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STATE OF OHIO  
DEPARTMENT OF HEALTH

**GUIDANCE ABOUT LICENSES AUTHORIZING DISTRIBUTION  
TO GENERAL LICENSEES**

**NMS-LIC-16**

**Rev. 1**

**Effective Date: November 1, 2007**

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This consolidated guidance is based on the NRC's NUREG 1556, Volume 16, and along with the State of Ohio Radioactive Materials Licensing Program provides the applicants and reviewers with information concerning how to file a request, a listing of the applicable regulations and industry standards, policies affecting evaluation and registration, certain administrative procedures to be followed, information on how to perform the review and write a license and the responsibilities of the licensee.

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## ABBREVIATIONS

ALARA	As Low as Reasonably Achievable
ALI	Annual Limit on Intake
ANSI	American National Standards Institute
BRP	Bureau of Radiation Protection
Bq	Becquerel
CDROM	Compact Disk-read Only Memory
cpm	Counts Per Minute
Ci	Curie
DFP	Decommissioning Funding Plan
dpm	Disintegrations per minute
DIS	Decay-in-Storage
DOE	United States Department of Energy
DOT	United States Department of Transportation
GBq	Gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
IAEA	International Atomic Energy Agency
IN	Information Notice
kBq	Kilobecquerel
LLW	Low-Level [radioactive] Waste
MBq	Megabecquerel
mCi	Millicurie
mR	Milliroentgen
mrem	Millirem
mSv	Millisievert
$\mu$ Ci	Microcurie [greek letter mu-Ci]
NIST	National Institute of Standards and Technology
NMSS	NRC's Office of Nuclear Materials Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NVLAP	National Voluntary Laboratory Accreditation Program

OAC	Ohio Administrative Code
OCR	Optical Character Reader
ODH	Ohio Department of Health
R	Roentgen
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
SI	International System of Units
SSD	Sealed Source and Device
TEDE	Total Effective Dose Equivalent

# 1 PURPOSE OF REPORT

This report provides both guidance to an applicant in preparing an application to distribute generally licensed products or devices and Ohio Department of Health (ODH or Department) criteria for evaluating a general distribution license application. It also provides guidance to general licensees covered in Ohio Administrative Code (OAC) 3701:1-46-05 on the use, possession and registration requirements for general licensees.

General distribution licenses authorize the distribution (initial transfer) of byproduct material to persons generally licensed by OAC 3701:1-46-04, 05, 07, 08, 10 and 11. This report identifies the information needed to complete the department's "Application for Material License" for the use of byproduct material contained in devices or products distributed to general licensees.

The format within this document for each item of technical information is as follows:

**Regulations** - references the regulations applicable to the item.

**Criteria** - outlines the criteria the director uses to judge the adequacy of the applicant's response.

**Discussion** - provides additional information on the topic sufficient to meet the needs of most readers.

**Response from Applicant** - provides suggested response(s), offers the option of an alternative reply or indicates no response is needed on that topic during the licensing process.

Notes and references are self-explanatory and may not be found for each item on the application form.

The application form does not have sufficient space for applicants to provide full responses to Items 5 through 11. The answers to those items are to be provided on separate sheets of paper and submitted with the completed application form. Appendices B through L contain additional information on various radiation safety topics.

## **GENERAL**

Under current regulations certain persons may receive and use a device containing byproduct material under a general license if the device has been manufactured and distributed according to the specifications contained in a specific license issued by the director, Nuclear Regulatory Commission (NRC) or by an Agreement State. A specific license authorizing distribution of generally licensed devices is issued if a regulatory authority determines the safety features of the device and the instructions for safe operation of that device are adequate and meet regulatory requirements. The general licensee must comply with the requirements for labeling, instructions for use and proper storage or disposition of the device.

A generally licensed device usually consists of radioactive material, contained in a sealed source, within a shielded device. The device is designed with inherent radiation safety features so it can be used by persons with no radiation training or experience; thus, the general license is meant to simplify the licensing process so a case-by-case determination of the adequacy of the radiation training or experience of each user is not necessary.

The distributor of the generally licensed product/device is required to assure the director, NRC or the Agreement State that all products are distributed in accordance with the specifications provided in its license application. These specific licenses are issued by the director, NRC or an Agreement State and are referred to as "general distribution" licenses.

General distribution licenses only authorize the distribution of products and device(s) to general licensees and do not authorize possession or use of radioactive material. Therefore, specific licensees holding a broad scope license applying for general distribution licenses will need to file a separate application for a specific license authorizing possession and use of radioactive material, with the director, NRC Regional Office or the Agreement State for the state in which the material will be possessed and/or used. However, the determination of where to file the general distribution license application should be made based on the location from which the applicant wishes to distribute, not necessarily where the applicant possesses and/or uses the radioactive material (i.e., where the product is manufactured).

Licensees holding other than a broad scope license do not have to obtain a separate general distribution license. Authorization for the distribution of products and device(s) to general licensees may be incorporated into a specific license authorizing possession or use of radioactive material.

A specific license authorizing distribution to general licensees cannot be issued until the applicant (1) obtains a registration certificate (see Section 1.2) for the device (if applicable); and (2) obtains a possession and use license. To expedite the licensing process, the applicant should apply for the possession license and registration certificate concurrently, then apply for authorization to distribute once the registration certificate has been issued.

