological Health Program, **5455 Dr. Martin Luther King Jr Avenue, Suite 168** [4500 S. BONIFACE PKWY.], Anchorage, AK 99507-1270; telephone: (907) 334-2100; fax: (907) 334-2161.

7 AAC 18.390, including its header, is amended to read:

7 AAC 18.390. Vacating <u>or relinquishing</u> premises. No less than 30 days before vacating or relinquishing possession or control of a premises in which a registered radiation source has been stored or used, a registrant shall notify the department in writing of the registrant's intent to vacate or relinquish and **<u>shall</u>** allow the department the opportunity to survey the premises for contamination. If the department identifies contamination, or if the registrant's decommissioning plan **<u>required under 7 AAC 18.120(c)</u>** is not complete, the department will require the registrant to maintain control over the contaminated premises until the source of contamination is removed. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The editor's note for 7 AAC 18.390 is changed to read:

Editor's note: For the purpose of submitting the written notice required under 7 AAC 18.390, the department's contact information is Department of Health and Social Services, Radiological Health Program, **<u>5455 Dr. Martin Luther King Jr Avenue, Suite 168</u>** [4500 S. Boniface Pkwy.], Anchorage, AK 99507-1270; telephone: (907) 334-2100; fax: (907) 334-2161.

Article 4. Use of Radiation Sources in the Healing Arts.

Section

7 AAC 18.400(a) is amended to read;

7 AAC 18.400. General safety provisions. (a) A person may not construct, sell, lease, transfer, lend, or install medical or veterinary x-ray equipment or supplies used in connection with the equipment, unless the equipment and supplies, when properly installed and properly used, meet the **applicable** requirements of 7 AAC 18.410 – **7 AAC 18.590** [7 AAC 18.480].

. . . .
(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

7 AAC 18 is amended by adding a new section to read:

7 AAC 18.402. Approval required for healing arts screening program. (a) Except as provided in (b) of this section, a person who performs or intends to perform healing arts screening of human patients shall request and obtain department approval of the healing arts screening program and shall submit the following information and evaluation:

(1) the applicant's name and address and, where applicable, the name and address of each agent within this state;

(2) diseases or conditions for which the x-ray examinations are to be used in diagnoses;

(3) a detailed description of the x-ray examinations proposed in the screening program;

(4) a description of the population to be examined in the screening program, including age, gender, physical condition, and other appropriate information;

(5) an evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;

(6) an evaluation by a qualified expert of each x-ray system to be used in the screening program; the evaluation by the qualified expert must show that each system satisfies the applicable requirements of this chapter; the evaluation must include a calculated measurement of patient exposures from the x-ray examinations to be performed that is confirmed by measurement after initiating operation;

(7) 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;

(8) an indication of the frequency of screening and the duration of the entire screening program;

(9) a description of measures that will be taken to ensure that no member of the public is exposed to radiation in excess of the limits found in 7 AAC 18.240;

(10) a description of how the determination will be made regarding who may be exposed, and how that authority will be communicated to the individual who performs the screening;

(11) the name and address of the individual who will interpret the screening results;

(12) a description of the diagnostic x-ray quality control program;

(13) a copy of the technique chart for the x-ray examination procedures to be used;

(14) the qualifications of each individual who will be operating each x-ray system;

(15) the qualifications of the individual who will be supervising the operator of each x-ray system, specifying the extent of supervision and the method of work performance evaluation;

(16) a description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

(b) A person seeking approval of a healing arts screen program for bone densitometry screening is not required to submit the information required under (a)(13)-(16) of this section. (Eff. ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.410 is amended to read:

7 AAC 18.410. Proper use of equipment. (a) A registrant of medical or veterinary x-ray equipment is responsible for assuring that all **applicable** requirements of 7 AAC 18.400 – 7 AAC 18.590 are met.

(b) A registrant of medical or veterinary x-ray equipment shall assure that all x-ray equipment under the registrant's control is operated only by an individual who is adequately instructed **by an individual with demonstrated knowledge and skill** in safe operating procedures and **with competency** [COMPETENT] in **the** safe use of the equipment. The registrant shall provide safety rules to each individual operating x-ray equipment under the registrant's control, including any restrictions on the operating technique required for the safe operation of the particular x-ray apparatus, and **shall** require the operator to demonstrate familiarity with these rules. **The registrant shall ensure that each operator has applied for and been issued a valid permit under 7 AAC 18.900.** (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

The lead-in language of 7 AAC 18.420(a) is amended to read:

7 AAC 18.420. Instruction of medical radiation device operators. (a) **Except as provided in (f) of this section, for** [FOR] each individual who operates a medical or veterinary x-ray device, the registrant shall maintain a record of all training and educational programs attended by each operator to establish that the operator is able to independently **and safely** operate a device capable of emitting ionizing radiation. The record for each operator must **include a copy of a current permit issued under 7 AAC 18.900 and** identify the

. . .

The lead-in language of 7 AAC 18.420(b) is amended to read:

(b) **An operator of a medical diagnostic imaging device that causes exposure of a human to ionizing radiation must be registered by the American Registry of Radiologic Technologists or by another accredited certifying body with comparable standards acceptable to the department. In a facility where ionizing radiation exposures to humans are confined to the thorax, vertebral column, or appendicular skeleton, the department may approve an exemption to the requirements of this subsection if the operator has passed a qualifying examination that is comparable to the limited scope operator examination of the American Registry of Radiologic Technologists or a qualifying examination of another accredited certifying body with comparable standards acceptable to the department.** The minimum acceptable training curriculum for an operator of a medical x-ray device must include

. . .

7 AAC 18.420(b) is amended by adding a new paragraph to read:

(4) mentored practice of each aspect of each procedure that the operator will be performing independently.

7 AAC 18.420(c) is amended to read:

(c) An operator of medical fluoroscopic equipment must receive a minimum of 10 hours of instruction **specifically related to** [IN] the safe operation of the fluoroscope. **This requirement is in addition to the requirements of (b) of this section.**

7 AAC 18.420 is amended by adding new subsections to read:

(d) An individual who supervises or trains an operator of medical fluoroscopy equipment must meet minimum safety standards for education, credentialing, and competence specifically related to the use of medical fluoroscopic devices as follows:

(1) at least two years education in the medical use of radiation, including 40 hours in medical radiation safety and radiation biology;

(2) a medical radiology credential recognized by a national accrediting body; and

(3) demonstrated competence by practical demonstration before a qualified expert that the individual can direct the use of a medical fluoroscope using all reasonably available methods to achieve safe exposures to patients, staff, and the public.

(e) An operator of a medical radiation device must complete at least 24 hours of continuing medical imaging education approved by the department within each 24-month period, beginning 24 months after the operator meets the initial qualifications to operate that equipment. At least three of the 24 hours must be in each specific category for which the operator initially qualified. For purposes of this subsection, "medical radiation device" means a device subject to this section and to 7 AAC 18.410, 7 AAC 18.440 (fluoroscopy), 7 AAC 18.455 (computed tomography (CT) x-ray systems), 7 AAC 18.457 (bone densitometry systems), 7 AAC 18.460 (mammography devices), 7 AAC 18.620 (radiation therapy), and 7 AAC 18.800 (magnetic resonance imaging). The requirements of this subsection do not apply to veterinary use, industrial radiography, or ultraviolet radiation (indoor tanning).

(f) A licensed practitioner of the healing arts is exempt from the requirements of (a), (b), and (e) of this section if the practitioner's education and training included, at a minimum, the education and training required in (b) of this section. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.430(a) is amended to read:

7 AAC 18.430. Shielding. (a) A medical or veterinary x-ray installation must include the primary barriers and secondary barriers necessary to assure compliance with the provisions of 7 AAC 18.210, 7 AAC 18.240, and 7 AAC 18.250. The requirements of this section are met if the thickness and design of the barriers are equivalent to those computed and designed in accordance with the recommendations of the National Council on Radiation Protection and Measurements (NCRP) in NCRP Report No. 147, *"Structural Shielding Design for Medical X-ray Imaging Facilities,"* issued November 19, 2004, and adopted by reference. **The shielding plan must be designed by a qualified expert and approved by the department before construction, modification, or replacement of the radiation source by a higher intensity unit.**

. . . .
(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

7 AAC 18.440(a) is amended to read:

7 AAC 18.440. Fluoroscopic installation. (a) A healing arts fluoroscopic installation and C-arm must use an image **amplification** [INTENSIFICATION] assembly and a diagnostic-type protective x-ray tube housing and must meet the requirements of this section.

. . . .

The lead-in language of 7 AAC 18.440(d) is amended to read:

(d) The equipment must be constructed in a manner that ensures that the entire cross section of the useful beam is attenuated by a primary barrier designed to automatically terminate exposure when the barrier is removed from the useful beam, which is usually the image **amplification** [INTENSIFICATION] mechanism, and

• • •

7 AAC 18.440(d)(2) is amended to read:

(2) a collimator must restrict the cross-sectional dimensions of the useful beam to less than the corresponding dimensions of the barrier; the tube and collimating system must be linked with the image **amplification** [INTENSIFICATION] assembly so that the useful beam at the image **amplifier** [INTENSIFIER] input phosphor is confined within the barrier regardless of the panel-screen distance;

7 AAC 18.440(d)(3) is amended to read:

(3) the tube mounting and the barrier (the viewing device) must be linked together in a manner that **ensures that**, under conditions of normal use, the barrier always intercepts the entire useful beam; and

. . . .

7 AAC 18.440(k) is amended to read:

(k) Mobile fluoroscopic equipment must meet the **applicable** requirements of this section [, WHERE APPLICABLE,] and the following requirements:

(1) in the absence of a table top, a cone or spacer frame must limit the target-to-skin distance to not less than 30 centimeters, except that for mini C-arms and for C-arms used during a surgical application to an extremity, the distance may not be less than 20 centimeters;

(2) image **amplification** [INTENSIFICATION] must always be used;

(3) a machine must be inoperable, except when the collimating cone or diaphragm is in place and the entire useful beam is intercepted by the image **amplifier** [INTENSIFIER]; [AND]

(4) the exposure rate measured 30 centimeters from the image **amplifier** [INTENSIFIER] or input phosphor must be as low as practical, but not exceed 10 roentgens per minute**; and** [.]

(5) each person, other than the patient, must wear a personnel monitoring device while operating or assisting with the operation of mobile fluoroscopic equipment.

. . . .

(Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.450(f) is amended to read:

7 AAC 18.450. Medical radiographic installation.

. . . .

(f) The exposure switch must be [OF] a dead-man type switch and must be arranged in a manner that the switch cannot be operated outside a shielded area, except that exposure switches for spot film devices used in conjunction with fluoroscopic tables and for mobile diagnostic radiographic equipment are exempt from this shielding requirement.

. . . .

7 AAC 18.450(j) is amended to read:

(j) A primary barrier in a wall must extend to a height of at least 84 inches **(210 centimeters)** [OR 210 CENTIMETERS] above the floor.

. . . .

7 AAC 18.450(m) is amended to read:

(m) A window of lead equivalent glass, equal to that required by the adjacent barrier [, MIRROR SYSTEM,] or closed circuit television monitor, must be provided and it must be large enough and placed in a manner that the operator can see the patient during the exposure without having to leave the protective area.

. . . .

The lead-in language of 7 AAC 18.450(w) is amended to read:

(w) A registrant who uses film imaging and processing of the images shall establish processing quality control procedures at regular intervals that [AT LEAST] include**, at a minimum,**

. . . .

7 AAC 18.450(w)(5) and (6) are repealed:

(5) repealed ____/____/2014;

(6) repealed ____/____/2014.

7 AAC 18.450(x) is amended by adding a new paragraph to read:

(x) A registrant who uses electronic, digital, or computerized imaging methods shall establish quality control procedures that include at least

. . . .

(4) image critiques performed at least quarterly to evaluate the causes of spoiled images that require repeating a patient's exposure. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18 is amended by adding a new section to read:

7 AAC 18.455. Computed Tomography (CT) X-Ray Systems. (a) A registrant who uses a computed tomography (CT) x-ray system shall ensure that, in addition to other applicable requirements of this chapter, the requirements of this section are met.

(b) The registrant shall ensure that equipment requirements are met as follows:

(1) regarding termination of exposure:

(A) in the event of equipment failure affecting data collection, the means must be provided to terminate x-ray exposure automatically by de-energizing the x-ray source or by shuttering the x-ray beam; this termination must occur within an interval that limits the total scan time to no more than 110 percent of its pre-set value through the use of either a backup timer or a device that monitors equipment function;

(B) a visible signal must indicate when the x-ray exposure has been terminated as required by (A) of this paragraph; and

(C) the operator must be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration;

(2) regarding tomographic plane indication and alignment:

(A) for a single tomogram system, the means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane;

(B) for a multiple tomogram system, the means must be provided to permit visual determination of the location of a reference plane; this reference plane may be offset from the location of the tomographic planes; and

(C) if a device using a light source is used to satisfy the requirements of (A) or (B) of this paragraph, the light source must provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux;

(3) regarding beam-on and shutter status indicators and control switches:

(A) the CT x-ray control and gantry must provide visual indication whenever an x-ray is produced and, if applicable, whether the shutter is open or closed; and

(B) each emergency button or switch shall be clearly labeled as to its function;

(4) regarding indication of CT conditions of operation: the CT x-ray system must be designed so that the CT conditions of operation to be used during a scan or a scan sequence are indicated before initiation of a scan or a scan sequence; for equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings; indication of CT conditions of operation must be visible from any position from which scan initiation is possible;

(5) regarding extraneous radiation: when data are not being collected for image production, the radiation adjacent to the tube port may not exceed that permitted by 7 AAC 18.456;

(6) regarding maximum surface computed tomography dose index (CTDI) identification: the angular position where the maximum surface CTDI occurs must be identified to allow for reproducible positioning of a CT dosimetry phantom;

(7) regarding additional requirements applicable to a CT x-ray system containing a gantry manufactured after September 3, 1985:

(A) the total error in the indicated location of the tomographic plane or reference plane may not exceed 5 millimeters;

(B) if the x-ray production period is less than one-half second, the indication of x-ray production must be actuated for at least one-half second; each indicator at or near the gantry must be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible;

(C) the deviation of indicated scan increment versus actual increment may not exceed plus or minus 1 millimeter with any mass from 0 to 100 kilograms resting on the support device; the patient support device must be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position; measurement of actual versus indicated scan increment may be taken anywhere along this travel;

(D) premature termination of the x-ray exposure by the operator must necessitate resetting of the CT conditions of operation before initiation of another scan; and

(E) the operator shall ensure that patient exposure data for each study is recorded with the patients record, using standard radiation exposure units such as grays or DAP.

(c) The registrant shall ensure that facility design requirements are met as follows:

(1) regarding aural communication: provision must be made for two-way aural communication between the patient and the operator at the control panel;

(2) regarding viewing systems:

(A) windows, mirrors, closed-circuit television, or an equivalent 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;

(B) 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.

(d) The registrant shall ensure that survey, calibration, spot check, and operating procedure requirements are met as follows:

(1) regarding surveys:

(A) a CT x-ray system installed after _____, 2014 [*the department will insert the effective date of the regulations*] and any system not previously surveyed must have a survey made by, or under the direction of, a qualified expert; an additional survey must be done after any change in the facility or equipment that might cause a significant increase in radiation hazard; and

(B) the registrant shall obtain a written report of each survey from the qualified expert, and a copy of the report must be made available to the department upon request;

(2) regarding radiation calibrations:

(A) the calibration of the radiation output of a CT x-ray system must be performed by, or under the direction of, a qualified expert who is physically present at the facility during the calibration;

(B) the calibration of a CT x-ray system must be performed at intervals specified by a qualified expert and after any change or replacement of components that, in the qualified expert's opinion, could cause a change in the radiation output;

(C) the calibration of the radiation output of a CT x-ray system must be performed with a calibrated dosimetry system; the calibration must be traceable to a national standard, and the dosimetry system must have been calibrated within the preceding two years;

(D) one or more CT dosimetry phantoms must be used in determining the radiation output of a CT x-ray system and must meet the following specifications and conditions of use:

(i) each CT dosimetry phantom must be a right circular cylinder of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter; each phantom must be at least 14 centimeters in length and must have a diameter of 32.0 centimeters for testing a CT x-ray system designed to image any section of the body, and must have a diameter of 16.0 centimeters for a system designed to image the head or for whole body scanners operated in the head scanning mode;

(ii) each CT dosimetry phantom must provide the means for the placement of one or more dosimeters along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom; the means for the placement of dosimeters or alignment devices at other locations may be provided;

(iii) any effects on the doses measured due to the removal of phantom material to accommodate dosimeters must be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and

(iv) dose measurements must be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present;

(E) calibration must be required for each type of head, body, or whole-body scan performed at the facility;

(F) calibration must meet the following requirements:

(i) the dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant must be measurable; where less than three nominal tomographic thicknesses can be selected, the dose profile determination must be performed for each available nominal tomographic section thickness;

(ii) the CTDI along the two axes specified in (D)(ii) of this paragraph must be measured; the CT dosimetry phantom must be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified; the CT conditions of operation must correspond to typical values used by the registrant; for purposes of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be used; and

(iii) each spot check specified in (3) of this subsection must be made;

(G) calibration procedures must be in writing, and records of calibrations performed must be maintained for inspection by the department for at least three years;

(3) regarding spot checks:

(A) spot-check procedures must

(i) be in writing and must be developed by a qualified expert; and

(ii) incorporate the use of a CT dosimetry phantom with the capability to provide an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and to measure the mean CT number (CTN) for water or other reference material;

(B) spot checks must

(i) be included in the calibration required by (2) of this subsection and at time intervals and under system conditions specified by a qualified expert; and

(ii) include acquisition of images obtained with the CT dosimetry phantom, using the same processing mode and CT conditions of operation that are used to perform calibrations required by (2) of this subsection; the images must be retained, until a new calibration is performed, in two forms: photographic copies of the images obtained from the image display device, and images stored in digital form on a storage medium compatible with the CT x-ray system; and

(C) written records of spot checks performed must be maintained for inspection by the department for at least three years;

(4) regarding operating procedures:

(A) the CT x-ray system may be operated only by an individual specifically trained in its operation;

(B) information must be available at the control panel regarding the operation and calibration of the system, including

(i) the dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;

(ii) instructions on the use of the CT dosimetry phantom, including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;

(iii) the distance in millimeters between the tomographic plane and the reference plane if a reference plane is used; and

(iv) a current technique chart available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination;

(C) if the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients must be limited to those uses permitted by established written instructions of the qualified expert;

(D) each operator of a computed tomography system must have a valid permit issued by the department under 7 AAC 18.900 and must

(i) be licensed, certified, or registered as a radiologic technologist by the American Registry of Radiologic Technologists, or equivalent; or

(ii) be a licensed practitioner of the healing arts; and

(E) quality control procedures must be completed in accordance with the manufacturer's specifications and time frames. (Eff. ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18 is amended by adding a new section to read:

7 AAC 18.456. Leakage Radiation from the Diagnostic Source Assembly. The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 μC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. (Eff. ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18 is amended by adding a new section to read:

7 AAC 18.457. Bone densitometry systems. (a) A registrant who uses a bone densitometry system shall ensure that, in addition to the other applicable requirements of this chapter, the requirements of this section are met.

(b) A bone densitometry system must be

(1) certified by the manufacturer as required by the Medical Device Act and 21 U.S.C. 360hh – 360ss (Subchapter C – Electronic Product Radiation Control of Chapter V of the Federal Food, Drug and Cosmetic Act);

(2) registered in accordance with 7 AAC 18.105; and

(3) maintained and operated in accordance with the manufacturer's specifications.

(c) A bone densitometry system with stepless collimators must be provided with the means to size and align the x-ray field so that the x-ray field at the plane of the image receptor does not extend beyond two percent of the source-image receptor distance.

