U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03003388/2008002
Docket No.	03003388
License No.	47-09576-01
Licensee:	St. Mary's Medical Center
Location:	2900 First Avenue Huntington, West Virginia 25702-1241
Inspection Dates:	October 28, 2008 and February 6, 2009

Inspector:	___/RA by James D. Noggle For/_____ Richard McKinley Health Physicist	_____02/10/09_____ date
	___/RA by James D. Noggle For/_____ Farrah Gaskins Health Physicist	_____02/10/09_____ date
Approved By:	___/RA/_____ _____ James D. Noggle, Chief Medical Branch Division of Nuclear Materials Safety	_____02/10/09_____ date

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EXECUTIVE SUMMARY

St. Mary's Medical Center
NRC Inspection Report No. 03003388/2008002

An announced, special inspection was performed to follow up on the licensee's notification, on October 22, 2008, of a medical event that occurred on October 15, 2008. The medical event involved the administration of a capsule containing 150.7 millicuries of sodium iodide iodine-131 in which the capsule lodged for 2.5 hours in the upper esophagus. As a result, this region received a dose as high as 1798 rads, in comparison with the intended dose at that location of 1012 rads. The Radiation Safety Officer reported the dose six days immediately after the event, after he realized that the capsule had been lodged for 2.5 hours, rather than 1.5 hours.

REPORT DETAILS

I. Event Description

a. Inspection Scope

This inspection was limited to a review of the circumstances surrounding the iodine-131 medical event that occurred on October 15, 2008 and was reported to the NRC on October 22, 2008. The inspection consisted of observations of the inspector, interviews with licensee personnel, and a selective examination of records describing the event and follow up actions.

b. Observations and Findings

Iodine Thyroid Therapy Program

License No. 47-09576-01 authorizes any therapy procedure permitted by 10 CFR 35.300. The licensee uses mostly iodine-131, about 25 times per year. About 70 % of these cases are thyroid ablations involving more than 33 millicuries. The remainder are hyperthyroidism treatments involving less then 33 millicuries activities.

Event Description

At 11:30 a.m. on October 15, 2008, the licensee attempted to administer 150.7 millicuries of sodium iodide iodine-131 in one capsule to a patient for treatment of thyroid carcinoma. The patient had previously informed the nuclear medicine authorized user (AU) that she routinely crushed her medications because of difficulty swallowing, and that her gastroenterologist had performed dilations on her to stretch the esophageal muscles. The most recent dilation was performed in March 2007.

Since the AU was aware of the patient's swallowing problems, he called the nuclear medicine department on the day of the treatment to inquire about the patient's ability to swallow. The patient was asked by a nuclear medicine technologist (NMT) if she thought that she could swallow. The patient answered "yes" and also informed the NMT she had eaten food the previous day while in the hospital with no swallowing issues. The NMT informed the AU and based on the patient's answer and her recent food intake, the AU decided that the treatment should proceed. The capsule was administered by an NMT, with the patient's daughter nearby. The AU was in the hospital, but he was not present in the patient's room when the capsule was administered. When the patient swallowed the capsule, it lodged in the upper esophagus, behind the trachea. The NMT did not immediately call the AU but began administering applesauce and soda to dislodge the capsule. When that did not work, the NMT called the AU and the licensee's radiation safety officer (RSO), who is also a medical physicist. Administration of applesauce and soda was continued until the capsule was successfully dislodged 2.5 hours after the patient attempted to swallow the capsule and travelled into the stomach.

Capsule positions were confirmed by the licensee by use of a GM survey meter. During the 2.5 hours that the capsule remained lodged, the licensee calculated that the patient's esophagus received 786 rads in excess of the dose of 1012 rads that it would have

received during a routine treatment. This exceeded 50 rems to an organ or tissue other than the treatment site (thyroid) and more than 50% of the dose expected to the esophagus from the prescribed treatment, and therefore is a medical event. The licensee is potentially in violation of 10 CFR 35.41(a)(2). The licensee did not have a written procedure to address oral administration of capsules to a patient who cannot swallow.

