



# RADIATION SAFETY PLAN

## Approvals:

Title	Date	Title	Date
Title	Date	Title	Date
Title	Date	Title	Date
Title	Date	Title	Date
Title	Date	Title	Date
Title	Date	Title	Date

Rev	Description of Changes	Release Date
1	Initial Release	
2	Company has moved from New York to Connecticut, non-agreement state with NRC.	May 10, 2011
3	Changed references from NY DOH to US NRC	Feb 7, 2011
4	Changed SRO contact number. Added Steven Freshman as authorized user. Added License Numbers.	Feb 2, 2012
5	Connecticut in a process becoming an agreement state.	2021
6	In accordance with NRC Letter from June 3, 2021, mail control no. 625367	July 30, 2021
7		

## 1.0 PURPOSE AND SCOPE

The purpose of this document is to outline the methods used to control the radioactive material, sources, devices, and waste at Owlstone (or other) in Westport, CT, as well as outlining protection the employees against the potential dangers of radioactive materials.

- 1.1 Changes to this document may require notification to the NRC. The Radiation Safety Officer (RSO) must approve all changes to this document. The RSO must be kept informed of all correspondence with the NRC.
- 1.2 This document must be reviewed on an annual basis, and records of the review must be kept on file, to present as evidence in the event of an inspection from the NY RHU.

## 2.0 DEFINITIONS

- 2.1 Authorized user – an employee who is authorized by management to use or service devices containing radioactive material and who has been trained in the hazards of handling radioactive materials
- 2.2 CT DEEP – Connecticut Department of Energy and Environmental Protection
- 2.3 Device – means any machine containing radioactive material or capable of producing radiation
- 2.4 Dose – the amount of radiation received per unit of time
- 2.5 Exposure – the total dose received during an event or length of time; or the ionization of air
- 2.6 NRC – US Nuclear Regulatory Commission
- 2.7 Radiation area – an area in which the dose rate is greater than 5 mrem/hr at 30 cm from the source of the radiation
- 2.8 RSO – Radiation safety officer; the person direct responsible for maintaining the safety of employees and visitors in regards to the dangers of ionizing radiation present at the site

### 3.0 RESPONSIBILITY

#### 3.1 Radiation Safety Officer – Contact information

3.1.1 The Radiation Safety Officer for Owlstone is Mikaela Abraham.

3.1.2 To contact the RSO: (646) 291-7262.

#### 3.2 Authorized users

3.2.1 Authorized users are listed below:

3.2.1.1 Mark Brennan

3.2.1.2 Mikaela Abraham

3.2.1.3 Steven Freshman

#### 3.3 Duties of the RSO

3.3.1 To ensure that work is carried out in accordance with the requirements of state and Federal regulations and for taking all reasonable steps to ensure that these rules are followed at all times.

3.3.2 To prohibit any non-compliant activity associated with Owlstone, its employees, and contractors.

3.3.3 To ensure that survey meter(s) are properly calibrated and maintained.

3.3.4 To ensure that detailed records are kept for all receipts and transfers of devices and that these records are kept current.

3.3.5 To ensure that personnel follow proper procedures for handling devices, demonstrations.

3.3.6 To ensure that amendments to radioactive materials licenses are filed, as necessary.

3.3.7 To ensure that exposure levels are kept as low as reasonably achievable.

3.3.8 To ensure that all potentially exposed employees are properly trained in the handling of radioactive material or other radiation sources.

- 3.3.9 To maintain the proper inventory level of devices, which shall not exceed the amount stated in the radioactive materials license # 06-31440-01.
- 3.3.10 To be the liaison between Owlstone and the NRC and CT DEEP or other pertinent agencies.
- 3.3.11 To ensure proper storage and/or disposal of any potential radioactive waste.
- 3.3.12 To ensure that personnel are provided with personal monitoring devices, if necessary.
- 3.3.13 To ensure that packages are properly shipped and received.
- 3.4 Responsibilities of authorized users
  - 3.4.1 Authorized users are to follow safe working practices, assure that devices are protected against unauthorized removal, and report any events involving radioactive material.

