U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

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Inspection No.	03037454/2007001
Docket No.	03037454
License No.	52-31241-01
Licensee:	Centro Cardiovascular del Este, CSP
Address:	PMB 202, P. O. Box 70005, Fajardo, PR 00738
Locations Inspected:	Avenida General Valero, #375 Suite 102, Fajardo, Puerto Rico
Inspection Dates:	November 15 and 26, 2007; February 5 and 6, 2008; and October 8, 2008

Inspectors:

/RA/ ***10/16/08***

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Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

Centro Cardiovascular del Este, CSP
NRC Inspection Report No. 03037454/2007001

During a routine, initial inspection performed on November 15, 2007, inspectors noted that the Nuclear Medicine Technologist (NMT) split radiopharmaceutical unit dosages on many occasions so that she could perform a larger number of diagnostic procedures than had been originally scheduled. The NMT explained that, because of a problem with the licensee's scheduling system, on many occasions patients would present themselves for scans and they were not on the schedule. The NMT discussed the splitting of dosages with the Medical Director and received his approval to do so; however, the Medical Director was not an authorized user and he was therefore not qualified to approve of this practice. The Authorized User had provided specific instructions to the NMT regarding the preparation of patient dosages. Inspectors determined that neither the Medical Director nor the NMT sought or received approval to split dosages from the Authorized User listed on the license. An apparent violation of 10 CFR 35.27(b) and 10 CFR 35.63(d) was identified for failure of the licensee to follow the instructions of the Authorized User regarding the preparation of byproduct material for medical use. An apparent violation of 10 CFR 35.2063 was also identified for failure to record, in the record of dosage determinations, the dosage and the date and time of dosage determination. The inspectors noted that the failure of the Medical Director and the NMT to notify the Authorized User and the Radiation Safety Officer that they had been splitting dosages resulted in the practice continuing for nearly 3 months. The inspectors also noted that the monthly audits performed by the Radiation Safety Officer were of insufficient depth and scope to identify the practice or the violations.

REPORT DETAILS

I. Management Oversight of the Program

a. Inspection Scope

The inspectors reviewed the licensee's management controls, including the oversight provided by the Authorized User for medical use of radioisotopes. The inspection included interviews with personnel and review of selected records.

b. Observations and Findings

The senior licensee representative routinely present at the location of use for licensed materials is the Medical Director; however, the Medical Director is not an authorized user of licensed radioactive materials. The Authorized User supervises the use of licensed material but he is not typically present at the licensee's facilities during the conduct of licensed activities. The Nuclear Medicine Technologist (NMT) is the person responsible on a daily basis for receipt, use, transfer and control of licensed materials. The inspectors determined that the Authorized User provided initial instruction to the NMT concerning the medical use of licensed materials and he regularly reviewed the results of these scans; however, the Authorized User did not regularly communicate with the NMT. The Radiation Safety Officer (RSO) visits the licensee's facility monthly, performing a review of licensed activities. The inspectors noted that language differences hinder communication between the RSO and the NMT and that this impacts the thoroughness of these periodic reviews.

c. Conclusions

The oversight provided by the licensee was not adequate to identify and prevent violations of NRC requirements. These violations are described more fully in Section II of this report.

II. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspectors reviewed the licensee's procedures and practices for ordering, receiving, using and controlling radioactive materials. The inspection included observations of activities as they were performed, personnel interviews, and review of selected records.

b. Observations and Findings

The inspectors noted that the licensee receives patient dosages on a daily basis, with the pharmacy delivery person placing the materials into a secure location within the licensee's facility.

The inspectors reviewed patient dosage determination/administration records and noted

a number of examples from August 2007 through November 15, 2007, including but not limited to August 27 & 29, September 10, 14, & 20, and November 8, 2007, where two patients received dosages from the same prescription number.

When asked to explain what was observed in the record, the NMT stated that radiopharmaceutical dosages were ordered from the pharmacy on the day before the dosages were required and the number of dosages ordered was based on the number of patients scheduled. The NMT and other licensee personnel stated that, since the use of NRC-licensed materials began in August 2007, there had been ongoing problems with the computer-based system used to schedule patients. Specifically, some of the patient appointments that were made did not show up on the daily schedule. This resulted in some days where not enough dosages were ordered for the number of patients who presented themselves for diagnostic procedures. The NMT stated that she had observed dosages being split between patients at another licensed facility and, during a discussion of the problem with the Medical Director, she offered that the splitting of dosages was a practice that could be used to serve the additional patients. The NMT stated that the Medical Director approved of the splitting of dosages in order to serve the additional patients. The Medical Director confirmed that he had approved of this practice. The inspector determined that neither the Medical Director nor the NMT consulted with the Authorized User regarding the splitting of dosages and the Authorized User was not aware that it was being done.

