NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

November 1, 2019
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on the adoption of amendments to and repeal of the following regulations in Title 180 of the Nebraska Administrative Code (NAC) – *Control of Radiation*.

The following chapter is proposed for AMENDMENT:

180 NAC 6 – *Diagnostic X-Rays Other Than Dental Radiation Generating Equipment in the Healing Arts*. The chapter governs the use of diagnostic x-ray equipment and imaging systems to engage in the hearing arts, dental healing arts, or veterinary medicine. The proposed changes add the use of dental radiation generating equipment; add requirements outlining the radiation safety attributes for hand-held dental intraoral equipment; add requirements specific to cone beam computed tomography equipment; allow for radiation exposure for research purposes provided the research is approved by an institutional review board and is conducted under federal regulations; remove unnecessary language, repeated language found in federal regulations, and repeated statutory language from the regulations; and update formatting.

The following chapter is proposed for REPEAL in its entirety:

180 NAC 21 – *Dental Radiographic Equipment*. This chapter is proposed for repeal as it is a repeat of requirements found in other chapters within Title 180.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at http://www.sos.ne.gov, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call

DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title: 180	Prepared by: Julia Schmitt
Chapter: 6	Date prepared: 6/25/2018
Subject: Diagnostic X-Rays In The Healing Arts	Telephone: 402/471-0528

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☒)
Increased Costs	(☐)	(☐)	(☐)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

FISCAL IMPACT STATEMENT

Agency: **Department of Health and Human Services**	
Title: 180	Prepared by: Julia Schmitt
Chapter: 21	Date prepared: 05/8/2019
Subject: Dental Radiographic Equipment	Telephone: 402-471-0528

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(☒)	(☒)	(☒)
Increased Costs	(☐)	(☐)	(☐)
Decreased Costs	(☐)	(☐)	(☐)
Increased Revenue	(☐)	(☐)	(☐)
Decreased Revenue	(☐)	(☐)	(☐)
Indeterminable	(☐)	(☐)	(☐)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public:

If indeterminable, explain why:

PROPOSED REGULATION QUESTIONNAIRE

Title 180 NAC 6

1) Is the regulation essential to the health, safety, or welfare of Nebraskans?

Yes. The purpose of the regulations are to institute and maintain a program to permit development and utilization of sources of radiation for peaceful purposes consistent with the protection of occupational and public health and safety and the environment. The regulations in this chapter apply to entities using x-ray generating equipment in medicine. Ionizing radiation has a number of beneficial uses, including visualizing inner structures of the human body. However, ionizing radiation is potentially harmful if not used correctly. As such, it is important that the regulated entities use radiation in a manner that protects the user and the public.

2) Do the costs of the regulation outweigh the benefits? Provide specific data and reasoning.

Yes. The use of x-ray equipment provide benefits to the public in a number of medical situations. Misuse of ionizing radiation can have catastrophic health consequences. The regulations provide safeguards that allow the benefits while minimizing risks.

3) Does a process exist to measure the effectiveness of the regulation? If so, explain.

Yes. Registrants are inspected for compliance with the radiation safety regulations.

4) Has a less restrictive alternative been considered?

The least restrictive alternative has been chosen where possible. For example, requirements regarding the use of cone beam computed tomography and hand-held dental and veterinary equipment have been eased.

5) Was the regulation solely promulgated due a state statutory requirement? If so, provide citations.

Yes, Neb. Rev. Stat. § 71-3505 (1) requires regulations. However, even if the statute were to be changed to “may”, regulations would be needed to ensure public safety and safe radiation use by the regulated entities.

6) Was the regulation promulgated as a result of a federal mandate? If so, include copies of the applicable federal statutes and regulations.

No.

PROPOSED REGULATION QUESTIONNAIRE

Title 180 NAC 21

1) Is the regulation essential to the health, safety, or welfare of Nebraskans?

No. 180 NAC 21 contains requirements that are addressed in other chapters of the regulations. Chapter 21 has created so that dentists would have to look at only one chapter to see what regulations applied to them.

2) Do the costs of the regulation outweigh the benefits? Provide specific data and reasoning.

N/A. The proposal is to repeal Chapter 21.

3) Does a process exist to measure the effectiveness of the regulation? If so, explain.

N/A. The proposal is to repeal Chapter 21.

4) Has a less restrictive alternative been considered?

Yes. The proposal is to repeal Chapter 21.

5) Was the regulation solely promulgated due a state statutory requirement? If so, provide citations.

N/A. 180 NAC contains items that are addressed in other chapters of the regulations.

6) Was the regulation promulgated as the result of a federal mandate? If so, include copies of the applicable federal statutes and regulations.

No.

PROPOSED REGULATION
POLICY PRE-REVIEW CHECKLIST

Agency: DHHS – Division of Public Health
Title, Chapter of Regulation: Title 180 NAC 6
Subject: Control of Radiation – Diagnostic X-Rays In The Healing Arts
Prepared by: Julia Schmitt
Telephone: 401-471-0528

A. Policy Changes and Impacts

1. What does the regulation do and whom does it impact? Provide a brief description of the proposed rule or regulation and its impacts on state agencies, political subdivisions, and regulated persons or entities.

   The regulations apply to persons who use x-ray radiation generating equipment in medicine.

   This revision re-promulgates Title 180 NAC 6 to comply with the formatting requirements of the Secretary of State. In addition, the regulations remove any unnecessary language, repeated statutory language and language found in 21 Code of Federal Regulations (CFR) Part 1020, Performance Standards for Ionizing Radiation Emitting Products.

   The requirements regarding the use of dental radiation generating equipment were placed in Chapter 6, since the chapter of the regulations specific to dental intraoral, cephlometric and panographic equipment is to be deleted. Additionally, the requirements outlining the radiation safety attributes that hand-held dental intraoral equipment must have was added. Currently, only specific brands and models of hand-held equipment have been approved for use. By specifying the safety attributes that must be in place, users can choose any brand or model of hand-held equipment that has those safety attributes.

   Requirements specific to cone beam computed tomography equipment was added. Currently, users of that equipment must comply with the requirements that are applicable to all types of computed tomography equipment. The radiation output of cone beam computed tomography equipment is less than traditional types of computed tomography equipment, so the requirements specific to those units are less stringent.

   A provision was added allowing radiation exposure for research purposes provided that the research is approved by an institutional review board

and is conducted under federal regulations for the protection of human subject in research.

2. Describe changes being proposed to current policy and briefly provide rationale.

   There is no change to current policy.

B. <u>Why is the rule necessary? Explain and provide an identification of authorizing statute(s) or legislative bill(s).</u>

1. Update of regulation (repeal of obsolete statutes, reflect current policy, editing or technical language changes, etc.)

   This revision re-promulgates Title 180 NAC 6 to comply with the formatting requirements of the Secretary of State. In addition, the regulations remove any unnecessary language, repeated statutory language and language found in 21 Code of Federal Regulations (CFR) Part 1020, Performance Standards for Ionizing Radiation Emitting Products.

2. Annual changes – cost of living, hunting season schedules, etc.

   No

3. Law was changed – federal ___ or state ___ [Cite authorizing statute(s) or legislative bill(s)]

   No

4. Extension of established policy or program, new initiatives or changes in policy (within statutory authority) No

5. Constituent initiated No

6. Financial needs – increases/decreases in fees No

7. Litigation requires changes in rules No

8. Addresses legal or constitutional concerns of Attorney General's office No

9. Implements federal or court mandate No

10. Other (explain)

C. What happens if these rules are not adopted?

Unnecessary language, repeated statutory language and language found in 21 CFR Part 1020, Performance Standards for Ionizing Radiation Emitting Products would remain in place. Additionally, hand-held radiation generating equipment use would remain restricted, cone beam computed tomography users would still have to comply with more stringent requirements and the use of radiation in research on human subjects would not be addressed.

D. Policy Checklist

1. Is this an update or editorial change reflecting essentially no change in policy? Yes

2. Does the policy in the proposed regulation reflect legislative intent? Yes

3. Is the policy proposed in the regulation a state mandate on local government? No Is it funded? N/A

4. Is the policy proposed in the regulation a federal mandate on local government? No Is it funded? N/A

E. Fiscal Impact. In addition to completing the required Fiscal Impact Statement (a copy must be attached to this document), the agency must address the following:

1. Will the proposed regulation reduce, increase, or have no change in resources – funds, personnel or FTE?

   No change.

2. Have initial contacts been made with citizens or organizations that may be impacted by the proposed regulation?

   We will solicit public comment before a public hearing.

3. Does the proposed regulation impact another agency? No Explain the impact. No impact.

4. Will the proposed regulation reduce, increase, or have no change on reporting requirements of businesses?

   No Change.

5. What is the agency's best estimate of the additional or reduced spending? If there is none, please note. If receipt of federal funds is contingent upon approval of the proposed regulation, then indicate the amount and nature of the federal funds affected, and enclose laws or correspondence from federal officials substantiating the information.

   N/A

6. Include a description of the impact that the proposed regulation will have on the number of state employees and how the agency intends to address proposed increases or decreases in FTE.

   No Impact.

F. Unique problems or issues and recommendations.

No known problems or issues.

G. Who is expected to be affected, or to oppose or support the proposed regulation? Explain what initial informal contacts have been made with organizations or citizens who may be affected by the regulation prior to the public hearing.

No known supporters or opponents.

DHHS will solicit public comment on the proposed regulations before the public hearing.

H. Are these proposed rules a likely candidate for negotiated rulemaking? Explain. Has the process been completed? If so, explain how the issues were addressed.

No.

DHHS Division Director's Verification of Review

I have reviewed these proposals and verify that, at this stage of the regulation's development, these questions have been accurately addressed.

_____ _____

Bo Botelho
Interim Director, Division of Public Health
Department of Health and Human Services

Date

PROPOSED REGULATION
POLICY PRE-REVIEW CHECKLIST

Agency: DHHS – Division of Public Health
Title, Chapter of Regulation: Title 180 NAC 21
Subject: Dental Radiographic Equipment
Prepared by: Julia Schmitt
Telephone: 402-471-0528

A. Policy Changes and Impacts

1. What does the regulation do and whom does it impact? Provide a brief description of the proposed rule or regulation and its impacts on state agencies, political subdivisions, and regulated persons or entities.

   Chapter 21 existed as a regulation that contained all of the requirements from other chapters of 180 NAC that applied to dental intraoral practices. Dentists have had to look in only one chapter to see what regulations applied to them. Chapter 21 is proposed to be repealed because repeats requirements from other chapters.

2. Describe changes being proposed to current policy and briefly provide rationale.

   There are no changes to current policy.

B. Why is the rule necessary? Explain and provide an identification of authorizing statute(s) or legislative bill(s).

Chapter 21 is not necessary. It is proposed to be deleted because it covers requirements that exist in other chapters.

1. Update of regulation (repeal of obsolete statutes, reflect current policy, editing or technical language changes, etc.)

   N/A. Repeal of Chapter.

2. Annual changes – cost of living, hunting season schedules, etc.

   No.

3. Law was changed – federal ___ or state ___ [Cite authorizing statute(s) or legislative bill(s)]

N/A

4. Extension of established policy or program, new initiatives or changes in policy (within statutory authority) No

5. Constituent initiated No

6. Financial needs – increases/decreases in fees No

7. Litigation requires changes in rules No

8. Addresses legal or constitutional concerns of Attorney General's office No

9. Implements federal or court mandate No

10. Other (explain)

C. What happens if these rules are not adopted?

If this chapter is not repealed, unnecessary and redundant regulations would remain.

D. Policy Checklist

1. Is this an update or editorial change reflecting essentially no change in policy? Yes

2. Does the policy in the proposed regulation reflect legislative intent? Yes.

3. Is the policy proposed in the regulation a state mandate on local government? No Is it funded? N/A

4. Is the policy proposed in the regulation a federal mandate on local government? No Is it funded? N/A

E. Fiscal Impact. In addition to completing the required Fiscal Impact Statement (a copy must be attached to this document), the agency must address the following:

No fiscal impact.

1. Will the proposed regulation reduce, increase, or have no change in resources – funds, personnel or FTE? No change.

1. Have initial contacts been made with citizens or organizations that may be impacted by the proposed regulation? We will solicit public comment on the repeal of the regulation before a public hearing.

2. Does the proposed regulation impact another agency? No Explain the impact.

3. Will the proposed regulation reduce, increase, or have no change on reporting requirements of businesses?

   No Change

5. What is the agency's best estimate of the additional or reduced spending? If there is none, please note. If receipt of federal funds is contingent upon approval of the proposed regulation, then indicate the amount and nature of the federal funds affected, and enclose laws or correspondence from federal officials substantiating the information.