#### **4.0 DOCUMENTATION/ REFERENCE MATERIALS**

- 4.1 Radioactive Materials Licenses: 06-31440-01
- 4.2 US NRC Regulatory Guide 6.9
- 4.3 NY RHU Regulations 10 NYCRR Part 16
- 4.4 OSHA Regulation 29 CFR 1910.1096
- 4.5 Owlstone servicing, shipping and receiving procedures.
- 4.6 NRC Form-3, Notice to Employees

#### **5.0 EQUIPMENT**

- 5.1 Survey Meters
  - 5.1.1 All survey meters must be calibrated annually.
  - 5.1.2 Survey meters must be kept in good repair and working order.
  - 5.1.3 Any damage or malfunctions should be reported to the RSO as soon as possible.

- 5.1.4 One survey meter should be kept at the facility at all times. A second survey meter may be purchased or rented for times when the primary meter is sent out for calibration.
- 5.1.5 The instrumentation used at Owlstone to perform surveys and wipes 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.
- 5.1.6 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,
- 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.
- 5.2 Radioactive Materials
- 5.2.1 Byproduct: Nickel-63
- 5.2.2 Chemical and/or physical form: Foils (Eckert Zeigler, Model NER-004; QSA Global Inc., Model NBC)
- 5.2.3 Maximum amount that Owlstone may possess at any one time under the current license: 15 millicuries per source and 600 millicuries total.

## **6.0 PROGRAM**

### **6.1 Dose/Exposure**

- 6.1.1 Since the radioactive material used is Ni-63, and because the source is fully enclosed within the device, there is no risk of receiving an external skin dose, as the 67Kev Beta particles produced are not energetic enough to penetrate outer layer of the skin. Therefore, no dosimetry is necessary for employees. {Note: There is the potential for inhalation or ingestion of contamination associated with the gross mishandling of the source. Yet, even in this case, the dose received would not require an employee to wear dosimetry.}
- 6.1.2 Owlstone embraces the ALARA principle, and, since Ni-63 does not pose a significant risk of deep dose, the doses expected in all areas of the facility are “as low as reasonably achievable”, provided that proper procedures are followed.
- 6.2 Training
- 6.2.1.1 The RSO is responsible for assuring that training is provided to affected employees. 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.
- 6.2.2 Shippers/Receivers
- 6.2.2.1 Shippers/Receivers must be trained in US DOT Hazardous Materials and IATA Dangerous Goods by Air, particularly in reference to Class 7 radioactive material and any exemptions under, which the Owlstone’s devices fall. {Note: retraining is required every 3 years for the DOT HazMat training and every 2 years for IATA DG training.}
- 6.2.3 All Other Personnel
- 6.2.3.1 All employees working from and/or at the Owlstone site must be trained on radiation awareness. This may be part of Hazard Communications training and is to be performed annually.

6.2.3.2 All personnel who repair the devices, must have radiation safety training that outlines the hazards of radiation and the procedures to take to avoid contact with the radioactive source. Repair 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.

### 6.3 Postings

6.3.1 The storage area must be marked with the radiation symbol and the words, CAUTION RADIOACTIVE MATERIALS. See the example below:



6.3.2 The most recent revision of the NRC Form-3, Notice to Employees, must be posted in a conspicuous location in the workplace, and is available from the NRC.

6.3.3 A copy of all radioactive materials licenses and registrations must be kept on site and made available to all employees. The location of these documents must be posted conspicuously in the workplace.

6.3.4 Any notice of violation received from the NRC or other pertinent agency, must be posted for employees to view.

6.3.5 A copy of the NRC regulations must be made available to all employees.

### 6.4 Servicing Devices

- 6.4.1 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.
- 6.4.2 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 222dpm/cm<sup>2</sup>.
- 6.4.3 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 222dpm/cm<sup>2</sup>.
- 6.5 Storage
- 6.5.1 Devices which are not in transit, nor being serviced, must be kept in a lockable location to prevent unauthorized removal.
- 6.6 Inventory
- 6.6.1 An inventory of devices shall be conducted every 6 months in accordance with license #06-31440-01.
- 6.6.2 The quantity of devices (source material) shall not exceed that stated on license #06-31440-01.
- 6.6.3 A record of this inventory must be maintained for a minimum of 3 years.
- 6.7 Device Procurement

