

Regulatory Reform for Clinician Safety

[all proposed changes shown in blue]

§ 482.26 Condition of Participation: Radiologic Services

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) Standard: Radiologic services. The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) Standard: Safety for patients and personnel. The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(i) Radiation Exposure Limits. Facilities must maintain shielding, procedural safeguards, and engineering controls sufficient to ensure that no individual engaged in interventional imaging procedures receives occupational exposure exceeding 20 millisieverts (mSv) per year. Facilities must implement exposure-mitigation protocols for personnel approaching these limits.

(ii) Monitoring and Dosimetry Requirements.

(A) Facilities must provide, maintain, and require the use of individual, clinician-worn dosimetry badges for all personnel routinely working in interventional or fluoroscopic suites.

(B) Dosimetry badges must:

(1) be worn at the collar, outside the protective apron;

(2) be exchanged and analyzed as required by the radiation monitoring manufacturer and the local radiation safety officer; and

(3) provide cumulative dose measurements meeting or exceeding national dosimetry standards.

(C) Facilities must investigate and document any dosimetry badge exposure readings that exceed action levels established in the facility's radiation-safety plan and immediately notify the clinician of their potential risk and departmental management for corrective action.

(D) Facilities must provide a monthly report to each person working in the interventional suite including his/her radiation exposure for the respective month and cumulative annual exposure all based on the person's dosimetry badge reading.

(E) Facilities must install at least one real-time scatter radiation monitoring system per facility to accurately measure real-time radiation exposure and in a location visible to all clinicians.

(iii) Protective Measures

(A) Protective Shielding. Facilities must provide permanent, portable, disposable, or other forms of protective shielding in all interventional and diagnostic settings that are routinely staffed during ionizing-radiation procedures such that no individual engaged in interventional imaging procedures receives occupational exposure exceeding 20 millisieverts (mSv) per year.

(I) Shielding must be sufficient so that physician and medical staff exposure readings are not above the maximum annual limit in compliance with paragraph 482.26(b)(1)(i).

(II) Shielding must be established to provide full-body protection when personnel are positioned at the operating table or procedure field.

(III) Shielding must be capable of being mounted, positioned, or suspended for protection without interference with the clinician's ability to perform the procedure compatible with standard interventional workflows, allowing clear visualization, unobstructed patient access, and rapid repositioning for emergent interventions.

(IV) Facilities must inspect all shielding utilized by the facility at least annually, with documentation of barrier integrity, attenuation performance, mechanical stability, and full operational function.

(V) Facilities must immediately remove from service any shielding that fails integrity or performance testing and must provide alternative protection in accordance with the exposure-control limits in § 482.26(b)(1)(i).

(B) Personal Protective Equipment. Facilities must provide protective apparel or other personal protective equipment in all interventional and diagnostic settings that are routinely staffed during ionizing-radiation procedures such that radiation exposure levels are as low as reasonably achievable (ALARA) and no individual engaged in interventional imaging procedures receives occupational exposure exceeding 20 millisieverts (mSv) per year.

(I) To reduce orthopedic strain and musculoskeletal injury, protective apparel or other personal protective equipment must be of the lowest weight necessary to prevent orthopedic strain and ensure compliance with section (b)(1)(i).

(II) Protective apparel must undergo annual inspection and integrity testing. Any defective items must be replaced promptly.

(C) Continuing Safeguards. Facilities must make every reasonable effort to keep exposure to radiation below 20 millisieverts (mSv) per year, utilizing advances in technology and the economics of technology improvements.

(iv) Training Requirements. All clinical and support personnel assigned to interventional imaging areas must complete annual training addressing:

(A) radiation-exposure risks, including cancer, vascular disease, ocular disease, physical burns, reproductive and fetal health, and other forms of iatrogenic harm;

(B) strategies to mitigate such risks to the greatest extent achievable;

(C) proper use and limitations of personal protective equipment;

- (D) orthopedic risks and mitigation through safe-practice alternatives;
- (E) techniques to minimize exposure time, maximize distance, and optimize shielding;
- (F) proper use of all radiation safety devices used in the facility; and,
- (G) emergency procedures related to fluoroscopic or radiologic equipment malfunction.

Training completion must be documented before personnel are permitted to work in interventional imaging environments.

(v) Compliance and Corrective Action.

(A) Facilities must evaluate compliance with the shielding, exposure-control, and orthopedic-safety standards in this section on not less than an annual basis, implement corrective actions where deficiencies exist, and make full records available for survey review.

(B) Payment to a facility may only be made if such facility is accredited in compliance with this section by an accreditation organization designated and approved by the Secretary.

(2) Periodic inspection on not less than an annual basis of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation exposure of radiation workers serving in fluoroscopic procedural areas must be checked by the facility's radiation safety officer or department manager on a monthly basis, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) Standard: Personnel.

(1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in interventional radiology, cardiology, or other medical specialty where ionizing radiation is used.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) Standard: Records. Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years: (i) Copies of reports and printouts, including monthly dosimetry badge results. (ii) Films, scans, and other image records, as appropriate.