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RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM

Item 12.1

1. Objective

". . .to provide high confidence that byproduct material will be administered as directed by the authorized user."

2. Responsibility, Authority, and Review

The responsibility and authority to establish and implement the Quality Management (QM) Program shall be given to the Chief Nuclear Medicine Technologist.

3. Instruction

All individuals responsible for prescribing, preparing, or administering dosages which require written directives as outlined in this program will be instructed in the requirements of the Quality Management Program on an annual basis.

4. Elements for Medical Use - Radiopharmaceutical Therapies and NaI I-125 or NaI-131 >30 uCi

A. Prior to administration, a written directive will be prepared for:

i. any therapeutic administration of a radiopharmaceutical and
ii. any administration of NaI I-125 or Na-131 greater than 30 uCi.

With regard to diagnostic and therapeutic radiopharmaceuticals "A written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

patient name
patient identification number, if available
radiopharmaceutical
dosage
route of administration
the type of procedure desired

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Revisions to written directives may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage.

Oral revision to a written directive is acceptable if, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user within 48 hours of the oral revision.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information provided in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

B. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive by the person administering the radiopharmaceutical.

1. The patient shall be called by name.
2. The patient shall be asked to spell their name.
3. The patient shall be asked to state their birth date.
4. The patient shall be asked to state their Social Security Number.
5. The patient shall be asked for some identification such as driver's license.
6. The in-patient's wrist band shall be checked.

If the information obtained from both of any two of these methods do not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification that this procedure is intended for this patient is obtained.

C. Each administration is in accordance with the written directive.

The technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear to the technologist, they shall contact an authorized user for clarification.
The radiopharmaceutical shall not be administered until the intent of the written directive is thoroughly understood by the technologist. If the technologist preparing the dose is different from the technologist administering the dose, both technologists shall read and understand the written directive.

The technologist shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

After administration of a radiopharmaceutical, the individual administering the dosage shall make a written record that documents the administered dosage in reviewable form, date the written record, and sign or initial the written record.

D. Retention of written directives

Each written directive and a record of each administered radiopharmaceutical dosage shall be retained for three years after the date of administration.

E. Any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Upon identification of an unintended deviation, an investigation of the incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of Part 35.

F. Recordable Events

All recordable events shall be evaluated within thirty(30) days after discovery. A recordable event shall be responded to by: (1) assembling the relevant facts including the cause; (2) identifying what, if any, corrective action is required to prevent recurrence; and (3) retaining a record, in an reviewable form, for three years, of the relevant facts and what corrective action was taken.

5. Annual Review

The review shall determine the effectiveness of the QM program. Areas identified as inadequate shall be modified to meet the objectives of 35.32(a).

Records of each review, including the evaluations and findings in an reviewable form for three years will be retained for three years.

Frequency: A review of the quality management program shall be conducted at twelve (12) month intervals.

Responsibility: The review shall be conducted by the consulting medical physicist. Management shall be briefed in writing of the findings.

Sampling: If patient administrations exceed 100, 20% of these will be used for the review.
If patient administrations exceed 20 but are less than 100, 20 of these will be used for the review.
If patient administrations are less than 20, all of these will be used for the review.

All misadministrations and recordable events previously identified will be included in the annual review.

If misadministrations are identified during the course of the annual review, the sample size will be increased to include all procedures of the type involved in the misadministration.

If recordable events are identified during the course of the annual review, the sample size will be increased to include all procedures of the type involved in the recordable event.

Scope: The review shall evaluate the following items.

1. The compliance rate of having written directives prior to administration of a radiopharmaceutical or radiation in those cases where written directives are required.

2. The content of the written directive is as required.

3. The instruction of the supervised individual(s) in the licensee's written quality management program and requirement of following the authorized user's instructions.

4. The methods of verifying the patient's identity by more than one method is performed as stated in the QM program.

5. The compliance rate of verifying the patient's identity by more than one method.

6. Radiopharmaceutical or radiation administrations are in accordance with the written directives.

7. The compliance of the staff in identifying, evaluating, and taking appropriate corrective actions for unintended deviations from the written directive.

8. The compliance with the requirement to respond to each recordable event.

9. The compliance with the requirements to notify and report a misadministration.

10. The compliance with the requirements to keep the appropriate records, including:
    the annual reviews,
    the written directives
    the radiopharmaceutical dosages
    the recordable events
    the misadministrations

6. Revisions to the program

If the program is revised, the revisions will be submitted to the NRC within 30 days after the revision has been made.