- 6.7.1 Devices will be imported from Owlstone's manufacturing facility currently in Cambridge, England.
- 6.7.2 The number of devices should be verified before receiving any further devices, to assure that the possession quantity is not exceeded.
- 6.8 Receiving Devices
- 6.8.1 Upon receipt of a device, the outer package should immediately, be visually inspected for damage. If the package is significantly damaged, the shipment should be rejected. The package should be quarantined; the delivery driver should immediately notify the shipping company and follow the guidance given by the shipping company's compliance person. Once the device has been removed from the area, the area must be cleaned with decontamination cleaner and tested for removable contamination using wipes. The wipes must be analyzed by an approved laboratory. A record of this event and the test results should be made by Owlstone.
- 6.8.2 In addition, because no single package will contain more than 15mCi of Ni-63 per radioactive source, surveys for contamination will be performed only on packages that are damaged to the extent that the integrity of the device might be jeopardized and otherwise, randomly on incoming packages. Records of these surveys will be kept by Owlstone as specified in 10 CFR 30.50(c)(2).
- 6.8.3 Once received, the package should be opened to verify that the device has not been damaged, and that the serial number of the device can be verified against the shipping records and other pertinent documents. If the device appears damaged, a wipe must be taken to assure that no removable contamination is present. Results of this wipe test and a record of the damage to the device must be maintained.
- 6.8.4 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 manufacture in the UK as part of the final product testing.

6.9 Shipping of Devices

6.9.1 Only qualified shippers are to prepare the devices for shipment.

6.9.2 Shipping of the devices must be in accordance with applicable US DOT and IATA regulations.

6.10 Surveys

6.10.1 Before performing a survey check the following items and do not use the meter if any of the items are questionable:

6.10.1.1 Battery level

6.10.1.2 Meter function with “check source”

6.10.1.3 Calibration due date

6.10.2 Area surveys should be performed as listed in Sections 6.4 Servicing, 6.8 Receiving, and 6.16 Changes to areas.

6.10.3 Each survey must be documented by using the survey form in Appendix A of this document.

6.11 Employee Notifications

6.11.1 In the event that an employee is exposed to radiation or contaminated with radioactive material, the employee must be notified immediately or as soon as reasonably possible.

6.11.2 In the event that an employee is required to wear a personal monitoring device, the employee must be made aware of exposures reported through the monitoring device contractor.

6.11.3 In the event that a female employee is assigned to work in an area where radiation levels above background are expected, and the worker is or may become pregnant, the worker may declare her pregnancy or intention to become pregnant using the Declared Pregnant Worker form in Appendix C of this document.

**6.12 Agency Notifications and Reports**

- 6.12.1 In the event that an employee or member of the public is exposed to undue radiation or radioactive material, the RSO must be notified. The RSO will then make the determination of reporting requirements to the NRC or other pertinent agency.
- 6.12.2 In the event that a leak test returns results above 0.005 $\mu$ Ci, the RSO must notify the NRC in accordance with item 13 of our current license.
- 6.12.3 If a device is lost or stolen, the RSO must notify the NRC as stipulated in 10 CFR 20.2201.
- 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).
- 6.12.5 Annual distribution reports must be filed with the NRC in accordance with 10 CFR 32.16.
  - 6.12.5.1 Devices used at Owlstone's facility are exempt from reporting requirements.
  - 6.12.5.2 End users of the devices are exempt from all regulatory requirements as outlined in 10 CFR 30.20.
  - 6.12.5.3 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.
- 6.12.6 The RSO must be notified of any other significant events that involve radiation or radioactive material, to determine the course of action to be taken and to determine any notification requirements.

**6.13 Records**

- 6.13.1 The RSO or designee will keep the following records, (period of retention is in parenthesis):
- 6.13.1.1 Radiation safety training; (at least 7 years)
  - 6.13.1.2 Annual Radiation Safety Program (this document) Reviews; (at least 7 years)
  - 6.13.1.3 Results of annual internal or third-party program audits; (at least 7 years)
  - 6.13.1.4 Area surveys; (at least 7 years)
  - 6.13.1.5 Package surveys and wipes; (at least 7 years)
  - 6.13.1.6 Copy of Device Leak Test Results; (indefinitely, or until the instrument is disposed of)
  - 6.13.1.7 Employee exposure records, if any, will be kept by the RSO; (keep for 30 years after employee has left the company).
- 6.14 Inspections/Audits
- 6.14.1 Owlstone's facility may be inspected for compliance with applicable regulations from the NRC at the agencies' discretion.
  - 6.14.2 Periodic audits of the radiation safety program should be performed annually, and the results maintained for potential inspections. These audits may be performed by Owlstone staff or a consultant such as IRSC, Inc. ([www.irsc-inc.com](http://www.irsc-inc.com)).
- 6.15 Amendments to Licenses and Registrations
- 6.15.1 The RSO shall review and submit all amendments to licenses and/or registrations.
  - 6.15.2 An Executive Officer of Owlstone must sign an amendment request for radioactive material licenses. If such an "officer" is not available, an authorized legal representative may sign the amendment request.
- 6.16 Changes to Areas
- 6.16.1 Any changes proposed to the storage, service or shipping/receiving area(s) must be approved by the RSO prior to implementation.

