



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

April 16, 2025

EAO-OIP-2025-0051

John Sanders, President
Sanders Medical Products, Inc.
10475 Dutchtown Road
Knoxville, TN 37932

SUBJECT: SANDERS MEDICAL PRODUCTS, INC.- U.S. NUCLEAR REGULATORY
COMMISSION REVIEW RELATED TO EXPORTS OF BYPRODUCT MATERIAL
AND APPARENT VIOLATION

Dear Mr. Sanders:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) review of Sanders Medical Products, Inc. (Sanders) export records conducted from August 2024 through March 2025. The review examined Sanders' export of byproduct material to Pakistan without an export license and whether you were in compliance with applicable requirements. On March 13, 2025, Ms. Joanne Savoy and Ms. Andrea Jones of the NRC discussed the preliminary results of our review with you as documented in the enclosure.

Based on the results of this review, an 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 website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violation involves 15 Germanium-68 exports to Pakistan without filing an application for a specific export license as required by NRC Order, "Order Suspending General License Authority to Export Byproduct Material to Pakistan," dated April 16, 2020 (85 *FR* 22181). This Order suspended NRC general license authority for exports of byproduct material to Pakistan under Section 82 of the Atomic Energy Act and Title 10 of the *Code of Federal Regulations* (10 CFR) 110.23. Accordingly, any person wishing to export byproduct material to Pakistan must apply for a specific license in accordance with 10 CFR 110.31 requirements. The apparent failures to conduct activities in accordance with the Order is significant because it impacts the NRC's ability to conduct regulatory oversight to ensure the safe and appropriate use of radioactive material. Since the NRC has not made a final determination in this matter, a notice of violation is not being issued at this time. In addition, be advised that the characterization of the apparent violation may change as a result of further NRC review.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond in writing to the apparent violation addressed in this letter 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 Ms. Joanne Savoy at 301-287-9092 or via email at Joanne.Savoy@nrc.gov 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 - EAO-OIP-2025-0051" and should include: (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 U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555- 0001; with a copy mailed to David L. Skeen, Director, Office of International Programs, 11555 Rockville, MD 20852, or via email to David.Skeen@nrc.gov, 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 "Rules of Practice," a copy of this letter, its enclosure(s), 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 the NRC on this matter should be clearly labeled on the first page with the case reference number: EAO-OIP-2025-0051.

Should you have any questions, please contact Ms. Joanne Savoy 301-287-9092 or via email at Joanne.Savoy@nrc.gov.

Sincerely,



Signed by Skeen, David
on 04/16/25

David L. Skeen, Director
Office of International Programs

Enclosure:
As stated

SUBJECT: SANDERS MEDICAL PRODUCTS, INC.- U.S. NUCLEAR REGULATORY
COMMISSION REVIEW RELATED TO EXPORTS OF BYPRODUCT MATERIAL
AND APPARENT VIOLATION DATED: APRIL 16, 2025

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BASIS FOR APPARENT VIOLATION
BEING CONSIDERED FOR ESCALATED ENFORCEMENT

From August 2024 through March 2025, the NRC conducted a review of Sanders Medical Product's export records. The review examined Sanders' export of byproduct material to Pakistan. Based on its review, the NRC identified that Sanders Medical Products Inc. on 15 occasions, exported 29 Germanium-68 sources, ranging in activity from 3.5 megabecquerels (MBq) to 185 MBq to Pakistan without an NRC specific license that resulted in an apparent violation, which is being considered for escalated enforcement.

Apparent Violation:

NRC Order, "Order Suspending General License Authority to Export Byproduct Material to Pakistan," dated April 16, 2020, states, in part, that any person wishing to export byproduct material to Pakistan must apply for a specific license in accordance with Title 10 of the *Code of Federal Regulations* 110.31.

Contrary to the above, between November 17, 2020 and August 15, 2024, Sanders Medical Products exported byproduct sources to Pakistan, without filing an application for a specific export license as required by the NRC April 16, 2020, Order. Specifically, on 15 occasions Sanders Medical Products exported 29 Germanium-68 byproduct sources, ranging in activity from 3.5 to 185 MBq, to Pakistan which were not authorized for export under a general license and without Executive Branch review.