Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 40
"Registration and Safety Requirements for Radiation Emitting Machines in the Healing Arts—Medicine, Podiatry, Dental, Chiropractic, and Veterinary Medicine"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 136C
State or federal law(s) implemented by the rulemaking: Iowa Code chapter 136C

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

November 4, 2025 10 a.m.	Microsoft Teams Meeting ID: 256 572 060 444 0 Passcode: SG2Vc96j

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed chapter is one of eight chapters pertaining to radiologic health matters regulated by the Department. This proposed chapter and the seven others underwent a fulsome review as a part of the Red Tape Review process laid out in Executive Order 10. As a result of this review, restrictive terms were removed, areas that were duplicative were combined or eliminated, and editorial updates were made to processes and procedures to ensure they reflect current policies and procedures. This proposed chapter establishes the requirements of registrants or people seeking to be certified in the use of dental, medical, diagnostic, interventional, and veterinary radiation machines.

Analysis of Impact

1. **Persons affected by the proposed rulemaking:**

- **Classes of persons that will bear the costs of the proposed rulemaking:**

There are not any expected costs for this rulemaking beyond administrative costs for the Department.

- **Classes of persons that will benefit from the proposed rulemaking:**

Those seeking certification in the use of dental, medical, diagnostic, interventional, and veterinary radiation machines will benefit from clarified and updated rules.

2. **Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:**

- **Quantitative description of impact:**

Not applicable.

- **Qualitative description of impact:**

Those seeking certification in the use of dental, medical, diagnostic, interventional, and veterinary radiation machines will benefit from clarified and updated rules.

3. **Costs to the State:**

- **Implementation and enforcement costs borne by the agency or any other agency:**

The Department incurs personnel and other administrative costs associated with enforcement of this proposed chapter.

- **Anticipated effect on State revenues:**

This rulemaking is not expected to have any impact on State revenues.

4. **Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:**

The regulation of radiation machines is required by Iowa Code chapter 136C.

5. **Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:**

Not applicable.

6. **Alternative methods considered by the agency:**

- **Description of any alternative methods that were seriously considered by the agency:**

Not applicable.

- **Reasons why alternative methods were rejected in favor of the proposed rulemaking:**

Not applicable.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

This rulemaking is not expected to have an impact on small business.

Text of Proposed Rulemaking

ITEM 1. Rescind 641—Chapter 40 and adopt the following **new** chapter in lieu thereof:

CHAPTER 40
REGISTRATION AND SAFETY REQUIREMENTS FOR RADIATION EMITTING MACHINES IN THE HEALING ARTS—MEDICINE, PODIATRY, DENTAL, CHIROPRACTIC, AND VETERINARY MEDICINE

641—40.1(136C) General provisions. This rule establishes the requirements of a registrant for the use of diagnostic X-ray equipment and imaging systems. Such equipment shall be used only by, or under the supervision of, an individual who is authorized to operate the equipment and is licensed in

accordance with state statutes to practice in the healing arts, including medicine, podiatry, dentistry, chiropractic, or veterinary medicine.

40.1(1) The provisions of Chapter 40 are in addition to, and not in substitution for, any other applicable portions of 641—Chapters 37 through 42.

40.1(2) All references to any Code of Federal Regulations (CFR) in this chapter are those as amended to August 1, 2025.

641—40.2(136C) Definitions. The definitions provided in 641—Chapter 37 may also apply to the provisions of this chapter. Additionally, the following definitions set forth below are specific to this chapter.

"Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

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

"Automatic exposure control" or *"AEC"* (see also "phototimer") means a device that 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).

"C-arm fluoroscope" means a fluoroscopic X-ray system in which the image receptor and the X-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

"Computed radiography" or *"CR"* (see also "DR") means a digital X-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be integrated into a digital radiography system.

"Computed tomography dose index" or *"CTDI"* 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:

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

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:

1. The dose profile is centered around z = 0; and
2. For a multiple tomogram system, the scan increment between adjacent scans is nT.

"Cone beam computed tomography" or *"CBCT"* is a volumetric imaging modality. Volumetric data are acquired using two dimensional digital detector arrays and a cone-shaped (instead of fan-shaped) X-ray beam that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

"CT conditions of operation" means all selectable parameters governing the operation of a CT X-ray system, including but not limited to nominal tomographic section thickness, filtration, and the technique factors as defined in this chapter.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers that hold and enclose these components within a computed tomography system.

"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.

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

"Digital radiography" or *"DR"* means an X-ray imaging method (or radiography) that produces a digital rather than analog image. "DR" includes both computed radiography (CR) and direct digital radiography (DDR).

"Direct digital radiography" or *"DDR"* (see also "CR" and "DR") means an X-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an X-ray image. Some DDR systems use a scintillator to convert X-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert X-rays directly to charge, which is stored on the thin-film transistor.

"Dose area product," "DAP," "kerma-area product," or *"KAP"* mean the product of the air kerma and the area of the irradiated field and are typically expressed in Gy-cm^2, so do not change with distance from the X-ray tube.

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

"Entrance exposure rate" means the exposure free in air per unit time at the point where the center of the useful beam enters the patient.

"Field emission equipment" means equipment that 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.

"Fluoroscopically guided interventional," "FGI" or *"special procedures"* means an interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, that uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site; to monitor the procedure; and to control and document therapy. These procedures could result in extended fluoroscopy examination times and higher doses than typical imaging procedures.

"Fluoroscopic imaging assembly" means a subsystem in which X-ray photons produce a visual image. It includes the image receptor(s) such as the image intensifier and spot-film device; electrical interlocks, if any; and structural material providing linkage between the image receptor and diagnostic source assembly.

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

"Focal spot size" means the area of the target or anode that is bombarded by electrons from the cathode of the X-ray tube to produce X-rays. The smaller the focal spot, the better the limited spatial resolution of the X-ray system, especially in magnification mammography.

"Healing arts screening" means the testing of human beings using X-ray machines for the detection or evaluation of health indications for which the individual is considered at high risk when such tests are not specifically and individually ordered by:

1. An individual authorized under subrule 40.4(10), or
2. An individual licensed as a physician in Iowa.

"Image intensifier" means a device, installed in its housing, that instantaneously converts an X-ray pattern into a corresponding light image of higher energy intensity.

"Image receptor" means any device, such as a fluorescent screen, radiographic film, X-ray image intensifier tube, solid-state detector, or gaseous detector that transforms incident X-ray photons either into a visible image or into another form that can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, "image receptor" means the preselected portion of the device.

