

December 13, 2017

EA-17-074

Mr. Joel Kirsch
Vice President and
Associate General Counsel
Siemens Corporation
527 Madison Avenue – Eighth Floor
New York, NY 10022

SUBJECT: NOTICE OF VIOLATION – U.S. NUCLEAR REGULATORY COMMISSION
INVESTIGATION REPORT 4-2012-007, SIEMENS CORPORATION

Dear Mr. Kirsch:

This letter provides you with the U.S. Nuclear Regulatory Commission's (NRC) enforcement decision for the apparent violation identified during the NRC's investigation initiated October 25, 2011, and concluded on February 28, 2017. The purpose of the investigation was to determine whether Siemens employees willfully exported nuclear material, described in Title 10 of the *Code of Federal Regulations* (10 CFR), Section 110.9, to an embargoed country listed in 10 CFR 110.28 without obtaining a specific license from the NRC authorizing the shipment.

In a telephone conversation on September 14, 2017, and in the NRC letter transmitting the investigation results, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated October 13, 2017, Agencywide Documents Access and Management System [ADAMS] Accession No. ML17291A419, you provided a response to the apparent violation and summarized your corrective actions and compliance enhancements to prevent recurrence.

Based on the information developed during the investigation and the information that you provided in your response, dated October 13, 2017, 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 the violation was described in detail in the Factual Summary contained in NRC's September 14, 2017, letter to you.

The NRC considers the violation against 10 CFR 110.5 and 10 CFR 110.20 to be significant because the NRC was not able to make the requisite finding that the exports of radioactive material by Siemens were not inimical to the common defense and security of the United States and precluded review of intended foreign recipients. The failure to obtain appropriate license authorization to export byproduct material is significant because it resulted in the shipment of over 385 radioimmunoassay (RIA) kits containing I-125 to a consignee in Syria, without a specific license authorizing the export as required by 10 CFR 110.5 and 110.20, on at least

37 occasions between May 2005 and September 2010. This impacted the NRC's ability to perform its regulatory function in this regard. Specifically, the export of nuclear material to an embargoed destination requires the highest level of review under the Atomic Energy Act of 1954, as amended, and 10 CFR Part 110. Although the safety significance associated with the byproduct material (I-125) is very low, the failure to obtain a specific license before exporting the RIA kits to Syria raises significant regulatory concerns because it impacted the U.S. Government's ability to provide a finding that the exports were not inimical to the common defense and security of the United States. Normally, the NRC would have sought Executive Branch review as per 10 CFR 110.41; however, given that Syria is listed as an embargoed destination, the NRC would have also sought Commission level review prior to granting a license because these exports raise important policy considerations. Siemens' failure to apply for, and receive, a specific export license significantly impacted NRC's regulatory process.

In your letter dated October 13, 2017, Siemens indicated that NRC's September 14, 2017, letter had several significant omissions. Specifically, you stated that the NRC letter omits the substantial export control corrective action and compliance enhancements Siemens immediately took when it identified the concerning shipments, which Siemens outlined to the NRC in 2011. These steps included: (1) the suspension of all shipments of RIA kits to embargoed countries; (2) the comprehensive training of relevant personnel concerning NRC export controls; (3) additional review and approval of all licensed export deliveries of medical apparatus to countries specified in 10 CFR 110.28 prior to shipment release; (4) the revision of Siemens Healthcare's export control procedures to incorporate NRC export controls; and (5) internal reviews of all exports of Siemens Healthcare entities delivering products to countries specified in 10 CFR 110.28. We take note of these corrective actions.

You further indicate that all of the relevant shipments were made pursuant to valid Commerce Department export licenses in support of your position that Siemens fully intended to comply with applicable law. However, the fact remains, that the appropriate license to export was not obtained in accordance with application 10 CFR Part 110 regulations. You indicate that that on 37 occasion, RIA kits were exported to Syria, without obtaining a specific licenses, as opposed to the 46 occasions that the NRC documented in the September 14, 2017, letter. The Notice will reflect that "on at least 37 occasions," RIA kits containing I-125, were sere shipped to Syria without obtaining a specific license authorizing the export as required by 10 CFR 110.5 and 110.20.

Based on its review of information concerning the exports, the NRC has determined that a violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy (Policy) and was characterized at a Severity Level III violation, in accordance with the current Enforcement Policy, included on the NRC's Web site <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforcement-pol.html>.

However, based on the circumstances of this case, I have been authorized, after consultation with the Director, Office of Enforcement, to exercise enforcement discretion and to reduce the violation to a Severity Level IV violation in accordance with Section 3.5 of the Policy because of: (1) the low safety significance of the violation; (2) the fact that your company has not been subjected to any enforcement actions related to 10 CFR Part 110 requirements within the last two years, (3) the comprehensive corrective actions taken, and (4) the length of time that has transpired since the violation occurred.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed in your letter dated October 13, 2017. 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, its enclosures, and 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>. 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. 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 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/

Peter J. Habighorst, Chief
Export Controls Nonproliferation Branch
Office of International Programs

Enclosure:
Notice of Violation

J. Kirsch

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SUBJECT: NOTICE OF VIOLATION – U.S. NUCLEAR REGULATORY COMMISSION
INVESTIGATION REPORT 4-2012-007, SIEMENS CORPORATION DATED
DECEMBER 13, 2014

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NOTICE OF VIOLATION

Siemens Corporation
New York, NY 10022

EA-17-074

Based on the U.S. Nuclear Regulatory Commission's (NRC's) evaluation of Siemens export activity associated with radioimmunoassay (RIA) kits containing iodine-125 (I-125), including an investigation conducted by the NRC's Office of Investigations, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 110.5 states, in part, that no person may export any nuclear equipment or material listed in 10 CFR 110.9, unless authorized by a general or specific license issued under 10 CFR Part 110. The list in 10 CFR 110.9 includes byproduct material.

10 CFR 110.20(a) states, in part, that if an export or import is not covered by the NRC general licenses in §§ 110.21 through 110.27, a person must file an application with the Commission for a specific license in accordance with §§ 110.31 through 110.32.

10 CFR 110.23(a) states, in part, that a general license is issued to any person to export byproduct material to any country not listed in § 110.28.

10 CFR 110.28 lists Syria as an embargoed destination.

Contrary to the above, on at least 37 occasions between May 2005, and September 2010, Siemens and its predecessor, Diagnostic Products Corporation, shipped over 385 RIA kits containing I-125 to a consignee in Syria without obtaining a specific license authorizing the export as required by 10 CFR 110.5 and 110.20.

This is a Severity Level IV violation (Section 6.15).

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 in Siemens' letter dated October 13, 2017. 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-17-074" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, 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, Siemens may be required to post this Notice within two working days of receipt.

Dated this 13th day of December 2017