   No change in spending.

6. Include a description of the impact that the proposed regulation will have on the number of state employees and how the agency intends to address proposed increases or decreases in FTE.

   No Impact.

F. Unique problems or issues and recommendations.

No known problems or issues.

G. Who is expected to be affected, or to oppose or support the proposed regulation? Explain what initial informal contacts have been made with organizations or citizens who may be affected by the regulation prior to the public hearing.

No known supporters or opponents. However, dentists have commented that they have appreciate only having to look at one chapter of the regulations to know what requirements apply to them.

DHHS will solicit public comment on the proposed regulations before the public hearing.

H. <u>Are these proposed rules a likely candidate for negotiated rulemaking? Explain. Has the process been completed? If so, explain how the issues were addressed</u>.

No.

<u>DHHS Division Director's Verification of Review</u>

I have reviewed these proposals and verify that, at this stage of the regulation's development, these questions have been accurately addressed.

_____ _____

Bo Botelho
Interim Director, Division of Public Health
Department of Health and Human Services

Date

TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS IN THE HEALING ARTS

001. SCOPE AND AUTHORITY. This chapter establishes requirements for the use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed according to State statutes to engage in the healing arts, dental healing arts, or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Nebraska Revised Statute (Neb. Rev. Stat.) §§ 71-3501 to 71-3520. The requirements of this chapter are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 18, and 20.

001.01 PART 21 CODE OF FEDERAL REGULATIONS. Part 21 Code of Federal Regulations (CFR) as published on April 1, 2017 and referred throughout this Chapter are incorporated by reference and available for viewing at the Department of Health and Human Services, Division of Public Health, Radiological Health, 301 Centennial Mall South, 3rd Floor, Lincoln, Nebraska 68509.

002. DEFINITIONS. The following definitions apply:

002.01 AIR KERMA RATE (AKR). Air kerma rate (AKR) has the same meaning as set out in 21 CFR §1020.30(b).

002.02 ALUMINUM EQUIVALENT. Aluminum equivalent has the same meaning as set out in 21 CFR §1020.30(b).

002.03 AUTOMATIC EXPOSURE CONTROL (AEC). Automatic exposure control (AEC) has the same meaning as set out in 21 CFR §1020.30(b).

002.04 BARRIER. See “Protective barrier”.

002.05 BEAM-LIMITING DEVICE. Beam-limiting device has the same meaning as set out in 21 CFR §1020.30(b).

002.06 BONE DENSITOMETRY SYSTEMS. A bone densitometry system is a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients.

002.07 C-ARM FLUOROSCOPIC SYSTEM. C-arm fluoroscopic system has the same meaning as set out in 21 CFR §1020.30(b).

002.08 CASSETTE HOLDER. Cassette holder has the same meaning as set out in 21 CFR §1020.30(b).

002.09 COEFFICIENT OF VARIATION OR "C". Coefficient of variation or “C” has the same meaning as set out in 21 CFR §1020.30(b).

002.10 COMPUTED TOMOGRAPHY. Computed tomography has the same meaning as set out in 21 CFR §1020.30(b).

002.11 CONE BEAM COMPUTED TOMOGRAPHY (CBCT). Cone beam computed tomography (CBCT) is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays, and a cone-shaped x-ray beam that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

002.12 CONTINUOUS PRESSURE SWITCH. A continuous pressure switch is a switch constructed so that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

002.13 CONTROL PANEL. Control panel has the same meaning as set out in 21 CFR §1020.30(b).

002.14 COOLING CURVE. Cooling curve has the same meaning as set out in 21 CFR §1020.30(b).

002.15 DENTAL RADIATION GENERATING EQUIPMENT. Dental radiation generating equipment is equipment specifically used for making dental radiographs of the human teeth or tissues or the oral cavity. Dental radiographic equipment does not include dental tomography, dental computed tomography, cone beam dental computed tomography, dental fluoroscopic equipment, or rotating anode tube radiation generating equipment.

002.16 DIAGNOSTIC X-RAY SYSTEM. Diagnostic x-ray system has the same meaning as set out in 21 CFR §1020.30(b).

002.17 EQUIPMENT. See "X-ray equipment".

002.18 EXPOSURE (X). Exposure or “X” has the same meaning as set out in 21 CFR §1020.30(b).

002.19 FACILITY. A facility is the location at which one or more radiation generating devices or sources of radiation are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

002.20 FILTER. A filter is material placed in the useful beam to preferentially absorb selected radiations.

002.21 FLUOROSCOPY. Fluoroscopy has the same meaning as set out in 21 CFR §1020.30(b).

002.22 GENERAL PURPOSE RADIOGRAPHIC X-RAY SYSTEM. General purpose x-ray system has the same meaning as set out in 21 CFR §1020.30(b).

002.23 GONAD SHIELD. A gonad shield is a protective barrier for the testes or ovaries.

002.24 HAND HELD X-RAY EQUIPMENT. Hand held x-ray equipment is equipment that is designed to be hand-held during operation.

002.25 HEALING ARTS SCREENING. A healing arts screening is the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe x-ray tests for the purpose of diagnosis or treatment.

002.26 IMAGE INTENSIFIER. Image intensifier has the same meaning as set out in 21 CFR §1020.30(b).

002.27 IMAGE RECEPTOR. Image receptor has the same meaning as set out in 21 CFR §1020.30(b).

002.28 INTERIM INSPECTION. An interim inspection is an examination by the Department of information submitted by the registrant on a form provided by the Department.

002.29 INTERPRETATIVE FLUOROSCOPIC PROCEDURES. See Neb. Rev. Stat. §38-1904.

002.30 IRRADIATION. Irradiation is the exposure of matter to ionizing radiation.

002.31 KERMA. Kerma has the same meaning as set out in 21 CFR §1020.30(b).

002.32 KILOVOLTS PEAK (KVP). See "Peak tube potential".

002.33 LEAD EQUIVALENT. Lead equivalent is the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

002.34 MOBILE X-RAY EQUIPMENT. See “X-ray equipment”.

002.35 NON-IMAGE-INTENSIFIED FLUOROSCOPY. Non-image-intensified fluoroscopy has the same meaning as set out in 21 CFR §1020.30(b).

002.36 PATIENT. A patient is an individual subjected to healing arts examination, diagnosis, or treatment.

002.37 PEAK TUBE POTENTIAL. Peak tube potential has the same meaning as set out in 21 CFR §1020.30(b).

002.38 PHANTOM. A phantom is a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number, Z, and the density of the material be similar to that of tissue.

002.39 PORTABLE X-RAY EQUIPMENT. See “X-ray equipment”.

002.40 POSITION INDICATING DEVICE (PID). A position indicating device (PID) is a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface of the skin distance. It may or may not incorporate, or serve as, a beam-limiting device.

002.41 PRIMARY PROTECTIVE BARRIER. Primary protective barrier has the same meaning as set out in 21 CFR §1020.30(b).

002.42 PROTECTIVE APRON. A protective apron is an apron made of radiation absorbing materials used to reduce radiation exposure.

002.43 PROTECTIVE GLOVE. A protective glove is a glove made of radiation absorbing materials used to reduce radiation exposure.

002.44 QUALIFIED EXPERT. A qualified expert is an individual who meets the requirements of 180 NAC 15-004.03.

002.45 RADIATION THERAPY SIMULATION SYSTEM. Radiation therapy simulation system has the same meaning as set out in 21 CFR §1020.30(b).

002.46 RADIOGRAPH. A radiograph is an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

002.47 RADIOGRAPHY. Radiography has the same meaning as 21 CFR §1020.30(b).

002.48 RADIOLOGICAL MEDICAL PHYSICIST. A radiological medical physicist is an individual who meets the requirements of 180 NAC 15-004.01.

002.49 RADIOLOGICAL HEALTH PHYSICIST. A radiological health physicist is an individual who meets the requirements of 180 NAC 15-004.02.

002.50 RATING. Rating has the same meaning as set out in 21 CFR §1020.30(b).

002.51 RECORDING. Recording has the same meaning as set out in 21 CFR §1020.30(b).

002.52 SCAN. Scan has the same meaning as set out in 21 CFR §1020.30(b).

002.53 SCAN TIME. Scan time has the same meaning as set out in 21 CFR §1020.30(b).

002.54 SCATTERED RADIATION. Scattered radiation is radiation that during passage through matter has been deviated in direction.

002.55 SHUTTER. A shutter is a device attached to the tube housing assembly which can intercept the entire cross sectional area of the useful beam and has a lead equivalency not less than that of the tube housing assembly.

003.06(B) DENTAL RADIATION GENERATING EQUIPMENT. Registrants using dental radiation generating equipment must have a technique chart displayed in the vicinity of the x-ray machine's control panel.

003.07 WRITTEN SAFETY PROCEDURES. The registrant must create and make available to x-ray operators written safety procedures, to include patient holding and any restriction of the operating technique required for the safe operation of the particular x-ray system. The operator must be able to demonstrate familiarity with these procedures.

003.08 INDIVIDUALS PRESENT DURING A RADIOGRAPHIC EXPOSURE. Except for patients who cannot be moved out of the room only the staff, ancillary personnel, or other persons required for the medical procedure or training may be in the room during the radiographic exposure. Other than the patient being examined:

(A) Each individual must be positioned so that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent;

(B) The x-ray operator, other staff, ancillary personnel, and other persons required for the medical procedure must be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent; and

(C) Human patients who cannot be removed from the room must be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or must be positioned so the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

003.09 GONAD SHIELDING. Except for cases where gonad shielding would interfere with the diagnostic procedure, gonad shielding of not less than 0.5 millimeter lead equivalent must be used for human patients that have not passed the reproductive age during radiographic procedures where the gonads are in the useful beam.

003.10 EXPOSURE TO THE USEFUL BEAM. Individuals must not be exposed to the useful beam except for healing arts purposes unless the exposure has been specifically and individually ordered by a licensed practitioner of the healing arts. This provision prohibits deliberate exposure for the following purposes:

(A) Exposure to an individual for training, demonstration, or other non-healing-arts purposes; and

(B) Exposure to an individual for the purpose of healing arts screening except as authorized by 180 NAC 6-003.14.

003.11 EXPOSURE FOR RESEARCH PURPOSES. Radiation exposure to an individual for research is prohibited, except when the research has been approved by an institutional review board and is conducted under federal regulations for the protection of human subjects in research under 45 CFR §46 (October 1, 2016 edition).

003.12 AUXILIARY SUPPORT. Auxiliary support must be used when a patient or film must be provided with supplemental support during a radiation exposure. The following requirements apply:

(A) When a patient or image receptor must be held in position during radiography, mechanical supporting or restraining devices must be used except in individual cases

where the registrant has determined the devices used for holding are contraindicated. The written safety procedures, required by 180 NAC 6-003.07, must list projections where holding devices cannot be utilized;

(B) The human holder must be instructed in personal radiation safety and protected as required by 180 NAC 6-003.08;

(C) An individual must not be used routinely to hold film or patients;

(D) Written safety procedures, as required by 180 NAC 6-003.07, must indicate the requirements for selecting a holder and the procedure the holder must follow;

(E) In those cases where the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam must be protected by not less than 0.5 millimeter lead equivalent material; and

(F) Each registrant must have leaded protective aprons and protective gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are not shielded.

003.13 PROCEDURES AND EQUIPMENT. Procedures and equipment designed to minimize patient and personnel exposure while providing the needed diagnostic information must be utilized. The following requirements apply:

(A) The speed of film or screen and film combinations must be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens must not be used for any routine diagnostic radiological imaging, with the exception of veterinary radiography;

(B) The radiation exposure to the patient must be the minimum exposure required to produce images of good diagnostic quality;

(C) Portable or mobile x-ray equipment must be used only for examinations where it is not feasible to transfer the patient or patients to a stationary x-ray installation;

(D) X-ray systems subject to this chapter must not be used in procedures where the source to patient distance is less than 30 centimeters, except for veterinary systems; and

(E) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid must be positioned properly and, if the grid is of the focused type, be the proper focal distance for the source to image distance (SID) being used.

003.14 HEALING ARTS SCREENING. An individual requesting to conduct a healing arts screening must submit information about the healing arts screening on a form provided by the Department. If any information submitted to the Department becomes invalid or outdated, the Department must be notified immediately.

003.15 X-RAY ROOM DOORS. Doors that are an integral part of room shielding must be closed during x-ray procedures and must be posted "Close door during x-ray procedures" or words having a similar intent.

