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March 27, 2007

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

MSIB
Q-5

Reference: Your letter of February 26, 2007
Docket No. 030-37392
Control No. 139970

37-23527-02

Dear Ms. Ullrich,

We respond to your request for additional information concerning our recent license application below. In addition, we enclose Revision #1 of our Application to Possess Radioactive Materials. This revision includes the necessary modifications to comply with the issues raised in your letter.

1. Yes, Isolite intends to be the initial importer and distributor of self-luminous products. This is clarified in the enclosed license application under item 6. If NRC wishes to specify Isolite as a "manufacturer" for regulatory purposes, that is acceptable. Please note that Isolite is not an actual manufacturer, i.e., no physical manufacturing process will be conducted by Isolite at any facility.

   In our first application submission in January, 2007, we used the gauge license guidance (NUREG-1556, Vol. 1) based on what we thought was your suggestion in our teleconference of December 11, 2006. The idea at the time was that our self-luminous devices would be carried to remote sites (trade shows), similar to gauge licensees carrying gauges in the field. We assumed that all distribution aspects of licensing would be addressed in our distribution license application (37-23527-01G). Nevertheless, we have now modified the possession license application to address the requirements in both NUREG-1556 Vol. 1 and Vol. 12 per your request.

2. Yes, we confirm that possessing and using the self-luminous products at trade shows and customer sales calls are specific license events.

   a. A statement to this effect has been included under Item 6.2 of the revised application.

   b. Model numbers have been included in Table 5.1 of the application. However, we request that model numbers not be included on the new

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NMSS/RGN1 MATERIALS-002

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

distribution and manufacturing/possession licenses, as they are not specifically listed on the present license (37-23527-01G). In this way, models added to the SSD in the future, will be covered under the licenses without the need to file amendments.

c. Each device to be distributed (Table 5.1) and to be possessed (Table 5.2) is or will be registered by the NRC or an Agreement State before distribution commences in late 2007. Please note that in our teleconference of December 11, 2006, you initially required that the SSD be issued before you would issue the licenses and Dr. Jankovich required that the licenses be issued before he would issue the SSD. At the time, you both agreed to cooperate and simultaneously issue the SSD from headquarters and the possession and distribution licenses from Region I so that the process could be expedited more smoothly.

3. We are presently licensed for possession of 20,000 Ci and presently possess less than 3000 Ci. However, upon further estimation of future needs, we wish to change the possession limit of 3,000 Ci initially requested to 10,000 Ci in Item 5.1 of the enclosed Revision #1.

4. Yes, we have corrected the application to include possession of a small quantity of products for G-distribution.

5. Isolite is not the initial importer and distributor of gun sights in the U.S,. therefore we do not require an E-license to re-distribute this product. The application has been modified to clarify this. We do, however, request the ability to possess and re-distribute any licensed devices on valid E licenses.

6. Yes, in Item 5.2 of the original application, we erroneously stated that the financial assurance threshold is 10 Ci of unsealed tritium when in fact it is 1 Ci.

   a. If it were necessary to possess any loose tritium, Isolite would apply for a license amendment for such. However, Isolite has no intention to possess loose tritium in any form, especially as surface contamination.

   b. We do not foresee any way in which Isolite could possess more than 1 Ci of loose tritium for the reasons stated in item 5.2 of Revision #1, thus no financial assuredness is necessary.

   c. In Item 5.2 of Revision #1, an additional statement was added to specify that Isolite will keep specific records of broken device incidents.

7. Temporary job sites:

   a. In item 6.2, Isolite confirms that self-luminous products taken to trade shows or customer sites do not fall under general license purview but must be controlled by specific license requirements.

b. In item 6.2, Isolite confirms that this license would apply to locations in NRC jurisdiction and that reciprocity must be obtained for locations in Agreement States.

8. In Item 6.3 of Revision #1, we confirm that the quality assurance activities required to meet the requirements for aircraft products will be performed at the manufacturer, Shield Source, Inc. in Canada. Isolite will ensure that 10CFR32.53 to 32.56 requirements or NRC approved alternatives are met at Shield Source via the Isolite / SSI Quality Management System (QMS).

