
CMS Manual System

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Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 141

Date: July 10, 2015

SUBJECT: Revisions to the State Operations Manual (SOM), Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: The Interpretative Guidelines is being revised for 42 CFR 482.26 concerning radiologic services and 42 CFR 482.53 concerning nuclear medicine.

NOTE: Tag A-0545 has been deleted and the regulations and revised Interpretive Guidelines have been relocated to Tag A-0546. Tags A-0554 and Tag A-0555 have been deleted and the regulations and revised Interpretive Guidelines can be found at Tag A-0553. Tag A-1025 is new and contains the condition-level regulation previously located at Tag A-1026. Tag A-1026 is now the standard level Tag for items found under the condition statement. Tags A-1028 and A-1029 have been deleted and the regulations and Interpretive Guidelines can be found at Tag A-1027. Tag A-1045 has been deleted and the regulations and revised Interpretive Guidelines are now at Tag A-1044. Finally, Tags A-1052 and A-1053 have been deleted and the regulations and revised Interpretive Guidelines can be found at Tag A-1051.

**NEW/REVISED MATERIAL - EFFECTIVE DATE: July 10, 2015
IMPLEMENTATION DATE: July 10, 2015**

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/A-0528/§482.26 Condition of Participation: Radiologic Services
R	Appendix A/A-0529/§482.26 & /§482.26 Condition of Participation: Radiologic Services
R	Appendix A/A-0535/§482.26 Condition of Participation: Radiologic Services
R	Appendix A/A-0536/§482.26(b)(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.
R	Appendix A/A-0537/§482.26(b)(2) - Periodic inspection of equipment must be made and hazards identified must be properly corrected.
R	Appendix A/A-0538/§482.26(b)(3) - Radiation workers must be checked

	periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.
R	Appendix A/A-0539/§482.26(b)(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.
D	Appendix A/A-0545/§482.26(c) Standard: Personnel
R	Appendix A/A-0546/§482.26(c)-Standard: Personnel
R	Appendix A/A-0547/§482.26(c)(2) - Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.
R	Appendix A/A-0553/§482.26(d) Standard: Records
D	Appendix A/A-0554/§482.26 (d)(1) - The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.
D	Appendix A/A-0555/§482.26 (d)(2) - The hospital must maintain the following for at least 5 years:
N	Appendix A/A-1025/§482.53 Condition of Participation: Nuclear Medicine Services
R	Appendix A/A-1026/Standard-level Tag §482.53Condition of Participation: Nuclear Medicine Services
R	Appendix A/A-1027/§482.53(a) Standard: Organization and Staffing
D	Appendix A/A-1028/§482.53(a)(1) - There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.
D	Appendix A/A-1029/§482.53(a)(2) - The qualifications, training, functions and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.
R	Appendix A/A-1035/§482.53(b) Standard: Delivery of Service
R	Appendix A/A-1038/§482.53(b)(3) - If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.
R	Appendix A/A-1044/§482.53(c) Standard: Facilities
D	Appendix A/A-1045/§482.53(c) [The equipment must be--]
R	Appendix A/A-1051/§482.53(d) Standard: Records
D	Appendix A/A-1052/§482.53(d)(1) - The hospital must maintain copies of nuclear medicine reports for at least 5 years.
D	Appendix A/A-1053/§482.53(d)(2) - The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.
R	Appendix A/A-1054/§482.53(d)(3) - The hospital must maintain records of the receipt and distribution of radio pharmaceuticals.
R	Appendix A/A-1055/§482.53(d)(4) - Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals

III. FUNDING: No additional funding will be provided by CMS.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-0528

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§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.

Interpretive Guidelines §482.26

Hospitals must offer diagnostic radiologic services and may also offer therapeutic radiologic services. No matter where they are furnished in the hospital (including all departments on all campuses and off-site locations) radiologic services must satisfy professionally approved standards for safety and personnel qualifications. Hospitals are expected to take a consistent approach in their policies and procedures for radiologic services safety and personnel qualifications throughout the hospital. This may be accomplished in several ways, including by having one organized radiologic service under the direction of the radiologist who supervises all ionizing radiology services (see §482.26(c)(1)), or by the governing body ensuring a uniform approach to radiologic services that are offered in multiple departments of the hospital. .

The elements of the Condition’s regulatory language (the Condition “stem” statement) are close, but not identical, to those found in the standards at §§482.26(a) and (b). We have, therefore, repeated elements of this Condition regulatory language in the Tags for both §§482.26(a) and (b), in order to permit citation of deficiencies that are specific to requirements found in the Condition stem statement at either the standard or condition level, as appropriate. The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.

What is included in Radiologic Services?

Radiologic services encompass many different modalities used for the purpose of diagnostic or therapeutic medical imaging and radiation therapy. Each type of technology yields different information about the area of the body being studied or treated, related to possible disease, injury, or the effectiveness of medical treatment. All the modalities use some form of radiation, which is a term for energy waves or particles that pass through a medium, such as light or radio signals through the air. Some of these modalities (radiography, computed tomography, fluoroscopy) utilize ionizing radiation, which has enough energy to potentially cause damage to DNA, while others (ultrasound, magnetic resonance imaging) use other forms of non-ionizing radiation to view the human body in order to diagnose, monitor, or treat medical conditions.

Most of the definitions and terms referred to in this guidance are based on technical information available on the U.S. Food and Drug Administration’s (FDA) website, located at <http://www.fda.gov/Radiation-EmittingProducts/default.htm> or from the Radiologic Society of North America’s (RSNA) website, located at <http://www.radiologyinfo.org> .

Diagnostic & Therapeutic Radiologic Services

Diagnostic and therapeutic radiologic services may use the same modalities, but for different purposes. Diagnostic services are performed to determine a specific cause of the medical problem with which the patient presents (e.g., fractured bone, occluded artery, tumor), while therapeutic services are performed to treat a specific problem (e.g., stenting of an artery or embolization of a blood vessel, lithotripsy of a renal stone, external beam radiation therapy to a cancerous tumor). Regardless of the purpose of the radiologic services, the risks to the patient and staff, if applicable, depend on the modality used, the length of the study/procedure, the size of the patient, the specifics of the device being used, and other factors.

Modalities that use Ionizing Radiation

Radiography (X-rays) is a technique for generating and recording an x-ray pattern for the purpose of providing the user with a static image(s) after termination of the exposure. During a radiographic procedure, an x-ray beam is passed through the body. A portion of the x-ray is absorbed or scattered by the body's internal structure and the remaining x-ray pattern is transmitted to a detector, so that an image may be recorded for later evaluation. The recording of the pattern may occur on film or through electronic means (digital). X-rays are used to diagnose or treat patients by displaying images of the internal structure(s) of the body to assess the presence or absence of disease, foreign objects, and structural damage or anomaly.

Some common examples include:

- *Verification of correct placement of invasive catheters, tubes, or devices;*
- *Orthopedic evaluations for fractured or dislocated bones;*
- *Chest x-ray to identify common conditions, such as congestive heart failure or pneumonia;*
- *Evaluations of radio-opaque foreign bodies in soft tissues; and*
- *Mammography.*

Dual-energy X-ray absorptiometry (DEXA) is a form of medical imaging that uses very small amounts of ionizing radiation to measure bone mineral density and determine an individual's risk for bone fractures or establish the diagnosis of osteoporosis. The amount of radiation used is less than one-tenth the dose of a traditional chest X-ray and less than one day's exposure to natural radiation.

Computed Tomography (CT) scanning, also called computerized axial tomography (CAT) scanning, is a medical imaging procedure that uses x-rays to show cross-sectional images of the body. A CT imaging system produces cross-sectional images or "slices" of areas of the body, like the slices in a loaf of bread. During a CT scan, a patient undergoes several consecutive and simultaneous X-rays that can be configured as a three dimensional reconstruction of the part of the body that is being imaged. Thus, a CT scan delivers more ionizing radiation to the patient than radiography. CTs are better able to distinguish between different types of tissues in the body than radiography and, given its ability to image large areas over a short period of time, CT offers significantly improved resolution of many different structures in a variety of spatial configurations. Often a CT scan will be performed using x-ray dye or contrast agent, which can

be administered by mouth or by vein. This technique further helps to identify the intestines or vasculature, which can assist with the diagnosis of disease or injury.

