



March 26, 2007

Q-5

Ms. Elizabeth Ullrich
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406-1415

Reference: Our letter of March 23, 2007 responding to your letter of February 15, 2007
Docket No. 030-28619
Control No. 139969

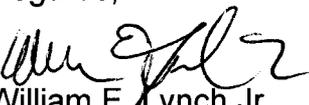
37-23527-016

Dear Ms. Ullrich,

The Revised License Application included with our letter of March 23, 2007 failed to include the required Model Designation information in the Table associated with Item 6. We therefore replace the Application to Distribute Generally Licensed Products – Revision #1 with the enclosed Revision #1.1.

We apologize for our oversight.

Regards,


William E. Lynch Jr.
President

Encl.

RECEIVED
REGION 1
2007 MAR 27 AM 10:24

139969

NMSS/RGN1 MATERIALS-002

Addendum to USNRC FORM 313

Application to Distribute Generally-Licensed Products: Revision #1

1. This is an application for: Amendment to 37-23527-01G

The purpose of this amendment is to convert the existing dual possession and distribution license to a distribution only, G-license. Possession and "manufacturing" of the products will be performed under a separate license, presently under application as mail control # 139970.

This license concerns distribution of self-luminous devices to persons generally licensed under §31.5 pursuant to §32.51, 51a, and 52 and luminous safety devices for use in aircraft to persons generally licensed under §31.7 pursuant to §32.53 through 56.

2. Applicant: Isolite Corporation
31 Waterloo Ave.
Berwyn, Pa. 19312

3. Address from which Licensed Material will be distributed:

Most of the generally-licensed products to be distributed under this Distribution License will be directly shipped from a Canadian manufacturer to our customers. A small amount of product will be shipped from the licensee's Berwyn location to customers.

a. Address of License: (location of distribution records and point of distribution of minor quantities of product):

Isolite Corporation 610-647-8200
31 Waterloo Ave.
Berwyn, Pa. 19312

b. Manufacturer of products and point of distribution of most of the products will be:

Shield Source, Inc. (CNSC license NSPFOL-12.02/2009)
Peterborough, Ontario, K9J6X6

Most of the generally-licensed products to be distributed under this Distribution License will be directly shipped from Shield Source, Inc. to customers. Only a small quantity of products will be stored at the Berwyn offices. This small quantity (less than 10000 Ci) includes a minimal sales inventory for urgent customer needs, sales displays and sample products. Possession of the inventory at Berwyn will be covered by a separate USNRC possession license (under application).

Regardless of the point of physical shipment to the customer (general licensee), the Isolite facility in Berwyn, Pa. will be the "official" importer of record and place of records maintenance for distribution of these products within the US. In addition, customers will not have to export the used devices back to Canada. They will be instructed to ship the used devices to Isolite in

California from which Isolite will consolidate and export the used devices back to Canada under the Isolite export license (application in progress).

4. Contact: William Lynch, President
610-647-8200

5. Radionuclide Material:

All products to be distributed will be manufactured using gaseous, elemental tritium. The products have as the basic light-producing component, a gaseous tritium light source (GTLS) which consists of a sealed glass tube or other glass shape containing elemental tritium.

6. Purpose for which licensed material will be used:

Type of Business

Isolite Corporation is a Pennsylvania-based corporation that specializes in the sale and distribution of self-luminous products based on tritium. Typically, the products are safety-oriented such as EXIT signs, egress markers, aircraft safety signs, etc. Most products are manufactured by Shield Source, Inc. (SSI), a Canadian firm, for Isolite as the US distributor.

All generally-licensed products shipped from both Berwyn and Canada will be distributed under this Distribution License. Records of shipments from both facilities will be kept on file at the Isolite offices in Berwyn, Pa.

Product Description

Two (2) general product types will be distributed:

- a. Commercial Signs: Products for the production of light for distribution as generally-licensed products under 10CFR32.51 and 31.5, including EXIT signs, light sources, aisle markers, warning signs, and any other devices as identified in the SSDR. Maximum activity not to exceed 25 curies per device.
- b. Aircraft Products: Luminous safety devices for use in aircraft for distribution as generally-licensed products under 10CFR32.53 and 31.7, including EXIT and warning signs, comparators, light sources, marker lights, and any other devices as identified in the SSDR. Maximum activity not to exceed 10 curies per device.

Isotope for all devices: tritium (H-3)

The products to be distributed are listed in the Registry of Radioactive Sealed Sources and Devices as follows:

SSD number	Device Type / Purpose	Manufacturer	Model Designations		Maximum Activity (Ci)
To be provided by NRC HQ	Light Modules and Luminous Devices	Shield Source, Inc	2000-XX 2040-XX 880-12-6-XX 101 2088 2090 2091 2092 2170 2171 SLX-60 DXT LTE-XX XT C3	L3 SL LE 602 604 616 758-14 758-B 758-D 758-H AC SERIES DB SERIES HM-99 618-5791 DB-45-COMPARATOR	25 (commercial signs) 10 (aircraft products)
NR-0579-D-101-G	Light Modules and Luminous Devices for Commercial Distribution	Safety Light, Inc.	2000-XX 2040-XX 880-12-6-XX 101 2088 2090 2091 2092 2170 2171 SLX-60 DXT LTE-XX XT C3 L3 SL LE		25
NR-0579-D-112-G	Aircraft Emergency Lights	Safety Light, Inc.	602 604 616 758-14 758-B 758-D 758-H AC SERIES DB SERIES HM-99 618-5791 DB-45 COMPARATOR		10

10. Radiation Safety Program

10.1 Quality Assurance

Isolite Corporation and Shield Source, Inc. (SSI) have developed and documented a joint Quality Management System (QMS). If Isolite makes use of other suppliers of self-luminous products, then this QMS would also apply to those vendors.