According to the RSO, at first, he believed that the capsule had been lodged in the esophagus for a shorter period of time and calculated that the dose to the esophagus would not constitute a medical event. The RSO contacted the NRC to discuss the event immediately, and then NRC concurred that based on the dose estimate, the event did not constitute a medical event. Later when reviewing the technologist's notes, he realized that the capsule had been lodged for 2.5 hours and that a medical event had occurred. Following identification on October 21, 2008, the licensee reported the medical event the following day in accordance with 10 CFR 35.3045(a)(3).

Written Directive Procedures

The licensee had a “quality management program” to assure that each iodine-131 treatment was administered in accordance with the written directive. Item 3 of the patient screening guide requires that the licensee determine whether or not the patient has trouble swallowing capsules. The licensee did determine that the patient had a history of esophageal strictures. However, the last treatment for this condition had been more than a year previous, and the patient reported that she had been having no problems swallowing food or medication while in the hospital. Therefore the licensee decided to proceed with the administration.

Notification of the Event

At the time of the event, the RSO believed that the incident had started just prior to his arrival. Based on the time factor, his calculations showed that the incident did not constitute a medical event. One week later, on October 21, 2008, it came to his attention that the incident had started earlier. New calculations showed that a medical event had occurred. The licensee then notified the NRC Operations Center of the event on October 22, 2008. The same day, a written report was submitted to NRC and the referring physician.

Licensee’s Corrective and Preventive Actions

During the inspection, the licensee described their corrective actions as follows:

1) All patients will be questioned regarding their ability and willingness to swallow a large capsule or pill.

2) The existence and significance of esophageal strictures will be assessed.

3) Swallowing a dummy capsule may be tried.

4) Pre-therapy esophageal dilation will be performed when appropriate.

5) A barium swallow procedure within 2 weeks of therapy will be considered for patients with a known esophageal stricture condition.

6) A smaller capsule size may be ordered with enough advance notice.

7) Liquid iodine-131 will be considered as a last resort.

c. Conclusions

The inspector concluded that the licensee administered an iodine-131 capsule on October 15, 2008, and that this capsule stuck in the patient's esophagus for approximately 2.5 hours. As a result, this portion of the patient's esophagus received 1798 rads in comparison to the 1012 rads it would have received in a routine administration. Because the dose to the esophagus exceeded the dose expected from the written directive by more than 50 % and by more than 50 rem, this administration met the medical event reporting definition in 10 CFR 35.3045(a)(3).

The root cause of this event was procedures which were inadequate to lead the licensee to properly evaluate the possible consequences of recurrent swallowing difficulties suffered by the patient. The following Non-Cited Violation (NCV) was identified:

The licensee's procedures for compliance with 10 CFR 35.41 (a) to verify that iodine-131 treatments are administered in accordance with the written directive did not address steps to be taken in case a patient cannot swallow the capsule.

The licensee's corrective actions directly address the cause of the medical event. The corrective actions appear to be adequate to prevent recurrence of this type of medical event.

II. Medical Consultant's Report

The NRC contracted a medical consultant to review this event, its effect on the patient, and the licensee's corrective actions taken to prevent recurrence of similar events. The medical consultant's report was received on December 22, 2008. The consultant concluded that no significant adverse effect to the patient is expected.

III. Exit Meeting

A preliminary exit meeting was conducted on October 28, 2008 to discuss the scope of the inspection and the inspector's initial observations. On February 6, 2009, at the conclusion of the inspection, an exit meeting was held by telephone to discuss the inspector's observation and the medical consultant's report.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

*Susan Bellamy, Radiology Coordinator
*Tyson Smith M.D., Vice President of Medical Affairs
*Stacy Ross, Clinical Manager
*Aynessa Moudlak, Director of Oncology Services
*Vera Rocims, Vice President of Oncology Services
*Pat Stultz, Director of Nursing
*Linda Queener, Director of Risk Management
#*James Norweck, Radiation Safety Officer
Michael Sellards, President and CEO

* Present at preliminary exit meeting conducted on October 28, 2008
# Participated in telephonic exit meeting conducted on February 6, 2009