Some common examples include:

- *CT of the brain to distinguish between an ischemic or hemorrhagic stroke;*
- *CT of the abdomen and pelvis to evaluate for internal bleeding following trauma;*
- *CT of the chest to determine the presence of a pulmonary embolus; and*
- *CT of the aorta with intravenous contrast agent to determine a ruptured aneurysm.*

***Fluoroscopy** is a type of medical imaging that shows a continuous x-ray image on a monitor, much like an x-ray movie. It is used to diagnose or treat patients by displaying the movement of a body part, or of an instrument or x-ray dye (contrast agent) through the body.*

Fluoroscopy is used in many types of examinations and procedures. Some examples include:

- *Barium upper GI (gastrointestinal) series and enemas (to view movement through the GI tract);*
- *Catheter insertion (to direct the placement of a catheter in a blood vessel);*
- *Orthopedic surgery (to view fracture treatments); and*
- *Angiography (to determine if there are blockages in arteries).*

The amount of ionizing radiation that a patient and the medical staff receive during the procedure depends on the procedure's length and complexity.

Radiation Therapy

Ionizing radiation can also be used for therapeutic purposes, in which the energy is utilized to directly kill cancerous cells.

***External beam therapy (EBT)** is a method to deliver a beam of high-energy x-rays to a patient's tumor. The beam is generated outside the patient and is targeted at the tumor site. The goal is to deposit the energy to kill the cancer cells while sparing the normal tissue. EBT is often used to treat cancers of the breast, head and neck, prostate, lung, and brain. It also can be used to provide palliative care for painful sites of metastases to bone.*

***Brachytherapy** is a type of radiation therapy in which radioactive material is placed directly inside or next to the tumor. This type of therapy allows for a higher dose of radiation to treat a smaller area and in a shorter time than with EBT. It can be either temporary, in which the radioactive material is placed inside or near a tumor for a specified amount of time, often via a catheter; or permanent, in which radioactive seeds or pellets are placed near or inside a tumor and left there permanently, eventually decaying so that the radioactivity diminishes to nothing. Brachytherapy is often used to treat solid tumors, including prostate, breast, and gallbladder cancer.*

Radiologic Services modalities that do not use ionizing radiation

Ultrasound

Ultrasound imaging (sonography) uses high-frequency sound waves to view soft tissues, such as muscles and internal organs. Because ultrasound images are captured in real-time, they can show movement of the body's internal organs as well as blood flowing through blood vessels. This imaging modality has no documented evidence of dangers to the patient or staff administering it, however, caution about the frequency of use has been encouraged, particularly in the imaging of fetuses. Ultrasound imaging is used in many types of examinations and procedures. Some examples include:

- *Doppler ultrasound (to visualize blood flow through a blood vessel);*
- *Echocardiogram (to view the heart);*
- *Fetal ultrasound (to view the fetus in pregnancy);*
- *Ultrasound-guided biopsies of suspicious masses;*
- *Doppler fetal heart rate monitors (to listen to the fetal heart beat); and*
- *Lithotripsy to break up kidney stones; this procedure uses high energy sound waves (shock waves), but there is minimal risk to the patient and staff from this form of energy. Pre- and post-procedure radiographs are taken of the patient, which confer the same risk as a standard X-ray of that part of the body.*

Magnetic resonance imaging (MRI) *is a medical imaging procedure that uses strong magnetic fields and radio waves to produce cross-sectional images of organs and internal structures in the body. Because the signal detected by an MRI machine varies depending on the water content and local magnetic properties of a particular area of the body, different tissues or substances can be distinguished from one another in the study image.*

MRI can give different information about structures in the body than can be obtained using a standard x-ray, ultrasound, or computed tomography (CT) exam. For example, an MRI study of a joint can provide detailed images of ligaments and cartilage, which are not visible using other modalities. In some cases, an MRI contrast agent is given by vein to show internal structures or abnormalities more clearly.

In most MRI devices, an electric current is passed through coiled wires to create a temporary magnetic field in a patient's body. (In open-MRI devices, permanent magnets are used.) Radio waves are sent from and received by a transmitter/receiver in the machine, and these signals are used to produce digital images of the area of interest.

MRI scans facilitate diagnosis or monitoring of treatments for a variety of medical conditions, including:

- *Abnormalities of the brain and spinal cord;*
- *Tumors, cysts, and other abnormalities in various parts of the body;*
- *Injuries or abnormalities of the joints;*
- *Certain types of heart problems;*
- *Diseases of the liver and other abdominal organs;*
- *Causes of pelvic pain in women (e.g., fibroids, endometriosis); and*

- *Suspected uterine abnormalities in women undergoing evaluation for infertility.*

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[§482.26 Condition of Participation: Radiologic Services

The hospital must maintain, or have available, diagnostic radiologic services...]

§482.26(a) Standard: Radiologic Services

The hospital must maintain, or have available, radiologic services according to the needs of the patients.

Interpretive Guidelines §482.26 (a)

Mandatory and Optional Radiologic Services

The hospital must maintain, or have available, diagnostic radiological services according to the needs of the volume and types of patients the hospital serves. “Maintain” in this context means furnishing radiologic services on-site, while having them available means providing access to radiologic services even when they are not furnished on-site. For example:

- *It would not be uncommon for a psychiatric hospital to maintain on-site relatively limited or no radiologic services, while making more extensive diagnostic services available under arrangement, at a site outside the psychiatric hospital.*
- *On the other hand, a short-term acute care hospital with a busy emergency department that handles trauma, stroke, and other complex medical and surgical cases would be expected to maintain on-site a wider range of diagnostic radiologic services that are ready to be furnished when needed.*

A hospital’s diagnostic radiologic services must be maintained or available at all times. Multi-campus hospitals must have diagnostic radiologic services that can be furnished when needed in a clinically appropriate timeframe for each location providing inpatient, same-day surgery, and emergency services. The scope and complexity of diagnostic radiological services maintained or available must be specified in writing, in order to demonstrate how the hospital meets the needs of its patients.

Therapeutic radiologic services are optional, but if they are offered, must also comply with the Radiologic Services requirements.

Radiological services may be provided by the hospital directly utilizing its own staff, or through a contractual arrangement. The hospital is responsible for ensuring that the services meet all the requirements of this regulation, regardless of whether they are provided directly or under

arrangement. Diagnostic radiologic services provided under *arrangement* may be provided either on the hospital's *campus* or in an adjacent or other nearby, readily accessible facility *so long as the services, including those required on an urgent or emergent basis, can be furnished within clinically appropriate timeframes.*

Increasingly, hospitals are also separating the performance of radiologic studies, which may be done on-site or at a readily accessible facility off the hospital's campus, from the interpretation of the studies, which can be performed remotely by a teleradiology practitioner in a timely fashion. This practice is acceptable, so long as the teleradiology practitioner is privileged in accordance with the requirements of the Governing Body (§482.12) and Medical Staff (§482.22) CoPs.

Survey Procedures §482.26(a)

- *With respect to assessing whether the diagnostic radiologic services meet the needs of the hospital's patients:*
 - *Ask the hospital for evidence of the scope and complexity of its diagnostic radiologic services.*
 - *Ask how the hospital has determined that the services meet the needs of its patients.*
- *Verify that the hospital either maintains or makes available diagnostic radiologic services that can be provided promptly when needed.*
 - *If the hospital has an emergency department, are diagnostic radiologic services maintained or available at all times to support the emergency department?*
 - *If the diagnostic radiologic services are not on the same campus as the hospital's emergency department, same-day surgery, inpatient locations, or other areas where services dependent upon radiologic services are provided, ask the hospital how it ensures that services are furnished within clinically required timeframes. Does the hospital have an arrangement with an off-site facility to furnish diagnostic services when needed?*
 - *How does the hospital ensure that staff authorized to interpret diagnostic studies are ready to furnish services within clinically required timeframes, either on-site or through telecommunications media that permit remote review and interpretation of studies?*

A-0535

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[§482.26 Condition of Participation: 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.]

§482.26(b) Standard: Safety for Patients and Personnel

The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

Interpretive Guidelines §482.26(b)

The hospital must adopt and implement *radiologic services* policies and procedures that provide safety for *affected* patients and *hospital* personnel *and which are consistent with accepted professional standards for radiologic services*.