The Isolite/SSI QMS covers the design, production, and shipping of self-luminous products within the US, Canada, and other countries. Quality assurance (QA) of the manufacturing operation is performed by SSI under the SSI Quality Assurance Manual. The Isolite Quality Assurance Manual provides instructions for the oversight of the SSI QA implementation with respect to the Isolite-USNRC product registration certificates, guidance with respect to FAA QA requirements for aircraft products, and QA guidance for product distribution within the US.

The Isolite Quality Assurance program includes the inspection of the Shield Source Quality Assurance program to assure that the products being manufactured at SSI are manufactured in accordance with the applicable Sealed Source and Device Registries (SSDR).

The Isolite and SSI QA Manuals have been submitted as part of the SSDR application.

10.2 Reporting and information requirements

a. Commercial Signs: Isolite will provide transfer reports in accordance with 10 CFR 32.52(a) and (b) and will maintain records in accordance with 10 CFR 32.52(c). Isolite will provide information required by 10 CFR 32.51 a (a) and (b) to customers prior to shipment. A prototype letter is shown in Attachment A. The letter and the regulation excerpts shown in Attachment B will be sent to the customer responsible person separately from the product itself.

b. Aircraft Products: Isolite will provide annual material transfer reports in accordance with 10 CFR 32.56.

10.3 Device Return Procedure

Isolite will assign an RMA (Return Merchandise Authorization) Number for all authorized returns of product from customers. This number must be clearly identified on the outside of any carton or its acceptance will be refused. Prior to providing an RMA Number, the customer will be sent HAZMAT Training Instructions via fax or e-mail, as shown in Attachment C. We will require a signed copy of these instructions returned to us to confirm that they been trained in compliance with 49 CFR 172 Subpart H and agree to follow its direction before we will issue the required RMA Number.

With the RMA Number, customers are instructed to return used or unneeded products to the Isolite West facility in San Luis Obispo, Ca. which is licensed to do so under its California license. An example of the instructions is shown in Attachment C. To ensure that each package meets the design requirements of 49CFR 173.410, customers will be instructed to visually inspect each old sign. If the sign is intact, then we can conclude that the "active material is completely enclosed by non-active components". If the customer uses a shipping box that has never been used for radioactive materials and never has been in a controlled area, then as an alternative means per

173.443(a), we can logically conclude that the removable contamination would be at background which is far less than 220 dpm/sq.cm. Prior experience with thousands of returned self-luminous products at Shield Source, Safety Light and SPL has shown no detectable contamination on the exterior of any container.

The returned signs will be consolidated at the San Luis Obispo, Isolite facility and then shipped to Shield Source in Canada or another licensed facility for recycling or disposal. The Canadian shipments will be performed under a specific export license (Isolite application in process).

Customers with broken or damaged signs will be sent instructions on how to handle the damaged device. An example of the instructions is shown in Attachment C. The damaged sign will be sent to a licensed radioactive waste facility equipped to handle such packages or to Shield Source under the Isolite Export License (application in process).

Customers will also be instructed to report any incidents in accordance with 49CFR 171.15 & 171.16.

10.4 Labeling

Labeling of generally-licensed devices will be in accordance with 10CFR32.54.

An example of a 31.5 commercial exit sign label is shown below:

The receipt, possession, use and transfer of this device are subject to a general license or the equivalent and the regulations of the US NRC or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority.	
This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.	Caution: Radioactive
No leak test required. Distributed by Isolite Corporation. 610-647-8200	Material
Dispose of by licensed facility.	
DO NOT DISCARD.	
MODEL: _____ SER: _____ Contains _____ curies tritium h3 DMF ____ / ____	

An example of a 31.7 aircraft product label is shown below:

	CAUTION — RADIOACTIVE MATERIAL. Receipt, possession, use, and transfer of this device are subject to a general license and the regulations of the U.S. NRC or Agreement State.		
	Manufactured by Shield Source, Inc. Do not remove this label.		
	Distributed by Isolite Corporation 610-647-8200		
	PNR: _____	SER _____	DMF _____
	Contains _____ curies H3 (tritium)		

The exact wording used on a specific product may be different than that in the examples above. Small signs and aircraft devices may have truncated labeling depending on space limitations. Certain gauge markers (small glass dots mounted on a small metal disk) will only have the radiation symbol prescribed by 10CFR 20.1901.