(d) An operator of a bone densitometry systems must have a valid permit issued by the department under 7 AAC 18.900 and must

(1) be licensed, certified, or permitted as a radiologic technologist by the American Registry of Radiologic Technologists, or equivalent;

(2) be a licensed practitioner of the healing arts;

(3) be permitted or approved the department as a bone densitometry operator; or

(4) complete a training course on bone densitometry approved by the department; the training course must include

(A) basic radiation protection;

(B) operating procedures for bone densitometry systems, to include use of various system functions, safety, and maintenance; and

(C) patient positioning for each type of examinations performed.

(e) During the operation of any bone densitometry system

(1) the operator, ancillary personnel, and members of the general public must be positioned at least one meter from the patient and bone densitometry system during the examination; and

(2) the operator must advise the patient that the bone densitometry examination is a type of x-ray procedure.

(f) The registrant shall keep maintenance records for each bone densitometry system. These records must be maintained for inspection by the department for at least three years.

(g) Bone densitometry on human patients may be conducted only under a prescription of a licensed practitioner of the healing arts or under a screening program approved by the department under 7 AAC 18.402. (Eff. ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

. . . .

The heading for 7 AAC 18.470 is changed to read:

7 AAC 18.470. Veterinary medicine radiographic installation <u>and operation</u>.

. . . .

7 AAC 18.470(c) is amended to read:

(c) A hand-held fluoroscopic screen may not be used. **A hand-held radiographic device may be used if the operator follows the manufacturer's recommendations and the owner of the device has established safety rules specific to the use of the hand-held device that are approved by the department before initial use of the device.**

7 AAC 18.470 is amended by adding a new subsection to read:

(d) An operator of a veterinary ionizing radiation emitting device must

(1) have a valid operator's permit issued under 7 AAC 18.900; and

(2) complete at least four hours of continuing education every 24 months pertaining to application of ionizing radiation and safety. (Eff. 4/9/2009, Register 190; am ____/____/2014, Register ____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.480 is repealed:

7 AAC 18.480. Sealed sources: interstitial, intercavitary, and superficial applications. Repealed. (Eff. 4/9/2009, Register 190; repealed ____/____/2014, Register ____)

. . . .

7 AAC 18 is amended by adding new sections to read:

Article 6. Radiation Therapy.

Section

7 AAC 18.600. Applicability and scope of 7 AAC 18.600 – 7 AAC 18.690. (a) The provisions of 7 AAC 18.600 – 7 AAC 18.690 apply to a person in this state who receives, possesses, uses, transfers, owns, or acquires a therapeutic radiation machine. These provisions are in addition to other applicable requirements of this chapter.

(b) A person described in (a) of this section shall ensure that each therapeutic radiation machine is

(1) registered in accordance with 7 AAC 18.110 – 7 AAC 18.115, and that an authorization to operate has been issued under 7 AAC 18.120;

(2) operated in accordance with the applicable requirements of this chapter;

(3) used by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria established under 7 AAC 18.610; and

(4) in compliance with all other applicable requirements of this chapter.

(b) A therapeutic radiation machine that does not meet the applicable provisions of this chapter may not be used for irradiation of patients.

(c) A person who fails to comply with an applicable requirement of this chapter is subject to the penalty provisions of AS 18.60.535. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485 AS 18.60.535

7 AAC 18.605. Prohibited uses. An individual may not be exposed to the useful beam except for medical therapy purposes and unless that exposure has been ordered in writing by an authorized user of a therapeutic radiation machine and is delivered to the patient by an operator qualified as described in 7 AAC 18.620. The deliberate exposure of an individual for training, demonstration, or any other non-healing-arts purpose is prohibited. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.610. Training requirements for authorized users of therapeutic radiation machines. (a) The registrant shall ensure that an individual who uses a therapeutic radiation machine is an authorized user who is a physician

(1) certified in

(A) radiation oncology or therapeutic radiology by the American Board of Radiology; if certification occurred before 1976, the physician must be certified in radiology (combined diagnostic and therapeutic radiology program) by the American Board of Radiology;

(B) radiation oncology by the American Osteopathic Board of Radiology;

(C) radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or

(D) therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or

(2) in the active practice of therapeutic radiology, and who has completed at least

(A) 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit; to satisfy the requirements of this subparagraph, the classroom and laboratory training must include

(i) radiation physics and instrumentation;

(ii) radiation protection;

(iii) mathematics pertaining to the use and measurement of ionization radiation; and

(iv) radiation biology;

(B) 500 hours of supervised work experience; to satisfy the requirements of this subparagraph, training must be under the supervision of an authorized user and must include

(i) review of the full calibration measurements and periodic quality assurance checks;

(ii) evaluation of prepared treatment plans and calculation of treatment times and patient treatment settings;

(iii) the use of administrative controls to prevent a misadministration described in 7 AAC 18.645(b)(3) and (b)(4);

(iv) the implementation of emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(v) checking and using radiation survey meters; and

(C) three years of supervised clinical experience; to satisfy the requirements of this subparagraph, training must include

(i) at least one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user;

(ii) examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations or contraindications;

(iii) selecting the proper dose and how it is to be administered;

(iv) calculating the therapeutic radiation machine dose and collaborating with the authorized user in the review of the patient's progress and consideration of the need to modify the originally prescribed dose or treatment plan as warranted by the patient's reaction to radiation; and

(v) post-administration followup and review of case histories.

(b) Notwithstanding (a) of this section, the registrant for a therapeutic radiation machine of less than 500 kV that is subject to 7 AAC 18.650 may submit for department review and approval on a case-by-case basis the training of the prospective authorized user physician if the training does not fully meet the requirements of (a) of this section.

(c) A physician may not act as an authorized user for any therapeutic radiation machine until the department has reviewed and approved that physician's training. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.615. Training requirements for qualified medical physicists. (a) The registrant for a therapeutic radiation machine shall ensure that each qualified medical physicist is registered with the department under this chapter, as a provider of radiation services in the area of calibration and compliance surveys of external beam radiation therapy units. A qualified medical physicist must also be

(1) certified by the American Board of Radiology in

(A) therapeutic radiological physics;
(B) roentgen-ray and gamma-ray physics;
(C) X-ray and radium physics; or
(D) radiological physics;

(2) certified by the American Board of Medical Physics in Radiation Oncology Physics;

(3) certified by the Canadian College of Medical Physics; or

(4) subject to (b) of this section, hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and have completed at least one year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a qualified medical physicist at a medical institution; this training and work experience must be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV); to meet this requirement, the individual must have performed, under the supervision of a qualified medical physicist during the year of work experience, the tasks listed in

(A) 7 AAC 18.640(a);

(B) 7 AAC 18.650(p) or 7 AAC 18.659, as applicable; and

(C) 7 AAC 18.650(q) or 7 AAC 18.660, as applicable.

(b) On or before _____, 2014 [*the department will insert a date that is six months after the effective date of this section*], an individual who is a qualified medical physicist under the provisions of (a)(4) of this section must be certified under the provisions of (a)(1), (a)(2), or (a)(3) to maintain that qualification. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.620. Qualifications of operators. (a) An individual may operate a therapeutic radiation machine for medical use only if that individual has a valid permit issued by the department under 7 AAC 18.900 and

(1) is a registered radiation therapy technologist with the American Registry of Radiologic Technologists (ARRT); or

(2) submits evidence of satisfactory completion of a radiation therapy technologist training program that complies with the requirements of the Joint Review Committee on Education in Radiologic Technology set out in that committee's *Standards for an Accredited Educational Program in Radiologic Sciences*.

(b) The registrant shall ensure that

(1) written safety procedures and rules that have been developed by a qualified medical physicist are available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular machine; and

(2) the operator has demonstrated familiarity with the procedures and rules.

(c) The registrant shall ensure that the name and training information regarding each

(1) operator of a therapeutic radiation machine are kept on file at the facility; and

(2) former operator are retained for at least three years after the last date the operator was authorized to operate a therapeutic radiation machine at the facility. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.625. Visiting authorized users. (a) Notwithstanding the provisions of 7 AAC 18.610, a registrant may permit any physician to act as a visiting authorized user under the term of the registrant's registration for up to 60 days each calendar year if the visiting authorized user

(1) has the prior written permission of the registrant's management; if the use occurs on behalf of an institution, the visiting authorized user must also have the prior written permission of the radiation protection committee for that institution; and

(2) provides documentation that the physician meets the requirements 7 AAC 18.610(a)(1) or (2).

(b) For each visiting authorized user, the registrant shall maintain copies of each written permission required under (a)(1) of this section and the documentation required under (a)(2) of this section for at least five years after the date of the last visit by the visiting authorized user. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.630. Maintenance and associated records. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine, for inspection by the department:

(1) report of acceptance testing;

(2) records of each survey, calibration, and periodic quality assurance check of the machine as required by this chapter, including the name of each person who performed each activity;

(3) records of any maintenance or modification performed on the machine after _____, 2014 [*the department will insert the effective date of this section*], including the name of each person who performed the maintenance or modification;

(4) the signature of the person who authorized the return of the machine to clinical use after any service, repair, or upgrade. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.635. Records retention. The registrant shall ensure that any record required by this chapter is retained until disposal is authorized by the department, unless another retention period is specifically authorized in this chapter. The registrant shall retain records in an active file from the time of generation until at least the next inspection by the department. Any required record generated before the final inspection may be microfilmed or otherwise archived if a complete copy of the record can be retrieved until the department authorizes final disposal. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.640. General technical requirements. (a) The registrant shall ensure that a radiation protection survey is performed for each new facility, and for each existing facility for which a survey has not been performed as of _____, 2014 [*the department will insert the effective date of this section*]. Each survey must be performed using an operable radiation measurement survey instrument calibrated in accordance with 7 AAC 18.665. The survey must be performed by, or under the direction of, a qualified medical physicist or a qualified expert. The individual performing the survey shall verify, with the therapeutic radiation machine in a "beam-on" condition, with the largest clinically available treatment field, and with a scattering phantom in the useful beam of radiation, that

(1) radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in 7 AAC 18.210; and

(2) radiation levels in unrestricted areas do not exceed the limits specified in 7 AAC 18.240.

(b) I n addition to the requirements of (a) of this section, the registrant shall ensure that a radiation protection survey is performed before any subsequent medical use

(1) after making any change in the treatment room shielding;

(2) after making any change in the location of the therapeutic radiation machine within the treatment room;

(3) after relocating the therapeutic radiation machine to another treatment room; or

(4) before using the therapeutic radiation machine in a manner that could result in increased radiation levels in an area outside the external beam radiation therapy treatment room.

(c) The survey record must

(1) identify each instance that the facility, in the opinion of the qualified medical physicist or qualified expert, is in violation of an applicable regulation; and

(2) include

(A) the date of the measurements;

(B) the reason the survey is required;

(C) the manufacturer's name;

(D) the model number and the serial number of the therapeutic radiation machine;

(E) each instrument used to measure radiation levels;

(F) a floor plan of each area surrounding the treatment room that was surveyed;

(G) the measured dose rate at several points in each area, expressed in microsieverts or millirems per hour;

(H) the calculated maximum level of radiation over a period of one week for each restricted and each unrestricted area; and

(I) the signature of the individual responsible for conducting the survey.

(d) If the result of a survey required by (a) or (b) of this section indicates a radiation level in excess of the respective limit specified in (a)(1) or (a)(2), the registrant shall lock the control in the "off" position and prohibit use of the unit

(1) except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

(2) until the registrant has received a specific exemption from the department.

(e) If a survey required by this section indicates that an individual in an unrestricted area may be exposed to a level of radiation greater than permitted by 7 AAC 18.240, before beginning the treatment program the registrant shall

(1) equip the unit with beam direction interlocks or add additional radiation shielding to ensure compliance with7 AAC 18.240; the registrant shall ensure that another survey as required by this section is performed, and that the report required by (j) of this section includes the results of the initial survey, a description of the modification made to comply with this paragraph, and the results of the second survey; or

(2) request and receive a registration amendment under 7 AAC 18.240(b) that authorizes radiation levels in unrestricted areas greater than those permitted by 7 AAC 18.240.

(f) The registrant must have available for use a calibrated dosimetry system that has been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL) within the previous 24 months, and after any servicing that may have affected system calibration. For beams with energies greater than 1 MV (1 MeV), the dosimetry system must be calibrated for Cobalt-60. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system must be calibrated at an energy (energy range) appropriate for the radiation being measured.

(g) The registrant shall ensure that an independent survey of the calibrated dosimetry system is conducted by a qualified medical physicist or qualified expert other than the person who performed the original survey before the equipment is used, except as described in (d) of this section.

(h) The registrant must have available for use a dosimetry system for quality assurance check measurements. To meet this requirement, the system may be compared with a system that has been calibrated in accordance with (f) of this section. This comparison must have been performed within the previous 12 months and after each servicing that may have affected system calibration. The quality assurance check system may be the same system used to meet the requirements of (f) and (g) of this section.

(i) The registrant shall maintain a record of each dosimetry system calibration, intercomparison, and comparison for the duration of the registration under this chapter. For each calibration, intercomparison, or comparison, the record must include

(1) the date;

(2) the model number and the serial number of each instrument calibrated, intercompared, or compared as required by this section;

(3) each correction factor that is determined;

(4) the name of each individual who performed the calibration, intercomparison, or comparison; and

(5) evidence that each calibration, intercomparison, and comparison was performed by, or under the direct supervision and in the physical presence of, a qualified medical physicist or qualified expert.

(j) The registrant for any therapeutic radiation machine subject to 7 AAC 18.650 or 7 AAC 18.655 – 7 AAC 18.660 shall report each survey and measurements to the department by furnishing a copy of the records required under (a) – (d) of this section to the department within 30 days after completion of the action that initiated the record requirement. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.645. Quality management program. (a) The registrant shall ensure that each individual associated with the operation of a therapeutic radiation machine

(1) is instructed in and complies with the provisions of the quality management program developed under this section;

(2) complies with the applicable requirements of 7 AAC 18.600 – 7 AAC 18.690; and

(3) complies with the other applicable requirements of this chapter, including 7 AAC 18.210, 7 AAC 18.220, 7 AAC 18.280, and 7 AAC 18.340.

(b) Each registrant or applicant who is subject to 7 AAC 18.650, 7 AAC 18.655 – 7 AAC 18.660, or 7 AAC 18.680 shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the authorized user. The quality management program must, as a minimum, meet the following standards:

(1) written directives that meet the following requirements:

(A) each written directive must be dated and signed by an authorized user before administration of radiation; if, because of the patient's condition, a delay in the order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable if the oral revision is documented in writing in the patient's record as soon as possible and a revised written directive is signed by an authorized user within 48 hours of the oral revision;

(B) each written directive must contain the patient's, or human research subject's, name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions;

(C) a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the therapeutic radiation machine dose, or the next fractional dose;

(D) a copy of each written directive is retained by the registrant for at least three years;

(2) written procedures for administrations developed, implemented, and maintained by the registrant to provide high confidence that those procedures meet the following requirements:

(A) before the administration of each course of radiation treatments, the patient's, or human research subject's, identity is verified by more than one method as the individual named in the written directive;

(B) each administration is in accordance with the written directive;

(C) therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by

(i) checking both manual and computer-generated dose calculations to verify they are correct and in accordance with the written directive; and

(ii) verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

(D) any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken; and

(E) a copy of the procedures for administrations is retained by the registrant for the at least the duration of the registration under this chapter;

(3) the registrant shall report, as required in (5), (6), and (7) of this subsection, any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician;

(4) except for an event that results from the intervention by a patient or human research subject, the registrant shall report, as required in (5), (6), and (7) of this subsection, any event in which

(A) the administration of a therapeutic radiation machine therapy dose involves the wrong patient, wrong treatment modality, or wrong treatment site;

(B) the calculated weekly administered dose differs from the weekly prescribed dose by more than 30 percent; or

(C) the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose;

(5) the registrant shall notify the department by telephone no later than the next calendar day after the discovery of a misadministration described in (3) and (4) of this subsection;

(6) the registrant shall submit a written report to the department within 15 days after the discovery of a misadministration described in (3) and (4) of this subsection; the written report may not contain the individual's name, or any other information that could lead to the identification of the individual, but must include

(A) the registrant's name;
(B) the name of the prescribing physician;
(C) a brief description of the event;
(D) an explanation of why the event occurred;
(E) the effect, if any, on each individual who received the administration;
(F) any action taken, or planned, to prevent recurrence; and
(G) certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

(7) the registrant shall provide notification of a misadministration described in (3) and (4) of this subsection to the referring physician, and shall also notify the individual who is the subject of the misadministration, no later than 24 hours after discovering the misadministration, unless the referring physician personally informs the registrant that the physician will inform the individual or that, based on medical judgment, telling the individual would be harmful; the registrant is not required to notify the individual without first consulting the referring physician; if the referring physician or the affected individual cannot be reached within 24 hours, the registrant shall notify the individual as soon as possible thereafter; the registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification; to meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian; if a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event may be obtained from the registrant upon request; the registrant shall provide such a written description if requested;

(c) Aside from the notification requirements under (b) of this section, nothing in this section affects any right or duty of a registrant or physician in relation to each other, to individuals affected by a misadministration described in (b)(3) or (b)(4), or to that individual's responsible relatives or guardians.

(d) The registrant shall maintain a record of any misadministration and provide a copy of the record to the referring physician, if other than the registrant, within 15 days after discovery of the misadministration. A registrant shall retain a record of each misadministration for at least three years. The record must contain

(1) the registrant's name;

(2) the name of each individual involved;

(3) the social security number or other identification number, if one has been assigned, of each individual who is the subject of the misadministration;

(4) a brief description of the event, including an explanation of why it occurred and the effect, if any, on the individual;

(5) any action taken, or planned, to prevent recurrence; and

(6) information indicating whether the registrant notified the individual or the individual's responsible relative or guardian and, if not, whether such failure to notify was based on guidance from the referring physician. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.650. Therapeutic radiation machines of less than 500 kV. (a) Except for an electronic brachytherapy device subject to the requirements of 7 AAC 18.680, the requirements of this section apply to therapeutic radiation machines of less than 500 kV. The registrant shall ensure compliance with the requirements of this section.

(b) When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate may not exceed the value specified at the distance specified for that classification of therapeutic radiation machine in accordance with the following:

(1) for a 5-50 kV system, the leakage air kerma rate measured at any position five centimeters from the tube housing assembly may not exceed 1 mGy (100 mrad) in any one hour;

(2) for a system that is more than 50 kV and less than 500 kV, the leakage air kerma rate measured at a distance of one meter from the target in any direction may not exceed one cGy (one rad) in any one hour; this air kerma rate measurement may be averaged over areas no larger than 100 square centimeters; in addition, the air kerma rate at a distance of five centimeters from the surface of the tube housing assembly may not exceed 30 cGy (30 rad) per hour;

(3) for each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in (1) and (2) of this subsection for the specified operating conditions;

(4) the registrant shall maintain records on leakage radiation at the installation for inspection by the department.

(c) For a permanent beam limiting device, permanent diaphragms or cones used for limiting the useful beam must provide at least the same degree of attenuation as required for the tube housing assembly.

(d) For an adjustable or removable beam limiting device, diaphragms, cones, or blocks may not transmit more than five percent of the useful beam for the most penetrating beam used. If an adjustable beam limiting device is used, the position and shape of the radiation field must be indicated by a light beam.

(e) The filter system must be so designed that

(1) filters cannot be accidentally displaced at any possible tube orientation;

(2) for equipment installed after _____, 2014 [*the department will insert the effective date of this section*], an interlock system prevents irradiation if the proper filter is not in place;

(3) the air kerma rate escaping from the filter slot does not exceed one cGy (one rad) per hour at one meter under any operating conditions; and

(4) each filter is marked as to its material of construction and its thickness.

(f) For tube immobilization,

(1) the x-ray tube must be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

(2) the tube housing assembly must be capable of being immobilized for stationary portal treatments.

(g) For source marking, the tube housing assembly must be so marked that it is possible to determine the location of the source to within five millimeters. The marking must be readily accessible for use during calibration procedures.