Ionizing Radiology Procedures

Radiologic services modalities that use ionizing radiation have increased the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. When applied and performed appropriately, these radiologic studies or procedures can maintain or improve health and save lives.

X-ray energy used in radiologic services also has a potential to harm living tissue. The most significant risks are:

- *Cataracts and skin damage, but only at very high levels of radiation exposure; and*
- *An increase in the possibility that a person exposed to x-ray energy will develop cancer later in life. The risk of developing cancer from radiologic services radiation exposure is generally very small, and it depends on at least three factors—the amount of the radiation dose, the age of the person exposed, and the sex of the person exposed:*
 - *The lifetime risk of cancer increases the larger the dose and the more x-ray studies or procedures a patient undergoes;*
 - *The lifetime risk of cancer is larger for a patient who received x-rays at a younger age than for one who receives them at an older age; and.*
 - *Women are at a somewhat higher lifetime risk than men for developing radiation-associated cancer after receiving the same exposures at the same ages.*

MRI:

MRIs are useful when a soft tissue injury or disease process is suspected and are generally considered at low risk of causing harm to patients or staff. However, they also are not entirely risk-free. Potential risks include projectile risk of magnetic objects being sucked into the main magnet, thermal injury and burns, adverse effects on devices and leads implanted in patients, and hearing damage.

Provision of services in accordance with professionally approved standards for safety

All radiological services provided by the hospital, including both diagnostic and, if offered, therapeutic services, must be provided in accordance with acceptable standards of practice, including standards for safety.

Professionally approved standards include maintaining compliance with applicable Federal and State laws and regulations governing radiological services, including, but not limited to, facility licensure and/or certification requirements.

Professionally approved standards also include the recommendations or guidelines promulgated by expert governmental agencies, such as the U.S. Food and Drug Administration, as well as those issued by nationally recognized professional organizations, such as the American Medical Association, American College of Radiology, Radiological Society of North America, The Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, the American College of Cardiology, the American College of Neurology, the American College of Physicians, etc.

Generally, there are different standards for different imaging modalities used to provide radiologic services; there may also be different standards for diagnostic versus therapeutic uses, as well as for pediatric versus adult patients, etc. For example, the American College of Radiology has separate diagnostic radiology guidance documents for general radiology, CT, MRI, and ultrasound, among others. The hospital must be able to document the source standards that form the basis for its policies and procedures for each of its radiologic services modalities and/or settings. For example, if one organization's standards are used for mammography services, another's for CT services, another's for MRI, and another's for pediatric X-rays, this must be clearly indicated.

In order to ensure safety and freedom from hazards, the hospital's radiologic services policies and procedures must include, but are not limited to, provisions addressing the following:

- *For ionizing radiation services, application of the fundamental principle of As Low as Reasonably Achievable or ALARA, which is defined by the U.S. Environmental Protection Agency (EPA) as "A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account. The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved." (Federal Guidance Report No. 14, Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, p. 100, November, 2014) Although CMS does not interpret or enforce EPA guidance, the ALARA principle is considered an accepted standard of practice for ionizing radiation services to which hospitals must adhere.*
- *Written protocols developed or approved by the radiologist responsible for the radiologic services, in conjunction with other qualified radiologic services personnel (e.g., a medical physicist, radiologic technologists, patient safety officers, etc.) designed to ensure that diagnostic studies and therapeutic procedures are routinely performed in a safe manner, utilizing parameters and specifications that are appropriate to the ordered study/procedure.*

The hospital must ensure that protocols for the various types of ionizing radiation diagnostic or therapeutic imaging modalities are designed to minimize the amount of radiation while maximizing the yield and producing diagnostically acceptable image quality. Existing protocols must be reviewed periodically and updated as needed. The rationale and details for changes to technical parameters must be documented.

For Information Only – Not Required/Not to be Cited

*Hospitals are encouraged to follow the recommendation in the EPA's Guidance Report No. 14 concerning patient radiation dosage. The report says "As the ICRP [International Commission on Radiological Protection] has stated, 'Provided that the medical exposures of patients have been properly justified and that the associated doses are commensurate with the medical purpose, it is not appropriate to apply dose limits or dose constraints to the medical exposure of patients, because such limits or constraints would often do more harm than good' (ICRP 2007b). While dose limits do not apply to medical exposures, radiation doses to patients should always be optimized. All responsible parties should always strive to minimize patient irradiation to the dose that is necessary to perform the procedure with adequate image quality. **The recommendation against establishing absolute dose limits should not discourage a facility from implementing diagnostic reference levels for imaging and interventional procedures. Exceeding these levels should prompt a review of practice at the facility as a quality assurance measure. Dose notification and alert values for CT, notification levels for use during interventional procedures, and trigger levels for follow-up after interventional procedures are also appropriate QA measures [emphasis added]...**(EPA Guidance Report No. 14, p.6)*

- *Policies and protocols to identify patients at high risk for adverse events for whom the radiologic study or procedure might be contraindicated, e.g., pregnant women, individuals with known allergies to contrast agents, individuals with implanted devices, etc. Policies would address the steps to be taken, and by which personnel, if an order is written for a radiologic study or procedure for an individual identified in the radiologic services policies as potentially at high risk (e.g., notify the ordering physician, cancel the procedure personally, etc.).*
- *Specific requirements related to procedures to mitigate radiation hazards are discussed in the guidance for §482.26(b)(1).*
- *Procedures to address risks associated with modalities that do not use ionizing radiation. For example, with respect to MRI:*
 - *Measures to prevent magnetic materials from being closer than is safe to the MRI suite, per nationally recognized guidelines;*
 - *If equipment and supplies, such as fire extinguishers and oxygen tanks, are located in the MRI area, they are MR-safe, i.e., they are non-ferromagnetic;*

- *Provision of adequate and effective hearing protection to patients, staff and others who might be in the MRI suite while the scans are taking place; and*
- *Measures to reduce the risk of thermal injuries/burns during MRI. This would include, but is not limited to, screening patients to identify those who may have metallic tattoos or metal in them, proper patient positioning, ensuring implants are MR Conditional, checking for electrically conductive materials that might be in close proximity to the patient and taking the appropriate precautions, and instructing the patient to immediately report any burning sensations experienced during the scan.*
- *Training required by personnel permitted to enter areas where radiologic services are provided.*
- *Training and, as applicable, qualifications, required for personnel who perform diagnostic imaging studies or therapeutic procedures utilizing radiologic services equipment. This includes proper operation of equipment per manufacturer's instructions and hospital policy.*
- *Areas where radiologic services are provided must be equipped with the necessary equipment or materials to immediately respond to potential adverse events. This could include, but is not limited to, things like a crash cart, emergency stop mechanisms, cleaning and decontamination agents if applicable, etc.*

For Information Only – Not Required/Not to be Cited

Hospitals are encouraged to also address the following in their Radiologic Services:

- *Encouraging physicians and other practitioners with privileges to order radiologic studies or procedures that utilize ionizing radiation to consider both the benefits and risks of the procedures.*
- *Recording and tracking the dosing patients receive. There are several nationally recognized quality assurance programs designed to assist health care providers in developing and maintaining this data, including, but not limited to:*
 - *The Alliance for Safety in Pediatric Imaging ([www.Imagegently.org](http://www.imagegently.org))*
 - *The Conference of Radiation Control Program Directors*
 - *The American College of Radiology data registry (<http://nrdr.acr.org>)*
 - *The Nationwide Evaluation of X-ray Trends (NEXT program)*

Further, although the EPA's Guidance Report No. 14 was developed by an Interagency Working Group on Medical Radiation specifically to provide guidance to Federal facilities that use diagnostic and interventional X-ray equipment, it should also be useful to non-Federal medical facilities and hospitals are encouraged to review it. The Guidance Report addresses the following topics:

- *Radiation Safety Standards and General Concerns*
- *Structural Shielding and Door Interlock Switches*
- *Requesting and Performing Studies Involving X-rays*
- *Technical Quality Assurance*
- *General Guidelines for Clinical Imaging, organized into separate sections for Medical and Dental, and further broken down by modality*
- *Imaging Informatics*
- *Recommendations for Facility Action*

Medical Physicists

According to the American Association of Physicists in Medicine, the practice of Medical Physics means the use of principles and accepted protocols of physics to ensure the correct quality, quantity, and placement of radiation during the performance of a radiological procedure. Hospitals are not required under the regulations to have a medical physicist on staff or under contract. However, since radiologic services are required to be free from hazards to patients and hospital personnel, hospitals must ensure that qualified personnel, whether or not they are medical physicists, develop and carry out protocols and test, calibrate, and maintain radiologic services equipment and that there is a reliable means to validate the results.

