U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-20121/90001(DRSS)

Docket No. 030-20121

License No. 21-21265-01 Category G Priority 3

License: Standish Community Hospital
P.O. Box 579
Standish, MI 48658

Inspection Conducted: October 9, 1990

Purpose of Inspection: This was an announced, special inspection conducted to review allegations received by Region III on July 18, 1990, relating to the licensee's use of radioactive materials.

Inspector: Gary L. Shear, Senior Radiation Specialist — 10/31/90 Date

Reviewed By: Roy J. Caniano, Chief, Nuclear Materials Safety Section 2 — Oct. 31, 1990 Date

Approved By: John A. Grobe, Chief, Nuclear Materials Safety Branch — 11-2-90 Date

Inspection Summary

Inspection on October 9, 1990 (Report No. 030-20121/9000. (DRSS)

Areas Inspected: This was an announced, special inspection conducted at the licensee's facility located in Standish, Michigan, to review allegations received by Region III on July 18, 1990, relating to the licensee's use of radioactive material (AMS No. RIII-90-A-0074). The inspection included a review of licensee records and interviews with licensee personnel.

Results: Both allegations received by Region III were substantiated and two violations of NRC requirements were identified: (1) Radiation Safety Committee failed to meet quarterly, 10 CFR 35.22(a)(2) (Section 4) and (2) the licensee was without an RSO for a period of approximately six weeks, License Condition No. 11, (Section 4).

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DETAILS

1. Persons Contacted

   *James Polonis, Chief Executive ' 'ficer
   *Lora Shumway, Nuclear Medicine Technologist
   Marshall S. Grillo, D.O., Former Radiation Safety Officer

*Indicates those present at Exit Meeting conducted on October 9, 1990.

2. Licensed Program

   Standish Community Hospital possesses NRC Byproduct Material License No. 21-21265-01 which authorizes the possession of any byproduct material identified in 10 CFR Parts 35.100 and 200 (excluding xenon-133 and generators). The byproduct material is authorized for medical use as described in the above referenced sections of 10 CFR Part 35. The Radiation Safety Officer and only authorized user on the license currently is Edward F. Martin, D.O. The licensee utilizes only unit doses from a local radiopharmaceutical supplier and conducts approximately 40 procedures monthly. No radiopharmaceutical or sealed source therapy is authorized or conducted by the licensee.

3. Purpose of Special Inspection

   This special inspection was initiated by the receipt of allegations on July 18, 1990 (AMS No. RIII-90-A-0074). The allegations concerned the licensee's use of byproduct material and NRC requirements associated with this use. The specific allegations are as follows:

   a. There was no RSO from June 4 to July 18, 1990.

   b. A Radiation Safety Committee (RSC) meeting was not held during the second quarter of 1990 and if one was held the Radiation Safety Officer (RSO) was not present, therefore no quorum was established.

   In addition to these allegations, two other concerns were raised by the alleger: 1) the RSO/authorized user was denied access to the nuclear medicine department and 2) several sealed calibration sources owned by the RSO/authorized user were confiscated by the hospital.

4. Inspection Findings

   On October 9, 1990, an inspection was conducted at the licensee's facility to review the previously addressed allegations and concerns. Interviews were conducted with all individuals identified in Section 1 of this report. The inspection revealed that during the week of June 4, 1990, Mr. Polonis, the hospital's Chief Executive Officer (CEO), told Marshall Grillo, D.O., the licensee's RSO and only authorized user at that time that the hospital was purchasing some used nuclear medicine

equipment to replace the existing equipment which was owned by Dr. Grillo. The conversation that ensued between Mr. Polonis and Dr. Grillo at this point is not clear, however it appears that Dr. Grillo indicated to Mr. Polonis that no equipment could be moved or any changes made without the authorization of the RSO. Mr. Polonis stated that he told Dr. Grillo that he was removing the RSO responsibility from him and appointing another individual as RSO, thus indicating that Dr. Grillo had no say in the matter. Dr. Grillo would remain as an authorized user on the license.