(h) To meet beam blocking requirements, the contact therapy tube housing assembly must have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

(i) Timers are subject to the following requirements:

(1) a suitable irradiation control device must be provided to terminate the irradiation after a pre-set time interval;

(2) a timer with a display must be provided at the treatment control panel; the timer must have a pre-set time selector and an elapsed time or time remaining indicator;

(3) the timer must be a cumulative timer that activates with an indication of "beam-on" 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;

(4) the timer must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

(5) the timer must permit accurate pre-setting and determination of exposure times as short as one second;

(6) the timer may not permit an exposure if set at zero;

(7) the timer may not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

(8) the timer must be accurate to within one percent of the selected value or one second, whichever is greater.

(j) The control panel, in addition to the displays required by this section, must have

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

(2) an indication of whether x-rays are being produced;

(3) a means for indicating x-ray tube potential and current;

(4) a means for terminating an exposure at any time;

(5) a locking device that prevents unauthorized use of the therapeutic radiation machine; and

(6) for a therapeutic radiation machine manufactured after _____, 2014 [*the department will insert the effective date of this section*], a positive display of each specific filter in the beam.

(k) If a control panel may energize more than one x-ray tube,

(1) it must be possible to activate only one x-ray tube at any time

(2) there must be an indication at the control panel identifying which x-ray tube is activated; and

(3) there must be an indication at the tube housing assembly when that tube is energized.

(*l*) There must be a means of determining the central axis Target-to-Skin Distance (TSD) to within one centimeter and of reproducing this measurement to within two millimeters thereafter.

(m) Unless it is possible to bring the x-ray output to the prescribed exposure parameters within five seconds after the x-ray "on" switch is energized, the beam must be attenuated by a shutter with a lead equivalency of not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter must be controlled by the operator from the control panel. An indication of shutter position must appear at the control panel.

(n) Each therapeutic radiation machine equipped with a beryllium or other low-filtration window must be clearly labeled as such upon the tube housing assembly and must be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

(o) In addition to shielding that is adequate to meet the requirements of 7 AAC 18.670, a treatment room for a machine subject to this section must meet the following design requirements:

(1) provision must be made to permit

(A) continuous two-way aural communication between the patient and the operator at the control panel; and

(B) continuous observation of the patient during irradiation; the viewing system must be so located that the operator can observe the patient from the control panel; the therapeutic radiation machine may not be used for patient irradiation unless at least one viewing system is operational;

(2) a treatment room that contains a therapeutic radiation machine capable of operating above 150 kV must meet the following additional requirements:

(A) protective barriers must be fixed except for entrance doors or beam interceptors;

(B) the control panel must be located outside the treatment room or in a totally enclosed booth, with a ceiling, inside the room;

(C) interlocks must be provided so that entrance doors, including doors to any interior booth, are 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; and

(D) when any door referred to in (C) of this paragraph is opened while the x-ray tube is activated, the air kerma rate at a distance of one meter from the source must be reduced to less than one mGy (100 mrad) per hour.

(p) Full calibration measurements of a therapeutic radiation machine subject to this section must meet the following requirements:

(1) full calibration must be performed by, or under the direct supervision of, a qualified medical physicist or qualified expert

(A) before the first medical use following installation or reinstallation of the machine;

(B) at intervals not exceeding one year; and

(C) subject to (2) of this subsection, before medical use under the following conditions:

(i) if quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; and

(ii) after any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

(2) notwithstanding the requirements of (1)(C) of this subsection,

(A) full calibration of a therapeutic radiation machine with multi-energy capabilities is required only for those modes or energies that are not within their acceptable range; and

(B) if the repair, replacement, or modification does not affect all energies, full calibration must be performed on the affected energy that is in most frequent clinical use at the facility and the remaining energies may be validated with quality assurance check procedures against the criteria in (1)(C)(i) of this subsection;

(3) full calibration must include all measurements recommended for annual calibration by NCRP Report 69, *Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV* (1981), the provisions of which are adopted by reference;

(4) the registrant shall maintain a record of each calibration for the duration of the registration that includes

(A) the date of the calibration;

(B) the manufacturer's name, model number, and serial number for the therapeutic radiation machine;

(C) the manufacturer's name, model number, and serial number for the x-ray tube;

(D) the model number and the serial number of each instrument used to calibrate the therapeutic radiation machine; and

(E) the signature of the qualified medical physicist or qualified expert responsible for performing the calibration.

(q) The registrant shall ensure that periodic quality assurance checks are performed on each therapeutic radiation machines subject to this section. Each quality assurance check must meet the following requirements:

(1) the registrant shall perform each quality assurance check in accordance with written procedures established by the qualified medical physicist; these procedures must specify

(A) the frequency at which tests or measurements are to be performed;

(B) that the quality assurance check must be performed during the calibration specified in (p) of this section; and

(C) the acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in (p) of this section;

(2) if any parameter exceeds a tolerance set by the qualified medical physicist, the registrant shall investigate and correct the cause before the system is used for patient irradiation;

(3) if a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the quality assurance check procedures, the system must be recalibrated as required in (p) of this section;

(4) the registrant shall use the dosimetry system described in 7 AAC 18.640(h) to make the quality assurance check required under this subsection;

(5) the registrant shall ensure that the qualified medical physicist reviews and signs the results of each radiation output quality assurance check within 30 days after the check was performed;

(6) the registrant shall ensure that safety quality assurance checks of each therapeutic radiation machine subject to this section are performed at intervals not to exceed 30 days; each safety quality assurance check must ensure proper operation of

(A) electrical interlocks at each external beam radiation therapy room entrance;

(B) each "beam-on" and termination switch;

(C) beam condition indicator lights on each access door, control console, and in the radiation therapy room;

(D) viewing systems; and

(E) each electrically-operated treatment room door, from inside and outside the treatment room, if applicable;

(7) the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to humans unless the quality assurance checks required by this subsection have been performed within 30 days immediately before any administration;

(8) the registrant shall maintain a record of each quality assurance check required under this subsection for at least three years, and shall ensure that the record includes

(A) the date of each quality assurance check;

(B) the manufacturer's name, and the model number and serial number of each therapeutic radiation machine;

(C) the manufacturer's name and the model number and serial number for each instrument used to measure the radiation output of the therapeutic radiation machine; and

(D) the signature of the individual who performed the periodic quality assurance check.

(r) The registrant shall ensure that the following operating procedures are followed:

(1) a therapeutic radiation machine may not be used for irradiation of patients unless the requirements of (p) and (q) of this section have been met;

(2) a therapeutic radiation machine may not be left unattended unless it is secured in accordance with (j)(5) of this section;

(3) if a patient must be held in position for radiation therapy, mechanical supporting or restraining devices must be used;

(4) the tube housing assembly may not be held by an individual during operation unless

(A) the assembly is designed to require such holding;

(B) the peak tube potential of the system does not exceed 50 kV; and

(C) the holder wears protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV;

(5) a copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console;

(6) no individual other than the patient may be in the treatment room during an exposure from a therapeutic radiation machine operating above 150 kV;

(7) at energies less than or equal to 150 kV, any individual, other than the patient, in the treatment room must be protected by a barrier sufficient to meet the requirements of 7 AAC 18.210.

(s) The registrant shall ensure that each facility location authorized to use a therapeutic radiation machine possesses appropriately calibrated portable monitoring equipment. At a minimum, this equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 .Sv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. Each survey instrument must be operable and calibrated in accordance with7 AAC 18.665. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

Editor's Note: The NCRP Report No 69, *Dosimetry of X-Ray and Gamma Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV* (1981), adopted by reference in 7 AAC 18.650(p)(3), may be viewed at the department's office at 5455 Dr. Martin Luther King Jr. Avenue, Anchorage, Alaska, and is available from NCRP Publications, 7910 Woodmont Avenue, Suite 400, Bethesda, MD 20814-3095 or at the following Internet site: www.ncrponline.org.

7 AAC 18.655. Therapeutic radiation machines: photon therapy systems (500 kV and above) and electron therapy systems (500 keV and above). (a) The registrant of a facility location authorized to use a photon therapy system (500 kV and above) or an electron therapy system (500 keV and above) shall ensure that the facility possesses appropriately calibrated portable monitoring equipment. At a minimum, this equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. Each survey instrument must be operable and calibrated in accordance with 7 AAC 18.665.

(b) The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two meters that is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (patient plane) may not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters at a minimum of 16 points uniformly distributed in the plane.

(c) Except for the area described in (b) of this section, the absorbed dose due to leakage radiation (excluding neutrons) at one meter from the electron path between the electron source and the target or electron window may not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements must be averaged over an area not exceeding 100 square centimeters.

(d) For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in (b) – (c) of this section for the specified operating conditions. The registrant shall maintain at the installation records on leakage radiation measurements for inspection by the department.

(e) For photon radiation, each adjustable or interchangeable beam limiting device must attenuate the useful beam so that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device does not exceed two percent of the maximum absorbed dose on the central axis of the useful beam measured in a 100 square centimeters radiation field, or maximum available field size if less than 100 square centimeters.

(f) For electron radiation, each adjustable or interchangeable electron applicator must attenuate the radiation, including photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, so that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance does not exceed

(1) a maximum of two percent and an average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance; this limit applies beyond a line seven centimeters outside the periphery of the useful beam; and

(2) a maximum of 10 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance; this limit applies beyond a line two centimeters outside the periphery of the useful beam.

(g) For photon radiation, measurements of leakage radiation through the beam limiting devices must be made with the beam limiting devices closed and any residual aperture blocked by at least two tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set must be measured independently at the depth of maximum dose. Measurements must be made using a radiation detector of area not exceeding ten square centimeters.

(h) For electron radiation, measurements of leakage radiation through the electron applicators must be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one square centimeter suitably protected against radiation that has been scattered from material beyond the radiation detector. Measurements must be made using one centimeter of water equivalent build up material.

(i) Each wedge filter that is removable from the system must be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle must appear on the wedge, or on the wedge tray if permanently mounted to the tray. If the wedge or wedge tray is significantly damaged, the wedge transmission factor must be re-determined;

(j) If the absorbed dose rate information required by (q) of this section relates exclusively to operation with a field flattening filter or beam scattering foil in place, that foil or filter must be removable only by the use of tools.

(k) For equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*], that utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

(1) irradiation is not possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, manually or automatically;

(2) an interlock system must be provided to prevent irradiation if the filter selected is not in the correct position;

(3) a display must be provided at the treatment control panel showing each wedge filter, interchangeable field flattening filter, or interchangeable beam scattering foil in use; and

(4) an interlock must be provided to prevent irradiation if any filter and/or beam scattering foil selection operation carried out in the treatment room does not agree with the filter or beam scattering foil selection operation carried out at the treatment control panel.

(*l*) Each therapeutic radiation machine subject to this section must be provided with a redundant beam monitoring system. The sensors for each system must be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

(m) Equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*], must be provided with at least

(1) two independently powered integrating dose meters; alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element; and

(2) one radiation detector incorporated into a useful beam monitoring system;

(n) The detector and the system into which that detector is incorporated must meet the following requirements:

(1) each detector must be removable only with tools and, if movable, must be interlocked to prevent incorrect positioning;

(2) each detector must form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

(3) each beam monitoring system must be capable of independently monitoring, interrupting, and terminating irradiation; and

(4) f or equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*], the design of the beam monitoring systems must ensure that the

(A) malfunctioning of one system does not affect the correct functioning of another system; and

(B) failure of either system terminates irradiation or prevents the initiation of radiation;

(5) each beam monitoring system must have a legible display at the treatment control panel; for equipment manufactured _____, 2014 [*the department will insert the effective date of this section*], each display must

(A) maintain a reading until intentionally reset;

(B) h ave only one scale and no electrical or mechanical scale multiplying factors;

(C) utilize a design so that increasing dose is displayed by increasing numbers; and

(D) in the event of power failure, the beam monitoring information required in (C) of this paragraph displayed at the control panel at the time of failure must be retrievable in at least one system for a 20-minute period.

(o) A bent-beam linear accelerator with one or more beam flattening filters subject to this section must be provided with one or more auxiliary devices to monitor beam symmetry. Each device must be able to detect field asymmetry greater than 10 percent and must be configured to terminate irradiation if that specification cannot be maintained.

(p) The registrant shall ensure that irradiation is not possible until a new selection of a number of dose monitor units has been made at the treatment control panel. The pre-selected number of dose monitor units must be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it must be necessary to reset the dosimeter display before subsequent treatment can be initiated. For equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*], after termination of irradiation, it must be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

(q) For equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*], the registrant shall ensure that a system is provided from which readings the air kerma rate or absorbed dose rate at a reference point can be calculated. The radiation detectors specified in (*l*) – (n) of this section may form part of this system. In addition:

(1) the dose monitor unit rate must be displayed at the treatment control panel;

(2) if the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device must be provided that terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum; the dose rate at which the irradiation will be terminated must be a record maintained by the registrant;

(3) if the equipment can deliver under any fault conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than 10 times the maximum value specified by the manufacturer, a device must be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

(4) for each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, each maximum value specified in (2) and (3) of this subsection for the specified operating conditions; the registrant shall maintain at the installation records of these maximum values for inspection by the department.

(r) Each primary system must terminate irradiation when the pre-selected number of dose monitor units has been detected by the system. If the original design of the equipment included a secondary dose monitoring system, that system must be capable of terminating irradiation when not more than 15 percent 40 dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system. For equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*], an indicator on the control panel must show which monitoring system has terminated irradiation.

(s) The registrant shall ensure that it is possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

(t) If a therapeutic radiation machine has an interrupt mode, it must be possible to interrupt irradiation and equipment movements at any time from the treatment control panel. After 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 pre-selected value during an interruption, irradiation and equipment movements must be automatically terminated.

(u) The registrant shall provide a suitable irradiation control device to terminate the irradiation after a pre-set time interval. A timer must be provided that has a display at the treatment control panel. The timer must have a pre-set time selector and an elapsed time indicator. The timer must be a cumulative timer that activates with an indication of "beam-on" 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. The timer must terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

(v) The registrant shall ensure that

(1) equipment capable of both x-ray therapy and electron therapy meets the following additional requirements:

(A) irradiation is not possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

(B) the radiation type selected is displayed at the treatment control panel before and during irradiation;

(C) an interlock system is provided to ensure that the equipment can principally emit only the radiation type that has been selected;

(D) an interlock system is provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

(E) an interlock system is provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

(F) an interlock system is 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; and

(2) equipment capable of generating radiation beams of different energies meets the following requirements:

(A) irradiation is not possible until a selection of energy has been made at the treatment control panel;

(B) the nominal energy value selected is displayed at the treatment control panel until reset manually for the next irradiation; after termination of irradiation, it must be necessary to reset the nominal energy value selected before subsequent treatment can be initiated; and

(C) irradiation is not possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location;

(3) therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy meet the following requirements:

(A) irradiation is not possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

(B) the mode of operation is displayed at the treatment control panel;

(C) an interlock system is provided to ensure that the equipment can operate only in the mode that has been selected;

(D) an interlock system is provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

(E) moving beam radiation therapy is controlled to obtain the selected relationships between incremental dose monitor units and incremental movement;

(F) for equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*], the registrant shall ensure that

(i) an interlock system is provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of rotation or one centimeter of linear motion differs by more than 20 percent from the selected value;

(ii) where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered differ by less than five percent from the dose monitor unit value selected;

(iii) an interlock is provided to prevent motion of more than five degrees or one centimeter beyond the selected limits during moving beam radiation therapy;

(iv) an interlock is provided to require that a selection of direction be made at the treatment control panel in all units capable of both clockwise and counter-clockwise moving beam radiation therapy;

(v) moving beam radiation therapy are controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;

(vi) where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation must be as required by (t) of this section; and

(vii) an interlock system is provided to terminate irradiation if movement occurs during stationary beam radiation therapy or if the beam arm does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.656. Facility design requirements for therapeutic radiation machines operating above 500 kV. In addition to shielding that is adequate to meet requirements of 7 AAC 18.670, the registrant shall ensure that the following design requirements are met for a therapeutic radiation machine operating above 500 kV:

(1) protective barriers must be fixed, except for access doors to the treatment room or movable beam interceptors;

(2) in addition to other applicable requirements specified in 7 AAC 18.600 – 7 AAC 18.690, the control panel must

(A) be located outside the treatment room;

(B) provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

(C) provide an indication of whether radiation is being produced; and

(D) include an access control locking device that will prevent unauthorized use of the therapeutic radiation machine;

(3) windows, mirrors, closed-circuit television or an equivalent viewing system permit continuous observation of the patient after positioning and during irradiation and are located so that the operator may observe the patient from the treatment control panel; the therapeutic radiation machine may not be used for patient irradiation unless at least one viewing system is operational;

(4) a continuous two-way aural communication is provided between the patient and the operator at the control panel; the therapeutic radiation machine may not be used for irradiation of patients unless continuous two-way aural communication is possible;

(5) each treatment room entrance is provided with warning lights in a readily observable position near the outside of all access doors, that indicate when the useful beam is "on" and when it is "off";

(6) entrance interlocks are provided so that all access controls are activated before treatment can be initiated or continued; if the radiation beam is interrupted by any access control, it must not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

(7) if the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with 7 AAC 18.240, interlocks must be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at each designated barrier;

(8) at least one emergency power cutoff switch is located in the radiation therapy room that will terminate all equipment electrical power including radiation and mechanical motion; this switch is in addition to the termination switch required by 7 AAC 18.655(s) all emergency power cutoff switches must include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

(9) safety interlocks are designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

(10) surveys for residual activity are conducted on all therapeutic radiation machines capable of generating photon and electron energies above 10 MV prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.657. Qualified medical physicist support for therapeutic radiation machines with energies of 500 kV and above. Subject to 7 AAC 18.658(7), the registrant shall ensure that the services of a qualified medical physicist are provided in a facility with one or more therapeutic radiation machines with energies of 500 kV and above, and that the qualified medical physicist is responsible for

(1) full calibration as required by 7 AAC 18.659 and protection surveys as required by 7 AAC 18.640(a)-(d);

(2) supervision and review of dosimetry;

(3) beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

(4) quality assurance, including quality assurance check reviews as required by 7 AAC 18.660;

(5) consultation with the authorized user in treatment planning, as needed; and

(6) performing calculations and assessments regarding a misadministration described in 7 AAC 18.645(b)(3) and (4). (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.658. Operating procedures for therapeutic radiation machines with energies of 500 kV and above. The registrant for a facility with one or more therapeutic radiation machines with energies of 500 kV and above shall develop and enforce written operating procedures that ensure the following:

(1) no individual, other than the patient, may be in the treatment room during treatment or during any irradiation for testing or calibration purposes;

(2) a therapeutic radiation machine may not be made available for medical use unless the requirements of 7 AAC 18.640(a)-(d), 7 AAC 18.659, and 7 AAC 18.660 have been met;

(3) a therapeutic radiation machine, when not in operation, must be secured to prevent unauthorized use;

(4) when adjustable beam limiting devices are used, the position and shape of the radiation field must be indicated by a light field;

(5) if a patient must be held in position during treatment, a mechanical supporting or restraining device must be used;

(6) a copy of the current operating and emergency procedures must be maintained at the therapeutic radiation machine control console; and

(7) if the qualified medical physicist required under 7 AAC 18.657 is not a full-time employee of the registrant, the operating procedures must also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be contacted. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.659. Acceptance testing, commissioning and full calibration measurements for therapeutic radiation machines with energies of 500 kV and above. (a) The registrant shall ensure that acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to 7 AAC 18.600 – 7 AAC 18.690 is performed by, or under the direct supervision of, a qualified medical physicist.

(b) Acceptance testing and commissioning must be performed in accordance with *AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47*, prepared by Radiation Therapy Task Group 45, adopted by reference, and the manufacturer's contractual specifications. Acceptance testing and commissioning must be conducted before the first medical use after installation or reinstallation of the therapeutic radiation machine.