## 1.2 LICENSING AND SEALED SOURCE/DEVICE REGISTRATION

Applicants for a general distribution license are required to provide specific information about the sources and products, as outlined in OAC 3701:1-46-30, 33, 37, 40 and 42, concerning the radionuclides and activities, containment and construction, labeling, quality control and assurance programs, etc. The department will evaluate the information submitted in the application to ensure it meets all applicable standards and regulations and will contact the applicant, if necessary, to obtain additional clarification or information.

A sealed source and device (SSD) safety evaluation will be performed on the sealed sources and devices the applicant proposes to distribute to general licensees. Information about the review and approval process for SSDs is contained in NMS-LIC-03. Upon completion of the SSD evaluation, a registration certificate will be issued. The registration certificate must be complete and available before the licensing reviewer may issue the license. An SSD evaluation and registration certificate is required for all devices authorized in OAC 3701:1-46-04, 05, 07 and 10. An SSD evaluation is not required for devices/products authorized in OAC 3701:1-46-08 and 11. An example of a registration certificate is provided in Appendix B of this document.

**Notes:**

- The licensee can only distribute devices as described in the registration certificate.
- Modifications to a device require an amendment to the registration certificate.
- Devices that have been modified cannot be distributed until the registration certificate has been amended.

After the issuance of a license, licensees must conduct their programs for the distribution of generally licensed products/devices in accordance with the following:

- Statements, representations and procedures contained in their application, and other correspondence with the department.
- Terms and conditions of the license.
- Device registration, if applicable.
- Applicable ODH regulations.

Rule 3701:1-40-05 of “Licensing of Byproduct or Accelerator Produced Material,” requires the information provided in the application to be complete and accurate in all material respects. Information is considered to be material if it is likely to change or affect the director’s decision on issuing the license; therefore, information should be clear, specific and accurate.

It is important applicants and licensees understand the information provided in an application and approved in the license is considered a limitation by the director on the licensee to engage only in those activities and products as described in the application or license. The director should be notified of any changes or additions to the information submitted in the application. While some changes may not result in an amendment to the license, licensees should not assume an amendment is not needed or an amendment request has been granted until they receive a written confirmation in the form of a letter or license amendment.

### **1.3 TYPES OF GENERALLY LICENSED DEVICES**

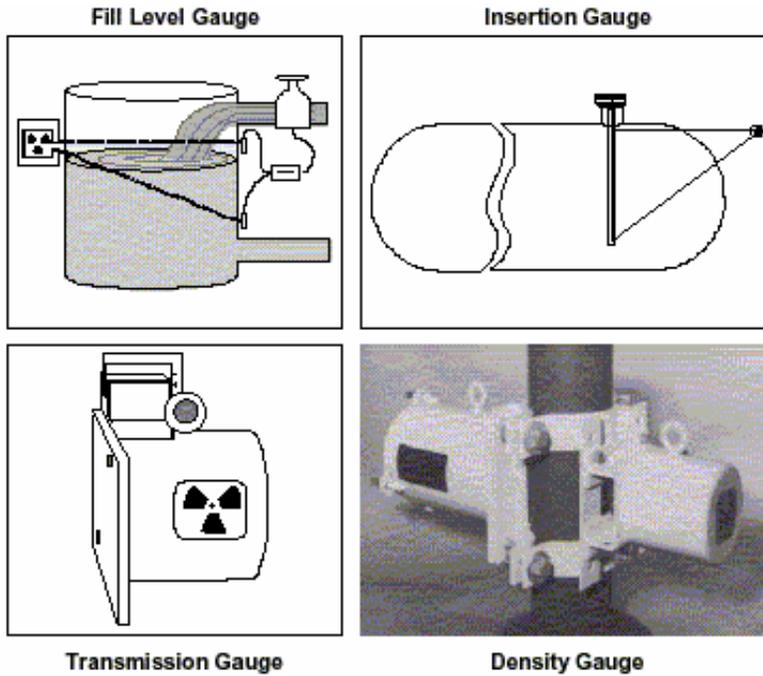
General distribution licenses are based on the types of products/devices to be distributed according to the six categories of products/devices found in OAC 3701:1-46. The following provides the applicable regulation and some examples of products/device(s) that may be distributed under a general distribution license and possessed by a general licensee:

#### **1.3.1 OAC 3701:1-46-04 Certain Devices and Equipment; and OAC 3701:1-46-05 Certain Measuring, Gauging or Controlling Devices.**

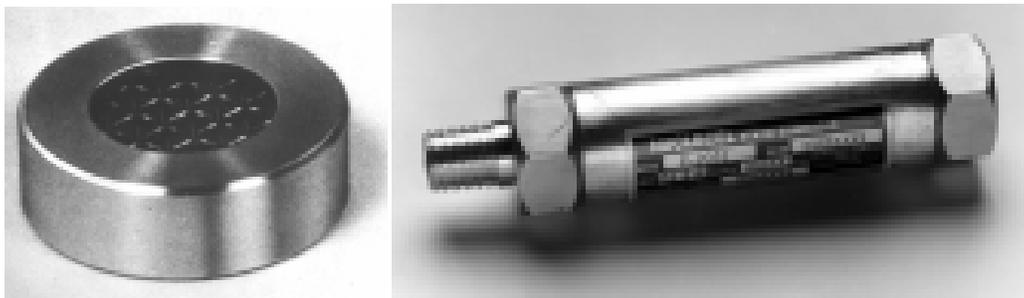
Byproduct material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.



