QUALITY MANAGEMENT PROGRAM

PURPOSE: To establish an environment which will provide high confidence that radiopharmaceuticals and brachytherapy sources will be administered as directed by the authorized user.

SCOPE: The stipulations of this policy shall apply to all authorized users of radiopharmaceuticals and brachytherapy sources as noted in 10 CFR 35.32.

RESPONSIBILITY: The responsibility and authority to establish and implement the Quality Management Program shall be given to the Radiation Safety Officer through the Radiation Safety Committee.

RADIOPHARMACEUTICAL SECTION

1. Prior to administration of the following radiopharmaceuticals, a written directive shall be prepared for a specific patient, dated and signed by an authorized user. Written directives shall be prepared for the dispensing and prior to the administration of:

   A. any therapeutic administration of a radiopharmaceutical; and,
   B. any administration of NaI I-125 or NaI I-131 greater than 30 uCi for either diagnostic or therapeutic purposes.

   The following information will comprise the written directive:

   ent Name
   Patient Identification, if available
   Radiopharmaceutical
   Dosage
   Route of Administration
   Type of Procedure Desired

   An oral revision to a written directive will be acceptable when made necessary by the patient's condition. The oral revision will be documented immediately in the patient's record and a revised written directive will be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision.

   An oral directive will be acceptable when made necessary by patient's emergent condition. The oral directive will be documented immediately in the patient's record and a written

directive will be prepared within 24 hours of the oral directive.

2. Prior to administration, the authorized personnel administering the radiopharmaceutical will verify the patient's identity as the individual named in the written directive. At least two of the following approved methods of verification will be utilized:

    Patient can be called by name
    Patient can be asked to spell their name
    Patient can be asked to state their birth date
    Patient can be asked to state their Social Security number
    Patient can be asked for some identification
    Patient's wristband can be visually inspected

    If the information obtained from any two of these methods does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive evidence is obtained that this agent/procedure is intended for the patient in question.

3. Each administration will be in accordance with the written directive. The written directive shall be interpreted before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear, the prescriber will be contacted for clarification. The radiopharmaceutical shall not be prepared or administered until the intent of the written directive is thoroughly understood. If the authorized personnel assaying the dosage is different from the authorized personnel administering the dose, both shall read and understand the written directive.

    The details of the administration (radiopharmaceutical, dosage and route of administration) shall be in accordance with the written directive. The actual dose calibrator assay shall be verified against the dosage listed on the written directive. Assay must be within +/- 10% of dosage listed on the written directive.

    A procedure manual will be available and contain the protocols used in the performance of clinical procedures affected by this program. Each procedure will be approved by an authorized user and will contain the associated radiopharmaceutical, dosage, route of administration, indications and contraindications. Changes in the protocols shall be approved by an authorized user before the change is implemented and before the change is incorporated into the manual. Involved staff will be inserviced on the change prior to implementation or inclusion.

4. Upon identification of an unintended deviation from the written directive, an investigation

of the incident shall be made. The root cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documentation and reporting of the unintended deviation shall be in accordance with the notification regulations in Part 35.33.

5. Written policies and procedures will be available to address the following issues:

   A. Written directives to include all treatment parameters will be prepared prior to each patient administration.
   B. Verification of the patient's identity by more than one (1) method prior to administration.
   C. Assurance that each administration is in accordance with the written directive.
   D. Instruction to all workers to seek guidance if they do not understand how to carry out the written directive.
   E. Identification, evaluation and corrective action for any unintended deviations from the written directive.
   F. Confirmation of the radiopharmaceutical, dosage and route of administration by the person administering the radiopharmaceutical for verification of agreement with the written directive.
   G. Measurement of the dosage in the dose calibrator and comparison of the results with the prescribed dosage in the written directive.

BRACHYTHERAPY SECTION

1. Prior to administration, a written directive will be prepared for any brachytherapy radiation dose.

   With regard to brachytherapy, a written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, containing the following information:

   A. For all brachytherapy other than high-dose-rate after loading:
      i. Prior to implantation:
         - Radioisotope
         - Number of Sources
         - Source Strengths
      ii. After implantation, but prior to completion of the procedure:
         - Radioisotope
         - Treatment Site
         - Total Source Strength

- Exposure Time or equivalently the Total Dose

An oral revision to a written directive will be acceptable when made necessary by the patient's condition. The oral revision will be documented immediately in the patient's record and a revised written directive will be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision.