(c) Full calibration must include measurement of all applicable parameters required by Table II of *Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46*, prepared by Committee Task Group 40, adopted by reference, and must be performed in accordance with *AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47*, adopted by reference in (b) of this section. Although it is not necessary to complete all elements of a full calibration at the same time, all applicable parameters, for all energies, must be completed at intervals not exceeding 12 calendar months, unless a more frequent interval is required in Table II.

(d) The qualified medical physicist shall perform all elements of a full calibration necessary to determine that all parameters are within acceptable limits

(1) if quality assurance check measurements indicate that the radiation output differs by more than five percent from the value obtained at the last full calibration and the difference cannot be reconciled; a therapeutic radiation machine with multi-energy or multi-mode capabilities only requires measurements for those modes and energies that are not within their acceptable range; and

(2) after any component replacement, major repair, or modification of a component that could significantly affect the characteristics of the radiation beam; if the repair, replacement, or modification does not affect all modes or energies, measurements must be performed on the effected mode or energy that is in most frequent clinical use at the facility; the remaining energies and modes may be validated with quality assurance check procedures against the criteria in (d)(1) of this section.

(e) The registrant shall maintain a record of each calibration in an auditable form for the duration of the registration. The record must include

(1) the date of the calibration;

(2) the manufacturer's name, model number and serial number for the therapeutic radiation machine;

(3) the model number and serial number of each instrument used to calibrate the therapeutic radiation machine; and

(4) the signature of the qualified medical physicist responsible for performing the calibration. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

Editor's note: A copy of *AAPM Code of Practice for Radiotherapy Accelerators :AAPM Report No. 47*, prepared by Radiation Therapy Task Group 45, and *Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy: AAPM Report No. 46*, prepared by Committee Task Group 40, adopted by reference in 7 AAC 18.659, are available for review at the department's office at 5455 Dr. Martin Luther King Jr. Avenue, Anchorage, Alaska, and may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740, Phone 301-209-3350, Fax 301-209-0862, or online at http://www.aapm.org/pubs/reports/

7 AAC 18.660. Periodic quality assurance checks for therapeutic radiation machines with energies of 500 kV and above. (a) The registrant shall ensure that periodic quality assurance checks are performed on therapeutic radiation machines subject to 7 AAC 18.600 – 7 AAC 18.690 at intervals not to exceed those specified in *Comprehensive QA for Radiation Oncology: AAPM Report No. 46*, adopted by reference in 7 AAC 18.659(c). Each quality assurance checks must include determination of central axis radiation output and a representative sampling of periodic quality assurance checks contained in *Comprehensive QA for Radiation Oncology: AAPM Report No. 46*. Representative sampling must include all applicable referenced periodic quality assurance checks in an interval not to exceed 12 consecutive calendar months.

(b) The registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described in 7 AAC 18.640(f) to make the periodic quality assurance checks required by this section and shall ensure that each check is performed in accordance with procedures established by the qualified medical physicist.

(c) The registrant shall review the results of each periodic radiation output check according to the following procedures:

(1) the authorized user and the qualified medical physicist must be immediately notified if any parameter is not within its acceptable tolerance; the registrant shall ensure that the therapeutic radiation machine is not made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within acceptable tolerances;

(2) if all quality assurance check parameters appear to be within acceptable range, the quality assurance check must be reviewed and signed by either the authorized user or qualified medical physicist within three treatment days; and

(3) the qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days.

(d) The registrant shall ensure that each therapeutic radiation machine has applicable safety quality assurance checks listed in *Comprehensive QA for Radiation Oncology: AAPM Report No. 46*, adopted by reference in 7 AAC 18.659(c), performed at intervals not to exceed one week. Each safety quality assurance check must ensure proper operation of

(1) electrical interlocks at each external beam radiation therapy room entrance;

(2) the "beam-on", interrupt, and termination switches;

(3) beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

(4) viewing systems;

(5) each electrically operated treatment room door from inside and outside the treatment room;

(6) at least one emergency power cutoff switch; if more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch must be tested on a rotating basis; safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

(e) The registrant shall promptly repair any system identified during a safety quality assurance check under (d) of this section that is not operating properly.

(f) The registrant shall maintain a record of each quality assurance check required by this section for at least three years. For each check, the record must include

(1) the date of the quality assurance check;

(2) the manufacturer's name, model number, and serial number of each therapeutic radiation machine;

(3) the manufacturer's name, model number, and serial number for each instrument used to measure the radiation output of the therapeutic radiation machine; and

(4) the signature of the individual who performed the periodic quality assurance check.

(g) A quality assurance checks for intensity modulated radiation therapy (IMRT) must

(1) include commissioning and testing of the treatment planning and delivery systems, routine quality assurance of the delivery system, and patient-specific validation of treatment plans;

(2) be performed in accordance with *Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82*, adopted by reference;

(3) be performed in accordance with the manufacturer's contractual specifications; and

(4) incorporate knowledge gained as new issues arise that could degrade machine performance. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

Editor's note: A copy of *Guidance document on delivery, treatment planning, and clinical implementation of IMRT: Report of the IMRT subcommittee of the AAPM radiation therapy committee: AAPM Report No. 82*,, adopted by reference in 7 AAC 18.660, are available for review at the department's office at 5455 Dr. Martin Luther King Jr. Avenue, Anchorage, Alaska, and may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740, Phone 301-209-3350, Fax 301-209-0862, or online at http://www.aapm.org/pubs/reports/

7 AAC 18.665. Calibration of survey instruments. (a) The registrant shall ensure that survey instruments used to show compliance with 7 AAC 18.600 – 7 AAC 18.690 have been calibrated as required under this section before the first use, at intervals thereafter not to exceed 12 months, and after each repair.

(b) The registrant shall

(1) calibrate required scale readings up to 10 mSv (1000 mrem) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST); and

(2) calibrate at least two points on each scale to be calibrated at approximately one-third and two-thirds of full-scale;

(3) consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than

(A) 10 percent; or

(B) 20 percent if a correction factor or graph is conspicuously attached to the instrument.

(c) The registrant shall maintain a record of each calibration for at least three years. The record must include

(1) a description of the calibration procedure; and
(2) a description of the source used;
(3) the certified dose rates from the source;
(4) the rates indicated by the instrument being calibrated;
(5) the correction factors deduced from the calibration data;
(6) the signature of the individual who performed the calibration; and
(7) the date of calibration.

(d) The registrant may obtain the services of individuals licensed by the U.S. Nuclear Regulatory Commission or an agreement state to perform calibrations of survey instruments required under this section. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

Editor's note: A list of agreement states referred to in 7 AAC 18.665(d) is available from the United States Nuclear Regulatory Commission, Region IV, may be contacted at 612 E. Lamar Boulevard, Suite 400, Arlington, Texas 76011-4125; telephone (817) 860-8100; Website: www.nrc.gov.

7 AAC 18.670. Shielding and safety design requirements. Each therapeutic radiation machine subject to 7 AAC 18.650 or 7 AAC 18.655 – 7 AAC 18.660 must be provided with such primary and/or secondary barriers as are necessary to ensure compliance with 7 AAC 18.210 and 7 AAC 18.240.

(b) Facility design information for each new installation of a therapeutic radiation machine or each installation of a therapeutic radiation machine of higher energy into a room not previously approved for that energy must be submitted for department approval before installation. The minimum facility design information that must be submitted is contained in 7 AAC 18.690. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.675. Quality assurance For radiation therapy simulation systems. Quality assurance for a conventional or virtual simulator must

(1) include acceptance testing and periodic verification of system performance;

(2) be performed in accordance with

(A) *Comprehensive QA for Radiation Oncology: AAPM Report No. 46,* adopted by reference in 7 AAC 18.659(c) for a conventional simulator; or

(B) *Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No. 83,* adopted by reference, for a virtual simulator; and

(3) incorporate knowledge gained as new issues arise that could degrade machine performance. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

Editor's note: A copy of *Quality assurance for computed tomography simulators and the computed tomography-simulation process: Report of the AAPM Radiation Therapy Committee Task Group No. 66: AAPM Report No.* 83, adopted by reference in 7 AAC 18.675, is available for review at the department's office at 5455 Dr. Martin Luther King Jr. Avenue, Anchorage, Alaska, and may be obtained from the American Association of Physicists in Medicine, One Physics Ellipse, College Park, MD 20740, Phone 301-209-3350, Fax 301-209-0862, or online at http://www.aapm.org/pubs/reports/.

7 AAC 18.680. Electronic brachytherapy. (a) The registrant shall ensure that each electronic brachytherapy device meets the requirements of this section. An electronic brachytherapy device that does not meet the requirements of this section may not be used for irradiation of patients.

(b) An electronic brachytherapy device be used only for human use applications specifically approved by the U.S. Food and Drug Administration unless the registrant is participating in a research study approved by the registrant's Institutional Review Board.

(c) Each facility location authorized to use an electronic brachytherapy device in accordance with this section must possess appropriately calibrated portable monitoring equipment. As a minimum, this equipment must include a portable radiation measurement survey instrument capable of measuring dose rates over the range 10 µSv (1 mrem) per hour to 10 mSv (1000 mrem) per hour. Each survey instrument must be operable and calibrated in accordance with 7 AAC 18.665 for the applicable electronic brachytherapy source energy.

(d) In addition to shielding adequate to meet requirements of 7 AAC 18.670, the treatment room must meet the following design requirements:

(1) if applicable, provision must be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room;

(2) access to the treatment room must be controlled by a door at each entrance;

(3) each treatment room must have provisions to permit continuous aural communication and visual observation of the patient from the treatment control panel during irradiation; the electronic brachytherapy device shall not be used for patient irradiation unless the patient can be observed;

(4) for electronic brachytherapy devices capable of operating below 50 kV, radiation shielding for the staff in the treatment room must be available, either as a portable shield or as localized shielded material around the treatment site;

(5) for electronic brachytherapy devices capable of operating at greater than 150 kV, the control panel must be located outside the treatment room, and electrical interlocks must be provided for each door to the treatment room that will

(A) prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

(B) cause the source to be shielded when an entrance door is opened; and

(C) prevent the source from being exposed after an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

(e) The high voltage transformer must

(1) be electrically isolated to prevent electrical and magnetic interference with the surrounding environment and ancillary equipment.

(2) be isolated from the operator and other personnel and from the environment by a protective housing that can only be accessed through a cover requiring a tool for access or with electrical interlocks to prevent operation while open;

(3) have appropriate safety labels warning personnel of potential electrical shock or heat related injuries.

(f) The registrant shall ensure that equipment manufactured after _____, 2014 [*the department will insert the effective date of this section*] complies with the most current revision of the following International Electrotechnical Commission (IEC) documents, adopted by reference:

(1) IEC 60601-1:1998+A1+A2:1995;
(2) IEC 60601-1-2:2001;
(3) IEC 60601-2-8:1999; and
(4) IEC 60601-2-17:2004.

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(g) The control panel, in addition to the displays required by other provisions of this section must

(1) provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

(2) provide an indication of whether x-rays are being produced;

(3) provide a means for indicating electronic brachytherapy source potential and current;

(4) provide the means for terminating an exposure at any time; and

(5) include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device.

(h) The registrant must provide a suitable irradiation control device (timer) to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor. The timer

(1) must be provided at the treatment control panel;

(2) must indicate planed setting and the time elapsed or remaining;

(3) may not permit an exposure if set at zero;

(4) must be a cumulative device that activates with an indication of "BEAM ON" 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;

(5) must terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation;

(6) must permit setting of exposure times as short as 0.1 second; and

(7) must be accurate to within one percent of the selected value or 0.1 second, whichever is greater.

(i) The services of a qualified medical physicist are required in a facility with one or more electronic brachytherapy devices. The qualified medical physicist is responsible for

(1) evaluation of the output from the electronic brachytherapy source;

(2) generation of the necessary dosimetric information;

(3) supervision and review of treatment calculations prior to initial treatment of any treatment site;

(4) establishing the periodic and day-of-use quality assurance checks and reviewing the data from those checks as required in (n) of this section;

(5) consultation with the authorized user in treatment planning, as needed; and

(6) performing calculations or assessments regarding patient treatments that may constitute a misadministration described in 7 AAC 18.645(b)(3) and (4).

(j) If the qualified medical physicist required under (i) of this section is not a full-time employee of the registrant, the operating procedures required by (k) of this section must also specifically address how the qualified medical physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the qualified medical physicist can be
contacted.

(k) The registrant shall ensure that the following operating procedures are followed:

(1) only individuals approved by the authorized user, radiation safety officer, or qualified medical physicist may be present in the treatment room during treatment;

(2) electronic brachytherapy devices may not be made available for medical use unless the requirements of 7 AAC 18.640(a)-(d), (*l*) of this section, and (m) of this section are met;

(3) the electronic brachytherapy device must be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

(4) during operation, the electronic brachytherapy device operator must monitor the position of all persons in the treatment room, and all persons entering the treatment room, to prevent unshielded exposure from the treatment beam;

(5) if a patient must be held in position during treatment, mechanical supporting or restraining devices must be used;

(6) written procedures must be developed, implemented, and maintained for responding to an abnormal situation; these procedures must include

(A) instructions for responding to equipment failures;

(B) the name of each individual responsible for implementing corrective actions; and

(C) the name and telephone number of each authorized user, the qualified medical physicist, and the radiation safety officer to be contacted if the device or console operates abnormally;

(7) a copy of the current operating and emergency procedures must be physically located at the electronic brachytherapy device control console; if the control console is integral to the electronic brachytherapy device, these procedures must be kept where the operator is located during electronic brachytherapy device operation;

(8) instructions must be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the authorized users, the qualified medical physicist, and the radiation safety officer to be contacted if the device or console operates abnormally; and

(9) the radiation safety officer, or designee, and an authorized user must be notified as soon as possible if the patient has a medical emergency, suffers injury or dies ; the radiation safety officer or the qualified medical physicist shall inform the manufacturer of the event.

(*l*) The registrant shall ensure that the following safety precautions are followed:

(1) a qualified medical physicist shall determine which persons in the treatment room require monitoring when the beam is energized;

(2) an authorized user and a qualified medical physicist must be physically present during the initiation of a patient treatment involving the electronic brachytherapy device;

(3) a qualified medical physicist must be physically present during continuation of a patient treatment involving the electronic brachytherapy device, and must be accompanied by

(A) an authorized user;

(B) a physician who

(i) is under the supervision of an authorized user; and

(ii) has been trained in the operation and emergency response for the electronic brachytherapy device; or

(C) an electronic brachytherapy device operator who

(i) is under the supervision of an authorized user; and

(ii) has been trained in the operation and emergency response for the electronic brachytherapy device;

(4) when shielding is required by (d)(4) of this section, the electronic brachytherapy device operator shall use a survey meter to verify proper placement of the shielding immediately upon initiation of treatment; alternatively, a qualified medical physicist shall designate shield locations sufficient to meet the requirements of 7 AAC 18.210 for any individual, other than the patient, in the treatment room; and

(5) personnel in the treatment room must remain behind shielding during treatment; a qualified medical physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

(m) The registrant shall ensure that the following electronic brachytherapy source calibration measurement requirements are met:

(1) calibration of the electronic brachytherapy source output for an electronic brachytherapy device subject this section

(A) must be performed by, or under the direct supervision of, a qualified medical physicist;

(B) must be made for each electronic brachytherapy source, or after any repair affecting the x-ray beam generation, or when indicated by the electronic brachytherapy source quality assurance checks;

(C) must utilize a dosimetry system described in 7 AAC 18.640(f)-(j);

(D) must include, as applicable, determination of

(i) the output within two percent of the expected value, if applicable, or determination of the output if there is no expected value;

(ii) timer accuracy and linearity over the typical range of use;

(iii) proper operation of backup exposure control devices;

(iv) evaluation that the relative dose distribution about the source is within five percent of that expected; and

(v) source positioning accuracy to within one (1) millimeter within the applicator;

(E) must be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available); in the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol must be followed;

(2) the registrant shall maintain a record of each calibration in an auditable form for the duration of the registration; the record must include

(A) the date of the calibration;

(B) the manufacturer's name, model number and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source;

(C) the model number and serial number of each instrument used to calibrate the electronic brachytherapy device; and

(D) the name and signature of the qualified medical physicist responsible for performing the calibration.

(n) The registrant shall ensure that the following requirements periodic and day-of-use quality assurance checks for electronic brachytherapy devices are met:

(1) quality assurance checks must be performed on each electronic brachytherapy device subject to this section

(A) at the beginning of each day of use;

(B) each time the device is moved to a new room or site; for purposes of this subparagraph, "site" includes each day of use at each operating location for a self-contained electronic brachytherapy unit transported in a van or trailer; and

(C) after each x-ray tube installation;

(2) the registrant shall perform periodic quality assurance checks required by this subsection in accordance with procedures established by the qualified medical physicist;

(3) radiation output quality assurance checks must include as a minimum:

(A) verification that output of the electronic brachytherapy source falls within three percent of expected values, as appropriate for the device, as determined by

(i) output as a function of time, or

(ii) output as a function of setting on a monitor chamber;

(B) verification of the consistency of the dose distribution to within three percent of that found during calibration required by (m) of this section; and

(C) validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within one mm;

(4) the registrant shall use a dosimetry system that has been intercompared within the previous 12 months with the dosimetry system described 7 AAC 18.640(f) to make the quality assurance checks required in (3) of this subsection;

(5) the registrant shall review the results of each radiation output quality assurance check according to the following procedures:

(A) an authorized user and a qualified medical physicist must be immediately notified if any parameter is not within its acceptable tolerance; the electronic brachytherapy device may not be made available for subsequent medical use until the qualified medical physicist has determined that all parameters are within their acceptable tolerances;

(B) if all radiation output quality assurance check parameters appear to be within their acceptable range, the quality assurance check must be reviewed and signed by either the authorized user or qualified medical physicist within two days; and

(C) the qualified medical physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed 30 days;

(6) safety device quality assurance checks must, at a minimum, assure

(A) proper operation of radiation exposure indicator lights on the electronic brachytherapy device and on the control console;

(B) proper operation of viewing and intercom systems in each electronic brachytherapy facility, if applicable;

(C) proper operation of radiation monitors, if applicable;

(D) the integrity of all cables, catheters or parts of the device that carry high voltages; and

(E) connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation;

(7) if the results of the safety device quality assurance checks required in (6) of this subsection indicate the malfunction of any system, the registrant shall secure the control console in the "off" position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system;

((8) the registrant shall maintain a record of each quality assurance check required by this subsection in an auditable form for at least three years; the record must include

(A) the date of the quality assurance check;

(B) the manufacturer's name, model number, and serial number for the electronic brachytherapy device;

(C) the name and signature of the individual who performed the periodic quality assurance check;

(D) the name and signature of the qualified medical physicist who reviewed the quality assurance check;

(E) for radiation output quality assurance checks required by this subsection, the record must also include

(i) the unique identifier for the electronic brachytherapy source; and

(ii) the manufacturer's name; model number and serial number for each instrument used to measure the radiation output of the electronic brachytherapy device.

(o) For each therapy-related computer system, the registrant shall perform acceptance testing on the treatment planning system of each electronic brachytherapy-related computer system in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol must be followed. Acceptance testing must be performed by, or under the direct supervision of, a qualified medical physicist. At a minimum, the acceptance testing must include, as applicable, verification of

(1) the source-specific input parameters required by the dose calculation algorithm;

(2) the accuracy of dose, dwell time, and treatment time calculations at representative points;

(3) the accuracy of isodose plots and graphic displays;

(4) the accuracy of the software used to determine radiation source positions from radiographic images; and

(5) if the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

(p) For each therapy-related computer system, the position indicators in the applicator must be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning. Before each patient treatment regimen, the parameters for the treatment must be evaluated and approved by the authorized user and the qualified medical physicist for correctness through means independent of that used for the determination of the parameters.