12. Fees – see Form 313

13. Certification – see Form 313

ATTACHMENT A

EXAMPLE LETTER OF CUSTOMER OBLIGATIONS

REGULATORY OBLIGATIONS

<<Date>>

«Company»
«Address1»
«Address2»
«City», «State» «PostalCode»
«Country»

Attn: «Title» «FirstName» «LastName»

Reference: Purchase Order # for Self-Luminous EXIT signs

Dear «Title» «LastName»,

Congratulations! You have purchased the most energy efficient EXIT sign available today. These signs require no wiring, no batteries, no external power supply, no maintenance, and will meet all applicable fire safety codes for the next ___ years. In addition to thanking you for your business, we want to take this opportunity to make sure that you are aware of your obligations related to these signs.

Self-luminous signs are classified as Generally Licensed Devices by the Nuclear Regulatory Commission. As the owner of these signs, you become a General Licensee and are bound by the regulations for their proper use and disposal. These obligations are contained in the Code of Federal Regulations: Title 10, Section 31.5. We summarize your obligations as follows:

1. Report the loss or theft of any self-luminous sign(s) to your state regulatory authority or the US Nuclear Regulatory Commission (phone numbers are attached).
2. Retain records of the receipt, transfer or disposal of the sign(s) for a period of 3 years.
3. Do not sell, transfer, abandon or dispose of any sign(s) except by transfer to persons specifically licensed by the NRC or Agreement State unless such transfer involves the sale of the building or structure in which the sign(s) are already installed. Reports of transfers are required.

The primary goal of these requirements is to insure that self-luminous signs are handled in a responsible manner and that they do not end up in your trashcan or dumpster. In fact, the NRC is authorized to issue high civil penalties for improper disposal. Self-luminous signs must be sent to a facility licensed to handle their disposal, such as Isolite.

As part of our service program, we will contact you three months prior to the expiration of your sign's effective life to remind you of your disposal obligations and to assist you with the transfer and replacement of your signs. At present, we take back and dispose of any expired sign *free of charge* with the purchase of a replacement self-luminous sign. If, however, for some reason, you choose not to purchase a replacement, we will take back your expired sign for proper disposal for a charge of \$___. In either case, we will provide you with the paperwork required to fulfill your reporting requirements.

The complete text of the applicable regulations is enclosed. Call us with any questions and we'll help guide you. This is our business. We want to make it easy for you.

Regards,

Closing Signature

ATTACHMENT B

EXCERPTS FROM TITLE 10 CFR PROVIDED WITH:

§31.5 GENERALLY-LICENSED PRODUCTS

&

INFORMATION PROVIDED PER §31.51a TO RESPONSIBLE PERSON

**EXCERPTS FROM TITLE 10 CODE OF FEDERAL REGULATIONS UNITED STATES
 NUCLEAR REGULATORY COMMISSION PARTS 20, 30, AND 31
 AND NOTIFICATIONS TO GENERAL LICENSEES**

TITLE 10 - ENERGY

Chapter 1

PART 20- STANDARDS FOR PROTECTION AGAINST RADIATION

§ 20.2201 Reports of theft or loss of licensed material.

(a) Telephone reports. (1) Each licensee shall report by telephone as follows:
 (i) Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in appendix C to part 20 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or
 (ii) 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.
 (2) Reports must be made as follows:
 (i) Licensees having an installed Emergency Notification System shall make the reports to the NRC Operations Center in accordance with § 50.72 of this chapter, and
 (ii) All other licensees shall make reports by telephone to the NRC Operations Center (301-951-0550).
 (b). Written reports. (1) Each licensee required to make a report under paragraph (a) of this section shall within 30 days after making the telephone report, make a written report setting forth the following information:
 (i) A description of the licensed material involved, including kind, quantity and chemical and physical form; and
 (ii) A description of the circumstances under which the loss or theft occurred; and
 (iii) A statement of disposition, or probable disposition, of the licensed material involved; and
 (iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and
 (v) Actions that have been taken or will be taken, to recover the material; and
 (vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.
 (2) Reports must be made as follows:
 (i) For holders of an operating license for a nuclear power plant, the events included in paragraph (b) of this section must be reported in accordance with the procedures described in § 50.73(b), (c), (d), (e), and (g) of this chapter and must include the information required in paragraph (b)(1) of this section, and
 (ii) All other licensees shall make reports to the Administrator of the appropriate NRC Regional Office listed in appendix D to part 20.

(c) A duplicate report is not required under paragraph (b) of this section if the licensee is also required to submit a report pursuant to §§ 30.55(c), 40.64(c), 50.72, 50.73, 70.52, 73.27(b), 73.67(e)(3)(vi), 73.67(g)(3)(iii), 73.71, or § 150.19(c) of this chapter.

(d) Subsequent to filing the written report, the licensee shall also report any additional substantive information on the loss or theft within 30 days after the licensee learns of such information.

(e) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separated and detachable part of the report.

§ 20.2202 Notification of incidents.

(a) Immediate notification. Notwithstanding any other requirements for notification, each licensee shall immediately report any event involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause any of the following conditions —
 (i) An individual to receive —
 (i) A total effective dose equivalent of 25 rems (0.25 Sv) or more; or
 (ii) A lens dose equivalent of 75 rems (0.75 Sv) or more; or
 (iii) A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or
 (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(b) Twenty-four hour notification. Each licensee shall, within 24 hours of discovery of the event, report any event involving loss of control of licensed material possessed by the licensee that may have caused, or threatens to cause, any of the following conditions:
 (1) An individual to receive, in a period of 24 hours—
 (i) A total effective dose equivalent exceeding 5 rems (0.05 Sv); or
 (ii) A lens dose equivalent exceeding 15 rems (0.15 Sv); or
 (iii) A shallow-dose equivalent to the skin or extremities exceeding 50 rems (0.5 Sv); or
 (2) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake in excess of one occupational annual limit on intake (the provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures).

