

Prepublication Requirements

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Revised Requirements for Diagnostic Imaging Services

APPLICABLE TO HOSPITALS AND CRITICAL ACCESS HOSPITALS

Effective July 1, 2015

Environment of Care (EC)


Standard EC.02.01.01

The [critical access] hospital manages safety and security risks.

Elements of Performance for EC.02.01.01

A 14. The [critical access] hospital manages magnetic resonance imaging (MRI) safety risks associated with the following:

- Patients who may experience claustrophobia, anxiety, or emotional distress
- Patients who may require urgent or emergent medical care
- Patients with medical implants, devices, or imbedded metallic foreign objects (such as shrapnel)
- Ferromagnetic objects entering the MRI environment
- Acoustic noise

A 16. The [critical access] hospital manages magnetic resonance imaging (MRI) safety risks by doing the following: 

- Restricting access of everyone not trained in MRI safety or screened by staff trained in MRI safety from

the scanner room and the area that immediately precedes the entrance to the MRI scanner room.

- Making sure that these restricted areas are controlled by and under the direct supervision of staff trained in MRI safety.
- Posting signage at the entrance to the MRI scanner room that conveys that potentially dangerous magnetic fields are present in the room. Signage should also indicate that the magnet is always on except in cases where the MRI system, by its design, can have its magnetic field routinely turned on and off by the operator.




Standard EC.02.02.01

The [critical access] hospital manages risks related to hazardous materials and waste.

Element of Performance for EC.02.02.01

A 17. For [critical access] hospitals that provide computed tomography (CT), positron emission tomography (PET), or nuclear medicine (NM) services: The results of staff dosimetry monitoring are reviewed at least quarterly by the radiation safety officer, diagnostic medical physicist, or health physicist to assess whether staff radiation exposure levels are "As Low As Reasonably Achievable" (ALARA) and below regulatory limits.

Note 1: For the definition of ALARA, please refer to U.S. Nuclear Regulatory Commission federal regulation 10 CFR 20.1003.

Key: **A** indicates scoring category A; **C** indicates scoring category C; **D** indicates that documentation is required; **M** indicates Measure of Success is needed;  indicates an Immediate Threat to Health or Safety;  indicates situational decision rules apply;  indicates direct impact requirements apply; **R** indicates an identified risk area

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Standard EC.02.04.01

The [critical access] hospital manages medical equipment risks.

Element of Performance for EC.02.04.01

A 10. The [critical access] hospital identifies quality control and maintenance activities to maintain the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced. The [critical access] hospital identifies how often these activities should be conducted. (See also EC.02.04.03, EP 15)

Standard EC.02.04.03

The [critical access] hospital inspects, tests, and maintains medical equipment.

Elements of Performance for EC.02.04.03

C 15. The [critical access] hospital maintains the quality of the diagnostic computed tomography (CT), positron emission tomography (PET), magnetic resonance imaging (MRI), and nuclear medicine (NM) images produced. (See also EC.02.04.01, EP 7)

A 17. **ⓐ For [critical access] hospitals in California that provide computed tomography (CT) services:** A qualified medical physicist measures the actual radiation dose * produced by each diagnostic CT imaging system at least annually and verifies that the radiation dose displayed on the system for standard adult brain, adult abdomen, and pediatric brain protocols is within 20 percent of the actual amount of radiation dose delivered. The dates of these verifications are documented. **Ⓜ**

Note: *This element of performance is applicable only for systems capable of calculating and displaying radiation doses.*

* For the definition of "radiation dose" refer to section 115111(f) of the California Health and Safety Code.

For diagnostic computed tomography (CT) services: At least annually, a diagnostic medical physicist does the following: **Ⓜ**

- Measures the radiation dose (in the form of volume computed tomography dose index [CTDIvol]) produced by each diagnostic CT imaging system for the following four CT protocols: adult brain, adult

abdomen, pediatric brain, and pediatric abdomen. If one or more of these protocols is not used by the [critical access] hospital, other commonly used CT protocols may be substituted.

- Verifies that the radiation dose (in the form of CTDIvol) produced and measured for each protocol tested is within 20 percent of the CTDIvol displayed on the CT console. The dates, results, and verifications of these measurements are documented.

