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
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 this chapter.

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 (1.0 m) 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(19)*"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. Alternate viewing system as backup. 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.

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