Title	Injection of Radiopharmaceuticals	**Policy #**	05-003

POLICY

In accordance with 10 CFR-35.63(d), Nuclear Medicine technologists will ensure that all patients or human research subjects undergoing nuclear imaging studies are injected with a dose that falls within the prescribed range or does not differ from the prescribed dose (35.40(a)(1)) by more than ± 20% without prior physician approval. For unit doses, the dose determination must be made by direct measurement of radioactivity; or a decay correction based on activity or activity concentration determined by the radiopharmacy.

PROCEDURE

1. Radioisotope Injection Not Requiring a Written Directive

    a. Prior to administration of the dosage, the Nuclear Medicine technologist must verify the patient's identity by a least two methods. These may include:
        i. Asking the patient or guardian to state his/her name, social security number, birth date, or address; **and**
        ii. Examining the patient's ID bracelet, hospital ID card, driver's license, or social security card.

    b. Records of all dosage administrations must include the following (10 CFR 35.2063):
        i. Radiopharmaceutical
        ii. Patient's or human research subject's name or ID number, if assigned
        iii. Prescribed dosage (activity)
        iv. Determined dosage (activity)
        v. Date and time of the dosage determination
        vi. Name of person who determined the dosage

2. Administration Requiring a Written Directive (10 CFR 35.40, 35.41)

    a. Prior to administration of the dosage, a written directive must be completed, and signed and dated by an Authorized User for the following procedures:
        i. Any therapeutic radiopharmaceutical
        ii. I-131 sodium iodine in quantities greater than 30 microcuries (µCi)

    b. The written directive must include the following information (10 CFR 35.40(b)):
        i. Patient's or human research subject's name
        ii. Radiopharmaceutical
        iii. Route of administration
        iv. Dosage (activity)

v. Dated signature of the Authorized User

c. Prior to administration of the dosage, the Nuclear Medicine technologist and Authorized User must verify all aspects of the administration are in accordance with the completed written directive.
   i. At least two methods must be used to positively identify the patient's identity. These may include:
      1. Asking the patient to state his/her name, social security number, birth date, or address; **and**
      2. Examining the patient's ID bracelet, hospital ID card, driver's license, or social security card.
   ii. After determining the dosage, directly verify with an Authorized User that the dosage, radiopharmaceutical, and route of administration are in accordance with the written directive.
   iii. If there are any questions concerning either the written directive or the procedure being performed, the procedure must be stopped until all questions are resolved.

d. If the emergent nature of the patient's condition, a delay to provide a written directive (or a revision of the written directive) would jeopardize the patient's health, a Nuclear Medicine technologist may accept an oral directive. The written directive must be documented into the patient's record as soon as possible but within 48 hours.

3. Immediate Notification to Radiation Safety Officer (RSO) or Medical Physicist (MP) in RSO Absence

a. The administration of a radiopharmaceutical that results in:
   i. A dose that differs from the prescribed dose by greater than ± 20 percent without prior physician approval; or
   ii. The total dose falls outside the prescribed dose range.

b. The administration of a radiopharmaceutical:
   i. That is the wrong radioactive drug
   ii. Via the wrong route of administration
   iii. To the wrong patient or human research subject; or,
   iv. To the wrong mode of treatment.

c. A dose to the skin, an organ or tissue other than the treatment site

d. The RSO (or MP) will determine whether the administration is considered a medical event, and whether notification to the Nuclear Regulatory Commission is required along with the preparation and submission of written reports.

Approved by:

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