For Information Only - Not Required/Not to be Cited

Definition of a Medical Physicist

An example of a definition of and qualifications for a medical physicist is provided by the American Association of Physicists in Medicine:

“For the purpose of providing clinical professional services, a Qualified Medical Physicist (QMP) is an individual who is competent to independently provide clinical professional services in one or more of the subfields¹ of medical physics. The subfields of medical physics are:

- *Therapeutic Medical Physics*
- *Diagnostic Medical Physics*
- *Nuclear Medicine Physics*
- *Medical Health Physics*

.... A Qualified Medical Physicist meets each of the following credentials:

- *Has earned a master’s and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and*
- *Has been granted certification in the specific subfield(s) of medical physics with its associate medical health physics aspects by an appropriate national certifying body and abides by the certifying body’s requirements for continuing education.”*

<http://www.aapm.org/org/default.asp>

For Information Only - Not Required/Not to be Cited

The responsibilities of the medical physicist in a hospital may include:

- *protection of the patient and others from potentially harmful or excessive radiation;*
- *establishment, with the approval of the Director of Radiologic Services, of adequate protocols to ensure accurate patient dosimetry;*
- *measurement and characterization of radiation;*
- *determination of delivered dose;*
- *promotion of procedures necessary to ensure image quality;*
- *development and direction of quality assurance programs; and assistance to other healthcare professionals in optimizing the balance between the beneficial and deleterious effects of radiation.*

Hospitals are also encouraged to involve a medical physicist in the calibration of the radiologic services equipment and monitoring of radiation dosage exposures to staff.

Consistent with the requirements under the Quality Assessment and Performance Improvement (QAPI) CoP at 42 CFR 482.21, the hospital must monitor the quality and safety of radiologic services.

Examples of indicators of potential quality and safety problems could include, but are not limited to:

- *Improper patient preparation, such as inadequate intravenous access or lack of pre-medication, such that procedures must be cancelled or reordered;*
- *Repeats of the same studies in the hospital for the same patient within a short time span, which may be an indicator of poor image quality; or*
- *Diagnostic imaging studies or therapeutic procedures performed in a manner inconsistent with the applicable hospital written protocol.*

Under the QAPI CoP, hospitals are required to undertake improvement activities in areas that represent high risk, high volume, or problem-prone areas. Problems identified in radiologic services may meet these criteria. In addition, adverse events related to radiologic services must be analyzed for their causes, and preventive actions must then be undertaken. Deficiencies identified related to tracking, analyzing, and addressing adverse event and quality indicator data and performance improvement activities must be cited under the applicable QAPI standards.

Survey Procedures §482.26(b)

- *Verify that there are written hospital policies and procedures and protocols for specific radiologic services modalities that are based on identified professionally approved standards, and which address the ALARA principle as well as the other safety and risk-reduction measures discussed in the guidance.*
- *Ask for evidence that safety protocols are reviewed periodically and, if applicable, updated.*
- *Determine if the radiologic services staff are familiar with the policies and procedures related to safety in general and specific clinical protocols.*
- *Observe whether the policies and procedures are followed when radiologic services are delivered to patients. Ask for the protocol(s) for one or more studies/procedure(s) you observed and check if they were followed.*
- *Verify that radiologic services staff are trained at appropriate intervals to ensure that they are operating the equipment according to manufacturer's instructions and hospital policy*
- *Verify that radiologic services staff know how to respond to adverse events.*
- *Confirm that areas where radiologic services are provided are equipped with the equipment or materials to immediately respond to an adverse event.*
- *Ask the radiologist who supervises ionizing radiologic services how the hospital monitors the quality and safety of radiologic services.*
- *Verify that adverse events are analyzed for their causes and that preventive actions are taken (deficiencies to be cited both here and under the applicable QAPI citation).*

A-0536

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§482.26(b)(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.

Interpretive Guidelines §482.26(b)(1)

The hospital must adopt and implement written policies and procedures to ensure safety from radiation hazards. The policies and procedures must include, but are not limited to, consideration of the following:

- *Clear and easily recognizable signage identifying hazardous radiation areas;*

- *Limitations on access to areas containing radiologic services equipment.*
- *Appropriate use of shielding, including:*
 - *Types of personal protective shielding (e.g., lead aprons, lead gloves, protective eyewear, thyroid shields, portable individualized lead panels, stationary barriers) to be used, under what circumstances, for patients, including high-risk patients as identified in radiologic services policies and procedures, patient family members or support persons who may be needed to be with the patient during a study or procedure, and hospital personnel;*
 - *Lead and concrete barriers built into the walls and other structures of the imaging areas;*
- *Identification and use of appropriate containers to be used for various radioactive materials, if applicable, when stored, in transport between locations within the hospital, in use, and during/after disposal.*

For Information Only - Not Required/ Not to be Cited

The Occupational Health and Safety Administration (OSHA) has requirements for protecting hospital staff from radiation exposure, some of which are summarized below:

- *“For information about exposure limits see: 29 CFR 1910.1096, Ionizing Radiation Standard. The standard also requires:*
 - *Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol, with the wording ‘Caution Radiation Area’ [29 CFR 1910.1096(e)(2)]”*

Survey Procedures §482.26(b)(1)

- Verify that *personal* shielding, *supplies and equipment* are properly maintained and routinely inspected by the hospital.
- *Determine if the proper shielding is applied to a patient who is undergoing a procedure using ionizing radiation.*
- *Determine if staff members appropriately extricate themselves from the immediate exposure field while performing a study or procedure using ionizing radiation.*
- *Determine if staff wear shielding as appropriate, per hospital policy.*
- Verify that any hazardous *radiation* materials *are clearly labeled*, properly stored in a safe manner *in the requisite containers, and disposed of in the appropriate manner.*

A-0537

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§482.26(b)(2) - Periodic inspection of equipment must be made and hazards identified must be properly corrected.

Interpretive Guidelines §482.26(b)(2)

The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner. *Equipment includes not only devices used to deliver diagnostic or therapeutic radiologic services, but also exposure meters, badges, or personal radiation monitoring devices used by staff, as well as equipment the hospital uses to inspect or calibrate devices used to deliver diagnostic or therapeutic radiologic services.* The hospital must ensure that equipment is inspected in accordance with *manufacturer's instructions and* Federal and State laws, regulations, and guidelines, and hospital policy, *as applicable.* *Inspections and maintenance, including correction of identified hazards, must be performed by qualified employees (e.g., medical physicists, qualified biomedical technicians, etc.) or through contractual arrangements with vendors with appropriate expertise.*

Hospitals must follow the manufacturer's instructions as to how to inspect and maintain radiologic equipment. This includes acceptance testing (i.e., upon initial installation and after major upgrades) as well as ongoing inspection and maintenance. Documentation of preventive maintenance, quality control tests, service records, and major software/hardware upgrades must be maintained by the hospital and be readily available for inspection.

The hospital must *also* have a system in place, *to identify and remedy equipment hazards in a timely manner. This system must include, but is not limited to: periodic and consistent calibration of equipment and, for equipment using ionizing radiation, monitoring of dosimetry*

parameters with phantoms to ensure that an accurate dose of radiation is delivered per the applicable protocol. In addition, hospitals must also have a system to track all modifications made to the equipment that would significantly impact the accuracy of the dosage delivered. Any adverse events related to over- or under-dosing must be identified and addressed.

