

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No. 03038382/2014001

Docket No. 03038382

License No. 06-32815-01

Licensee: General Electric Company
d/b/a GE Healthcare

Location: Tolland, Connecticut and Birmingham, Alabama

Inspection Dates: January 30, 2014, February 5, 2014, and March 12, 2014

Additional Information: Safety notification dated February 5, 2014 and letters dated February 28, 2014 and March 5, 2014

Inspector: Kathy Modes
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Decommissioning and Technical
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Decommissioning and Technical
Support Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

General Electric Company
NRC Inspection Report No. 03038382/2014001

An announced safety inspection of General Electric Company d/b/a GE Healthcare (GEHC) was conducted in Tolland, Connecticut on January 30, 2014. GEHC is a service provider licensee authorized under U.S. Nuclear Regulatory Commission (NRC) License No. 06-32815-01 to remove, replace and install sealed sources that have been registered either with the NRC under 10 CFR 32.210 or with an Agreement State. GEHC customers are medical facilities.

The primary focus of the inspection was a September 13, 2013, event in which a depleted gadolinium-153 (Gd-153) sealed source was damaged by a field service engineer (FE) at a customer facility in Biloxi, Mississippi. The inspector also observed the performance of licensed activities by GEHC at a different customer's facility in Birmingham, Alabama on February 5, 2014.

The inspection was conducted pursuant to Inspection Manual Chapter (IMC) 2800 and Inspection Procedure (IP) 87126. The IP Focus Elements addressed were 03.01 through 03.07. The inspector interviewed GEHC personnel, reviewed records and procedures, and corrective actions taken by GEHC

Based on the results of this inspection, and as described in this report, the inspector identified two violations of procedures that were required to be followed in accordance with Condition 16 of GEHC's NRC License No. 06-32815-01. Specifically, although GEHC procedures stated that FEs should not fix or attempt to fix bent radioactive pin sources, a GEHC FE attempted this activity and broke the source into two pieces. Additionally, GEHC procedures require immediate reporting to the Radiation Safety Officer (RSO) of all incidents and unusual situations involving radioactive material. However, GEHC personnel did not inform the RSO of the damaged Gd-153 sealed source until three days after the event.

REPORT DETAILS

1. **Sequence of Events**

a. Inspection Scope

General Electric Company d/b/a GE Healthcare (GEHC) is a service provider licensee authorized under NRC License No. 06-32815-01 to remove, replace and install germanium-68 (Ge-68) and gadolinium-153 (Gd-153) sealed sources that have been registered either with the U.S. Nuclear Regulatory Commission (NRC) under 10 CFR 32.210 or with an Agreement State. GEHC customers are medical facilities.

During an inspection of one of GEHC's customers in December 2013 in Biloxi, Mississippi, an NRC Region III inspector identified an event in which a depleted gadolinium-153 (Gd-153) sealed source was damaged by a GEHC field service engineer (FE) at a customer's facility in Biloxi, Mississippi on September 13, 2013. The NRC Region III Office provided the information to the NRC Region I Office. The NRC Region I Office performed an announced safety inspection of GEHC in Tolland, Connecticut on January 30, 2014 to review the September 13, 2013 event during a medical device source exchange of a depleted Gd-153 source. The inspector also observed the performance of licensed activities by GEHC at a different customer's facility in Birmingham, Alabama on February 5, 2014.

The inspection was conducted pursuant to Inspection Manual Chapter (IMC) 2800 and Inspection Procedure (IP) 87126. The IP Focus Elements addressed were 03.01 through 03.07. The inspector interviewed GEHC personnel, reviewed records and procedures, reviewed and corrective actions taken by GEHC.

b. Observations and Findings

On September 13, 2013, a GEHC field service engineer (FE) conducted licensed activities at a customer's facility in Biloxi, Mississippi. The FE attempted to perform a medical device source exchange of a depleted Gd-153 source. While attempting the source exchange, the Gd-153 source did not fully insert and became stuck partially out of the transportation container in an unshielded manner. Sealed Source and Device Registration (No. CA-0406-S-204-S) for this type of source describes it as being 20 inch active length, with the radioactive material uniformly incorporated into an epoxy matrix.

Based on interviews with GEHC personnel, the inspector determined that the FE attempted to move the source back and forth manually without success and tapped the source with a rubberized handle of a screwdriver to try to dislodge it. The FE also attempted to physically pull the source the rest of the way out of its holder by gripping it with gloved hands. The source came free and bent. The FE subsequently tried to straighten the source and in the process broke it into two pieces, one piece was eight inches long and the other was twelve inches long. The FE, with the customer's assistance, secured one piece in the shipping transport container and the other was shielded behind lead bricks. The customer performed radiation surveys and determined that the FE, the FE's tools, and the room were not contaminated as a result of the

broken Gd-153 source. The inspector also noted that the GEHC customer was responsible for the safe transportation of the source back to the manufacturer and as a result, the FE decamped the work site without taking further action. Based on a review of GEHC's Radiation Safety Program and GEHC's Incident Log, the inspector determined that the RSO was notified of the event on Monday September 16, 2013.

