



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 7, 2005

Docket No. 03028619

License No. 37-23527-01G

William E. Lynch
President
Isolite Corporation
31 Waterloo Avenue
Berwyn, PA 19312

SUBJECT: INSPECTION 03028619/2005001, ISOLITE CORPORATION, BERWYN,
PENNSYLVANIA SITE AND NOTICE OF VIOLATION

Dear Mr. Lynch:

On September 7, 2005, Joseph Nick and Betsy Ullrich of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. The findings of the inspection were discussed with Bill Rowan and Edward Silverthorn of your organization at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Item A in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities and documented in a Notice of Violation enclosed with our letter dated September 15, 1999. Based on the results of this inspection, it appears that your corrective actions were not effective since this item has recurred. Recurrent and uncorrected violations are given additional weight in the consideration and selection of appropriate enforcement action. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material**; then **toolkit index page**. The Current General Policy and Procedure for NRC Enforcement Actions are included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement**

W. Lynch
Isolite Corporation

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Policy. Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Commonwealth of Pennsylvania

W. Lynch
Isolite Corporation

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	JNick/JLN		Eullrich/EXU		JDwyer/JPD			
DATE	signed on 9/16/2005		signed on 9/16/2005		10/7/2005			

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NOTICE OF VIOLATION

Isolite Corporation
Berwyn, PA

Docket No. 03028619
License No. 37-23527-01G

During an NRC inspection conducted on September 7, 2005, six violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189 (Subchapter A).

49 CFR 172.702 requires, in part, that each hazmat employer ensure that each hazmat employee is trained and tested at least once every three years, and that a hazmat employee may not perform any function subject to the requirements of Subchapter A unless instructed in the requirements of Subchapter A that apply to that function.

Contrary to the above, as of September 7, 2005, licensee employees transported licensed material outside the site of usage and did not have the required training and testing at least once every three years. Specifically, hazmat employees were last trained and tested June 1, 2001, and no training and testing were provided as of September 7, 2005, a period of greater than three years; and employees transported luminous devices containing tritium outside the site of usage during the period of June 1, 2004 through September 7, 2005.

This is a repeat violation.

This is a Severity Level IV violation (Supplement V)

- B. 10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license.

1. Condition No. 9 of License No. 37-23527-01G authorizes the licensee to receive, store, and re-distribute Shield Source, Inc. and Safety Light Corporation luminous devices which have been evaluated and approved for distribution to general licensees as defined by Sections 31.5 and 31.7 of 10 CFR Part 31, or the equivalent provisions of the regulations of an Agreement State.

Contrary to the above, as of September 7, 2005, for an unknown period of time, the licensee possessed an experimental model luminous device, Serial No. N2601, manufactured by Shield Source, Inc., containing tritium, and the experimental model was not evaluated and approved for distribution.

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

2. Condition No. 10 of License No. 37-23527-01G authorizes the licensee to store licensed material at 31 Waterloo Avenue, Berwyn, Pennsylvania.

Contrary to the above, the licensee stated that on various dates since the last inspection, they possessed material at locations other than 31 Waterloo Avenue, Berwyn, Pennsylvania, for sales demonstration purposes.

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

3. Condition No. 14 of License No. 37-23527-01G requires that the licensee conduct a physical inventory every six months to account for all sealed sources and/or devices received and possessed under the license; and that records of inventories shall be maintained for five years from the date of each inventory.

Contrary to the above, as of September 7, 2005, the licensee did not conduct a physical inventory every six months or maintain records as required. Specifically, since the last inspection in June 2000, a physical inventory was performed once in 2004 and once in 2005, and only one record of a physical inventory performed December 31, 2004, was maintained.

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

4. Condition No. 15 of License No. 37-23527-01 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated January 18, 2002, and the letter dated February 12, 2002, and December 16, 2004.

Appendix C, Item No. 8, of the application dated January 18, 2002, requires that all employees that would potentially handle luminous devices be provided training every three years about the types and effects of various forms of radiation and the shipping requirements; and that a test be given and kept on file.

Contrary to the above, as of September 7, 2005, training had not been provided at least every three years and tests were not kept on file. Specifically, the last training provided was on June 1, 2001, and tests were not maintained for review during the inspection; and no training was provided during the period of June 1, 2004 through September 7, 2005.

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

- C. 10 CFR 32.52(a) requires, in part, that each licensee report to the NRC, within 30 days of the end of each calendar quarter, all transfers of devices distributed to persons generally licensed pursuant to 10 CFR 31.5, and if no transfers were made, the report must so indicate.

Contrary to the above, as of September 7, 2005, reports of transfers to the NRC of devices distributed to general licensees pursuant to 10 CFR 31.5 were not in compliance with 10 CFR 32.52(a). Specifically, no reports of transfers were made since April 1999, and reports were not submitted to the NRC stating that no transfers were made since the first calendar quarter of 1999.

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

Pursuant to the provisions of 10 CFR 2.201, Isolite Corporation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, 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" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site.

Current NRC regulations and the General Policy and Procedure for NRC Enforcement Actions are available at the NRC web site at <http://www.nrc.gov/materials/miau/mat-toolkits.html> and <http://www.nrc.gov/what-we-do/regulatory/enforcement>, or by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays). To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated this 7th day of October 2005