June 28, 2007

EA-07-146

Corinne Mancevice
Assistant Radiation Safety Officer
Thermo Niton Analyzers LLC
900 Middlesex Turnpike, Building 8
Billerica, MA 01821

SUBJECT: NOTICE OF VIOLATION - SELF-DISCLOSURE OF UNREPORTED SHIPMENTS OF WELL LOGGING SOURCES CONTAINING AMERICIUM-241 IN VIOLATION OF 10 CFR 110.23

Dear Ms. Mancevice:

This refers to your letter dated February 21, 2007, notifying the Nuclear Regulatory Commission (NRC) of your failure to report exports of devices containing americium-241 covered by general license for calendar years 2002, 2003, 2004, 2005 and 2006. Specifically, contrary to 10 CFR 110.23(b)[1], between May 31, 2002, and December 30, 2006, you made 934 shipments of devices containing americium-241 under the general license established by 10 CFR 110.23(a) to 39 destinations but failed to submit by February 1st of each year one copy of a report of all americium shipments during the previous calendar year.

Based on the information you provided, the NRC has determined that a violation of the NRC requirements occurred. In accordance with NRC Enforcement Policy, this violation was categorized at Severity Level IV. The current edition of the Enforcement Policy can be found at the NRC Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html The violation is cited in the enclosed notice of Violation (Notice) and the criteria in section VI.A on the NRC Enforcement Policy were not met in that Thermo NITON Analyzers LLC (a) failed to initiate prompt and comprehensive corrective actions to prevent recurrence, and (b) the violation was repetitive as a result of inadequate corrective actions.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action" is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and

[1]10 CFR Part 110, Appendix L, lists americium-241 as byproduct material under NRC export/import licensing authority. 10 CFR 110.23(a) allows for the exports of byproduct material under a general license with specific exceptions. 10 CFR 110.23(b) states that persons making exports under the general license established by paragraph (a) of this section shall submit by February 1st of each year one copy of a report of all americium and neptunium shipments during the previous calendar year including (1) a description of the components keyed to the categories listed in Appendix A of this part, (2) approximate shipment dates, and (3) a list of recipient countries and end-users keyed to the items shipped.

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 Website 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/

Cynthia Carpenter, Director
Office of Enforcement

Docket No.

Enclosures:
1. Notice of Violation
2. Excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

cc:
U.S. Department of Energy
Office of Non-Proliferation Policy
ATTN: Sean Oehlbert
1000 Independence Avenue, SW
Washington, DC 20585

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

Customs & Border Protection
Attn: Christopher Baugues
LSS Technical Data Assessment & Teleforensics Center
12379 Sunrise Valley Drive, Suite C
Reston, Virginia 20191

U.S. Department of Energy, NA-243
Office of International Regimes and Agreements
ATTN: Mr. Richard S. Goorevich
1000 Independence Avenue, SW
Washington, DC 20585

U.S. Department of Energy, NA-243
Office of International Regimes and Agreements
ATTN: Ms. Ingrid Bruns
1000 Independence Avenue, SW
Washington, DC 20585

Bureau of Industry and Security
Office of Nuclear and Missile Technology
ATTN: Steve Clagett
14th Street & Penn Avenue, NW, Room 2631
Washington, DC 20230

NAC/NMMSS
ATTN: Michelle Romano
NMMSS
P.O. Box 922088
Norcross, GA 30010

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 Website 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/
Cynthia Carpenter, Director
Office of Enforcement

Docket No.

Enclosures:
1. Notice of Violation
2. Excerpt from NRC Information Notice 96-28,
"Suggested Guidance Relating to Development
and Implementation of Corrective Action"

cc: (See page 3)

DISTRIBUTION:
J. Dunn Lee, OIP
S. Dembek, OIP
S. Baker, OIP
B. Moran, NRC/NMSS
C. Carpenter, OE
D. Solorio, OE
L. Sreenivas, OE
OE Case File EA-07-146
OE Day File

