

INSPECTION RECORD

Region I Inspection Report No. 2006-026 License(s) No. File No. 184
Docket(s) No. 9999-90001

Licensee (Name and Address): Accelinear Service Co., d/b/a Oncology Services, Int. 500 N. Franklin Turnpike, MB8, Ramsey, NJ 07446

Location (Authorized Site) Being Inspected: 1970 Rutgers University Blvd., Lakewood, NJ

Licensee Contact: Kevin Zarko, Service Engineer Telephone No. 732-730-8774

Priority: N/A Gen. Lic. Program Code: 11210

15 REC 9/15/06

Date of Last Inspection: N/A Date of This Inspection: March 14, 2006

Type of Inspection: () Initial () Announced () Unannounced
() Increased Controls () Routine (√) Special

Next Inspection Date: N/A () Normal () Reduced

Justification for reducing the routine inspection interval: N/A: General Licensee

Summary of Findings and Actions:

- () No Violations cited, clear U.S. Nuclear Regulatory Commission (NRC) Form 591 or regional letter issued
- (√) Non-cited violations (NCVs)
- () Violation(s), Form 591 issued
- () Violation(s), regional letter issued
- () Followup on previous violations

Inspector(s): Randolph C. Ragland, Jr., / Ronald Rolph Date: 8/11/06

Name(s)

Handwritten signatures of Randolph C. Ragland, Jr. and Ronald Rolph

Signature(s)

Approved: Pamela J. Henderson, Chief, Medical Branch Date: 8/11/06

Name

Handwritten signature of Pamela J. Henderson

Signature

SUNSI Review Completed By: / RA / R. C. Ragland, Jr. [X] Non-Public [X] Non-Sensitive

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

- 1. AMENDMENTS AND PROGRAM CHANGES:
(License amendments issued since last inspection, or program changes noted in the license)

<u>AMENDMENT No.</u>	<u>DATE</u>	<u>SUBJECT</u>
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N/A: General Licensee

- 2. INSPECTION AND ENFORCEMENT HISTORY:
(Unresolved issues; previous and repeat violations; Confirmatory Action Letters; and orders)

On September 28, 2000, the licensee inadvertently transferred approximately 70 pounds (i.e., 25 millicuries) of depleted uranium in the form of a primary collimator from a linear accelerator to Waste Management, Inc., a company not authorized to receive the material. Therefore, the transfer was not authorized by 10 CFR 40.51. A SL IV Violation, Supplement VI was issued on 11/6/2000.

- 3. INCIDENT/EVENT HISTORY:
(List any incidents, or events reported to NRC since the last inspection. Citing "None" indicates that regional event logs, event files, and the licensing file have no evidence of any incidents or events since the last inspection.)

On September 28, 2000, the licensee inadvertently transferred approximately 70 pounds (i.e., 25 millicuries) of depleted uranium in the form of a primary collimator from a linear accelerator to Waste Management, Inc., a company not authorized to receive the material. Therefore, the transfer was not authorized by 10 CFR 40.51.

PART II - INSPECTION DOCUMENTATION

- 1. ORGANIZATION AND SCOPE OF PROGRAM:
(Management organizational structure; authorized locations of use, including field offices and temporary job sites; type, quantity, and frequency of material use; staff size; delegation of authority)

On July 20, 1999, NRC issued a general license to Accelinear Service Company, Ltd., located in Ramsey, New Jersey (File No. 184), authorizing the use of depleted uranium (DU) contained in devices. Accelinear d/b/a Oncology Services International receives, refurbishes, resells, and disposes of linear accelerators. Some of the accelerators that they receive contain depleted uranium as shielding. Typically, DU is only contained in the older accelerators and the DU is removed, placed into drums, and shipped to a licensed waste broker (e.g., Philotechnics, Ltd., State of Tennessee License No. R-01084-A08). Since 2004, 12 linear accelerators that contained DU have been dismantled at the 1970 Rutgers University Boulevard, Lakewood, NJ site.