In addition to owning the existing nuclear medicine equipment Dr. Grillo also owned several sealed calibration sources utilized by the hospital. These sources were possessed under the hospital's NRC license but had been purchased by Dr. Grillo and transferred to the hospital license when Dr. Grillo terminated his own NRC license sometime earlier.

On June 6, 1990, Mr. Polonis sent a letter to the Region III office requesting that Dr. Grillo be removed as RSO and Edward F. Martin, D.O. be designated the RSO. Dr. Martin was not approved by the NRC as RSO until July 16, 1990. License Condition No. 11 of the NRC license states that the Radiation Safety Officer for the license is Marshall S. Grillo, D.O. The inspection revealed that Dr. Grillo was removed as RSO during the week of June 4, 1990, and Dr. Martin was not authorized as the new RSO until July 16, 1990. Therefore, the licensee was without an RSO from sometime during the week of June 4, 1990 to July 16, 1990. The failure of the licensee to have an approved RSO during the referenced time period constitutes an apparent violation of License Condition No. 11 and substantiates the first allegation. The cause of this violation appears to be a misunderstanding of the regulations by the licensee which require that the NRC approve a new RSO.

On June 6, 1990, the new nuclear medicine equipment was received by the hospital and the existing equipment removed. Nuclear medicine services were suspended from this date to June 11, 1990 when the new equipment was completely installed and operational. Dr. Grillo continued to serve as authorized user until July 18, 1990 when he resigned from the hospital staff.

The inspection further revealed that during the month of June 1990, an RSC meeting was required pursuant to the requirements of 10 CFR Part 35.22. The alleger indicated that either no meeting was held during the month of June or that a meeting was held and the RSO was not present and no minutes were taken of the meeting. 10 CFR 35.22(a)(2) requires the RSC to meet quarterly. A review of RSC meeting minutes showed that no meeting was held during the second quarter of 1990 which included the month of June. The failure of the RSC to meet during the second quarter of 1990 constitutes an apparent violation of 10 CFR Part 35.22(a)(2) and substantiates the second allegation. According to the licensee, this violation was a result of the hospital's removal of the RSO and attempts to name a new RSO at the time the meeting was due.

A review of the concerns, raised by the alleger and detailed in Section 3, showed that Dr. Grillo, as an authorized user, was not denied access to the nuclear medicine department during operational hours. The departmental policy is to keep the department door locked at all times when authorized personnel are not present. Interviews with hospital personnel revealed [illegible] the door is locked when authorized personnel are not present, however [illegible] is available and access would have been allowed to Dr. Grillo in the event of an emergency during non-regular hours.

In addition to the above concern, the alleger stated that the sealed calibration sources owned by Dr. Grillo but possessed under the NRC license were confiscated by the licensee. The inspection revealed that Dr. Grillo wanted to remove the sealed calibration sources, which had been purchased by him, at the time he removed his other equipment. However, the sources were not removed by him from the department until July 17, 1990, the day before he resigned from the hospital. The sealed sources consisted of three cobalt-57 sources (maximum activity approximately 2 millicuries), two cesium-137 sources (approx. 200 microcuries and 20 microcuries) and one barium-133 source (approximately 200 microcuries). The sources were transferred on July 17, 1990, to the Veterans Administration Medical Center in Saginaw, MI, NRC License No. 21-25815-01. Although Dr. Grillo had paid for the sources, the sources were possessed by the hospital under the NRC license and therefore, from a regulatory standpoint were the responsibility of the licensee. Consequently, it does not appear that the sources were confiscated from Dr. Grillo and the source transfer was performed in accordance with regulatory requirements.

Two apparent violations of NRC requirements were identified and both allegations were substantiated.

5. <u>Exit Meeting</u>

An Exit Meeting was conducted with those individuals indicated in Section 1 at the conclusion of the inspection. The allegations and concerns, the inspection findings, the apparent violations and the NRC Enforcement Policy were discussed. No information contained in this report was indicated as proprietary by the licensee.