Note 1: *This element of performance is only applicable for systems capable of calculating and displaying radiation doses.*

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Note 3: *Medical physicists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist. (See also HR.01.02.01, EP 1; HR.01.02.05, EP 20; HR.01.02.07, EPs 1 and 2; HR.01.06.01, EP 1; and LD.03.06.01, EP 4)*

A 19. **ⓐ For diagnostic computed tomography (CT) services:** At least annually, a diagnostic medical physicist conducts a performance evaluation of all CT imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics: **Ⓜ**

- Image uniformity
- Slice thickness accuracy
- Slice position accuracy (when prescribed from a scout image)
- Alignment light accuracy
- Table travel accuracy
- Radiation beam width
- High-contrast resolution
- Low-contrast resolution
- Geometric or distance accuracy
- CT number accuracy and uniformity
- Artifact evaluation

Note 1: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the*

maxillofacial region or to obtain guidance for the treatment of such conditions.

Note 2: Medical physicists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist. (See also HR.01.02.01, EP 1; HR.01.02.05, EP 20; HR.01.02.07, EPs 1 and 2; HR.01.06.01, EP 1; and LD.03.06.01, EP 4)

A 20. Ⓣ At least annually, a diagnostic medical physicist or magnetic resonance imaging (MRI) scientist conducts a performance evaluation of all MRI imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluation includes the use of phantoms to assess the following imaging metrics: ⚠

- Image uniformity for all radiofrequency (RF) coils used clinically
- Signal-to-noise ratio (SNR) for all coils used clinically
- Slice thickness accuracy
- Slice position accuracy
- Alignment light accuracy
- High-contrast resolution
- Low-contrast resolution (or contrast-to-noise ratio)
- Geometric or distance accuracy
- Magnetic field homogeneity
- Artifact evaluation

Note: Medical physicists or MRI scientists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the medical physicist or MRI scientist. (See also HR.01.02.01, EP 1; HR.01.02.05, EP 20; HR.01.02.07, EPs 1 and 2; HR.01.06.01, EP 1; and LD.03.06.01, EP 4)

A 21. Ⓣ At least annually, a diagnostic medical physicist or nuclear medicine physicist conducts a performance evaluation of all nuclear medicine imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluations are conducted for all of the image types produced clinically by each NM scanner (for example, planar and/or tomographic) and include the use of phantoms to assess the following imaging metrics: ⚠

- Image uniformity/system uniformity
- High-contrast resolution/system spatial resolution

- Sensitivity
- Energy resolution
- Count-rate performance
- Artifact evaluation

Note 1: The following test is recommended, but not required: Low-contrast resolution or detectability for non-planar acquisitions.

Note 2: The medical physicist or nuclear medicine physicist is accountable for these activities. He or she may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the medical physicist or nuclear medicine physicist. (See also HR.01.02.01, EP 1; HR.01.02.05, EP 20; HR.01.02.07, EPs 1 and 2; HR.01.06.01, EP 1; and LD.03.06.01, EP 4)

A 22. Ⓣ At least annually, a diagnostic medical physicist conducts a performance evaluation of all positron emission tomography (PET) imaging equipment. The evaluation results, along with recommendations for correcting any problems identified, are documented. The evaluations are conducted for all of the image types produced clinically by each PET scanner (for example, planar and/or tomographic) and include the use of phantoms to assess the following imaging metrics: ⚠

- Image uniformity/system uniformity
- High-contrast resolution/system spatial resolution
- Low-contrast resolution or detectability (not applicable for planar acquisitions)
- Artifact evaluation

Note 1: The following tests are recommended, but not required, for PET scanner testing: sensitivity, energy resolution, and count-rate performance.

Note 2: Medical physicists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the medical physicist. (See also HR.01.02.01, EP 1; HR.01.02.05, EP 20; HR.01.02.07, EPs 1 and 2; HR.01.06.01, EP 1; and LD.03.06.01, EP 4)

A 23. **For computed tomography (CT), positron emission tomography (PET), nuclear medicine (NM), or magnetic resonance imaging (MRI) services:** The annual performance evaluation conducted by the diagnostic medical physicist or MRI scientist (for MRI only) includes testing of image acquisition display

monitors for maximum and minimum luminance, luminance uniformity, resolution, and spatial accuracy.

Note 1: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Note 2: *Medical physicists or MRI scientists are accountable for these activities. They may be assisted with the testing and evaluation of equipment performance by individuals who have the required training and skills, as determined by the physicist or MRI scientist. (See also HR.01.02.01, EP 1; HR.01.02.05, EP 20; HR.01.02.07, EPs 1 and 2; HR.01.06.01, EP 1; and LD.03.06.01, EP 4)*

Standard EC.02.06.05

The [critical access] hospital manages its environment during demolition, renovation, or new construction to reduce risk to those in the organization.

