



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION I
2100 RENAISSANCE BLVD., SUITE 100
KING OF PRUSSIA, PA 19406-2713

April 10, 2015

EA-15-008

Michael Guin
Vice President, Corporate Services
Siemens Medical Solutions USA, Inc.
221 Gregson Drive
Cary, NC 27511

**SUBJECT: SIEMENS MEDICAL SOLUTIONS USA, INC., NOTICE OF VIOLATION - NRC
INSPECTION REPORT NO. 15000032/2014001**

Dear Mr. Guin:

This letter provides you the U.S. Nuclear Regulatory Commission's (NRC) enforcement decision for the apparent violation identified during the NRC safety inspection conducted on-site on October 2, 2014, at the Siemens Medical Solutions USA, Inc. (Siemens) facility in Cary, North Carolina, with continued in-office review through February 6, 2015. The inspection consisted of interviews with Siemens personnel and the examination of selected records to evaluate Siemens' licensed activities as they relate to radiation safety and to compliance with NRC regulations. Mr. Craig Gordon, of this office, discussed an apparent violation with you during a telephonic exit meeting on February 6, 2015. The apparent violation was also described in the NRC inspection report sent to you with a letter dated February 20, 2015 (ML15054A379¹).

In the February 20, 2015, letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference (PEC), by providing a written response, or by accepting the violation as characterized in the letter. We also informed you that we had sufficient information regarding the apparent violation and Siemens' corrective actions to make an enforcement decision without the need for a PEC.

In a letter dated March 17, 2015, you provided a response to the apparent violation. Your letter stated that you understand the importance of maintaining a comprehensive and effective radiation safety program and maintaining compliance with regulations and the conditions within your material license. In your response, you described how you are communicating the importance of maintaining licensing requirements and meeting regulatory commitments throughout your organization. Specifically, you are providing licensing and regulatory training to your senior management team. Additionally, you are requiring that Radiation Safety Officers (RSO) attend prerequisite RSO training and are providing them with regulatory guidance for the Radiation Safety program. The Annual Radiation Safety training for Authorized Users now includes a discussion of essential regulatory and licensing requirements.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS

Based on the information developed during the inspection, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it were described in detail in the February 20, 2015, letter and in the subject inspection report. The violation involved the failure to file for reciprocity prior to conducting work in NRC jurisdiction, as required by 10 CFR 150.20. Specifically, between September 6, 2011, and August 8, 2014, Siemens used byproduct material within NRC jurisdiction, on numerous occasions, without submitting NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of its Agreement State specific license, and the appropriate fee for calendar years 2011, 2012, and 2013, with the Regional Administrator of the appropriate NRC regional office.

The violation has been categorized at Severity Level (SL) III in accordance with the NRC Enforcement Policy because the NRC was not informed of the activities occurring in NRC jurisdiction and therefore, was not provided an opportunity to conduct inspections of licensed activities. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because Siemens has not been the subject of escalated enforcement action within the last two years or two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC has concluded that credit is warranted for Siemens' corrective actions taken to address the violation. Specifically, Siemens: (1) submitted NRC Form 241 and the appropriate fee for subsequent work activities to be conducted in NRC jurisdiction; and (2) submitted an application for an NRC license (an NRC license was issued in November 2014).

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, after consultation with the Director, Office of Enforcement, I have been authorized not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reasons for the violation; (2) the actions planned or already taken to correct the violation and prevent recurrence; and, (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 15000032/2014001 and in this letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

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

M. Guin

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such information, you must specifically identify the portions of your response that you seek to have withheld, and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Daniel H. Dorman
Regional Administrator

Docket No. 15000032

Enclosure: Notice of Violation

cc w/enclosure:
State of North Carolina

M. Guin

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such information, you must specifically identify the portions of your response that you seek to have withheld, and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

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Sincerely,

/RA/

Daniel H. Dorman
Regional Administrator

Docket No. 15000032

Enclosure: Notice of Violation

cc w/enclosure:
State of North Carolina

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Distribution: see next page

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| DATE | 3/23/15 | 3/23/15 | 3/24/15 | 3/30/15 | 3/27/15 |
| OFFICE | OE | NMSS | RI/DNMS | RA | |
| NAME | L Sreenvias via email* | R Sun via email* | D Collins/DSC* | D Dorman | |
| DATE | 4/7/15 | 4/2/15 | 4/8/15 | 04/09/2015 | |

* See previous concurrence page

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Region I OE Files (with concurrences)

NOTICE OF VIOLATION

Siemens Medical Solutions USA, Inc.
Cary, North Carolina

Docket No. 15000032
EA-15-008

During an NRC inspection conducted on October 2, 2014, with continued in-office review through February 6, 2015, for which an exit meeting was conducted on February 6, 2015, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 30.3 requires, in part, that except for persons exempt as provided in this part and part 150 of this chapter, no person shall own, possess, or use byproduct material except as authorized in a specific or general license issued pursuant to the regulations in 10 CFR Part 30.

10 CFR 150.20(a) states, in part, that any person who holds a specific license from an Agreement State is granted an NRC general license to conduct the same activity in Non-Agreement States and areas of exclusive Federal jurisdiction within Agreement States, subject to the provisions of 10 CFR 150.20(b).

10 CFR 150.20(b)(1) requires, in part, that any person engaging in activities in Non-Agreement States shall, at least 3 days before engaging in each such activity, file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States," a copy of its Agreement State specific license, and the appropriate fee, with the Regional Administrator of the appropriate NRC regional office.

Contrary to the above, between September 6, 2011, and August 8, 2014, Siemens Medical Solutions USA, Inc., a licensee of the State of North Carolina, used byproduct material within NRC jurisdiction, on numerous occasions without filing NRC Form 241, "Report of Proposed Activities in Non-Agreement States," at least 3 days before engaging in such activity, a copy of its Agreement State specific license, and the appropriate fee for calendar years 2011, 2012, and 2013, with the Regional Administrator of the appropriate NRC regional office.

This is a Severity Level III violation (Enforcement Policy Example Section 6.9).

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the actions planned or already taken to correct the violation and prevent recurrence; and (3) the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 15000032/2014001 and in the letter transmitting this Notice. Therefore, you are not required to respond to this Notice. 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 EA-15-008," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 10th day of April, 2015