Condition 16 of License No. 06-32815-01 requires, in part, that GEHC conduct its program in accordance with the statements, representations, and procedures contained in the application dated October 26, 2011 [Agencywide Documents Access and Management System (ADAMS) Accession No. ML113060205] and the letter dated March 5, 2012 (ADAMS Accession No. ML120660117) with attached Technical Publication Direction 2346591DRS (ADAMS Accession No. ML120660135). The inspector noted that Section d.ix of GEHC's Technical Publication Direction 2346591DRS Revision 9 titled "Nuclear and Positron Emission Tomography (PET) Scanner Radioactive Material Guidelines" stated that a GEHC FE should not fix or attempt to fix bent radioactive pin sources. The inspector also noted that Section 6.4 (Radiation Incident Communications) of GEHC's Radiation Safety Program, contained in the license application dated October 26, 2011, stated the FE is responsible to immediately report to the RSO all incidents and unusual situations involving radioactive material. Section 6.4.2 of the GEHC Radiation Safety Program states that a suspected damage to sealed radioactive material sources is an example of an unusual situation.

In accordance with GEHC's procedures, the RSO initiated an investigation of the event on September 17, 2013. The RSO interviewed the FE, obtained the FE's written account of the event, and contacted the source manufacturer. The RSO determined that the sources involved in the event could be damaged if they are forced or if they are not properly inserted into the container with the proper alignment. Based on the information gathered by the RSO on October 4, 2013, the RSO concluded that the immediate cause of the event was an "unsafe act by improper force." The RSO documented the lessons learned, which noted that FEs must be very careful when inserting the source into the transportation container and if they encounter resistance, they should call the source manufacturer. The RSO stated to the inspector that this was communicated to the FE involved in the event, but was not documented and distributed to all of GEHC's other FEs. The inspector also noted that based on interviews with GEHC personnel, the FE may not have been as familiar with the Gd-153 source exchange process because it had not been performed as frequently by the FE as other activities.

The inspector determined that, based on the activity of the depleted Gd-153 source, the lack of contamination at the Mississippi facility, and the low dose attributed to this event, GEHC was not required to report this event to the NRC (ref: 10 CFR 20.2202, 10 CFR 20.2203, and 10 CFR 30.50).

The inspector determined that GEHC's initial corrective actions were not thorough because they were limited to the FE involved in the event and the lessons learned were not incorporated into GEHC's procedures. Consequently, on February 5, 2014, GEHC distributed a Safety Notification for Pin Source Handling that communicated the lessons learned from the event to all company FEs. Specifically, the Safety Notification documented that FEs are responsible to stop work when necessary and contact the

RSO immediately. GEHC also committed to revise applicable procedures to incorporate the lessons learned from the September 2013 event.

On February 5, 2014, the inspector observed the replacement of a Ge-68 source at a customer's facility in Alabama. The FE followed GEHC procedures including the use of ALARA concepts of time, distance and shielding. The FE wore proper dosimetry and conducted surveys before, during, and after the source exchange using a calibrated and operable survey instrument. The FE was knowledgeable of the process and informed the inspector that if the need would arise, they would feel comfortable stopping work and contacting the RSO.

c. Conclusions

Based on the results of this inspection, the NRC identified two violations of procedures required to be followed in accordance with Condition 16 of GEHC's NRC License No 06-32815-01 that occurred during a source exchange activity on September 13, 2013. Specifically, although GEHC procedures stated that FEs should not fix or attempt to fix bent radioactive pin sources, a GEHC FE attempted this activity and broke the source into two pieces. Additionally, GEHC procedures require immediate reporting to the RSO of all incidents and unusual situations involving radioactive material. However, GEHC personnel did not inform the RSO of the damaged Gd-153 sealed source until three days after the event.

2. Exit Meeting

An exit meeting was held by telephone on March 12, 2014 with Richard Vignocchi, Arthur Larson, Megan Rae, and Tracy Gale to discuss the scope of the inspection, the inspector observations and findings, the circumstances surrounding the violations, and the corrective actions taken, and planned to be taken, by GEHC. GEHC acknowledged the violation and corrective actions taken. In GEHC letters dated February 28, 2014, and March 5, 2014, GEHC's RSO documented the corrective actions taken and planned to be completed.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Tracy Gale, Radiation Safety Officer
Mike Blackwell, Field Service Engineer
Russell Green, Field Service Engineer
Megan Rae, Environmental Health and Safety (EHS) Director, Americas
Richard Vignocchi, EHS Leader, Global
Arthur Larson, GM, Product Service US/Canada
Richard Neff, Vice President & General Manager, US & Canada Service

INSPECTION PROCEDURES USED

IMC 2800 Materials Inspection Program
IP 87126 Industrial/Academic/Research Programs

ITEMS OPEN, CLOSED, AND DISCUSSED

None

LIST OF DOCUMENTS REVIEWED

GEHC application dated October 26, 2011 (ADAMS Accession No. ML113060205)
GEHC Radiation Safety Program (ADAMS Accession No. ML113060205)
GEHC letter dated March 5, 2012 (ADAMS Accession No. ML120660117)
GEHC Technical Publication Direction 2346591DRS Revision 9 titled "Nuclear and PET Scanner Radioactive Material Guidelines" (ADAMS Accession No. ML120660135)
Millennium MG ATC Option – Service Manual Direction 2263786-100 Revision 5 dated September 1, 2005
GEHC Safety Notification about Pin Source Handling dated February 5, 2014

LIST OF ACRONYMS USED

ADAMS	Agencywide Documents Access and Management System
EHS	Environmental Health and Safety
Gd	gadolinium
Ge	germanium
GEHC	General Electric Healthcare
FE	Field Service Engineer
IMC	Inspection Manual Chapter
IP	Inspection Procedure
NRC	Nuclear Regulatory Commission
PET	Positron Emission Tomography
RSO	Radiation Safety Officer