9. Item 6.3 of Revision #1 states that the requirements in 10 CFR 32.51, 51a, and 52 and 10CFR 32.53 to 32.56 or NRC approved alternatives will be met by the QMS. This information has been provided to the NRC Headquarters as part of our Sealed Source and Device Registration Certificate Application.

10. Item 6.2 of Revision #1 states that personnel from related companies must undergo the same training as Isolite personnel if they are to use devices at trade shows and customer sites. The President of Isolite has authority over all personnel from each of the related companies, thus each employee is obligated to meet all radiation safety guidelines as specified by the Isolite President and his designate, the Radiation Safety Officer.

11. Item 7.1 has been modified to indicate that Isolite is undergoing a personnel search for a fulltime RSO / QA Manager. Upon location of a suitable candidate (by mid-2007), Isolite will submit his or her qualifications to NRC for review at that time. Until a qualified individual has been hired and approved by NRC, William Lynch, presently RSO under 37-23527- 01G, will continue the RSO duties.

12. Personnel who will handle radioactive materials are listed in Item 7.3 along with their duties and most recent training.

13. Item 8 of Revision #1 has been modified consistent with your request.

14. Item 9 of Revision #1 has been modified to show shipping and receiving areas and has been drawn to scale.

15. Item 10.1 of Revision #1 has been modified consistent with your request.

16. Item 10.1 of Revision #1 has been modified consistent with your request.

17. Item10.4 of Revision #1 has been modified consistent with your request.

18. Item 10.4 of Revision #1 also describes the steps that will be taken to maintain security of devices while at remote job sites.

19. Item 10.5 of Revision #1 has been modified consistent with your request.

20. Item 10.6 of Revision #1 has been modified and expanded consistent with your request.

21. Item 10.7 of Revision #1 has been modified consistent with your request.

22. Item 10.7 of Revision #1 has been modified consistent with your request.

23. Item 10.9 of Revision #1 has been modified to discuss inspection of devices and surveys.

24. Item 11of Revision #1 has been modified to include clean-up materials.

25. Item 11of Revision #1 has been modified to specify that used devices will be returned via a specific export license.

We trust that the above responses and the corresponding modifications to our Application in the enclosed Revision #1 address the issues raised in your letter. Please contact me if you have any questions.

Regards,

William E. Lynch Jr.
President

Encl.

Addendum to USNRC FORM 313

Application to Possess Radioactive Materials

1. This is an application for: New License (expected #: 37-23527-02)

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

3. Address at which Licensed Material will be used or possessed:

Isolite Corporation
31 Waterloo Ave.
Berwyn, Pa. 19312

And

At trade shows and client sites as product sales displays

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

5. Radionuclide Material:

5.1 Sealed Sources and Devices

Nuclide: Hydrogen-3 Possession limit: 3.7E8 MBq (10,000 Ci)

Chemical / Physical Form: Sealed Sources

The radioactive material will be gaseous, elemental tritium (hydrogen-3) contained in self-luminous products. 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. Each sealed source, device, and source/device combination will be registered as an approved sealed source or device by NRC or an Agreement State. The activity per source and maximum activity in each device will not exceed the maximum activity listed on the approved certificate of registration (see Table 5.1 and 5.2 below).