(q) The registrant shall provide instruction, initially and at least annually, to each individual who operates the electronic brachytherapy device, as appropriate to the individual's assigned duties, in the operating procedures identified in (k) of this section. If the interval between patients exceeds one year, retraining of the individuals must be provided. In addition to the requirements 7 AAC 18.610 for therapeutic radiation machine authorized users and 7 AAC 18.615 for qualified medical physicists, the registrant shall ensure that these individuals also receive device specific instruction initially from the manufacturer, and annually from either the manufacturer or other qualified trainer. The training must be of a duration recommended by a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of any training protocol recommended by a national professional association, the manufacturer's training protocol must be followed. Training required under this subsection must include, at a minimum

(1) device-specific radiation safety requirements;

(2) device operation;
(3) clinical use for the types of use approved by the FDA;
(4) emergency procedures, including an emergency drill; and
(5) the registrant's quality assurance program.

(r) The registrant shall retain a record of individuals receiving instruction required by (q) of this section for at least three years. The record must include a list of the topics covered, the date of the instruction, the name of each attendee, and the name of each individual who provided the instruction.

(s) A registrant providing mobile electronic brachytherapy service shall, at a minimum,

(1) check each survey instrument before medical use at each address of use or on each day of use, whichever is more restrictive;

(2) account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address;

(3) perform, at each location on each day of use, each required quality assurance check specified in (n) of this section to assure proper operation of the device. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

Editor's note: A copy of IEC 60601-1:1998+A1+A2:1995, IEC 60601-1-2:2001, IEC 60601-2-8:1999, and IEC 60601-2-17:2004, adopted by reference in 7 AAC 18.680, are available for review at the department's office at 5455 Dr. Martin Luther King Jr. Avenue, Anchorage, Alaska, and may be obtained from IEC Central Office, 3, rue de Varembé , P.O. Box 131, CH - 1211 Geneva 20 - Switzerland, Phone : +41 22 919 02 11, Fax : +41 22 919 03 00, http://www.iec.ch/.

7 AAC 18.685. Other use of electronically-produced radiation to deliver therapeutic radiation dosage. (a) A person may not use any device that is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and that is not appropriately regulated under any existing category of therapeutic radiation machine, until

(1) the applicant or registrant has, at a minimum, provided the department with

(A) a detailed description of the device and each intended application;

(B) facility design requirements, including shielding and access control;

(C) documentation of appropriate training for each authorized user and each qualified medical physicist;

(D) methodology for measurement of dosages to be administered to patients or human research subjects;

(E) documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

(F) radiation safety precautions and instructions; and

(G) other information requested by the department in its review of the application;

(2) the applicant or registrant has received written approval from the department to use the device in accordance with the applicable requirements of this chapter and any specific conditions the department considers necessary for the medical use of the device. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18.690. Information on radiation shielding required for plan reviews. The registrant shall ensure that the requirements of this section are met, as applicable:

(1) f or all therapeutic radiation machines:

(A) provide basic facility information including

(i) the name, telephone number, and department registration number of the individual responsible for preparation of the shielding plan;

(ii) the name and telephone number of the facility supervisor; and

(iii) the street address, including the room number, of the therapeutic radiation machine facility; an indication of whether this is a new structure or a modification to an existing structure;

(B) ensure that all wall, floor, and ceiling areas struck by the useful beam have primary barriers;

(C) ensure that secondary barriers are provided in all wall, floor, and ceiling areas not having primary barriers;

(2) for therapeutic radiation machines up to 150 Kv (photons only), in addition to the requirements of (1) of this section, the registrant for a therapeutic radiation machine facility that produces only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans that contain, as a minimum, the following additional information:

(A) equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

(B) maximum design workload for the facility including

(i) total weekly radiation output, expressed in gray (rad) or air kerma at 1 meter;

(ii) total beam-on time per day or week;

(iii) the average treatment time per patient; and

(iv) the anticipated number of patients to be treated per day or week;

(C) facility blueprints or drawings indicating

(i) scale [preferably 0.25 inch = 1 foot];

(ii) direction of North;

(iii) normal location of each radiation port for each therapeutic radiation machine;

(iv) the radiation port's travel and traverse limits;

(v) each general direction of the useful beam;

(vi) locations of any windows and doors; and

(vii) the location of the therapeutic radiation machine control panel; if the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth must be noted on the plan and the operator's station at the control panel must be behind a protective barrier sufficient to ensure compliance with 7 AAC 18.210;

(D) the structural composition and thickness or lead/concrete equivalent of all walls, doors, partitions, floor, and ceiling of each room concerned;

(E) the type of occupancy of all adjacent areas inclusive of space above and below each room concerned; if there is an exterior wall, show distance to each closest area where it is likely that individuals may be present; and

(F) at least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition such as primary and secondary barriers, leakage barriers, restricted and unrestricted areas, and entry doors, and that shows shielding material in the facility; if commercial software is used to generate shielding requirements, identify the software used and the version and revision date of that software; if the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with the software that was used;

(3) for therapeutic radiation machines over 150 kV, in addition to the requirements of (1) of this section, the registrant for a therapeutic radiation machine facility that produces photons with a maximum energy in excess of 150 kV and/or electrons shall submit shielding plans that contain, at a minimum, the following additional information:

(A) equipment specifications, including

(i) the manufacturer and model number of the therapeutic radiation machine;

(ii) gray (rad) at the isocenter;

(iii) the energy and type of radiation produced; and

(iv) the target to isocenter distance;

(B) maximum design workload for the facility, including

(i) total weekly radiation output, expressed in gray (rad) at one meter;

(ii) total beam-on time per day or week;

(iii) the average treatment time per patient; and

(iv) the anticipated number of patients to be treated per day or week;

(C) facility blueprints or drawings, including both floor plan and elevation views, indicating

(i) relative orientation of the therapeutic radiation machine;

(ii) scale [preferably 0.25 inch = 1 foot];

(iii) each type, thickness, and minimum density of shielding material;

(iv) direction of North;

(v) the location and size of each penetration through each shielding barrier (ceiling, walls, and floor); and

(vi) details regarding each door and maze;

(D) the structural composition and thickness or concrete equivalent of the walls, doors, partitions, floor, and ceiling of each room concerned;

(E) the type of occupancy of all adjacent areas inclusive of space above and below each room concerned; if there is an exterior wall, show distance to each closest area where it is likely that individuals may be present;

(F) a description of all assumptions that were in shielding calculations including

(i) design energy; for example, the room may be designed for 6 MV unit although only a 4 MV unit is currently proposed;

(ii) workload;

(iii) presence of integral beam-stop in unit;

(iv) occupancy and uses of adjacent areas;

(v) fraction of time that useful beam will intercept each permanent barrier [walls, floor and ceiling]; and

(vi) "allowed" radiation exposure in restricted and in unrestricted areas; and

(G) at least one example calculation that shows the methodology used to determine the amount of shielding required for each physical condition [for example, primary and secondary leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors, and maze] and shielding material in the facility; if commercial software is used to generate shielding requirements, identify the software used and the version and revision date of that software; if the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with that software;

(4) in addition to the requirements of (3) of this section, the registrant of a therapeutic radiation machine facilities that are capable of operating above 10 MV shall submit shielding plans that contain, at a minimum, the following additional information:

(A) the structural composition, thickness, minimum density and location of all neutron shielding material;

(B) a description of all assumptions that were used in neutron shielding calculations including neutron spectra as a function of energy, neutron fluence rate, absorbed dose and dose equivalent (due to neutrons) in restricted and in unrestricted areas;

(C) at least one example calculation that shows the methodology used to determine the amount of neutron shielding required for each physical condition [for example, restricted and unrestricted areas, entry doors, and maze] and neutron shielding material used in the facility; if commercial software is used to generate shielding requirements, identify the software used and the version and revision date of the software; if the software used to generate shielding requirements is not in the open literature, submit quality control sample calculations to verify the result obtained with that software;

(D) each method and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility. (Eff. ____/____/2014, Register _____)

Authority: AS 18.60.475 AS 18.60.485

7 AAC 18 is amended by adding new sections to read:

Article 7. Ultraviolet Radiation (Indoor Tanning).

Section

7 AAC 18.700. Applicability and scope of 7 AAC 18.700 - 7 AAC 18.745 . (a) The provisions of 7 AAC 18.700 - 7 AAC 18.745 apply to a person who owns a facility in this state that uses ultraviolet lamps or other equipment intended for indoor tanning. In addition to other applicable requirements, that person shall ensure that the tanning facility is

(1) registered under 7 AAC 18.715;

(2) constructed and operated in compliance with 7 AAC 18.725; and

(3) operated only by individuals who meet the training requirements of 7 AAC 18.730.

(b) A tanning facility may not operate if it fails to meet an applicable requirement. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.705. Exemptions. (a) Nothing in 7 AAC 18.700 – 7 AAC 18.745 limits the intentional exposure of a patient to ultraviolet radiation for treatment by a licensed practitioner of the healing arts.

(b) The following are exempt from the provisions of 7 AAC 18.700 - 7 AAC 18.745:

(1) equipment that is intended for purposes other than the deliberate exposure of any part of the living human body to ultraviolet radiation, and that produces or emits ultraviolet radiation incidental to the equipment's proper operation;

(2) a radiation machine while in transit or in storage related to transit; and

(3) an individual who owns a tanning device that is exclusively for personal use; for purposes of this paragraph, "personal use" means operating a single tanning unit for the purpose of cosmetic tanning and not for any business purpose; multiple tanning units may not be considered personal use.

(c) The department may grant an additional exemption or an exception from an applicable requirement of this chapter if it determines that the exemption or exception is authorized by law and that public health and safety are protected. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.710. Application for registration. (a) A person who owns a tanning facility subject to 7 AAC 18.700 – 7 AAC 18.745 shall apply to the department for registration of the facility

(1) no later than _____, 2014 [*the department will insert a date that is six months after the effective date of this section*], if the facility began operation before _____, 2014 [*the department will insert the effective date of this section*];

(2) before operating a facility intended to begin operation on or after _____, 2014 [*the department will insert the effective date of this section*].

(b) An application required under this section must be submitted on a form approved and supplied by the department and must include

(1) the owner's name, mailing address, electronic mail address, telephone number, and facsimile number;

(2) the location, electronic mail address, telephone number, and facsimile number of the tanning facility; if the facility is a mobile facility, this information must clearly identify each geographic area within the state where the facility will be operated;

(3) the manufacturer, model number, and type of each ultraviolet lamp or other tanning equipment located within the facility;

(4) the name, mailing address, telephone number, and electronic mail address of the tanning equipment

(A) supplier;
(B) installer; and
(C) service agent;

(5) a signed and dated certification stating that the applicant has read and understands the applicable requirements of this chapter;

(6) a copy of operating and safety procedures unique to the facility's operation;

(7) for each person who will operate tanning equipment, a copy of the training certificate required under 7 AAC 18.730, showing satisfactory completion of formal operator training; and

(8) each applicable fee required by 7 AAC 18.030(c);

(9) any additional information requested by the department. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.715. Certificate of registration; renewal of certification. (a) No person may operate a tanning facility unless the department has issued a certificate of registration under this section. A person who fails to comply with an applicable requirement is subject to the penalty provisions of AS 18.60.535.

(b) The department will issue a certificate of registration if the department determines that the information submitted under 7 AAC 18.710 is satisfactory. The department may incorporate in the certificate of registration at issuance, or at any time after issuance, any additional requirement or condition that the department determines is appropriate or necessary to protect public health or safety.

(c) The registrant shall display the certificate in a conspicuous location on the premises of the facility so that the certificate is visible to persons entering the facility.

(d) Except as provided in (e) of this section, a certificate of registration is valid through December 31 of the year in which it was issued. At least 30 days before the certificate expires, the registrant shall apply for renewal of registration, using a form approved and supplied by the department, and providing the information required by 7 AAC 18.710.

(e) If a registrant submits a timely application for renewal under (d) of this section, the registrant's certificate of registration will not expire until the department determines whether that certificate should be renewed.

(f) A certificate of registration

(1) may not be transferred from one person to another or from one tanning facility to another; and

(2) is subject to the advertising restrictions set out in 7 AAC 18.722. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.485 AS 18.60.535
AS 18.60.475

7 AAC 18. 717. Denial, suspension, or revocation of certificate of registration. (a) The department may, for good cause shown, deny, suspend, or revoke a certificate of registration sought or issued under 7 AAC 18.700 – 7 AAC 18.745 for any of the following reasons:

(1) failure to have reports, plans, or specifications showing that the tanning facility complies with the applicable requirements of 7 AAC 18.700 – 7 AAC 18.745;

(2) submission of incorrect, false, or misleading information;

(3) failure to construct, operate, or maintain the facility in accordance with the application, plans and specifications approved by the department, or as otherwise required by applicable law; this paragraph does not apply to the replacement of lamps referred to in 7 AAC 18.720;

(4) operation of the facility in a way that causes or creates a nuisance or hazard to the public health or safety;

(5) violation of any applicable requirement of 7 AAC 18.700 – 7 AAC 18.745;

(6) violation of any condition included in the certificate of registration;

(7) failure to allow the department or its designee to conduct an inspection during the facility's hours of operation and in a proper protocol;

(8) failure to pay an applicable fee under 7 AAC 18.030(c).

(b) If a certificate of registration is denied, suspended, or revoked under this section, the applicant or registrant may request a review under 7 AAC 18.950 or an evidentiary hearing under 7 AAC 18.955. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.720. Report of change. A registrant shall notify the department in writing before making any change related to information provided in an application for registration or renewal that deal with matters set out in 7 AAC 18.710(b)(1)-(3) or 7 AAC 18.710(b)(6). The requirements of this section do not apply to replacement of designated original equipment lamp types with lamps certified by the United States Food and Drug Administration as equivalent replacement of the lamps. The facility owner shall maintain the manufacturer's literature that demonstrates the equivalency of any replacement lamps. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.722. Advertising restrictions. No registrant may, in any written, verbal, electronic, or other advertisement,

(1) refer to the fact that the tanning facility is registered with the department;

(2) state or imply that any activity conducted at the facility has been approved by the department; or

(3) state or imply that

(A) tanning has any health benefit; or

(B) the tanning device is free of hazards from ultraviolet radiation. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.725. Construction and operation of a tanning facility. (a) In addition to other applicable requirements, and unless otherwise required or approved by the department, a tanning facility must be constructed, operated, and maintained to, at a minimum, meet the requirements of this section.

(b) The registrant shall ensure that the warning sign required by this subsection is in the immediate proximity, and within three feet, of each piece of tanning equipment. The sign must be clearly visible, readily legible, and may not be obstructed in any way, so that the client can easily view the warning sign before the tanning equipment is energized. The lettering on each sign must be at least one-half inch high for all words shown in capital letters and at least one-quarter inch high for all lower case letters. The wording of the warning sign must be as shown in the following example:

DANGER – ULTRAVIOLET RADIATION

Follow instructions. Avoid over-exposure. As with natural sunlight, over-exposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer.

WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES.

Abnormal skin sensitivity or burning may be caused by certain foods, cosmetics. or medications, including, but not limited to, tranquilizers, diuretics, antibiotics, high blood pressure medicines, and birth control pills.

Consult physician before using sunlamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from the use of this product.

Any person with a family or medical history of skin cancer should avoid an ultraviolet tanning device.

If you believe that you have been injured by this tanning equipment, you should contact the Alaska Department of Health and Social Services, 5455 Dr. Martin Luther King Jr. Ave, Anchorage, Alaska 99507. (907) 334-2100.

(c) The registrant shall post next to each warning sign required under (b) of this section a list of photosensitizing agents. For purposes of this subsection, "photosensitizing agents" includes anything that can increase sensitivity to ultraviolet light, including medications, allergies, diseases, creams, lotions, and cosmetics, the use of which may cause skin cancer, premature aging, skin and eye burns, cataracts, allergic reactions, reduced immunity, or blood vessel damage when used in conjunction with an ultraviolet light emitter.

(d) The registrant shall ensure that

(1) only tanning equipment manufactured and certified to comply with the 21 C.F.R. 1040.20, are used in the tanning facility, based on the standard in effect at the time of manufacture as shown on the device identification label required by 21 C.F.R. 1010.3;

(2) tanning equipment has a timer that complies with 21 C.F.R. 1040.20(c)(2), with a maximum timer interval that does not exceed the manufacturer's maximum recommended exposure time and no interval with an error greater than 10 percent of the maximum timer interval for the product;

(3) the timer will not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle when emission from the tanning device has been interrupted;

(4) each tanning device is equipped with an on/off switch and an emergency shut-off mechanism that are readily accessible to the client to allow manual termination of the UV exposure in accordance with 21 C.F.R. 1040.20(c)(3);

(5) each tanning device has the labels required by 21 C.F.R. 1040.20(d)(1)(i-vi);

(6) tanning equipment must be provided with ground fault protection on the electrical circuit.

(7) there are physical barriers to protect clients from injury induced by touching or breaking the lamps;

(8) for each stand-up tanning booth,

(A) there is a physical barrier or other means, such as a handrail or floor markings, to indicate the proper exposure distance between ultraviolet lamps and the client's skin;

(B) the construction of the booth will withstand the stress of use and the impact of a falling person;

(C) access to the booth is of rigid construction, with outward-opening doors, and with handrails and nonslip floors;

(9) protective eyewear

(A) is provided to each client, with written instructions for proper use; in addition, the tanning facility operator shall instruct the client in the proper use of the protective eyewear;

(B) meets the requirements of 21 C.F.R. 1040.20 (c)(4); and

(C) is properly sanitized before each use with a sanitizing agent in accordance with the manufacturer's instructions; for purposes of this subparagraph, exposure to the ultraviolet radiation produced by the tanning equipment itself is not a sanitizing agent.

(e) The registrant shall ensure that

(1) only persons who have successfully completed training required under 7 AAC 18.730 are allowed to operate tanning equipment;

(2) tanning equipment is operated only when a trained tanning operator is present at the tanning facility to supervise or assist with operation of the equipment.

(f) The registrant shall ensure that each assembly of tanning equipment is designed for use by only one client at a time.

(g) Defective or nonlighting filters or lamps, or filters or lamps at the end of their useful UV emitting life must be replaced with a type intended for use in that device as specified on the product label on the tanning equipment, or, with lamps or filters that are registered with the United States Food and Drug Administration as compatible to the original lamp and according to the regulations and policies at the time of lamp manufacture. Expired lamps must be disposed of in accordance with state and federal regulations for disposal of the type of lamp used, including regulations of the U.S. Environmental Protection Agency. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

Editor's note: A list of medications that are known photosensitizing agents is set out in *Medications That Increase Sensitivity to Light: A 1990 Listing*, prepared by Jerome I. Levine, M.S., R.Ph., December 1990, may be obtained from the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Avenue, Silver Spring, MD 20993-0002; telephone: (888) 463-6332. It is also available at http://www.fda.gov/downloads/RadiationEmittingProducts/RadiationEmittingProductsandProcedures/SurgicalandTherapeutic/UCM135813.pdf.

7 AAC 18.730. Operator training. (a) The registrant shall ensure that each tanning equipment operator is adequately trained before operating tanning equipment, through satisfactory completion of a formal operator training course pre-approved by the department. Proof of training must be maintained at the facility and be available for inspection by the department or its designee. For a tanning facility that was operating on or before _____, 2014 [*the department will insert the effective date of this section*], each operator employed by the facility on or before that date must complete the required training no later than _____, 2014 [*the department will insert a date that is 60 days after the effective date of this section*].