"Last-image hold (LIH) radiograph" means an image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

"Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

"mA" means milliampere.

"mAs" means milliampere second.

"Multiple tomogram system" means a computed tomography X-ray system that obtains X-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"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.

"Peak tube potential," "Kilovolts peak" or *"kVp"* means the maximum value of the potential difference across the X-ray tube during an exposure.

"Phototimer" (see also "automatic exposure control") means a method for controlling radiation exposures to image receptors by the amount of radiation that reaches a radiation-monitoring device(s). The radiation-monitoring device(s) is part of an electronic circuit that controls the duration of time the tube is activated.

"Position indicating device" or *"PID"* means a device on dental X-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Protective apron" means an apron made of radiation-absorbing materials used to reduce radiation exposure.

"Protective glove" means a glove made of radiation-absorbing materials used to reduce radiation exposure.

"Radiation detector" means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

"Radiation therapy simulation system" means a radiographic or fluoroscopic X-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an X-ray pattern and results in a permanent record.

"Radiography" means a technique for generating and recording an X-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

"Recording" means producing a retrievable form of an image resulting from X-ray photons.

"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.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT X-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a preselected set of two or more scans performed consecutively under preselected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of X-ray transmission data accumulation for a single scan.

"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.

"Source" means the focal spot of the X-ray tube.

"Source-image receptor distance" or *"SID"* means the distance from the source to the center of the input surface of the image receptor.

"Spot film" means a radiograph that is made during a fluoroscopic examination to permanently record conditions that exist during that fluoroscopic procedure.

"Technique factors" means the following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

2. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of X-ray pulses;

3. For CT X-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either:

A. Tube current in mA, X-ray pulse width in seconds, and the number of X-ray pulses per scan, or

B. The product of tube current, X-ray pulse width, and the number of X-ray pulses in mAs;

4. For CT X-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

"Tomogram" means the depiction of the X-ray attenuation properties of a section through the body.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose X-ray attenuation properties are imaged in a tomogram.

"Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam-limiting device when the exposure controls are in a mode to cause the system to produce radiation.

"Visible area" means that portion of the input surface of the image receptor over which incident X-ray photons are producing a visible image.

"X-ray control" or *"control panel"* means a device that controls input power to the X-ray high-voltage generator and the X-ray tube, including equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices that control the technique factors of an X-ray exposure.

"X-ray equipment" or *"equipment"* means an X-ray system, subsystem, or component thereof. Types of X-ray equipment are as follows:

1. "Mobile X-ray equipment" means X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled.

2. "Portable X-ray equipment" means X-ray equipment designed to be hand-carried but used with a tripod or other stabilization mechanism so the operator is not holding the equipment during exposure.

3. "Stationary X-ray equipment" means X-ray equipment that is installed in a fixed location.

4. "Handheld X-ray equipment" means X-ray equipment designed by the manufacturer to be handheld by the operator during the exposure. X-ray equipment designed without a back-scatter shield is prohibited.

"X-ray exposure control" means a device, a switch, a button, or similar means by which an operator initiates or terminates the radiation exposure. The X-ray exposure control may include such associated equipment as timers and backup timers.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the X-ray control to the tube operating potential. The device may also include

means for transforming alternating current to direct current, filament transformers for the X-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

"X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

"X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes but is not limited to any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, image intensifier, or spot-film device beneath the tabletop.

641—40.3(136C) General regulatory requirements.

40.3(1) The registrant shall be responsible for directing the operation of the X-ray system(s) under the registrant's administrative control and shall ensure that the requirements of these regulations are met in the operation of the X-ray system(s).

40.3(2) In addition to the rules of this chapter, registrants shall also comply with the requirements of the rules in 641—Chapter 37, including but not limited to:

a. Requirements for registration in rule 641—37.8(136C);

b. Fees in rule 641—37.9(136C);

c. Administrative enforcement actions in rule 641—37.10(136C);

d. Standards for protection against radiation in rule 641—37.11(136C);

e. Record requirements in rule 641—37.12(136C);

f. Notifications and reporting requirements of a reportable radiation incident in 641—subrule 37.13(3);

g. Notices, instructions, and reports to workers in rule 641—37.14(136C).

641—40.4(136C) Administrative controls.

40.4(1) *Registrant.* The registrant shall be responsible for:

a. Maintaining and directing the operation of the X-ray system(s) under the registrant's administrative control for ensuring that the requirements of these rules are met in the operation of the X-ray system(s).

b. Ensuring the X-ray equipment is maintained and tested by a registered service provider, and qualified expert when applicable, through an equipment performance evaluation based on manufacturer recommendations or according to the following minimum tests and schedule, whichever is more frequent. Veterinary systems are exempt from the equipment performance evaluation requirements of paragraph 40.4(2)*"b."*

40.4(2) *Equipment performance evaluation (EPE).*

a. EPE following installation or modifications. For X-ray, fluoroscopic, and CT systems, an EPE shall be performed under the following conditions:

(1) Within 30 days after initial installation of new machines;

(2) Within 30 days after reinstallation of a machine; or

(3) Within 30 days after repair of a machine component that would affect the radiation output that includes but is not limited to the timer, tube, and power supply.

b. EPE frequency. For X-ray, fluoroscopic, and CT systems, excluding veterinary, an EPE shall be performed at the frequency and by the appropriately trained service provider or qualified expert as required in the following table:

Type of Machine	Frequency	Performed By
CT	Annually	Qualified expert
Fluoroscopy	Annually	Qualified expert

Type of Machine	Frequency	Performed By
Dental (intraoral and panoramic/cephalometric)	4 years	Service provider
CBCT	2 years	Qualified expert
All other X-ray equipment (medical/chiropractic/podiatric)	2 years	Service provider

c. *Records of EPE results.* Records of the test results shall:

(1) Include measurements and numerical readings;

(2) Indicate a pass or fail for each test; and

(3) Be reviewed and signed by a registered service provider or qualified expert.

d. *Correction of EPE results.* Any items not meeting the specifications of the EPE shall be corrected or repaired.

(1) The correction or repair shall begin within 30 days following the EPE and shall be performed according to a plan designated by the registrant.

(2) Correction or repair shall be completed no longer than 90 days from discovery unless authorized by the department.

(3) The registrant shall maintain records of corrections or repairs in accordance with this chapter.

(4) These records must be retained and made available to the department upon request.

40.4(3) *EPEs for service and installation.* All EPEs for service and installation shall be performed by a person registered as a radiation machines service provider or qualified expert under 641—subrules 37.8(3) and 37.8(4).