003.16 INFORMATION AND MAINTENANCE RECORDS FOR X-RAY SYSTEMS. The registrant must maintain the following records on each x-ray system for inspection by the Department:

(A) The model and serial numbers of all certifiable components, and user's manuals for those components;
(B) The records of surveys, calibrations, maintenance, and modifications performed;
(C) The tube rating charts and cooling curves; and
(D) A copy of all correspondence with the Department regarding each x-ray system.

003.17 X-RAY UTILIZATION LOG. Except for registrants using only dental radiation generating equipment, registrants must maintain an x-ray log or chart containing the patient's identification, the type of examinations, the dates the examinations were performed, and the x-ray equipment operator's name.

003.18 SCALE DRAWING. Except for registrants using only dental radiation generating equipment or bone densitometers, a scale drawing must be available of the room where a stationary x-ray system is located. The drawing must indicate the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in those areas. The drawing must include:
(A) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or
(B) The type and thickness of materials, or lead equivalency, of each protective barrier.

003.19 PLAN REVIEW. Except for registrants using only dental radiation generating equipment or bone densitometers, the following requirements apply:
(A) The floor plans and equipment arrangement of all new installations, modifications of existing installations, or any analysis of operating conditions that indicates an individual may receive a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 or 4-013, must be submitted within 30 days to an individual meeting the requirements of 180 NAC 2-005.04(C) for review and comment; and
(B) All permanent protective barriers must be constructed so the requirements of 180 NAC 4-005, 4-011, and 4-013 will be met.

003.20 X-RAY FILM PROCESSING. A registrant using radiographic film must have equipment for handling and processing radiographic film.

003.20(A) MANUALLY DEVELOPED FILM. The following requirements apply to film that is developed manually:
(i) Processing tanks must be constructed of mechanically rigid, corrosion resistant material; and
(ii) The temperature of solutions in the tanks must be maintained within the range of 60º Fahrenheit to 80º Fahrenheit (16º Celsius to 27º Celsius). Film must be developed according to the time-temperature relationships recommended by the film manufacturer, or, in the absence of those recommendations, with the following time chart:

Time-Temperature Chart		
Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
ºCelsius	ºFahrenheit	
26.7	80	2
26.1	79	2
25.6	78	2.5
25.0	77	2.5
24.4	76	3
23.9	75	3
23.3	74	3.5
22.8	73	3.5
22.2	72	4
21.7	71	4
21.1	70	4.5
20.6	69	4.5
20.0	68	5
19.4	67	5.5
18.9	66	5.5
18.3	65	6
17.8	64	6.5
17.2	63	7
16.7	62	8
16.1	61	8.5
15.6	60	9.5

(iii) Devices must be used that indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required.

(iv) The specified developer temperature and development time must be posted in the darkroom.

003.20(B) AUTOMATIC FILM PROCESSING. Films must be developed according to the time-temperature relationships recommended by the film manufacturer; in the absence of those recommendations, the film must be developed using the following chart:

Developer Temperature (Degrees)		Minimum Immersion Time (Seconds)
ºCelsius	ºFahrenheit	
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23

33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
39.5	85	30
Immersion time only, no crossover time included.		

003.20(C) FILM PROCESSING REQUIREMENTS. Processing deviations and the reason for the deviation from the requirements of 180 NAC 6-003.20 must be documented by the registrant.

003.20(D) DARKROOM REQUIREMENTS. Registrants must maintain a light-tight darkroom, as applicable, use proper safelights and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.

(i) Each darkroom, other than those used for dental, podiatric and veterinary purposes, must use proper safelights so that any film type exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed must not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes must prevent fogging of the film.

003.20(E) FILM. Film must be stored in a cool, dry place and must be protected from exposure to stray radiation. Film in open packages must be stored in a light tight container.

003.20(F) FILM CASSETTES. Film cassettes and intensifying screens must be inspected periodically and must be cleaned and replaced as necessary to assure radiographs of good diagnostic quality.

003.20(G) OUTDATED FILM. Outdated x-ray film must not be used for diagnostic radiographs, except when the film has been stored according to the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

003.20(H) FILM DEVELOPING SOLUTIONS. Film developing solutions must be prepared according to the directions given by the manufacturer and must be maintained in strength by replenishment or renewal, so full development is accomplished within the time specified by the manufacturer.

003.20(I) PASS BOXES. Pass boxes must be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes. Pass Boxes must have adequate shielding from stray radiation to prevent exposure of undeveloped film.

003.20(J) ALTERNATIVE PROCESSING SYSTEMS. The use of daylight processing systems, laser processors, self-processing film systems, or other alternative processing systems will follow manufacturer's recommendations for image processing.

004. GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC AND INTERVENTIONAL X-RAY SYSTEMS. In addition to other requirements of 180 NAC 6-004, all diagnostic and interventional x-ray systems must meet the specifications of 21 CFR §1020.30.

004.01 FILTRATION CONTROL. X-ray systems that have variable kilovolt peak (kVp) and variable filtration for the useful beam must have a device to link the kilovolt peak (kVp) selector with the filter or filters and must prevent an exposure unless the minimum amount of filtration required in 21 CFR §1020.30(m) is in the useful beam for the kVp that has been selected.

004.02 BEAM LIMITATION. The useful beam must be limited to the area of clinical interest.

004.03 MULTIPLE TUBES. When two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated prior to initiation of the exposure. This indication must be on the x-ray control panel and at or near the tube housing assembly that has been selected.

004.04 MECHANICAL SUPPORT OF TUBE HEAD. The tube housing assembly supports must be adjusted so that the tube housing assembly will remain stable during the exposure except when the tube housing movement is a designed function of the x-ray system.

004.05 MAINTAINING COMPLIANCE. Diagnostic x-ray systems and their associated components used on humans and certified under the Federal X-ray Equipment Performance Standard, 21 CFR Part 1020, must be maintained in compliance with applicable requirements of that standard.

004.06 LOCKS. All position locking, holding, and centering devices on x-ray systems components and systems must function as intended.

004.07 EQUIPMENT PERFORMANCE EVALUATION. For all radiation generating equipment, except bone densitometry , veterinary, computed tomography (CT), and cone beam computed tomography (CBCT) the registrant must perform, or cause to be performed, tests necessary to insure the proper function of equipment. These tests must be performed every three years. For dental radiation generating equipment, these tests must be performed every five years. The evaluation must include the following measures.

004.07(A) TIMER. The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy must be within plus or minus 10% of the indicated time with testing performed at 0.5 second.

004.07(B) EXPOSURE REPRODUCIBILITY. When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems will not exceed 0.05. This requirement applies to clinically used techniques.

004.07(C) KILOVOLT PEAK (kVp). The kilovolt peak (kVp) must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the indicated kilovolt peak must be accurate to within plus or minus 10% of the indicated setting or settings. For dental radiation generating equipment, with fewer than three fixed kilovolt peak (kVp) settings, the machine must be checked at those settings.

004.07(D) TUBE STABILITY. The x-ray tube must remain physically stable during exposures. When tubes are designed to move during exposure, the registrant will assure proper and free movement of the radiation generating equipment.

004.07(E) COLLIMATION. Field limitation must meet the requirements of 21 CFR §1020.32(b) for fluoroscopic systems, 21 CFR §1020.31(d) for radiographic systems, 21 CFR §1020.31(f)(1), for dental intraoral equipment, or 21 CFR §1020.31(f)(4) for dental extraoral equipment.

004.07(F) CORRECTION OR REPAIR. Any items not meeting the specifications of the tests must be corrected or repaired. Correction or repair must begin within 30 days following the check and must be performed according to a plan developed by the registrant. Correction or repair must be completed 90 days from discovery unless authorized by the Department.

004.07(G) IN-AIR EXPOSURE. A measurement of the in-air exposure or exposures at a technique factor or factors for an average adult thickness for the most common procedure or procedures performed.

004.07(H) DOSIMETRY SYSTEM. The measurement of the radiation output of an x-ray system must be performed with a calibrated dosimetry system. The calibration of that system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years. During the calendar year the dosimetry system is not calibrated, an intercomparison to a system calibrated within the previous 12 months must be performed.

005. FLUOROSCOPIC X-RAY SYSTEMS. Fluoroscopic x-ray systems must meet the machine performance standards of 21 CFR §1020.32. Use of non-image intensified fluoroscopic equipment is prohibited. The provisions of this chapter apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography (CT) x-ray systems manufactured on or after November 29, 1984.

005.01 PERIODIC MEASUREMENT OF AIR KERMA RATE (AKR). A periodic measurement of air kerma rate (AKR) must be performed as follows.

005.01(A) MEASUREMENTS OF AIR KERMA RATE (AKR). Measurements must be made for both typical and maximum values of the air kerma rate (AKR), materials may be placed in the useful beam to protect the imaging system when performing the periodic measurements.

005.01(A)(i) Measurements must be made annually or after any maintenance of the system which might affect the air kerma rate (AKR.

005.01(A)(ii) For units manufactured before June 10, 2006, results of the measurements must be posted where a fluoroscopist may have access to those results while using the fluoroscope.

005.01(B) RECORDS OF MEASUREMENTS OF AIR KERMA RATE (AKR).The measurement results may be stated in roentgens per minute (R/min) or milliGray per minute (mGy/min). The results must include the technique factors used to determining the results, the name of the individual that performed the measurements, and the date the measurements were performed.

005.01(C) CONDITIONS OF PERIODIC MEASUREMENT OF TYPICAL AIR KERMA RATE (AKR). The following conditions apply to the periodic measurement of the typical Air Kerma Rate (AKR):

(i) The measurement must be made under the conditions that satisfy the requirements of 21 CFR §1020.32(d)(3);
(ii) Fluoroscopic systems that do not incorporate automatic exposure rate control (AERC) must use a milliamperage (mA) and kilovolt peak (kVp) typical of clinical use of the fluoroscopic system; and
(iii) Fluoroscopic systems that incorporate automatic exposure rate control (AERC) must have sufficient material placed in the useful beam to produce a milliamperage (mA) and kilovolt peak (kVp) typical of the clinical use of the fluoroscopic system.

005.01(D) CONDITIONS OF PERIODIC MEASUREMENT OF MAXIMUM AIR KERMA RATE (AKR). The following conditions apply to the periodic measurement of the maximum air kerma rate (AKR):

(i) The measurement must be made under the conditions that satisfy the requirements of 21 CFR §1020.32(d)(3);
(ii) Fluoroscopic systems that do not incorporate automatic exposure rate control (AERC) must be adjusted to those settings which give the maximum air kerma rate (AKR); and
(iii) Fluoroscopic systems that incorporate automatic exposure rate control (AERC) must have sufficient material placed in the useful beam to produce the maximum air kerma rate (AKR) of the system.

005.02 CONTROL OF SCATTERED RADIATION. The following requirements apply to controlling the scatter of radiation.

005.02(A) FLUOROSCOPIC TABLE DESIGNS. Fluoroscopic table designs, when combined with the procedures performed at the registrant’s facility, must ensure that no unprotected part of any staff or ancillary individual's body is exposed to unattenuated scattered radiation that originates from under the table. The attenuation provided must be not less than 0.25 millimeter lead equivalent.

005.02(B) EQUIPMENT CONFIGURATION. Equipment configuration, when combined with procedures performed at the registrant’s facility, must ensure that no portion of any staff or ancillary individual's body, except the extremities, is exposed to the unattenuated scattered radiation that originates from above the tabletop unless:

(i) That individual is 120 centimeters from the center of the useful beam; or

(ii) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, bucky-slot cover panel, or self-supporting curtains. This requirement is in addition to any lead equivalency provided by the protective apron specified in 180 NAC 003.08.

005.02(C) EXEMPTIONS TO THE USE OF PROTECTIVE BARRIERS. When a sterile field will not permit the use of the normal protective barriers or drapes, the shielding required by 180 NAC 6-005.02(B) must be maintained to the degree possible under the clinical conditions.

005.03 FLUOROSCOPIC RADIATION THERAPY SIMULATION SYSTEMS. Fluoroscopic radiation therapy simulation systems are exempt from the requirements of 180 NAC 6-005.01. In addition, these systems are exempt from the requirements of 21 CFR §1020.32(a) provided these systems are designed and used in a manner that no individual other than the patient is in the x-ray room during the time the system is producing x-rays.

005.04 EQUIPMENT OPERATION. The following requirements apply to the operation of fluoroscopic equipment.

005.04(A) Images formed by the use of fluoroscopic x-ray systems must be under the direction of and interpreted by a licensed practitioner of the healing arts.

005.04(B) Only a licensed practitioner may perform interpretative fluoroscopic procedures.

005.04(C) Fluoroscopy must not be used as a positioning tool for general purpose radiographic examinations.

