

§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.