File Name: C:\FileNet\ML071690197.wpd

ACCESSION NOS.: ML071660224 (Package),
ML071690121 (Incoming-Memo), ML071660237 (Incoming-2002), ML071660338 (Incoming-2003), ML071690046 (Incoming-2004), ML071690091 (Incoming-2005), ML071690106 (Incoming-2006), ML071690128 (Incoming-Spreadsheet), ML071690197 (Response)

* previously concurred
■ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ■ Non-Sensitive

OFFICE	OIP/ECIOB	OIP/ECIOB:BC	OIP:DD
NAME	S. Baker	S. Dembek	M. Doane
DATE	06/12/07	06/12/07	06/18/07

OFFICE	OE/EPPO	OE/EPPO:SC	OE:DD	OE:D
NAME	L. Sreenivas	D. Solorio	C. Carpenter for S. Magruder	C. Carpenter
DATE	06/28/07	06/29/07	06/28/07	06/28/07

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Thermo Niton Analyzers LLC
Billerica, MA EA-07-146

During the review of information you submitted to the NRC with your cover letter dated February 21, 2007, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> Between May 31, 2002 and December 30, 2006, Thermo Niton Analyzers LLC exported devices containing americium-241 on 934 occasions from their facility at 900 Middlesex Turnpike, Building 8, Billerica, MA 01821, but failed to submit by February 1st, one copy of a report of all americium shipments during the previous calendar year.
>
> 10 CFR Part 110, Appendix L, lists americium-241 as byproduct material under NRC export/import licensing authority. 10 CFR 110.23(a) allows for the exports of byproduct material under a general license with specific exceptions. 10 CFR 110.23(b) states that persons making exports under the general license established by paragraph (a) of this section shall submit by February 1st of each year one copy of a report of all americium and neptunium shipments during the previous calendar year including (1) a description of the components keyed to the categories listed in Appendix A of this part, (2) approximate shipment dates, and (3) a list of recipient countries and end-users keyed to the items shipped.
>
> Contrary to the above, between May 31, 2002 and December 30, 2006, Thermo Niton Analyzers LLC exported devices containing americium-241 on 934 occasions, but failed to submit by February 1st, one copy of a report of all americium shipments during the previous calendar year.
>
> This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Thermo Niton Analyzers LLC is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, 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 of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation: EA-07-146" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can

be made available to the public without redaction. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. 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 basis 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this ____day of _____ 2007

NOTE: The following information is an updated excerpt from NRC Information Notice 96-28 issued during 1996.

NRC INFORMATION NOTICE 96-28

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION

Addressees

All material and fuel cycle licensees.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Background

On June 30, 1995, NRC revised its Enforcement Policy, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VI.A of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence.

In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions.

The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:

    - Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.

    - Tours and observations of the area where the violation occurred, particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.

    - Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its

overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the **current** requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an record that can be audited and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.

2. Identify the root cause of the violation.

   Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns **and** prevent recurrence of the violation.

   It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, **immediate** corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?

2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?

3. Have precursor events been considered and factored into the corrective actions?

4. In the event of loss of radioactive material, should security of radioactive material be enhanced?

5. Has your staff been adequately trained on the applicable requirements?

6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?

7. Has your staff been notified of the violation and of the applicable corrective action?

8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?

9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?

10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?

12. Does your staff appreciate the need to consider safety in approaching daily assignments?

13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?

14. Have work hours affected the employees' ability to safely perform the job?

15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?

16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?

17. Has management established a work environment that encourages employees to raise safety and compliance concerns?

18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?

19. Has management communicated its expectations for safety and compliance?

20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

Robert C. Pierson, Director
Division of Fuel Cycle Safety and Safeguards
Office of Nuclear Material Safety and Safeguards

Donald A. Cool, Director
Division of Industrial and Medical Nuclear
Office of Nuclear Material Safety and Safeguards

Technical contacts: (Updated as of November 22, 2005)

Sally Merchant, Office of Enforcement
(301) 415-2747
Internet:slm2@nrc.gov

Daniel J. Holody, RI
(610) 337-5312
Internet:djh@nrc.gov

Carolyn Evans, RII
(404) 562-4414
Internet:cfe@nrc.gov

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