005.04(D) Operators must be competent in the standard operating procedures of the unit in use.

005.04(E) Registrants must maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record must include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

006. REQUIREMENTS FOR RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, BONE DENSITOMETRY, VETERINARIAN, OR COMPUTED TOMOGRAPHY (CT) X-RAY SYSTEMS. In addition to the requirements of 180 NAC 6-006, radiographic systems other than fluoroscopic, bone densitometry, veterinarian, or computed tomography (CT), must meet the specifications of 21 CFR §1020.31.

006.01 INITIATION AND INDICATION OF RADIATION EXPOSURE. The following apply to the initiation and indication of radiation exposure.

006.01(A) EXPOSURE INITIATION. Means must be provided to initiate the radiation exposure by a deliberate action on the part of the operator. In addition, it must not be possible to initiate an exposure when the timer is set to a “zero” or ”off” position if either position is provided.

006.01(B) EXPOSURE INDICATION. Means must be provided for visual indication, observable at or from the operator's protected position, whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated.

006.01(C) OPERATOR PROTECTION. Initiation of the production of x-rays must occur in an area that protects the operator from radiation exposure.

006.01(C)(i) STATIONARY X-RAY SYSTEMS. Stationary x-ray systems must have the x-ray control, including the exposure switch, permanently mounted in a protected area so that the operator must remain in that protected area during the entire exposure.

006.01(C)(ii) DENTAL X-RAY SYSTEMS. The x-ray control for dental x-ray systems must be positioned so the operator must stand at least six feet from the useful beam or behind a protective barrier, except when using units designed to be hand-held.

006.01(D) EXPOSURE CONTROL LOCATION. The x-ray exposure control must be placed so the operator can maintain verbal, aural, and visual contact with the patient while making any exposure.

006.02 TUBE STANDS FOR PORTABLE X-RAY SYSTEMS. A tube stand or other mechanical support must be used for portable x-ray systems so the x-ray tube housing assembly is not hand-held during exposures.

007. VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS. This section applies to registrants using x-ray generating equipment in veterinary medicine.

007.01 VETERINARY MEDICINE EQUIPMENT REQUIREMENTS. Radiation generating equipment used in veterinary medicine must meet the following requirements:

(A) The protective tube housing must be constructed to meet the specifications of 21 CFR §1020.30(k);
(B) Diaphragms or cones must be provided for collimating the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the tube housing;
(C) The total filtration permanently in the useful beam must not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kilovolt peak (kVp), 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kilovolt (kVp), and 2.5 millimeters aluminum equivalent for machines operating above 70 kilovolt peak (kVp);
(D) A device must be provided to terminate the exposure after a preset time or exposure; and
(E) A continuous pressure type of exposure switch must be provided, with an electrical cord of adequate length, so the operator can stand out of the useful beam and at least 6 feet (1.83 meters) from the animal during all x-ray exposures.

007.02 OPERATING PROCEDURES. The following requirements apply to the operation of x-ray generating equipment used in veterinary medicine.

007.02(A) The operator must be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or must be positioned so the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor.

007.02(B) When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, the individual must be protected with appropriate shielding devices, and be positioned so no part of the body will be struck by the useful beam.

007.03 VETERINARY ASSISTANT OR VETERINARY TECHNICIAN TRAINING REQUIREMENTS. Veterinary assistants and veterinary technicians must meet the following requirements prior to operating x-ray generating equipment:

(A) Eight hours of classroom instruction in the fundamentals of radiation safety, radiographic equipment, state regulations, and operating and emergency procedures; or

(B) Be a graduate of an accredited veterinarian technician's program.

008. COMPUTED TOMOGRAPHY (CT) AND CONE BEAM COMPUTED TOMOGRAPHY (CBCT) SYSTEMS. This section applies to registrants using computed tomography (CT) systems and cone beam computed tomography (CBCT) systems.

008.01 DEFINITIONS. In addition to the definitions provided in 180 NAC 1-002 and 180 NAC 6-002, the following definitions apply to 180 NAC 6-008.

008.01(A) CONTRAST SCALE. Contrast scale has the same meaning as 21 CFR §1020.33(b).

008.01(B) COMPUTED TOMOGRAPHY (CT) CONDITIONS OF OPERATION. Computed tomography (CT) conditions of operation are all selectable parameters governing the operation of a computed tomography (CT) system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in this chapter.

008.01(C) COMPUTED TOMOGRAPHY (CT) NUMBER. Computed tomography (CT) number has the same meaning as set out in 21 CFR §1020.33(b).

008.01(D) NOISE. Noise has the same meaning as set out in 21 CFR §1020.33(b).

008.01(E) NOMINAL TOMOGRAPHIC SECTION THICKNESS. Nominal tomographic section thickness has the same meaning as set out in 21 CFR §1020.33(b).

008.01(F) REFERENCE PLANE. Reference plane is a plane which is displaced from and parallel to the tomographic plane.

008.01(G) SCAN. Scan is the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

008.01(H) SCAN INCREMENT. Scan increment has the same meaning as set out in 21 CFR §1020.33(b).

008.01(I) SCAN SEQUENCE. Scan sequence has the same meaning as set out in 21 CFR §1020.33(b).

008.01(J) TOMOGRAPHIC PLANE. Tomographic plane has the same meaning as set out in 21 CFR §1020.33(b).

008.01(K) TOMOGRAPHIC SECTION. Tomographic section has the same meaning as set out in 21 CFR §1020.33(b).

008.02 COMPUTED TOMOGRAPHY (CT) AND CONE BEAM COMPUTED TOMOGRAPHY (CBCT) EQUIPMENT REQUIREMENTS. Computed tomography (CT) and cone beam computed tomography (CBCT) equipment must meet the following requirements, except for fluoroscopic systems capable of performing cone beam computed tomography (CBCT).

008.02(A) TERMINATION OF EXPOSURE. The timer must meet the specifications of 21 CFR §1020.33(f)(2).

008.02(B) TOMOGRAPHIC PLANE INDICATION AND ALIGNMENT. Tomographic plane indication and alignment must meet the specifications of 21 CFR §1020.33(g).

008.02(C) BEAM-ON AND SHUTTER STATUS INDICATORS AND CONTROL SWITCHES. Visual indication of x-ray production and shutter status must meet the specifications of 21 CFR §1020.33(h). Each emergency button or switch must be clearly labeled as to its function.

008.02(D) INDICATION OF CONDITIONS OF OPERATION. Visual indication of the conditions of operation to be used during a scan or scan sequence must meet the specifications of 21 CFR §1020.33(f).

008.02(E) SCAN INCREMENT ACCURACY. The accuracy of scanning increments must meet the specifications of 21 CFR §1020.33(i).

008.02(F) MEAN AND STANDARD DEVIATION. The method used to calculate the mean and standard deviation must meet the specifications of 21 CFR §1020.33(j).

008.03 FACILITY DESIGN REQUIREMENTS. Registrants using computed tomography (CT) equipment must meet facility design specifications.

008.03(A) AURAL COMMUNICATION. There must be two-way aural communication between the patient and the operator at the control panel.

008.03(B) VIEWING SYSTEMS. Viewing systems must include the following:

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

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

008.04 PLAN REVIEWS, CALIBRATIONS, SPOT CHECKS, AND OPERATING PROCEDURES. Plan reviews, calibration, spot checks and operating procedures for computed tomography (CT) and cone beam computed tomography (CBCT) systems must meet the following requirements..

008.04(A) PLAN REVIEWS. For computed tomography (CT) and cone beam computed tomography (CBCT) x-ray systems, the plan review required by 180 NAC 6-003.19 must be performed by, or under the direction of, a radiological medical physicist or radiological health physicist meeting the requirements of 180 NAC 2-005.04(C)(ii). In addition, radiation surveys must be performed after any change in the registrant's facility or equipment that might cause an individual to receive a dose in excess of the limits prescribed in 180 NAC 4-005, 4-011 or 4-013.

008.04(B) PLAN REVIEW RESULTS. The registrant must obtain a written report of the results of the plan review from the radiological medical physicist or radiological health physicist. A copy of the report must be maintained for inspection by the Department.

008.04(C) RADIATION CALIBRATIONS OF COMPUTED TOMOGRAPHY (CT) AND CONE BEAM COMPUTED TOMOGRAPHY (CBCT) SYSTEMS. The calibration of radiation output of computed tomography (CT) or cone beam computed tomography (CBCT) system must be performed by, or under the direction of, a radiological medical physicist or radiological health physicist meeting the requirements of 180 NAC 2-005.04(C)(ii) who is physically present at the registrant's facility during the calibration. Calibration procedures must be in writing.

008.04(C)(i) FREQUENCY OF CALIBRATION. The calibration of a computed tomography (CT) or cone beam computed tomography (CBCT) system must be performed after initial installation, prior to the first use on a patient, and at intervals specified by a radiological medical physicist or radiological health physicist, not to exceed two years. Additionally, a calibration must be performed by a radiological medical physicist or radiological health physicist within 30 days after any change or replacement of components that, in the opinion of the radiological medical physicist or radiological health physicist, could cause a change in the radiation output. Calibration of a computed tomography (CT) system must include the spot-checks specified in 180 NAC 6-008.05(A)(ii). Calibration of a cone beam computed tomography (CBCT) system must include the quality control checks specified in 180 NAC 6-008.07(C).

008.04(C)(ii) DOSIMETRY SYSTEM. The measurement of the radiation output of a computed tomography (CT) or cone beam computed tomography (CBCT) system must be performed with a calibrated dosimetry system. The calibration of that system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years.

008.04(C)(iii) DOSIMETRY PHANTOMS. Computed tomography (CT) dosimetry phantom or phantoms must be used to ensure the computed tomography (CT) system meets the specifications of 21 CFR §1020.33(b)(6).

008.04(C)(iv) HEAD, BODY, OR WHOLE-BODY SCANS. A computed tomography (CT) system must be calibrated for each type of head, body, or whole-body scan or scans performed at the registrant's facility to ensure that the system meets the specifications of 21 CFR §1020.33(c)(2).

008.04(C)(v) RECORDS OF COMPUTED TOMOGRAPHY (CT) CALIBRATIONS AND CONE BEAM COMPUTED TOMOGRAPHY (CBCT). Records of calibrations performed must be maintained for inspection by the Department.

008.05 SPOT CHECKS OF COMPUTED TOMOGRAPHY (CT) EQUIPMENT. Spot-check procedures must be in writing and must be developed by a radiological medical physicist or radiological health physicist.

008.05(A) SPOT-CHECK PROCEDURES. Spot-check procedures must include the following:

(i) Use of a computed tomography (CT) phantom or phantoms that meets the requirements of 21 CFR §1020.33(d)(1);

(ii) A check of the contrast scale, noise, nominal tomographic section thickness, spatial resolution of the system for low and high contrast objects, and a measurement of the mean computed tomography (CT) number of water or a reference material; and

(iii) Acquisition of images must be obtained with the computed tomography (CT) phantom or phantoms using the same processing mode and computed tomography (CT) conditions of operation used to perform calibrations required by this chapter.

008.05(B) FREQUENCY OF SPOT-CHECKS. All spot checks must be performed at the frequency and under system conditions specified by a radiological medical physicist or radiological health physicist.

008.05(C) SPOT-CHECK RECORDS. Records of the spot-checks performed must be maintained for inspection by the Department.

008.06 OPERATING PROCEDURES FOR COMPUTED TOMOGRAPHY (CT) SYSTEMS. Registrants must develop written operating procedures for computed tomography (CT) systems as follows.

008.06(A) OPERATION OF THE COMPUTED TOMOGRAPHY (CT) SYSTEM. The system must only be operated by an individual who has been specifically trained in its operation and meets the requirements of 180 NAC 6-003.05.

008.06(B) INFORMATION ON OPERATION AND CALIBRATION. Information must be available in the operator control area regarding the operation and calibration of the system. The information must include:

(i) Dates of the latest calibration and spot-checks and the location where the results of those tests may be found;
(ii) Instructions on the use of the computed tomography (CT) phantom or phantoms including a schedule of spot-checks appropriate for the system, allowable variations for the indicated parameters, and the results of the most recent spot-checks performed on the system;
(iii) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and
(iv) A current technique chart available at the control panel which specifies, for each routine examination, the computed tomography (CT) conditions of operation and the number of scans for each examination.

008.06(C) OPERATING PARAMETERS. If the calibration or spot-check of the computed tomography (CT) system identifies that a system operating parameter has exceeded a tolerance established by the radiological medical physicist or radiological health physicist, use of the system on patients must be limited to those permitted by written instructions of the radiological medical physicist or radiological health physicist.