***For Information Only - Not Required/Not to be Cited
Requirements for Manufacturers Re: Instructions that Must be Made Available***

Below is an FDA summary of its requirements for manufacturers of x-ray systems to make available to purchasers and, upon request, to other parties, information related to maintenance of the following types of systems:

- For all diagnostic x-ray systems, manufacturers are required to provide to purchasers, and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets that include technical and safety information (21 CFR 1020.30(h)). This information must include a schedule of the maintenance necessary to keep the equipment in compliance with §§1020.30, 1020.31, 1020.32, and 1020.33 (21 CFR 1020.30(h)(1)(ii)). Manufacturers are also required to provide to assemblers, and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of specified components of diagnostic x-ray systems adequate to ensure that the products will comply with applicable provisions of §§1020.30, 1020.31, 1020.32, and 1020.33, when assembled, installed, adjusted, and tested as directed (21 CFR 1020.30(g)).*
- In addition to the requirements applicable to all diagnostic x-ray systems, there are also other requirements for specific systems:*
 - Manufacturers of fluoroscopic x-ray systems manufactured on or after June 10, 2006 are required to provide a schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of air kerma rate and cumulative air kerma within the limits of allowed uncertainty specified by 21 CFR 1020.32(k)(6). And, if the capability for user calibration of the display is provided, adequate instructions for such calibration must be supplied (21 CFR 1020.30(h)(6)(i)).*
 - Manufacturers of computed tomography (CT) systems are required to provide a specific phantom or phantoms for quality assurance testing of specific system parameters on these systems (21 CFR 1020.33(d)(1)), and instructions on the use of the phantom(s), including a schedule of testing appropriate for the system and allowable variations for the indicated parameters (21 CFR 1020.33(d)(2)).*
 - Manufacturers of cabinet x-ray systems are required to provide purchasers, and others, upon request, at a cost not to exceed the cost of preparation and distribution, manuals and instructions. These documents must include, among other technical and safety information, a schedule of maintenance necessary to keep the system in compliance with 21 CFR 1020.40 (21 CFR 1020.40(c)(9)(i)). Cabinet x-ray systems that are intended to be assembled or installed by the purchaser must be accompanied by instructions for*

assembly, installation, adjustment and testing of the cabinet x-ray adequate to ensure that the system is in compliance with the applicable provisions of 21 CFR 1020.40 when assembled, installed, adjusted and tested as directed (21 CFR 1020.40(c)(9)(ii)).

Survey Procedures §482.26(b)(2)

- Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with Federal and State laws, regulations and manufacturer's instructions.
- *Verify that inspection and maintenance activities were performed by qualified individuals*
- *Verify that the maintenance logs show documentation of the calibration upon installation and after major upgrades or servicing.*
- *Review with the appropriate personnel the inspection schedule and the mechanism for identifying hazards, including accurate dosimetry determinations with phantom patients, as applicable.*
- Determine that any problems identified *through the testing and maintenance program* are properly corrected in a timely manner *and the correction is maintained over time.*

A-0538

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§482.26(b)(3) - Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

Interpretive Guidelines §482.26(b)(3)

This requirement applies to radiologic services personnel, as well as other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include certain nursing and maintenance staff. The types or locations of employees who require monitoring for radiation exposure must be identified in the policies and procedures for the radiologic services developed or approved by the radiologist who supervises the services, in conjunction with the appropriately qualified radiation safety personnel. The monitoring of staff exposure must be documented by qualified personnel.

Hospitals are expected to educate staff who are monitored for radiation exposure about the appropriate use of the monitoring meters or badges (or through use of a "personal radiation monitoring device," which employs modern technology for the same measurement purpose). Hospitals must educate staff on the importance of tracking their radiation exposure over various timeframes, such as the most recent month and year, as well as their cumulative exposure through work. Staff also must be educated about the appropriate storage of the meters and/or badges as well as the procedures to follow if the exposure device exceeds cumulative dosage

parameters specified per hospital policy. The hospital is expected to proactively monitor staff cumulative dosage and take appropriate steps if an individual staff member's cumulative dosage level exceeds parameters specified per hospital policy.

For Information Only – Not Required/Not to be Cited

The Occupational Safety and Health Administration (OSHA) has requirements for protecting hospital staff from radiation exposure, some of which are summarized below:

- *“For information about exposure limits see: 29 CFR 1910.1096, Ionizing Radiation Standard. The standard also requires:*
 - *...Every employer shall supply appropriate personnel monitoring equipment, such as film badges, pocket chambers, pocket dosimeters, or film rings, and shall require the use of such equipment [29 CFR 1910.1096(d)(2)]*
 - *Employers shall maintain records of the radiation exposure of all employees for whom personnel monitoring is required under paragraph (d) of this section and advise each employee of his individual exposure at least yearly...*

See: <https://www.osha.gov/SLTC/etools/hospital/clinical/radiology/radiology.html#Radiation>

As a reminder, although hospitals are required to comply with applicable OSHA requirements, surveyors conducting surveys on behalf of CMS do not interpret or assess compliance with the requirements of OSHA or other Federal Agencies. Surveyors do assess compliance with Medicare requirements that may overlap or duplicate OSHA requirements.

Survey Procedures §482.26(b)(3)

- Verify that staff *being monitored have been trained about the appropriate use and storage of their badges/meters. Are staff knowledgeable about their personal radiation exposure over various timeframes?*
- Observe *whether staff in categories or locations identified for monitoring have radiation-detecting meters or badges and that they appropriately wear and store them.*
- Review records to verify that *monitoring of staff exposure is documented.*
 - *Ask the hospital what steps it takes if staff exposure exceeds parameters established per hospital policy. Can the hospital provide examples, or, if it asserts there have been no cases in the prior 12 – 24 months, do its records support this?*

A-0539

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§482.26(b)(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.

Interpretive Guidelines §482.26(b)(4)

The medical staff and the governing body determine the necessary qualifications and clinical privileges that practitioners must have to order diagnostic radiologic studies or therapeutic procedures.

For outpatient services, the governing body and medical staff may also authorize practitioners who do not have hospital privileges to order such studies or procedures, as permitted under State law. For example, a hospital may decide that it will routinely accept orders from physicians in the communities it services for outpatient diagnostic studies, regardless of whether those physicians have privileges to practice in the hospital. See the guidance for §482.54(c) for more information on requirements related to outpatient orders from practitioners who do not hold privileges to practice at the hospital.

The order must include information for the radiologic technologist about the study or procedure to be performed, and the technologist is expected to review this information prior to implementing the order.

For Information Only – Not Required/Not to be Cited

Hospitals are strongly encouraged, but not required, to develop standard formats for practitioner's orders for radiologic services that clearly document the diagnostic or therapeutic purpose of the study/procedure, as well as any other pertinent information that may lead to altering the dose of radiation, including, but not limited to:

- *Indication (reason) for the study/procedure*
- *Previous imaging studies of the body part(s) under investigation;*
- *Additional relevant radiation exposure; and*
- *Previous adverse events (e.g., over- or underexposure of dosing, allergic reaction to contrast dye) during radiologic procedures.*

In addition, hospitals are encouraged to adopt policies to ensure that the radiation technologist performing the study/procedure confirms the order with the ordering practitioner if there are any concerns about its appropriateness.

Survey Procedures §482.26(b)(4)

- *Review medical records to determine that there is an order for all radiologic services, and that the order was dated/timed and authenticated by an authorized practitioner prior to the diagnostic study or therapeutic procedure being performed.*
- *Observe whether a radiologic technologist confirms that there is an order from an authorized practitioner and reviews information included in the order before beginning a study or procedure.*

A-0546

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§482.26(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 radiology.

Interpretive Guidelines §482.26(c)(1)

The regulation defines a radiologist as a doctor of medicine (MD) or doctor of osteopathy (DO) who is qualified by education and experience in radiology. The medical staff must establish the specific criteria related to education and experience that must be met in order to be privileged as a radiologist in the hospital.

Ionizing radiologic services offered throughout the hospital must be under the supervision of a radiologist, who may be part-time, full-time, or consulting. This may be accomplished in several ways, including by having one organized radiologic service under the direction of the supervising radiologist, or by the governing body ensuring a uniform approach to ionizing radiologic services that are offered in multiple, separately organized departments of the hospital which collaborate with the supervising radiologist in developing their department-specific protocols for ensuring that these services are free from hazards for patients and personnel.

The supervising radiologist, including, if applicable, a consultant who provides such supervision, must be privileged as a radiologist at the hospital. The extent of radiologic services provided by the hospital determines whether the supervising radiologist must carry out these responsibilities full or part-time.