**Figure 1.1 Gas Chromatograph Units** *Certain gas chromatograph units (detector cells) used for analysis of chemical composition can be possessed under a general license (OAC 3701-46-05).*



**Figure 1.2 Fixed Gauging Devices** *Certain nuclear gauges can be possessed under a general license (OAC 3701-46-05).*



**Figure 1.3 Static Eliminators** *Certain static elimination devices can be possessed under a general license (OAC 3701-46-05).*



**Figure 1.4 Tritium Exit Signs** *Certain tritium exit signs can be possessed under OAC 3701-46-05 (typical devices contain 25 Ci of tritium per sign).*

### **1.3.2 Luminous Safety Devices for use in Aircraft**

- Luminous safety devices containing only hydrogen-3 (tritium) or promethium-147.
- Tritium devices not to exceed 370 gigabecquerels (GBq) (10 Ci) per device.
- Promethium-147 devices not to exceed 11 GBq (300 mCi) per device.



**Figure 1.5 Luminous Exit Sign** *Safety device, such as luminous exit signs, containing tritium or promethium-147 that are used in aircraft may be used under the OAC 3701:1-46-07 general license.*

### **1.3.3 Americium-241 in the Form of Calibration or Reference Standards**

Single source not to exceed 185 kilobecquerels (kBq) (5.0  $\mu$ Ci) at any one time and/or location of use or storage.



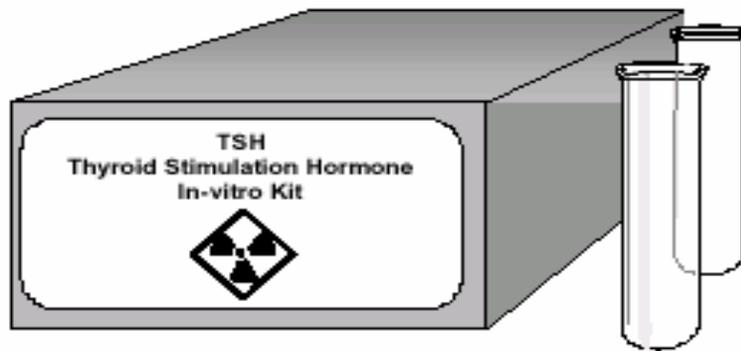
**Figure 1.6 Calibration Standards** *Certain calibration and reference sources containing americium-241 can be possessed under a general license authorized in OAC 3701:1-46-08.*

#### **1.3.4 Strontium-90 in Ice Detection Devices**

- Single sources not to exceed 1,850 kBq (50  $\mu$ Ci) per source.

#### **1.3.5 Byproduct or Accelerator Produced Material for Certain In Vitro Clinical or Laboratory Testing**

- Iodine-125 not to exceed 370 kBq (10  $\mu$ Ci).
- Iodine-131 not to exceed 370 kBq (10  $\mu$ Ci).
- Carbon-14 not to exceed 370 kBq (10  $\mu$ Ci).
- Hydrogen-3 not to exceed 1,850 kBq (50  $\mu$ Ci).
- Iron-59 not to exceed 740 kBq (20  $\mu$ Ci).
- Selenium-75 not to exceed 370 kBq (10  $\mu$ Ci).
- Mock iodine-125 not to exceed 1.85 kBq (0.05  $\mu$ Ci) of iodine-129 and 0.18 kBq (0.005  $\mu$ Ci) of americium-241.



**Figure 1.7 In Vitro Kit** Certain in vitro kits used in medicine, veterinary medicine, hospitals and clinical laboratories are authorized in OAC 3701:1-46-11.

#### **1.4 PROPRIETARY AND PRIVATE INFORMATION**

License applications are generally made available for review by the public. Private information including employee personal information (i.e., home address, home telephone number, Social Security Number, date of birth and radiation dose information), should not be submitted. Any trade secret information should be submitted in accordance with Appendix D.

## 2 AGREEMENT STATES

Certain states have entered into agreements with the Nuclear Regulatory Commission (NRC) as authorized by section 274(b) of the “Atomic Energy Act of 1954” 68 Stat 919, 42 USC 2011, as amended that gives Agreement States the authority to license and inspect byproduct, source or special nuclear materials used or possessed within their borders. A current list of Agreement States (including names, addresses and telephone numbers of responsible officials) may be obtained upon request from the NRC’s regional or field offices, or through the internet at <http://www.nrc.gov>. Any applicant other than a Federal agency who wishes to possess or use licensed material in one of these Agreement States needs to contact the responsible officials in that state for guidance on preparing an application; file these applications with state officials.

In general, materials licensees who wish to conduct operations at temporary job sites in an Agreement State should contact that state’s radiation control program office for information about state regulations. To ensure compliance with Agreement State reciprocity requirements, a licensee should request authorization well in advance of scheduled use.

Ohio Revised Code (ORC), Chapter 3748 “Radiation Control Program” provides the statutory basis for the regulatory control of radioactive materials and radiation generating equipment in the State of Ohio.