(b) Formal operator training under this section must consist of a course of instruction conducted or presented under formal classroom conditions, through a correspondence program, or through a computer-based program. The training must be presented by a person possessing adequate knowledge and experience to offer the curriculum, associated training, and certification testing pertaining to and associated with the safe use of tanning equipment. To be approved by the department, a training course must include, at a minimum,

(1) the applicable requirements of this 7 AAC 18.700 – 7 AAC 18.745;

(2) procedures for correct operation of the facility;

(3) recognition of injury or overexposure;

(4) manufacturers' procedures for operation and maintenance of tanning equipment;

(5) emergency procedures in case of overexposure or injury;

(6) procedures for correct cleaning, sanitizing, and operation of a tanning device;

(7) proper care and use of protective eyewear;

(8) the biological effects of ultraviolet radiation, maximum allowable time of exposure, photosensitivity, and the determination of human skin type as it relates to compliant use of the Food and Drug Administration's recommended exposure schedule set out in *Quality Control Guide for Sunlamp Products*, HHS Publication FDA 88-8234, March 1988;

(9) a review and explanation of lamp compatibility for tanning equipment;

(10) and explanation of the requirements of applicable federal and state requirements, including at a minimum, requirements of the Food and Drug Administration, Federal Trade Commission, the United States Environmental Protection Agency, the national electrical code, and applicable state regulations;

(11) the preparation and maintenance of a client record form;

(12) training aids, including at a minimum

(A) written material related to the required subjects, such as a training manual;

(B) audio-visual presentations related to the required subjects, such as slides or videos;

(C) copies of the applicable requirements of this chapter;

(D) copies of 21 C.F.R. 1040.20; and

(E) a question and answer period for trainees; and

(13) a review of known photosensitizing agents.

(b) Each operator must

(1) have a valid permit issued by the department under 7 AAC 18.900; and

(2) complete at least four hours of continuing education every 24 months.

(c) The registrant shall maintain a list of operators trained as required under this section, and shall make the list available at the facility for inspection by the department or its designee. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

Editor's note: For a list of training courses approved by the department under 7 AAC 18.730(b), contact the Department of Health and Social Services, Division of Public Health, Radiological Health Program, 5455 Dr. Martin Luther King Jr Avenue, Suite 168, Anchorage, AK 99507-1270; telephone: (907) 334-2100.

Quality Control Guide for Sunlamp Products, HHS Publication FDA 88-8234, March 1988, referred to in 7 AAC 18.730 may be obtained from the United States Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD 20857, or may be downloaded from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM119279.pdf.

7 AAC 18.735. Requirements and restrictions related to clients. (a) The registrant shall ensure that, before initial exposure and on periodic visits after that, the operator provides each client with the opportunity to read a copy of the warning specified in 7 AAC 18.725(b) and the list of photosensitizing agents specified in 7 AAC 18.725(c). The operator shall then request that the client sign a statement that the information has been read and understood. For an illiterate or visually handicapped person, the operator shall read the warning sign and list in the presence of a witness, and the witness and the operator shall sign the statement, attesting that this has been done.

(b) Before a client's initial exposure, the registrant shall ensure that the operator

(1) conducts an assessment of the client's skin type to determine which industry standard related to skin type applies to the client; and

(2) records this information on the client record form required under (e) of this section.

(c) The registrant shall ensure that no client is permitted to use a tanning device more than once every 24 hours.

(d) The registrant shall ensure that no minor is allowed to use tanning device equipment unless the facility has on file a consent that has been signed by the parent or legal guardian and witnessed by an operator, and that states that the parent or legal guardian has read and understands the warnings given by the tanning facility, consents to the minor's use of the tanning device, and agrees that the minor will use federally-compliant protective eyewear. The registrant shall ensure that the parent or legal guardian is provided with the basic information required under 7 AAC 18.725(b) and (c). If the facility has on file a signed and witnessed statement on file for a minor

(1) between the ages of 14 and 18, that minor may use tanning device equipment;

(2) under the age of 14, that minor may use tanning device equipment only if accompanied by the parent or legal guardian who signed the statement required by this subsection.

(e) The registrant shall ensure that a client record form is prepared and maintained for each client, and that the record includes at a minimum,

(1) the client's name, age, address, and an emergency contact number;

(2) the client's tanning history, including a record of the total number of tanning visits and total accumulated exposure times;

(3) medications used, including any that are known to have potential to cause photosensitization;

(4) vitamins and cosmetic substances used, including any that are known to have potential to cause photosensitization;

(5) results of the skin typing assessment required in (g) of this section;

(6) any previous incident of injury from ultraviolet exposure that required intervention by a health care professional;

(7) if the client is under the age of 18, the client record form must also contain the signed permission for the exposure to ultraviolet radiation required under (d) of this section; and

(8) a signed disclaimer stating that the client has been informed and understands that excessive ultraviolet exposure may cause skin cancer, increase the effects of certain skin conditions, and result in damage to the eyes.

(f) The registrant shall verify the accuracy of the information on the client record for before each tanning session, especially to determine if there have been any changes in medications or other potentially sensitizing agents, and in the customer's tanning history.

(g) The client record form must be retained for at least three years from the last date on which tanning services were used at the facility, or until the customer signs a new statement. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.740. Report of injury. (a) The registrant shall submit a written report of any alleged tanning injury to the department within five working days of the occurrence or knowledge of the occurrence. The report must include

(1) the name of affected individual;

(2) the name and location of the tanning facility;

(3) the nature and circumstance of the alleged injury;

(4) the name and address of the health care provider, if any;

(5) a ny other information considered relevant to the situation.

(b) Compliance with the applicable requirements of 7 AAC 18.700 – 7 AAC 18.745 does not relieve the registrant, any operator, or any employee of the facility from liability for an injury sustained by a customer from use of a tanning device. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.745. Definitions related to 7 AAC 18.700 – 7 AAC 18.745. In addition to any applicable definition set out in 7 AAC 18.990, for purposes of 7 AAC 18.700 – 7 AAC 18.745, and unless the context indicates otherwise,

(1) "C.F.R." means the Code of Federal Regulations;

(2) "client" means a member of the public who is provided access to a tanning facility in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning facility as a condition or benefit of membership or access;

(3) "client record form" means a record, in card form or electronic format, that is maintained on file for each client under 7 AAC 18.735(e);

(4) "inspection" means an official examination or observation including tests, surveys, monitoring, and inspection of records to determine compliance with applicable requirements;

(5) "minor" means an individual who is under 18 years of age;

(6) "operator" means an individual who has completed formal operator training and is designated by the registrant to control operation of the tanning facility and to instruct and assist the client in the proper operation of tanning equipment;

(7) "protective eyewear" means an apparatus that is designed to be worn over the eyes by a client of a tanning facility and that absorbs UV-A, UV-B, and visible light up to 500 nanometers while permitting sufficient light to pass through to allow a client to safely negotiate obstacles, in compliance with the standards set out in 21 CFR 1040.20;

(8) "registrant" means a person who owns a tanning facility and has been issued a certificate of registration for that facility by the department under 7 AAC 18.700 – 7 AAC 18.745;

(9) "registration" means a certificate of registration issued by the department under 7 AAC 18.700 – 7 AAC 18.745;

(10) "tanning device" means equipment that emits electromagnetic radiation having a wavelength in air of 200 - 400 nanometers and that is used for tanning human skin with a sun lamp product and any accompanying equipment, including timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows, and handrails; "tanning device" does not include a phototherapy device used by a physician;

(11) "tanning facility" means a location, place, area, structure, or business that provides a client access to tanning equipment;

(12) "ultraviolet radiation" means electromagnetic radiation with a wavelength in air of 200 - 400 nanometers;

(13) "UV-A" means ultraviolet radiation having a wavelength in air of 320 - 400 nanometers; and

(14) "UV-B" means ultraviolet radiation having a wavelength in air of 290 - 319 nanometers. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18 is amended by adding new sections to read:

Article 8. Magnetic Resonance Imaging.

Section

7 AAC 18.800. Applicability and scope of 7 AAC 18.800 - 7 AAC 18.845. The provisions of 7 AAC 18.800 - 7 AAC 18.845 apply to a person who owns a magnetic resonance imaging facility in this state with equipment that is a source of magnetic or radio-frequency radiation. In addition to the other applicable requirements of 7 AAC 18.800 - 7 AAC 18.845, the owner of a magnetic resonance imaging facility shall ensure that the facility is

(1) registered under 7 AAC 18.815;

(2) constructed and operated in compliance with 7 AAC 18.825; and

(3) operated only by individuals who meet the training requirements of 7 AAC 18.830 and have a valid permit issued under 7 AAC 18.900.

(b) A magnetic resonance imaging facility may not operate if it fails to meet applicable requirements of this chapter. A person subject to 7 AAC 18.800 – 7 AAC 18.845 who fails to comply with an applicable requirement is subject to the penalty provisions of AS 18.60.535. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.805. Exemptions. (a) Nothing in 7 AAC 18.800 – 7 AAC 18.845 limits the intentional exposure of a patient to magnetic or radio-frequency radiation for treatment by a licensed practitioner of a healing art.

(b) The following are exempt from the provisions of 7 AAC 18.800 - 7 AAC 18.845:

(1) equipment that is intended for purposes other than the deliberate exposure of any part of the living human body to magnetic radiation, and that produces or emits magnetic radiation incidental to the equipment's proper operation; and

(2) a magnetic resonance imaging device and its component parts while in transit or in storage related to transit.

(c) The department may grant an additional exemption or an exception from an applicable requirement of this chapter if it determines that the exemption or exception is authorized by law and that public health and safety are protected. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.810. Application for registration. (a) A person who owns, or intends to construct, a magnetic resonance imaging facility subject to 7 AAC 18.800 – 7 AAC 18.845 shall apply to the department for registration of the facility

(1) no later than _____, 2014 [*the department will insert a date that is 30 days after the effective date of this section*], if the facility began operation before _____, 2014 [*the department will insert the effective date of this section*];

(2) before constructing a facility intended to begin operation on or after _____, 2014 [*the department will insert the effective date of this section*];

(3) before re-structuring a building to incorporate magnetic resonance imaging.

(b) An application required under this section must be submitted on a form approved and supplied by the department and must include

(1) the owner's name, mailing address, electronic mail address, telephone number, and facsimile number;

(2) the location, electronic mail address, telephone number, and facsimile number of the facility; if the facility is a mobile facility, this information must clearly identify each geographic area within the state where the facility will be operated;

(3) for a new or re-structured, building, the structural plans for the building;

(4) the manufacturer, model number, and type of magnetic resonance equipment located within the facility;

(5) the name, mailing address, telephone number, and electronic mail address of the magnetic resonance imaging equipment

(A) supplier;
(B) installer; and
(C) service agent;

(6) a signed and dated certification stating that the applicant has read and understands the applicable requirements of 7 AAC 18.800 - 7 AAC 18.845;

(7) a copy of operating and safety procedures unique to the facility's operation;

(8) a copy of each certification, license, or registration that demonstrates each operator has met applicable training and credentialing requirements for the proper and safe operation of a magnetic resonance imaging device;

(9) each applicable fee required by 7 AAC 80.030(c); and

(10) any additional information requested by the department. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.815. Certificate of registration; renewal of certification. (a) No person may operate a magnetic resonance imaging facility unless the department has issued a certificate of registration under this section.

(b) The applicant shall notify the department when construction of, or re-structuring for, a magnetic resonance facility is completed. The department will conduct an onsite inspection to assess the structure. The department will review the safety policies, operator credentials, quality control procedures, and other information submitted with the application for registration.

(c) The department will issue a certificate of registration if the department determines that the information submitted under 7 AAC 18.810 is satisfactory. The department may incorporate in the certificate of registration at issuance, or at any time after issuance, any additional requirement or condition that the department determines is appropriate or necessary to protect public health or safety.

(d) The registrant shall display the certificate in a conspicuous location on the premises of the facility so that it is visible to persons entering the facility.

(e) Except as provided in (f) of this section, a certificate of registration is valid through December 31 of the year in which it was issued. At least 30 days before the certificate expires, the registrant shall apply for renewal of registration, using a form approved and supplied by the department, and providing the information required by 7 AAC 18.810.

(f) If a registrant submits a timely application for renewal under (e) of this section, the registrant's certificate of registration will not expire until the department determines whether that certificate should be renewed.

(g) A certificate of registration

(1) may not be transferred from one person to another or from one magnetic resonance imaging facility to another; and

(2) is subject to the advertising restrictions set out in 7 AAC 18.822. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.485 AS 18.60.535
AS 18.60.475

7 AAC 18. 817. Denial, suspension, or revocation of certificate of registration. (a) The department may, for good cause shown, deny, suspend, or revoke a certificate of registration sought or issued under 7 AAC 18.800 – 7 AAC 18.845 for any of the following reasons:

(1) failure to have reports, plans, or specifications showing that the magnetic resonance imaging facility complies with the applicable requirements of 7 AAC 18.800 – 7 AAC 18.845;

(2) submission of incorrect, false, or misleading information;

(3) failure to construct, operate, or maintain the facility in accordance with the application, plans and specifications approved by the department, or as otherwise required by applicable law;

(4) operation of the facility in a way that causes or creates a nuisance or hazard to the public health or safety;

(5) violation of an applicable requirement of 7 AAC 18.800 – 7 AAC 18.845;

(6) violation of a condition included in the certificate of registration;

(7) failure to allow the department or its designee to conduct an inspection during the facility's hours of operation and in a proper protocol;

(8) failure to pay an applicable fee required under 7 AAC 18.030(c).

(b) If a certificate of registration is denied, suspended, or revoked under this section, the applicant or registrant may request a review under 7 AAC 18.950 or an evidentiary hearing under 7 AAC 18.955. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.820. Report of change. A registrant shall notify the department in writing before making any change related to information provided in an application for registration or renewal that deals with matters set out in 7 AAC 18.810(b)(1)-(3) or 7 AAC 18.810(b)(6). (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.822. Advertising restrictions. No registrant may, in any written, verbal, electronic, or other advertisement,

(1) refer to the fact that the facility is registered with the department; or

(2) state or imply that any activity conducted at the facility has been approved by the department. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.825. Construction and operation of a magnetic resonance imaging facility. (a) In addition to other applicable requirements, and unless otherwise required or approved by the department, a magnetic resonance imaging facility must be constructed, operated, and maintained to, at a minimum, meet the requirements of this section.

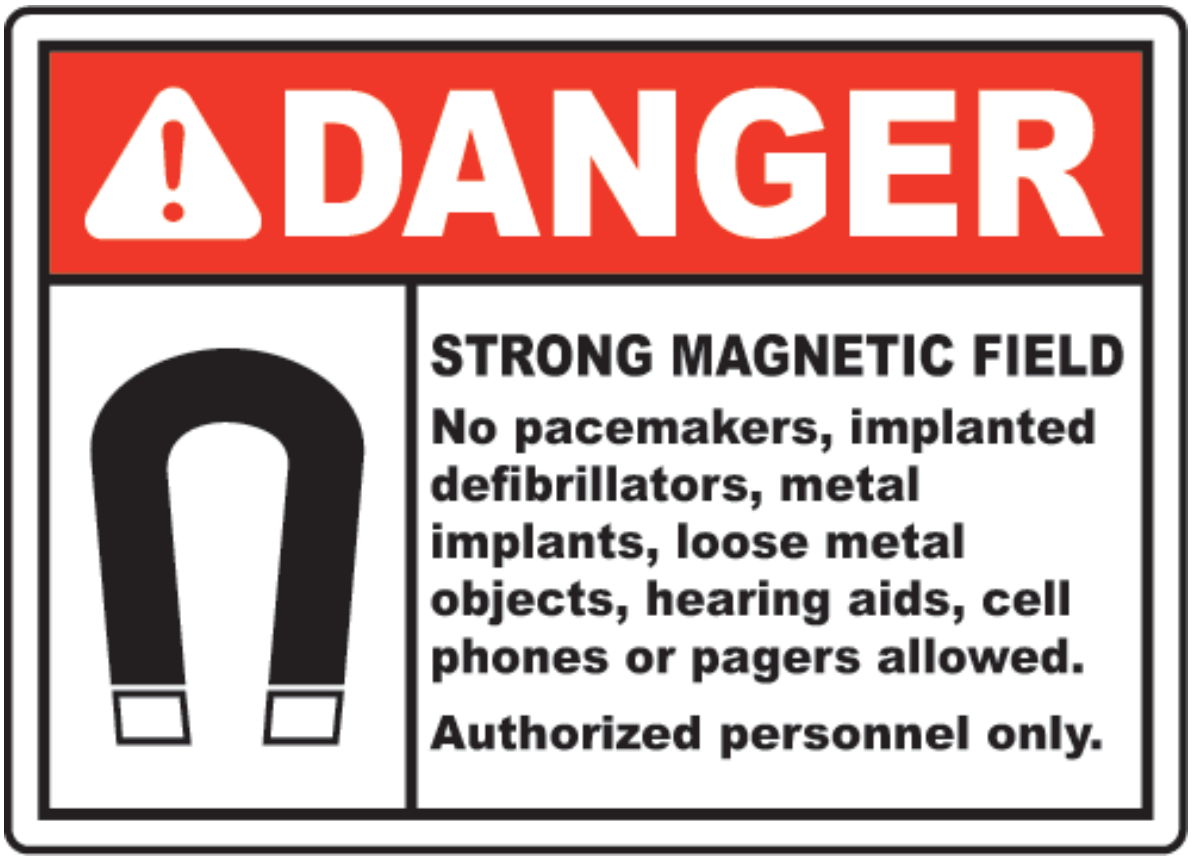
(b) The owner of a magnetic resonance imaging facility shall ensure that only magnetic resonance equipment manufactured to comply with the 21 C.F.R., Subchapter J, as amended through _____, 2014 [*the department will insert the effective date of this section*], and adopted by reference, is used in the magnetic resonance imaging facility.

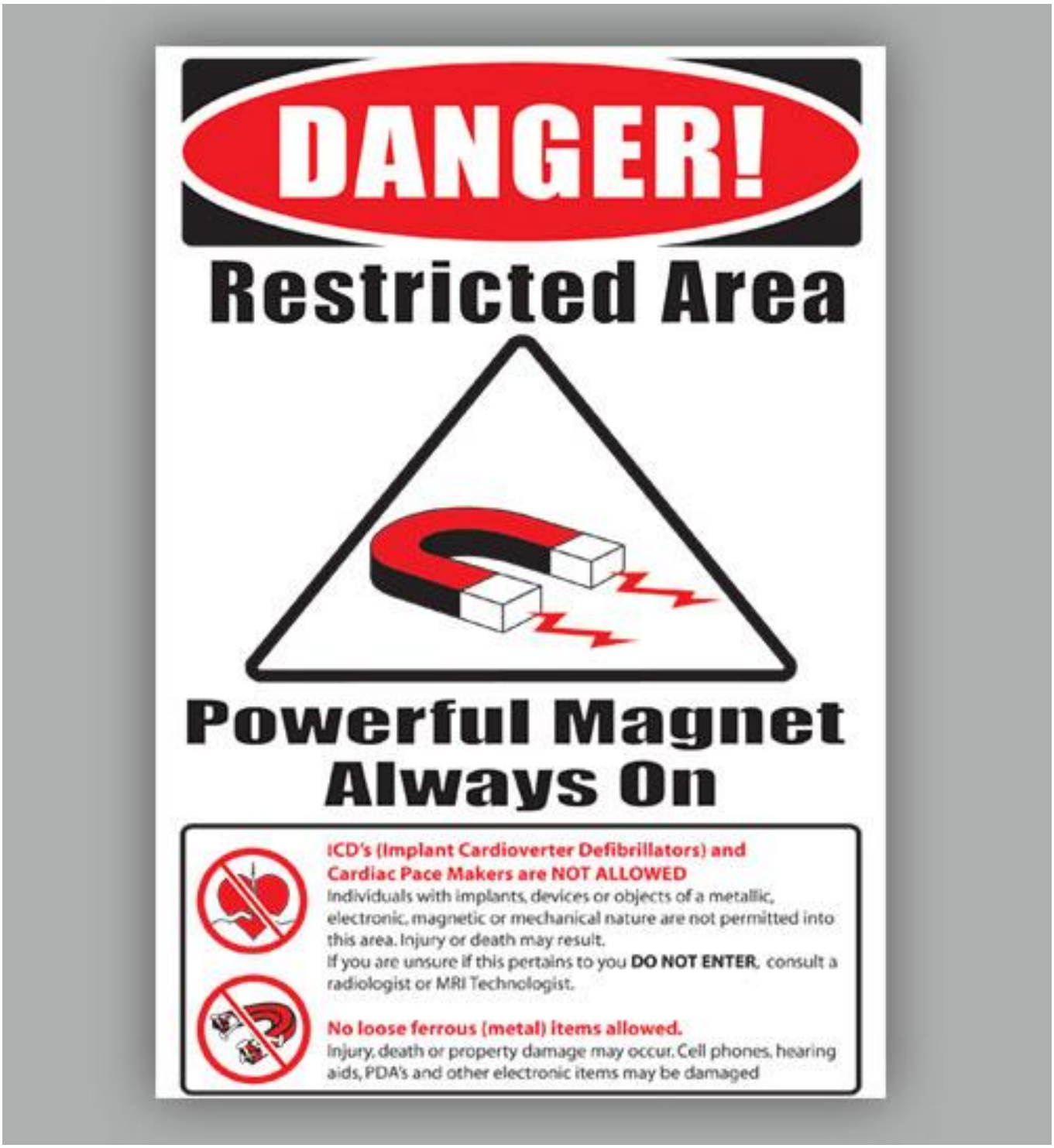
(c) The owner shall ensure that the facility design meets

(1) the standards described in *Site Planning for Magnetic Resonance Imaging Systems*, by the Nuclear Magnetic Resonance Committee Task Group #2, published for the American Association of Physicists in Medicine by the American Institute of Physics (AAPM Report No. 20), dated December 1986, as amended through _____, 2014 [*the department will insert the effective date of this section*], and adopted by reference; or

(2) standard that are at least equivalent to the standards referred to in (1) of this subsection.

