



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

May 20, 2015

Ludlum Measurements, Inc.  
ATTN: William Huckabee  
P.O. Box 810  
Sweetwater, TX 79556

SUBJECT: SECOND REQUEST FOR ADDITIONAL INFORMATION REGARDING  
LUDLUM MEASUREMENTS, INC. EXEMPT DISTRIBUTION LICENSE  
RENEWAL APPLICATION

Dear Mr. Huckabee:

This letter refers to your response letter dated April 3, 2015, Agencywide Documents Access and Management System (ADAMS) Accession No. ML15100A043, which responds to our request for additional information dated March 10, 2015 (ADAMS Accession No. 15061A254), regarding the renewal of the Nuclear Regulatory Commission (NRC) Exempt-Distribution Materials License no. 42-21454-01E. In reviewing your response letter, we find additional information is required to complete our review.

In order to continue our review, please address the issues listed below, either as a statement within the new document itself, or by referring to an attached, previously-submitted document.. This information is required by the regulations in 10 CFR 32.14, "Certain items containing byproduct material; requirements for license to apply or initially transfer," 10 CFR 32.18, "Manufacture, distribution and transfer of exempt quantities of byproduct material: Requirements for license," and described in the relevant guidance document NUREG-1556 Volume 8 titled "Program-Specific Guidance about Exempt Distribution Licenses." It is acceptable to reuse previously submitted documents as long as they are provided as attachments to a new document describing your current program.

1. Your current NRC exempt distribution license no. 42.21454-01E, amendment no. 08, authorizes you under 10 CFR 32.14 to distribute radiation measuring instruments containing Americium-241, not to exceed 0.05 microcuries, for purposes of internal calibration or standardization, to persons exempt from licensing. Your letter dated April 3, 2015, only discussed the sealed source counting standards or encapsulated check sources for the purpose of calibration or operational checks for radiation survey, detection, or measuring equipment. Please clarify if you will still be distributing radiation measuring instruments containing Americium-241 under 10 CFR 32.14. If this is the case, please provide the following information as required by 10 CFR 32.14:
  - a. A description of the product and the purpose of use.
  - b. The chemical and physical form and maximum quantity of byproduct material in the product.
  - c. A detail description of construction and design of the product.
  - d. The method of containment or binding of the byproduct material in the product.

- e. 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 likely to be encountered in normal use of the product.
  - f. Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet.
  - g. The proposed method of labeling or marking each unit and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;
2. As required under 10 CFR 32.18(b) please state that the byproduct material you will be distributing under 10 CFR 32.18 is not contained in any food, beverage cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, a human being.
3. As required under 10 CFR 32.18(c), please state that the byproduct material you will be distributing under 10 CFR 32.18 is in the form of processed chemical elements, compounds, or mixtures, tissue samples, bioassay samples counting standards, plated or encapsulate sources, or similar substances, identified as radioactive and to be sued for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution.
4. In our letter dated March 10, 2015, we requested the amount of exempt quantities that will be sold or transferred in any single transaction. In your response dated April 3, 2015, you stated that Ludlum Measurements Inc. has, is, and will continue to distribute exempt quantity of byproduct material in accordance with ALL applicable federal rules and regulations. The information you provided is incomplete. As required under 10 CFR 32.19(a), please state that no more than 10 exempt quantities set forth in 10 CFR 30.71, Schedule B shall be sold or transferred in any single transaction. For purposes of this requirement, an individual exempt quantity may be composed of fractional parts of one or more of the exempt quantities in 10 CFR 30.71, Schedule B, provided that the sum of such fractions shall not exceed unity.
5. In our letter dated March 10, 2015, we requested to describe the byproduct material packaging process as stipulated in 10 CFR 32.19(b) and provide the dose rate at the external surface of the external surface of the byproduct material package. In your response dated April 3, 2015, you stated that Ludlum Measurement, Inc. has, is, and will continue to distribute exempt quantity of byproduct material in accordance with ALL applicable federal rules and regulations. You stated that the methodology of packaging assures that the external surface of outer package reading does not exceed 0.5 millirem per hour. The information you provided is incomplete. As required under 10 CFR 32.19(b), please state that each quantity of byproduct material set forth in 10 CFR 30.71, Schedule B shall be separately and individually packaged. No more than 10 such packaged exempt quantities shall be contained in any outer package for transfer to persons exempt pursuant to 10 CFR 30.18 of this chapter.
6. In our letter dated March 10, 2015, we requested the proposed process of labeling as required by 10 CFR 32.19(c). In your response dated April 3, 2015, you provided a diagram with the proposed labeling, but the labeling is missing required information. Please provide a diagram or picture of the label which identifies the radioisotope and the quantity of radioactivity and bear the words "Radioactive Material."

Any correspondence regarding your application should reference the control number specified below. Please submit the requested information within 30 days of the date of this letter. If we have not received complete information within 30 days of the date of this letter, we will assume that you do not wish to pursue your application, and we will take regulatory action to your current NRC License, 42-21454-01E.

Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

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) 415-6004 or electronic mail: [Hector.Rodriguez-Luccioni@nrc.gov](mailto:Hector.Rodriguez-Luccioni@nrc.gov).

Sincerely,

**/RA/**

Hector Rodriguez-Luccioni, Ph.D.  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 030-20785  
Mail Control No. 585914  
License No. 42-21454-01E

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If you have any questions, please contact me at (301) 415-6004 or electronic mail: [Hector.Rodriguez-Luccioni@nrc.gov](mailto:Hector.Rodriguez-Luccioni@nrc.gov).

Sincerely,

*/RA/*

Hector Rodriguez-Luccioni, Ph.D.  
Materials Safety Licensing Branch  
Division of Material Safety, State, Tribal  
and Rulemaking Programs  
Office of Nuclear Material Safety  
and Safeguards

Docket No. 030-20785  
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License No. 42-21454-01E

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<b>OFC</b>	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB	NMSS/MSTR/MSLB
<b>NAME</b>	Hector Rodriguez-Luccioni	Shirley Xu	Hipolito Gonzalez	Hector Rodriguez-Luccioni
<b>DATE</b>	05/19/2015	05/20/2015	05/20/2015	05/20/2015

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