

December 17, 2012

**Subject:** Response to November 1, 2012 letter (Attachment A) from J. Owens (NRC Branch Chief, Office of International Programs) to Jim Blute (RSO, Thermo Scientific Portable Analytical Instruments Inc.) regarding late submission of annual Am-241 export reports.

Dear Ms. Owens,

This letter is in regards to reports submitted in 2009 and 2010 of Am-241 exports made by Thermo Scientific Portable Analytical Instruments Inc. (Formerly Thermo Niton Analyzers LLC). As identified in your November 1, 2012 letter, the report of 2008 exports required by 10 CFR 110.23(b) was submitted 4 days past due on February 5, 2009. Also, as I discussed with Steve Baker of your office in a telephone conversation on November 27<sup>th</sup> of this year, our report of 2009 exports was submitted one year past due. This report of 2009 exports was made on (or about) January 24, of 2011 along with the 2010 exports.

This report is typically prepared by a Radiation Safety Associate and reviewed by the RSO. After reviewing the late report events, it was concluded that there were programmatic weaknesses relating to awareness of the report deadline and communication of its completion status in the critical month of January. Also, it was identified that the existing controls were not sufficiently robust if one of the two staff positions were to vacate, as was the case during the 2009 reporting period.

**Corrective/Preventative Action:**

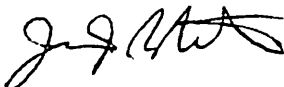
The following steps have been taken to address the identified programmatic weaknesses and ensure timely submission of the 10 CFR 110.23(b) report.

- Both the Radiation Safety Associate and the RSO have set reoccurring computer calendar reminders regarding the report. A report preparation reminder is set for January 1<sup>st</sup> of each year.
- Added this year, a report submission reminder is set for January 15<sup>th</sup> of each year.
- Added this year, a pdf copy of the November 1, 2012 letter from your agency, and this response letter, is to be attached to each of the above reminders to emphasize the prior compliance issues and commitments.
- The EHS group began using a posted "Compliance Calendar" last year to track all reoccurring compliance tasks. The annual Am-241 export report has been incorporated into the compliance calendar. Completion of tasks is recorded on this calendar which is posted in the EHS group area.
- Added this year, upcoming and completed tasks on the compliance calendar are reviewed at least monthly during an EHS staff meeting.
- Added this year, a standard operating procedure has been developed that describes our regulatory reporting processes including the annual AM-241 export report.

**ThermoFisher**  
S C I E N T I F I C

It is our conclusion that the compliance calendar was a critical process improvement that occurred last year and, in combination with the newly added controls, will adequately address the weaknesses that led to the two late report events and prevent a reoccurrence. Please let me know if you need additional information.

Sincerely,



James Blute, CHP  
Health and Safety Manager / RSO  
Thermo Scientific Portable Analytical Instruments

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[www.thermoscientific.com/pai](http://www.thermoscientific.com/pai)

**ATTACHMENT A**  
**Nov. 1<sup>st</sup> 2012 Letter from J. Owens to Jim Blute**



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

November 1, 2012

James Blute, CHP  
Radiation Safety Officer  
Thermo Scientific Portable Analytical Instruments  
2 Radcliff Road  
Tewksbury, MA 01876

SUBJECT: THERMO NITON ANALYZERS LLC - LATE REPORTING OF AMERICIUM-241  
SHIPMENTS

Dear Mr. Blute:

This letter refers to Thermo NITON Analyzers LLC (NITON) (now Thermo Scientific Portable Analytical Instruments Inc.) letter dated February 5, 2009, (enclosure 1) notifying the U.S Nuclear Regulatory Commission (NRC) of certain exports of americium-241 (Am-241) during calendar year 2008. NITON reported 161 shipments of Am-241 under the NRC general license from January 2, 2008, to December 30, 2008, to fourteen countries (Australia, Canada, Finland, Hong Kong, South Korea, Malaysia, Mexico, Norway, Philippines, Singapore, South Africa, Thailand, Turkey and United Kingdom), but failed to submit a copy of the annual report in a timely manner, by February 1, 2009, in accordance with 10 CFR 110.23(b).

Additionally, on June 28, 2007, a Notice of Violation was issued for a Severity Level IV violation for failure to submit an annual report of Am-241 exports for calendar years 2002 through 2006. In letters dated February 21, 2007 (enclosure 2), and July 27, 2007 (enclosure 3), NITON acknowledged having failed to submit required annual reports for calendar years 2002 - 2006, and cited the corrective actions to prevent recurrence of the violation.

The NRC has determined that failure to submit the annual report in a timely manner constitutes a violation of minor significance that is not subject to enforcement action, in accordance with Section 2.3 of the Enforcement Policy. Generally, minor violations are not documented in an inspection report, but must be corrected and the results of the corrective actions typically will be reviewed during the next inspections. Because the Office of International Program does not normally conduct inspections, you are requested to respond to this letter, providing the corrective action steps taken to ensure a timely submission of the annual report.

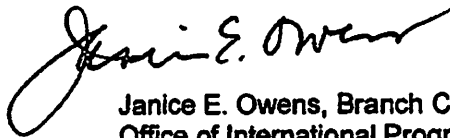
In accordance with Title 10 of the *Code of Federal Regulations* Section 2.390, "Public inspections, exemptions, and requests for withholding," a copy of this letter, its enclosure, and your response (if any) will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (Agencywide Documents Access and Management System (ADAMS)). ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room).

J. Blute

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Should you have any questions concerning this letter, please contact Stephen Baker at (301) 415-3329 or by electronic mail at [Stephen.Baker@nrc.gov](mailto:Stephen.Baker@nrc.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Janice E. Owens". The signature is fluid and cursive, with a large initial "J" and "O".

Janice E. Owens, Branch Chief  
Office of International Programs

**Enclosures:**

1. Thermo NITON report dated February 5, 2009
2. Thermo NITON self-disclosure letter dated February 21, 2007
3. Thermo NITON Reply to a Notice of Violation: EA-07-146 dated July 27, 2007

cc: (See page 3)

cc:

**Mr. Sean E. Oehlbert**  
**Global Regimes Program Director**  
**Office of Nonproliferation and International Security (NA-24)**  
**National Nuclear Security Administration**  
**U.S. Department of Energy**  
**1000 Independence Avenue, S.W.**  
**Washington, D.C. 20585-1615**

**Defense Threat Reduction Agency (OP-CSNSP)**  
**ATTN: Mr. David McDarby**  
**8725 John J. Kingman Road, MSC-6201**  
**Fort Belvoir, VA 22060-6201**

**LSS Technical Data Assessment & Teleforensics Center, DHS/CBP**  
**ATTN: Christopher Baugues**  
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**Herndon, VA 20170**

**Mr. Richard S. Goorevich, Director**  
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