- 2. SCOPE OF INSPECTION:
(Identify the inspection procedure(s) used and focus areas evaluated. If records were reviewed, indicate the type of record and time periods reviewed)

Inspection Procedure(s) Used: IP 87126: Industrial/Academic/Research

On March 7, 2006, Mr. Kevin Zarko, an Oncology Services Service Engineer, at the request of his management, contacted the NRC public affairs office to seek guidance regarding NRC requirements for reporting transfers of DU under their general license. On March 14, 2006, Richard McKinley and Randolph C. Ragland, Jr., of the NRC Region I office contacted Mr. Zarko to address his questions. Mr. Zarko reported that since 2004, Oncology Services had dismantled approximately 12 linear accelerators containing DU, and currently three dismantled linear accelerators remained on-site. Oncology Services had not previously notified NRC of the transfers of DU. Mr. McKinley and Mr. Ragland informed Mr. Zarko that general licensees are required to notify NRC of all transfers of DU in accordance with 10 CFR 40.25 (d)(4) and removal and direct handling of DU was not authorized by their general license.

On March 15, 2006, NRC Region I inspectors, Mr. Ragland and Ronald Rolph, performed an inspection at Oncology Services facilities located at 1970 Rutgers University Boulevard and 950 Airport Road in Lakewood, New Jersey. The accelerators are refurbished or dismantled at the 1970 Rutgers University Boulevard, Lakewood, NJ facility. The inspectors noted that Mr. Zarko had been assigned primary responsibility for removal and handling of DU. Mr. Zarko explained and demonstrated that he wore radiation dosimetry supplied by Landauer whenever he handled DU and also demonstrated use of a calibrated radiation survey instrument to identify DU shielding/collimators in the linear accelerators. Mr. Zarko also demonstrated the techniques he used to unbolt and disassemble DU, the transfer and DU into drums, and the preparation of drums for shipment to a licensed waste broker. Mr. Zarko had a written procedure for disposal of depleted uranium. The procedure included guidance to identify accelerator models containing DU (e.g., Varian 4/80, 6/80, 6/100, and 600C), guidance for surveying and controlling DU, and guidance for packaging DU for shipment. The inspectors noted that the licensee maintained records of the receipt and transfer of DU. The inspectors noted that although Mr. Zarko demonstrated appropriate radiological survey techniques and use of dosimetry, he did not utilize protective clothing (e.g., plastic gloves) during handling of DU components. The inspectors performed independent radiological surveys of both the 1970 Rutgers University Boulevard and the 950 Airport Road facilities and found no unusual radiation levels or loose smearable contamination on any tools, work areas, clothing or on Mr. Zarko's hands. Based on the survey results and lack of contamination on tools and in the workplace, the inspectors concluded that potential exposures to Mr. Zarko from loose contamination on DU was likely to be negligible. See Section 3 below for details of NRC radiological surveys.

On March 17, 2006, Randolph C. Ragland, Jr., NRC Region I, contacted the licensee including Mr. James Sharkey, Senior Vice President, Oncology Services, Mr. Glenn Davis, VP Installation, and Kevin Zarko, Service Engineer, and informed them that their practices for direct handling of DU was of particular concern to the NRC because a general licensee is not expected to come into contact with elevated radiation levels or loose smearable contamination and therefore a general licensee is exempted from the requirements in 10 CFR 20, "Standards for Protection Against Radiation." Mr. Ragland emphasized that activities that include the removal, handling, and packaging of DU for disposal involve direct handling of radioactive material and therefore require a formal radiation protection program that is reviewed by the NRC and approved via a specific license. During that conversation, Mr. Sharkey committed that Oncology Services would:

1. Immediately stop all operations involving the removal and handling of DU shielding components from linear accelerators;
2. Will not machine, drill or in any way change the size or shape of the DU shielding components that they currently possess;
3. Within 60 days, apply for a specific NRC license to authorize DU possession and use (i.e., to include the removal of DU shielding components from linear accelerators);
4. Within 30 days, provide a written report to the NRC Region I office and to the Director, Division of Nuclear Materials Safety documenting all DU transfers conducted under the general license by Acceliner Service Company or Oncology Services, International, that were not reported to NRC under their general license in accordance with the requirements of 10 CFR 40.25; and
5. Within 30 days, provide the names and addresses of all facilities that transferred DU to your facility. Include in the report the make and model number of each accelerator received.

Mr. Sharkey, Mr. Davis, and Mr. Zarko explained that they originally notified NRC of this issue because after a close reading of their general license they suspected that they were not in compliance with the notification requirements of their general license and wanted to obtain guidance from the NRC in order to come into compliance.

