

§482.53(d)(3) - The hospital must maintain records of the receipt and distribution of radio-pharmaceuticals.**Interpretive Guidelines §482.53(d)(3)**

Hospitals receive their radiopharmaceuticals from manufacturers, either for further in-house preparation, or ready to use. Regardless of the source of the material, the hospital must have records that track the movement of the radiopharmaceuticals upon receipt, throughout the hospital. The records must specify:

- the type of radiopharmaceutical;
- the location in the hospital where it was received, stored and dispensed;
- the amount received or dispensed at each location;
- the staff member receiving or dispensing; and
- when applicable, how/when it is disposed of and by whom. This would also include, when applicable, the type and amount of any radiopharmaceuticals returned to the source vendor.

Additional information, including special transport instructions or precautions, may be included.

The hospital must also have policies and procedures that address how often it reviews these records and how it reconciles discrepancies between inventory on hand and records of receipt, distribution, use, disposal and/or return to the source vendor.

Surveyor Procedures §482.53(d)(3)

- Ask the hospital to demonstrate how it maintains accurate records of the receipt and distribution of radiopharmaceuticals at all locations throughout the hospital.
- Ask what the hospital's policy is for frequency of review of the records; is there evidence that the hospital complies with its policy?
- Ask the hospital to explain how it addresses discrepancies in the records.
 - What actions does it take to determine whether there are errors in the records versus unaccounted for loss of materials?
 - If applicable, what further actions does it take to locate unaccounted for radioactive materials?
 - If applicable, what further actions does it take to prevent future recordkeeping errors?