(c) The licensee shall prepare any report filed with the Commission pursuant to this section so that names of individuals who have

received exposure to radiation or radioactive material are stated in a separate and detachable part of the report.

(d) Reports made by licensees in response to the requirements of this section must be made as follows:

(1) Licensees having an installed Emergency Notification System shall make the reports required by paragraphs (a) and (b) of this section to the NRC Operations Center in accordance with 10 CFR 50.72; and

(2) All other licensees shall make the reports required by paragraph (a) and (b) of this section by telephone to the NRC Operations Center (301) 816-5100.

(e) The provisions of this section do not include doses that result from planned special exposures, that are within the limits for planned special exposures, and that are reported under § 20.2204.

PART 30 - RULES OF GENERAL APPLICABILITY TO LICENSING OF BYPRODUCT MATERIAL

§ 30.34 Terms and conditions of licenses.

(a) Each license issued pursuant to the regulations in this part and Parts 31 through 36 and 39 of this chapter shall be subject to all the provisions of the Act, now or hereafter in effect, and to all valid rules, regulations and orders of the Commission.

(b) No license issued or granted pursuant to the regulations in this part and Parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily; directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

(c) Each person licensed by the Commission pursuant to the regulations in this part and Parts 31 through 36 and 39 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to the regulations in this part and Parts 31 through 36 and 39 of this chapter shall carry with it the right to receive, acquire, own, and possess byproduct material. Preparation for shipment and transport of byproduct material shall be in accordance with the provisions of Part 71 of this chapter.

(d) Each license issued pursuant to the regulations in this part and Parts 31 through 36 and 39 shall be deemed to contain the provisions set forth in section 183b-d., inclusive, of the Act, whether or not these provisions are expressly set forth in the license.

(e) The Commission may incorporate, in any

license issued pursuant to the regulations in this part and Parts 31 through 36 and 39, at the time of issuance, or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use and transfer of byproduct material as it deems appropriate or necessary in order to:

- (1) Promote the common defense and security;
- (2) Protect health or to minimize danger to life or property;
- (3) Protect restricted data,
- (4) Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and regulations thereunder.

§ 30.51 Records.

(a) Each person who receives byproduct material pursuant to a license issued pursuant to the regulations in this part and Parts 31 through 36 and 39 of this chapter shall keep records showing the receipt, transfer, and disposal of the byproduct material as follows:

(1) The licensee shall retain each record of receipt of byproduct material as long as the material is possessed and for three years following transfer or disposal of the material.

(2) The licensee who transferred the material shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this chapter dictates otherwise.

(3) The licensee who disposed of the material shall retain each record of disposal of byproduct material until the Commission terminates each license that authorizes disposal of the material.

(b) The licensee shall retain each record that is required by the regulations in this part and Parts 31 through 36 and 39 of this chapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record must be retained until the Commission terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c)(1) Records which must be maintained pursuant to this part and Parts 31 through 36 and 39 of this chapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Commission regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials and signatures. The licensee shall maintain

Appendix D to part 20 — United States Nuclear Regulatory Commission Regional Offices

	Address	Telephone (24 hour)
Region I: Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Vermont.	USNRC, Region I, 475 Allendale Road, King of Prussia, PA 19406.	(610) 337-5000, (FTS) 346-5000.
Region II: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee, Virginia, Virgin Islands and West Virginia.	USNRC, Region II, Atlanta Federal Center, 61 Forsyth Street, SW., Suite 23T85, Atlanta, GA 30303.	(404) 562-4400.
Region III: Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin.	USNRC, Region III, 801 Warrenville Road, Lisle, IL 60532-4351.	(708) 829-9500, (FTS) 829-9500.
Region IV: Alaska, Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Kansas, Louisiana, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wyoming and the U.S. territories and possessions in the Pacific.	USNRC, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, TX 76011	(817) 860-8100 (FTS) 728-8100.
Region IV: Field Offices	USNRC, Region IV, Walnut Creek Field Office, 1450 Marie Lane, Suite 300, Walnut Creek, CA 94596.	(510) 875-0200.

adequate safeguards against tampering with and loss of records.

(2) If there is a conflict between the Commission's regulations in this part and Parts 31 through 36 and 39 of this chapter, license condition, or other written Commission approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this part and Parts 31 through 36 and 39 of this chapter for such records shall apply unless the Commission, pursuant to §30.11, has granted a specific exemption from the record retention requirements specified in the regulations in the part or Parts 31 through 36 and 39 of this chapter.

(d) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the appropriate NRC Regional Office:

(1) Records of disposal of licensed material made under §§20.2002 (including burials authorized before January 28, 1981¹), 20.2003, 20.2004, 20.2005; and

(2) Records required by §20.2103(b)(4).

(e) If licensed activities are transferred or assigned in accordance with §30.34(b), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under §§20.2002 (including burials before January 28, 1981¹), 20.2003, 20.2004, 20.2005; and

(2) Records required by §20.2103(b)(4).