Elements of Performance for EC.02.06.05

A 4. For computed tomography (CT), positron emission tomography (PET), or nuclear medicine (NM) services: Prior to installation of new imaging equipment, replacement of existing imaging equipment, or modification to rooms where ionizing radiation will be emitted or radioactive materials will be stored (such as scan rooms or hot labs), a medical physicist or health physicist conducts a structural shielding design * assessment to specify required radiation shielding.

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

* For additional guidance on shielding designs and radiation protection surveys, see National Council on Radiation Protection and Measurements Report No. 147 (NCRP-147).

A 6. For computed tomography (CT), positron emission tomography (PET), or nuclear medicine (NM) services: After installation of imaging equipment or construction in rooms where ionizing radiation will be emitted or radioactive materials will be stored, a medical physicist or health physicist conducts a radiation protection survey to verify the adequacy of installed shielding. * This survey is conducted prior to clinical use of the room.

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the*

maxillofacial region or to obtain guidance for the treatment of such conditions.

* For additional guidance on shielding designs and radiation protection surveys, see National Council on Radiation Protection and Measurements Report No. 147 (NCRP-147).

Human Resources (HR)

Standard HR.01.02.05

The [critical access] hospital verifies staff qualifications.

Element of Performance for HR.01.02.05

C 20. (D) The [critical access] hospital verifies and documents that diagnostic medical physicists who support computed tomography (CT) services have board certification in diagnostic radiologic physics or radiologic physics by the American Board of Radiology, or in Diagnostic Imaging Physics by the American Board of Medical Physics, or in Diagnostic Radiological Physics by the Canadian College of Physicists in Medicine, or meet all of the following requirements: (M)

- A graduate degree in physics, medical physics, biophysics, radiologic physics, medical health physics, or a closely related science or engineering discipline from an accredited college or university
- College coursework in the biological sciences with at least one course in biology or radiation biology and one course in anatomy, physiology, or a similar topic related to the practice of medical physics
- Documented experience in a clinical CT environment conducting at least 10 CT performance evaluations under the direct supervision of a board-certified medical physicist

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Standard HR.01.05.03

Staff participate in ongoing education and training.

Elements of Performance for HR.01.05.03

C 14. (D) The [critical access] hospital verifies and documents that technologists who perform diagnostic computed tomography (CT) examinations participate in ongoing education that includes annual training on the following: (M)

- Radiation dose optimization techniques and tools for pediatric and adult patients addressed in the Image Gently® and Image Wisely® campaigns

- Safe procedures for operation of the types of CT equipment they will use

Note 1: Information on the Image Gently and Image Wisely initiatives can be found online at <http://www.imagegently.org> and <http://www.imagewisely.org>, respectively.

Note 2: This element of performance does not apply to CT systems used for therapeutic radiation treatment planning or delivery, or for calculating attenuation coefficients for nuclear medicine studies.

Note 3: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

- C 25.** Ⓓ The [critical access] hospital verifies and documents that technologists who perform magnetic resonance imaging (MRI) examinations participate in ongoing education that includes annual training on safe MRI practices in the MRI environment, including the following:
Ⓜ

- Patient screening criteria that address ferromagnetic items, electrically conductive items, medical implants and devices, and risk for Nephrogenic Systemic Fibrosis (NSF)
- Proper patient and equipment positioning activities to avoid thermal injuries
- Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional) *
- MRI safety response procedures for patients who require urgent or emergent medical care
- MRI system emergency shutdown procedures, such as MRI system quench and cryogen safety procedures
- Patient hearing protection
- Management of patients with claustrophobia, anxiety, or emotional distress

* Terminology for defining the safety of items in the magnetic resonance environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (<http://www.astm.org>).

Medication Management (MM)

Standard MM.06.01.01

The [critical access] hospital safely administers medications.

Element of Performance for MM.06.01.01

- C 13.** Before administering a radioactive pharmaceutical for diagnostic purposes, staff verify that the dose to be administered is within 20% of the prescribed dose, or, if the dose is prescribed as a range, staff verify that the dose to be administered is within the prescribed range.

⚠ Ⓜ

Provision of Care, Treatment, and Services (PC)

Standard PC.01.02.15

The [critical access] hospital provides for diagnostic testing.