Ohio became an Agreement State in August 1999 with the NRC in accordance with ORC 3748.03. The Department of Health (hereafter “department”) is designated the Ohio radiation control agency in ORC 3748.02.

The governor-appointed Public Health Council is granted authority in ORC 3748.04 including, but not limited to: adopt, amend or rescind rules; radiation standards; set fees; and other regulatory items.

The duties and authority of the director of health (hereafter “director”) are identified in ORC 3748.05.

Within the department Bureau of Radiation Protection (BRP) is the designated agency to handle day-to-day activities on behalf of the director and the department.

Table 2.1 provides a quick way to check on which agency, if any, has regulatory authority.

**Table 2.1, Who Regulates the Activity?**

APPLICANT AND PROPOSED LOCATION OF WORK	REGULATORY AGENCY
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [OAC 3701:1-40-06])	NRC
Non-federal entity in non-Agreement State, US territory or possession	NRC
Non-federal entity in Agreement State at non-federally controlled site	Agreement State
Non-federal entity in Agreement State at federally controlled site Not subject to exclusive federal jurisdiction	Agreement State
Non-federal entity in Agreement State at federally controlled site subject exclusive federal jurisdiction.	NRC

### 3 MANAGEMENT RESPONSIBILITY

The department recognizes that effective radiation safety program management is vital to achieving safe and compliant operations. The department also believes consistent compliance with its regulations provides reasonable assurance licensed activities will be conducted safely. Ineffective management is frequently the underlying cause of safety and compliance problems. The term “management” refers to a senior-level manager who has responsibility for overseeing licensed activities.

To ensure adequate management involvement, a management representative must sign the submitted application acknowledging management’s commitments and responsibility for the following:

- Radiation safety, security and control of radioactive materials, and compliance with regulations.
- Completeness and accuracy of the radiation safety records and all information provided to the ODH (OAC 3701:1-40-05).
- Knowledge about the contents of the license and application.
- Committing adequate resources (including space, equipment, personnel, time and, if needed, contractors) to the radiation protection program to ensure public and worker safety is protected from radiation hazards and compliance with regulations is maintained.
- Selecting and assigning qualified individuals to serve on the Radiation Safety Committee, if required, and to serve as radiation safety officer (RSO) for their licensed activities.
- Prohibition against discrimination of employees engaged in protected activities.
- Commitment to provide information to employees regarding the employee protection and deliberate misconduct provisions in OAC 3701:1-38-09.
- Obtaining the ODH’s prior written consent before transferring control of the license.
- Notifying the ODH in writing, within 10 business days following filing of petition for voluntary or involuntary bankruptcy.

For further discussion of management responsibilities, see section 7.7. For information on inspection, investigation, enforcement and other compliance issues, contact the BRP at (614) 644-2727, or visit the ODH Web site at <http://www.odh.ohio.gov>, and look for “Nuclear Material Safety” under ODH Programs and the OAC under “Rules”

## 4 HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the most recent guidance in preparing an application.
- Complete the application form HEA5133 (Appendix A) Items 1 through 4 and 12 through 15 on the form itself.
- Complete the application form Items 5 through 11 on supplementary pages or use Appendix A.
- For each separate sheet, other than Appendix A, that is submitted with the application, identify and key it to the item number on the application or the topic to which it refers.
- Submit all documents, typed, on 8-1/2 - x - 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary. If necessary, mark all such pages prominently with the words, "Trade Secret," along with a cover sheet for those pages also so marked. Do not include personal information such as individuals' Social Security numbers, birth dates, etc., unless specifically requested.
- Submit an original, signed application and one copy.
- Retain one copy of the license application for future reference.

All license applications will be available for review by the general public by contacting the ODH BRP. Employee personal information, i.e., home address, home telephone number, Social Security number, date of birth, radiation dose<sup>1</sup> information, should not be submitted unless specifically requested.

The department's licensing process involves pre-payment of the application fee to the Treasurer, State of Ohio. Therefore, processing of electronic applications is not currently possible. However, submission of the signed application form, specifying that the amplifying information is in electronic form, is acceptable.

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<sup>1</sup>In this document, dose or radiation dose is used as defined in 3701:1-38-01, i.e., a generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent or total effective dose equivalent. These latter terms are also defined therein.

To ensure a smooth process, applicants are requested to follow these suggestions for attachments:

- Submit printed or typewritten text on smooth crisp paper that will feed easily into a copier.
- Choose 12-point or larger font size.
- Avoid stylized characters such as script, italic, etc.
- Be sure the print is clear and sharp.
- Be sure there is high contrast between the ink and paper (black ink on white paper is best).

## **5 WHERE TO FILE**

Applicants wishing to possess or use licensed material subject to ODH jurisdiction must file an application with the department at:

Ohio Department of Health  
246 North High Street  
Bureau of Radiation Protection  
Columbus, Ohio 43215

In general, applicants wishing to possess or use licensed material in Ohio must file an application with the department, not the NRC. However, if work will be conducted at federally controlled sites in Ohio, applicants must first determine the jurisdictional status of the land in order to determine whether the NRC or the Agreement State has regulatory authority. See the section on “Agreement States” for additional information.

## **6 LICENSE FEES**

Each application, for which a fee is specified, including applications for new licenses and license amendments, must be accompanied by the appropriate fee. Refer to Appendix A of Rule 3701:1-38-02 of the OAC, to determine the amount of the fee. The ODH will not review the license application prior to fee receipt, except those designated full cost. Once technical review has begun, fees will generally not be refunded; application fees will be charged regardless of disposition of an application or the withdrawal of an application.

