

December 27, 2004

Ms. Rhonda Harris, RSO
Ludlum Measurements, Inc.
501 Oak Street
P.O. Box 810
Sweetwater, Texas 79556

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON THE APPLICATION FOR
RENEWAL OF EXEMPT DISTRIBUTION LICENSE NO. 42-21454-01E

Dear Ms. Harris:

We have reviewed your application, dated July 30, 2004, to the U.S. Nuclear Regulatory Commission (NRC), for the renewal of exempt distribution License No. 42-21454-01E. In reviewing the application, we find that additional information is needed for us to reach a decision. Therefore, we request that you address the issues outlined in the Enclosure.

Please refer to NRC's NUREG-1556, Volume 8, Sections 9.3 and 9.5, and 12, for guidance on the type of information that would fully address these issues, and for guidance submitting an application for renewal of an exempt distribution license issued under 10 CFR 32.14 and 32.18. The NUREG series and all relevant regulations are accessible through the Electronic Reading Room of NRC's main web site (www.nrc.gov).

In accordance with 10 CFR 2.390 of NRC's "Rules of Practice", a copy of this letter and its enclosure will be available electronically for public inspection in NRC's Public Document Room or from the Publicly Available Records (PARS) component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible, through NRC's main web site, at <http://www.nrc.gov/NRC/ADAMS/index.html>.

R. Harris

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Please submit the requested information within thirty days of the date of this letter and be sure that all areas of concern cited herein are addressed. If the requested information is not submitted within thirty days, the application will be considered abandoned without prejudice to its re-submission. If you have any questions, please feel free to contact me at (301) 415-5810 (email: jxr4@nrc.gov), or Anthony Kirkwood at (301) 415-6140 (email: ask@nrc.gov).

Sincerely,

/RA/

Jonathan Rivera,
General Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Deficiencies Issues

Docket No. 030-20785
License No. 42-21454-01E
Mail Control No. 022429

R. Harris

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Enclosure:
Deficiencies Issues

Docket No. 030-20785
License No. 42-21454-01E
Mail Control No. 022429

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**DEFICIENCY ISSUES TO ADDRESS
LUDLUM MEASUREMENTS, INC.**

1. NUREG-1556, Volume 8, Section 5.3, explains the requirement for persons who initially transfer for sale products containing byproduct material to be authorized, under a specific license issued by the NRC or an Agreement State, to possess and use the byproduct material. In your application, dated July 30, 2004, requesting the renewal of Ludlum Measurements, Inc. exempt distribution license no. 42-21454-01E, under item 4 you state that Ludlum Measurements, Inc. has a specific license (LO-1963) from the State of Texas. Please provide an up-to-date copy of Ludlum Measurements, Inc. possession and use license issued by the State of Texas.
2. Under 10 CFR 30.15 (a) (9), any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns, or acquires ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of byproduct material. Under item 8 of your renewal application, you state "...calibration check sources of exempt quantities would be transferred to general licensed customers...." Under item 10 of your renewal application, you provide the text for labeling and the written statement provided with the instruments, which states "The receipt...of this instrument...is subject to a general license...." Please clarify the intent of whom the instruments containing check sources and counting standards would be distributed to, whether to persons exempt from licensing requirements, or to persons subject to a general license, or both.
3. Please provide a list of each isotope that you request to be re-distributed under a renewed license. Include the chemical and physical form of each isotope, the quantity (radioactivity) for each check source and counting standard, and the maximum quantity in each type of survey, detection, and measuring instrument.
4. Under item 9 of your renewal application, you state that the exempt sources are described in the source manufacturer sales catalog. Please provide a copy of this catalog.
5. Please provide a description of the method in which the check sources and counting standards would be packaged and transferred, including the number of check sources and counting standards that would be distributed per transaction.
6. Please provide a description of what the dose rate would be at the external surface of the outer package containing the check sources and counting standards to be transferred.
7. Please describe the physical construction of, as well as the wording on, the label on the immediate container of the check sources and counting standards to be transferred. If a brochure providing the user with safety precautions is included in the immediate container in place of the label on the container, then please provide a copy of the brochure.

Enclosure

8. Please provide the information required, under 10 CFR 32.14 (b) on the survey, detection, and measuring instruments to be transferred. Specifically:
 - (a) The details and construction of each instrument;
 - (b) The method of mounting the check sources and counting standards into each instrument;
 - (c) Procedures for and results of prototype testing to demonstrate that the check sources would not become detached from the instruments and the byproduct material would not be released to the environment under the most severe conditions likely to be encountered in normal use, and;
 - (d) Quality control procedures to be followed in the fabrication of production lots of the instruments and quality control standards the instruments would be required to meet.
9. Under item 10 of your renewal application, you provide the text for the labeling of, and statement to be sent with, the instruments. 10 CFR 32.15 (d) requires the label to identify the byproduct material in the instruments. Please provide an updated copy of the labeling that would include the byproduct material identification.
10. Please confirm your understanding of the record and material transfer reporting requirements for the check sources and calibration standards, as well as the instruments, specified under 10 CFR 32.16 and 32.20. Specifically:
 - (a) The maintenance of records that identify, by name and address, each person to whom byproduct material is transferred to, as well as the kinds and quantities of byproduct material transferred, for the period specified in 10 CFR 32.20 and 32.16;
 - (b) The filing of summary reports with the NRC, within the time period specified in 10 CFR 32.20, that state the total quantity of each isotope transferred under the exempt distribution license, and;
 - (c) The filing of reports with the NRC, within the time period specified in 10 CFR 32.16, that include, for each instrument transferred, a description or identification of the type of each instrument, the total quantity of the radionuclide in each type of instrument, and the number of units of each type of instrument transferred.
11. Please provide the reports mentioned in 10 (b) and (c) above for products transferred since the filing of the last report with the NRC.
12. NUREG-1556, Volume 8, Section 8.8, explains the requirement that the representative signing the application be authorized to make binding commitments and sign official documents on behalf of the applicant, Ludlum Measurements Inc. Please confirm your signature authorization.