January 24, 1996

Nuclear Medicine Services, Inc.
ATTN: Dr. Steven A. Artz
Radiation Safety Officer
1201 Washington Street East
Suite 105
Charleston, WV 25301-1814

SUBJECT: NRC INSPECTION REPORT NO. 47-16156-01/95-01

Gentlemen:

Thank you for your response of January 9, 1996, to our Notice of Violation, issued on December 29, 1995, concerning activities conducted under NRC License No. 47-16156-01. We have evaluated your response and found that it meets the requirements of 10 CFR 2.201. We will examine the implementation of your corrective actions during future inspections.

We appreciate your cooperation in this matter.

Sincerely,

Original signed by
John Potter

John P. Potter, Chief
Materials Licensing/Inspection Branch 2
Division of Nuclear Materials Safety

Docket No. 030-10506
License No. 47-16156-01

cc: State of West Virginia

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H. Bermudez
PDR

STEVEN A. ARTZ, M.D., F.A.C.P.
NUCLEAR MEDICINE SERVICES, INC.

January 9, 1996

U.S. Nuclear Regulatory Commission
Materials Licensing/Inspection Branch
Region II
101 Marietta Street, Suite 2900
Atlanta, Georgia 30323
ATTN: Document Control Desk, Washington, D.C. 20555

RE: Reply to a Notice of Violation

Dear Sir or Madam,

This acknowledges receipt of notice of violation (NRC inspection report number 47-16150-01/95-01).

1. Administered therapeutic doses of Phosphorus 32 on August 12, 1994 and on May 24, 1994 were apparently administered without implementing appropriate quality management report. The technologist responsible at that time left employment on November 3, 1995 and is unavailable for comment.

2. The appropriate P32 form has been generated. See Attachment 1. A copy of the QM plan is also enclosed.

3. The Technologist and the Radiation Safety Officer have reviewed the Quality Management steps necessary to prevent further violations.

4. Full compliance is achieved as of this date.

Sincerely,

Steven A. Artz, M.D.
Radiation Safety Officer

Enclosures

cc: Regional Administrator, Region II

Suite 105 • 1201 Washington St. East • Charleston, West Virginia 25301-1853 • (304) 343-7651 • Fax (304) 344-1902

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RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM

The following policies and procedures for certain radiopharmaceutical uses have been implemented to assure that the objectives of 10 CFR 35.32 are met.

A. This institution requires a written directive/order for a specific patient developed in accordance with 35.2 which will be dated and signed by the authorized user prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131. The written directive/order shall among other items, contain the dosage to be administered, the name of the specific patient, the radiopharmaceutical, and the route of administration.

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

   2. If, because of the patient's medical condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is dated and signed by the authorized user within 48 hours of the oral revision.

   3. A written revision to an existing written directive is allowed 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.

B. Prior to the administration of any dose covered by the QM Rule, a "QM checklist" shall be initiated and completed during each phase of the procedure.

   1. The "QM checklist" contains areas detailing the following:
      a. Verification of presence of written directive.
      b. Verification of patient identity.
      c. The date and signature of an authorized user.
      d. Patient dosage and verification of dosage.
      e. Route of administration.
      f. Post dosage information area.

   2. All information is in auditable form.

C. Before administering a radiopharmaceutical dosage, the department will verify by more than one method, the identity of the patient as the individual named in the written directive.

1. The procedure used to identify the patient is to ask the patient's name and confirm the name by comparison with corresponding information in the patient's record: birth date, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

2. For female patients, their pregnancy and/or nursing status will be assessed and documented prior to any administration of radiopharmaceuticals covered by the QM rule.

D. The radiopharmaceutical dosage will be verified by measurement in the dose calibrator and the results will be compared with the prescribed dosage in the written directive.

1. The radiopharmaceutical, dosage, and route of administration will be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive.

Workers will seek guidance if they do not understand how to carry out the written directive. Workers will ask the Nuclear Medicine supervisor or an authorized user any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt concerning the written directive.

