



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001**

June 03, 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: SOURCE PRODUCTION & EQUIPMENT COMPANY, INC. – NOTICE OF VIOLATION AND OFFICE OF INVESTIGATIONS REPORT NO. OI-2017-001

Dear Ms. Kusy:

This letter refers to the U.S. Nuclear Regulatory Commission's (NRC) review of information concerning the import of non-United States (U.S.) origin byproduct material (disused sealed sources) by Source Production & Equipment Company (SPEC), from the United Kingdom between 2012 and 2017. The NRC initiated its review following 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 No. ML17088A529 and ML17125A090, respectively). The letters notified the NRC about the import of 155 disused sealed sources of non-U.S. origin, which are considered radioactive waste. During this time frame, 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 into these issues. On September 20, 2018, the NRC OI completed its investigation into the circumstances surrounding SPEC's import of non-U.S. origin disused sources without having the required license. The NRC did not identify any apparent willful violations as a result of this investigation.

In the letter dated February 14, 2019 (ADAMS Accession No. ML19032A001), transmitting the OI investigation report, we provided you with the opportunity to address the apparent violation identified in the letter by either: (1) providing a written response; (2) attending a predecisional enforcement conference; or (3) participating in an Alternative Dispute Resolution mediation, before we made our final enforcement decision. SPEC submitted its written response on April 1, 2019 (ADAMS Accession No. ML19133A280) and provided supplemental information on May 1, 2019 (ADAMS Accession No. ML19133A281).

Based on a review of the information provided by SPEC in its VSD letters dated March 28, 2017 and April 27, 2017, the NRC OI investigation, and SPEC's response to NRC's letter dated February 14, 2019, the NRC has determined that a violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice). The violation involves the import of 155 non-U.S. origin disused sources containing the byproduct material iridium-192, selenium-75, and ytterbium-169 into the U.S. between 2012 and 2017, without obtaining a

specific license authorizing the import of radioactive waste as required by Title 10 *Code of Federal Regulations* (10 CFR) Parts 110.5, 110.9a., 110.20(a), and 110.27(c). 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 to the definition of "radioactive waste" in 10 CFR 110.2. 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." Accordingly, disused sources containing byproduct material that satisfy an exclusion to the definition of "radioactive waste" are authorized for import under an NRC general license under 10 CFR 110.27 requirements provided that the U.S. recipient is authorized to receive and possess the materials.

The NRC considers the violation against 10 CFR 110.5, 110.9, 110.20(a), and 110.27(c) to be significant because it resulted in the NRC not being able to conduct its regulatory responsibilities to ensure that the imported byproduct material was possessed, stored, or used adequately to protect public health and safety, and the environment. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III (SLIII). The NRC Enforcement Policy may be found on the NRC website at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$36,250 is considered for an SLIII violation. Because your facility has been the subject of escalated enforcement action within the last 2 years, the NRC considered whether the November 16, 2018 enforcement action (EA-18-116) related to a violation of 10 CFR Parts 110.20(a) and 110.27(a) should be considered as history for this violation. The apparent violation related to the import of non-U.S. origin disused sealed sources (EA-18-170) was identified as part of SPEC's internal investigation and reported to the NRC staff in March and April 2017, resulting in the NRC OI investigation. The November 2018 violation (EA-18-116) was also identified as part of SPEC's ongoing internal investigation and reported to the NRC in May 2018. Because these violations were identified by SPEC through the same internal investigation, the NRC does not consider the November 2018 violation (EA-18-116) as history for this violation (EA-18-170).

The NRC also considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. In SPEC's letter dated April 1, 2019, as supplemented by correspondence dated May 1, 2019, SPEC identified comprehensive corrective actions which include: (1) informing SPEC's foreign sealed source customers of the conditions under which SPEC will authorize import of sealed sources for disposal, including the exchange of sealed sources on a one-for-one basis in accordance with NRC's Branch Technical Position (BTP), "Branch Technical Position on the Import of Non-U.S. Origin Radioactive Sources", published August 28, 2013 (ADAMS Accession No. ML13177A163); (2) developing and implementing processes to monitor sealed source imports, which include a procedure to determine shipment eligibility prior to import; (3) revising its internal work instructions to reflect the NRC's policy on the import of non-U.S. origin disused sealed sources; (4) conducting training of its shipping and receiving personnel to ensure proper knowledge of NRC's requirements for the import of non-U.S. origin disused sealed sources; and (5) re-emphasizing to all SPEC personnel that concerns regarding compliance with the NRC and other regulatory agencies' rules and regulations should be promptly brought to the attention of senior management.

