

January 5, 2005

Mr. Larry Harmon
Plant Manager
Safety Light Corporation
4150-A Old Berwick Road
Bloomsburg, PA 17815

Dear Mr. Harmon,

This is a response to your letter dated December 28, 2004, sent to Ms. Elizabeth Ullrich, U. S. Nuclear Regulatory Commission (NRC) Region I office, requesting the transfer of your device registrations NR-0579-D-101-G and NR-0579-D-112-G to Isolite Corporation. The information in the letter is insufficient for NRC to change the registration of these devices.

Please note that, to change the device registrations, NRC needs a formal application from Isolite Corporation to manufacture and distribute the devices in the U. S. The information that the application must contain is delineated in the applicable NRC guidance: NUREG-1556, Vol. 3, Rev. 1, entitled "Consolidated Guidance About Materials Licences: Applications for Sealed Source and Device Evaluation and Registration." You can find the document at the NRC web-site under Electronic Reading Room or at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556>.

Specifically, Section 13.6 of the Guidance lists the issues that must be addressed in Isolite's application. Since the transfer of the registrations is somewhat different situation than the one described in the Guidance, Isolite must address the following additional issues:

- demonstrate that Isolite Corporation is in possession of all the documents that are referenced in device registrations NR-0579-D-101-G and NR-0579-D-112-G;
- describe the quality assurance measures that will be implemented regarding the supplier Shield Source, Inc., located in Peterborough, Ontario, Canada. Please see Section 10.7 in the Guidance regarding quality assurance measures for products manufactured in foreign countries;
- describe the functions that Isolite Corporation intends to perform at the distribution center that is to be located in Berwyn, PA;
- address the provisions of Section 9.2 of the Guidance for expedited review of the application.

L. Harmon

2

Regarding application and annual fees, Isolite should contact Ms. Rosalyn Jones, of the License Fee and Debt Collection Branch, at (301) 415-7300, or by e-mail at: www.rcj1@nrc.gov, for fee information. Payment of the fee should be mailed, along with the application package, to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety, Washington, DC 20555. Please note that this fee is only for an NRC device review and registration.

If you need further information, please contact me by e-mail at jpj2@nrc.gov or call at (301) 415-7904.

Sincerely,

/RA/

John P. Jankovich, Ph.D., Team Leader
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

cc: EUllrich/Region I

L. Harmon

2

Regarding application and annual fees, Isolite should contact Ms. Rosalyn Jones, of the License Fee and Debt Collection Branch, at (301) 415-7300, or by electronic mail at: www.rcj1@nrc.gov, for fee information. Payment of the fee should be mailed, along with the application package, to the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety, Washington, DC 20555. Please note that this fee is only for an NRC device review and registration.

If you need further information, please contact me by e-mail at jpj2@nrc.gov or call at (301) 415-7904.

Sincerely,

/RA/

John P. Jankovich, Ph.D., Team Leader
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Materials Safety
and Safeguards

cc: EUllrich/Region I

Distribution:

IMNS/ r/f

E:\Filenet\ML050050546.wpd

OFFICE	MSIB	MSIB
NAME	JJankovich	THarris
DATE	1/4/ 05	1/5/ 05

OFFICIAL RECORD COPY