



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

March 3, 2020

EA-2019-141

Mr. John Sanders
Sanders Medical Products
520 Bearden Park Circle
Knoxville, TN 37919

SUBJECT: EXPORT OF NUCLEAR MATERIAL UNDER U.S. NUCLEAR REGULATORY
COMMISSION'S LICENSING AUTHORITY – NOTICE OF VIOLATION

Dear Mr. Sanders:

This letter refers to a review of information relating to the export of byproduct material [germanium-68 (Ge-68)], under the U.S. Nuclear Regulatory Commission's (NRC) licensing authority, by Sanders Medical Products (SMP). On July 18, 2019, U.S. Customs and Border Protection (CBP), requested NRC assistance concerning an attempt to export a 1,581 microcurie (μCi) Ge-68 source to Tehran, Iran. Specifically, SMP attempted to export the Ge-68 source without filing an application for a specific license. Subsequent to the CBP notification, SMP revealed a November 26, 2018, unauthorized export of a Ge-68 1,581 μCi source to Baghdad, Iraq, without filing and obtaining a specific license.

The NRC discussed its preliminary findings with you on February 5, 2020, in a telephone conversation with Ms. Andrea R. Jones, Senior Licensing Officer, Export Controls & Nonproliferation Branch, Office of International Programs. During the telephone conversation, you were informed that the NRC determined that apparent violations of NRC requirements occurred and that the violations are being considered for escalated enforcement 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>. Based on your conversation with Ms. Jones, you agreed to decline the opportunity to request a Pre-decisional Enforcement Conference with the NRC or to respond in writing to the apparent violations.

Based on a review of information provided electronically and subsequent discussion with you and NRC staff, the NRC has sufficient information to make an enforcement decision regarding this matter, and is issuing you a Notice of Violation (Notice) formally citing the two violations of NRC requirements. The violations are cited in the enclosed Notice. The first violation involves SMP's attempt to export a Ge-68 1,581 μCi source to Tehran, Iran, without filing an application for a specific license, as per Title 10 of the *Code of Federal Regulations* (10 CFR) Part 110.31, "Application for a Specific License". Although the transfer of the Ge-68 source to the ultimate consignee in Iran was intercepted by CBP, the NRC views the attempted export significant because there was an actual "intent to export", on the part of SMP.

The second violation involves the November 26, 2018, export of a Ge-68 1,581 μ Ci source to Baghdad, Iraq. This export was not authorized by a specific license, in accordance with 10 CFR Part 110.5, "Licensing Requirements". The safety significance associated with Ge-68 source is very low, but the failure to file an application and obtain a specific license, before exporting the byproduct material raises significant regulatory concerns. This export required Commission level review prior to granting the license due to significant foreign policy considerations with Iraq in accordance with requirements in 10 CFR 110.40(d), "Commission Review".

Both exports required Executive Branch Reviews in accordance with 10 CFR 110.41, "Executive Branch Review." The Executive Branch was not able to give its judgment on whether the proposed exports were inimical to the common defense and security of the United States, and consistent with the provisions of the Atomic Energy Act. Therefore, each violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level (SL) III.

Because your facility has not been the subject of escalated enforcement actions within the last 2 years, the NRC 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. Your corrective actions included your August 14, 2019, submission of license application XB1342 [Agencywide Documents Access and Management System (ADAMS), ML19227A082] for a proposed shipment of Ge-68 to Iraq, and the August 22, 2019, submission of export application XB1343 (ADAMS ML19238A004), for the June 2019 intercepted shipment to Iran.

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 oversight in the future.

The NRC has concluded that information regarding: (1) the reasons for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket. Therefore, you are not required to respond to this letter and Notice 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 "Agency Rules of Practice and Procedures," a copy of this letter, its enclosure, 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>. If you choose to respond to this letter and Notice, 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.

J. Sanders

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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/>).

Please contact Andrea R. Jones at (404) 997-4443, if you have any questions regarding this matter.

Sincerely,

/RA/

George A. Wilson, Director
Office of Enforcement

Enclosure:
Notice of Violation

SUBJECT: EXPORT OF NUCLEAR MATERIAL UNDER U.S. NUCLEAR REGULATORY
COMMISSION'S LICENSING AUTHORITY – NOTICE OF VIOLATION
DATED: MARCH 3, 2020

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NOTICE OF VIOLATION

Sanders Medical Products
Knoxville, TN

EA-2019-141

Based on the U.S. Nuclear Regulatory Commission's (NRC) evaluation of Sanders Medical Products (SMP) activities associated with the export of byproduct material in July 2019, and November 2018, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. Title 10 of the *Code of Federal Regulations* (10 CFR) Part 110.31, states a person shall file an application for a specific license to export or import with the Deputy Director of NRC's OIP, using an appropriate method listed in 10 CFR Part 110.4.

10 CFR Part 110.4 states in part, that all communication and reports concerning regulation in this part should be addressed to the Deputy Director of NRC's OIP; either by telephone; by mail hand delivery; or where practicable, electronic submission.

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 Iran as an embargoed destination.

Contrary to the above, SMP did not file an application for a specific license to the Deputy Director of OIP, to export a Ge-68 1,581 μCi source, using an appropriate method listed in 10 CFR Part 110.4. Specifically, on June 3, 2019, SMP attempted to export a Ge-68 1,581 μCi source to Tehran, Iran, without filing an application for a specific license, when such activity would have been required to be authorized by the NRC. Therefore, no export application was filed and the shipment was not authorized by a specific license issued under 10 CFR Part 110.

This is a Severity Level III Violation (NRC Enforcement Policy Section 6.15.c.4).

- B. 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 Iraq as an embargoed destination.

Contrary to the above, SMP exported a Ge-68 1,581 µCi source without being authorized by a specific license issued under 10 CFR Part 110. Specifically, on November 26, 2018, SMP exported to Alchemy Scientific Bureau in Baghdad, Iraq, a Ge-68 1,581 µCi source without a specific license, when such activity would have been required to be authorized by the NRC. Therefore, no export license was issued, and the shipment was not authorized by a specific license issued under 10 CFR Part 110.

This is a Severity Level III Violation (NRC Enforcement Policy Section 6.15.c.4).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed in your August 14, 2019, and August 22, 2019, license applications submission. 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-19-141" and send it to the NRC, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Director, Office of International Programs, within 30 days of the date of the letter transmitting this Notice. 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.

Dated this 3rd day of March 2020.