

§482.53(b)(1) In-house preparation of radio pharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy.

Interpretive Guidelines §482.53(b)(1)

If the hospital prepares radio pharmaceuticals in-house, such preparation must be performed by, or supervised by, a registered pharmacist or MD/DO who is qualified through education, experience and training, in the preparation of radio pharmaceuticals, consistent with Federal and State law. Hospitals must establish policies and procedures for in-house preparation of radiopharmaceuticals, including by nuclear medicine technologists under supervision.

The policies and procedures must identify the qualifications, roles and responsibilities of staff preparing radiopharmaceuticals under supervision. The hospital must ensure that all staff who are involved in the preparation and/or supervision of radiopharmaceuticals are trained and demonstrate competencies in accordance with acceptable standards of practice.

Hospitals are expected to develop policies and procedures with respect to supervision of nuclear medicine technologists. CMS anticipates that most hospitals will follow the supervision recommendations of the Society of Nuclear Medicine and Molecular Imaging, but there is no mandate that every hospital does so. (79 FR 27120, May 12, 2014) Recommendations are available at: <http://www.snmami.org/files/docs/NMT%20SOP%20Clinical%20Performance%20Standards%20June%202013.pdf> If a hospital is not following this guidance, then it must be able to explain the basis for the supervision policies and procedures it has developed.

Survey Procedures §482.53(b)(1)

- If radio pharmaceuticals are prepared in-house, determine that the preparation is performed by, or supervised by, a registered pharmacist or MD/DO.

- Review personnel records of pharmacists, MDs/DOs and nuclear medicine personnel involved in the preparation and supervision of radio pharmaceuticals to verify they have required qualifications per State law and hospital policy.
- Verify that the hospital has policies regarding the supervision of nuclear medicine personnel and the in-house preparation of radio pharmaceuticals.
- Ask the supervising pharmacist or MD/DO how technicians who prepare radio pharmaceuticals are supervised. Are the supervision policies based on the recommendations of the Society of Nuclear Medicine and Molecular Imaging? If not, what is the basis for the supervision policies?
 - Ask what policies/procedures the hospital uses to assure proper preparation.
 - Ask what guidelines the hospital relies upon for radio pharmaceutical preparation.