40.4(4) *Compliance prior to operation.* The registrant or the registrant's agent shall ensure that the requirements of these rules are met prior to the operation of the X-ray system(s).

40.4(5) *Compliance or prior approval by department.* An X-ray system that does not meet the provisions of these rules cannot be operated for diagnostic purposes without prior approval by the department. To ensure compliance, the following provisions must be met:

a. All position locking, holding, and centering devices on X-ray system components and systems shall function as intended.

b. All X-ray systems shall be maintained in good mechanical repair and comply with all state and local electrical code requirements.

c. The registrant cannot operate an X-ray machine for diagnostic or therapeutic purposes when the X-ray machine:

(1) Does not meet the provisions of this chapter; or

(2) Is malfunctioning and threatens the health or safety of the patient, operator, or general public.

40.4(6) *Operator competency and training.* Individuals who will be operating the X-ray systems shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment. In addition:

a. Operators shall meet the requirements of 641—Chapter 38, as applicable, and shall make the permit available at the individual's place of employment.

b. If the permit holder works at more than one facility, a duplicate of the permit shall be kept at each facility.

c. Operators of diagnostic X-ray systems for clinical purposes should receive training specific to the equipment, procedures, and examination protocols specific to the facility's operations.

40.4(7) *Protocol—no operational anatomic programming.* For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include the following:

a. Patient's body part and anatomical size (adult and pediatric, if appropriate);

b. Technique factors;

c. Type of image receptor used;

d. Source to image receptor distance used (except for dental intraoral radiography); and

e. Type of grid, if any.

40.4(8) *Written safety procedures.* Written safety procedures, as outlined in 641—Chapter 37, shall be established and provided to each individual operating X-ray equipment. The procedures shall include:

a. Patient holding requirements and any restrictions on operating technique necessary for the safe operation of the specific X-ray system.

b. Procedures with which the operator shall be able to demonstrate familiarity, including:

(1) Except for patients who cannot be moved out of the room, only staff and ancillary personnel required for the medical procedure or training shall be present in the room during the radiographic exposure.

(2) Other than the patient being examined, all individuals shall be positioned so that no part of the body is struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

(3) The X-ray operator, other staff, ancillary personnel, and any other persons required for the medical procedure, with the exception of handheld dental operators, shall be protected from scattered primary radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent. This requirement does not apply to the use of dental handheld X-ray units, provided the device's backscatter shield is in place and used as intended by the manufacturer and as specified in subrule 40.7(5).

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

40.4(9) *Protective apparel.* A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with X-ray operations.

a. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with lead equivalent.

b. Registrants shall maintain a patient shielding policy consistent with ALARA principles. The use of shielding shall be determined in accordance with the radiation machine facility's established policy in alignment with national guidance. The policy should include procedures for addressing patient requests for shielding.

40.4(10) *Exposure to the useful beam.*

a. Individuals cannot be exposed to the useful beam unless:

(1) The radiation exposure occurs in the context of a previously established professional relationship between a licensed practitioner of the healing arts or a licensed registered nurse who is registered as an advanced registered nurse practitioner (ARNP) pursuant to Iowa Code chapter 152 and a patient, which includes a physical examination by the practitioner of the patient unless such examination is not clinically indicated; and

(2) Such practitioner issues a written order for the radiation exposure. The written order shall be issued prior to the exposure unless the exposure results from care provided in an emergency or surgery setting. A verbal order may be issued provided the licensed practitioner is supervising the procedure and the order is documented in the patient's record after the procedure is completed.

b. This provision specifically prohibits deliberate exposure for the following purposes:

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

(2) Exposure of an individual for the purpose of healing arts screening except as authorized by subrule 40.4(14).

40.4(11) *Auxiliary support.* When a patient or image receptor must be provided with auxiliary support during a radiation exposure:

a. Mechanical holding devices shall be used when the technique permits. The written safety procedures, required by subrule 40.4(8), shall list individual projections where holding devices cannot be utilized;

b. Written safety procedures, as required by subrule 40.4(8), shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

c. A human holder shall be instructed in personal radiation safety and protected as required by subrule 40.4(8);

d. No individual shall be used routinely to hold image receptors or patients; and

e. Each facility shall have lead aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with X-ray operations and who are otherwise not shielded.

40.4(12) *Procedures and auxiliary equipment.* Facilities shall use procedures and auxiliary equipment that reduce radiation exposure to patients and staff, as much as reasonably possible, while still obtaining the necessary diagnostic information.

a. Radiation exposure to the patient shall be limited to the minimum exposure required to produce images of good diagnostic quality.

b. Portable or mobile X-ray equipment shall be used only for examinations, excluding intraoral dental imaging, where it is impractical to transfer the patient(s) to a stationary X-ray installation.

c. Handheld mobile X-ray equipment may be used for routine intraoral dental imaging in place of stationary equipment, provided the device's backscatter shield is in place and used as intended by the manufacturer as specified in subrule 40.7(5).

d. X-ray systems subject to 641—Chapter 40 shall not be used in procedures where the source to human patient distance is less than 30 centimeters.

e. If grids are used between the patient and the image receptor to decrease scatter and improve contrast, the grid shall:

(1) Be positioned properly, including the tube side facing the correct direction, and the grid centered to the central ray; and

(2) For focused type grids, be at the proper focal distance for the SIDs being used.

40.4(13) *Personnel monitoring devices.* All individuals who are associated with the operation of an X-ray system are subject to the requirements of rule 641—37.11(136C) for standards for protection against radiation. In addition:

a. When protective clothing or devices are worn on portions of the body and a personnel monitoring device(s) is present, the device(s) shall be worn in accordance with the recommendations found in Chapter 4 of the National Council of Radiation Protection and Measurements Report No. 57 as amended to August 1, 2025.

b. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

40.4(14) *Healing arts screening program.* The registrant shall not initiate a healing arts screening program in which an individual is exposed to the useful beam without an order as specified in subrule 40.4(10) without prior written approval from the department.

a. An application for approval shall be submitted to the department in accordance with requirements specified in Appendix A of this chapter.

b. The department cannot approve a healing arts screening program unless the applicant submits data supporting the efficacy of the screening test in diagnosing the disease or condition being screened.

c. If any information submitted to the department becomes invalid or outdated, the applicant shall notify the department in writing within five calendar days.