(d) One or both of the following warning signs, with the wording shown, must be posted at each entry to an area where magnetic resonance imaging is conducted, and must meet the minimum requirements of (e) of this section:




DANGER!
Restricted Area
Powerful Magnet
Always On
ICD's (Implant Cardioverter Defibrillators) and
Cardiac Pace Makers are NOT ALLOWED
Individuals with implants, devices or objects of a metallic, electronic, magnetic or mechanical nature are not permitted into this area. Injury or death may result.
If you are unsure if this pertains to you DO NOT ENTER, consult a radiologist or MRI Technologist.
No loose ferrous (metal) items allowed.
Injury, death or property damage may occur. Cell phones, hearing aids, PDA's and other electronic items may be damaged

(e) The lettering on each warning sign must be at least two inches high for all words shown in capital letters and at least one inch high for all lower case letters.

(f) The owner shall ensure that there are adequate physical and administrative controls to protect consumers from injury due to inadvertent entry into a restricted area. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

Editor's note: A copy of the report adopted by reference in 7 AAC 18.825 may be found at http://www.aapm.org/pubs/reports/ or may be obtained from Order Department, Medical Physics Publishing, 4513 Vernon Boulevard, Madison WI 53705; telephone: (800) 442-5778 or (608) 262-4021; facsimile: (608) 265-2121.

7 AAC 18.830. Personnel. The registrant shall ensure that each operator has a valid permit issued by the department under 7 AAC 18.900, and that each operator of

(1) a medical magnetic resonance imaging device

(A) is registered or certified by the American Registry of Radiologic Technologists, or holds an unlimited state license as a medical radiologic technologist; and

(B) has completed a at least 40 hours of training in the proper operation of a magnetic resonance imaging device; that training must, at a minimum, include

(i) safety procedures and precautions;
(ii) emergency procedures;
(iii) patient preparation;
(iv) image display and archiving;
(v) quality control procedures;
(vi) applicable state and federal regulations;
(vii) image quality; and
(viii) optimizing imaging protocols; and

(C) maintains currency with continuing education requirements of the certifying body;

(2) a medical or nonmedical (magnetic resonance imaging or nuclear magnetic resonance) device is a scientist or physicist who

(A) holds a science-based college or university degree at the bachelor's level or higher;

(B) is familiar with

(i) magnetic resonance imaging safety for patients, personnel, and the public;

(ii) guidance from the United States Food and Drug Administration for magnetic resonance imaging devices and

(iii) applicable state and federal regulations;

(C) is knowledgeable in the field of magnetic resonance physics, magnetic resonance technology, calibration processes, and limitations of the performance testing hardware, procedures, and algorithms. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.835. Quality assurance and safety; emergency procedures. (a) The registrant shall establish a quality assurance and safety committee to establish, implement, and maintain current magnetic resonance imaging safety policies and procedures, to review and report adverse events or incidents as required by 7 AAC 18.840, and to address any deviation from normal operation of a magnetic resonance imaging device.

(b) The quality assurance and safety committee must include at least one operator, an individual responsible for periodic calibration of the device, a representative from facility management, and a physician who uses the capabilities of the device for clinical diagnostic activities.

(c) The registrant shall ensure that emergency procedures are published to establish

(1) policies to protect patients, staff, and the public from risks of injury due to

(A) electrical, fire, physical, or chemical hazards;
(B) pressure changes;
(C) radiofrequency fields;
(D) magnetic effects;
(E) psychological responses; and
(F) other sources of potential harm; and

(2) procedures that minimize the potential for injury due to the inadvertent entry into the magnet area by emergency responders, including firefighters, security personnel, police officers, a medical response team, or others who may not know about the unique risks associated with a magnetic field or in responding to a quench; for purposes of this paragraph, "quench" means a rapid helium or nitrogen evaporation and the loss of superconductivity of the current-carrying magnet coil that may occur unexpectedly, or from pressing the emergency button in a superconducting magnet. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.840. Notification of event or incident. (a) A registrant shall immediately notify the department by telephone or facsimile, followed by a confirming letter, of an event or incident involving magnetic resonance imaging that requires medical intervention to anyone in the area of a magnetic resonance imaging device, and that involves

(1) missile effect; for purposes of this paragraph, "missile effect" means the capability of the fringe field component of the static magnetic field of a magnetic resonance imaging system to attract a ferromagnetic object, drawing it rapidly into the scanner by considerable force, posing a significant risk to the patient and anyone else who is in the path of the projectile;

(2) skin burn;

(3) a contrast agent reaction;

(4) quenching of unit; and

(5) other unintended, significant adverse health consequence;

(b) A report filed with the department under this section must be prepared in a manner that the name of the individual involved is stated in a separate part of the report. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.842. Patient records. The registrant shall ensure that each patient's records include details on the imaging factors used, including, at a minimum,

(1) the patient's name, address, telephone number, gender, age, and electronic mail address, if any;

(2) verification that the patient completed a patient history form indicating potential conditions that would increase risk to strong magnetic fields, contrast media, or other factors of concern;

(3) the settings that were used while obtaining magnetic resonance images;

(4) any unexpected event that occurred related to operation of the magnet;

(5) f or female patients, pregnancy status at time of performance of imaging procedure; and

(6) acoustic protection provided. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.845. Definitions related to 7 AAC 18.800 – 7 AAC 18.845. In addition to any applicable definition set out in 7 AAC 18.990, for purposes of 7 AAC 18.800 – 7 AAC 18.845, and unless the context indicates otherwise,

(1) "AAPM" means the American Association of Physicists in Medicine;

(2) "C.F.R." means the Code of Federal Regulations;

(3) "inspection" means an official examination or observation including tests, surveys, monitoring, and inspection of records to determine compliance with applicable requirements;

(4) "magnetic field" means an energy form that is undetectable to ordinary human senses, capable of exerting its effects at a distance, and has the potential to cause serious harm either directly through the interaction of its energy emissions with tissue or indirectly by the manner in which it interacts in the environment; and that has demonstrated through historic events that ignorance of its influences can result in serious injury, including death, to patients, operators, healthcare staff, and others in the vicinity;

(5) "magnetic resonance imaging" means a medical imaging technique that involves a combination of magnetic and radiofrequency radiation used to produce images of the internal areas of the human body;

(6) "nuclear magnetic resonance" means a combination of magnetic and radiofrequency radiation used to conduct research;

(7) "operator" means an individual designated by the registrant to control operation of a magnetic resonance imaging device and to instruct and assist the patient in safe practices related to their proximity to magnetic resonance imaging equipment;

(8) "registrant" means a person who owns a magnetic resonance imaging facility and has been issued a certificate of registration for that facility by the department under 7 AAC 18.800 – 7 AAC 18.845; and

(9) "registration" means a certificate of registration issued by the department under 7 AAC 18.800 – 7 AAC 18.845. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

Article 6 of 7 AAC 18 is renumbered and the heading is changed to read:

Article 9. General Provisions [6. DEFINITIONS].

Section
900. Operator permit required
950. First-level review
955. Evidentiary hearing
980. Severability
990. Definitions

7 AAC 18 is amended by adding new sections to read:

7 AAC 18.900. Operator permit required. (a) Except as provided in (d) of this section, each operator of a radiation device regulated under this chapter must apply for and receive from the department a valid permit authorizing that individual to operate each device identified on the permit. The permit application must be submitted on a form supplied by the department, must include each applicable fee required by 7 AAC 80.030(c) and documentation that the applicant has met, as applicable, the requirements of

(1) 7 AAC 18.410 (medical or veterinary radiation device);

(2) 7 AAC 18.420 (medical or veterinary radiation device);

(3) 7 AAC 18.450 (medical radiographic device);

(4) 7 AAC 18.455(c)(4)(D) (computed tomography x-ray system);

(5) 7 AAC 18.457(d) (bone densitometry system);

(6) 7 AAC 18.470 (veterinary medicine radiographic device);

(7) 7 AAC 18.620 (radiation therapy);

(8) 7 AAC 18.730 (ultraviolet radiation device); and

(9) 7 AAC 18.830 (magnetic resonance imaging).

(b) A permit issued under this subsection is valid for 24 months unless denied, suspended, or revoked by the department under this section. The department may deny, suspend, or revoke an operator's permit sought or issued under this section for

(1) failure to provide documentation showing that the individual has met the applicable training and educational requirements applicable to the specific permit requested;

(2) submission of incorrect, false, or misleading information;

(3) failure to operate a radiation device in accordance with this chapter or as otherwise required by applicable law;

(4) operation of a radiation device in a way that causes or creates a nuisance or hazard to public health or safety;

(5) violation of an applicable requirement of this chapter;

(6) violation of any condition included in the permit; or

(7) failure to pay an applicable fee required under 7 AAC 18.230(c).

(c) If a permit is denied, suspended, or revoked under this section, the applicant or operator may request a review under 7 AAC 18.950 or an evidentiary hearing under 7 AAC 18.955.

(d) The requirements of this section do not apply to the operator of an industrial radiographic device regulated under 7 AAC 18.500 – 7 AAC 18.590. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.950. First-level review. (a) An applicant, registrant, or operator who is not satisfied with the department's decision to deny, suspend, or revoke a certificate of registration or a permit required under this chapter may request

(1) a first-level review under this section; or

(2) an evidentiary hearing under 7 AAC 18.955.

(b) To seek a review under this section, the applicant, registrant or operator must, no later than 30 days after the date of the department's decision, request a review. The request may be made by telephone, by electronic mail, by facsimile transmission, or in writing to the department. A request for review under this section does not affect the right to an evidentiary hearing under 7 AAC 18.955.

(c) At any time during a review under this section, the applicant, registrant or operator may be represented by an attorney or may be self-represented. A self-represented party may be assisted by a person who is not an attorney. The department's designee under (d) of this section may impose reasonable limits on participation by the assistant.

(d) The department will designate an individual, other than the individual who issued the decision being reviewed, to conduct the review under this section. The department's designee may request additional information from the requestor. No later than 10 business days after receipt of the request for review, or any request for additional information, whichever is later, the designee shall review the information related to the department's decision, any additional information requested under this subsection, and applicable statutes and regulations and shall render a written decision on the first-level review. In this subsection, "business day" means a day other than Saturday, Sunday, or a state holiday.

(e) An applicant, registrant or operator who is not satisfied with the department's first-level review decision may request an evidentiary hearing under 7 AAC 18.955.

(f) If an applicant, registrant or operator does not submit a request for a first-level review, the department's original decision is a final administrative action unless a written request for an evidentiary hearing is submitted under 7 AAC 18.955. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.955. Evidentiary hearing. (a) An applicant, registrant or operator who is not satisfied with the department's decision to deny, suspend, or revoke a certificate of registration may request an evidentiary hearing under this section without seeking a first-level review under 7 AAC 18.950 or may request an evidentiary hearing of a decision rendered under 7 AAC 18.950.

(b) A request for an evidentiary hearing under this section must be submitted in writing no later than 30 days after the date of the department's original decision or a decision under a first-level review under 7 AAC 18.950.

(c) A request for an evidentiary hearing under this section must

(1) describe the issue or decision being appealed;

(2) specify the basis upon which the decision is challenged;

(3) include all information and materials that the applicant, registrant or operator requests the department to consider in resolving the matter, including a copy of the first-level review decision if the applicant, registrant or operator participated in a first-level review under 7 AAC 18.950; and

(4) be submitted to the department at the address set out in the department's

(A) original decision, if the requestor did not seek a first-level review under 7 AAC 18.950;

(B) decision issued under 7 AAC 18.950, if the request is for an evidentiary hearing of a decision rendered under 7 AAC 18.950.

(d) At any time during the hearing, the applicant, registrant or operator may be represented by an attorney or may be self- represented. A self-represented party may be assisted by a person who is not an attorney as provided in 2 AAC 64.160.

(e) Upon receipt of a timely request under this section, the department will request the chief administrative law judge, appointed under AS 44.64.020, to appoint an administrative law judge employed or retained by the office of administrative hearings to preside over a hearing requested under this section in accordance with AS 44.64.060 and 2 AAC 64.

(f) If an applicant, registrant or operator does not submit a request under this section no later than 30 days after a department decision described in (b) of this section, that decision is the department's final administrative action. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.980. Severability. If a provision of this chapter is held invalid, the invalidity does not affect any other provision of this chapter that can be given effect without the invalid provision. (Eff. ____/____/2014, Register _____)

Authority: AS 18.05.040 AS 18.60.475 AS 18.60.485

7 AAC 18.990 is repealed and readopted to read:

7 AAC 18.990. Definitions. Unless the context requires otherwise, in this chapter,

(1) "absorbed dose" means the mean energy imparted by ionizing radiation to matter, determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM; the SI unit of absorbed dose is joule per kilogram and the special name of the unit of absorbed dose is the gray (Gy), previously referred to as the rad);

(2) "absorbed dose rate" means absorbed dose per unit time, for a machine with a timer, or dose monitor unit per unit time for a linear accelerator;

(3) "accessible surface" means the surface of equipment, or of an equipment part, that can be easily or accidentally touched by persons without the use of a tool;

(4) "activity" means the rate of disintegration, transformation, or decay of radioactive material, and for which a unit of activity is the curie and the Becquerel;

(5) "added filtration" means filtration that is in addition to the inherent filtration;

(6) "air kerma (K)" means the kinetic energy released in air by ionizing radiation, determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM; the SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy);

(7) "aluminum equivalent" means the thickness of aluminum allowing, under specific condition, the same attenuation as the material in question;

(8) "amplification" means the image has increased in brightness several thousand times the brightness of a traditional zinc cadmium sulfide screen by using an electronic method of enhancement;

(9) "barrier" means protective barrier;

(10) "beam axis" means the axis of rotation of the beam limiting device;

(11) "beam-limiting device" means a field defining collimator, integral to the therapeutic or diagnostic radiation machine, that provides a means to restrict the dimensions of the useful beam;

(12) "beam monitoring system" means a system designed and installed in the radiation head to detect and measure the radiation present in the useful beam;

(13) "beam scattering foil" means a thin piece of material, usually metallic, placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam;

(14) "Becquerel" means a unit for the measurement of radioactivity that is equal to one disintegration per second;

(15) "bent beam linear accelerator" means a linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet;

(16) "bioassay" means the determination of kinds, quantities, concentrations, and locations of radioactive material in the human body, by direct measurement, *in vivo* counting, or by analysis and evaluation of materials excreted or removed from the human body;

(17) "C-arm" means a kind of mobile fluoroscope that allows for quick repositioning of the radiation tube during use;

(18) "cabinet radiography" means industrial radiography with the use of an ionizing radiation machine conducted in an enclosed, interlocked cabinet, in a manner that the

(A) radiation machine does not operate unless all openings are securely closed; and

(B) cabinet is shielded so that every location on the exterior meets conditions for an uncontrolled area;

(19) "changeable filters" means a filter, exclusive of inherent filtration, that can be removed from the useful beam through an electronic, mechanical, or physical process;

(20) "collimator" means an adjustable beam-restricting device constructed of attenuating material used to confine a useful beam within a designated solid angle;

(21) "commissioner" means the commissioner of health and social services;

(22) "committed dose equivalent" means the dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following the uptake;

(23) "committed dose equivalent maximally exposed organ" means the largest dose to any organ from the intake of radioactive material;

(24) "committed effective dose equivalent" means the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to each of these organs or tissues;

(25) "computed tomography dose index" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan;

(26) "cone" means a type of beam-restricting device that does not permit adjustment of the beam size;

(27) "contact therapy system" means a therapeutic radiation machine with a short target to skin distance (TSD), usually less than five centimeters;

(28) "controlled area"

(A) means an area that is outside of a restricted area, but inside the site boundary, and to which access is controlled by a registrant for purposes of protection of individuals from exposure to radiation and radioactivity;

(B) does not include residential quarters, except that a separate room or rooms in a residential building may be set apart as a controlled area;

(28) "conventional simulator" means an x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment;

(29) "CT conditions of operation" means the selectable parameters governing the operation of a CT x-ray system, including nominal tomographic section thickness, filtration, and the technique factors used to control image quality and exposure, as defined by the manufacturer of the control software;

(30) "CTDI" means computed tomography dose index;

(31) "CTN" means CT number;

(32) "CT number" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image;

(33) "curie" means that quantity of radioactive material that decays at the rate of 3.7×10^{10} disintegrations per second;

(34) "dead-man type switch" means a switch constructed in a manner that a circuit-closing contact can only be maintained by continuous pressure by the operator;

(35) "deep dose equivalent" means the dose equivalent at a tissue depth of one centimeter used as a measure of external whole body exposure;

(36) "department" means the Alaska Department of Health and Social Services;

(37) "detector" means radiation detector;

(38) "diagnostic-type tube housing" means an x-ray tube housing constructed in a manner that the leakage X-radiation at a distance of one meter from the target cannot exceed 100 milliroentgens in one hour when the tube is operated at any of the tube's specified ratings;

(39) "diaphragm" means a beam restricting device that is made of a flat piece of attenuating material with an aperture that restricts the useful beam;

(40) "dose"

(A) means

(i) the quantity of radiation absorbed, per unit of mass, by the whole body or by any portion of the body;

(ii) in connection with a period of time, the total quantity of radiation absorbed, per unit of mass, during that period of time;

(B) includes

(i) absorbed dose;
(ii) committed dose equivalent;
(iii) committed effective dose equivalent;
(iv) dose equivalent;
(v) effective dose equivalent; and
(vi) total effective dose equivalent;

(41) "dose area product" or "DAP" means the radiation dose in the air, times the area of the x-ray field, expressed in gray-cm^3 (gy - cm^3);

(42) "dose equivalent" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest, and a unit of which is the rem and sievert;

(43) "dose monitor unit (DMU)" means a unit response from the beam monitoring system from which the absorbed dose can be calculated;

(44) " dose profile" means the dose as a function of position along a straight line of a measured distance;

(45) "effective dose equivalent" means the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated;

(46) "electronic brachytherapy" means a method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation dosage;

(47) "electronic brachytherapy device" means the system used to produce and deliver therapeutic radiation, including the x-ray tube, the control mechanism, the cooling system, and the power source;

(48) "electronic brachytherapy source" means the x-ray tube component used in an electronic brachytherapy device;

(49) "elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted;

(50) "enclosure" means a cabinet, box, or other container, provided by the manufacturer or user of a radiation machine, from which the source of the radiation cannot be removed without destroying the function of the source;