008.07 CONE BEAM COMPUTED TOMOGRAPHY (CBCT) SYSTEMS. In addition to other requirements of this chapter, this section applies to registrants using with cone beam computed tomography (CBCT) systems.

008.07(A) OPERATION OF THE CONE BEAM COMPUTED TOMOGRAPHY (CBCT) SYSTEM. The cone beam computed tomography (CBCT) system must only be operated by an individual who has been specifically trained in its operation and meets the requirements of 180 NAC 6-003.05.

008.07(B) BEAM ALIGNMENT. The x-ray field in the plane of the image receptor must not exceed beyond the edge of the image receptor by more than two percent of the source-to-image distance (SID) when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field must be aligned with the center of the image receptor to within 2 percent of the source-to-image distance (SID).

008.07(C) QUALITY CONTROL. The registrant must follow the quality control recommendations of the manufacturer. If manufacturer recommendations are not obtainable, the registrant must perform quality control on the cone beam computed tomography (CBCT) system that has been developed by a radiological medical physicist or radiological health physicist.

008.07(D) INFORMATION FOR THE CONE BEAM COMPUTED TOMOGRAPHY (CBCT) OPERATOR. The following information must be readily available to the operator of the cone beam computed tomography (CBCT) system:
(i) Instructions on performing quality control on the cone beam computed tomography (CBCT) system;
(ii) The time interval for performing quality control on the cone beam computed tomography (CBCT) system;
(iii) The allowable uses of the cone beam computed tomography (CBCT) system if a quality control check identifies a system operating parameter has exceeded a

tolerance established by the manufacturer. If tolerances from the manufacturer are not obtainable, a radiological medical physicist or radiological health physicist must establish the tolerances and the cone beam computed tomography (CBCT) system must be limited to those uses allowed by the radiological medical physicist or radiological health physicist; and

(iv) The results of the most recent quality control completed on the cone beam computed tomography (CBCT) system.

009. DENTAL REGISTRANTS. In addition to other requirements of this chapter, this section applies to registrants using dental radiation generating equipment.

009.01 EXEMPTION FROM INDIVIDUAL MONITORING. Individual monitoring is not required for personnel operating only dental radiation generating equipment for dental diagnostic purposes.

009.02 TUBE HOUSING. The tube housing and position indicating device (PID) must not be hand-held during an exposure, except for units designed to be hand-held.

009.03 TUBE HOUSING SUPPORT. The tube housing support must be constructed and adjusted so that the tube housing will not drift from its set position during an exposure.

009.04 X-RAY CONTROL. Each x-ray system must have a control that allows the operator to terminate the exposure at any time, except for exposures of 0.5 second or less. The exposure switch will be of the continuous pressure type.

009.05 SOURCE-TO-SKIN DISTANCE (SSD). X-ray systems designed for use with an intraoral image receptor must be provided with means to limit the source-to-skin distance (SSD) to meet the requirements of 21 CFR §1020.31(i).

009.06 KVP LIMITATIONS. Dental x-ray radiation generating equipment with a fixed kilovolt peak (kVp) of less than 50 kilovolt peak (kVp) must not be used to make diagnostic dental radiographs of humans.

009.07 DENTAL INTERIM INSPECTIONS. This subsection addresses interim inspections of dental registrants.

009.07(A) INTERIM INSPECTIONS. For interim inspections of dental radiation generating equipment, each registrant must:

(i) Respond to a request from the Department for an interim inspection;

(ii) Complete the Interim Inspection Form NRH-6. Form NRH-6 is set out as Attachment 1 to this chapter; and

(iii) Return the completed interim inspection form with documentation of the most recent equipment performance evaluation or evaluations performed according to 180 NAC 6-004.07 by the deadline indicated in the inspection notice.

010. HAND-HELD DENTAL AND VETERINARY EQUIPMENT. In addition to the requirements of this chapter, hand-held dental and veterinary equipment must meet these requirements.

010.01 BACKSCATTER SHIELD. Hand-held dental and veterinary equipment must be equipped with a backscatter shield of at least 0.25 millimeter (mm) lead equivalent and be at least 15.2 centimeters (cm) in diameter. The shield must be positioned as close as practical to the distal end of the position indicating device (PID).

010.02 MANUFACTURER TRAINING. Individuals operating hand-held dental and veterinary equipment must complete training as specified by the manufacturer.

010.03 MANUFACTURER PROTOCOLS. Registrants with hand-held dental and veterinary equipment must follow manufacturer protocols for the safe operation of the equipment.

010.04 UNAUTHORIZED REMOVAL OR USE. The registrant must secure hand-held dental and veterinary equipment from unauthorized removal or use.

010.05 EXPOSURE PREVENTION. Hand-held dental or veterinary equipment must be kept in a mode that prevents an exposure when the device is not being used.

NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

Attachment 1

Form NRH-6
Effective Date

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH
X-RAY PROGRAM

DENTAL INTERIM INSPECTION FORM

Registration Number: _____ **Date:** _____
Name: _____
Address: _____ **City, State, Zip:** _____
_____ _____
Phone Number: _____
Email: _____ **Fax Number:** _____

- Complete this form and return it to this Department by the date specified in the enclosed letter.
- Submit copies of the most recent equipment performance evaluation results for each dental radiation generating equipment.

1.	Yes	No		Has your registration of radiation generating equipment expired? (180 NAC 2)
2.	Yes	No		Is all operable dental radiation generating equipment at this facility properly registered? (180 NAC 2)
3.	Yes	No		Has your service provider performed equipment performance evaluations on all dental radiation equipment at the facility at the required five year interval? (180 NAC 6-004.07)

Comments:

Form Completed by: _____ Date _____

- Please retain a copy of this completed inspection form for your records

TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS OTHER THAN DENTAL RADIATION GENERATING EQUIPMENT IN THE HEALING ARTS

APPENDIXES

Copies of the Code of Federal Regulations (CFR) cited in this Chapter are located at:
http://www.gpoaccess.gov/cfr/index.html

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EFFECTIVE DATE NEBRASKA DEPARTMENT OF
NOVEMBER 28, 2016 HEALTH AND HUMAN SERVICES 180 NAC 6

TITLE 180 CONTROL OF RADIATION

CHAPTER 6 DIAGNOSTIC X-RAYS OTHER THAN DENTAL RADIATION GENERATING EQUIPMENT IN THE HEALING ARTS

6-001 SCOPE AND AUTHORITY

6-001.01 180 NAC 6 establishes requirements, for which a registrant is responsible, for use of diagnostic x-ray equipment and imaging systems by or under the supervision of an individual authorized by and licensed in accordance with State statutes to engage in the healing arts or veterinary medicine. The regulations are authorized by and implement the Nebraska Radiation Control Act, Neb. Stat. Rev. §§ 71-3501 to 71-3520. Remains in section 001 as modified.

6-001.02 The use of x-ray equipment for the intentional exposure of individuals for diagnosis or treatment must be by or under the supervision of one licensed to practice the healing arts in Nebraska. Moved to section 003.01.

6-001.03 The use of x-ray equipment in the practice of veterinary medicine must be by or under the supervision of an individual licensed to practice veterinary medicine in the State of Nebraska. Moved to section 003.02.

6-001.04 The provisions of 180 NAC 6 are in addition to, and not in substitution for, other applicable provisions of 180 NAC 1, 2, 4, 9, 10, 15, 16, 17 , 18, and 20. Remains in section 001 as modified.

6-002 DEFINITIONS: As used in Title 180, the following definitions apply:

Accessible surface means the external surface of the enclosure or housing provided by the manufacturer.

Accessory component means:

(1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of 180 NAC 6 but which requires an initial determination of compatibility with the system; or

(2) A component necessary for compliance of the system with applicable provisions of 180 NAC 6 but which may be interchanged with similar compatible components without affecting the system's compliance, such as one of a set of interchangeable beam-limiting devices; or

(3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder.

Air kerma means kerma in air [see definition of "Kerma"]

Air kerma rate (AKR) means the air kerma per unit time. Remains in section 002 as modified.

Aluminum equivalent means the thickness of type 1100 aluminum alloy[1] affording the same attenuation, under specified conditions, as the material in question Remains in section 002 as modified.

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

Attenuation block means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[2] or other materials having equivalent attenuation.

Automatic exposure control (AEC) means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation (Includes devices such as phototimers and ion chambers). Remains in section 002 as modified.

Automatic exposure rate control (AERC) means a device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

Barrier [See "Protective barrier"] Remains in section 002 as modified.

Beam axis means a line from the source through the centers of the x-ray fields.

Beam-limiting device means a device that provides a means to restrict the dimensions of the x-ray field. Remains in section 002 as modified.

Bone densitometry systems means a medical device which uses electronically-produced ionizing radiation to determine the density of bone structures of human patients. Remains in section 002 as modified.

C-arm fluoroscopic system means an x-ray system in which the image receptor and x-ray tube housing assembly are connected or coordinated to maintain a desired spatial relationship. Such a system allows a change in the directions of the beam axis with respect to the patient. Remains in section 002 as modified.

Certified diagnostic x-ray components means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968 because they come within the definitions in Section 355 (1) and (2) of that law, attached hereto as Attachment Number 6-1 and incorporated herein by this reference.

[1]The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, maximum 0.12 percent copper.
[2]Ibid.

Cassette holder means a device, other than a spot-film device, that supports and/or fixes the position of an x-ray film [imaging] cassette during an x-ray exposure. Remains in section 002 as modified.

Coefficient of variation or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation: Remains in section 002 as modified.

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}(x_1 - \bar{x})^2}{n-1}\right]^{1/2}$$

where

s = Estimated standard deviation of the population.
X = Mean value of observations in sample.
X_i = i^{th} observation in sample.
n = Number of observations in sample.

Computed tomography means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. Remains in section 002 as modified.

Control panel means that part of the x-ray control upon which are mounted the switches, knobs, push-buttons, and other hardware necessary for manually setting the technique factors. Remains in section 002 as modified.

Cooling curve means the graphical relationship between heat units stored and cooling time. Remains in section 002 as modified.

Cradle means:

(1) A removable device which supports and may restrain a patient above an x-ray table; or

(2) A device:

(i) Whose patient support structure is interposed between the patient and the image receptor during normal use;

(ii) Which is equipped with means for patient restraint; and

(iii) Which is capable of rotation about its long (longitudinal) axis.

"CT" [See "Computed tomography"]

CT gantry means tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold and/or enclose these components.

Cumulative air kerma means the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Deadman switch means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector [See "Radiation detector"]

Diagnostic source assembly means the tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system means an x-ray system designed for irradiation of any part of the human [or animal] body for the purpose of diagnosis or visualization. Remains in section 002 as modified.

Direct scattered radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam [See "Scattered radiation"].

Equipment [See "X-ray equipment"] Remains in section 002 as modified.

Exposure (X) means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation. Remains in section 002 as modified.

Field emission equipment means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter means material placed in the useful beam to preferentially absorb selected radiations. Remains in section 002 as modified.

Fluoroscopic imaging assembly means a subsystem in which x-ray photons produce a visible fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time means the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

Fluoroscopy means a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission. Remains in section 002 as modified.

Focal spot (actual) means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions. Remains in section 002 as modified.

Gonad shield means a protective barrier for the testes or ovaries. Remains in section 002 as modified.

Developer Temperature		Minimum Immersion Time[a/]
°C	°F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30
[a/] *Immersion time only, no crossover time included.*		

c. Processing deviations from the requirements of 180 NAC 6-003.04 item 1 must be documented by the registrant in such manner that the requirements are shown to be met or exceeded (e.g., extended processing, and special rapid chemistry). Remains in section 003 as modified.

2. Other Requirements.

a. The darkroom must be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed must not suffer an increase in density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes must preclude fogging of the film. Remains in section 003 as modified.

b. Film must be stored in a cool, dry place and must be protected from exposure to stray radiation. Film in open packages must be stored in a light tight container. Remains in section 003 as modified.

c. Film cassettes and intensifying screens must be inspected periodically and must be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality. Remains in section 003 as modified.

d. Outdated x-ray film must not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed. Remains in section 003 as modified.

e. Film developing solutions must be prepared in accordance with the directions given by the manufacturer, and must be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer. Remains in section 003 as modified.

f. Pass boxes, if provided, must be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film. Remains in section 003 as modified.

6-004 GENERAL REQUIREMENTS FOR ALL DIAGNOSTIC X-RAY SYSTEMS: In addition to other requirements of 180 NAC 6-004 all diagnostic x-ray systems must meet the following requirements: Remains in section 004 as modified.