Table 5.1 - G-Distribution Devices to be possessed

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

Table 5.2 – Other Radioactive Materials to be Possessed

SSD number	Device Type / Purpose	Manufacturer	Model Designations	Maximum Activity (Ci)
As Assigned to manufacturer/initial importer by NRC	Exempt Gun Sights for re-sale	Any licensed manufacturer	Any licensed device on any valid E-License	0.3

5.2 Financial Assurance and Record Keeping for Decommissioning

Not applicable: The proposed possession limit is less than the financial surety threshold for sealed sources specified in 10CFR30.35(a)(2) and (d) (i.e., 1E9 Ci). If a commercial exit sign were to be crushed thus releasing the elemental tritium gas and causing the remaining fragments to be considered loose radioactivity, then the loose radioactivity financial surety threshold of 1 Ci 10CFR30.35 (d) would apply. However, the quantity of oxidized tritium remaining in a broken tube has been determined to be less than 2% of the original elemental tritium amount (Ref: NRPB Report# NRPB/CP/3/092, Leeds, England, 22 September 2000.). Thus, an originally 20 Ci crushed sign would have less than 0.4 Ci of loose tritium remaining which is under the financial surety threshold for unsealed tritium.

In addition, any damaged product would be immediately cleaned-up and the potentially-affected area surveyed and cleaned as necessary to limit residual contamination to less than the following level:

- 100,000 dpm/100cm^2 removable tritium

This cleanup limit is well within the NRC screening guideline for tritium in NUREG 1556 Vol. 11, Table 11.1 and would not comprise a "licensable" quantity of loose tritium. There will be no contaminated areas that would have to be included as radioactivity possessed under this license.

Isolite will keep records of any broken products, including date, place, description of the incident and cleanup performed, and results of follow-up surveys. This includes incidents are Berwyn and at remote job sites.

6. Purpose for which licensed material will be used:

Isolite Corporation is a Pennsylvania-based corporation that specializes in the importation, 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. These products are imported or domestically-purchased and are not manufactured at the Isolite Berwyn facility.

6.1 Purposes

There are 3 general purposes for which licensed material will be used:

1. possession of self-luminous products as sales displays and samples for showing at trade shows and customer sites,
2. possession of self-luminous products for shipment/distribution to general licensees under Isolite distribution license 37-23527-01G

3. redistribution of exempt products (gun sights) first distributed by third party firms under their E-distribution licenses.

Product types to be possessed include:

a. Commercial Signs: Products for the production of light for intended 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 Registry of Radioactive Sealed Sources and Devices. Maximum activity not to exceed 25 curies per device.

b. Aircraft Products: Luminous safety devices for use in aircraft intended 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 Registry of Radioactive Sealed Sources and Devices. Maximum activity not to exceed 10 curies per device.

c. Exempt Products: luminous devices as exempt products under 10CFR30.19, mainly gun sights.

6.2 Use at Temporary Job Sites

Devices destined to be used at trade shows and client sites will be possessed and used as specifically-licensed radioactive material in accordance with 10 CFR Parts 20 and 32 while at the Berwyn facility or at trade shows and customer sites. They will not be considered generally-licensed devices while possessed by Isolite.

Use of this license at trade shows and customer sites would apply to locations only within NRC jurisdiction. Reciprocity must be obtained for locations in agreement states.

Other related companies, such as Self Powered Lighting, Inc. and Evenlite that are part of the Isolite corporate group, may use the sample self-luminous products in sales displays. Personnel from these companies will undergo the same training as Isolite personnel and must follow the same radioactive materials handling guidelines. Because of the President's authority over the entire corporate structure of Isolite, Evenlite and SPL, all personnel are obligated to meet all Isolite radioactive materials handling guidelines under the President's and RSO's supervision. The President will ensure that all necessary corporate directives and agreements are in place to maintain control over all Isolite group personnel and associates such that all radiation safety guidelines are followed.

6.3 Distribution Considerations

Isolite will import and physically distribute only a small quantity of generally-licensed products from the Berwyn, Pa. office. Most products will be directly shipped from the foreign manufacturer to the end-user. However, all records of such distribution will be maintained at Isolite in Berwyn. The distribution will be performed under license # 37-23527-01G, presently under an amendment application.

No manufacturing, repair, or QA testing of products will be performed at the Isolite, Berwyn facility.

Isolite, as the distribution licensee, will be responsible for quality oversight of the products to be distributed. Isolite will ensure that the QA requirements in 10 CFR 32.51, 51a, and 52 and 10CFR 32.53 to 32.56 or NRC-approved alternative QA methods per 32.53(b)(5) are met at Shield Source

via the Isolite / SSI Quality Management System (QMS). The manuals for the QMS were submitted as part of the SSD application to NRC headquarters.