Elements of Performance for PC.01.02.15

- C 5.** Ⓓ For [critical access] hospitals in California that provide computed tomography (CT) services: The [critical access] hospital documents in the patient's record the radiation dose index (CTDIvol, DLP, or size-specific dose estimate [SSDE]) on every study produced during a diagnostic computed tomography (CT) examination. The radiation dose index must be exam specific, summarized by series or anatomic area, and documented in a retrievable format. ⚠ Ⓜ

Note 1: This element of performance is *only* applicable *only* for systems capable of calculating and displaying radiation doses *indices*.

Note 2: This element of performance does not apply to systems used for therapeutic radiation treatment planning or delivery, or for calculating attenuation coefficients for nuclear medicine studies.

Note 3: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.

Note 4: While the CTDIvol, DLP, and SSDE are useful indicators for monitoring radiation dose indices from the CT machine, they do not represent the patient's radiation dose.

* For the definition of "radiation dose" refer to section 115111(f) of the California Health and Safety Code.

- C 6.** For [critical access] hospitals that provide diagnostic computed tomography (CT) services: The interpretive report of a diagnostic CT study includes the volume computed tomography dose index (CTDIvol) or dose-length product (DLP) radiation dose. The dose is either recorded in the patient's interpretive report or included on the protocol page.

C-7. For [critical access] hospitals in California that provide computed tomography (CT) services: The [critical access] hospital electronically sends each CT study and protocol page that lists the radiation dose* and related technical factors to the [critical access] hospital's electronic picture archiving and communications system.

Note: *This element of performance is applicable only for systems capable of calculating and displaying radiation doses.*

* For the definition of "radiation dose" refer to section 115111(f) of the California Health and Safety Code.

A 10. For [critical access] hospitals that provide diagnostic computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), or nuclear medicine (NM) services: Prior to conducting a diagnostic imaging study, the [critical access] hospital verifies the following:

- △
- Correct patient
- Correct imaging site
- Correct patient positioning
- For CT only: Correct imaging protocol
- For CT only: Correct scanner parameters

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

A 12. For [critical access] hospitals that provide diagnostic computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET), or nuclear medicine (NM) services: The [critical access] hospital considers the patient's age and recent imaging exams when deciding on the most appropriate type of imaging exam. △

Note 1: *Knowledge of a patient's recent imaging exams can help to prevent unnecessary duplication of these examinations.*

Note 2: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Standard PC.01.03.01

The [critical access] hospital plans the patient's care.

Elements of Performance for PC.01.03.01

A 25. The [critical access] hospital establishes or adopts diagnostic computed tomography (CT) imaging protocols based on current standards of practice, which address key criteria including clinical indication, contrast administration, age (to indicate whether the patient is pediatric or an adult), patient size and body habitus, and the expected radiation dose index range. △

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

A 26. Diagnostic computed tomography (CT) imaging protocols are reviewed and kept current with input from an interpreting radiologist, medical physicist, and lead imaging technologist to make certain that they adhere to current standards of practice and account for changes in CT imaging equipment. These reviews are conducted at time frames identified by the [critical access] hospital. △

Note: *This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.*

Performance Improvement (PI)

Standard PI.01.01.01

The [critical access] hospital collects data to monitor its performance.

Elements of Performance for PI.01.01.01

A 46. The [critical access] hospital collects data on patient thermal injuries that occur during magnetic resonance imaging exams.

A 47. The [critical access] hospital collects data on the following:

- Incidents where ferromagnetic objects unintentionally entered the magnetic resonance imaging (MRI) scanner room
- Injuries resulting from the presence of ferromagnetic objects in the MRI scanner room

Standard PI.02.01.01

The [critical access] hospital compiles and analyzes data.

Element of Performance for PI.02.01.01

A 6. The [critical access] hospital reviews and analyzes incidents where the radiation dose index (CTDIvol, DLP, or size-specific dose estimate [SSDE]) from diagnostic CT examinations exceeded expected dose index ranges identified in imaging protocols. These incidents are then compared to external benchmarks.

Note 1: While the CTDIvol, DLP, and SSDE are useful indicators for monitoring radiation dose indices from the CT machine, they do not represent the patient's radiation dose.

Note 2: This element of performance does not apply to dental cone beam CT radiographic imaging studies performed for diagnosis of conditions affecting the maxillofacial region or to obtain guidance for the treatment of such conditions.