Tulsa Regional Medical Center
AN OSTEOPATHIC INSTITUTION

February 9, 1994

U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555

RE: Reply to Notice of Violation

Gentlemen:

This is a response to your letter dated 01/11/94 regarding "Notice of Violation" from NRC Inspection Report 030-02893/93-01. This reply includes: 1) Reason for violation; 2) Corrective steps that have been taken and results achieved; 3) Corrective steps that will be taken to avoid further violations and 4) Date when full compliance is achieved.

A special announced inspection was conducted on 08/10-11/1993 by Ms. McLean, accompanied by Ms. Hernandez, to review the activities authorized by byproduct materials license #35-05863-01 with regard to a misadministration which occurred at Tulsa Regional Medical Center on 07/27/93.

1) The violation involves the misadministration of 5mCi ^{131}I NaI which occurred as a result of a failure to follow the Quality Management Program. The technologist's failure to properly verify a patient's identity as the individual named in a written directive, and a failure to verify that the radiopharmaceutical being administered to this patient was in accordance with the written directive prepared for that patient.

2) The following corrective actions were taken: The technologist was entered into the hospital's Progressive Disciplinary Program as a result of the incident and the current Quality Management Program was reviewed with him. The program was reviewed by the Radiation Safety Committee and the following changes were made:

a) Attached is the new Quality Management Program Procedure (**Exhibit A**) to be followed for any therapy administration or any ^{131}I administration over 30uCI. Changes include a provision for stating what the written directive shall contain and what second forms of identification are acceptable. Also, the prescribing radiologist will be present at the time of dosing and the technologist will have the written directive and request in hand at the time of dosing.

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These changes will result in correct patient identification and prevent any possibility of misadministration of I131 over 30uCl.

b) Attached is the new Quality Management Program Review Procedure (**Exhibit B**) to be followed annually.

3) The following corrective actions were implemented to avoid further violations: The Quality Management Program will be reviewed annually with all technologists. Also, find attached a copy of the memorandum to our hospital's Outpatient Scheduling Department (**Exhibit C**). They are instructed to schedule outpatients every 30 minutes so there are no dosing conflicts in the future.

4) Full compliance was achieved on 02/03/94 when the Radiation Safety Committee approved the Quality Management Program revisions.

Sincerely,

Dean Fullingim DO

Dean Fullingim, D.O.,
Radiation Safety Officer

SL:DF:new

Attachments: Exhibit A - Quality Management Program Procedure
Exhibit B - Quality Management Program Review Procedure
Exhibit C - Memo to Outpatient Scheduling

cc: USNRC
Regional Administrator, Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011

Mr. James MacCallum
Chief Executive Officer
Tulsa Regional Medical Center

EXHIBIT A

QUALITY MANAGEMENT PROGRAM PROCEDURE
FOR ANY ^{131}I OR THERAPEUTIC ADMINISTRATION

1. All ^{131}I administrations over 30uCi or any therapeutic administration will have a written prescription signed by a staff radiologist stating date, patient name, dose, route of administration and radiopharmaceutical.

2. The staff radiologist will interview the patient prior to prescribing the dose and will be present at the time of dosing.

3. Prior to dosing, the patient will be identified by name and by driver's license. If a driver's license is not available then a social security card or number, birth date, signature, address, hospital I.D. band, or if a relative is with the patient and confirms their identity, this is acceptable.

4. The technologist administering the dose must verify the type of radiopharmaceutical from the nuclear pharmacy's prescription. The route of administration from the prescribing radiologist prescription and the dose in the dose calibrator.

5. The dosing technologist will have the request and prescription in hand at dosing and will cross check name, dose, route of administration and radiopharmaceutical. If there is any doubt whether the radiopharmaceutical available is the correct one for the patient, the person administering the dose should re-do steps 3 and 4.

6. A file folder must be made containing a copy of the driver's license or a notation of second form of I.D., the results of the pregnancy test on all women of childbearing age, the results of any thyroid lab testing, the results of the RAIU or any diagnostic testing done, a copy of the signed consent form and the exact dose administered. The folder is to be kept in the Nuclear Medicine Department.

7. The radiologist must make a signed written entry in the patient's file or chart after dosing. The entry should specify the exact dose administered and the date.

Doug Fullerton D 2/3/94

Approved **Date**

Tulsa Regional Medical Center
Radiation Safety Committee

EXHIBIT B

QUALITY MANAGEMENT PROGRAM REVIEW PROCEDURE

1. The Radiation Safety Committee will review the QMP at least annually in a regularly scheduled meeting to determine compliance. The review will include:

   A. A random and representative sample of patient folders and/or charts for administrations of all types of therapy and diagnostic doses of ^{131}I.
   B. If under 75 patients have been dosed since the last review then 25% of all patients dosed for therapy or with over 30uCI of ^{131}I will be reviewed.
   C. All misadministration and/or recordable events. The NRC Regional Office will be notified by the next calendar day and a report will be sent within 15 days of any such event. The report will include:
      1. Licensee's name
      2. Prescribing physician's name
      3. Brief description of the incident
      4. Why incident occurred
      5. Effect on patient
      6. Improvements needed
      7. Action taken
      8. No indication of the patient's name or identification
      9. Referring physician and patient will be notified within 24 hours.
      10. A written report will be sent to the patient within 15 days by sending either a copy of the report sent to the NRC or a statement that the report sent to the NRC can be obtained from them. The report must also include a brief description of the incident and the consequences to the patient.

2. Reviews will include:

   A. Comparison of the exact dose administered, route of administration and radiopharmaceutical used to the prescrciption.
   B. Record of treatment date, patient's age, name, pregnancy test results if needed, lab results, second form of I.D., signed progress note and signed consent form.
   C. An evaluation of the effectiveness of the QMP.
   D. Recommendations for modifications needed.

3. Copies of any modifications of the QMP must be submitted to the NRC Regional Office within 30 days.

4. Complete records of the review must be maintained for three years.

Dean F. Wenger MD 2/3/94

Approved **Date**

Tulsa Regional Medical Center
Radiation Safety Committee

EXHIBIT C

Tulsa Regional Medical Center
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TO: Marilyn Jensen
Outpatient Scheduling

FROM: Randy Arnold
Vice President/Professional Services

RE: Nuclear Medicine Scheduling

DATE: 08/09/93

PLEASE BE ADVISED THAT UNDER NO CIRCUMSTANCES ARE TWO PATIENTS TO BE SCHEDULED AT THE SAME TIME FOR PROCEDURES IN NUCLEAR MEDICINE.

ANY QUESTIONS CONCERNING THIS PROCEDURE SHOULD BE DIRECTED TO SHELLEY LAYNE, R.T.N.M., NUCLEAR MEDICINE SUPERVISOR, AT EXT. 5036 OR ME AT EXT. 5034.

D Fallergren 3/9/93

Approved **Date**
Tulsa Regional Medical Center
Radiation Safety Committee

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