The QMS includes quarterly QA reports from SSI to Isolite and annual on-site audits of SSI by the Isolite QA Manager such that Isolite can maintain assurance that NRC-approved QA requirements are followed at Shield Source, Inc.

Also sold from the Isolite, Berwyn, Pa. facility will be exempt gun sights for redistribution. These will be exempt-distribution products that have been initially transferred to Isolite by a manufacturer under their own E-distribution license. These products are included in this license application for possession purposes only. Isolite does not need distribution authorization for these products because the products will be distributed under other firms' licenses.

7. Individual(s) Responsible for Radiation Safety Program and Their Training and Experience

7.1 Radiation Safety Officer

Isolite will hire a new employee for the position of QC Officer and RSO. His / her qualifications will include:

- Bachelor's degree in a physical or life science or engineering, or at least 5 years experience in radioactive materials handling and performing radiation safety functions
- Completion of an 8-hour general radiation safety course;
- Completion of a 8-hour, specific course in tritium hazards and handling; and
- 8 hours in-plant experience in a tritium products manufacturing facility.

Upon location of a suitable candidate (by mid-2007), Isolite will submit his / her qualifications to NRC for review at that time. Until a qualified individual has been hired and approved by NRC, William Lynch, presently RSO under 37-23527-01G, will continue as RSO.

William E Lynch Jr., Training and experience: Mr. Lynch has been with the company for twelve years and is familiar with the tritium processing operation at the Safety Light Corporation and Shield Source, Inc. sites, reviewing the processes on numerous occasions. He has also been through the radiation training program for new employees at Safety Light Corporation and a refresher course at Isolite. His extensive management experience is sufficient to oversee the radiation safety program of a small device-type license and distribution company. He will serve as acting RSO until a fulltime candidate is found.

7.2 Authorized Users:

Sales personnel that may carry and use the tritium-containing devices at remote sites and shipping personnel that may distribute devices to general licensees must have training as indicated in item 8. All personnel will be authorized to handle up to 600 Ci of tritium in devices at remote sites. At Berwyn, shipping personnel may package and ship any amount up to the license limit.

The personnel who may handle tritium-containing devices at Berwyn and at remote job sites are listed below:

v William Lynch: Acting RSO, President

- v William Rowan: General Manager, Self-Powered Lighting
- v Richard Renzi: Regional Sales Manager
- v Edward Silverthorn: Chief Financial Officer
- v Kathy Fishel: Controller
- v Jennifer Jarratt: Customer Service
- v Nicole Springer: Customer Service
- v Carol Munchback: Customer Service
- v Sharon Harrington: Customer Service
- v Daniel Platte: Customer Service, Self-Powered Lighting
- v Gwen Dalesandro: Customer Service

With the exception of Gwen Dalesandro, who is a new employee, all of the above Berwyn employees received their most recent Radiation Safety Training and DOT HAZMAT Transportation Training on December 6, 2005. The training included the topics listed Item # 8 below. Gwen Dalesandro will receive training in 2007 before handling any devices.

The following personnel from our California office may handle tritium-containing devices at remote job sites within NRC jurisdiction:

- v Erik Smith: Regional Sales Manager
- v Sanford White: Customer Service
- v Betty Gillespie: Customer Service
- v Janel Peery: Customer Service

With the exception of Janel Peery, who is a new employee, all of the above California employees received their most recent Radiation Safety Training and DOT HAZMAT Transportation Training on December 12, 2006. Janel Peery will receive training during 2007, before handling any devices.

The following other personnel may handle tritium-containing devices at remote job sites after successful Radiation Safety Training and DOT HAZMAT Transportation Training are listed below:

- v Adrian Pavitt: President, Evenlite
- v Greg Bishop; National Sales Manager, Evenlite
- v Aengus Habersaat; Warehouse Manager, Evenlite

No one will ship, carry or be responsible for tritium-containing devices without first successfully completing Radiation Safety Training and DOT HAZMAT Transportation Training.

