

February 28, 2009

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

Docket No. 03002941
License No. 37-00148-06

Response to Notice of Violation

Sir/Madam:

This is in response to the Notice of Violation dated January 30, 2009, issued as a result of findings obtained during on-site inspection 03002941/2008001, conducted February 5-7, 2008.

The violation identified in the "Notice of Violation" involved the conduct of a physical inventory that was not in accordance with regulatory requirements.

Reason for Violation

We have concluded that the reason for the violation primarily arose from an inadequate understanding of the requirements for conducting a proper physical inventory on the part of the individual (a Nuclear Medicine Technologist) who had been assigned responsibility for performing this task [for sources within the Nuclear Medicine Division]. The lack of a formal written procedure (with corresponding staff training) for performance of physical inventories has subsequently been identified as a secondary, contributing factor.

Corrective Steps Taken/Steps Taken to Avoid Further Violations

1. At the time the violation was identified during the NRC inspection, Jefferson Office of Radiation Safety Staff assumed responsibility for the conduct of physical inventories of sealed sources within the Nuclear Medicine Division.
2. The Nuclear Medicine sealed source inventory was audited for accuracy by Radiation Safety personnel and corrected as necessary.
3. A physical inventory of the Nuclear Medicine sealed sources was completed by Radiation Safety staff on February 8, 2008, with complete and accurate information recorded in relation to this inventory.
4. Subsequent physical inventories of the Nuclear Medicine Sources were performed on 5/5/08; 5/21/08; 7/1/08; 9/30/08; and 12/30/08.

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5. Radiation Safety personnel, with one exception noted below, continued to conduct physical inventories (at least semi-annually) for all other sealed sources that require a physical inventory. [Radiation Safety had already been performing physical inventories for those areas.] All records related to these sources were audited for accuracy.
6. For Jefferson Heart Institute (JHI) locations, JHI staff continues to perform physical inventories. However, Radiation Safety Staff now also conduct confirmatory physical inventories at these locations during routine (quarterly) audits and inspections.
7. A written procedure has been generated (see attached) for the performance of physical inventories and the maintenance of relevant records.
8. Personnel assigned the task of performing physical inventories will be required to be familiar with and follow the written procedure.

We believe that we are currently in a state of full compliance and expect to remain so with the corrective actions that have been implemented.

Sincerely,



Richard Webster, RN, MSN
Vice President Clinical and Support Services

C: Dr. Intenzo
Dr. Leeper
Dr. Rao
Mr. Blob
Mr. Derstine (PA-DEP)
Mr. Lewis
Mr. McQuaid
Mr. Patel
Mr. Sarro
Regional Administrator – Region 1

INTERNAL PROTOCOL - RADIATION SAFETY

Sealed Source Physical Inventory

1.0 Purpose:

- 1.1. To comply with State regulations for the accountability of radioactive materials.
- 1.2. To comply with conditions of Jefferson's Radioactive Materials License(s).

2.0 Applicability

This protocol applies to physical inventory requirements for all sealed sources possessed under radioactive materials license numbers PA-130; PA-130A; and PA-0909, as issued by the Pennsylvania Bureau of Radiation Protection.

3.0 Responsibilities:

- 3.1 Designated Person or Department Personnel (e.g., Dept Manager; Chief Technologists; Physicist(s); etc.) are responsible for the following.
 - a) Maintaining, and properly securing against unauthorized access or theft, each sealed source on the Department's sealed source inventory. When not in use, sources are to be kept in their designated locations as identified by the Department's physical inventory record.
 - b) Notifying Radiation Safety of any plan or intent to (1) obtain new sealed sources, (2) relocate an existing source to a new storage location, or, (3) dispose of or "return to vendor" any source.
 - c) For Jefferson Heart Institute (JHI), and Jefferson Outpatient Imaging (JOI) [formerly, Jefferson Center City Imaging (JCCI)], perform physical inventories in accordance with the procedures and recordkeeping below.
- 3.2 Radiation Safety Personnel are responsible for the following.
 - a) performing all physical inventories of record (except JHI and JOI locations); i.e., for Radiology-Nuclear Medicine; Radiation Oncology; Radiation Safety; irradiator and research locations; and any other Department not identified herein.
 - b) Perform confirmatory physical inventories of JHI and JOI sources during routine quarterly audits of those locations.
 - c) Maintain and/or verify that appropriate records are generated and maintained.