6-004.01 Warning Label: The control panel containing the main power switch must bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

6-004.02 Battery Charge Indicator: On battery-powered x-ray generators, visual means must be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

6-004.03 Leakage Radiation from the Diagnostic Source Assembly: The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source must not exceed 0.88 milligray (mGy) air kerma (100 milliroetgen (mR)exposure) in 1 hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means must be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.04 Radiation from Components Other Than the Diagnostic Source Assembly: The radiation emitted by a component other than the diagnostic source assembly must not exceed an air kerma of 18 microgray (2 milliroentgens exposure) in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance must be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

6-004.05 Beam Quality

1. Half-value Layer: The half-value layer of the useful beam for a given x-ray tube potential must not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table #I, linear interpolation or extrapolation may be made. Positive means must be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system, which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked

~~with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.~~

TABLE I

Design Operating Range	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		All Other Diagnostic X-Ray Systems\1\	All Other Diagnostic X-Ray Systems\2\
Below 51	30	0.3	0.3
	40	0.4	0.4
	50	0.5	0.5
51 to 70	51	1.2	1.3
	60	1.3	1.5
	70	1.5	1.8
Above 70	71	2.1	2.5
	80	2.3	2.9
	90	2.5	3.2
	100	2.7	3.6
	110	3.0	3.9
	120	3.2	4.3
	130	3.5	4.7
	140	3.8	5.0
	150	4.1	5.4

\1\ All x-ray systems manufactured before June 10, 2006.
\2\ All x-ray systems manufactured on or after June 10, 2006.

2. Filtration Control:

a. Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of 1 kilowatt or more and an anode heat storage capacity of 1 million heat units or more must provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of this subsection. The selection of this additional x-ray filtration must be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam must be provided.

b. For x-ray systems which have variable kVp and variable filtration for the useful beam, a device must link the kVp selector with the filter(s) and must prevent an exposure unless the minimum amount of filtration required by 180

NAC 6-004.05, item 1.a. is in the useful beam for the given kVp which has been selected. Remains in section 004 as modified.

3. Measuring compliance. For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

6-004.06 Modification of certified diagnostic x-ray components and systems.

1. Diagnostic x-ray components and systems certified in accordance with 21 CFR Part 1020 must not be modified such that the component or system fails to comply with any applicable provision of this 180 NAC 6-004.

2. The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this 180 NAC 6. The owner who causes such modification need not submit the reports required by 180 NAC 6, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with 180 NAC 6-004.

6-004.07 Multiple Tubes: Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected must be clearly indicated prior to initiation of the exposure. This indication must be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

6-004.08 Mechanical Support of Tube Head: The tube housing assembly supports must be adjusted such that the tube housing assembly will remain stable during the exposure unless the tube housing movement is a designed function of the x-ray system.

6-004.09 Technique Indicators

1. The technique factors to be used during an exposure must be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure must be indicated.
2. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors must be visible from the operator's position except in the case of spot films made by the fluoroscopist.

6-004.10 Maintaining Compliance: Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-ray Equipment Performance Standard (21 CFR Part 1020) must be maintained in compliance with applicable requirements of that standard.

6-004.11 Locks: All position locking, holding, and centering devices on x-ray systems components and systems must function as intended.

6-004.12 Equipment Performance Evaluation: For all radiation generating equipment, except Bone Densitometry , Veterinary and Computed Tomography (CT), the registrant must perform

or cause to be performed, tests necessary to insure the proper function of equipment and a measurement of the in air exposure(s) at the technique factor(s) for an average adult thickness for most common procedure(s) preformed at the facility. At a minimum these tests must be at least performed every three years and must include: Remains in section 004 as modified.

1. Timer:

a. The accuracy of the timer must meet the manufacturer's specifications. If the manufacturer's specifications are not obtainable, the timer accuracy must be ±10% of the indicated time with testing performed at 0.5 second. Remains in section 004 as modified.

b. Means must be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it must not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

2. Exposure Reproducibility: When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems will not exceed 0.05. Remains in section 004 as modified.

3. Kilovolt Peak: If the registrant possesses documentation of the appropriate manufacturer's kilovolt peak specifications, the radiation machine must meet those specifications. If the registrant does not possess documentation of the appropriate manufacturer's kilovolt peak specifications, the indicated kilovolt peak must be accurate to within ± 10% of the indicated setting(s). Remains in section 004 as modified.

4. Tube Stability: The x-ray tube must remain physically stable during exposures. In cases where tubes are designed to move during exposure, the registrant will assure proper and free movement of the radiation generating equipment.

5. Collimation: Field limitation must meet the requirements of 180 NAC 6-005.01, item 2 and 6-006.01, item 1. Remains in section 004 as modified.

6. Any items not meeting the specifications of the tests must be corrected or repaired. Correction or repair must begin within 30 days following the check and must be performed according to a plan designated by the registrant. Correction or repair must be completed no longer than 90 days from discovery unless authorized by the Department. Records of corrections or repairs will be maintained by the registrant in accordance with 180 NAC 6-003.01, item 2. Remains in section 004 as modified.

6-005 FLUOROSCOPIC X-RAY SYSTEMS: Use of nonimage intensified fluoroscopic equipment is prohibited. All fluoroscopic x-ray systems must meet the following requirements: The provisions of this 180 NAC 6-005 apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984. Remains in section 005 as modified.

6-005.01 Primary Protective Barrier

1. Limitation of useful beam: The fluoroscopic imaging assembly must be provided with a primary protective barrier which intercepts the entire cross-section of the useful beam at any SID. The x-ray tube used for fluoroscopy must not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor must not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems will be exempt from this requirement provided the systems are intended only for remote control operation.

2. Measuring compliance: The AKR must be measured in accordance with 180 NAC 6-005.01, item 1. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor must be determined by measurements averaged over an area of 100 square cm with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement must be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement must be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices must be removed from the useful beam during the measurement. For all measurements, the attenuation block must be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

6-005.02 Field Limitation

1. Angulation: For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with 180 NAC 6-005.02, item 3 and 4 will be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. Further means for limitation: Means must be provided to permit further limitation of the x-ray field to sizes smaller than the limits of 180 NAC 6-005.02, item 3 and 4. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or capability of a visible area of greater than 300 square cm, must be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square cm must be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square cm or less. Stepless adjustment must, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm. 180 NAC 6-005.02, item 2 does not apply to non-image-intensified fluoroscopy.

3. Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors:

a. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

(1) Neither the length nor width of the x-ray field in the plane of the image receptor must exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width must be no greater than 4 percent of the SID.
(2) For rectangular x-ray fields used with circular image receptors, the error in alignment must be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

b. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation simulation systems, the maximum area of the x-ray field in the plane of the image receptor must conform with one of the following requirements:

(1) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent of the area of the x-ray field overlaps the visible area of the image receptor, or
(2) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm.

4. Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors: For x-ray systems manufactured on or after June 10, 2006, the following applies:

a. Neither the length nor width of the x-ray field in the plane of the image receptor must exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width must be no greater than 4 percent of the SID.
b. The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch must be clearly labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

6-005.02 Field Limitation and alignment for spot-film devices: The following requirements must apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment must be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size must not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the x-ray field in the plane of the image receptor must differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences must not exceed 4 percent of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance must be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the x-ray field in the plane of the image receptor must be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

4. Means must be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

   a. For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or
   b. For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, must be containable in a square of 5 cm by 5 cm.

5. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position must indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch must be clearly labeled as follows:

   For X-ray Field Limitation System Failure

6-005.03 Activation of the Fluoroscopic Tube: X-ray production in the fluoroscopic mode must be controlled by a device which requires continuous pressure by the fluoroscopist for

the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist must be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

6-005.04 Air Kerma Rates: For fluoroscopic equipment, the following requirements apply:

1. Fluoroscopic equipment manufactured before May 19, 1995.

a. Equipment provided with automatic exposure rate control (AERC) must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3, except as specified in 180 NAC 6-004.04, item 1.e.

b. Equipment provided without AERC must not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3, except as specified in 180 NAC 6-004.04, item 1.e..

c. Equipment provided with both an AERC mode and a manual mode must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) in either mode at the measurement point specified in 180 NAC 6-005.04, item 3., except as specified in 180 NAC 6-004.04, item 1.e..

d. Equipment may be modified in accordance with this 180 NAC 6-004.04 to comply with 180 NAC 6-005.04, item 2. When the equipment is modified, it must bear a label indicating the date of the modification and the statement:

MODIFIED TO COMPLY WITH 21 CFR 1020.32(H)(2)

e. Exceptions:

(1) During recording of fluoroscopic images, or

(2) When a mode of operation has an optional high-level control, in which case that mode must not be operable at any combination of tube potential and current that will result in an AKR in excess of the rates specified in 180 NAC 6-005.04, item 1. a. b. and c. at the measurement point specified in 180 NAC 6-005.04, item 3, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control must be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high-level control is being employed.

2. Fluoroscopic equipment manufactured on or after May 19, 1995.

a. Must be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (5 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3. Provision for manual selection of technique factors may be provided.

b. Must not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (10 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3, except as specified in 180 NAC 6-005.04, item 2(c).

c. Exceptions

(1) For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(2) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

(3) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (20 R/min exposure rate) at the measurement point specified in 180 NAC 6-005.04, item 3. Special means of activation of high-level controls must be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist must indicate that the high-level control is employed.

3. Measuring compliance: Compliance with this 180 NAC 6-005 must be determined as follows:

a. If the source is below the x-ray table, the AKR must be measured at 1 cm above the tabletop or cradle.

b. If the source is above the x-ray table, the AKR must be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

c. In a C-arm type of fluoroscope, the AKR must be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

d. In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR must be measured at the minimum SSD.

e. In a lateral type of fluoroscope, the air kerma rate must be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it must be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

4. Exemptions: Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in this subsection when used for therapy simulation purposes.

6-005.05 Indication of potential and current: During fluoroscopy and cinefluorography, x-ray tube potential and current must be continuously indicated. Deviation of x-ray tube potential and current from the indicated value must not exceed the maximum deviation as stated by the manufacturer.

6-005.06 Source skin distance:

1. Means must be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in 180 NAC 6-005.06, provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means must be provided to limit the source-skin distance to not less than 19 cm. Such systems must be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in 180 NAC 6-005.06, item 2, provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

6-005.07 Fluoroscopic irradiation time, display, and signal

1. Fluoroscopic equipment manufactured before June 10, 2006:

a. Must be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device must not exceed 5 minutes without resetting. A signal audible to the fluoroscopist must indicate the completion of any preset cumulative irradiation time. Such signal must continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of 180 NAC 6-005.07, item 1. When the equipment is modified, it must bear a label indicating the statement:

b. As an alternative to 180 NAC 7-005.07, item 2.b. radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

2. For x-ray controls manufactured on or after June 10, 2006, there must be provided for each fluoroscopic tube:

a. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display must function independently of the audible signal described in this 180 NAC 6-005. The following requirements apply:

(1) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every 6 seconds.

(2) The fluoroscopic irradiation time must also be displayed within 6 seconds of termination of an exposure and remain displayed until reset.

(3) Means must be provided to reset the display to zero prior to the beginning of a new examination or procedure.

b. A signal audible to the fluoroscopist must sound for each passage of 5 minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least 2 seconds.

6-005.08 Mobile and portable fluroscopes: In addition to the other requirements of 180 NAC 6-005, mobile and portable fluoroscopes must provide an image receptor incorporating more than a simple fluorescent screen.

6-005.09 Display of last image-hold (LIH): Fluoroscopic equipment manufactured on or after June 10, 2006, must be equipped with means to display LIH image following termination of the fluoroscopic exposure.

1. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection must be indicated prior to initiation of the fluoroscopic exposure.

2. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image must be selectable prior to the fluoroscopic exposure, and the combination selected must be indicated prior to initiation of the fluoroscopic exposure.

3. Means must be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph must be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

6-005.10 Displays of values of AKR and cumulative air kerma: Fluoroscopic equipment manufactured on or after June 10, 2006, must display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

1. When the x-ray tube is activated and the number of images produced per unit time is greater than six images per second, the AKR in mGy/min must be continuously displayed and updated at least once every second.

2. The cumulative air kerma in units of mGy must be displayed either within 5 seconds of termination of an exposure or displayed continuously and updated at least once every 5 seconds.

3. The display of the AKR must be clearly distinguishable from the display of the cumulative air kerma.

4. The AKR and cumulative air kerma must represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

   a. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location must be the respective locations specified in 180 NAC 6-005.04, item 3.a., b., or f.
   b. For C-arm fluoroscopes, the reference location must be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location must be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

5. Means must be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

6. The displayed AKR and cumulative air kerma must not deviate from the actual values by more than ±35 percent over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance must be determined with an irradiation time greater than 3 seconds.