(f) Prior to license termination, each licensee shall forward the records required by §30.35(g) to the appropriate NRC Regional Office.

§30.52 Inspections.

(a) Each licensee shall afford to the Commission at all reasonable times opportunity to inspect byproduct material and the premises and facilities wherein byproduct material is used or stored.

(b) Each licensee shall make available to the Commission for inspection, upon reasonable notice, records kept by him pursuant to the regulations in this chapter.

§30.53 Tests.

Each licensee shall perform, or permit the Commission to perform, such tests as the Commission deems appropriate or necessary for the administration of the regulations in this part and Parts 31 through 36 and 39 of this chapter, including tests of:

(a) Byproduct material;

(b) Facilities wherein byproduct material is utilized or stored;

(c) Radiation detection and monitoring instruments; and

(d) Other equipment and devices used in connection with the utilization or storage of byproduct material.

ENFORCEMENT

§30.61 Modification and revocation of licenses.

(a) The terms and conditions of each license issued pursuant to the regulations in this part and Parts 31 through 35 of this chapter shall be subject to amendment, revision or modification by reason of amendments to the Act, or by reason of rules, regulations and orders issued in accordance with the terms of the Act.

(b) Any license may be revoked, suspended or modified, in whole or in part, for any material false statement in the application or any statement of fact required under section 182 of the Act, or because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission to refuse to grant a license on an original application, or

for violation of, or failure to observe any of the terms and provisions of the Act or of any rule, regulation or order of the Commission.

(c) Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended or revoked unless prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

§30.62 Right to cause the withholding or recall of byproduct material.

The Commission may cause the withholding or recall of byproduct material from any licensee who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission, or who uses such materials in violation of law or regulation of the Commission, or in a manner other than as disclosed in the application therefor or approved by the Commission.

§30.63 Violations.

(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974, as amended; or

(3) A regulation or order issued pursuant to those Acts.

(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act:

(1) For violation of—

(i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954 as amended;

(ii) Section 206 of the Energy Reorganization Act;

(iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section;

(iv) Any term, condition, or limitation of any license issued under the sections specified in paragraph (b)(1)(i) of this section.

(2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.

§31.5 Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere.²

(a) A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of paragraph (b), (c) and (d) of this section, byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

(b)(1) The general license in paragraph (a) of this section applies only to byproduct material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in

(i) A specific license issued under to §32.51 of this chapter; or

(ii) An equivalent specific license issued by an Agreement State.

(2) The devices must have been received from one of the specific licensees described in paragraph (b)(1) of this section or through a transfer made under paragraph (c)(9) of this section.

(c) Any person who acquires, receives, possesses, uses or transfers byproduct material in a device pursuant to the general license in

paragraph (a) of this section:

(1) Shall assure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

(5) Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 becquerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under parts 30 and 32 of this chapter or by an Agreement State.

The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the byproduct material in the device or as otherwise approved by the Commission. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable radioactive material or failure of or damage to source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and the environs are acceptable for unrestricted use, must be furnished to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days. Under these circumstances the criteria set out in §20.1402, "Radiological criteria for unrestricted use," may be applicable, as determined by the Commission on a case-by-case basis;

(6) Shall not abandon the device containing byproduct material;

(7) Shall not export the device containing byproduct material except in accordance with Part 110 of this chapter;

(8)(X) Shall transfer or dispose of the device containing byproduct material only by export as provided by paragraph (c)(7) of this section, by transfer to another general license as authorized in paragraph (c)(9) of this section, or to a person authorized to receive the device by a specific license issued under parts 30 and 32 of this chapter, or part 30 of this chapter that authorizes waste collection, or equivalent regulations of an Agreement State, or as otherwise approved under paragraph (c)(8)(iii) of this section.

(ii) Shall furnish a report to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days after the transfer of a device to a specific licensee or export. The report must contain—

(A) The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number,

(B) The name, address, and license number of the person receiving the device (license number not applicable if exported); and

(C) The date of the transfer.

(iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(i) of this section.

(9) Shall transfer the device to another general licensee only if—

(i) The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of this section, a copy of §§31.2, 30.51, 20.2201, and 20.2202 of this chapter, and any safety documents identified in the label of the device. Within 30 days of the transfer, the transferor shall report to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001—

(A) The manufacturer's (or initial transferor's) name;

(B) The model number and the serial number of the device transferred;

(C) The transferee's name and mailing address for the location of use; and

(D) The name, title and phone number of the responsible individual identified by the transferee in accordance with paragraph (c)(12) of this section to have knowledge of and authority to take actions to ensure compliance with the appropriate regulations and requirements; or

(ii) The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

(10) Shall comply with the provisions of §§20.2201, and 20.2202 of this chapter for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of parts 19, 20 and 21, of this chapter.

(11) Shall respond to written requests from the Nuclear Regulatory Commission to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by submitting a letter to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 and provide written justification as to why it cannot comply.

(12) Shall appoint an individual responsible for having knowledge of the appropriate regulations and requirements and the authority for taking required actions to comply with appropriate regulations and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate regulations and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

(14) Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the Director of Nuclear Material Safety and Safeguards, ATTN: GLTS, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 within 30 days of the effective date of the change. For a portable device, a report of address change is only required for a change in the device's primary place of storage.