8. Training for Individuals Working with Radioactivity

Radiation safety training includes the following topics:

- General radiation safety concepts including units, measurements, biological effects, methods of protection, contamination control, ALARA, etc.
- General regulatory requirements
- Radioactive materials transportation hazmat training as in 49CFR 172 Subpart H;

- License-specific items for tritium devices: ordering, receiving, inventory control and security;
- Incident response (cleanup techniques, objectives and contamination control); and
- Conditions of distribution to general licensees in 10CFR 31.5 and 31.7.

The course will meet the criteria described in NUREG-1556, Vol. 1, Rev. 1, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Portable Gauge Licenses,' dated November 2001, in the section entitled "Appendix D – Criteria for Acceptable Training Courses for Portable Gauge Users" as modified for tritium products.

Such training will be provided to sales and shipping personnel handling the devices. The training will be provided initially upon assignment of duties with radioactive materials and refreshers every three years. Supplemental training will be provided whenever there are significant changes in applicable regulations, the conditions of this license, or the radiation safety program.

Instructors will be the Isolite RSO or consultants certified by the American Board of Health Physics.

QA Manager Training

Minimum training of the Quality Assurance Manager who will conduct audits of the manufacturer with regard to 10CFR 32 requirements for manufacturing generally licensed devices follow:

- 1 year job experience in quality control-related work;

- 1 day course in professional quality assurance systems, or equivalent training or college courses;

- radiation safety training as stated in Item 8 above, especially conditions of distribution to general licensees in 10CFR 31.5 and 31.7; and

- training in the QA requirements in 10 CFR 32.51, 51a, and 52 and 10CFR 32.53 to 32.56

The QA Manager may be the same individual as the RSO. In this case, that individual will satisfy the training and experience requirements for both positions.

9. Facilities and Equipment

9.1 Equipment

Tritium analysis equipment will not be used at the Berwyn site but will be available at the Shield Source facility in Canada, at CoPhysics Corporation (a licensed radiological services firm in New York) or at other licensed laboratories. Any need for wipe tests analyses can be met by these facilities via overnight shipment of samples. (Also see section 10.3 for a discussion of surveys.)

9.2 Facilities

The tritium products storage rooms are located on the ground floor of the Berwyn facility (see Figure 1 below) and on the 3rd floor (see Figure 2). The exempt gun sights are stored in the ground floor room on shelves in plastic bags organized by part number. Generally-licensed products are also stored in this room or in the storage room / office on the 3rd floor. These rooms are locked

during non-business hours. The entire building is monitored for burglary and fire via a 24 hour central security service.

