September 14, 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: SIEMENS CORPORATION – EXPORT OF BYPRODUCT MATERIAL TO SYRIA; U.S. NUCLEAR REGULATORY COMMISSION INVESTIGATION REPORT 4-2012-007

Dear Mr. Kirsch:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) investigation completed on February 28, 2017, relating to the Siemens Healthcare Diagnostics, Inc. (Siemens) facility located in Los Angeles, California. The purpose of the investigation was to determine whether or not 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. The enclosed factual summary provides the results of the investigation.

Based on the results of this investigation, an apparent non-willful violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy (Policy) is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The investigation determined that, on at least 46 occasions between May 2005, and September 2010, Siemens and its predecessor, Diagnostic Products Corporation, shipped over 385 radioimmunoassay (RIA) kits containing iodine-125 (I-125) to a licensed consignee in Syria without obtaining a specific license authorizing the export as required by 10 CFR 110.5 and 110.20. During this time, Syria was listed in 10 CFR 110.28 as an embargoed country and the export of the RIA kits containing byproduct material required a specific license issued by the NRC. Because the apparent violations occurred more than 5 years ago, a civil penalty is not being considered pursuant to Title 28 of the United States Code, Section 2462. The results of this review were further discussed with you during a September 14, 2017, phone call with Ms. Andrea Jones, Senior Licensing Officer, Office of International Programs, and Mr. David Cylkowski, Attorney, Office of General Counsel.

The apparent violation involves the export of RIA kits to Syria without a specific license authorizing the export. 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 on

whether or not these exports would have been inimical to the common defense and security of the United States. Normally, the NRC would have sought Executive Branch review 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.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond in writing to the apparent violation within 30 days of the date of this letter, or (2) request a Pre-decisional Enforcement Conference (PEC). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. If you decide to participate in a PEC, please contact Mr. Peter J. Habighorst at (301) 287-9241, within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation (EA-17-074)" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. Additionally, your response should be sent to the NRC's Document Control Center, with a copy mailed to Mr. Peter J. Habighorst, Chief, Export Controls and Nonproliferation Branch, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures and your response will be made available electronically for public inspection in the Public Document Room or from the NRC's document system Agencywide Documents Access and Management System 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 or proprietary 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).

Please contact Peter J. Habighorst at (301) 287-9241 if you have any questions regarding this matter.

Sincerely,

/RA/

Patricia K. Holahan, Director
Office of Enforcement

Enclosure:
Factual Summary

SUBJECT: SIEMENS CORPORATION – EXPORT OF BYPRODUCT MATERIAL TO SYRIA; U.S. NUCLEAR REGULATORY COMMISSION INVESTIGATION REPORT 4-2012-007 DATED SEPTEMBER 14, 2017

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FACTUAL SUMMARY

In 2010, the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), and the Department of Homeland Security, initiated an investigation into Siemens Medical Solutions USA regarding an apparent attempted export of germanium-68 to Iran, an embargoed destination under Title 10 of the *Code of Federal Regulations* (10 CFR), Section 110.28. In August 2011, and subsequent to the closure of the OI investigation, Siemens Medical Solutions USA and its U.S. affiliate, Siemens Healthcare Diagnostics (together, "Siemens") disclosed in a letter to OI that Siemens had made additional unauthorized shipments of byproduct material. Specifically, the letter explained that between 2006 and September 2010, Siemens made 37 shipments of radioimmunoassay (RIA) kits containing iodine-125 (I-125) to a licensed consignee in Syria, another embargoed destination.

On October 25, 2011, OI initiated an investigation to determine whether or not Siemens Healthcare Diagnostics, Inc., employees willfully shipped nuclear material described in 10 CFR 110.9, to an embargoed country listed in 10 CFR 110.28 without obtaining a specific license from the NRC authorizing the shipments. The OI investigation focused on the export of RIA kits containing byproduct material to Syria. The investigation determined that, on at least 46 occasions between May 2005, and September 2010, Siemens and its predecessor, Diagnostic Products Corporation, shipped over 385 RIA kits containing I-125 to a licensed consignee in Syria without obtaining a specific license authorizing the export as required by 10 CFR 110.5 and 110.20. The investigation was completed on February 28, 2017.

ENCLOSURE