

May 7, 2007

EA-07-097
NMED No. 070229

Thom Oltman, Production Manager
Smiths Medical ASD, Inc.
5700 W. 23rd Avenue
Gary, IN 46406

SUBJECT: NRC REVIEW OF REPORT FROM SMITHS MEDICAL ASD, INC.,
REGARDING LOST POLONIUM-210 STATIC ELIMINATOR AND NOTICE OF
VIOLATION

Dear Mr. Oltman:

This refers to your report received by the NRC on April 18, 2007, regarding the loss of a static eliminator containing an estimated 1.6 millicuries of polonium-210 from your facility in Gary, Indiana. Your report indicated that the static eliminator was last used on February 23, 2007, and you confirmed that it was lost between that date and February 26, 2007.

Based on our review of your report, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The first violation concerns the failure to properly transfer or dispose of a generally-licensed device to a person or persons that are authorized to receive the device as required by 10 CFR 31.5(c)(8). The second violation concerns the failure to report the loss of material by telephone within 30 days of your identification of the loss as required by 10 CFR 20.2201(a)(1)(ii). The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov>. The violations are cited in the enclosed Notice of Violation (Notice).

As corrective action for the violations, you have: (1) replaced the previous button holders with metal holders that are permanently attached to the extruder frames; (2) trained all employees on properly attending to and accounting for static eliminators; (3) included information on reporting requirements in the procedure describing the use of static eliminators; and (4) retained copies of all relevant regulations on file.

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 is already adequately addressed on the docket in your report received by NRC on April 18, 2007, and in this letter. Therefore, you are not required to respond to this letter regarding the violations unless the description 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.

T. Oltman

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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.

Sincerely,

/RA/

Robert G. Gattone, Acting Chief
Materials Inspection Branch

Docket No. 99990003
General License: 10 CFR 31.5

Enclosure:
Notice of Violation

cc w/encl: State of Indiana

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Letter to Thom Oltman from Robert G. Gattone dated May 7, 2007

SUBJECT: NRC REVIEW OF REPORT FROM SMITHS MEDICAL ASD, INC.,
REGARDING LOST POLONIUM-210 STATIC ELIMINATOR AND NOTICE OF
VIOLATION

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NOTICE OF VIOLATION

Smiths Medical ASD, Inc.
Gary, IN

Docket No. 99990003
General License: 10 CFR 31.5
EA-07-097

NRC's review of the licensee's report received April 18, 2007, indicated violations of NRC requirements. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. Title 10 CFR 31.5(c)(8) requires, in part, that any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to a general license shall, except as provided in 10 CFR 31.5(c)(9), transfer or dispose of the device containing byproduct material only by transfer to persons holding a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device.

Contrary to the above, between February 23 and February 26, 2007, the licensee disposed of a NRD Model P2042 static eliminator containing polonium-210. This disposal was made to a person who did not hold a specific license pursuant to 10 CFR Parts 30 and 32 or from an Agreement State to receive the device, and the exception in 10 CFR 31.5(c)(9) did not apply. Specifically, the device was disposed of in a landfill which was unlicensed to receive the device.

This is a Severity Level IV violation (Supplement VI).

2. Title 10 CFR 20.2201(a)(1)(ii) requires that each licensee shall report by telephone within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20 that is still missing at this time.

Contrary to the above, the licensee failed to report by telephone within 30 days after the occurrence of lost material became known to the licensee. Specifically, the licensee became aware that a static eliminator containing 1.6 millicuries of polonium-210, NRC-licensed material in a quantity greater than 10 times the quantity specified in Appendix C to Part 20, was missing on February 26, 2007, but did not report the missing material by telephone until April 18, 2007, a period exceeding 30 days.

This is a Severity Level IV violation (Supplement IV).

The NRC has concluded that information regarding the reason for the violations, 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 report and the letter transmitting this Notice of Violation (Notice). 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-07-097" and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice.

Enclosure

T. Oltman

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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 from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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

Dated this 7th day of May 2007

Enclosure