6-005.11 Periodic Measurement of AKR:

1. A periodic measurement of air kerma rate (AKR) must be performed for both typical and maximum values as follows:[3/]

   a. Such measurements must be made annually or after any maintenance of the system which might affect the AKR;
   b. Results of these measurements must be posted, for units manufactured before June 10, 2006, where any fluoroscopist may have ready access to such results while using the fluoroscope. Remains in section 005 as modified.

2. The measurement results may be stated in roentgens per minute (R/min) or milliGray per min (mGy/min) and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed must be included in the results; Remains in section 005 as modified.

3. Conditions of periodic measurement of typical AKR are as follows:

   a. The measurement must be made under the conditions that satisfy the requirements of 180 NAC 6-005.04, item 3;
   b. Fluoroscopic systems that do not incorporate an AERC must utilize a milliamperage and kVp typical of clinical use of the fluoroscopic system; and

[3/] *Materials should be placed in the useful beam to protect the imaging system when conducting these periodic measurements.*

c. Fluoroscopic systems that do incorporate an AERC must have sufficient material placed in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system. Remains in section 005 as modified.

4. Conditions of periodic measurement of maximum AKR rate are as follows:

a. The measurement must be made under the conditions that satisfy the requirements of 180 NAC 6-005.04, item 3.

b. Fluoroscopic systems that do not incorporate the AERC must be adjusted to those settings which give the maximum AKR;

c. Fluoroscopic systems that do incorporate AERC must have sufficient material placed in the useful beam to produce the maximum AKR of the system. Remains in section 005 as modified.

6-005.12 Control of Scattered Radiation

1. Fluoroscopic table designs when combined with procedures utilized must be such that no unprotected part of any staff or ancillary individual's body can be exposed to unattenuated scattered radiation which originates from under the table. The attenuation required must be not less than 0.25 millimeter lead equivalent Remains in section 005 as modified.

2. Equipment configuration when combined with procedures must be such that no portion of any staff or ancillary individual's body, except the extremities, can be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

a. Is at least 120 centimeters from the center of the useful beam, or

b. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains in addition to any lead equivalency provided by the protective apron referred to in 180 NAC 6-003.01, item 1.e. Remains in section 005 as modified.

3. The Department may grant exceptions to 180 NAC 6-005.12, item 2., where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Department will not permit such exception. See Appendix 6-C for a suggested list of fluoroscopic procedures where such exemptions will be automatically granted Remains in section 005 as modified.

6-005.13 Fluoroscopic Radiation Therapy Simulation Systems: Fluoroscopic radiation therapy simulation systems are exempt from all the requirements of 6-005.04. In addition, these systems are exempt from the requirements of 180 NAC 6-005.01 provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays. Remains in section 005 as modified.

6-005.14 Equipment Operation

1. All imaging formed by the use of fluoroscopic x-ray systems must be under the direction of and interpreted by a licensed practitioner of the healing arts.
2. Only a licensed practitioner can perform interpretative fluoroscopic procedures.
3. Fluoroscopy must not be used as a positioning tool for general purpose radiographic examinations.
4. Facilities must maintain a record of the cumulative fluoroscopic exposure time used and the number of fluorographic images recorded for each examination. This record must include patient identification, type and date of examination, the fluoroscopic system used, and operator's name.

6-006 RADIOGRAPHIC SYSTEMS OTHER THAN FLUOROSCOPIC, BONE DENSITOMETRY, VETERINARIAN, OR COMPUTED TOMOGRAPHY X-RAY SYSTEMS: Remains in section 006 as modified.

6-006.01 Control and indication of technique factors

1. Visual indication: The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

2. Timer: Means must be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

   a. Except during serial radiography, the operator must be able to terminate the exposure at any time during an exposure of greater than one-half second. Termination of exposure must cause automatic resetting of the timer to its initial setting or to zero. It must not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

   b. During serial radiography, the operator must be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

3. Automatic exposure controls: When an automatic exposure control is provided:

   a. Indication must be made on the control panel when this mode of operations is selected;
   b. When the x-ray tube potential is equal to or greater than 51 kilovolts peak (kVp), the minimum exposure time for field emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 milliampere-seconds (mAs), whichever is greater;

c. Either the product of peak x-ray tube potential, current, and exposure time must be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time must be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time must be limited to not more than 2,000 mAs per exposure; and

d. A visible signal must indicate when an exposure has been terminated at the limits described in 180 NAC 6-006.01, item 3.c., and manual resetting must be required before further automatically timed exposures can be made.

4. Accuracy: Deviation of measured technique factors from indicated values of kVp and exposure time must not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation must not exceed 10% of the indicated value for kVp and 10% for time.

6-006.02 Reproducibility: The following requirements must apply when the equipment is operated on an adequate power supply as specified by the manufacturer:

1. Coefficient of variation: For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma must be no greater than 0.05.

2. Measuring compliance: Determination of compliance must be based on 10 consecutive measurements taken within a time period of 1 hour. Equipment manufactured after September 5, 1978, will be subject to the additional requirement that all variable controls for technique factors must be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation must be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance must be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

6-006.03 Linearity: The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with 21 CFR Part 1020 for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

1. Equipment having independent selection of x-ray tube current (mA): The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

2. Equipment having selection of x-ray tube current-exposure time product (mAs). For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two consecutive mAs selector settings must not differ by more than 0.10 times their sum. This is: $|X_1 - X_2| \leq 0.10(X_1 + X_2)$; where X_1 and X_2 are the average mGy/mAs values

obtained at each of two consecutive mAs selector settings or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection.

3. Measuring compliance: Determination of compliance will be based on 10 exposures, made within 1 hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 mm and the other is greater than 0.45 mm. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

6-006.04 Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems. Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems must meet the following requirements:

1. Variable x-ray field limitation: A means for stepless adjustment of the size of the x-ray field must be provided. Each dimension of the minimum field size at an SID of 100 cm must be equal to or less than 5 cm

2. Visual definition

   a. Means for visually defining the perimeter of the x-ray field must be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field must not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.
   b. When a light localizer is used to define the x-ray field, it must provide an average illuminance of not less than 160 lux (15 footcandles) at 100 cm or at the maximum SID, whichever is less. The average illuminance must be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.
   c. The edge of the light field at 100 cm or at the maximum SID, whichever is less, must have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance 3 mm from the edge of the light field toward the center of the field; and I_2 is the illuminance 3 mm from the edge of the light field away from the center of the field. Compliance must be determined with a measuring aperture of 1 mm.

6-006.05 Field indication and alignment on stationary general purpose x-ray equipment: Except when spot-film devices are in service, stationary general purpose x-ray systems must meet the following requirements in addition to those prescribed in 180 NAC 6-006, item 4:

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

2. The beam-limiting device must numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs must be specified in centimeters and/or inches and must be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within 2 percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 cm and/or 36, 40, 48, 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 cm and/or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

6-006.06 Field limitation on radiographic x-ray equipment other than general purpose radiographic systems:

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

2. Other x-ray systems: Radiographic systems not specifically covered in 180 NAC 6-006.04, item 4, 5, 6.b., 6.c. and .6d, and ., and systems covered in 180 NAC 6-006.05, item 1., which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, must be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means must be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means must be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

   a. A system which performs in accordance with 180 NAC 6-004.04 and 6-004.05; or when alignment means are also provided, may be met with either;
   b. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device must have clear and

permanent markings to indicate the image receptor size and SID for which it is designed; or

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

6.006.07 Positive beam limitation (PBL) This requirements of this subsection must apply to radiographic systems which contain PBL

1. Field size: When a PBL system is provided, it must prevent x-ray production when:

   a. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID; or
   b. The sum of the length and width differences stated in 180 NAC 6-006.07 item 1, (a) without regard to sign exceeds 4 percent of the SID.
   c. The beam-limiting device is at an SID for which PBL is not designed for sizing.

2. Conditions for PBL: When provided, the PBL system shall function as described in 180 NAC 6-006.07 item 1. whenever all the following conditions are met:

   a. The image receptor is inserted into a permanently mounted cassette holder
   b. The image receptor length and width are less than 50 cm;
   c. The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 cm to 130 cm inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 cm to 205 cm inclusive;
   d. The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and
   e. Neither tomographic nor stereoscopic radiography is being performed.

3. Measuring compliance: Compliance with the requirements of 180 NAC 6-006.07. item 1.must be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of 180 NAC 6-006.07 item 2. are met. Compliance must be determined no sooner than 5 seconds after insertion of the image receptor.

4. Operator initiated undersizing: The PBL system must be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 cm must be equal to or less than 5 cm. Return to PBL function as described in 180 NAC 6-006.07, item 1 must occur automatically upon any change of image receptor size or SID.

5. Override of PBL: A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key must be required for any override capability that is accessible

to the operator. It must not be possible to remove the key while PBL is overridden. Each such key switch or key must be clearly and durably labeled as follows:

For X-Ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

6-006.08 Field limitation and alignment for spot-film devices: The following requirements must apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

1. Means must be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment must be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size must not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

2. Neither the length nor width of the x-ray field in the plane of the image receptor must differ from the corresponding dimensions of the selected portion of the image receptor by more than 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences must not exceed 4 percent of the SID. On spot film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means must be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

3. The center of the x-ray field in the plane of the image receptor must be aligned with the center of the selected portion of the image receptor to within 2 percent of the SID.

4. Means must be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

   a. For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square cm; or
   b. For spot-film devices used on fluoroscopic systems that have a variable SID and/or stepless adjustment of the field size, the minimum field size, at the greatest SID, must be containable in a square of 5 cm by 5 cm.

5. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position must indicate whenever the automatic x-ray field size adjustment override

is engaged. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

6-006.09 Source-to-Skin Distance: All mobile or portable radiographic systems must be provided with means to limit the source-to-skin distance to greater than or equal to 30 centimeter.

6-006.10 Radiation from Capacitor Energy Storage Equipment: Radiation emitted from the x-ray tube must not exceed:

1. An air kerma of 0.26 microGy (0.03 mR exposure) in 1 minute at 5 cm from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance must be determined by measurements averaged over an area of 100 square cm, with no linear dimensions greater than 20 cm: and

2. An air kerma of 0.88 mGy (100 mR exposure) in one hour at 100 cm from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in 1 hour (duty cycle). The measurements must be averaged over an area of 100 square cm with no linear dimension greater than 20 cm.

6-006.11 Beam Limitation, Except Mammographic Systems: The useful beam must be limited to the area of clinical interest. This must be deemed to have been met if a positive beam limiting device meeting manufacturer's specifications and the requirements of 180 NAC 6-006.08 have been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge).

6-006.12 Radiation Exposure Control

1. Exposure Initiation: Means must be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure must not be initiated without such an action. In addition, it must not be possible to initiate an exposure when the timer is set to a “zero” or ”off” position if either position is provided. Remains in section 006 as modified

2. Exposure Indication: Means must be provided for visual indication observable at or from the operator’s protected position whenever x-rays are produced. In addition, a signal audible to the operator must indicate that the exposure has terminated. Remains in section 006 as modified

3. Operator Protection: Stationary x-ray systems must be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure. Remains in section 006 as modified.

4. Exposure Control Location: The x-ray exposure control must be so placed that the operator can view the patient while making any exposure. Remains in section 006 as modified

6-006.13 Tube Stands for Portable X-Ray Systems: A tube stand or other mechanical support must be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures. Remains in section 006 as modified

6-007 VETERINARY MEDICINE RADIOGRAPHIC INSTALLATIONS

6-007.01 Equipment

1. The protective tube housing must be equivalent to the requirements of 180 NAC 6-004.03.
2. Diaphragms or cones must be provided for collimating the useful beam to the area of clinical interest and must provide the same degree of protection as is required of the housing.
3. The total filtration permanently in the useful beam must not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70 kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.
4. A device must be provided to terminate the exposure after a preset time or exposure.
5. A dead-man type of exposure switch must be provided, together with an electrical cord of sufficient length, so that the operator can stand out of the useful beam and at least 6 feet (1.83m) from the animal during all x-ray exposures. Remains in section 007as modified.

6-007.02 Structural Shielding: All wall, ceiling, and floor areas must be equivalent to or provided with applicable protective barriers to assure compliance with 180 NAC 4-005, 4-011, and 4-013.

6-007.03 Operating Procedures: Remains in section 007as modified.

1. The operator must be protected from the direct scatter radiation by a whole body protective barrier of 0.25 millimeter lead equivalent or must be so positioned that the nearest portion of the body is at least 2 meters from the tube head and the nearest edge of the image receptor. Remains in section 007as modified.

