Enclosure 6 – Inspection Record

Region III Inspection Report No. 2011-001 License No. 13-32241-01
Docket No. 030-35383

Licensee (Name and Address): Indiana University Health Hematology & Oncology Clinic

1346 East County Line Road, Indianapolis, IN 46227

Location (Authorized Site) Being Inspected: 6845 Rama Dr., Indianapolis, IN and 10212 Lantern Rd. Fisher, IN

Licensee Contact: Yun Wang, Ph.D. Telephone No. 317-250-7435

Priority: 2 Program Code: 2230

Date of Last Inspection: 2/18-19/2009 Date of This Inspection: 7/21-22/2011

Type of Inspection: ( ) Initial ( ) Announced (X) Unannounced
(X) Routine ( ) Special

Next Inspection Date: July 2013 (X) Normal( ) Reduced

Justification for reducing the routine inspection interval:

Summary of Findings and Actions:
( ) No violations cited, clear NRC Form 591 or regional letter issued
( ) Non-cited violations (NCVs)
( ) Violation(s), Form 591 issued
(X) Violation(s), regional letter issued
(X) Follow-up on previous violations

Inspector(s) Tara L. Weidner Date 9/6/11

(Signature)

Approved Tammy Bloomer Date 9/7/11

(Signature)

PART I-LICENSE, INSPECTION, INCIDENT/EVENT, AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES:

   A. License amendments issued since last inspection - None ( ) or,

AMENDMENT #	DATE	SUBJECT
14	6/1/09	addition of mobile PET
15	9/16/10	add Authorized Users (AU)
16	11/29/10	renewal of license
17	4/19/11	changes in AUs and authorizations
18	6/22/11	change in ownership

   B. Program changes since the last inspection

      Since the last inspection in 2009, the licensee has added a mobile PET trailer that travels between three of the locations of use.

2. INSPECTION AND ENFORCEMENT HISTORY:

Four violations were identified during the February 2009 inspection:

1. 10 CFR 20.1802 – Failure to maintain control and constant surveillance over the high dose rate remote afterloader (HDR) unit when transporting the unit to multiple locations of use. Specifically, licensee personnel left the HDR in an unlocked vehicle while moving other equipment associated with the HDR into the location of use.

2. 49 CFR 172.403 – Failure to place Radioactive Yellow II labels on the opposite sides of a package containing an iridium-192 sealed source being transported on public highways.

3. 49 CFR 172.310 – Failure to mark the outside of the packaging being offered for transport as a Type A package.

4. 49 CFR 172.301 – Failure to have the proper shipping name and identification number on a shipping package containing an iridium-192 sealed source being transported on public highways.

There were no other unresolved issues including repeat violations, CALs, or Orders. During the 2011 inspection, implementation of the corrective actions for the previous violations was verified. The HDR was appropriately labeled with Radioactive Yellow II labels on the opposite sides of the unit, a Type A label, and the proper shipping name and UN identification number. In addition, the inspector confirmed that the procedure for transport of the HDR had been revised to require two individuals to be present during the loading and unloading of the unit to ensure that it is under constant surveillance when it is in an unrestricted area and not in storage.

3. INCIDENT/EVENT HISTORY:

(X) None. From review of regional event logs, event files, and the licensing file, there was no evidence of any incidents or events since the last inspection.

PART II - INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Indiana University Health Hematology & Oncology Clinic (IUHHOC) is an outpatient clinic authorized for 10 CFR 35.100, 35.200, 35.300, 35.400 (I-125 and Pd-103) and 35.600 (mobile high dose rate remote afterloader only) materials. Although 35.400 materials are authorized by the license, permanent brachytherapy had not been performed in a number of years. There were four locations of use. The primary location of use was 6845 Rama Drive, Indianapolis. At this location, the inspector observed an HDR treatment as well as demonstrations of procedures performed in the nuclear medicine department. Mobile HDR is authorized at all four locations of use. In addition, the inspector visited the Lantern Road location and toured the facilities, including the mobile PET coach. Mobile PET operations are authorized at three locations.

Nuclear medicine was staffed by one technologist who used one camera to treat 3-5 patients per day. Bone and MUGA scans made-up the majority of imaging procedures. All were performed using unit dosages or capsules supplied by Cardinal Health. Therapeutic procedures included Iodine-131 for thyroid carcinoma (~ 10/year), Quadramet for the treatment of bone pain (~2/year) and Zevalin for the treatment of Non-Hodgkins Lymphoma (~2/year). Written directives were prepared for each administration. Each dosage was assayed in a dose calibrator prior to administration.

Mobile PET services were offered 5 days per week at one of the three locations. The PET coach was transported to each location by a licensed commercial driver who carried the appropriate shipping records in the cab of the truck. One technologist performed approximately 4 studies per day. Unit doses of F-18 FDG were delivered directly to the PET coach by Cardinal Health. Patients were injected in the Hot Lab and remained there for the 30 minutes to allow the radiopharmaceutical to circulate.

HDR brachytherapy was performed using a mobile Nucletron HDR. Approximately 60 fractions were performed on about 5 patients monthly with the majority being mammosite treatments. The HDR was transported in a dedicated van to each location of use. The driver carried the appropriate shipping papers and had been instructed not to leave the unit unattended. When the HDR equipment was offloaded at each location, a second individual was present to maintain constant surveillance over the HDR prior to it being placed in storage.

The HDR was stored in a secured facility when not in use. Quarterly source exchanges, annual maintenance, and training were provided by Nucletron. Each location where the HDR was used was equipped with all required warning lights, signs, remote monitoring cameras, and radiation detection equipment. Emergency procedures were kept on the cart that held the console. Daily spot checks were performed and were noted to include all required tests.

The Medical Physicist served as the Radiation Safety Officer and the Radiation Safety Committee met quarterly to discuss the radiation safety issues, dosimetry results, etc.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87132

Focus Areas Evaluated: 3.01-3.07

Records reviewed: Selected records including, written directives, surveys, HDR spot checks and full calibrations, training, dose calibrator QC, inventories/leak tests

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

( ) N/A

Instrument type: Model # Ludlum 2401-P
NRC S/N: 142673 calibration expiration date: 7/6/2012

Survey/measurement results: All survey results were comparable to the licensee's.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

10 CFR 35.92(a) states, in part, that, a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity. 10 CFR 35.92(b) states that, a licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

Contrary to the above, as of July 22, 2011, the licensee did not retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092. Specifically, no record of disposal of decay-in-storage waste was ever kept by either technologist in the nuclear medicine department or the PET coach.

This is a Severity Level IV violation (Enforcement Policy Section 6.3).

Corrective Actions included developing a waste disposal record and retraining staff.

5. PERSONNEL CONTACTED:

Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

#*Yun Wang, Ph.D. – Radiation Safety Officer
Paul Des Rosiers, M.D. – Authorized User
Teresa Dallas, R.N. – Brachytherapy Coordinator
Charles Brenneman - Nuclear Medicine Technologist
Nathan Wright - Nuclear Medicine Technologist (PET)

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