All licensees are also subject to annual fees; refer to OAC 3701:1-38-02 for these fees, and for additional information on reduced annual fees for licensees that qualify as “small entities.”

Direct all questions about fees or completion of Item 14 “Reduced Fees Certification” of the application form (Appendix A) to the Ohio Department of Health, Bureau of Radiation Protection, 246 North High Street, Columbus, Ohio 43215. You may also call (614) 644-2727.

## 7 CONTENTS OF AN APPLICATION

The following comments apply to the indicated items on application form (Appendix A).

### 7.1 TYPE OF APPLICATION

<b>This is an application for:</b> <input type="checkbox"/> <b>Initial License</b> <input type="checkbox"/> <b>Renewal</b> or <input type="checkbox"/> <b>Amendment of License Number:</b>
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Check box “Initial License” if the application is for a new general distribution license.

Check “Amendment to License No.” if the application is for an amendment<sup>2</sup> to an existing general distribution license.

Check “Renewal of License No.” if the application is for the renewal<sup>2</sup> of an existing general distribution license and provide the license number.

### 7.2 ITEMS 1 AND 2: APPLICANT’S NAME AND MAILING ADDRESS

<b>1. Name of Licensee</b> (Person or firm proposing to conduct the activities described below.)	<b>2. Address of Licensee</b> (Mailing address of licensee. This may be a PO Box.)
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List the legal name of the applicant’s corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. Because of the significant authority given a broad scope licensee to oversee licensed activities, it is not appropriate for an individual to apply for a broad scope license. No individual other than the duly authorized applicant may, for any licensing matter, act on behalf of the applicant or provide information without written authorization of the applicant.

**Note: The department must be notified in the event of change of ownership or control and bankruptcy proceedings; see the next page for more details.**

<sup>2</sup> See “Amendments and Renewals to a License” later in this document. Licensees are required to request and obtain an amendment to the license before making changes in their radiation safety program. Examples of changes that require amendment are change of radiation safety officer (RSO) and increases in the license possession limit.

## **Timely Notification of Transfer of Control**

**Regulations:** OAC 3701:1-40-16(A).

**Criteria:** Licensees must provide full information and obtain director's prior written consent before transferring control of the license, also commonly referred to as "transferring the license."

**Discussion:** Transferring control may be the result of mergers, buyouts or majority stock transfers. Although it is not the director's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior written consent from the director. This ensures:

- Radioactive materials are possessed, used or controlled only by persons who have valid NRC or Agreement State licenses.
- Materials are properly handled and secured.
- Persons using these materials are competent and committed to implementing appropriate radiological controls.
- A clear chain of custody is established to identify who is responsible for final disposal of the licensed materials.
- Public health and safety are not compromised by the possession and use of such materials.

**Response from Applicant:** None required from an applicant for a new license.

## **Notification of Bankruptcy Proceedings**

**Regulation:** OAC 3701:1-40-16(F).

**Criteria:** Within 10 business days of filing of a voluntary or involuntary petition for bankruptcy for or against a licensee, the licensee must notify the department, in writing, identifying the bankruptcy court in which the petition was filed and the date of filing.

**Discussion:** Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. The department needs to know when licensees are in bankruptcy proceedings in order to determine whether there are any public health and safety concerns (e.g., contaminated facility). The department shares the results of its determinations with other involved entities (e.g., trustee) so health and safety issues can be resolved before bankruptcy actions are completed.

**Response from Applicant:** None required at the time of application for a new license. Licensees must notify the department following the filing of a voluntary or involuntary petition for bankruptcy for or against the licensee.

**7.3 ITEM 3: ADDRESS (ES) FROM WHICH LICENSED MATERIAL WILL BE DISTRIBUTED**

<b>3. Location(s) of Use or Storage</b> (May not be a PO Box, an actual street address is required. Use additional pages if necessary.)
a. Address:
b. Address:
c. Address:

An applicant for a general distribution license must be an organization with an address in the State of Ohio from which it will distribute the items. The applicant must specify the street address, city or other descriptive address (e.g. on State Route 7, five miles east of the intersection of State Route 7 and State Route 35, some city in Ohio) for each and every facility used as a location from which distribution will occur. A post office box address will not be accepted for the distribution address. Each point of distribution will be listed on the general distribution license.

Being granted a radioactive materials license does not relieve a licensee from complying with other applicable federal, state or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of radioactive material).

**7.4 ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

<b>4. Licensee Contact Person</b>	If consultant or other non-employee, so indicate <input type="checkbox"/>		
Name:	Phone: ( )	Fax: ( )	E-Mail:

Identify the individual who can answer questions about the application, and include his or her telephone number. This is typically the proposed RSO, unless the applicant has named a different person as the contact. The Department will contact this individual if there are questions about the application.

Notify the department if the contact person or his or her telephone number changes so the department can contact the applicant or licensee in the future with questions, concerns or information. This notice is for "information only" and does not require a license amendment or a fee.