The department will review the QM rule annually. This defines another avenue of information that the technical staff may seek to eliminate any potential problems addressed by the QM rule.

E. The authorized user or a qualified person under the supervision of an authorized user (e.g., nuclear medicine physician, physicist, or technologist) will, after administering a radiopharmaceutical, (post administration) make date, sign or initial a written record that documents the administered dosage in the patient's chart or other appropriate record.

F. Procedures for performing periodic reviews of the radiopharmaceutical QM program are as follows:

1. After each radiopharmaceutical administration covered by the QM rule, the post administration area of the checklist will be completed by either the authorized user or technologist.

2. Coinciding with quarterly Health Physics consultants' survey, all QM paperwork generated during the previous three (3) months will be examined for recordable events or misadministrations.

3. At annual intervals (not to exceed 12 months), a representativesample (20%) of all patient administrations, written directives, radiopharmaceutical dosage, route of administration, misadministrations and all recordable events will be reviewed by a review panel consisting of the Nuclear Medicine supervisor, an authorized user, and the RSO. The review panel will always consist of at least two of the identified individuals.

   a. Patient cases will be selected randomly. For each case, a comparison will be made between what was the administered dose versus the prescribed dose in the written directive. If the difference in the administered dose and the prescribed dose exceeds the criteria for either a recordable event or a mis-administration , that comparison is unacceptable.

      Acceptance sampling will be as follows:

Total Pt. Admin.	Sample Group	Unacceptable #
100	20	>2
50	10	>1
<50	20% of total	0

      Maximum number recordable events: 10% of the sample group.

   b. The Radiation Safety Officer will document and sign the annual review results. Records of the review shall be available for review by the NRC for a period of three years. Specific records of misadministration shall be maintained for ten years in accordance with 10 CFR 35.33 (d).

   c. All deviations are to be identified, the cause of each deviation, and the action required to prevent recurrence. Suggested corrective actions may include new or revised policies or procedures, additional training, or increased supervisory review of work.

4. Should any deviation, recordable event, or misadministration be discovered at either step F(1), (2), or (3), (listed above) appropriate documentation and follow-up/steps to prevent reoccurrence will be initiated.

   a. Any discovery of a recordable event will be evaluated with 30 days of discovery. This evaluation will be performed and recorded in an audible form detailing the relevant facts including:

      1. Identifying the cause
      2. Identifying what, if any, corrective action is required to prevent recurrence
      3. Retaining all records of the relevant facts and corrective action taken for a period of three (3) years

   b. Any discovery of a "QM" misadministration will be evaluated immediately and the regional NRC office will be notified within 24 hours of the discovery.

   c. Due to the quarterly sampling of all QM generated paperwork by the consulting (HP), we believe the representative annual sampling defined in F(3)(a) is sufficient.

5. Should the corrective action require a change in the overall QM program, the NRC will be notified. Otherwise, unless the event was a misadministration, (*), the results of the follow-up investigation will be made available for regulatory review.

   (*) misadministration information will be made available to NRC within 24 hours of discovery

G. The QM program will be reevaluated after each annual review.

1. Policies and procedures will be examined to determine whether the program is still effective and to identify actions required to make the program more competent.

2. If the annual review demonstrates an unacceptable number of recordable events or misadministrations, the review panel will amended the program to reflect the necessary changes needed to comply with the facility commitment.

   a. If necessary, procedural amendments to the program will be forwarded to the NRC for review.

   b. Ministerial changes, (i.e. changes in the checklist format) will be made available to regulatory officials at the time of inspections.

3. The program will be deemed effective if the objectives of 10 CFR 35.32 are met and the number of recordable events are within those defined above in F.3.(a)

Administration — Date: 1/9/96

Radiation Safety Officer — Date: 1/9/96

STEVEN A. ARTZ, M.D.,F.A.C.P.
Nuclear Medicine Services, Inc.

