



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

June 3, 2021

Mark Brennan, Executive Vice President
Owlstone, Inc.
19 Ludlow Road, Suite 202
Westport, CT 06880

SUBJECT: OWLSTONE, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL
CONTROL NO. 625367

Dear Mr. Brennan:

This is in reference to your application dated March 17, 2021, requesting to renew NRC License No. 06-31440-01. In order to continue our review, we need the following additional information:

1. Your application did not describe the authorizations for radioactive materials and their associated uses. Confirm if the radionuclide, form, model numbers, and quantities listed on the current license are sufficient. If changes are needed, please submit the information required in NUREG-1556, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution (NUREG-1556, Volume 12, Revision 1), Section 8.5., "Radioactive Material". Here is a link to NUREG-1556, Volume 12, Revision 1: <https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v12/index.html>
2. Your application did not describe the purpose and use for the materials under your license. The current license authorizes possession, use, demonstration and distribution of Lonestar Industrial Chemical Monitors. Confirm if this is sufficient. We note that Section 6.2.3.2 of the "Radiation Safety Plan" refers to repair of the devices. If this is different than the servicing of devices described in Section 6.4, then provide a description of the repair activities so that it is clear if repair should be an authorized activity.
3. Confirm if Mikaela Abraham continues to perform the functions and responsibilities as the Radiation Safety Officer (RSO). If another individual will be the RSO, submit the information requested in NUREG-1556, Volume 12, Revision 1, Section 8.7 "Individual(s) Responsible for Radiation Safety Program and Their Training and Experience".
4. Condition 11 of your current license authorizes licensed material to be used by, or under the supervision of, individuals who have received the training described in the application dated May 10, 2011. The submission dated March 17, 2021, includes the same description in Section 6.2 and the license condition will be revised with the more recent date. In addition, describe your method(s) of providing training and how you assess the success of the training.

5. In accordance with NUREG-1556, Volume 12, Revision 1, Section 8.9, "Facilities and Equipment," provide a description of the facilities and equipment available where radioactive material will be possessed and used; and a description (or diagram) of the areas of your facility used for receipt, shipping, storage, servicing, and other activities with radioactive materials.
6. In accordance with NUREG-1556, Volume 12, Revision 1, Section 8.10.2, "Radiation Monitoring Instruments",
 - a. describe the instrumentation (type of survey or analytical instrument [or manufacturer and model number]) that will be used to perform the area surveys and analysis of wipes as described in your Radiation Safety Program.
 - b. State that "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix H in NUREG-1556, Volume 12, Revision 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution." We reserve the right to upgrade our radiation survey instruments as necessary;" and
 - c. State that "Instruments will be calibrated before first use, at least annually thereafter, and after any repair, by a vendor that the NRC or an Agreement State has licensed to perform instrument calibration."
7. In accordance with NUREG-1556, Volume 12, Revision 1, Section 8.10.6, "Safe Use of Radionuclides and Emergency Procedures", describe the activities you perform to ensure that the product you import and distribute is in accordance with the quality assurance program and in accordance with the statements contained in the registration certificate for the product.
8. Based on a review of the Radiation Safety Program, it appears that you perform radiation surveys during and after servicing devices (Section 6.4.2) and if a damaged package is received (Section 6.8.2). Although wipe surveys are required if a package is damaged (Sections 6.8.1 and 6.8.3) or if a change is made to areas where materials are used (Section 6.16), wipes of the servicing area are stated to be performed "periodically" (Section 6.4.2).
 - a. Provide the action levels for radiation surveys and wipe surveys which will required corrective actions, and state when wipes of the service areas will be performed, or state "We will survey our facility and maintain contamination levels in accordance with the survey frequencies and contamination levels published in Appendix M to NUREG-1556, Vol. 12, Rev. 1, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession Licenses for Manufacturing and Distribution."
 - b. The Radiation Safety Program refers to receiving results of leak tests (Section 6.12.2 and records of leak test (Section 6.13.1.6) but does not state when you will perform leak tests. Please explain when you would perform leak tests, and confirm that you will have the leak test samples analyzed by another company authorized to perform leak test analysis as stated in condition 13.F. of your current license.

9. Please note the following corrections to your Radiation Safety Program:
- a. Section 6.6.3 states that records of inventory must be maintained for 5 years. The current standard license condition requires that records of inventory be maintained for 3 years. No response is required.
 - b. Section 6.8.2 states that "no single package will contain more than 100 Ci of Ni-63." However, your license authorizes a maximum possession limit of 600 millicuries. Confirm that you will receive packages containing quantities such that you will not exceed the maximum possession limits of your license.
 - c. Section 6.12.2 and 6.12.4 state that certain events are required to be reported pursuant to 10 CFR 32.210. However, this regulation does not contain any reporting requirements.
 - i. Reports of leak test results in excess of 0.005 microcuries are required to be reported pursuant to condition 13 of your current license.
 - ii. Lost or stolen devices are required to be reported pursuant to 10 CFR 20.2201;
 - iii. Devices involved in a fire may be required to be reported in accordance with 10 CFR 30.50 (a) or (b)(4).
 - iv. 10 CFR 20, Subpart M "Reports" contains other events that may require reporting.

Confirm that you will correct the reporting requirement references.

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

Betsy Ullrich, Senior Health Physicist
Mail Control No. 625367
USNRC, Region I
Division of Radiological Safety and Security
2100 Renaissance Boulevard
King of Prussia, PA 19406

Or you may send a copy of the signed response as a pdf document by email to

R1DRSSMail.Resource@nrc.gov

Reference – Betsy Ullrich, Senior Health Physicist
Mail Control No. 625367

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 and Procedure," 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 by electronic mail to Elizabeth.ullrich@nrc.gov.

Thank you for your cooperation.

Sincerely,

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Radiological Safety and Security
Region I

License No. 06-31440-01
Docket No. 030-38451
Mail Control No. 625367

OWLSTONE, INC., REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 625367 DATED JUNE 3, 2021

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SUNSI Review Complete: Betsy Ullrich

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NAME	Betsy Ullrich						
DATE	6/3/21 exu						

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