40.4(15) *Maintenance of records.*

a. The registrant shall maintain all of the following records for each X-ray system until the X-ray system is removed from the facility, or as otherwise specified, and shall make such records available for inspection by the department:

(1) Model and serial numbers of all major components, and user's manuals for those components, including software;

(2) Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the X-ray system(s);

(3) A copy of all correspondence with the department regarding each X-ray system;

(4) Medical and imaging records as specified in 641—subrule 37.12(2);

(5) Personnel and dosimetry records as specified in 641—subrule 37.12(8);

b. X-ray utilization records shall be kept until the facility is inspected by this department or until all images listed on the utilization record log have been purged as specified in 641—subrule 37.12(2).

40.4(16) *X-ray utilization records.* Each facility, excluding veterinary, shall maintain a written or electronic utilization log that shall be made available to the department, upon request, for a date range specified by the department. The utilization record shall include but is not limited to all of the following:

a. The patient's name;

b. The type of examination(s);

c. The date the examinations were performed;

d. Dose information, when available from the imaging equipment or associated software.

40.4(17) *Quality assurance (QA).* The registrant shall establish and maintain a QA program, including but not limited to the following;

a. Maintain personnel qualifications as specified in 641—Chapter 38.

b. Establish and maintain written QA and quality control (QC) procedures, which shall be reviewed annually.

c. Conduct image evaluations at established intervals to identify operator training needs or imaging system deficiencies.

d. Retain QA/QC records of evaluations and reviews as specified in subrule 40.4(15).

40.4(18) *Shielding plan review.* Unless otherwise specified by the department, registrants shall ensure the following conditions related to shielding for X-ray machines are met:

a. Prior to construction of all new installations, modifications of existing installations, or installation of equipment into existing facilities where the X-ray machine is fixed in one location or otherwise routinely used in a specific location, the floor plans and equipment arrangements shall be submitted to the department for review and verification that national standards have been met. Required submission details are outlined in Appendix B of this chapter.

b. The department may require the applicant to utilize the services of a qualified expert to determine the shielding requirements prior to the plan review and approval.

c. The approval of such plans cannot preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in 641—Chapter 37.

40.4(19) *Design requirements for an operator's booth.*

a. Space requirements.

(1) The operator shall be allotted not less than 7.5 square feet (0.697 m) of unobstructed floor space in the booth.

(2) The operator's booth may be any geometric configuration with no dimension of less than two feet (0.61 m).

(3) The space shall be allotted excluding any encumbrance by the X-ray control panel, such as overhang, cables, or other similar encroachments.

(4) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall cassette will not reach the operator's station in the booth.

b. Structural requirements.

(1) The booth walls shall be permanently fixed barriers of at least seven feet (2.13 m) high.

(2) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock that will prevent an exposure when the door or panel is not closed.

(3) Shielding shall be provided to meet the requirements of 641—Chapter 40.

c. Radiation exposure control panel. The radiation exposure control for the system shall be fixed within the booth and shall:

(1) Be at least 40 inches (1.0m) from any point subject to direct scatter, leakage, or primary beam radiation.

(2) Allow the operator to use the majority of the available viewing windows or mirrors.

d. Viewing system requirements. Each booth shall have at least one viewing device that will:

(1) Be placed so that the operator can view the patient during any exposure.

(2) Be placed so that the operator can have full view of any occupant in the room and be able to view any entry into the room.

e. Warning devices. If any door that allows access to the room cannot be seen from the booth, there shall be an "x-ray on" warning sign outside that door that will be lighted anytime the rotor of the X-ray tube is activated.

f. Alternative to warning devices. A door as specified in paragraph 40.4(10)*"e"* must have an interlock controlling the exposure that will prevent the exposure if the door is not closed.

g. Additional requirements when the viewing system is a window. When the viewing system is a window, the following requirements also apply:

(1) The viewing area shall be at least one square foot (0.09 m^2);

(2) Regardless of size or shape, at least one square foot (0.09 m^2) of window area shall be centered no less than two feet (0.6 m) from the open edge of the booth and no less than five feet (1.5 m) from the floor;

(3) The window shall have the same lead equivalence as that required in the booth's wall on which it is mounted.

h. Additional requirements when the viewing system is by mirrors. The mirrors shall be located to meet the general requirements as specified in paragraph 40.4(19)*"d."*

i. Additional requirements when the viewing system is electronic. The camera shall be located as to accomplish the general requirements as specified in paragraph 40.4(19)*"d."*

j. An alternate viewing system shall be provided as a backup to the primary electronic system.

40.4(20) *Federal performance standards for equipment.* All X-ray equipment shall comply with the applicable performance standards of 21 CFR 1020.30 through 1020.40 that were in effect at the time the unit was manufactured. Persons registered to possess the affected radiation-emitting equipment in Iowa shall be responsible for maintaining the equipment in compliance with the appropriate federal performance standards.

40.4(21) *Modification of certified diagnostic X-ray components and systems.* Diagnostic X-ray components and systems certified in accordance with 21 CFR Part 1020 cannot be modified such that the component or system fails to comply with any applicable provision of this chapter.

a. 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 chapter.

b. The owner who causes such modification need not submit the reports required by this rule, 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 this chapter.

40.4(22) *X-ray film processing.* A registrant using analog image receptors (e.g., radiographic film) shall maintain equipment suitable for handling and processing radiographic film in accordance with manufacturer recommendations and appropriate nationally recognized standards for image processing and maintaining image quality. Facilities shall establish and follow an image quality control program in accordance with the recommendations of a qualified expert, the system manufacturer, or a nationally recognized organization.

40.4(23) *X-ray digital image processing facilities using CR or DDR.* When exposure indicators are available, the facility shall establish and document an acceptable range for the exposure values for examinations routinely performed at the facility.

a. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented.

b. Facilities shall establish and follow an image quality control program in accord with the recommendations of a qualified expert, the system manufacturer, or a nationally recognized organization.

c. CR facilities shall perform erasure of all CR cassettes at least on a weekly basis.

641—40.5(136C) General requirements for all diagnostic X-ray systems. In addition to the applicable requirements of this chapter, all diagnostic X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.30 and 1020.31.

40.5(1) *Warning label.* Diagnostic registrants shall comply with the warning label requirements of 21 CFR 1020.30(j).

40.5(2) *Leakage radiation from the diagnostic source assembly.* Diagnostic registrants shall comply with the leakage radiation from the diagnostic source assembly requirements of 21 CFR 1020.30(k).

40.5(3) *Radiation from components other than the diagnostic source assembly.* Diagnostic registrants shall comply with the radiation from components other than the diagnostic source assembly requirements of 21 CFR 1020.30(l).

40.5(4) *Beam quality.* Diagnostic registrants shall comply with the beam quality requirements of 21 CFR 1020.30(m).

