

February 14, 2019

EA-18-170

Ms. Sandra M. Kusy
Vice President and General Manager
Source Production & Equipment
Company, Inc.
113 Teal Street
St. Rose, LA 70087

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INFORMATION REVIEW,
SOURCE PRODUCTION & EQUIPMENT COMPANY, INC. RELATED TO THE
IMPORT OF BYPRODUCT MATERIAL AND OFFICE OF INVESTIGATION
REPORT - OI-2017-001

Dear Ms. Kusy:

This letter refers to the U.S. Nuclear Regulatory Commission's (NRC's) review of information concerning the import of non-U.S. origin (disused sealed sources) containing byproduct material by Source Production & Equipment Company (SPEC), from the United Kingdom between 2012 and 2017. The NRC initiated its review following our receipt of Voluntary Self-Disclosure (VSD) letters dated March 28, 2017, and April 27, 2017, from attorneys representing SPEC, (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML17088A529 and ML17125A090), respectively. The letters notified the NRC about the import of 155 disused sealed sources of non-U.S. origin, which meet the definition of radioactive waste in Title 10 of the *Code of Federal Regulations* (10 CFR) 110.2. SPEC was not in possession of a specific import license for radioactive waste.

On April 27, 2017, the NRC Office of Investigations (OI) initiated an investigation in response to the VSD letters regarding the import of non-US origin disused sources without the required specific import license at Source Production & Equipment Co., Inc. On September 20, 2018, the OI completed its investigation and as a result, did not identify any apparent willful violations.

Based on the information provided in SPEC's VSD letters dated March 28, 2017 and April 27, 2017, and the NRC OI investigation, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The apparent violation involves the importation of 155 non-U.S. origin disused sources containing the byproduct material iridium-192, selenium-75, and ytterbium-169 into the United States, without obtaining a specific license authorizing the import of radioactive waste as required by 10 CFR 110.5, 110.9a., 110.20(a), 110.27(c) and 110.43(d) between 2012 and 2017. The byproduct material meets the definition of radioactive waste in 10 CFR 110.2 because the 155 disused sealed sources were not of U.S. origin. Specifically, the NRC's regulations in 10 CFR Part 110 establish the general and specific export and import licensing requirements for byproduct material including radioactive waste. There are six exclusions in

10 CFR 110.2 to the definition of “radioactive waste.” The sealed source exclusion (exclusion one) is defined as radioactive material that is “[o]f U.S. origin and contained in a sealed source, or device containing a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device containing a sealed source.” Disused sources containing byproduct material that satisfy an exclusion to the definition of “radioactive waste” are authorized for import under NRC’s general license in 10 CFR 110.27 provided that the U.S. recipient is authorized to receive and possess the materials.

In the NRC’s “Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources” (BTP) (ADAMS Accession No. ML13177A16), the NRC staff clarified that under narrow circumstances disused sources may be construed to be of U.S.-origin for purposes of exclusion one, if the importer could not ascertain for certain whether or not a disused source was of U.S. origin without exposing personnel to additional doses. Fundamental to this construction of exclusion one, an importer must be able to show that it made a good faith effort to determine the source’s origin before an import occurs, which could include, among others, communications of U.S. import requirements with its foreign customers, examination of a photograph of the source the customer seeks to exchange, and obtaining other relevant information related to the disused sources’ origin. The BTP recommended that U.S. importers retain copies of their communications with their foreign customers regarding U.S. import requirements. The BTP noted that, consistent with 10 CFR 110.53, the licensee’s records, premises, and activities pertaining to its exports and imports were subject to NRC inspection to ensure compliance with the sealed source exclusion to the definition of “radioactive waste.”

It appears to the staff that SPEC did not make a good faith effort to determine the sources’ origin within the narrow policy exception reflected in the BTP. SPEC possessed the ability to determine whether a source originated with and was manufactured by Gilligan Engineering, an established SPEC customer for approximately five years, by, e.g., communicating with the foreign customer regarding the source(s) origin and U.S. import requirements; correlating source serial numbers; and obtaining decay charts - which specifically identified the country of origin. It does not appear to the staff that any such efforts were made.

The NRC considers the violation against 10 CFR 110.5, 110.9, 110.20(a), 110.27(c), and 110.43(d) to be significant because it resulted in the NRC not being able to conduct its regulatory responsibilities to ensure that the byproduct imported was possessed, stored, or used adequately to protect public health and safety, and the environment. NRC was not able to make the requisite finding that an appropriate facility has agreed to accept and is authorized to possess the waste for management or disposal as confirmed by NRC consultations with, as applicable, the Agreement State in which the facility is located and low-level waste compact commission.

During a December 19, 2018, telephonic exit meeting, Ms. Sophie Holiday, of my staff, and Ms. Andrea Jones, of the Office of International Programs, discussed the apparent violation, the significance of the issues, and the need for lasting and effective corrective actions with you. As discussed with you, the NRC has not made a final determination regarding the apparent violation or that enforcement action will be taken against SPEC; therefore, a Notice of Violation is not being issued at this time. You did not accept the violation; therefore, before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violation addressed in this letter within 30 days of the date of this letter; (2) request a Pre-decisional Enforcement Conference (PEC); or (3) request Alternative Dispute Resolution (ADR). Please contact Mr. Peter Habighorst, Chief, Export Controls and Nonproliferation

Branch, at 301-287-9241 or Ms. Andrea Jones, Sr. Licensing Officer, at 404-997-4443 within **10 days** of the date of this letter to notify the NRC of your intended response. A PEC should be held within 30-days and an ADR session within 45-days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations, EA-18-170" and should include for the 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. Your response should be sent to the NRC's Document Control Center, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; with a copy mailed to George Wilson, Acting Director, Office of Enforcement, 11555 Rockville Pike, Rockville, MD 20852, within 30 days of the date of this letter.

