



March 17, 2021

David Lew
Regional Administrator
Licensing Assistance Team Division of Nuclear Materials Safety
U.S. NRC Region I
2100 Renaissance Blvd., Suite 100
King of Prussia PA 19406-2713

REC RG 1 04 02 '21 PM 12:53

SUBJECT: License number 06-31440, Docket number 030-38451 Renewal Application

Dear David Lew,

Please find the attached renewal application for a radioactive materials possession license for Owlstone, Inc., located at 19 Ludlow Road, Suite #202, Westport, CT 06880. Included are Form 313 – Application for Materials License and Form 526 – Certification of Small Entity Status for the Purpose of Annual Fees, along with our current Radiation Safety Manual and fee payment check. Also, we would like to request a "Letter of Timely Renewal" since our possession license will expire on June 30, 2021.

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. 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.

(01-2020)
10 CFR 30, 32,
33, 34, 35, 36,
37, 39, and 40



APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-6 A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE, TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

IF YOU ARE LOCATED IN:

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
1600 E. LAMAR BOULEVARD
ARLINGTON, TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

A. NEW LICENSE

B. AMENDMENT TO LICENSE NUMBER

C. RENEWAL OF LICENSE NUMBER 06-31440-01

2. NAME AND MAILING ADDRESS OF APPLICANT (include zip code)

Owlstone, Inc.
19 Ludlow Rd., Suite 202
Westport, CT 06880

3. ADDRESS WHERE LICENSED MATERIALS WILL BE USED OR POSSESSED

19 Ludlow Rd.
Suite 202
Westport, CT 06880

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Mark Brennan

BUSINESS TELEPHONE NUMBER	BUSINESS CELLULAR TELEPHONE NUMBER
203-908-4848	203-803-5723

BUSINESS E-MAIL ADDRESS

mark.brennan@owlstoneinc.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSE FEES (Fees required only for new applications, with few exceptions*)
(See 10 CFR 170 and Section 170.31)
*Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE CATEGORY	AMOUNT ENCLOSED \$

PER THE DEBT COLLECTION IMPROVEMENT ACT OF 1996 (PUBLIC LAW 104-134), YOU ARE REQUIRED TO PROVIDE YOUR TAXPAYER IDENTIFICATION NUMBER. PROVIDE THIS INFORMATION BY COMPLETING NRC FORM 531: <https://www.nrc.gov/reading-rm/doc-collections/forms/nrc531info.html>

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.
WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Mark Brennan, Vice President		3/17/21

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

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10 RADIATION SAFETY PROGRAM

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CERTIFYING OFFICER -- TYPED/PRINTED NAME AND TITLE	SIGNATURE	DATE
Mark Brennan, Vice President		3/17/21

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APPROVED BY				DATE	



RADIATION SAFETY PLAN

Approvals:

	VP	5/10/11		RSO	May 10, 2011
Title		Date	Title		Date
	VP	3/17/21		RSO	March 17 2021
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	Connecticut in a process becoming an agreement state.	2021
4		
5		

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

3.3 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.

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 The RSO is responsible for assuring that training is provided to affected employees.
- 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. An outline of the training requirements is included in Appendix B of this document.

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 Devices may be maintained and serviced at the facility; however, no service may be performed on the head which houses the radioactive source. Servicing the head or replacing sources shall only be performed at Owlstone's UK facilities.

6.4.2 During and after servicing a device, a survey meter should be used to assure that levels of radiation are below the permissible exposure limit and that the area is free of removable contamination.

6.4.3 Wipes of the service area should be performed periodically to verify that removable contamination, which may not be detectable with a survey meter, is not present.

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 5 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 100 Ci of Ni-63, 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.

6.9 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 μ Ci, the RSO must notify the NRC in accordance with 10 CFR 32.210.
- 6.12.3 If a device is lost or stolen, the RSO must notify the NRC as stipulated in 10 CFR 32.210.
- 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 32.210.

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.

6.12.6 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).

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)