40.5(5) *Battery charge indicator.* Diagnostic registrants shall comply with battery charge indicator requirements of 21 CFR 1020.30(o).

40.5(6) *Multiple tubes.* Diagnostic registrants shall comply with multiple tube requirements of 21 CFR 1020.31(k).

40.5(7) *Technique indicators.* Diagnostic registrants shall comply with technique indicator requirements of 21 CFR 1020.31(a).

40.5(8) *Beam-on indicators.* Diagnostic registrants shall comply with beam-on indicator requirements of 21 CFR 1020.31(j).

40.5(9) *Maintaining compliance.* Diagnostic registrants shall comply with the performance standards for ionizing radiation emitting product requirements of 21 CFR 1020.

40.5(10) *Systems designed for mammography.* All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1998 and the provisions of 641—Chapter 41.

40.5(11) *Invasive breast localization X-ray machines.* All systems designed for invasive breast localization X-ray machines shall comply with the provisions of 641—Chapter 41.

40.5(12) *Medical cabinet X-ray machine for nonhuman use.* All systems designed for tissue specimen imaging shall comply with provisions of rules 641—37.8(136C) and 641—37.9(136C).

641—40.6(136C) General requirements for all fluoroscopy and interventional X-ray systems. In addition to the applicable requirements of this chapter, all fluoroscopic and interventional X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.32 to include all of the following minimum requirements.

40.6(1) *Fluoroscopic equipment.* Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy. Non-image intensified fluoroscopic equipment cannot be used.

40.6(2) *Primary protective barrier.* Fluoroscopic and interventional X-ray registrants shall comply with primary protective barrier requirements of 21 CFR 1020.32(a).

40.6(3) *Field limitation.* Fluoroscopic and interventional X-ray registrants shall comply with field limitation requirements of 21 CFR 1020.32(b).

40.6(4) *Activation of tube.* Fluoroscopic and interventional X-ray registrants shall comply with activation of tube requirements of 21 CFR 1020.32(c).

40.6(5) *Air kerma rates.* Fluoroscopic and interventional X-ray registrants shall comply with air kerma rate requirements of 21 CFR 1020.32(d).

40.6(6) *Measuring compliance of equipment parameters.* Compliance with fluoroscopy equipment parameters required in this chapter shall be conducted by a qualified expert and according to manufacturer or nationally recognized standards at intervals not to exceed 12 months.

40.6(7) *Indication of potential and current.* Fluoroscopic and interventional X-ray registrants shall comply with indication of potential and current requirements of 21 CFR 1020.32(f).

40.6(8) *Source-skin distance.* Fluoroscopic and interventional X-ray registrants shall comply with source-skin distance requirements of 21 CFR 1020.32(g).

40.6(9) *Fluoroscopic irradiation time, display, and signal.* Fluoroscopic and interventional X-ray registrants shall comply with fluoroscopic irradiation time, display, and signal requirements of 21 CFR 1020.32(h).

40.6(10) *Display of last-image-hold (LIH).* Fluoroscopic and interventional X-ray registrants shall comply with display of LIH requirements of 21 CFR 1020.32(j).

40.6(11) *Displays of values of AKR and cumulative air kerma.* Fluoroscopic and interventional X-ray registrants shall comply with displays of values of AKR and cumulative air kerma requirements of 21 CFR 1020.32(k).

40.6(12) *Protection from scatter radiation.*

a. For stationary fluoroscopic systems, ancillary shielding, such as drapes, self-supporting curtains, or viewing shields, shall be available and used as supplemental protection for all individuals other than the patient in the room during a fluoroscopy procedure.

b. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met:

(1) Shielding required under paragraph 40.6(2)*"a"* shall be maintained to the degree possible under the clinical conditions;

(2) All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm;

(3) The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest);

(4) Operating and safety procedures shall reflect the above conditions, and operators shall exhibit awareness of situations requiring the use and nonuse of the protective drapes.

40.6(13) *Equipment operation.* All imaging formed by the use of fluoroscopic X-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

a. Overhead fluoroscopy cannot be used as a positioning tool for general purpose radiographic examinations.

b. Facilities that use fluoroscopic X-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall include all of the following:

(1) Patient identification;

(2) Type of examination;

(3) Date of examination;

(4) Operator's name.

c. The operation of a fluoroscopy X-ray system for clinical purposes is limited to those individuals permitted to operate radiation machines as specified in 641—Chapter 38 and persons who have received additional training provided by a qualified expert specific to:

(1) Radiation protection methods for patients and staff;

(2) Units of measurement and dose, including DAP (dose-area product) values and air kerma;

(3) Factors affecting fluoroscopic outputs;

(4) High level control options;

(5) Dose management, including dose reduction techniques, monitoring, and recording;

(6) Principles and operation of the specific fluoroscopic X-ray system(s) to be used;

(7) Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically;

(8) Applicable requirements of these regulations.

d. Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features, and the relative radiation output rates of the various modes of operation.

e. Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.

f. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

g. The registrant monitor dose during a fluoroscopic procedure.

h. The facility shall establish a written policy regarding patient dose management in fluoroscopically guided procedures in conformance with the ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (ACR Resolution 44 – 2013), NCRP Report 168, or equivalent.

40.6(14) *Additional requirements for stationary fluoroscopic systems used for fluoroscopically-guided interventional or special procedures.* Protective barriers shall be available for use by individuals whose presence is required in the room during activation of the X-ray tube(s).

a. If a protective barrier includes or consists of a transparent viewing panel, the viewing panel shall afford protection of not less than 0.5 millimeter of lead equivalent.

b. Protective aprons of not less than 0.25 millimeter of lead equivalent shall be worn in the fluoroscopy room by all individuals (except the patient).

c. Any individual required to be in the room for short periods of time may not be required to wear a protective apron if exposure levels below minimum as seen on film badge reports can be verified.

d. Individuals not using protective aprons should follow ALARA by using time and distance to reduce exposure. Any declared pregnant individual must meet the requirements of 641—subrule 37.11(14).

40.6(15) *Supervision of fluoroscopy.* The use of fluoroscopy by radiologic technologists and radiologic students shall be performed under the direct supervision of a licensed practitioner, a radiologist assistant or an ARNP, pursuant to 481—subrule 621.4(5), for the purpose of localization or to obtain images for diagnostic or therapeutic purposes.

