



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

March 22, 2019

David Rhoe, Radiation Safety Officer
CRMI
Paseo de la Fuente
D-4 Calle Tivoli
San Juan, Puerto Rico 00926-6459

SUBJECT: CRMI, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO.
610717

Dear Mr. Rhoe:

This is in reference to your application dated November 28, 2018, requesting the renewal of NRC License No. 52-25430-01. The requests below will be referring to various sections of NRC Form 313, "Application for Material License", and NUREG-1556, Volume 18, Rev 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Service Provider Licenses, Final Report" (NUREG-1556, Vol. 18, Rev.1). In order to continue our review, we need the following additional information:

1. Under Item 3 of your application, please confirm if you are requesting authorization to use or possess licensed material at temporary jobsites.
2. Items 5 and 6 of Form 313 require information on the various unsealed and sealed radionuclides you are seeking authorization to possess. You requested analytical samples, liquid Tc-99m, and F-18, but stated that you will not possess unsealed radionuclides. You did not explain your reasoning for stating that you will not possess, or take possession from your clients, of, unsealed radionuclides. Your current license authorizes the possession of the analytical samples, Tc-99m, and F-18 in any form at your facilities located at Paseo de la Fuente, D-4 Calle Tivoli, San Juan, Puerto Rico and at temporary job sites of the licensee anywhere in the United States where the U.S. Nuclear Regulatory Commission maintains jurisdiction for regulating the use of licensed material.
 - a. Confirm if environmental samples are going to be analyzed at temporary jobsites only or if they will be analyzed at your authorized location as well. In addition, please describe the types of environmental samples you will analyze such as wipes, water, soil, vegetation, air samples, etc.
 - b. Please confirm that Tc-99m and F-18 will be possessed and used only at temporary jobsites during services provided to customers, and will not be received or stored at your Paseo de la Fuente, D-4 Calle Tivoli, San Juan, Puerto Rico facility. Alternately, confirm if such materials will be possessed and stored at your permanent location.
3. Your application appears to request all of the gauges contained in each of the documents contained in the attachment you labeled "Sealed Source Registration" for CPN, InstroTek,

Troxler, and Humboldt. Please confirm whether or not you are requesting authorization to perform calibrations (“E”) and service/repair (“I”) for all of the models listed in each of the documents provided in the attachment labeled “Sealed Source Registration” or only for the models currently listed on your license.

4. Your application requested authorization to perform calibrations (“E”) and service/repair (“I”) for Seaman Nuclear portable gauges. However, no Seaman Nuclear portable gauge model requests were contained in the attachment you labeled “Sealed Source Registration”. Please confirm you are requesting permission to perform the same services for Seaman Nuclear portable gauges as are currently authorized on your license, or provide an updated list.
5. Your application requested “any byproduct material with a half-life longer than 120 days” under the sealed sources heading (Table B-2) to be used for “quality control testing using ACR phantoms” and “waste management services”. Waste management services are not currently authorized on your license, and typically include waste evaluation, processing, and packaging of low-level radioactive wastes for customers. Such waste management services are authorized under Program Code 03234 in Fee Category 4B, which would require payment of a new application fee for this additional category and will incur an additional annual fee moving forward. Based on our conversation on March 22, 2019, we understand that you do not intend to perform waste services for customers, but are returning unneeded sources to the manufacturer for customers. Confirm that you are withdrawing your request to perform waste management services.
6. Your application contained an outline of your authorized user training outlines, your examination, and your “Principles of Radiation Protection” document in response to Item 7.2.
 - a. Please confirm that you reserve the right to revise the training outlines, your examination, and your “Principles of Radiation Protection” document, as appropriate.
 - b. Please confirm that your training program for portable gauge users will comply with the requirements of NUREG 1556, Volume 1, Rev. 2, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Portable Gauge Licenses, Final Report”, Appendix C, including 70% passing rate for an appropriate examination.
7. Under Item 9, “Facilities And Equipment”:
 - a. Please provide a diagram and description of the calibration facility that is an authorized location of use on your license. The description should include radiation safety and security equipment and/or requirements during use of the facility, and when the calibrator is in storage.
 - b. Please specify the shielding materials (e.g., concrete, lead) and means for securing radioactive materials from unauthorized removal at the locations where “high-risk activities” are performed.
 - c. Please confirm that no specialized handling tools or protective clothing are required associated with the servicing of portable gauges services you intend to provide, or provide a description of any specialized equipment.

8. Under Item 10.1, "Operating and Emergency Procedures", under the heading "High Risk Activities", you did not provide your procedures for the calibration of survey instruments and personnel dosimetry equipment as a service for others. Confirm that instrument calibration procedures will meet the requirements of Appendix F of NUREG-1556, Volume 18, Rev. 1. Additionally, provide procedures for calibrating personnel dosimetry equipment if you are also performing those activities.
9. Under Item 10.3, "Radiation Monitoring Instruments", you did not "describe the instrumentation that will be used to perform the required radiological surveys" including instrumentation used for analysis of environmental samples, leak tests, or other media. Please provide this information.
10. Under Item 10.4, given that you will be utilizing unsealed radioactive materials, confirm that you will conduct surveys and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Section 8.10.4 of NUREG-1556, Volume 18, Revision 1.
11. Under Item 10.5, you provided a copy of your instructions for leak testing a nuclear gauge. However, you did not describe how you will perform the analysis of leak test samples. Confirm that you will perform leak testing and sample analysis in accordance with the model procedures in Appendix G of NUREG-1556, Volume 18, Revision 1.
12. Under Item 10.9, you described non-routine maintenance for removing the cesium source from a nuclear gauge. However, you did not provide radiation safety procedures associated with this activity. Confirm that you will perform non-routine portable nuclear gauge maintenance in accordance with the criteria provided in Appendix F of NUREG-1556, Volume 1, Revision 1.

We will continue our review upon receipt of this information. Please reply to my attention at:

Jonathan Pfingsten, Health Physicist
Mail Control No. 610717
USNRC, Region I
Division of Nuclear Materials Safety
2100 Renaissance Boulevard
King of Prussia, PA 19406

Alternatively, the letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: www.nrc.gov. Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. 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.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5040 or via electronic mail at elizabeth.ullrich@nrc.gov.

Thank you for your cooperation.

Sincerely,



Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety

License No. 52-25430-01
Docket No. 030-34704
Mail Control No. 610717

D. Rhoe

CRMI, REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 610717 DATED
MARCH 22, 2019

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SUNSI Review Complete: Betsy Ullrich

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