6.16.2 After changes to the area(s) have been made, swipes must be taken in the previous area to ensure that no radioactive contamination remains.

6.16.3 Wipes are available through the RSO and must be processed by a company/establishment with Ni-63 detection capabilities.

6.16.4 If contamination is present, the area(s) must be decontaminated. The RSO will determine the proper method of decontaminating the area.

#### 6.17 New Devices

6.17.1 All new devices (instruments), which contain a radioactive source, must be registered with the US NRC before they can be sold.

6.17.2 The RSO will assure that an application for a device registration is filed in accordance with applicable US NRC regulations.

6.17.3 The UK Office of Owlstone should provide the US office with ample lead time on the development of new devices or major system modifications potentially affecting radiation safety in order to allow time to file for the proper regulatory approvals.

6.17.4 The RSO or radiation safety consultant, may recommend changes to the device if he/she sees that the device is not in compliance.

#### 6.18 Engineering Changes to Devices or Components

6.18.1 Major design changes to devices must be discussed with and approved by the RSO to ensure that there is no affect on the device registration.

6.18.2 Any changes to any component that may affect the device registration must be approved by the RSO.

#### 6.19 Special Projects

6.19.1 New special projects involving radiation, radiation emitting devices, radioactive sources, radioactive material, or any combination thereof, must be brought to the attention of the RSO for review. The RSO is responsible for the safety of the employees working on the project.

6.19.2 Any employee involved in special projects involving radiation, radiation emitting devices, radioactive sources, radioactive material, or any combination thereof, must be trained in the safety practices of the project before proceeding with the hands-on portion of the project.

## 6.20 Accidents

6.20.1 Devices that have been damaged must be reported to the RSO.

## 6.21 Radioactive Waste

### 6.21.1 Low Level Radioactive Waste (LLRW)

6.21.1.1 LLRW is waste which has come in contact with radioactive material and has the potential of being contaminated. It also includes wipes that may have contamination and devices which have been significantly damaged.

6.21.1.2 LLRW must be collected in a container which is separate from the normal trash.

6.21.1.3 A licensed radioactive material disposer must dispose of this waste.

Appendix A

Survey Form

Owlstone Radiation Survey Form

Name of person performing the survey: \_\_\_\_\_

Date of survey: \_\_\_\_\_

Survey Meter information:

Make/Brand: \_\_\_\_\_ Model: \_\_\_\_\_

Serial Number: \_\_\_\_\_ Calibration Due Date: \_\_\_\_\_

Background reading: \_\_\_\_\_ in units \_\_\_\_\_

Area being surveyed: \_\_\_\_\_

#	Measurement and units	Description/Comment
1		
2		
3		
4		
5		
6		
7		
8		
9		

Note: Indicate locations of surveys on an area map.

Appendix B

Owlstone Radiation Safety Training Topics

- Course Outline
  - Basic Overview
  - Regulatory Agencies
  - Definitions
  - Responsibilities
  - Dose
  - Exposure
  - Radiation
  - Biological Effects
  - Equipment Hazards
  - Radiation Protection
  - ALARA
    - Shielding
    - Surveys and Monitoring
  - Dosimetry
  - Access Control
  - Safe Working Practices
  - Shipping/receiving
  - Training
  - Notifications
  - Inventory
  - Additional Relevant Regulations
  - Inspections

Appendix C

Pregnancy Declaration Form

**FORM LETTER FOR DECLARING PREGNANCY**

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter, you may use a form letter the licensee has provided to you, or you may write your own letter.

**DECLARATION OF PREGNANCY**

To: \_\_\_\_\_

In accordance with the NRC's regulations at 10 CFR 20.1208, "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in \_\_\_\_\_ (only the month and year need be provided).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 0.5 rem (5 millisievert) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

\_\_\_\_\_  
**(Your Signature)**

\_\_\_\_\_  
**(Your Name Printed)**

\_\_\_\_\_  
**(Date)**