10 CFR 35.27(b) requires, in part, that a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of a physician who is an authorized user, as allowed by 10 CFR 35.11(b)(2), shall require the supervised individual to follow the instructions of the supervising authorized user regarding the preparation of byproduct material for medical use. Furthermore, 10 CFR 35.63(d) requires that unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. The supervising authorized user provided a written procedure that required patient dosages for a specific diagnostic scan range between 8 and 12 millicuries of technetium-99m for the resting portion of the scan and between 25 and 30 millicuries of technetium-99m for the stress portion of the scan. The inspectors determined that the licensee permitted the preparation of byproduct material for medical use by an individual under the supervision of a physician who is an authorized user; however, on several occasions including, but not limited to, August 27 & 29, September 10, 14 & 20, and November 8, 2007, the licensee did not require the supervised individual, the NMT, to follow the instructions of the Authorized User regarding the preparation of byproduct material for medical use. Specifically, the Authorized User provided a written procedure that required patient dosages for a specific diagnostic scan range between 8 and 12 millicuries of technetium-99m for the resting portion of the scan and between 25 and 30 millicuries of technetium-99m for the stress portion of the scan; however, on those dates, the NMT split patient dosages such that the dosages administered to the patients fell below the prescribed dosage range specified by the Authorized User. This is an apparent violation of 10 CFR 35.27(b) and 10 CFR 35.63(d).

The inspectors noted that when the Authorized User was made aware that the licensee had been splitting dosages, the Authorized User re-reviewed the patient scans and

concluded that a sufficient quantity of technetium-99 had been administered to the patients to allow an adequate diagnosis.

The inspectors questioned the NMT and reviewed the patient dosage administration/determination record in an attempt to determine the dosages that were actually administered to patients. The inspectors determined that the NMT's practice was to measure and record the actual dosages in the syringes received from the pharmacy at the beginning of the day and, when dosages were split, the NMT failed to document the determined dosage for each patient or the date and time of dosage determination.

10 CFR 35.2063 requires a licensee to retain a record of dosage determinations required by 10 CFR 35.63 for a period of 3 years and that the record contain the radiopharmaceutical; the patient's name, or identification number if one has been assigned; the prescribed dosages and the determined dosage; the date and time of the dosage determination; and the name of the individual who determined the dosage. The inspectors determined that, on several occasions including, but not limited to, August 27 & 29, September 10, 14 & 20, and November 8, 2007, the record of dosage determinations did not contain the determined dosage or the date and time of dosage determination. This is an apparent violation of 10 CFR 35.2063.

The RSO was also not informed that dosages were split between patients and he failed to identify this practice during his monthly audits.

c. Conclusions

An apparent violation of 10 CFR 35.27(b) and 10 CFR 35.63(d) was identified for failure to follow the instructions of the Authorized User regarding the preparation of byproduct material for medical use; and (2) an apparent violation of 10 CFR 35.2063 was identified for failure to record, in the record of dosage determinations, the dosage and the date and time of dosage determination. In addition, while the RSO should have been made aware of the dosage splitting practice by the Medical Director and the NMT, the monthly audits performed by the RSO were of insufficient depth and scope to identify the practice or the violations.

III. Training of Workers

a. Inspection Scope

The inspectors reviewed the content and adequacy of personnel training through personnel interviews and review of records.

b. Observations and Findings

The inspectors determined through interviews of the NMT and the RSO and review of training materials provided to the NMT by the RSO that the training provided the NMT prior to the commencement of licensed activities was minimal. Language differences between the NMT and the RSO significantly limited communication, resulting in training consisting of pre-printed information in English presented to the NMT, with little

opportunity for questions and discussion.

c. Conclusions

Although a contributing factor to the violations described in Section II of this report, the quality and level of training provided to licensee staff was not itself a violation of NRC requirements. No violation was identified.

IV. Radiation Surveys

a. Inspection Scope

The inspectors examined the licensee's practices and procedures for performing radiation surveys. The inspectors observed use of radiation survey instruments, interviewed personnel, and reviewed records.

b. Observations and Findings

The inspectors observed the surveys performed when radioactive material packages were received. Survey instruments were calibrated and radiation surveys were documented. No problems were identified with the maintenance or operation of survey instruments or with the performance of surveys.

c. Conclusions

No violations or safety concerns were identified.

V. Exit Meeting

At the conclusion of the initial site inspection on November 15, 2007, the inspectors met with the licensee representatives including the Medical Director, the Radiation Safety Officer, and the office administrator. Preliminary results of the inspection were presented and described, including the apparent violations. The licensee stated that, effective immediately, they would stop splitting dosages and record the actual dosage administered to patients. The final results of the inspection were communicated to the Medical Director on Obctober 8, 2008.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Edwin Marshall, MD, Medical Director*
Daisy Pedrogo-Casillas, Nuclear Medicine Technologist
David Rhoe, Radiation Safety Officer*
Rene Baez-Carattini, MD, Authorized User (contacted by telephone on November 26, 2007)
Alfredo Garcia-Alvarez, Administrator*#

* Denotes presence at the preliminary Exit Meeting on November 15, 2007

# Denotes presence at the Exit Meeting, by telephone, on October 8, 2008