(15) May not hold devices that are not in use for longer than 2 years. If devices with shutters are not being used, the shutter must be locked in the closed position. The testing required by paragraph (c)(2) of this section need not be performed during the period of storage only. However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use. Devices kept in standby for future use are excluded from the two-year time limit if the general licensee performs quarterly physical inventories of these devices while they are in standby.

(d) The general license in paragraph (a) of this section does not authorize the manufacture or import of devices containing byproduct material.

² Persons possessing byproduct material in devices under the general License in §31.5 before Jan. 15, 1975, may continue to possess, use or transfer that material in accordance with the requirements of §31.5 in effect on Jan 14, 1975.

NOTIFICATIONS TO GENERAL LICENSEES

(a) Exit signs can only be disposed of by sending the sign back to a specific licensee (the manufacturer of the sign) or at an approved site licensed to accept radioactive materials. It is NRC's policy to issue civil penalties for improper disposal.

(b) As part of our ongoing service program, we will contact you three months prior to the expiration of your signs effective life to remind you of your disposal requirements and to assist you with the transfer and replacement of your signs. Our return policy and costs associated with it can be found on our web site (<http://www.isolite.com/aboutluminous.htm>)

AGREEMENT STATE AUTHORITIES

USE OF SELF-LUMINOUS SAFETY MARKERS IS REGULATED BY THESE
AGREEMENT STATE AUTHORITIES UNDER REQUIREMENTS SUBSTANTIALLY THE
SAME AS THOSE REQUIREMENTS IN TITLE 10CFR PART 31

ALABAMA:
Phone: (334) 206-5391
Kirkaey E. Whitley, Director
Office Of Radiation Control
Alabama Dept. Of Public Health
The Rea Tower, Suite 700
P.O. Box 303017
Montgomery, AL 36130-3017

ARIZONA:
Phone: (602) 255-4845
Aubrey V. Godwin, Director
AZ Radiation Regulatory Agency
4614 S 40th St, Phoenix, AZ 85040

ARKANSAS:
Phone: (501) 661-2301
Fax: (501) 661-2468
David Snellings, Director
Radiation Control & Emer. Mgmt
Dept. Of Health
4815 W Martham St, Slot 30
Little Rock, AR 72205-3876

CALIFORNIA:
Phone: (916) 323-5027
Fax: (916) 324-3810
Gary Butler
Radiologic Health Branch
Attn: General Licensing
P.O. Box 942732
Ca Dept. Of Health Svcs.
Sacramento, CA 94234-7320

COLORADO:
Phone: (303) 692-3090
Fax: (303) 759-5355
Warren E. Jacobi
Laboratory & Radiation Svcs Div.
Dept. Of Public Health & Environ.
8100 Lowry Blvd
Denver, CO 80220-6928

FLORIDA:
Phone: (850) 245-4545
Fax: (850) 921-6384
Wm. A. Passetti, Chief
Bureau Of Radiation Control
Fl Dept. Of Health
4052 Bald Cypress Way, Bin C21
Tallahassee, FL 32309-1741

GEORGIA:
Phone: (404) 382-2675
Fax: (404) 382-2853
Thomas EL Hill, Manager
Radioactive Materials Program
Dept. Of Natural Resources
4244 Intl. Parkway, Suite 114
Atlanta, GA 30354

IDAHO:
Phone: (208) 334-5879
Brian Monson
Compliance Section
Idaho Dept. Of Health & Welfare
Statehouse
Boise, ID 83720

ILLINOIS:
Phone: (217) 785-8868
Fax: (217) 524-4724
Thomas W. Orfinger, Director
Illinois Dept. Of Nuclear Safety
1035 Outer Park Dr
Springfield, IL 62704

IOWA:
Phone: (515) 281-3478
Fax: (515) 242-8284
Donald A. Pitar, Chief
Bureau Of Radiological Health
Dept. Of Public Health
Lucas State Office Bldg.
Des Moines, IA 50319

KANSAS:
Phone: (913) 296-1561
Fax: (913) 296-0984
Vick L. Cooper, Chief
Radiation Control Program
Ks Dept. Of Health & Environ.
Bureau Of Air & Radiation
Topeka, KS 66620

KENTUCKY:
Phone: (502) 584-3700
Fax: (502) 584-6533
John A. Volpe, Manager
Radiation & Toxic Agents
Control Branch, Cabinet For
Health Svcs, 275 E Main St
Frankfort, KY 40621-0001

LOUISIANA:
Phone: (225) 765-0160
Fax: (225) 785-0220
Wm. H. Spell, Admn.
Radiation Protection Div.
Office Of Radiation Protection
7220 Bluebonnet Rd. P.O. Box 82135
Baton Rouge, LA 70884-2135

MAINE:
Phone: (207) 287-5698
Fax: (207) 287-4172
Jay Hyland, Program Mngr
Radiation Control Program
Div. Of Health Engineering
10 State House Station
Augusta, ME 04333

MARYLAND:
Phone: (410) 631-3300
Fax: (410) 631-3198
Roland G. Fletcher, Manager
Radiological Health Program
Air & Radiation Mngmt Admn.
MD Dept. Of The Environment
2500 Broening Hwy.
Baltimore, MD 21224