40.6(16) *Dose-area-product monitor requirements.* All fluoroscopic equipment used for interventional or special procedures shall be equipped with a dose-area-product monitor capable of recording the total radiation dose received by a patient when the fluoroscopic tube is used.

a. Each facility using fluoroscopic equipment for special procedures shall include in the patient's chart and in a log for department review the patient radiation exposure received per procedure.

b. The registrant shall maintain the records required by this subrule and shall make them available to the department upon request.

641—40.7(136C) General requirements for dental intra-oral, panoramic, cephalometric, and volumetric dental imaging equipment.

1. In addition to the applicable requirements of this chapter, all dental intra-oral, panoramic, cephalometric, and volumetric imaging X-ray systems shall meet the requirements for manufacture as specified in 21 CFR 1020.31, as well as the requirements of this chapter, unless otherwise specifically authorized by the department.

2. Dental facilities using CBCT technology shall follow applicable provisions of this chapter.

40.7(1) *X-ray systems used for dental imaging.* In addition to the applicable requirements of rule 641—40.5(136C), X-ray systems used for dental imaging must meet all of the following:

a. Intraoral dental units. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than 18 cm.

(1) The X-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 cm.

(2) Intraoral dental X-ray machines cannot be operated at less than a measured 51 kVp.

b. Extraoral, panoramic, and cephalometric units. X-ray systems designed for use with extraoral image receptors, and when used with an extraoral image receptor, shall:

(1) 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;

(2) 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 shall be provided to both size and alignment 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:

1. 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 shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

2. 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 shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

40.7(2) *Operators of dental X-ray systems.* Operators of dental X-ray machines must meet the requirements of rule 481—575.3(153) and be trained in the appropriate use of the radiation machines in operation at the registered dental facility.

40.7(3) *Exposure control location and operator protection.* Except for units designed to be handheld, the exposure control shall allow the operator to be:

a. Behind a protective barrier at least 6.5 feet (two meters) tall; or

b. At least 6.5 feet (two meters) from the tube housing assembly, outside the path of the useful beam, while making exposures.

40.7(4) *Administrative controls.* Patient and image receptor holding devices shall be used when the techniques permit.

a. Except for units designed to be handheld and allowed by these rules, the tube housing and position indicating device (PID) cannot be handheld during an exposure.

b. Dental fluoroscopy without image intensification cannot be used.

40.7(5) *Handheld intraoral equipment.* Only equipment specifically designed by the manufacturer to be held by the operator for intraoral dental X-ray exposures is allowed to be operated. In addition to the applicable requirements in this chapter, the following apply specifically to handheld devices:

a. The handheld X-ray system shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and six inches (15.2 cm) in diameter that is positioned as close as practicable to the distal end of the position indication device.

b. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer. Records of training shall be kept at the facility until the operator is no longer an employee or until the equipment is removed from the facility.

c. The facility shall adopt and follow protocols provided by the manufacturer regarding the safe operation of the device.

d. Protective aprons of not less than 0.25 millimeter lead equivalent shall be available for operators to wear while operating a handheld intraoral dental radiographic unit at the discretion of the facility's policy and procedures.

e. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

f. The equipment cannot be operated in hallways, waiting rooms, or other areas where access for individuals of the general public cannot be controlled.

g. When not in use, the equipment shall be stored in a manner that would prevent inadvertent exposures or use by unauthorized individuals.

641—40.8(136C) Computed tomography X-ray systems. In addition to the applicable requirements of this chapter, all computed tomography X-ray systems, except CT used exclusively for radiation therapy, shall meet the requirements for manufacture as specified in 21 CFR 1020.33 and the requirements set forth in this chapter at the time of installation and at all times when in use.

40.8(1) *Requirements for equipment.*

a. Conditions of operation. Computed tomography X-ray registrants shall comply with control and indication of conditions of operation as specified in 21 CFR 1020.33(f).

b. Visual indication. CT X-ray systems shall meet the requirements as specified in 21 CFR 1020.33(f)(1).

c. Timers. CT X-ray systems shall meet the requirements as specified in 21 CFR 1020.33(f)(2).

d. Tomographic plane indication and alignment. CT X-ray registrants shall comply with tomographic plane indication and alignment as specified in 21 CFR 1020.33(g).

e. Beam-on and shutter status indicators and control switches. CT X-ray registrants shall comply with beam-on and shutter status indicators as specified in 21 CFR 1020.33(h).

(1) The CT X-ray control and gantry shall provide visual indication whenever X-rays are produced and, if applicable, whether the shutter is open or closed as specified in 21 CFR 1020.33(h)(1).

(2) Each emergency button or switch shall be clearly labeled as to its function.

f. Information to be provided for users. CT X-ray registrants shall comply with information to be provided for users as specified in 21 CFR 1020.33(c).

g. Conditions of operation. CT X-ray registrants shall comply with conditions of operations as specified in 21 CFR 1020.33(c)(1).

h. Dose information. CT X-ray registrants shall comply with dose information as specified in 21 CFR 1020.33(c)(2).

i. Imaging performance information. CT X-ray registrants shall comply with imaging performance information as specified in 21 CFR 1020.33(c)(3).

j. Additional requirements applicable to CT X-ray systems containing a gantry manufactured after September 3, 1985.

(1) The total error in the indicated location of the tomographic plane or reference plane cannot exceed five millimeters as specified in 21 CFR 1020.33(g)(3).

(2) If the X-ray production period is less than one-half second, the indication of X-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall 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 as specified in 21 CFR 1020.33(h)(1).

(3) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device as specified in 21 CFR 1020.33(i).

(4) The patient support device shall 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 as specified in 21 CFR 1020.33(i).

(5) Measurement of actual versus indicated scan increment may be taken anywhere along this travel as specified in 21 CFR 1020.33(i).

(6) Premature termination of the X-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan as specified in 21 CFR 1020.33(f)(2)(ii).

40.8(2) *Facility design requirements.* The location of a mobile and fixed CT X-ray system must be designed and constructed as follows:

a. Aural communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

b. Viewing systems.

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

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

c. Within 30 days of first use of a mobile or fixed stationary CT X-ray system, the registrant shall complete and keep on file a radiation protection shielding survey of the room and surrounding areas consistent with the National Council on Radiation Protection and Measurements Report #147 (2004) and subrule 40.8(3).