4.0 Procedure for Conducting A Physical Inventory:

4.1 Inventory Record

NOTE:

For Radiation Safety, Physical Inventory lists are maintained on an EXCEL program on the server. The hard copies are located in a notebook in the Office of the Staff member responsible for this duty.

- 4.1.1 Have a copy of the current Inventory record (for the Department being inventoried) list for reference.
- 4.1.2 Each inventory record of sealed sources must have the following identified:
 - a. The Isotope
 - b. The Source Serial Number (if one has been assigned)
 - c. The date of calibration (date reference activity determined)
 - d. The manufacturer
 - e. The reference activity
 - f. The present activity
 - g. The actual location of the source
- 4.2 Go to each source storage location
- 4.3 Visually confirm that each source is present in that location identified for it in the current inventory record (item 4.1.2g)
 - 4.3.1 Verify for each source, items 4.1.2a and 4.1.2e
 - 4.3.2 To the extent possible and reasonable given ALARA considerations, visually verify items 4.1.2b, 4.1.2c, 4.1.2d.
 - 4.3.3 Determine current source activity (item 4.1.2f) through calculations or other appropriate means [may be handled on spreadsheet].
- 4.4 Note and describe whether any source is not in its prescribed location; where it is at the time of inventory; why it is in another location; and whether this is legitimate (e.g., source "is in active use.").
- 4.5 Document any discrepancies between the existing records and the findings obtained in steps 4.3 through 4.3.3.
- 4.6 Generate appropriate record (See Item 5.0).
- 4.7 Provide to Radiation Safety Officer for review.

NOTE:

For JHI and JOI, records can be faxed (215-923-9039) to Radiation Safety for review and RSO signature. See item 5 below.

5.0 Recordkeeping:

- 5.1 Records of physical inventories are to be maintained:
 - 5.1.1 Electronic (EXCEL or other computer-based) record is to be maintained.
 - 5.1.2 Paper record ("copy of record") for appropriate signatures is to be generated and maintained for each physical inventory conducted
- 5.2 Physical inventory records (electronic and paper) are to contain the following items.
 - 5.2.1 Each item identified above in item 4.1.2 [i.e., items 4.1.2a through g].
 - 5.2.2 The identity of the individual who performed the physical inventory.
 - 5.2.3 The date that the physical inventory (visual confirmation) was conducted.
 - 5.2.4 Except as per item 5.2.5 below, the physical inventory record is to contain the following attestation: "The sources identified in this record were visually observed by me to be present in the location(s) indicated" (or words to that effect); followed by initials or signature of the person who conducted the physical inventory, on the "copy of record".
 - 5.2.5 Document any discrepancies as per items 4.4 and 4.5.
- 5.3 Once completed (see item 6.3 below) the "copy of record" is to be filed in the designated location within the Radiation Safety Office.
- 5.4 For non-Radiation Safety Department sources, a copy (or copies) of the completed inventory record is to be sent to a designated, responsible individual in the "Owner" department (original filed as per item 5.3).

6.0 Scheduling:

- 6.1 Physical Inventories are to be conducted on a quarterly basis. (Radiation Safety personnel are to perform confirmatory physical inventories at the time of a routine inspection on-site at the JHI and JOI locations)
- 6.2 Under no circumstance is performance of a physical inventory to occur more than 180 calendar days after the most recent physical inventory.

NOTE: Failure to meet the 180-day requirement is a regulatory violation.

- 6.3 Draft ("rough") documentation of the performance of a physical inventory is to be made "on-the-spot" at the time of inventory. Generation of final ("clean") electronic and "copy of record" paper documentation is to occur within 3 working days. Once completed, the "copy of record" is to be presented to the RSO for review and signature.
- 6.4 Inventory records are to be maintained for 3 years.