

October 13, 2017

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VIA FIRST-CLASS MAIL

Mr. Peter J. Habighorst
Chief, Export Controls and Nonproliferation Branch
Office of International Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Response to an Apparent Violation (EA-17-074)

Dear Mr. Habighorst:

On behalf of Siemens Corporation, this is in response to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission's ("NRC") letter of September 14, 2017 ("NRC Letter") concerning the NRC's investigation of Siemens Healthcare Diagnostics Inc.'s shipments of certain radioimmunoassay ("RIA") medical kits to Syria between 2005 and 2010, which were brought to the NRC's attention through a Siemens voluntary disclosure in August 2011.

Siemens provides this response to clarify certain aspects of the NRC letter and to supplement the record with additional facts that the NRC should consider when rendering its decision. When considering all the relevant circumstances, Siemens believes enforcement action is not warranted and the matter should be closed.

The NRC Letter has several significant omissions. Most significantly, 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, shortly after its initial self-disclosure. 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.

The NRC Letter notes that the failure to obtain NRC licenses raises regulatory concerns because it impacted the NRC's ability to seek Executive Branch review of the exports. But it omits the fact that, as fully described in the 2011 self-disclosure, all of the relevant shipments were made pursuant to valid Commerce Department export licenses. The securing of Commerce Department licenses is prima facie evidence that Siemens fully intended to comply with applicable law.

Notably, when the relevant Commerce Department-licensed exports to Syria took place, there was apparent general uncertainty in the regulated community as to whether a specific NRC license was required for shipments to embargoed countries, prompting the NRC to issue a public Information Notice regarding the NRC's specific license requirement for exports to embargoed destinations. *See* NRC Information Notice 2011-07, ML110180287, April 14, 2011.

The NRC Letter refers to 46 shipments of 385 RIA kits between May 2005 and September 2010,¹ but omits mention of the relatively low value of those shipments. As noted in the August 2011 disclosure, the *total* value of the 37 shipments between 2006 and September 2010 was less than \$53,000.

In light of the above, and in accordance with the NRC Enforcement Policy 2.2.1, no enforcement action by the NRC is warranted in this case. Three of the four specific factors affecting the NRC's assessment of violations are not applicable:

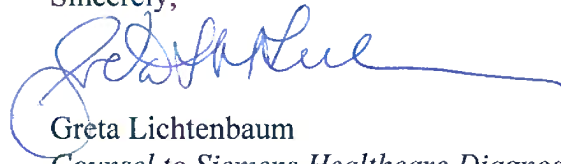
- (1) The apparent violation did not result in any actual safety or security consequences (NRC Enforcement Policy 2.2.1(a));
- (2) As the NRC letter itself recognizes, the apparent violation did not have any potential safety or security consequences (NRC Enforcement Policy 2.2.1(b)); and
- (3) As the NRC letter also recognizes, the apparent violations did not involve willfulness (NRC Enforcement Policy 2.2.1(d)).

Siemens fully recognizes the NRC's important interest in carrying out its oversight function. (NRC Enforcement Policy 2.2.1(c)). But the mitigating factors that exist here, namely: (1) the discovery and self-disclosure; (2) the immediate corrective action and compliance enhancements; (3) the demonstrated efforts to comply with government licensing requirements through the Commerce Department licenses; (4) the lack of any security or safety risk; and (5) the fact that Siemens as an enterprise has had no similar or related violations since 2010, dictate that no enforcement action is warranted here. Accordingly, we respectfully request that the matter be closed without further action.

¹ The August 2011 disclosure identified 37 shipments between 2006 and 2010. The NRC has not provided Siemens with any evidence of its determination of the additional nine.

Please do not hesitate to contact me if you have any questions.

Sincerely,



Greta Lichtenbaum
*Counsel to Siemens Healthcare Diagnostics
Inc.*

cc: Joel Kirsch, Vice President and Associate General Counsel, Siemens Corporation
NRC Document Control Center