



July 30, 2021

Betsy Ullrich  
Senior Health Physicist  
U.S. NRC, Region I  
Division of Nuclear Materials Safety  
2100 Renaissance Blvd., Suite 100  
King of Prussia PA 19406-2713

SUBJECT: Response to USNRC: Request for additional Information, mail control no. 625367

Dear Betsy Ullrich,

In response to the letter dated June 3, 2021, requesting additional information, please see below. For your convenience we have posted your questions along with our reply.

**Question 1: “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> “**

Answer:

We confirm that the radionuclide, form, model numbers, and quantities are the same as listed on the current license. The RSM was reviewed to include part 5.2 and description as following:

- **Byproduct:** Nickel-63

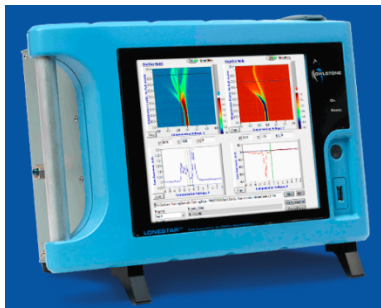


- **Chemical and/or physical form:** Foils (Eckert Zeigler, Model NER-004; QSA Global Inc., Model NBC)
- **Maximum amount that Owlstone may possess at any one time under the current license:** 15 millicuries per source and 600 millicuries total.

**Question 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. “**

Answer:

As per the current licenses, Owlstone is authorized for possession, use, demonstration, and distribution of Lonestar Industrial Chemical Monitors. This is sufficient.



Owlstone partners with market leaders to integrate its technology into next generation chemical sensing products and solutions. The model Lonestar device is a portable chemical monitor to be used to identify chemicals according to their characteristic mobility in electric fields.

The device is designed to be used in an indoor factory setting or for analysis in a research and development laboratory environment.

The Owlstone technology detects a wide range of chemicals with extreme sensitivity and selectivity. The technology has numerous applications - across industries from security and defense to automotive and healthcare - that depend on the rapid, accurate detection and measurement.

Owlstone works with market leaders within these applications to integrate its technology into next generation chemical sensing products and solutions. Owlstone offers a unique combination of benefits, including small form-factor, minimal power consumption, reduced false-positives, and a customizable platform. At the heart of this platform is a ground-breaking solid state sensor whose operational parameters can be fine-tuned to detect a wide range of airborne or dissolved chemical agents in extremely small quantities. Originally developed by the company's founders at the University of Cambridge, these pioneering technologies have already won Owlstone widespread commercial and academic recognition.

Repair mentioned in Section 6.2.3.2 refers to anything that is broken or not working and needs to be



repaired. Services that are described in Section 6.4 refers to calibration or similar services. ALL services and repair are done in Owlstone, Cambridge, UK. No services or repairs are done in the Westport, CT, location. Most customers will send the broken/serviced unit to Owlstone Inc., Westport, and Owlstone Inc. will forward ship it to Owlstone, Cambridge, UK.

**Question 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”. “**

Answer:

Mikaela Abraham continues to perform the functions and responsibilities as the radiation Safety Officer – RSO, and her contact information is [mAbraham@owlstone.com](mailto:mAbraham@owlstone.com), phone number 646.291.7262.

**Question 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. “**

Answer:

RSM part 6.2.1.1 was reviewed to include the following statement: Owlstone’s Radiation Safety Training is held annually for all radiation workers, and the current method is through an online presentation. To assess the success of the training, a quiz is sent to each radiation worker and the results are analyzed by the RSO. And RSO has the radiation safety training with an independent company.

**Question 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. “**

Answer:

Please see enclosed the facility floor plan. Lonestar Chemical Monitor is shipped in a black pelicase.



Lonestars are shipped to Owlstone Inc. , Westport, from Owlstone, Cambridge, UK. and will be received by Mikaela Abraham, who takes shipping notes/tracking numbers, confirms there is no damage to the pelicase, and confirms the serial number and the wipe test certificate. This instrument is shipped within 1-2 days to the customer and when needed is stored in the RAD material designated storage room until shipped out. This room has a label indicating Radioactive Material is store in that room. In the case Lonestar is received from the customer to Owlstone Inc., a wipe test is taken additionally to the above steps. Wipe tests are sent to a licensed vendor.

**Question 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.” “**

Answer:

- a- The RSM part 5.1.5 was reviewed to include the following statements “The instrumentation used at Owlstone to perform surveys analysis are two Ludlum Measurements, Inc., survey meters, Model-3, General Purpose Survey Meter, each which has a Model 44-9, Alpha-Beta-Gamma Detector, and Model 44-1, Beta Detector. The survey meters are calibrated annually. Wipe tests are sent to be analyzed by a licensed lab”.
- b- The RSM part 5.1.6 was reviewed to include the following statements:” 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- Part 5.1.7 “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”.

**Question 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. “**

Answer:

The licensee commits to auditing the quality program of the manufacturer on an annual basis, and enclosed is a copy of the report of their most recent quality audit. Because of the Covid-19 situation this past year and this year, we have not been able to visit Owlstone, Cambridge, UK. See attached the check list audit.

**Question 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).**

**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.”**

**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. “**

Answer:

- a- RSM was reviewed to include part 6.4.4 that states that “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.” The action level for surveys is 0.2mR/hr. The action level for contamination wipes is 222 dpm/cm<sup>2</sup>.

- b- RSM as reviewed to include part 6.8.4 that states that “A leak test will be performed by Owlstone or an independent company. The frequency of leak test is not required on the certificate issued by NRC, date July 1, 2019, No. 1321-D-101-E. Analysis of leak test samples and/or contamination shall be performed by persons specifically licensed by the U.S Nuclear Regulatory Commission or an Agreement State to perform such services”. The product is leak tested by the manufacturer in the UK as part of the final product testing.

**Question 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 than “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 you 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.**

**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.”**

Answer:

- a - RSM part 6.6.3 was reviewed and states that “A record of inventory must be maintained for a minimum of 3 years.”



b - Owlstone only receives packages containing quantities such that will not exceed the maximum possession limit of our license. In other words, 15 millicuries per source and 600 millicuries total. Therefore, the RSM part 6.8.2 was reviewed to correct the total amount according to the maximum possession limit.

c- References in Section 6.12.2 and 6.12.4 was reviewed and corrected according to:

- i. 6.12.2 - In the event that a leak test returns results above  $0.005\mu\text{Ci}$ , the RSO must notify the NRC in accordance with part 13 of our current license.
- ii. 6.12.3 - If a device is lost or stolen, the RSO must notify the NRC as stipulated in 10 CFR 20.2201.
- iii. 6.12.4 - In the event that the radioactive sources are involved in a fire, the RSO must notify the NRC of the event as stipulated in 10 CFR 30.50 (a) or (b)(4).
- iv. 6.12.5.3 – Including the statement: “10 CFR 20, Subpart M “Reports” contains other events that may require reporting, such as: Notification of accidents; Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits; Reports of planned special exposures; Reports of individual of exceeding dose limits; Reports of transactions involving nationally tracked sources”.

Should you have any questions, please contact me at 203-908-4848 (office) or 203-803-5723 (cell) or send an email to [mark.brennan@owlstoneinc.com](mailto:mark.brennan@owlstoneinc.com). IRSC, Inc. is our consultant for this application and is authorized to work with you on our behalf.

Sincerely,

Mark Brennan Executive  
Vice President Owlstone Inc.

Enclosure(s):

cc:

IRSC, Inc.