The individual named in Item 4 of the application may or may not be the same individual who signs the application as the "certifying official" on behalf of the licensee and has the authority to make commitments to the department (see Item 13 on Form HEA5133, Appendix A). Any commitments made by the applicant should be signed by the individual named in Item 13, because only that individual is considered by the department to have the authority to make commitments on behalf of the applicant. The department will not, therefore, accept license amendments or renewals signed by the individual identified in Item 4, if this person differs from the one named in Item 13.

The department recognizes licensees may use a consultant or consultant group to help prepare the license application and provide support to the radiation protection program. Licensees are reminded that regardless of the role of the consultant in radiation protection program management, the licensee remains ultimately responsible for all aspects of the licensed program, including the services performed by the consultant. When selecting the person to be contacted, be aware that further important ODH and NRC communications will be directed to this person.

**7.5 ITEMS 5 AND 6: RADIOACTIVE MATERIAL AND PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.**

<b>5. Radioactive Material</b>		
a. Element and Mass Number (e.g., Hydrogen-3)	b. Physical / Chemical Form (e.g., sealed source, liquid, metal foil)	c. Maximum Activity (in SI units)
<b>6. Purpose for which radioactive material will be used</b>		

**Regulations:** OAC 3701:1-40-15; OAC 3701:1-46-30; OAC 3701:1-46-32; OAC 3701:1-46-37; OAC 3701:1-46-40; and OAC 3701:1-46-42.

**Criteria:** An application for a general distribution license will be approved if the requirements of OAC 3701:1-40-15 and the applicable requirements of OAC 3701:1-46-30; OAC 3701:1-46-32; OAC 3701:1-46-37; OAC 3701:1-46-40; and/or OAC 3701:1-46-42 are met.

**Discussion:** Applicants should determine what devices or products are to be distributed and provide information about each type of product. Describe in general terms the purpose of each product. Activity should be specified in terms of "XX becquerels (YY curies)." For example, "the maximum activity per sealed source is 370 MBq (10 mCi) of cesium-137."

A safety evaluation of sealed sources and devices is required on certain generally licensed devices. An SSD evaluation is required for all devices authorized in OAC 3701:1-46-04, 05, 07 and 10. An SSD evaluation is not required for devices/products authorized in OAC 3701:1-46-08 and 11. This evaluation is performed by the director, NRC or an Agreement State before authorizing a manufacturer (or distributor) to distribute the device to general licensees. The safety evaluation is documented in an SSD Registration Certificate.

For additional guidance relating to sealed sources and devices, also see NMS-LIC-03.

You may not apply for a distribution license for devices that require an SSD evaluation and have not yet been through the above procedure. First obtain an SSD Registration Certificate and then apply for a distribution license.

**Response from Applicant:** The applicant should provide the following information for each device to be distributed:

- Isotope.
- Manufacturer and model number.
- Maximum activity per device.
- Purpose of the device.
- SSD Registration Certificate Number for all devices authorized for use under OAC 3701:1-46-04, 05, 07 and 10.

References: NMS-LIC-03, "Applications for Sealed Source and Device Evaluation and Registration." Also, see the Sample Registration Certificates for Generally Licensed Products, in Appendix B of this document.

**7.6 ITEMS 7, 8, 9 AND 11: NOT APPLICABLE**

<b>7. Radiation Safety Officer</b> (Include training and experience.)
<b>8. Training Program</b> (Include topics to be covered, frequency of training, and recipients.)
<b>9. Facilities and Equipment</b> (attach documentation and diagram of locations of use and storage.)
<b>11. Waste Disposal / Waste Management</b> (List methods to be used by name or reference.)

These items on Form HEA5133 are not applicable for general distribution licenses.

**7.7 ITEM 10: RADIATION SAFETY PROGRAM (REQUIREMENTS FOR A GENERAL DISTRIBUTION LICENSE**

<b>10. Radiation Protection Program</b> (Include personnel monitoring, instrumentation, and procedures.)
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**7.7.1 OAC 3701:1-46-30: REQUIREMENTS FOR INITIAL TRANSFER OF DEVICES FOR USE UNDER OAC 3701:1-46-05 (CERTAIN MEASURING, GAUGING, OR CONTROLLING DEVICES)**

**Regulations:** OAC 3701:1-46-05; OAC 3701:1-46-30; OAC 3701:1-46-31; OAC 3701:1-46-32.

**Criteria:** Applicants for a specific license to distribute generally licensed devices, as specified in OAC 3701:1-46-05, should provide information relative to the material transfer reports and records. Applicants should also provide a copy of the information packet to be sent to customers before transfer. An SSD review is required (See Section 1.2). All other requirements of OAC 3701:1-46-30 are handled in the SSD review.

**Discussion:** The following information must be submitted or addressed as part of the license application.

## Quarterly Material Transfer Reports

Licensees are required to file a report with the director, NRC, an Agreement State or NARM licensing state within 30 days of the end of each calendar quarter in accordance with OAC 3701:1-46-32. The report shall include the following information:

1. Name and license number of the specific licensee submitting the report.
2. Name and address of each general licensee to which a product was transferred.

This address is to be the mailing address of the location of use of the device. For devices that are portable, this address shall be the mailing address of the primary place of storage of the device.