An oral directive will be acceptable when made necessary by patient's emergent condition. The oral directive will be documented immediately in the patient's record and a written directive will be prepared within 24 hours of the oral directive.

2. Prior to administration, the patient's identity is verified by more than one method as the individual named in the written directive. The verification of the patient's identity will be performed by the Radiation Oncology Registered Nurse.

   If the information obtained from any of these methods does not correspond to the information on the written directive, the radiation shall not be administered until conclusive evidence is obtained that the agent/procedure is intended for the patient in question.

3. Each administration is in accordance with the written directive. If any portion of the written directive is unclear, the prescriber will be contacted for clarification. The radiation shall not be administered until the intent of the written directive is thoroughly understood.

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

5. Final plans of treatment and related calculations for brachytherapy are in accordance with the written directive.

6. Written procedures will be available to address the following issues:

   A. Written directives to include all treatment parameters will be prepared prior to each patient administration.
   B. Verification of the patient's identity by more than one (1) method prior to administration.
   C. Assurance that each administration is in accordance with the written directive.
   D. Instruction to all workers to seek guidance if they do not understand how to carry out the written directive.
   E. Identification, evaluation and corrective action for any unintended deviations from

the written directive.

F. Treatment plans will be prepared in accordance with the written directive.

G. Checks of the dose calculations, i.e. computer-generated dose calculations and/or manual dose calculations.

H. Verification of the position of dummy sources or fixed geometry applicators prior to insertion of sealed sources.

I. Acceptance testing on each planning or dose calculating computer program that could be used for dose calculations and checking computer generated dose calculations.

J. Confirmation of the radioisotope, number of sources, source strengths, treatment site, loading sequence and total dose by the person administering the brachytherapy treatment for agreement with the written directive and treatment plan.

K. Checking of the dose calculations before administration of the prescribed brachytherapy dose. Whenever possible, this should be done by someone who did not make the original calculations.

L. Documentation of the confirmation by the authorized user, after administration of the number of sources, the actual loading sequence of the sources implanted, i.e. location of each sealed source in a tube, tandem or cylinder, and the method of verification that the sources were loaded in the correct position.

M. After administration the authorized user must sign or initial the patient's chart or appropriate record.

ANNUAL REVIEW

An annual review shall be conducted to determine the effectiveness of the Quality Management Program. After completion, an evaluation of the findings will be conducted and resultant actions set in motion to comply with the objectives of Part 35.32. Changes in the Quality Management Program, generated to increase its efficiency, shall be furnished to the Nuclear Regulatory Commission Region III Office within thirty (30) days after the modifications have been made.

This review for the radiopharmaceutical section will be conducted at twelve (12) month intervals by a member of the consulting medical physicist group and/or the Supervisor of Nuclear Medicine; and, for the brachytherapy section a medical physicist from Radiation Oncology. Results of this review will be reported to the Radiation Safety Committee and maintained for three (3) years.

The audit of a representative sample of radiopharmaceutical and brachytherapy administrations 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 compliance rate of verifying the patient's identity by two methods.

4. Radiopharmaceutical or radiation administrations are in accordance with the written directive.

5. The compliance of staff in identifying, evaluating and taking appropriate corrective actions for UN-intended deviations from the written directive.

6. The compliance with the requirement to respond to each recordable event. This shall include a brief summary to include cause of event, and identification of corrective action, if any, was taken.

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

8. The instruction of supervised individuals in the principles of radiation safety and in the facility's quality management program.

9. The compliance with the requirements to keep the appropriate records, specifically:

   Annual Reviews (to include findings and evaluations)
   Written Directives
   Radiopharmaceutical and/or Radiation Dosages
   Recordable Events
   Misadministrations

10. The final treatment plans for brachytherapy and related calculations shall be reviewed by a medical physicist from Radiation Oncology.

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