For diagnostic radiologic services using ionizing radiation, policies and procedures must, in addition to the requirements addressed in other portions of the radiologic services CoP, identify which types of radiologic tests require interpretation by a radiologist, as opposed to another type of practitioner holding privileges; the hospital’s medical staff must approve this policy.

When interpretation of radiologic tests (studies) is provided via telemedicine, the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by State or local laws in the state where the hospital (and, therefore, the patient) is located. The requirements concerning granting of privileges to teleradiologists are addressed in the medical staff (§482.22) and governing body (§482.12) Conditions of Participation.

Survey Procedures §482.26(c)(1)

- *Review the medical staff privileging criteria for a radiologist. Review the credentialing and privileging file of the supervising radiologist to verify that he or she meets the qualifications established by the medical staff and has been granted privileges as a radiologist.*
 - *If the supervising radiologist is a part-time employee or consultant, ask him/her how much time/week is spent on supervising ionizing radiologic services.*
 - *Is there any evidence of problems within the radiologic services that suggest lack of supervision?*
- *Determine whether the medical staff has reviewed and approved a policy identifying the types of diagnostic radiologic tests (studies) that require interpretation by a radiologist. Review records to determine that a radiologist interprets those tests (studies) that have been designated.*

A-0547

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

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

Interpretive Guidelines §482.26(c)(2)

The medical staff must develop policies, consistent with State law, that govern the designation of all personnel who are qualified to use the radiologic equipment and perform diagnostic or therapeutic studies or procedures. Qualifications must include appropriate training and demonstrated competence in the use of equipment and administration of procedures prior to being designated as qualified. Only designated individuals may use the equipment and perform studies or procedures.

The use of the radiologic equipment includes, but is not limited to, functions such as operating the equipment according to the manufacturer's instructions and hospital policy, and interfacing with specialized technology as needed.

In addition to a radiologist, and although not specifically mentioned in the regulations, radiologic technologists are typically involved in the delivery of radiologic services in a hospital.

Radiologic technologists are medical personnel who typically perform diagnostic imaging examinations and administer radiation therapy treatments, as permitted under State law. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection, and basic patient care. All radiologic technologists using radiologic equipment or performing studies/procedures must be designated to do so.

Personnel also need to know how to respond to adverse events that may occur during a radiologic study or procedure.

Hospitals are expected to regularly reassess staff competency and to provide periodic training needed to keep staff skills up-to-date. The hospital must document training completion dates and evidence of satisfactory competence. Staff that complete training but cannot demonstrate satisfactory competence must not be permitted to use radiologic equipment and/or administer procedures.

Survey Procedures §482.26(c)(2)

- *Verify that the medical staff established criteria for personnel who use radiologic services equipment and perform studies or procedures.*
- Determine which staff are using *which* pieces of radiological equipment. Review their personnel folders to determine *if* they meet the qualifications established by the medical staff for the tasks they perform.
- *Verify that radiologic services staff are periodically trained and reassessed for competence to ensure that they are operating the equipment according to manufacturer instructions and hospital policy and know how to respond to adverse events related to their use of the equipment.*

A-0553

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§482.26(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.*
- (ii) Films, scans, and other image records, as appropriate.*

Interpretive Guidelines §482.26(d)

The hospital must maintain records for all *radiologic* procedures performed. At a minimum, the records *must* include *the orders for the services*, copies of reports and printouts, and any films, scans, *digital* or other image records, as appropriate.

Radiology films, image records, scans, *digital files*, reports, and printouts must be secure *and* properly stored *for at least five years*. *If State law requires a longer period, the hospital must comply, but surveyors do not assess compliance with State law requirements as part of the Federal survey. Patient radiologic services records are considered patient medical records and the hospital must comply with the requirements of the medical records CoP (§482.24). All reports of studies must be signed by the radiologist or other authorized practitioner (in the case of studies not designated as requiring a radiologist to interpret them) who reads and evaluates the findings of the study. Acceptable forms of signature include paper signatures as well as electronic signatures.*

Survey Procedures §482.26(d)

- Determine *whether* the hospital *maintains radiologic services records for at least 5 years after the study or procedure*. (*Assess them for compliance with the Medical Records CoP at §482.24 at the same time, but make sure to cite general medical record noncompliance under that CoP.*)
- *Request records for all different imaging modalities furnished by the hospital, to determine if the procedure for maintaining the records is consistent among all the radiologic services.*
- *Review radiologic records to determine that reports of studies are signed by the radiologist or other authorized practitioner (in the case of studies not designated as requiring a radiologist to interpret them) who read and evaluated the findings of the study*

A-1025

(Rev. 141, Issued: 07-10-15, Effective: 07-10-15, Implementation: 07-10-15)

§482.53 Condition of Participation: Nuclear Medicine Services

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretative Guidelines §482.53

This is an optional hospital service. However, if a hospital provides any nuclear medicine services to its patients, *it* must comply with the requirements of this Condition of Participation.

The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation. However, the regulatory language concerning provision of nuclear medicine services in a manner that meets

the needs of the patients in accordance with acceptable standards of practice appears only in the condition “stem” statement of this CoP. This does not mean, however, that deficiencies related to these requirements must automatically be cited at the condition level. To facilitate, when appropriate, citation of deficiencies associated with these requirements at the appropriate level, Tag A-1025 must be used for condition-level citations, while Tag A-1026 must be used for standard-level citations related to the stem statement language.

What is Nuclear Medicine and what is it used for?

Nuclear medicine uses radioactive material to diagnose or treat a variety of diseases and conditions.

Diagnostic Nuclear Medicine

When a diagnostic nuclear medicine study is performed, a patient inhales, swallows, or is injected with a small amount of a radiopharmaceutical that accumulates in a specific organ or area of the body. A radiopharmaceutical is a drug that contains a radioactive component. The energy emitted by the radioactive material is detected by a device, processed and measured by a computer, and then displayed as an image on a screen or on film that is then interpreted by a radiologist specially trained in nuclear medicine or another type of physician with specialized training as a nuclear medicine physician. The image(s) provide details on both the structure and function of organs and tissues.

For some studies, nuclear medicine techniques can be combined with other medical imaging devices, such as CT scans or MRIs, in which the same machine can deliver, detect, and process several types of images at the same time. The technique of combining various imaging modalities is called hybrid imaging. Hybrid imaging can provide more precise information and accurate diagnoses and is predominantly used in the diagnosis and treatment of cancer.

Nuclear medicine diagnostic imaging scans are commonly performed to:

- Visualize heart blood flow and function, e.g., a cardiac stress test or myocardial perfusion scan; this is the most frequent use of nuclear medicine diagnostic imaging.*
- Diagnose blood clots in the lungs (pulmonary emboli) with a ventilation/perfusion (V/Q) scan;*
- Identify areas of infection, inflammation, or cancer metastases with a bone scan;*
- Localize lymph nodes prior to surgery;*
- Determine gastrointestinal tract muscle function by measuring time for swallowing and emptying;*
- Determine the functioning and perfusion of many other organs, including the thyroid gland, kidneys, brain, and gall bladder*

Therapeutic Nuclear Medicine

Nuclear medicine can also be used to treat various diseases and conditions. For these types of procedures, a specific radiopharmaceutical agent is used to deliver a specific amount of radioactivity to a targeted cell type or organ. The energy emitted by the radioactive agent incapacitates or kills the diseased cells of that targeted tissue, and thus limits the exposure of healthy tissue to radioactivity.