When a customer has multiple locations of use, each location of use should be listed as a separate transfer, with the corresponding mailing address of each location of use (unless the multiple locations are contained within the same business campus or industrial complex). For example, suppose you transfer GL devices to Company A at two different locations (Plant 1 and Plant 2). Company A is considered two separate general licensees, one for each location of use. In other words, Company A-Plant 1 is considered a separate general licensee from Company A-Plant 2. Both general licensees, to which a product was transferred, should be reported.

Different facilities at the same industrial complex or business campus are not considered separate locations.

If there is no mailing address for the location of use, an alternative address for the general licensee should be submitted along with information on the actual location of use.

Reports to the director should include only transfers of devices where the place of use is within the director's jurisdiction.

Note: All portable devices containing radioactive material, used within the State of Ohio, shall be licensed in accordance with rules 3701:1-38-02 and paragraph (I) of rule 3701:1-40-14 of the OAC.

3. Name, title, and phone number of each general licensee's responsible individual (RI).

The RI is required to be an individual designated by the general licensee to be responsible for having knowledge of and authority to take required actions to ensure the day-to-day compliance with the appropriate regulations and requirements. Each general licensee must designate one RI per location and cannot designate more than one RI per location. An RI can; however, be assigned to more than one general licensee. This individual is not necessarily someone who

works onsite at the place of use of the device and is not necessarily conducting all required actions, but is responsible for ensuring that required actions are taken.

4. Date of transfer.
5. Type, model number and serial number of each product transferred.
6. Quantity and type of byproduct material contained in the product.

#### **Important Notes on Transfer Reports:**

- If one or more "intermediate persons" will temporarily possess the device at the intended place of use before the intended user takes possession, the report must include the same information for each intermediate person and clearly designate that person as an intermediate person. The term "intermediate person" means a person, company or corporation that will temporarily possess the device at an intended place of use prior to its possession by the intended user. For example, if XYZ Building Company owns an office building during its construction and the building contains self-luminous tritium exit signs (GL devices); XYZ Building Company is the intermediate person. When XYZ Building Company sells the office building to Company 123, then Company 123 becomes the general licensee. Note that an intermediate person should not hold a device in storage for longer than two years (OAC 3701:1-46-05(C)(14)).
- If a company will be a warehouseman prior to delivery to the final destination, the warehouseman is exempted under OAC 3701:1-40-07 to the extent that the company stores the GL device for the end user. The company does not need to be documented on the transfer report. For example, suppose Company A purchases a tritium exit sign through Electric Company X (a warehouseman), for use at a particular location L, which is currently under construction. Electric Company X can store the exit sign at its place of business prior to shipment to its final destination. The distributor (specific licensee with license for distribution) must list the general licensee as Company A at location L on the quarterly transfer report. The distributor cannot ship the exit sign to Electric Company X without knowing who Company X has sold the sign to, i.e., the end user or general licensee company name and location of use. Also, the distributor cannot ship multiple signs to Electric Company X for them to maintain in stock for resale, unless Electric Company X has a specific license for distribution of GL devices.
- If you receive a device from an OAC 3701:1-46-05 general licensee, the report must note this and identify the General Licensee by name and address, the type, model number and serial number of the device received, the date of receipt and in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.
- If no transfers or receipts were made during the reporting period, a report of no activity is required.

- If you make changes to a OAC 3701:1-46-05 device, such that the label must be changed to update required information, the report must identify the general licensee, the device and the change to information on the device label.
- Licensees must also submit a report containing the same information outlined above to the responsible Agreement State agency for transfers to or from general licensees in Agreement States. However, a report of no transfers is required only if an Agreement State requests it.

### **Record Keeping**

Information on all OAC 3701:1-46-05 transfers and receipts that supports the above reports, are required to be maintained for 3 years after the recorded event.

Licensees are required to make available, upon request, to the various regulatory agencies, records of final disposition of devices in the event the licensee files for bankruptcy or requests termination of the license.

### **Information to be Supplied to Customers**

Licensees are required to provide information to their generally licensed customers before transfer of devices in accordance with OAC 3701:1-46-31. The intent is for the customer to be aware of this information prior to making a commitment to purchase (e.g., so they can consider the requirements associated with the general license and the costs of disposal of the in making a decision to purchase).

If the customer is planning to use the device in an NRC or Agreement State regulated state, a copy of applicable federal or state regulations and the name, address and phone number of the contact at the NRC or Agreement State regulatory agency should be provided.

Note that Appendices J and K can be supplied to customers for information as well. In the easy-to-read question and answer format, these Appendices contain useful information regarding generally licensed devices. Appendix J may be helpful to a wide range of general licensees, and Appendix K may be helpful to general licensees who use Self-Luminous Exit signs.

### **Response from Applicant: Submit the Following:**

A statement that: "We will provide quarterly transfer reports in accordance with OAC 3701:1-46-32(A) and (B), and will maintain records in accordance with OAC 3701:1-46-32(C). We will provide information to customers prior to purchase in accordance with OAC 3701:1-46-31(A) and (B)."

**References:** Appendix E contains a checklist for use in reviewing general distribution license applications for OAC 3701:1-46-05 devices. Appendix J contains guidance for

general licensees in the form of questions and answers. Appendix K contains guidance specific to self-luminous exit signs (tritium exit signs) in the form of questions and answers.

