

### **§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.