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. If a PEC is held, it will be open for public observation and the NRC may issue a meeting notice and/or press release to announce the time and date of this open conference. 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 presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful, and is included on the NRC Web site at

<http://pbadupws.nrc.gov/docs/ML0612/ML061240509.pdf>.

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral third party (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at <http://www.nrc.gov/aboutnrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you choose ADR, you must contact ICR at (877) 733-9415 within 10-days from the date of this letter if you are interested in pursuing resolution of this issue through ADR. If you choose to request ADR, the ADR will be closed to the public; however, the NRC may issue a meeting notice and/or press release to announce the time and date of this closed conference.

If you choose not to respond within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management 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. Any information forwarded to NRC should be clearly labeled on the first page with the case reference number: EA-18-170.

Should you have any questions, please contact Mr. Peter Habighorst at 301-287-9241 or Ms. Andrea Jones at 404-997-4443.

Sincerely,

/RA/

George A. Wilson, Acting Director
Office of Enforcement

Enclosures:

1. Apparent Violation Being Considered
for Escalated Enforcement
2. Summary of Basis of Apparent Violation

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OFFICE	OGC	OGC	DD:OIP	OE
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APPARENT VIOLATION BEING CONSIDERED FOR ESCALATED ENFORCEMENT

Title 10 of the *Code of Federal Regulations* (CFR) section 110.5, states in part, "no person may import any nuclear equipment or material listed in 10 CFR 110.9a, unless authorized by a general or specific license issued under this part."

10 CFR 110.9a(d) indicates byproduct material (e.g. disused sealed sources containing iridium-191, selenium-75, and ytterbium-169) as nuclear equipment and material under NRC import licensing authority. Except as provided under subpart B of this part, no person may import any nuclear equipment or material listed in § 110.9a, unless authorized by a general or specific license.

10 CFR 110.20(a) states, "A person may use an NRC general license as an authority to export or import nuclear equipment or material, if the nuclear equipment or material to be exported or imported is covered by the NRC general licenses as described in §§ 110.21 through 110.27. If an export or import is not covered by the NRC general licenses described in 10 CFR Parts 110.21 through 110.27, a person must file with the Commission for a specific license in accordance with §§ 110.31 through 110.32."

10 CFR 110.27(c) states, "Paragraph (a) of 10 CFR Part 110.27 does not authorize the import under a general license of radioactive waste."

10 CFR 110.2 states in part, "Radioactive waste does not include radioactive material that is "[o]f U.S. origin and contained in a sealed source, that is being returned to a manufacturer, distributor or other entity which is authorized to receive and possess the sealed source or the device contained a sealed source."

10 CFR 110.43(d) states, in part, that with respect to the import of radioactive waste, an appropriate facility has agreed to accept and is authorized to possess the waste for management or disposal as confirmed by NRC consultations with, as applicable, the Agreement State in which the facility is located and low-level waste compact commission(s).

Contrary to the above, between 2012 and 2017, SPEC imported 155 non-U.S. origin disused sources containing the byproduct material iridium-192, selenium-75, and ytterbium-169 into the United States, without obtaining a specific license authorizing the import of radioactive waste as required by 10 CFR 110.5, 110.9a. and 110.43(d) between 2012 and 2017. The byproduct material meets the definition of radioactive waste in 10 CFR 110.2 because the 155 disused sealed sources were not of U.S. origin and the imports required a specific license. Moreover, no facility has agreed to accept and is authorized to possess the 155 disused sealed sources for management or disposal as confirmed by NRC consultations with, as applicable, the Agreement State in which the facility is located and low-level waste compact commission(s).

Summary of Basis of Apparent Violation

Source Production & Equipment Company (SPEC) is an American manufacturing company and supplier of industrial gamma radiography sources, devices and equipment. SPEC is located in St. Rose, Louisiana.

On March 28, 2017, SPEC self-identified the apparent violation (Accession No. ML17088AA529) and provided NRC with a copy of their internal investigation on April 27, 2017. (Accession No ML17125A090). The self-disclosure revealed that between 2012 and 2017, SPEC received 155 disused sealed sources of non-United States origin and no specific import license for waste was issued. Non-US origin disused sources are considered radioactive waste, and by definition in 110.2, required a specific import license.

The NRC initiated an investigation on June 1, 2017. to determine if employees of the Source Protection and Equipment Company Inc. in Rose, Louisiana. willfully imported radioactive waste without a specific license. Based on the evidence developed during this investigation, the NRC did not substantiate that employees of SPEC deliberately imported non-US origin disused sources without the required specific import license. However, the NRC staff did determine that a non-willful violation did occur.

Specifically, between 2012 and 2017, SPEC imported 155 non-U.S. origin disused sources containing the byproduct material iridium-192, selenium-75, and ytterbium-169 into the United States, without obtaining a specific license authorizing the import of radioactive waste as required by 10 CFR 110.5, 110.9a., 110.20(a), 110.27(c), and 110.43(d) between 2012 and 2017. The byproduct material meets the definition of radioactive waste in 10 CFR 110.2 because the 155 disused sealed sources were not of U.S. origin. The imports required a specific license.