(51) "exposure" means being exposed to ionizing radiation or to radioactive material;

(52) "external beam radiation therapy" means therapeutic irradiation in which the source of radiation is at a distance from the body;

(53) "FDA" means the Food and Drug Administration;

(54) "field-flattening filter" means a filter used to homogenize the absorbed dose rate over the radiation field;

(55) "field radiography" means industrial radiography using ionizing radiation machines, except for cabinet radiography and shielded room radiography;

(56) "filter" means

(A) for purposes of a diagnostic beam, material placed in a useful beam to preferentially absorb less penetrating radiations; or

(B) for purposes of a therapeutic beam, material placed in the useful beam to change beam quality;

(57) "gantry" means, for purposes of

(A) radiation therapy, that part of a radiation therapy system that supports and allows movement of the radiation head about a center of rotation;

(B) computed tomography, the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that hold these components in a diagnostic CT machine; and

(C) magnetic resonance imaging, the structure, connections, and assemblies that support the magnet and allow rotational image data collection;

(58) "gray" means the SI unit of absorbed dose, kerma, and specific energy imparted that is equal to an absorbed dose of one joule per kilogram;

(59) "half-value layer" means the thickness of a specified material that attenuates X-radiation or gamma radiation to an extent that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-half of the value measured without the material at the same point;

(60) "high ionizing radiation area" means an area that is accessible to an individual in which there exists ionizing radiation at a level that a major portion of the individual's body may receive a dose in excess of 100 millirems in a one hour period of time;

(61) "imaging" means the use of radiation of sufficient intensity to enable a photographic-like rendition of internal structures to be seen;

(62) "individual" means a natural person;

(63) "individual monitoring" means the assessment of

(A) dose equivalent by the use of devices designed to be worn by an individual;

(B) committed effective dose equivalent by bioassay or by determination of the time-weighted air concentrations to which an individual has been exposed; and

(C) dose equivalent by the use of survey data;

(64) "individual monitoring device" means a device designed to be worn by an individual for the assessment of dose equivalent, such as a film badge, thermoluminescence dosimeter, pocket ionization chamber, and personal air sampling device;

(65) "industrial radiography" means the examination of the internal structure of materials by nondestructive methods utilizing ionizing radiation sources;

(66) "intensity modulated radiation therapy (IMRT)" means radiation therapy that uses non-uniform radiation beam intensities that have been determined by various computer-based optimization techniques;

(67) "internal dose" means that portion of the dose equivalent received from radioactive material taken into the body;

(68) "interlocked" means the use of a device to prevent the start or continued operation of equipment unless the predetermined conditions set out in this chapter prevail;

(69) "interruption of irradiation" means to stop irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel;

(70) "ionizing radiation"

(A) means an electromagnetic or particulate radiation capable of producing ions, directly or indirectly, in the radiation's passage through matter;

(B) includes

(i) alpha and beta particles;
(ii) gamma rays;
(iii) high speed electrons;
(iv) neutrons;
(v) protons; and
(vi) x-rays;

(71) "ionizing radiation area" means an area that is accessible to an individual in which there exists ionizing radiation at a level that a major portion of the individual's body may receive a dose in excess of five millirems in an hour period of time or a dose in excess of 100 millirems in a five consecutive day period;

(72) "ionizing radiation source" means a device capable of producing ionizing radiation;

(73) "irradiation" means the exposure of a living being or matter to ionizing radiation;

(74) "isocenter" means the center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions;

(75) "kilovolt (kV)," for photons, or "kilo electron volt (keV)," for electrons, means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of 1000 volts in a vacuum;

(76) "kilovolts peak" means the crest value of kilovolts of the potential of a pulsating potential generator and, when only one-half of the wave is used, the value refers to the useful half of the wave;

(77) "lens dose equivalent" means the external exposure to the lens of the eye, measured as the dose equivalent at a tissue depth of 0.3 centimeter;

(78) "lead equivalent" means the thickness of the material in question, under specified conditions, that allows the same attenuation as lead;

(79) "leakage radiation" means radiation emitted from an enclosure, except for the useful beam;

(80) "licensed practitioner of the healing arts" means a practitioner licensed by this state and includes

(A) a chiropractor;
(B) a dentist;
(C) a nurse practitioner;
(D) an osteopath;
(E) a physician, including a surgeon;
(F) a physician assistant; and
(G) a podiatrist;

(81) "light field" means the area illuminated by light, simulating the radiation field;

(82) "limits" or "dose limits" means the upper bounds of radiation doses permitted under this chapter;

(83) "mA" means milliampere;

(84) "medical" means related to a practice engaged in by a licensed practitioner of the healing arts;

(85) "medical fluoroscopic equipment" means a device that produces ionizing radiation in a manner capable of creating real-time dynamic images of human anatomy;

(86) "medical imaging equipment" means a device used to acquire images of the human body for the purpose of establishing a health status diagnosis or to treat disease in humans by using radiation, including any associated device necessary to process those images;

(87) "megavolt (MV)," for photons, or "mega electron volt (MeV)," for electrons, means the energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one million volts in a vacuum;

(88) "microcurie" means one millionth of a curie or 3.7×10^7 disintegrations per second;

(89) "millisievert" means one-thousandth of a sievert;

(90) "minor" means an individual less than 18 years of age;

(91) "misadministration" means an event that meets the criteria in 7 AAC 18.645(b)(3) and (4), and that must be reported as required in 7 AAC 18.645;

(92) "mobile electronic brachytherapy service" means the transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record;

(93) "monitor unit (MU)" means dose monitor unit;

(94) "moving beam radiation therapy" means radiation therapy with a planned displacement of radiation field or patient relative to each other, or with a planned change of absorbed dose distribution; "moving beam radiation therapy" includes arc, skip, conformal, intensity modulation, and rotational therapy;

(95) "multiple tomogram system" means a computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram;

(96) "noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water;

(97) "nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected;

(98) "nominal treatment distance" means

(A) for electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam; or

(B) for x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam; for non-isocentric equipment, this distance is that specified by the manufacturer;

(99) "non-ionizing radiation" means energy that is below the minimum required to remove an electron from matter and create an ionic state (a charged particle);

(100) "non-ionizing radiation source"

(A) means a source that may be electromagnetic in nature, including ultraviolet below a threshold energy, infrared, visible light, radio waves, microwaves, laser light, and EMF;

(B) includes radiation that is not electomagnice in nature, including sonic, infrasonic, and ultrasonic energy, magnetic fields, and thermal energy;

(101) "nonstochastic effect"

(A) means a health effect that occurs only after a minimum threshold exposure to radiation, the severity of which varies with the dose;

(B) includes radiation-induced cataract formation;

(102) "occupational dose"

(A) means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material, whether in the possession of the registrant or other person;

(B) does not include doses received

(i) from background radiation;

(ii) from any medical administration the individual has received;

(iii) from exposure to individuals administered radioactive material from voluntary participation in medical research programs; or

(iv) as a member of the public;

(103) "operator" means an individual who conducts an activity resulting in the production of ionizing radiation, or that is intended or expected to cause the production of ionizing radiation;

(104) "operator of medical fluoroscopic equipment" means an individual who controls the amount of exposure that a patient receives by either directly manipulating the radiation exposure controls, or by directing the person who manipulates the exposure controls when to begin and terminate the exposure, maintaining control of the process throughout the duration of the exposure.

(105) "patient" means an individual subjected to machine-produced radiation for the purposes of medical diagnosis or therapy;

(106) "peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure;

(107) "periodic quality assurance check" means a procedure performed to ensure that a previous parameter or condition continues to be valid;

(108) "person" includes

(A) a business;
(B) a health facility;
(C) an individual;
(D) an institution;
(E) a municipal corporation;
(F) a partnership;
(G) a political subdivision;
(H) a public or private corporation; and
(I) any other entity;

(109) "personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring doses, such as a

(A) film badge;
(B) film ring;
(C) pocket chamber; or
(D) pocket dosimeters;

(110) "phantom" means an object that behaves in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question;

(111) "practical range of electrons" means a range that corresponds to classical electron range where the only remaining contribution to dose is from bremsstrahlung x-rays;

(112) "practitioner of the healing arts" has the meaning given "licensed practitioner of the healing arts" in this section;

(113) "prescribed dose" means the total dose and dose per fraction as documented in the written directive; the prescribed dose is a estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique;

(114) "primary dose monitoring system" means a system that will monitor the useful beam during irradiation and terminate irradiation when a pre-selected number of dose monitor units have been delivered;

(115) "primary protective barrier" means

(A) for diagnostic purposes, a barrier sufficient to attenuate a useful beam to a required degree; or

(B) for therapeutic purposes, the material, excluding filters, placed in the useful beam;

(116) "protective apron" means an apron made of attenuating materials used to reduce radiation exposure;

(117) "protective barrier"

(A) means a barrier of attenuating materials used to reduce radiation exposure;

(B) includes a

(i) primary protective barrier; and
(ii) secondary protective barrier;

(118) "protective glove" means a glove made of attenuating materials used to reduce radiation exposure;

(119) "qualified expert" means an individual determined by the department to be qualified by education, training, and experience to evaluate radiation matters and make competent recommendations concerning a particular installation or application of a radiation machine;

(120) "qualified medical physicist" means an individual who meets the standards of 7 AAC 18.615;

(121) "radiation" means energy transmitted in the form of ionizing or non-ionizing radiation in sonic, infrasonic, or ultrasonic waves from any source that arises either naturally or by an electrical device that is energized to produce effects that are undetectable by ordinary human senses, that can exert effects at a distance, and that have the potential to cause serious harm to humans, either directly through interactions of its energy in tissue, or indirectly by interacting with the environment to create harmful effects invisibly;

(122) "radiation detector" means a device that, in the presence of radiation, provides by direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation;

(123) "radiation device" means an electrical or electronic device capable of producing radiation at intensity levels sufficient to present a potential health risk;

(124) "radiation field" means useful beam;

(125) "radiation head" means the structure from which the useful beam emerges;

(126) "radiation machine"

(A) means a device capable of producing radiation;

(B) does not include a device that produces ionizing radiation only from radioactive material;

(127) "radiation source"

(A) has the meaning given "radiation sources" in AS 18.60.545; and

(B) includes a radiation device, a radiation machine, and radioactive material;

(128) "radioactive material" means a solid, liquid, or gas material that emits ionizing radiation spontaneously and that is regulated by the Alaska Department of Environmental Conservation or the USNRC as stated at 7 AAC 18.010(h);

(129) "radiographer" means an individual who performs, or who, in attendance at a site where ionizing radiation sources are being used, personally supervises industrial radiographic operations;

(130) "radiographer's assistant" means an individual who uses ionizing radiation sources, related handling tools, or survey instruments in industrial radiography under the personal supervision of a radiographer;

(131) "radionuclide" has the meaning given in AS 18.60.545;

(132) "redundant beam monitoring system" means a combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units;

(133) "reference plane" means a plane that is displaced from and parallel to the tomographic plane;

(134) "registrant" means an individual who has registered a radiation source under this chapter;

(135) "rem" means the special unit of any of the quantities expressed as dose equivalent, and which the dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor;

(136) "roentgen" means an amount of X-radiation or gamma radiation in which the associated corpuscular emission per 0.001293 grams of air produces in air ions carrying one electrostatic unit of quantity of electricity of either sign;

(137) "restricted area"

(A) means an area that access is limited by the registrant for the purpose of protecting individuals against undue risks from exposure to radiation;

(B) does not include an area used as residential quarters, except that separate rooms in a residential building may be set apart as a restricted area;

(138) "scan" means the complete process of collecting x-ray transmission data for the production of a tomogram, including data collected simultaneously during a single scan for the production of one or more tomograms;

(139) "scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of the displacement;

(140) "scan sequence" means a pre-selected set of two or more scans performed consecutively under preselected CT conditions of operation;

(141) "scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan;

(142) "scattered radiation" means ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam;

(143) "secondary dose monitoring system" means a system that will terminate irradiation in the event of failure of the primary dose monitoring system;

(144) "secondary protective barrier" means a barrier sufficient to attenuate stray radiation to a required degree;

(145) "shadow tray" means a device attached to the radiation head to support auxiliary beam blocking material;

(146) "shallow-dose equivalent" means the dose equivalent at a tissue depth of 0.007 centimeter and applies to the external exposure of the skin of the whole body or the skin of an extremity;

(147) "shallow-dose equivalent maximum extremity" means the dose equivalent at a tissue depth of 0.007 centimeter and applies to the maximum external exposure of the skin of an extremity;

(148) "shallow-dose equivalent whole body" means the dose equivalent at a tissue depth of 0.007 centimeter based on the external radiation exposure of the skin of the whole body;

(149) "shielded room radiography" means industrial radiography, with the use of ionizing radiation machines, that is conducted in an enclosed room, in which

(A) the interior is not occupied during radiographic operations;

(B) is shielded so that every location on the exterior meets conditions for an uncontrolled area as specified in 7 AAC 18.240; and

(C) the only access is through openings which are interlocked so that the ionizing radiation machine will not operate unless all openings are securely closed;

(150) "shutter" means a device that is attached to the tube housing assembly, that can totally intercept the useful beam, and that has a lead equivalency not less than that of the tube housing assembly;

(151) "sievert" means the SI unit of the dose equivalent; the unit of dose equivalent is the joule per kilogram; "sievert" is replacing the previous unit of dose equivalent (rem; 1 Sv=100 rem);

(152) "simulator" or "radiation therapy simulation system" means an x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field;

(153) "single tomogram system" means a CT x-ray system that obtains x-ray transmission data during a scan to produce a single tomogram;

(154) "source" means the region or material from which radiation emanates;

(155) "source material"

(A) means uranium or thorium, or any combination of uranium or thorium, in any physical or chemical form or ores which contain 0.05 percent or more of uranium, thorium, or any combination of them;

(B) does not include special nuclear material;

(156) "source-skin distance (SSD)" means target-skin distance;

(157) "special nuclear material" means Uranium^{233}, Uranium^{235}, and plutonium;

(158) "stationary beam radiation therapy" means radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation;

(159) "stochastic effects" means health effects, including hereditary effects and cancer incidence, that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold;

(160) "stray radiation"

(A) means radiation not serving any useful purpose; and

(B) includes leakage radiation and scattered radiation;

(161) "survey"

(A) means an evaluation of radiation protection practices;

(B) includes

(i) a physical survey of the location of material and equipment; and

(ii) measurements of levels of radiation or concentration of radioactive materials present;

(162) "target" means that part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles;

(163) "target-skin distance (TSD)" means the distance measured along the beam axis from the center of the front surface of the x-ray target or electron virtual source to the surface of the irradiated object or patient;

(164) "technique chart" means a paper or electronic based graph, such as a device-operational software, generated for the particular machine that establishes the optimal exposure by considering the essential variables of a radiographic examination, enabling an operator to select an exposure appropriate for each patient and procedure combination;

(165) "tenth-value layer (TVL)" means the thickness of a specified material that attenuates x-radiation or gamma radiation to an extent that the air kerma rate, exposure rate, or absorbed dose rate is reduced to one-tenth of the value measured without the material at the same point;

(166) "termination of irradiation" means to stop irradiation in a way that prevents continued irradiation unless operating conditions are reset at the control panel;

(167) "therapeutic radiation machine" means x-ray or electron-producing equipment designed and used for external beam radiation therapy; "therapeutic radiation machine" includes a device used to administer electronic brachytherapy;

(168) "tomographic plane" means that geometric plane which is identified as corresponding to the output tomogram.

(169) "tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram;

(170) "total effective dose equivalent" means the sum of the

(A) deep-dose equivalent for external exposures; and

(B) committed effective dose equivalent for internal exposures;

(171) "total organ dose equivalent" means the shallow-dose equivalent whole body dose plus the maximum organ dose for any internally deposited radionuclide, if applicable;

(172) "tube" means an x-ray tube, unless otherwise specified;

(173) "tube housing assembly" means the tube housing with tube installed, including high-voltage or filament transformers and other appropriate elements when those transformers or other elements are contained within the tube housing;

(174) "uncontrolled area" means an area to which access is not controlled by the registrant for purposes of protection of individuals from exposure to radiation, and any area used for residential quarters;

(175) "useful beam" means that part of an ionizing radiation that passes through a window, aperture, cone, or other collimating device of a tube housing;

(176) "very high radiation area" means an area that is accessible to an individual in which radiation levels from radiation sources external to the body may result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one hour at one meter from a radiation source or one meter from any surface that the radiation penetrates;

(177) "virtual simulator" means a computed tomography (CT) unit used in conjunction with relevant software that recreates the treatment machine and that allows import, manipulation, display, and storage of images from CT or other imaging modalities;

(178) "virtual source" means a point from which radiation appears to originate;

(179) "wedge filter" means a filter that effects continuous change in transmission over all or a part of the useful beam;

(180) "weighting factor" means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly;

(181) "whole body" means, for purposes of external exposure, the

(A) head;
(B) trunk, including male gonads;
(C) arms above the elbow; and
(D) legs above the knee;

(182) "written directive" means an order in writing for the administration of radiation to a specific patient or human research subject, as specified in 7 AAC 18.645(a)(1);

(183) "x-ray" means ionizing electromagnetic radiation emitted by an electrical device in the range of 0.01 nanometers to 20 nanometers;

(184) "x-ray tube" means any electron tube designed to be used primarily for the production of x-rays. (Eff. 4/9/2009, Register 190; am ____/____/2014 Register ____)

Authority: AS 18.60.475 AS 18.60.485

Part 6. Miscellaneous.
Chapter 80. Fees for Department Services.
Article 1. Public Health Services.

The "Radiologic Health Services" portion of 7 AAC 80.130(a) is repealed and readopted to read:

7 AAC 80.030. Fee schedule and procedures. (a) Following are the fees for the listed public health services:

SERVICE **FEE**

RADIOLOGIC HEALTH SERVICES	See (c) of this section.

. . . .

7 AAC 80.030(c) is repealed and readopted to read:

(c) Each registrant for a radiation device that is regulated under 7 AAC 18 shall pay the applicable registration fee set out in the table in this subsection. Unless stated otherwise in the table, each registration fee is an annual fee for the year in which the device is registered. The initial registration fee is a one-time fee unless the registrant allows the registration to lapse for six months or longer. The fee for a registration initiated after July 1 is one-half of the initial registration fee, if the device was not in operation before June 30 of that year. The fee for registration of a device in use before June 30 of the registration year is the full initial registration fee. Each renewal fee is due no later than December 1 each year. If a renewal fee is not paid when due, the initial registration fee applies in addition to the late fee set out in the following table. The registrant or operator shall pay other fees set out in this table as applicable.

TABLE OF FEES FOR RADIATION DEVICES REGULATED UNDER 7 AAC 18		
Registration Fees		
Device	**Initial Registration Fee**	**Annual Renewal Fee**
Radiographic ionizing radiation device	$180 per tube	$140 per tube
Radiation therapy, accelerators, cyclotrons	$700 per machine	$500 per machine
Indoor tanning	$100 per bed or booth	$90 per bed or booth
Magnetic resonance device	$400 per device	$300 per device
Other ionizing radiation device (non-materials)	$120 per device	$100 per device
Other non-ionizing radiation device (non-materials)	$120 per device	$100 per device
Other Fees		
Late registration	An additional $30 per tube, machine, bed, booth, or device	
Shielding plan review	$250 per device or site	
Department followup inspection or review after notification of violation and order of abatement under AS 18.60.495	$350 per inspection or review	
Vendor registration under 7 AAC 18.130	$100	
Operator permit under 7 AAC 18.900	$90 for a 24-month permit; renewal fee: $45	

. . . .

(Eff. 12/6/86, Register 100; am 2/3/88, Register 105; am 4/28/94, Register 130; am 8/19/98, Register 147; am 10/1/2003, Register 167; am 12/24/2006, Register 180; am 1/1/2009, Register 188; am ____/____/2014, Register ____)

Authority: AS 18.05.040 AS 44.29.020 AS 44.29.022