2. No individual other than the operator may be in the x-ray room while exposures are being made unless such individual's assistance is required.
3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual must be protected with appropriate shielding devices, such as protective gloves and apron, and be so positioned that no part of the body will be struck by the useful beam. Remains in section 007as modified.

6-007.04 Veterinary Assistant's Training Requirements: Remains in section 007as modified.

1. Eight hours of classroom instruction in the fundamentals of radiation safety, radiographic equipment, state regulations, and operating and emergency procedures or
2. Have graduated from an accredited veterinarian technicians program. Remains in section 007as modified.

6-008 COMPUTED TOMOGRAPHY SYSTEMS Remains in section 008 as modified.

6-008.01 Definitions: In addition to the definitions provided in 180 NAC 1-002 and 180 NAC 6-002, the following definitions must be applicable to 180 NAC 6-008:

1. 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, that is:

$$CTDI = \frac{1}{nT} \int_{-7T}^{+7T} D(z)\, dz$$

where:

z = Position along a line perpendicular to the tomographic plane.
D(z) = Dose at position z.
T = Nominal tomographic section thickness.
n = Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

2. TDI (See "Computed tomography dose index").

3. Contrast scale means the change in the linear attenuation coefficient per CTN relative to water, that is:

$$\overline{CS} = \frac{\mu_x - \mu_w}{\overline{CTN}_x - \overline{CTN}_w}$$

where:

u_x = Linear attenuation coefficient of the material interest.
u_w = Linear attenuation coefficient of water.
$\overline{CTN}_x$ = CTN of the material of interest.
$\overline{CTN}_w$ = CTN of water. Remains in section 008 as modified.

4. CS (See "Contrast scale").

5. CT conditions of operation means all selectable parameters governing the operation of a CT system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined in 180 NAC 6-002. Remains in section 008 as modified.

6. CTDI (See "Computed tomography dose index").

7. CT Gantry means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames which hold these components.

8. CTN (See "CT number").

9. CT number means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$CTN = \frac{k(u_x - u_w)}{u_w}$$

where:

k = A constant, a normal value of 1,000 when the Houndsfield scale of CTN is used;
u_x = Linear attenuation coefficient of the material of interest;
u_w = Linear attenuation coefficient of water. Remains in section 008 as modified.

11. Dose profile means the dose as a function of position along a line.

12. Elemental area means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element").

13. Modulation transfer function means the modulus of the Fourier transform of the impulse response of the system.

14. Multiple tomogram system means a computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

15. Noise means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (s_n) is calculated using the following expression:

$$S_n = \frac{100 \times CS \times s}{u_w}$$

where:

CS = Linear attenuation coefficient of the material of interest.
u_w = Linear attenuation coefficient of water.

s = Estimated standard deviation of the CTN of picture elements in a specified area of the CT image. Remains in section 008 as modified.

16. 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. Remains in section 008 as modified.

17. Picture element means an elemental area of a tomogram.

18. Reference plane means a plane which is displaced from and parallel to the tomographic plane. Remains in section 008 as modified.

19. Remanufacturing means modifying a CT system in such a way that the resulting dose and imaging performance become substantially equivalent to any CT x-ray system manufactured by the original manufacturer on or after November 29, 1984. Any reference in this subsection to "manufacture," "manufacturer," or "manufacturing" includes remanufacture, remanufacturing, respectively.

20. Scan means the complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms. Remains in section 008 as modified.

21. Scan increment means the amount of relative displacement of the patient with respect to the CT system between successive scans measured along the direction of such displacement. Remains in section 008 as modified.

22. Scan sequence means a pre-selected set of two or more scans performed consecutively under preselected CT conditions of operation. Remains in section 008 as modified.

23. Sensitivity profile means the relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

24. Single tomogram system means a CT system which obtains x-ray transmission data during a scan to produce a single tomogram.

25. Tomographic plane means that geometric plane which is identified as corresponding to the output tomogram. Remains in section 008 as modified.

26. Tomographic section means the volume of an object whose x-ray attenuation properties are imaged in a tomogram. Remains in section 008 as modified.

6-008.02 Requirements for Equipment Remains in section 008 as modified.

1. Termination of Exposure

a. Means must be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination must

occur within an interval that limits the total scan time to no more than 110% of its preset value through the use of either a backup timer or devices which monitor equipment function.

b. A visible signal must indicate when the x-ray exposure has been terminated through the means required by 180 NAC 6-008.02, item 1.a.

c. The operator must be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT system control, of greater than one-half second duration. Remains in section 008 as modified.

2. Tomographic Plane Indication and Alignment

a. For any single tomogram system, means must be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

b. For any multiple tomogram system, means must be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

c. If a device using a light source is used to satisfy the requirements of 180 NAC 6-008.02, item 2.a. or b., 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. Remains in section 008 as modified.

3. Beam-on and Shutter Status Indicators and Control Switches

a. The CT x-ray control and gantry must provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

b. Each emergency button or switch must be clearly labeled as to its function. Remains in section 008 as modified.

4. Indication of CT Conditions of Operation: The CT System must be designed such that the CT conditions of operation to be used during a scan or a scan sequence must be indicated prior to the initiation of a scan or a scan sequence. On 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. Remains in section 008 as modified.

5. Entraneous Radiation: When data are being collected for image production, the radiation adjacent to the tube port must not exceed that permitted by 180 NAC 6-004.03.

6. Maximum Surface 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. Additional Requirements Applicable to CT X-Ray Systems Containing a Gantry Manufactured After September 3, 1985:

a. The total error in the indicated location of the tomographic plane or reference plane must 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. Indicators 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 must not exceed plus or minus 1 millimeter with any mass of 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. Remains in section 008 as modified.

d. Premature termination of the x-ray exposure by the operator must necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

6-008.03 Facility Design Requirements Remains in section 008 as modified.

1. Aural Communication Provision must be made for two-way aural communication between the patient and the operator at the control panel. Remains in section 008 as modified.

2. 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. Remains in section 008 as modified.

6-008.04 Surveys, Calibrations, Spot Checks, and Operating Procedures Remains in section 008 as modified.

1. Surveys

a. All CT x-ray systems must have a survey made by, or under the direction of, a radiological medical physicist or radiological health physicist. In addition, such surveys must be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

b. The registrant must obtain a written report of the survey from the radiological medical physicist or radiological health physicist, and a copy of the report must be made available to the Department upon request. Remains in section 008 as modified.

2. Radiation Calibrations

a. The calibration of the radiation output of the CT x-ray system must be performed by, or under the direction of, a radiological medical physicist or radiological health physicist who is physically present at the facility during such calibration.

b. The calibration of a CT x-ray system must be performed at intervals specified by a radiological medical physicist or radiological health physicist and after any change or replacement of components which, in the opinion of the radiological medical physicist or radiological health physicist could cause a change in the radiation output and at least every two years.

c. The calibration of the radiation output of a CT x-ray system must be performed with a calibrated dosimetry system. The calibration of such system must be traceable to a national standard. The dosimetry system must have been calibrated within the preceding two years. Remains in section 008 as modified.

d. CT dosimetry phantom(s) must be used in determining the radiation output of a CT x-ray system. Such phantom(s) must meet the following specifications and conditions of use:

(1) The phantom must be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom must be at least 14 centimeters in length and must have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. Remains in section 008 as modified.

(2) The phantom must provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. Remains in section 008 as modified.

(3) Any effect 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. Remains in section 008 as modified.

(4) All dose measurements must be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present. Remains in section 008 as modified.

e. The calibration must be required for each type of head, body, or whole-body scan performed at the facility. Remains in section 008 as modified.

f. Calibration must meet the following requirements:

(1) 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.

(2) The CTDI[4] along the two axes specified in 180 NAC 6-008.04, item 2.d.(2) 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.

(3) The spot checks specified in 180 NAC 6-008.04, item 3. must be made. Remains in section 008 as modified.

g. Calibration procedures must be in writing. Records of calibrations performed must be maintained for inspection by the Department. Remains in section 008 as modified.

3. Spot Checks Remains in section 008 as modified.

a. The spot-check procedures must be in writing and must have been developed by a radiological medical physicist or radiological health physicist. Remains in section 008 as modified.

b. The spot-check procedures must incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material. Remains in section 008 as modified.

c. All spot checks must be included in the calibration required by 180 NAC 6-008.04, item 2. and at time intervals and under system conditions specified by a radiological medical physicist or radiological health physicist. Remains in section 008 as modified.

d. Spot checks must include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by 180 NAC 6-008.04, item 2. The images must be retained, until a new calibration is performed, in two forms as follows:

(1) Photographic copies of the images obtained from the image display device; or

(2) Images sorted in digital form on a storage medium compatible with the CT x-ray system. Remains in section 008 as modified.

e. Written records of the spot checks performed must be maintained for inspection by the Department. Remains in section 008 as modified.

4. Operating Procedures Remains in section 008 as modified.

[4]For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

a. The CT x-ray system must not be operated except by an individual who has been specifically trained in its operation. Remains in section 008 as modified.

b. Information must be available in the control area regarding the operation and calibration of the system. Such information must include the following:

(1) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained.

(2) Instructions on the use of the CT dosimetry phantom(s) 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.

(3) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and

(4) A current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination. Remains in section 008 as modified.

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 radiological medical physicist or radiological health physicist, use of the CT x-ray system on patients must be limited to those uses permitted by established written instructions of the radiological medical physicist or radiological health physicist. Remains in section 008 as modified.

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APPENDIX 6-A
INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Department approve a healing arts screening program must submit the following information and evaluation:

1. Name and address of the applicant and, where applicable, the names and addresses of agents 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. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information.

5. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used in preference to the x-ray examinations.

6. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert must show that such system(s) do satisfy all requirements of Title 180. The evaluation must include a measurement of patient exposure from the x-ray examination to be performed.

7. A description of the diagnostic film quality control program.

8. A copy of the technique chart for the x-ray examination procedures to be used.

9. The qualifications of each individual who will be operating the x-ray system(s).

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

11. The name and address of the individual who will interpret the radiograph(s).

12. 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.

13. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

14. An indication of the frequency of screening and the duration of the entire screening program.

15. Documentation that supports this procedure as being of benefit to public health.

APPENDIX 6-B

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

1. The plans should show, as a minimum, the following:

   (a) The normal location of the x-ray system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; the location of the operator's booth; and the location of the x-ray control panel.

   (b) The structural composition and thickness or lead equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned.

   (c) The dimensions of the room(s) concerned.

   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present.

   (e) The make and model of the x-ray equipment and the maximum technique factors.

   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the x-ray system(s).

3. A report, including all basic assumptions used, must be included with the plans.

APPENDIX 6-C
EXEMPTIONS FROM SHIELDING FOR CERTAIN FLUOROSCOPIC PROCEDURES

a. Angiograms

b. Arthrograms

c. Biliary drainage procedures

d. Fluoroscopic biopsy procedures

e. Myelograms

f. Percutaneous cholangiograms

g. Percutaneous nephrostomies

h. Sinograms or fistulograms

i. T-tube cholangiograms

Public Law 90-602
90th Congress, H. R. 10790
October 18, 1968

An Act

amend the Public Health Service Act to provide for the protection of the public health from radiation emissions from electronic products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Radiation Control for Health and Safety Act of 1968.

SHORT TITLE

SECTION 1. This Act may be cited as the "Radiation Control for Health and Safety Act of 1968".

AMENDMENTS TO PUBLIC HEALTH SERVICE ACT

SEC. 2. Part F of title III of the Public Health Service Act is amended—

58 Stat. 703; 81 Stat. 536. 42 USC 262-263a.

(1) by striking out the heading for such part and inserting in lieu thereof the following:

"PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES AND CONTROL OF RADIATION

"SUBPART 1—BIOLOGICAL PRODUCTS";

(2) by inserting immediately above the section heading of section 353 the following:

"SUBPART 2—CLINICAL LABORATORIES"; and

(3) by adding at the end of such part F the following new subpart:

"SUBPART 3—ELECTRONIC PRODUCT RADIATION CONTROL

"DECLARATION OF PURPOSE

"SEC. 354. The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions.

82 STAT. 1173
82 STAT. 1174

"DEFINITIONS

"SEC. 355. As used in this subpart—

"(1) the term 'electronic product radiation' means—

"(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

"(B) any sonic, infrasonic, or ultrasonic wave,

which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

"(2) the term 'electronic product' means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) elec-

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TITLE 180 - CONTROL OF RADIATION

CHAPTER 21 - (Repealed)