40.8(3) *CT shielding requirements for mobile and stationary fixed CT X-ray systems.* The operator's booth and surrounding occupied areas must be designed and constructed in accordance with the National Council on Radiation Protection and Measurements Report #147 (2004) or other nationally accepted standard.

a. Protective barriers must be provided in the ceiling, floor, and walls of the CT X-ray system enclosure to ensure exposure does not exceed acceptable dose limits established in 641—subrule 37.11(7).

b. The control panel must be shielded by a protective position between the operator and the radiation source during CT X-ray system operation.

c. The registrant shall submit a revised radiation shielding plan for department review in accordance with this rule after replacement of a mobile or fixed stationary CT X-ray system or any change in the CT X-ray system room's construction or surrounding rooms construction.

d. Rooms in which a mobile CT X-ray system is used are exempt from the requirements of paragraphs 40.8(3)*"a," "b,"* and *"c."* However, the operator must be protected to ensure exposure does not exceed dose limits established in 641—Chapter 37 for dose limits to members of the public.

40.8(4) *Surveys, calibrations, and routine QC.*

a. All CT X-ray systems shall have a survey made by, or under the direction of, a qualified expert within 30 days of installation.

b. Existing systems not previously surveyed shall have a survey made by, or under the direct supervision of, a qualified expert within 12 months of the effective date.

c. Such surveys shall be done after any change in the facility or equipment that might cause a significant increase in radiation hazard.

d. The registrant shall obtain a written survey report from the qualified expert. A copy of the report shall be retained and made available to the department upon request for the duration of use and registration of the CT X-ray system.

40.8(5) *System performance evaluation.* The calibration of the radiation output of the CT X-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.

a. The calibration of a CT X-ray system shall be performed annually as specified in paragraph 40.4(2)*"b"* by a qualified expert and after any change or replacement of components which, in the opinion of the qualified expert, could cause a change in the radiation output.

b. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system.

(1) The calibration of such system shall be traceable to a national standard.

(2) The dosimetry system shall have been calibrated within the preceding two years.

c. The use of a water equivalent CT phantom shall be incorporated. At a minimum, noise, CT number, and artifacts shall be evaluated.

40.8(6) *Calibration.* Calibration shall meet the following requirements:

a. 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 shall be measurable.

b. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness, the CTDI3 along the two axes specified in paragraph 40.8(5)*"c"* shall be measured for the purpose of determining the CTDI, and the manufacturer's statement as to the nominal tomographic section thickness for that particular system may be utilized.

c. The CT dosimetry phantom shall be oriented so that the measurement point one 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.

d. The CT conditions of operation shall correspond to typical values used by the registrant, and the spot checks specified in subrule 40.8(7) shall be made as specified in 21 CFR 1020.33(c)(2)(iv).

40.8(7) *Routine QC (spot checks).* Spot check procedures shall be in writing and shall have been verified by a qualified expert.

a. The spot check procedures shall incorporate the use of a CT dosimetry phantom that 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 as specified in 21 CFR 1020.33(d)(1).

b. All spot checks shall be included in the calibration required by subrules 40.8(5) and 40.8(6) and at time intervals and under system conditions specified by a qualified expert.

c. Spot checks shall 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 subrules 40.8(5) and 40.8(6).

d. The images shall be retained until a new calibration is performed and retained in two forms:

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

(2) Images stored in digital form on a storage medium compatible with the CT X-ray system.

e. Written records of the spot checks performed shall be retained and made available to the department upon request as specified in subrule 40.4(15).

40.8(8) *CT operating procedures.* The CT X-ray system cannot be operated except by a licensed practitioner or an individual who has been specifically trained in its operation and holds a current permit to practice as a general radiologic technologist as defined under the provisions of 641—Chapter 38. The following information shall be readily available to the CT operator:

a. Instructions on performing routine QC;

b. Scanning protocols for operators;

c. A record of radiation output information, maintained by the registrant, so the radiation dose may be estimated in accordance with established protocols in accordance with the utilization log requirements of this chapter.

40.8(9) *CT systems used for radiation therapy including PET CT, SPECT CT and CT simulation systems.*

a. PET CT and SPECT CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements of this chapter.

b. Operators must meet the requirements of 641—Chapter 38 and be specifically trained in the operation of the PET CT or SPECT CT system.

c. CT systems used exclusively for radiation therapy simulation treatment planning shall be subject to the requirements of this chapter.

40.8(10) *Remote CT scanning requirements.*

a. Operator requirements. Each person who seeks to operate CT X-ray systems in Iowa from a remote location outside of Iowa must possess a current Iowa permit to practice in accordance with 641—Chapter 38 before engaging in remote CT procedures.

b. Facility requirements. Facilities utilizing remote CT scanning shall ensure qualified operators meet the following requirements:

(1) The facility shall maintain documentation demonstrating that each remote operator of a CT system meets the qualification requirements specified in 641—Chapter 38, applicable to the location of the CT system.

(2) The facility shall verify that each operator meets the qualifications outlined in 641—Chapter 38, including operators located out of state, to ensure compliance with Iowa requirements.

c. On-site personnel. Each on-site personnel shall receive training specific to the personnel's assigned responsibilities in the operation of the remote CT system. Training shall include, at a minimum, both of the following:

(1) Patient positioning;

(2) Administration of contrast.

d. Procedures. Procedure review to ensure safe operation and compliance with state regulations will include, at a minimum, all of the following:

(1) Patient ID procedures;

(2) Protocol management procedures;

(3) Emergency procedures.

e. Radiation safety program elements for remote CT. The facility shall ensure all of the following are met. In addition, records should be maintained and made available upon request to the department.

(1) Use only remote CT systems and components that can adequately protect patient information and to establish policies and procedures for ensuring patient information is protected at the imaging facility, remote imaging locations, and locations where other members of the medical team will view or access patient information.

(2) Maintain a list of the remote operating locations and associated imaging sites. The list must contain the name of the facility, location, and a contact person.

(3) Define the roles and responsibilities and develop procedures for the remote CT technologist and the on-site personnel.

(4) Ensure the on-site personnel completes annual radiation safety training related to the personnel's CT responsibilities.

(5) Ensure the on-site personnel maintains constant surveillance of the patient throughout the CT imaging procedure and performs only one CT imaging procedure at a time.

(6) Ensure remote CT will not be performed if communications (verbal and virtual) or connectivity between the remote site and the imaging facility are not functioning properly or are otherwise unreliable.

(7) Perform checks of the communication system (verbal and visual) and the functionality and connectivity between the remote location and the imaging facility prior to initiating each CT imaging procedure.

(8) Develop procedures for responding to emergencies and situations where there may be a loss of connectivity between the remote site and the imaging facility.

(9) Ensure the remote CT technologist maintains constant surveillance via vocal and visual communications throughout a CT imaging procedure and performs only one CT imaging procedure at a time.

