



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

June 17, 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 NOTICE OF 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 and details of the review were provided to you in an NRC letter, dated April 16, 2025, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML25092A056).

In the NRC letter dated April 16, 2025, we provided you with the opportunity to address the apparent violation by either attending a predecisional enforcement conference, or by providing a written response before we made our final enforcement decision. In a letter dated May 14, 2025 (ADAMS No. ML25135A349), you provided your written response to the apparent violations.

Based on the information developed during our review of records, discussions with you on March 13, 2025, and your response to the April 16, 2025, letter, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding the violation are described below in this letter. The violation involved Sander's failure to obtain a specific license before exporting byproduct material to Pakistan.

The failure to obtain a specific license before exporting high risk sources raises significant regulatory concerns. Specifically, the NRC considers the export to be significant because it impacted the NRC's ability to perform its regulatory oversight function and wherein the U.S. Government would have requested Executive Branch views, prior to granting the license, due to foreign policy considerations and public health and safety and security implications. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity

Level III. The current Enforcement Policy can be found on the NRC's website at <http://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 \$9,000 is considered for a Severity Level III violation.

Because your facility has not been the subject of prior escalated enforcement action, 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 NRC Enforcement Policy. The NRC has determined that *Corrective Action* credit is warranted based on the corrective actions you implemented as described in your letter dated May 14, 2025.

Therefore, in recognition of the absence of previous escalated enforcement action, and your prompt and comprehensive corrective actions, I am not proposing a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased NRC oversight.

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 was achieved is already adequately addressed on the docket in your letter dated May 14, 2025. Therefore, you are not required to respond to this letter 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 Procedure," a copy of this letter, the enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

J. Sanders

- 3 -

Should you have any questions, please contact Ms. Andrea Ferkile at 301-287-9084 or Ms. Joanne Savoy at 301-287-9092 and or Ms. Andrea Jones at 404-997-4443.

Sincerely,

A handwritten signature in black ink, appearing to read "D. L. Pelton", followed by a horizontal line extending to the right.

Signed by Pelton, David  
on 06/17/25

David L. Pelton, Director  
Office of Enforcement

Enclosure:  
Notice of Violation

## NOTICE OF VIOLATION

Sanders Medical Products, Inc.  
Knoxville, TN

EAO-OIP-2025-0051

During a U.S. Nuclear Regulatory Commission (NRC) in-office review of Sanders Medical Products' export records that was completed in March 2025, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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

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 was achieved is already adequately addressed on the docket on May 14, 2025.

However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EAO-OIP-2025-0051," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to David Skeen, Director, Office of International Programs.

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, U.S. 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 website at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy or proprietary 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 that such material is withheld from public disclosure, you must specifically identify

Enclosure

J. Sanders

- 2 -

the portions of your response that you seek to have withheld and provide in detail the basis for your claim (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 17th day of June 2025