Examples of therapies that use nuclear medicine include (but are not limited to):

- *Radioactive iodine to treat hyperthyroidism (Graves' disease);*
- *Radioactive antibodies that target specific forms of lymphoma;*
- *Radioactive agents to relieve pain in areas of bony metastases.*

A-1026

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Standard-level Tag

§482.53 Condition of Participation: Nuclear Medicine Services

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

Interpretative Guidelines §482.53

Nuclear medicine services must be provided in accordance with acceptable standards of practice. Acceptable standards of practice include maintaining compliance with applicable Federal and State law and regulations governing the use of nuclear medicine, including facility licensure requirements, as well as standards and recommendations promoted by nationally recognized professional organizations. *Examples of nationally recognized professional organizations in the area of nuclear medicine include, but are not limited to, organizations such as the American College of Radiology, the Radiological Society of North America, the Society of Nuclear Medicine and Molecular Imaging, the American Society of Nuclear Cardiology, and the American Association of Physicists in Medicine.*

If nuclear medicine services are provided under arrangement, the governing body must, *in accordance with §482.12(e)*, ensure that the services are provided in a manner *that complies with the requirements of the nuclear medicine CoP.*

Minimizing the risks of nuclear medicine

Nuclear medicine studies and procedures provide useful diagnostic information and targeted therapies for patients. However, since they use radioactive materials that produce high energy,

there are also risks associated with the exposure to radioactivity. Specifically, the risk involves exposure to ionizing radiation, which is a form of energy given off by atomic particles that can cause damage to DNA in various living tissues. The most significant risks include, but are not limited to:

- *A small increase in the possibility that a person exposed to ionizing radiation will develop cancer later in life.*

The risk of developing cancer from nuclear medicine radiation exposure is generally small and depends on at least three factors—the amount of the radiation dose, the age of the patient or staff member at the time of the exposure, and the sex of the person exposed:

- *The lifetime risk of cancer increases the larger the dose and the greater the number of studies or treatments involving radioactivity which he/she undergoes;*
- *The lifetime risk of cancer is larger for a patient who received exams that involve radioactivity at a younger age, since less mature cells are more radiosensitive; and*
- *Women are at somewhat higher lifetime risk than men for developing radiation-associated cancers after receiving the same exposures at the same age.*

In order to minimize the risks of ionizing radiation and maximize patient safety during nuclear medicine studies and procedures, hospitals are expected to apply the fundamental principle of “As Low as Reasonably Achievable” or “ALARA,” which is defined by the U.S. Environmental Protection Agency (EPA) as “A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account. The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved.” (Federal Guidance Report No. 14, Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, p. 100, November, 2014) Although CMS does not interpret or enforce EPA guidance, the ALARA principle is considered an accepted standard of practice for nuclear medicine that hospitals must adhere to.

Hospitals are expected to be able to demonstrate how they incorporate ALARA into their nuclear medicine services. They are also expected to have nuclear medicine policies and procedures that take into consideration classes of patients who may be at higher risk for over-exposure, as well as the radiation exposure of staff when preparing, storing, transporting, administering and disposing of radioactive materials.

For Information Only – Not Required/Not to be Cited

Hospitals are encouraged to develop protocols for the use of radiopharmaceuticals designed to achieve an optimal balance between minimizing the amount of radiation exposure while maximizing the diagnostic image quality or therapeutic benefit.

The risk of excessive exposure for both patients and staff can be reduced by designing and

implementing nuclear medicine study protocols that:

- *Minimize the distance between the source of radiation and its target; and*
- *Follow published guidelines for administered activity, i.e., the amount of radiation administered by the radiopharmaceutical.*

In addition, the hospital's nuclear medicine services must be integrated into its hospital-wide Quality Assessment and Performance Improvement (QAPI) program, as required by §482.21. Consistent with these requirements, the hospital must monitor the quality and safety of nuclear medicine services. Examples of nuclear medicine indicators of potential quality and safety problems could include, but are not limited to:

- *Incidents of improper patient preparation, such as inadequate intravenous access or lack of pre-medication, such that procedures must be cancelled or reordered;*
- *Incidents of the wrong radiopharmaceutical being used, i.e., not the radiopharmaceutical prescribed for the patient, or of the wrong dose of the prescribed radiopharmaceutical being administered, or of use of the wrong route of administration for the prescribed radiopharmaceutical.*
- *Repeats of the same diagnostic studies within a short time span, which may be an indicator of poor image quality; or*
- *Diagnostic studies or therapeutic procedures performed in a manner inconsistent with the applicable hospital written protocol.*

In addition, the hospital is also required under the QAPI CoP to track medical errors and adverse events related to nuclear medicine services. Adverse events related to nuclear medicine services must be analyzed for their causes, and preventive actions must then be undertaken. Deficiencies identified related to tracking, analyzing and addressing adverse event and quality indicator data and performance improvement activities must be cited under the applicable QAPI standards.

Survey Procedures §482.53

- **If nuclear medicine services are offered, determine the type(s) of services provided and the location where each service is provided.**
- *Ask the director of nuclear medicine services how the hospital ensures that the services are provided in accordance with acceptable standards of practice.*
 - *Can the director point to accepted guidelines or State or other Federal law that support the hospital's nuclear medicine policies and procedures?*
 - *Can the director explain how the hospital's policies, procedures, and protocols are consistent with ALARA principles?*

- *Observe one or more nuclear medicine studies to determine whether the staff follows the hospital's protocols for that study. Ask the staff after the observation to show you the applicable protocol and explain how they complied with it.*

A-1027

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§482.53(a) Standard: Organization and Staffing

The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

- (1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.**
- (2) The qualifications, training, functions and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.**

Interpretive Guidelines §482.53(a)

The scope of nuclear medicine services offered by the hospital, including which types of diagnostic studies and/or therapeutic procedures are provided, where they are provided in the hospital, and the appropriately-trained staff and equipment needed to provide these services must be specified in writing. Hospitals may choose to provide nuclear medicine services in one location or at several different locations in the hospital, including, but not limited to, inpatient and outpatient locations of the radiology, cardiology, and oncology departments. The organization of the nuclear medicine service must encompass the full scope and complexity of nuclear services offered throughout the hospital.

Nuclear Medicine Director

The hospital is required to have a director responsible for nuclear medicine services offered throughout the hospital. The director must be a doctor of medicine (MD) or osteopathy (DO) and must demonstrate through education, experience and specialized training that he/she is qualified in nuclear medicine. Nuclear medicine physicians utilize radioactive materials to diagnose and treat disease either by interpreting the images created by radioisotopes or by prescribing and evaluating therapeutic interventions involving radiopharmaceuticals. Typically these MDs/DOs initially specialize in radiology or internal medicine and then complete subspecialty training in nuclear medicine.

The hospital must describe in writing the qualifications it requires for the director of nuclear medicine services.

Other Nuclear Medicine Personnel

Although not mentioned specifically in the regulation, there are several different categories of personnel that may typically be involved in the provision of nuclear medicine services, including (but not limited to):

- *Nuclear medicine pharmacists: these individuals are pharmacists who specialize in preparing, dispensing, and distributing radiopharmaceuticals;*
- *Nuclear medicine technologists: these individuals are trained to administer radioactive materials and perform the specific imaging procedures and often process the images for interpretation; and*
- *Nuclear medicine physicists.*

The hospital must *specify in writing the qualifications, training, functions and responsibilities of each category of personnel used by the hospital, whether personnel are employees or contractors, in the delivery of nuclear medicine services. The written specifications must be developed by the Director and approved by the hospital's medical staff.* Qualifications include at a minimum, job title, education, experience, specialized training, and licensure/certification, consistent with *any applicable* Federal and State law.

The specifications must also address ongoing training for personnel.

Survey Procedures §482.53(a)

- *Determine whether* the scope of the nuclear medicine services offered is *specified* in writing.
- *Determine whether there are nuclear medicine policies developed by the director of nuclear medicine governing provision of these services in every part of the hospital offering nuclear medicine services.*
- *Verify that the hospital has a written description of the qualifications of the nuclear medicine services director.*
- Review the service director's file to verify that he/she is a MD or DO and has the necessary education, experience and specialized training in nuclear medicine, *per the hospital's written policies.*
- Verify that the qualifications, training, functions and responsibilities of *the various categories of* nuclear medicine staff *the hospital uses* are specified by the director and approved by the medical staff.
- *Review personnel files for a sample of nuclear medicine staff to determine if they meet the prescribed qualifications and have received ongoing training as required in the hospital's policies and procedures.*

A-1035

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§482.53(b) Standard: Delivery of Service

Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

§482.53(b)(2) There is proper storage and disposal of radioactive material.

