

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.