Therefore, to encourage prompt identification and comprehensive correction of violations, the NRC will not propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this SLIII violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC staff notes that, at all times, U.S. importers must comply with the specific license requirement for disused sources known to be of non-U.S. origin prior to import into the U.S. But, as explained in the BTP, a source may be deemed to be of U.S. origin (and thus subject to exclusion one in 10 CFR 110.2) if a licensee makes a good faith effort to determine the origin. The BTP states that a good faith effort by the importer includes, but is not limited to, communication 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 origin of disused sources. The BTP also recommends that U.S. importers retain copies of their communications with their foreign customers regarding U.S. import requirements.

In its May 1, 2019, letter to NRC addressing the NRC's request for clarification regarding corrective actions previously described in its April 1, 2019 letter, SPEC included an excerpt from its work instruction SH16 (Importing Shipments) regarding the applicability of the BTP in the determination of origin of disused sources. The NRC staff recognizes SPEC's procedures for making a good faith effort as outlined in sections 7.2.1 and 7.2.2 of SH16, including reviewing the source identification document supplied by the customer for origin; the recognition of U.S. companies that manufacture, assemble or distribute sealed sources or devices; and the scenarios in which the imports may not be of U.S. origin and would require consultations with SPEC's Vice President or Director. However, the statement in section 7.2.3 of SH16 that a source will be deemed to be of US origin "only if the disused source is being exchanged for a new source on a one-for-one basis . . ." is inconsistent with the BTP if the one-for-one exchange is applied as one of the criteria to determine whether a source is of U.S. origin and may be imported under a general license.

Under the BTP, in order for a source to be treated as of U.S. origin for the purpose of excluding it from the definition of radioactive waste in 10 CFR Part 110, a licensee must make a good faith effort to determine whether or not the source can reasonably be considered to be of U.S. origin. The BTP does not provide that a one-for-one exchange be part of that [good faith] determination, and the fact that an import meets a one-for-one limitation does not automatically mean that the source may be imported under the general license. The statements about one-for-one exchange in the BTP were an observation of typical industry practice for import and export of sources that are of U.S. origin. While not part of the good faith effort, a one-for-one exchange is consistent with the BTP and the objective of exclusion one to the definition of radioactive waste in part 110 to restrict the general import license to U.S. origin sources.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket in letters dated April 1, 2019 and May 1, 2019. Therefore, you are not required to respond to this letter unless the NRC staff's conclusions regarding your procedures and their relation to the BTP, as described above, do not accurately reflect your corrective actions or your position on this matter.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedures," a copy of this letter, its enclosure(s), and your response will be made available electronically for public inspection in the NRC Public Document Room and in 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. 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/

George A. Wilson, Director
Office of Enforcement

Enclosure:
Notice of Violation

SUBJECT: SOURCE PRODUCTION & EQUIPMENT COMPANY, INC. – NOTICE OF VIOLATION AND INVESTIGATIONS REPORT NO. OI-2017-001.
 DATED: JUNE 03, 2019

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NOTICE OF VIOLATION

Source Production & Equipment Company, Inc.
St. Rose, LA

EA-18-170

Based on the U.S. Nuclear Regulatory Commission's (NRC's) evaluation of Source Production & Equipment Company (SPEC) activity associated with the import of non-United States (U.S.) origin byproduct material from the United Kingdom, between 2012 and 2017, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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 110.20(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, for the purposes of this part, means any material that contains or is contaminated with source, byproduct, or special nuclear material that by its possession would require a specific radioactive material license in accordance with this Chapter. . . . 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. . . ."

Contrary to the above, between 2012 and 2017, SPEC failed to obtain a specific license authorizing the import of material not covered by the NRC general licenses described in 10 CFR Parts 110.21 through 110.27. Specifically, SPEC imported 155 non-U.S. origin disused sealed sources containing the byproduct material (iridium-192, selenium-75, and ytterbium-169) into the U.S. without a specific license as required by 10 CFR 110.20(a).

This is a Severity Level III 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 was achieved, is already adequately addressed in your April 1, 2019 and May 1, 2019 letters. 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-2018-170" and send it to the NRC, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the with a copy to the Director, Office of International Programs, within 30 days of the date of the letter transmitting this Notice.

Enclosure

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in 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. If personal privacy or proprietary information is necessary to provide an acceptable response, then 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 material, 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

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

Dated this third day of June 2019.