MASSACHUSETTS:
Phone: (617) 727-8214
Fax: (617) 727-2098
Robt. M. Halliley, Director
Radiation Control Program
Dept. Of Public Health
174 Portland St, 5th Floor
Boston, MA 02114

MISSISSIPPI:
Phone: (801) 354-6657
Fax: (601) 354-6167
Robt. W. Goff, Director
Div. Of Radiological Health
3150 Lawson St, P.O. Box 1700
Jackson, MS 39215-1700

NEBRASKA:
Phone: (402) 471-2133
Fax: (402) 471-0820
Radioactive Matls. Program Manager
Dept. Of Regulation & Licensure
No Health & Human Svcs System
301 Centennial Mall, P.O. Box 95007
Lincoln, NE 68509-5007

NEVADA:
Phone: (702) 887-5394
Fax: (702) 887-5751
Stanley R. Marshall, Supervisor
Radiological Health Sec., Health Div.
Dept. Of Human Resources
1179 Fairview Dr, Suite 102
Carson City, NV 89701-5405

NEW HAMPSHIRE:
Phone: (603) 271-4588
Fax: (603) 225-8325
Diane E. Tefft, Administrator
Radiological Health Bureau
Div. Of Public Health Svcs
Health & Welfare Bldg, 6 Hazen Dr
Concord, NH 03301-8527

NEW MEXICO:
Phone: (505) 827-1557
Fax: (505) 827-1544
Benito Garcia, Chief
Bureau Of Haz. & Radioactive Materials
Water & Waste Mngmt Div., Dept. Of Env.
2044 Galisteo Rd, P.O. Box 28110
Santa Fe, NM 87502

NEW YORK:
Phone: (518) 457-1202
Fax: (518) 485-7408
Rita Aldrich, Principal Radiophysicist
Radiological Health Unit, Ny State
Dept. Of Labor, Ny State Office Campus
Bldg. 12, Room 134a
Albany, NY 12240

NORTH CAROLINA:
Phone: (919) 571-4141
Fax: (919) 751-4148
Richard M. Fry, Director
Div. Of Radiation Protection
Dept. Of Environ. & Natural Resources
3825 Barrett Dr
Raleigh, NC 27609-7221

OHIO:
Phone: (614) 644-2727
Mr. Roger L. Suppes, Chief
Bureau Of Radiation Protection
Ohio Dept. Of Health
P.O. Box 118
Columbus, Oh 43266-0118

Oregon:
Phone: (503) 731-4014
Fax: (503) 731-4081
Ray D. Paris, Manager
Radiation Protection Svcs
880 N.E. Oregon St, Suite 280
Portland, OR 97232

RHODE ISLAND:
Phone: (401) 222-2438
Fax: (401) 222-2458
Marie Stoeckel, Chief
Div. Of Occupational & Radiological
Health, Dept. Of Health
3 Capitol Hill, Room 206
Providence, RI 02908-5097

SOUTH CAROLINA:
Phone: (803) 896-4244
Fax: (803) 896-4242
T. Pearce O'Kelleys, Chief
Radiological Health Branch
Sc Dept. Of Health & Environ. Control
2900 Bull St
Columbia, SC 29201

TENNESSEE:
Phone: (615) 532-0360
Fax: (615) 532-7938
Michael H. Mobley, Director
Div. Of Radiological Health
Tn Dept. Of Environ. & Conservation
LAC Annex, 3rd Floor
401 Church St
Nashville, TN 37243-1532

TEXAS:
Phone: (512) 834-8688 Ext. 2210
Fax: (512) 3239-8362
Mr. Philip Shaver, Director
Texas Dept. Of Health
Bureau Of Radiation Control
1100 W 49th St
Austin, TX 78756-3189
Phil.Shaver@Tdh.State.Tx.Us

UTAH:
Phone: (801) 536-4250
Fax: (801) 533-4067
Wm. J. Sinclair, Director
Div. Of Radiation Control
Dept. Of Environmental Quality
188 N 1960 West
P.O. Box 144850
Salt Lake City, UT 84114-4850

WASHINGTON:
Phone: (360) 236-3210
Fax: (360) 236-2255
John L. Erickson, Director
Div. Of Radiation Protection
Dept. Of Health, P.O. Box 47827
7171 Clean Water Lane
Olympia, WA 98504-7827

WISCONSIN:
Phone: (608) 267-4797
Fax: (608) 267-3695
dnhs.wisconsin.gov
Paul Schmidt, Chief
Dept. Of Health & Family Svcs.
Div. Of Public Health
1 West Wilson Street
P.O. Box 2659
Madison, WI 53701-2659

