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.