UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

June 28, 2012

Herley Industries, Inc.
ATTN: Peter E. McGondel, RSO
10 Sonar Drive
Woburn, MA 01801

Mail Control No. 577730

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION

Dear Mr. McGondel:

This refers to your letter dated June 15, 2012, requesting renewal of Nuclear Regulatory Commission (NRC) Exempt-Distribution Materials License No. 20-13270-02E. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office. We currently do not have sufficient information to complete the review of your amendment request. In order to continue our review we ask that you provide additional information as specified below.

Your renewal application indicated that you desire to distribute electron tubes containing promethium-147. However, this radionuclide was not authorized on your existing license. Our letter of July 1, 2002, which transmitted Amendment 8 to your license, stated that we did not authorize the use of promethium-147 at that time because additional information was still needed, and contained an enclosure that lists the questions which needed to be addressed in order to authorize the distribution of promethium-147 on your license. We have reviewed our files and could not find a response from Herley Industries to the requested information. Also, this radionuclide was not authorized on the most recent amendment to your license, Amendment 9, issued on August 22, 2002. We are providing these questions again as an enclosure to this letter. It will be necessary for you to respond to these questions if you desire to distribute electron tubes containing promethium-147.

The letter accompanying your renewal application stated that Herley New England's radiation safety program has remained unchanged since the previous renewal. This is related to, but not a complete response to the NRC's guidance concerning exempt-distribution license renewal. As described in Section 12 of NUREG-1556, Vol. 8, licensees may choose to take one of three approaches when requesting license renewal:

- Submit an entirely new application for renewal as if it were an application for a new license, without referring to previously submitted information; or

- Review the current license to determine if it accurately represents the current radiation safety program and the products currently distributed, and submit an application that identifies any necessary additions, deletions, or other changes; or

- Review the documents submitted to the NRC in the past to determine if the information is up to date and accurately represents the current licensed activities and products. Identify in the application, by date, those documents that are applicable and those that are out-of-date or superseded, and indicate any changes necessary to reflect the current program.

Please indicate which option you intend to follow. Regardless of the option chosen, we may need to follow up with additional questions. If the second or third option is chosen, you should supply the supporting information and documentation, and provide clear indication as to the purpose of each submitted document.

Please also note that, per Section 6 of NUREG-1556, Vol. 8, an application for a distribution license should not contain information concerning the possession and use of radioactive material covered in the possession license. Since items 7 through 11 of NRC Form 313 pertain to possession and use license and are not applicable to the exempt distribution license, applicants should only complete items 1 through 6, 12 and 13. These latter sections are the ones that are reviewed for the purpose of your exempt-distribution license. Therefore, in the second option for renewal, above, substitute the words "current licensed activities" for "radiation safety program."

Any correspondence regarding the renewal application should reference the control number specified above.

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). ADAMS is accessible from the NRC web site at http://www.nrc.gov/NRC/ADAMS/index.html (the Public Electronic Reading Room).

If you have any questions, please contact me at (301) 415-5477 or by electronic mail: richard.struckmeyer@nrc.gov.

Sincerely,
/RA/
Richard K. Struckmeyer
Licensing Branch
Division of Materials Safety and
State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Docket No.: 030-04746
License No.: 20-13270-02E

Enclosure: Questions related to Pm-147

Please indicate which option you intend to follow. Regardless of the option chosen, we may need to follow up with additional questions. If the second or third option is chosen, you should supply the supporting information and documentation, and provide clear indication as to the purpose of each submitted document.

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Docket No.: 030-04746
License No.: 20-13270-02E

Enclosure: Questions related to Pm-147

DISTRIBUTION: MSSA r/f JJankovich JFoster TKime MArribas-Colon RJones,LFARB RI/DNMS

ML12180A103 (Pkg.)

OFC	FSME: MSSA							
NAME	RStruckmeyer							
DATE	June 28, 2012							

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ENCLOSURE: QUESTIONS RELATED TO PM-147

Title 10, Code of Federal Regulations, Section 32.14, requires the submission of certain information in support of an application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in Section 30.15 of chapter 32 or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to Section 30.15. In order to amend your license to authorize the distribution of electron tubes containing Pm-147, please provide the following information:

1) The maximum quantity of byproduct material in each product.

2) Details of construction and design of each product.

3) The method of containment or binding of the radioactive byproduct material in the product be described.

4) Procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions to be encountered in normal use of the product.

5) Quality control procedures to be followed in the fabrication of production lots of the product and a description of the quality standards the product will be required to meet.

6) A description of the proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor and the byproduct material in the product.

7) The radiation level and the method of measurement for products for which limits on levels of radiation are specified in Section 30.15; 10 CFR 30.15(a)(8) specifies such limits for electron tubes.

8) Describe how the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

9) Describe your quality assurance practices in the manufacture of the part or product, or the installation of the part into the product.

10) Section 32.15(a)(3) requires that each person licensed under Section 32.14 shall visually inspect each unit in inspection lots. Any unit that has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit. Describe how you shall visually inspect each unit in inspection lots for defects.

11) Section 32.15(c) requires that no person licensed under Section 32.14 shall transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any defective part or product. Describe how you shall prevent transfer to other persons for use under Section 30.15 of this chapter or equivalent regulations of an Agreement State any defective part or product.