Interpretive Guidelines §482.53(b) and (b) (2)

The hospital must establish, in writing, *and implement policies and procedures addressing the use of* radioactive materials *within the hospital. The policies and procedures must be based on acceptable standards of practice for the medical use of radioactive materials and must address,* at a minimum:

- *Security of radioactive materials at every stage and location of their use within the hospital, including determining who may have access to them, implementing procedures to control access, and a system to track the receipt, usage and disposal of all radioactive materials;*
- *Safe storage of radioactive materials, including radioactive waste awaiting disposal outside the hospital;*
- *Clear, recognizable labeling of radioactive materials, waste, and hazardous areas in all locations of the hospital, including during the preparation of such materials, if applicable;*
- *Safe and secure transport of radioactive materials between locations within the hospital;*
- *Safe handling with the appropriate personal and container protections, as applicable, by personnel who prepare and administer radiopharmaceuticals within the hospital;*
- *Protection of patients from radiation hazards, including screening for high-risk patients (for example, possible pregnancy, multiple nuclear medicine studies, children, etc.);*
- *Maintenance and proper use of personal radiation monitoring devices (dosimeters) for staff working in the vicinity of radiopharmaceuticals, according to manufacturer's instructions, particularly regarding the appropriate placement of the dosimeter on the body, as indicated on the dosimeter;*
- *Safe and secure disposal of radioactive waste, including unused but unneeded radioactive materials as well as, when extra precautions are applicable, human waste products.*

Survey Procedures §482.53(b)

- Verify *through observation and document review* that radioactive materials are prepared, labeled, used, transported, stored, and disposed of in accordance with *hospital policies that are based on* acceptable standards of practice.
- *Ask the hospital to demonstrate how it limits access to radioactive materials at all times.*
 - *Verify that the hospital maintains accurate records of the receipt, distribution, and disposal of radioactive materials, including radiopharmaceuticals.*
- *If the hospital prepares radiopharmaceuticals on site, observe the preparation to verify that proper safety precautions are utilized to protect staff from excess radiation and once prepared, stored in appropriate containers. If the radiopharmaceuticals are obtained from an outside source, verify that the receipt and storage are appropriately tracked.*
- *Verify that a clear, recognizable label for nuclear material is appropriately displayed in all relevant areas throughout the hospital and on all radioactive materials.*
- Verify that safety precautions are followed in the *operations* of the nuclear medicine service and that personnel and patients *maintain and* wear appropriate body shielding (e.g., lead aprons, lead gloves, *thyroid shields*) when appropriate.
- *Observe a staff member deliver a nuclear medicine procedure to a patient, paying particular attention to adherence to hospital safety protocols during the delivery of the radiopharmaceutical.*
- *Through interview and observation, determine if staff use their dosimeters according to manufacturer's instructions, particularly in the appropriate placement of the dosimeter on the body, as indicated on the dosimeter.*
- *Ask the responsible staff to demonstrate how they ensure safe transport of radioactive materials in the hospital.*
- *Interview the responsible staff to determine whether the appropriate container protection devices—e.g., lead for gamma emitters—are being utilized for storage and administration of radioactive materials.*
- *Ask staff to show the policy for disposal methods for radioactive waste or unused material and to explain how they ensure that these procedures are followed.*

A-1038

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§482.53(b)(3) - If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in §482.27.

Interpretive Guidelines §482.53(b)(3)

Any laboratory tests performed in connection with nuclear medicine services must comply with the hospital Condition of Participation of laboratory services, including a requirement to comply with 42 CFR Part 493, which establishes the Clinical Laboratory Improvement Act (CLIA) requirements for laboratories.

Survey Procedures §482.53(b)(3)

The applicable survey procedures for the laboratory services Condition of Participation must be used.

A-1044

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§482.53(c) Standard: Facilities

Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be--

- (1) *Maintained in safe operating condition; and***
- (2) *Inspected, tested and calibrated at least annually by qualified personnel.***

Interpretive Guidelines §482.53(c)

The nuclear medicine service must use equipment and supplies that are designed and, when applicable, approved to be used in conjunction with radioactive materials.

Equipment must be maintained so that it operates safely to minimize hazards to patients and hospital personnel as much as possible. Accordingly, it must be inspected, tested, and calibrated by personnel with the necessary qualifications. Personnel may be either hospital employees or contracted. Personnel must follow the manufacturer's quality assurance instructions for acceptance testing (upon installation and after major upgrades) and maintenance testing. Inspections, testing and calibration must occur at least annually unless required to be more frequent according to the manufacturer's instructions.

The hospital must have a policy and procedure for staff who operate the equipment to follow if they suspect a malfunction.

Survey Procedures §482.53(c)

- Does the hospital have documentation that indicates that the equipment and supplies it uses in nuclear medicine services are appropriate for use with radioactive materials?*

- *Is the hospital able to demonstrate how personnel, whether employees or contractors, who inspect, test, calibrate, and maintain nuclear medicine services equipment are qualified to do so?*
- *Review equipment maintenance records. Verify that equipment is tested, calibrated and otherwise maintained at least annually, following the manufacturer's recommended procedures. Verify that if the manufacturer requires more frequent than annual testing and maintenance that the hospital adheres to the manufacturer's prescribed schedule.*
- *Ask nuclear medicine services staff who operate equipment what they would do if they suspected a malfunction. Does the hospital have a policy to address this and are staff familiar with it?*

A-1051

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§482.53(d) Standard: Records

The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

- (1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.**
- (2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.**

Interpretive Guidelines §482.53(d)(1) & (2)

Nuclear medicine patient records, *including interpretations, consultations, and procedures are patient medical records and the hospital must comply* with the Medical Records CoP (§482.24).

Nuclear medicine patient records, like all patient medical records, must be maintained for at least five years. If State law requires a longer period, the hospital must comply, but surveyors do not assess compliance with State law requirements as part of the Federal survey. Each report of an interpretation of a nuclear medicine diagnostic study must be signed and dated by the practitioner who made the interpretation, as authorized by the medical staff. Deficient nuclear medicine medical records practices related to these two requirements must be cited under this regulation; depending on the specific facts, citation under the Medical Records CoP might also be appropriate.

Survey Procedures §482.53(d)(1) & (2)

- Verify that copies of nuclear medicine reports are maintained for at least 5 years.
- Verify that reports of nuclear medicine interpretations are signed and dated only by the practitioner *who interpreted the study's results, as authorized by* the medical staff to perform

these interpretations

A-1054

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§482.53(d)(3) - The hospital must maintain records of the receipt and distribution of radiopharmaceuticals.

Interpretive Guidelines §482.53(d)(3)

Hospitals receive their radiopharmaceuticals from manufacturers, either for further in-house preparation, or ready to use. Regardless of the source of the material, the hospital must have records that track the movement of the radiopharmaceuticals upon receipt, throughout the hospital. The records must specify:

- *the type of radiopharmaceutical;*
- *the location in the hospital where it was received, stored and dispensed;*
- *the amount received or dispensed at each location;*
- *the staff member receiving or dispensing; and*
- *when applicable, how/when it is disposed of and by whom. This would also include, when applicable, the type and amount of any radiopharmaceuticals returned to the source vendor.*

Additional information, including special transport instructions or precautions, may be included.

The hospital must also have policies and procedures that address how often it reviews these records and how it reconciles discrepancies between inventory on hand and records of receipt, distribution, use, disposal and/or return to the source vendor.

Surveyor Procedures §482.53(d)(3)

- *Ask the hospital to demonstrate how it maintains accurate records of the receipt and distribution of radiopharmaceuticals at all locations throughout the hospital.*
- *Ask what the hospital's policy is for frequency of review of the records; is there evidence that the hospital complies with its policy?*
- *Ask the hospital to explain how it addresses discrepancies in the records.*
 - *What actions does it take to determine whether there are errors in the records versus unaccounted for loss of materials?*
 - *If applicable, what further actions does it take to locate unaccounted for radioactive materials?*

- *If applicable, what further actions does it take to prevent future recordkeeping errors?*

A-1055

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§482.53(d)(4) - Nuclear medicine services must be ordered only by practitioners whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

Interpretive Guidelines §482.53(d)(4)

Nuclear medicine services may only be ordered by practitioners holding privileges that permit them to do so, consistent with State scope of practice law. However, for outpatient services, consistent with the provisions of §482.54, the governing body and medical staff may also authorize practitioners who do not have hospital clinical privileges to order such studies or procedures, as permitted under State law.

Survey Procedures §482.53(d)(4)

- Verify that nuclear medicine services are ordered only by practitioners *who have privileges to do so or, for outpatient services when authorized consistent with the provisions of §482.54, by other practitioners* authorized to do so by the medical staff, consistent with Federal and State law.