Patient Name:_____

Written Directive	Inpatient/Outpatient
Date	
Radiopharmaceutical	
Dose (millicuries)	
Route of Administration	
Rx & Dose ticket attached?	Yes ☐ No ☐

Dose Confirmation	Date
Radiopharmaceutical	
Dose Drawn (millicuries)	
Dose Ordered (millicuries)	
Within 10% ?	Yes ☐ No ☐
Signature of Preparer	
Signature of Verifier	

Patient Confirmation	Check Two
Name	
Birthdate	
Hospital I.D.	
Wrist Band	
Drivers License	
Relative/Friend	

Before Dosing, Confirm.....		Date
Male ☐	Female ☐	
	Pregnant ?	Yes ☐ No ☐
	Nursing ?	Yes ☐ No ☐
Signature of Patient		
Signature of Authorized User (Giver)		
Signature of Verifier		
Information Sheet Given to Patient ?		Yes ☐ No ☐

Post Dose QM	Date
Followed Directive ?	Yes ☐ No ☐
Radiopharmaceutical	
Dose	
Route of Administration	
Date	

NUCLEAR MEDICINE QUALITY MANAGEMENT FORM
STRONTIUM - 89 CHLORIDE THERAPY

Patient Name:_____ Hospital Number:_____
Location:_____ Division:_____

Written Directive	Inpatient / Outpatient
Date	
Radiopharmaceutical	Sr-89
Dose (millicuries)	
Route of Administration	
Rx & dose ticket attached?	Yes No

Dose Confirmation	Date / /
Radiopharmaceutical	Sr-89
Dose Drawn (millicuries)	
Dose Ordered (millicuries)	
Within 10% ?	Yes No
Signature of Preparer	
Signature of Verifier	

Patient Confirmation	Check Two
Name	
Birthdate	
Hospital I.D.	
Wrist band	
Drivers License	
Relative/Friend	

Before Dosing, Confirm	Date / /
Male Female	
Pregnant ?	Yes No
Nursing?	Yes No
Information Sheet Reviewed, Questions Answered, Given To Patient?	Yes No
Signature of Patient	
Signature of Authorized User (Giver)	
Signature of Verifier	
Lab Results: WBC_____ Platelet_____ HCT_____ Hg_____	 greater than 2,400 greater than 60,000

Post Dose QM & Survey			Date / /
Followed Directive ?	Yes	No	Survey Meter
Radiopharmaceutical			Model S/N
Dose			Background mR/hr
Route of Administration			Floor / Inj. Area mR/hr
Date			

STEVEN A. ARTZ, M.D.,F.A.C.P.
Nuclear Medicine Services, Inc.
PHOSPHORUS-32 THERAPIES

Patient Name:_____

Written Directive	Outpatient
Date	
Radiopharmaceutical	
Dose (millicuries)	
Route of Administration	
Rx & Dose ticket attached?	Yes ☐ No ☐
Is chemical form chromic phosphate? If so administer intracavity only.	Yes ☐ No ☐
Is chemical form sodium phosphate? If so, administer intravenously.	Yes ☐ No ☐

Dose Confirmation	Date
Radiopharmaceutical	
Chemical Form?	
Dose Drawn (millicuries)	
Dose Ordered (millicuries)	
Within 10% ?	Yes ☐ No ☐
Signature of Preparer	
Signature of Verifier	

Patient Confirmation	Check Two
Name	
Birthdate	
Hospital I.D.	
Wrist Band	
Drivers License	
Relative/Friend	

Before Dosing, Confirm.....	Date
Male ☐ Female ☐	
Pregnant ?	Yes ☐ No ☐
Nursing ?	Yes ☐ No ☐
Signature of Patient	
Signature of Authorized User (Giver)	
Signature of Verifier	
Information Sheet Given to Patient ?	Yes ☐ No ☐

Post Dose QM	Date
Followed Directive ? Yes No	Survey Meter
Radiopharmaceutical	Model S/N
Dose	Background mR/hr
Route of Administration	Floor/Inj. Area mR/hr
Date	