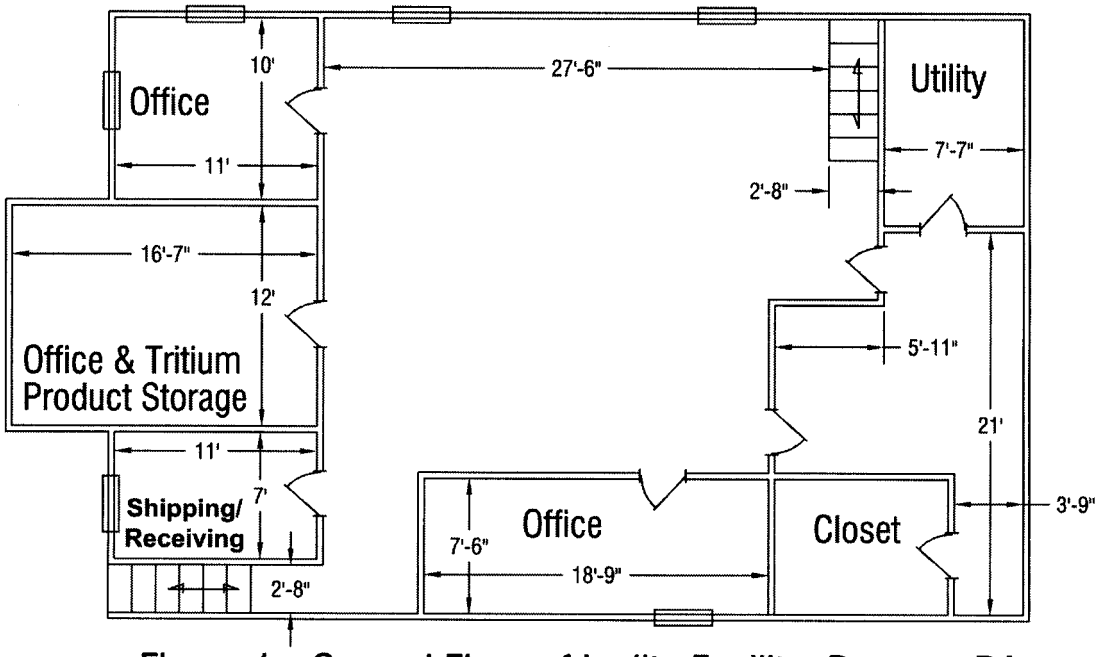

Figure 1 - Ground Floor of Isolite Facility, Berwyn, PA

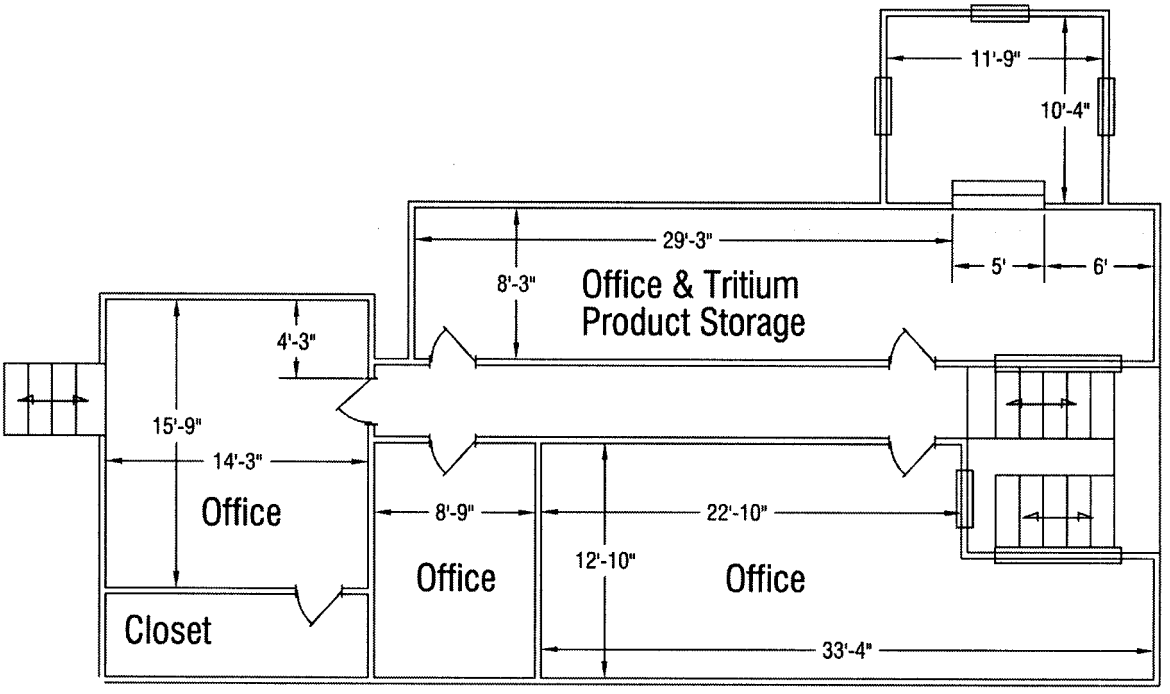

Figure 2 - Third Floor of Isolite Facility, Berwyn, PA

10. Radiation Safety Program

10.1 Audit Program

Annual audits of the radiation safety program will be conducted by the RSO or designate. The various types of audits and their descriptions follow:

10.1.1. Audit of the Berwyn facility:

a. Objective: To confirm that all radiation safety requirements per 10CFR, the license, and the radiation safety program are being met.

b. Scope: Radiation safety aspects of shipping, receiving, inventory control, security, incident response and surveys, training of personnel, records review.

c. Minimum Qualifications of Auditor: same as for RSO (see item 7.1)

d. Auditing Techniques: review of records, visual observation of personnel performing duties during audit

e. Process to address deficiencies: written notice of deficiency to employee, supervisor, and management; auditor to perform follow-up check of progress of remedial actions

f. Audit records: auditor checklist / notes of observations and findings

10.1.2. Audit of activities at temporary job sites:

a. Objective: To confirm that all radiation safety requirements per 10CFR, the license, and the radiation safety program are being met.

b. Scope: Radiation safety aspects of shipping, receiving, inventory control, security, incident response and surveys, training of personnel, records review.

c. Minimum Qualifications of Auditor: same as for RSO (see item 7.1)

d. Auditing Techniques: review of records, visual observation of personnel performing duties

e. Process to address deficiencies: written notice of deficiency to employee, supervisor, and management; auditor to perform follow-up check of progress of remedial actions

f. Audit records: auditor checklist / notes of observations and findings

10.1.3. Audits to ensure imported devices sent directly to customers will meet the requirements for (1) luminous devices (10CFR 31.5, 32.51a and 32.52 and (2) luminous devices in aircraft (10CFR 31.7, 32.53, 32.54, and 32.56) or alternate, NRC-approved procedures:

a. Objective: To confirm that QA procedures cited above and requirements in 49CFR are being met.

b. Scope: Audit procedures are specified in the Isolite/SSI QMS which are to be followed by the Isolite QA Manager while conducting an on-site audit at SSI. Items for inspection include

source integrity and radiation safety aspects of manufacturing, packaging, and shipping; review of enclosed customer documentation.

c. Minimum Qualifications of Auditor: same as for RSO (see item 7.1)

d. Auditing Techniques: visual observation of packaging, review of enclosed documentation

e. Process to address deficiencies: written notice to Isolite / SSI President and QA Manager; auditor to perform follow-up check of progress of remedial actions

f. Audit records: auditor checklist / notes of observations and findings

10.2 Termination of Activities – not applicable (NRC Form 314 will be submitted upon cessation of radioactive materials activities.)

10.3 Instruments and Surveys

Tritium analysis equipment will not be used at the Berwyn site but will be available at the Shield Source facility in Canada, at CoPhysics Corporation (a licensed radiological services firm in New York) or at other licensed laboratories. Any need for wipe tests analyses can be met by these facilities via overnight shipment of samples.

This off-site laboratory arrangement is justified because Isolite at Berwyn will only receive packages and possess sealed sources that have already been wipe-tested at the manufacturer. Any damage or GTLS leakage in transit would be readily visible via package damage or non-glowing tubes. Operating procedures will specify how to spot potentially contaminated packages, survey them, and isolate them.

The USDOT permits alternative means to estimate if surface contamination limits are met (173.443(a)). In that regard, Isolite wishes to use logical deduction and numerous years of experience to conclude that packages shipped from Berwyn are free of contamination. For example, if Isolite re-ships a product in an undamaged box originally received from the manufacturer, we can logically conclude that the removable contamination would not have changed from the time of manufacturer's shipment (which had undergone a successful contamination survey at the manufacturer's facility). Similarly, if Isolite personnel re-packages a device using a new shipping box that has never been used for radioactive materials and never has been in a controlled area, then 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 undamaged shipping container containing these devices.