(10) Develop policies and procedures to ensure adequate management oversight of remote operations, including all of the following:

1. Audits to evaluate the effectiveness and safety of the remote CT operations;
2. Reportable radiation incidents;
3. Observations of work being performed at both the imaging facility and the remote location;
4. Processes to identify, track, investigate, and implement corrective actions for incidents where CT examinations are incomplete or repeated.

40.8(11) *Cone-beam CT (CBCT) X-ray systems; equipment requirements.* The CBCT X-ray system must meet the applicable requirements of this chapter.

a. The X-ray field in the plane of the image receptor may not exceed beyond the edge 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.

b. The registrant shall document and follow QC recommendations in accordance with manufacturer recommendations or as established by a qualified expert in accordance with nationally recognized guidelines.

c. The registrant shall document and implement imaging protocols and a policy addressing deviations from established protocols.

d. The CBCT X-ray system shall only be operated by an individual who meets the requirements of 641—Chapter 38 or rule 481—575.4(153) and who has been specifically trained in the operation of the CBCT X-ray system.

e. The registrant shall maintain documentation of the established protocols, policies, and QC testing until the X-ray system is removed from the facility for inspection by the department.

f. The CBCT operator shall have instructions on all of the following:

(1) Instructions on performing routine QC;

(2) Scanning protocols for operators;

(3) CT systems, including CBCT systems, solely used in nonhuman imaging refer to rule 641—40.10(136C).

641—40.9(136C) Dual-energy X-ray absorptiometry (DXA). DXA systems shall be registered in accordance with 641—subrule 37.8(2) and maintained and operated, at a minimum, in accordance with the manufacturer's specifications.

40.9(1) *Shielding.* No additional shielding for the room is required.

40.9(2) *Operator requirements.* Operators shall meet the requirements of 641—Chapter 38 and be trained in the safe and effective operation of the specific equipment used at the facility.

a. Specific operating procedures must be prepared and made available to the operator.

b. DXA imaging on human patients shall be conducted only under a prescription of a licensed physician, a licensed physician assistant as defined in Iowa Code section 148C.1(7), or a licensed registered nurse who is registered as a qualified ARNP.

40.9(3) *Operation of the DXA system.*

a. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and DXA system during the examination.

b. The operator shall advise the patient that the DXA examination is a type of X-ray procedure.

641—40.10(136C) Veterinary medicine X-ray systems. Veterinary registrants shall be registered in accordance with 641—subrule 37.8(2) and maintained and operated, at a minimum, in accordance with the manufacturer's specifications.

40.10(1) *Equipment.* All veterinary equipment shall follow the general requirements as specified in rule 641—40.5(136C).

40.10(2) *Operator and ancillary personnel protection for veterinary systems.* All wall, ceiling, and floor areas shall be equivalent to or provided with applicable protective barriers to ensure compliance with the provisions of this chapter.

a. All stationary, mobile, or portable X-ray systems used for veterinary work shall be provided with either a 6.5 feet (two meters) high protective barrier for operator protection during exposures or shall be provided with means to allow the operator to be at least 6.5 feet (two meters) from the tube housing assembly during exposures.

b. Otherwise, in cases where animals are held, the operator and ancillary personnel shall be protected by a minimum of 0.25 mm lead equivalent from scatter radiation and 0.5 mm from the useful beam.

40.10(3) *Operating procedures.* Veterinary medicine radiographic registrants are exempt from the requirements of this chapter, except for the provisions of rules 641—40.4(136C), 40.5(136C), and 641—40.10(136C).

a. No individual other than the operator shall be in the X-ray room while exposures are being made unless such individual's assistance is required.

b. The operator shall stand behind the protective barrier of nine feet from the useful beam and the animal during radiographic exposures.

c. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used.

d. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

40.10(4) *Tube stands for portable X-ray systems.* Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support shall be used for portable X-ray systems so that the X-ray tube housing assembly need not be handheld during an exposure.

40.10(5) *Veterinary handheld equipment.* Handheld intraoral dental X-ray units used in veterinary practice shall meet the requirements of subrule 40.7(5).

40.10(6) *Veterinary CT systems.* CT systems, including CBCT systems, solely used in nonhuman imaging shall meet the requirements of paragraph 40.4(2)*"a"* but are otherwise exempt from the standards of paragraph 40.4(2)*"b."*

These rules are intended to implement Iowa Code chapter 136C.

Appendix A—Healing Arts Screening Program

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING PROGRAM

For the purposes of this program, healing arts screening refers to testing human subjects with X-ray machines to detect or evaluate health indications in individuals considered at high risk, when such tests are not specifically and individually ordered by:

a. An individual authorized under subrule 40.4(10); or

b. An individual licensed as a physician in Iowa.

Persons requesting that the department approve a healing arts screening program shall 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, e.g., age, sex, physical condition, and other appropriate information. Any person conducting a screening program for cardiac scoring shall conduct screening only on either women over the age of 45 or men over the age of 50 who meet any two of the following criteria: family history, smoker, high blood pressure, high cholesterol, obesity (at least 20 pounds overweight), diabetes.

5. An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the X-ray examinations.

6. An evaluation by a qualified expert of the X-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) does satisfy all requirements of these regulations. The evaluation shall include a measurement of patient exposures from the X-ray examinations to be performed.

7. A description of the registrant's applicable 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 the individual who will be supervising the operators of the X-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified.

11. The name and address of the physician who will interpret the images and a copy of the physician's license to practice in Iowa.

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 of images 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 justifying the reason for the screening. The applicant must submit data that supports the efficacy of the screening test in diagnosing the disease or condition being screened. Data that will be acceptable to the department includes but is not limited to the following:

(1) The recommendation of a nationally recognized certifying medical or government body;

(2) The recommendation of one of the following national organizations: American Cancer Association, American Lung Association, American Heart Association; or

(3) Medical literature from peer-reviewed journals supporting the screening.

16. The procedures for preventing pregnant individuals from participating in the screening or justification for allowing pregnant individuals to participate.

17. The dates of the screening to include beginning and ending dates.

18. A copy of the Institutional Research Board approval for a research project or information justifying the research project.

Appendix B

INFORMATION ON RADIATION SHIELDING
REQUIRED FOR PLAN REVIEWS

In order for the department to provide an evaluation and verification that national standards have been met on shielding requirements for a radiation installation, the following information shall be submitted.

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, the energy waveform (single phase, three phase, etc.), and the maximum technique factors.

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

2. Information on the anticipated workload of the X-ray system(s) in mA-minutes per week.

3. If the services of a qualified expert have been utilized to determine the shielding requirements, a report, including all basic assumptions used, shall be submitted with the plans.