Southwood
Community Hospital

111 Dedham Street
Norfolk, Massachusetts 02056
Telephone (617) 668-0385

Docket No. 030-19406

License No. 20-20554-01

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

November 16, 1993

RE: "Reply to a Notice of Violation"

Dear NRC Representative,

This correspondence is written in response to a NOTICE OF VIOLATION transmitted to Southwood Community Hospital from the United States Nuclear Regulatory Commission on October 19, 1993 (see attachment **A**).

(1) The Reason for the Violation follows:

- The violation of 10 CFR 35.53(a) was the result of a flawed Radiation Therapy Iodine-131 administration protocol/policy. The flaw in said Iodine-131 administration policy was discovered by Dr. Sattar Lodhi during Routine Inspection No. 030-19406/93-001 of Southwood Community Hospital, conducted on October 05, 1993. Specifically, each Iodine-131 therapy dose would be shipped to Southwood Community Hospital from the local Mallinckrodt distributorship. Each dose would arrive with the appropriate accompanying Mallinckrodt documentation, stating the dose requested, lot number etc. Rather than measuring the dose a second time, prior to administration to the patient, the Radiation Therapy personnel accepted the Mallinckrodt documentation and performed their own patient measurements post-administration of the Iodine-131 (see attachment **B**). Ultimately, by the methods noted in attachment **B** the Radiation Therapy physicist would present his case for the second dose measurement.

(2) The Corrective Steps Taken and the Results Achieved follow:

- Corrective steps taken include the writing of a new, specific, and definitive policy regarding a dose calibrator measurement of Iodine-131 by both Nuclear Medicine and Radiation Therapy personnel immediately prior to the administration of any Iodine-131 patient dose (read summary below).

Iodine-131 therapy capsules will be measured in the Nuclear Medicine Dose Calibrator, Model No. CRC-30, Serial No. 30346 currently listed on our license. Both the Nuclear Medicine Technologist and the Radiation Therapy Physicist will measure the dosage immediately prior to administration.

- In addition to the new Iodine-131 dose calibrator measurement policy, the Radiation Therapy Department Quality Management Program now specifically addresses a section on the measurement of Iodine-131 therapy capsules immediately prior to administration.

- Aside from the new dose calibrator measurement policy, and the Quality Management Program, it should be noted that no Iodine-131 therapy doses have since been administered.

(3) The Corrective Steps that will be taken to avoid Further Violations follow:

- As stated in (2) corrective steps have been taken and put in place in the form of the new Iodine-131 dose calibrator measurement policy, and the Quality Management Program upgrade. Application of the new policy and the QM Program will lead to avoidance of further violations.

(4) The Date when Full Compliance will be achieved follows:

- Full Compliance was achieved as of 10/06/93.

Sincerely,

Yolanda C. Landrau

Yolanda Landrau, Ed.D., Executive Vice President
Southwood Community Hospital (a member of Neponset Valley Health System)

cc: Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406

ESTIMATION OF I-131 ACTIVITY GIVEN TO TWO PATIENTS

All the estimates are based on the measurements of exposure @ 1 meter distance from patient's thyroid gland.

Patient Ms. Campbell, received 29.8 mCi. of I-131 Radio pharmaceutical in the form of capsule. Activity of this Radio isotope pharmaceutical was measured using a dose calibrator from Nuclear Medicine department at Southwood Community Hospital. Accuracy of the dose calibrator is +/-2%. Two hours later, after administering the above radio pharmaceutical, an exposure of 3.8 mR/hr. was measured at 1 meter distance from patient's thyroid gland.

Patient Ms. McDonald, Esabella also received I-131 Radio pharmaceutical on November 22, 1991. Unfortunately the activity of the I-131 was not measured prior to the administration. But based on the measurement of the exposure level at 1 meter distance from her thyroid gland (4.2 mR/hr.) after two hours of administration, I can make an approximate estimation of 32.94 mCi. was given to the patient. Patient should receive an activity of 31 mCi. of I-131 and is off by 6%.

Also patient Mc Cluckey, Marcia received I-131 Radio pharmaceutical on March 7, 1991. Patient should receive 30.5 mCi. of I-131. Once again based on the measurement of exposure at 1 meter distance from her thyroid gland (3.5 mR/hr.), I can make an approximate estimation of 27.5 mCi. of I-131 was administered, which is off by 10%.

Once again these estimates have margin of error of 2% from the calibrator and also depends on patient's thickness at thyroid gland. If patient's thickness at thyroid gland differ by more than 2 cm. estimation may be off by 10%.

Under these circumstances, one can argue that the discrepancy between the prescription and administration is not off by more than 20 %. Discrepancy of 20% is misadministration.

S.N. RAO

Consulting Physicist

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

OCT 19 1993

Docket No. 030-19406

License No. 20-20554-01

Southwood Community Hospital
ATTN: Yolanda Landrau, Executive Vice President
of Operations
111 Dedham Street
Norfolk, Massachusetts 02056

OCT 1993
Received
Sr. V.P., Pt Ser.
Behav. Med.

Dear Dr. Landrau:

Subject: Routine Inspection No. 030-19406/93-001

On October 5, 1993, Dr. Sattar Lodhi of this office conducted a routine safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with Mr. Thomas Theroux and other members of your staff, at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed as Appendix A and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

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The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

Your cooperation with us is appreciated.

Sincerely,

Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Enclosure(s):
Appendix A, Notice of Violation

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts

APPENDIX A

NOTICE OF VIOLATION

Southwood Community Hospital
Norfolk, Massachusetts

Docket No. 20-20554-01
License No. 030-19406

During an NRC inspection conducted on October 5, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

> 10 CFR 35.53(a) requires that a licensee measure the activity of each radiopharmaceutical dosage that contains more than 10 microcuries of a photon-emitting radionuclide before medical use.
>
> Contrary to the above, on March 7, 1991 and on November 22, 1991, the licensee did not measure radiopharmaceuticals containing 30.5 and 31.0 millicuries respectively, of iodine-131, a photon-emitting radionuclide, before they were administered to patients for medical use.
>
> This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Southwood Community Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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