10.4 Material Receipt and Accountability

Isolite will develop and implement procedures for ordering and receiving, package opening, conducting inventories (at 6 month intervals), security of materials, transfer of materials, disposal, and recordkeeping and retention. The procedures will be designed such that material possession limits are not exceeded, all material is accountable at any time whether at Berwyn or remote job sites, and records of transfer are maintained per NRC regulations.

Devices taken to trade shows or client sites will either be under visual supervision by a license-authorized user (during show hours), be physically affixed to a show display (as would the device be affixed to a wall in a generally-licensed use), or be locked in a storage trunk (overnight storage).

10.5 Occupational Dosimetry

Not applicable. We have performed an exposure evaluation and determined that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20. A contamination survey of the Berwyn facility has shown no detectable loose radioactivity, even after 15 years of maintaining possession of up to 10,000 Ci of tritium in devices, indicating no leakage of tritium over this period and thus no personnel exposure.

10.6 Public Dose

Portable generally-licensed products stored at Isolite and taken off-site to customer facilities and trade shows will be used, transported and stored such that breakage and unauthorized removal or use will be prevented. Thus, there will be no pathway for routine emission that would cause any public dose. In the event of device leakage, then the potential public dose would be estimated and addressed under incident response (emergency) procedures.

10.7 Operating and Emergency Procedures

Operating and emergency procedures will be developed, implemented, and maintained, and will meet the criteria in the section entitled 'Radiation Safety Program – Operating and Emergency Procedures' in NUREG-1556, Vol. 1, Rev. 1, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Portable Gauge Licenses,' dated November 2001 and in NUREG-1556, Vol. 12 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution ,' dated December 2000, both modified as applicable to tritium-containing products.

Operating and emergency procedures will contain the following elements:

- standard operating procedures for routine receipt, storage, control, inventory, security and packaging for transportation of devices at the Berwyn facility,
- standard operating procedures for receipt, storage, control, inventory, security and packaging for transportation of devices used at temporary job sites,
- emergency procedures in the event of breakage or leakage, including instructions for contamination control, personnel monitoring, contamination monitoring, use protective clothing and equipment, recordkeeping requirements, reporting requirements, packaging and shipment of broken devices, and waste disposal requirements.
- Procedures for customers for return of intact or damage devices (also see G-license application)

These procedures will be revised only if (1) the changes are reviewed and approved by Isolite management and the RSO in writing; (2) Isolite staff will be trained in the revised procedures prior to implementation, (3) the changes are in compliance with NRC regulation and the license; and (4) the changes do not degrade the effectiveness of the program.

10.8 Leak Tests

Not required.

10.9 Maintenance

No mechanical maintenance of the products is necessary.

To ensure that reoccurring shipments of devices as sales displays do not damage the devices, routine inspections will be conducted each time the devices are packaged and shipped. The inspection will be visual, to ensure that all internal GTLS tubes are glowing, thus indicating that they have not leaked. The results of each inspection will be recorded on the inventory sheet accompanying the shipment. Each device in the shipment will be recorded on the inventory sheet, including model, serial number (if applicable), curie content, and a check box indicating that all internal tubes were inspected and all were glowing.

A confirmatory survey of the device storage rooms in Berwyn will be performed once per year. If any device were leaking and had not been visually observed, the storage rooms would be the best location to attempt detection of residual activity. The annual survey will consist of wipe tests of storage shelves and other fixtures analyzed via liquid scintillation counting at SSI or a 3rd party laboratory.

10.10 Transportation

Applicable regulations in 49CFR and 10CFR71.5 will be followed when transporting the generally-licensed products to trade shows and customer sites and when shipping products to customers.

11. Waste Management – Disposal and Transfer

Unneeded products will be returned to the Shield Source, Inc. facility in Canada. This will be performed under a specific export license via the Isolite California facility.

Any broken or damaged products will be packaged per Isolite emergency procedures (to be developed per item 10.7) and sent to a licensed radioactive waste facility equipped to handle such packages containing loose radioactivity. Any towels and other materials used during the cleanup will be also included as radioactive waste.

12. Fees – see Form 313

13. Certification – see Form 313