ATTACHMENT C

**EXAMPLE INSTRUCTIONS FOR HANDLING RETURNED PRODUCTS
&
DOT HAZMAT TRAINING**



PACKAGING INSTRUCTIONS
FOR THE RETURN OF SELF-LUMINOUS EXIT SIGNS

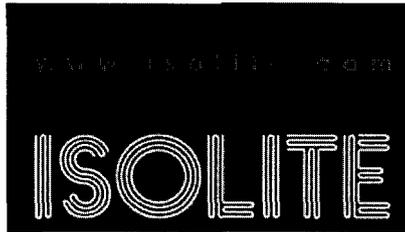
- Obtain RMA# (Return Merchandise Authorization #) from Isolite. Ensure that you have completed the DOT Hazmat Training Sheet from Isolite.
- Visually inspect each sign to ensure that it is not crushed or punctured in a way that might cause an inner light-producing tube to be broken. Just like a bottle of insecticide or drain cleaner, as long as the container is intact, you don't have to worry about any hazardous material on the outside of the container.
- Pack the signs in a clean, sturdy cardboard carton or in a plastic or steel pail or drum. Ensure that the container is brand new or, if used, has never been used near any radioactive materials.
- Limit the number of signs in each carton so that the total amount of tritium in the carton is less than 200 curies. See each individual sign label for curie content and add them up.
- Use filler materials to assure a tight, rattle-free fit.
- If using cardboard, tape & seal the flaps and seams, place this package into a second sturdy cardboard carton, use filler materials to assure a tight fit, and tape & seal the outer carton flaps and seams.
- The following items must appear on the outer-package or label:
 1. **Shipper's Address (your return address)**
 2. **Consignee's Address (Isolite in California - see below)**
 3. **"UN2911" on a label or handwritten in bold marker**
 4. **The RMA #**
- Send to our licensed facility:
Isolite Corporation
ATTN: Health Safety Officer
3563 Sueldo, Suite M
San Luis Obispo, Ca 93401



DO NOT SHIP USPS

HEADQUARTERS • 31 Waterloo Avenue • Berwyn, PA 19312 • 800-888-5483 • 610-647-8200 • FAX 610-296-8952
WESTERN OFFICE • 3563 Sueldo, Suite M • San Luis Obispo, CA 93401 • 800-799-5343 • 805-546-9669 • FAX 805-546-9564

RETURN SIGN Packaging Instructions ISOLITE - 03-23-07.doc



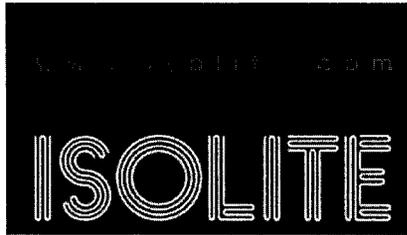
DAMAGED SIGN CLEANUP INSTRUCTIONS

FOR DAMAGED SELF-LUMINOUS EXIT SIGNS

- > **Wear rubber gloves and eye protection:** you may come in contact with broken glass

- > **There is a small amount of non-hazardous radioactive material in the sign:** it can be cleaned-up as you would a small amount of spilled insecticide or drain cleaner.

-
- If the area is a small room, open the doors and windows to allow in fresh air. If the area is a warehouse or large room, no special ventilation is necessary.
 - Using gloves, place the damaged sign and any fragments into a plastic bag (ie: garbage bag) and tape it closed.
 - DO NOT use a broom or vacuum cleaner to clean up small sign fragments - use a moisten paper towel.
 - Place cleanup towels and your gloves into another plastic bag and seal with tape.
 - Wash your hands with soap and water
 - Place the bag with the sign and the bag with your cleanup materials into a third plastic bag and tape it closed
 - Wash your hands with soap and water
 - Package and ship the bagged sign using instructions in the sheet entitled: "Isolite Packaging Instructions for the Return of Self-Luminous EXIT Signs".



DOT Hazmat Training and Acknowledgement

FOR RETURN OF SELF-LUMINOUS EXIT SIGNS

- > **Self-Luminous EXIT signs are illuminated with internal light sources powered by tritium gas. Tritium gas is a radioactive isotope of hydrogen. For this reason, Federal Regulations require that any person shipping this product must have training sufficient to comply with US Department of Transportation regulations in the Code of Federal Regulations #49 Part 172.**
- > **To receive this training, the shipper must read, understand and perform the following steps. Place a check mark at each step after complete. Sign and date this form. Upon receipt of this completed form we will provide you with the RMA Number required for the return of these signs and complete shipping instructions.**
- > **Keep this completed form in your files for at least 3 years in case of regulatory inspection.**

- The EXIT signs are to be shipped as excepted packages for radioactive instruments and articles (49CFR 173.424). No special packaging is necessary.
- A sturdy cardboard box, plastic drum, or metal drum will be sufficient to ship the signs because they all meet the general package design requirements of 49CFR173.410. The package must withstand normal conditions of transport without any deterioration. The container must be clean and never have been near other radioactive material so that the shipper can be sure that there is no radioactive contamination on the outside of the container.
- You must ensure that the active materials (the glowing inner tubes) are completely enclosed by non-active components (the plastic sign housing). Therefore, each sign must be visually inspected to ensure that it is not crushed or punctured in a way that might cause an inner light tube to be broken.
- Each sign must contain less than 20 curies of tritium (see the sign's rear label). The total amount of curies to be placed into each container must be less than 200 Ci. (Add up the curie content of each sign as you put them into the container.)
- If a transportation incident occurs, you must report the incident to the USDOT per 49 CFR 171.15 and 171.16.
- Read and understand the Isolite "Packaging Instructions" and follow each step exactly.

Name (Printed)

Company

Signature

Date

If you have any questions, call Isolite at 800-888-5483.