



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PA 19406-2713

April 3, 2014

Docket No. 03038382

License No. 06-32815-01

Richard Neff  
VP & GM, US & Canada Service  
General Electric Company  
d/b/a GE Healthcare  
9900 W Innovation Drive, RP-2171  
Wauwatosa, WI 53226-4856

SUBJECT: NRC INSPECTION REPORT NO. 03038382/2014001, GENERAL ELECTRIC COMPANY D/B/A GE HEALTHCARE, TOLLAND, CONNECTICUT AND NOTICE OF VIOLATION

Dear Mr. Neff:

On January 30, 2014, Kathy Modes of this office conducted an announced safety inspection of General Electric Company d/b/a GE Healthcare (GEHC) in Tolland, Connecticut of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a review of procedures and records. Additional information provided in your safety notification dated February 5, 2014 and your correspondence dated February 28 and March 5, 2014 was also examined as part of the inspection. The primary focus of the inspection was a September 13, 2013, event in which a depleted gadolinium-153 (Gd-153) sealed radioactive source was damaged during a source exchange activity by a field service engineer at a GEHC customer's facility in Biloxi, Mississippi. The inspector also observed the performance of licensed activities at the Birmingham, Alabama facility of a different GEHC customer on February 5, 2014. The results of the inspection are described in the enclosed report and were discussed with your Environment, Health and Safety (EHS) Leader Global, General Manager for Product Service in the US, EHS Director Americas, and the Radiation Safety Officer (RSO) of your organization during a telephone exit meeting on March 12, 2014.

Based on the results of this inspection, the NRC 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 that occurred during the source exchange activity on September 13, 2013. Specifically, although GEHC procedures state that field service engineers should not fix or attempt to fix bent radioactive pin sources, a GEHC field service engineer attempted this activity and broke the depleted Gd-153 source into two pieces. Additionally, GEHC procedures required 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.

The NRC considered the event an isolated occurrence which did not result in radioactive contamination of either the GEHC field service engineer or any of the GEHC customer's

personnel or facility. Additionally, the NRC confirmed that the event did not result in any individuals receiving radiation exposure in excess of regulatory limits. The NRC also considered that the violations were directly related to the same event. Therefore, the violations have been categorized collectively as a Severity Level IV problem in accordance with the NRC Enforcement Policy. The violation is cited in the enclosed Notice of Violation (Notice), because the violation was self-revealing.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

R. Neff

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Please contact Kathy Modes at (610) 337-5251 if you have any questions regarding this matter.

Sincerely,

***Original signed by Marc S. Ferdas***

Marc S. Ferdas, Chief  
Decommissioning and Technical  
Support Branch  
Division of Nuclear Materials Safety

Enclosures:

Notice of Violation

Inspection Report 03038382/2014001

cc w/enclosures:

Tracy L. Gale, Radiation Safety Officer  
State of Connecticut

R. Neff

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Please contact Kathy Modes at (610) 337-5251 if you have any questions regarding this matter.

Sincerely,

***Original signed by Marc S. Ferdas***

Marc S. Ferdas, Chief  
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Enclosures:

1. Notice of Violation
2. Inspection Report 03038382/2014001

cc w/enclosures:

Tracy L. Gale, Radiation Safety Officer  
State of Connecticut

Distribution w/enclosures:

B. Bickett, RI  
M. Ferdas

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L06-32815-01.2014001.docx

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**ML14093B050**

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## **NOTICE OF VIOLATION**

General Electric Company d/b/a GE Healthcare  
Tolland, CT

Docket No. 03038382  
License No. 06-32815-01

During an NRC inspection conducted on January 30, 2014 and February 5, 2014, as well as an in-office review of information provided in written correspondence from General Electric Company d/b/a GE Healthcare (GEHC) dated February 5 and 28, 2014, and March 5, 2014, violations of NRC requirements were identified. The violations were discussed during a telephone exit meeting on March 12, 2014. In accordance with the NRC Enforcement Policy, the violations are listed below:

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 and the letter dated March 5, 2012 with attached Technical Publication Direction 2346591DRS Revision 9 titled "Nuclear and PET Scanner Radioactive Material Guidelines."

- A. GEHC's Technical Publication Direction 2346591DRS Revision 9 states, in part, that GEHC field service engineers should not fix or attempt to fix bent radioactive pin sources.

Contrary to the above, on September 13, 2013, GEHC did not conduct its program in accordance with procedures contained in the letter dated March 5, 2012, in that a GEHC field service engineer attempted to fix a bent radioactive pin source, resulting in the source breaking.

- B. GEHC's application dated October 26, 2011, contained the GEHC Radiation Safety Program which, in Section 6.4, "Radiation Incident Communications," requires that the field service engineer immediately report to the Radiation Safety Officer (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.

Contrary to the above, on September 13, 2013, GEHC did not conduct its program in accordance with procedures contained in the application dated October 26, 2011, in that a GEHC field engineer did not immediately report that a sealed radioactive material source had been damaged until three days after the occurrence.

These violations constitute a Severity Level IV problem (Section 6.3.d)

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control

Notice of Violation  
General Electric Company

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Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 3rd day of April 2014