On March 17, 2006, NRC Region I issued Confirmatory Action Letter No. 1-06-002 (ML060760492) to Mr. James Sharkey Senior Vice President Oncology Services Service Company. In response to the CAL, on March 23, 2006, NRC Region I received two undated letters (ML060860345 and ML060860350) with records of receipt and transfer of DU in accordance with items 3 and 4 of the CAL. In addition, by letter dated May 11, 2006, NRC received an application from Oncology Services for a specific license to possess, use, and transfer DU in response to item 4 of the CAL. On August 8, 2006, NRC Region I issued NRC License SUB-1590 to Oncology Services International.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

(Areas surveyed, both restricted and unrestricted, and measurements made; comparison of data with licensee's results and regulations; and instrument type and calibration date)

On March 15, 2006, NRC Region I inspectors, Mr. Ragland and Ronald Rolph, performed radiological surveys at Accelinear/Oncology Services facilities located at 1970 Rutgers University Boulevard and 950 Airport Road in Lakewood, New Jersey. The inspectors used a Ludlum 14-C, Serial No. 17288, Calibration due 4/25/06 and an Eberline RO-2 Serial No. 1172, calibration due date 4/25/2006. No unusual radiation levels or loose smearable contamination was found in any work areas, on tools, clothing, or on Mr. Zarko's hands. The only measurable radiation levels identified were associated with a drum containing DU that had been bolted closed and prepared for shipment. Dose rates on the outside of the drum were approximately 1 - 1.5 mR/h on contact; 0.15 - 0.18 mR/hr at one meter; and 0.1 - 0.15 mR/h at 5 feet. Dose rates on contact with the DU were approximately 4 - 5 mR/h. Ten contamination smears were obtained from the warehouse floor, outside the drum, and on the DU inside the drum. As measured by the Ludlum 14c, no smearable contamination was found at any location outside of the drum of DU. Smearable contamination was identified on three pieces of DU that were contained inside the drum. All 10 of the smear samples were forwarded to NRC's contractor, the Oak Ridge Institute for Science and Education (ORISE), for Gross Beta and Gross Alpha analysis. By letter dated April 6, 2006, ORISE provided their analytical results that confirmed that three of the pieces of DU inside the drum had loose smearable contamination. These results are attached to this document. The positive results were as follows:

Wipe Test Results From Depleted Uranium in a Drum on March 15, 2006, located at
Accelinear Service Company d/b/a Oncology Services, International
1970 Rutgers University Boulevard, Lakewood, New Jersey.
Wipes obtained by NRC and Analyzed by NRC's Contractor ORISE

<u>Sample ID</u>	<u>DU Description</u>	<u>Gross Alpha (dpm/wipe)</u>	<u>Gross Beta (dpm/wipe)</u>
DU1	Round Plate	14 ± 10	17 ± 11
DU2	Rectangular Collimator	1,200 ± 100	2,580 ± 220
DU3	Rectangular Collimator	760 ± 80	1,970 ± 180

The MDC for gross alpha for a 2 minute count was 8.9 dpm/wipe
The MDC for gross beta for a 2 minute count is 15 dpm/wipe
Uncertainties represent the 95% confidence level

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

(State the requirement, how and when the licensee violated the requirement, and the licensee's proposed corrective action plan. For NCVs, indicate why the violation was not cited. Attach copies of all licensee documents needed to support violations.)

10 CFR 40.25(d)(4) requires a general licensee who receives, possesses, or uses depleted uranium pursuant to a general license to report in writing, within 30 days of any transfer, to the Director, Division of Industrial and Medical Nuclear Safety, with a copy to the Regional Administrator of the appropriate Regional Office, the name and address of the person receiving the source material pursuant to such transfer.

Contrary to the above, the licensee did not provide written notification to NRC within 30 days of transfer of DU the name and address of the person receiving source material. Specifically, from February 2004 - March 2006, Accelinear Services, International, d/b/a Oncology Services International received 12 linear accelerators containing DU and made 4 separate shipments of DU and did not provide written notification to NRC of the transfers. Upon identification, the licensee provided records of receipt and transfer to NRC, and submitted an application to NRC for a specific license. This licensee identified and corrected violation was dispositioned as a SL IV, Supplement IV Non-cited Violation (NCV) .

5. PERSONNEL CONTACTED:

(Identify licensee personnel contacted during the inspection, including those individuals contacted by telephone.)

Use the following identification symbols:
Individual(s) present at entrance meeting
* Individual(s) present at exit meeting

- o Philip R. Podmore, President
- o James Sharkey, Senior Vice President
- *# Glenn Davis, Vice President, Installation (Exit meeting by telephone held on 8/11/06)
- # Kevin Zarko, Service Engineer

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