### **7.7.2 OAC 3701:1-46-33: REQUIREMENTS FOR INITIAL TRANSFER OF LUMINOUS SAFETY DEVICES FOR USE IN AIRCRAFT**

**Regulations:** OAC 3701:1-46-07; OAC 3701:1-46-33; OAC 3701:1-46-36.

**Criteria:** Applicants for a specific license to initially transfer luminous safety devices for use in aircraft containing tritium or promethium-147, for distribution to general licensees under OAC 3701:1-46-07, must provide sufficient information relative to annual material transfer reports. All devices distributed under OAC 3701:1-46-07 require an SSD review. All other requirements of OAC 3701:1-46-33 are handled in the SSD review (See Section 1.2).

For products distributed to general licensees pursuant to OAC 3701:1-46-07, the specific licensed distributor is required under OAC 3701:1-46-36 to file an annual report with the department before July 30 of each year, covering the year ending June 30. The report must include the following information:

- Name of each general licensee to which a product was transferred (distributed).
- Types and numbers of each product transferred (distributed).
- Quantity of tritium or promethium-147 contained in each type of product.
- Total quantity of tritium or promethium-147 transferred (distributed).

The report should also identify the specific licensee submitting the report (the distributor) and the specific license number.

**Response from Applicant:** Submit the following:

A statement that: "We will provide annual material transfer reports in accordance with OAC 3701:1-46-36."

**References:** Appendix F contains a checklist for use in reviewing a general distribution license application for luminous safety devices for aircraft.

### **7.7.3 OAC 3701:1-46-37: REQUIREMENTS FOR INITIAL TRANSFER OF CALIBRATION OR REFERENCE SOURCES CONTAINING AMERICIUM-241**

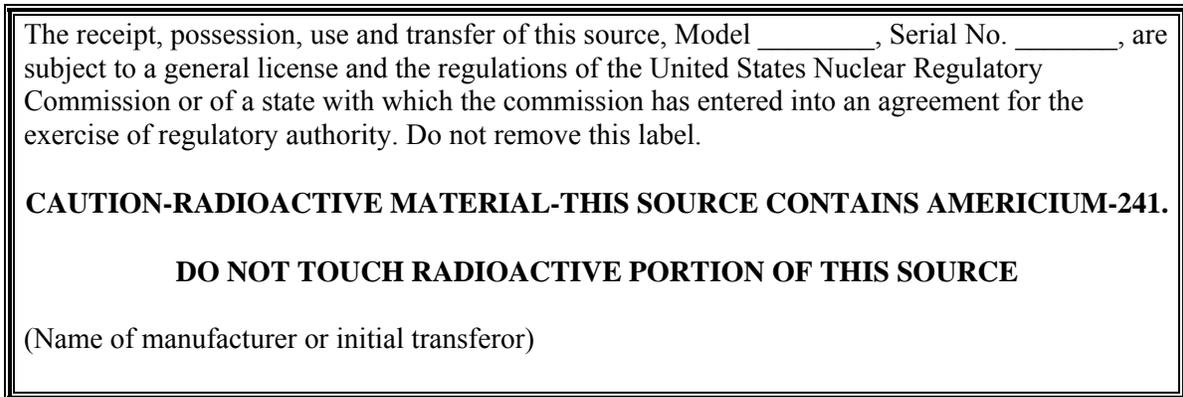
**Regulations:** OAC 3701:1-46-08; OAC 3701:1-46-37; OAC 3701:1-46-38; OAC 3701:1-46-39.

**Criteria:** Applicants for a specific license to initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under OAC 3701:1-46-08, must provide sufficient information relative to OAC 3701:1-46-38. Note that an SSD registration certificate is not required for americium-241 calibration sources that contain no more than 185 kBq (5.0 microcuries), and thus, the application process for a manufacturing license of such sources should include a review of OAC 3701:1-46-37 and OAC 3701:1-46-39. For information regarding applications for manufacturing, see NMS-LIC-12.

**Discussion:** This section outlines the requirements to obtain a license for an applicant wishing to distribute americium-241 reference and calibration sources.

The byproduct material must be prepared for distribution in calibration or reference sources consisting of americium-241 not exceeding 185 kBq (5.0 microcuries).

Each source or storage container for the source must bear a label that contains sufficient information relative to safe use and storage of the source and the following statement (or a substantially similar statement):



**Figure 7.1 Label**

Response from Applicant: Submit an actual label for each americium-241 check or reference source to be distributed. These labels must contain the information described in the Discussion section above.

Reference: Appendix G contains a checklist for use in reviewing a general distribution license application for americium-241 calibration or reference sources under OAC 3701:1-46-08.

#### **7.7.4 OAC 3701:1-46-40: REQUIREMENTS FOR INITIAL TRANSFER OF ICE DETECTION DEVICES CONTAINING STRONTIUM-90**

**Regulations:** OAC 3701:1-46-10, OAC 3701:1-46-40.

**Criteria:** Applicants for a specific license to initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under OAC 3701:1-46-10, must only provide sufficient information relative to Items 1 through 6 of Form HEA 5133. An SSD review is required (See Section 1.2). All other requirements of OAC 3701:1-46-40 are handled in the SSD review.

**Response from Applicant:** No specific response required.

**References:** Appendix H contains a checklist for use in reviewing general distribution license applications for ice detection devices.

#### **7.7.5 OAC 3701:1-46-42: REQUIREMENTS FOR INITIAL TRANSFER IN VITRO KITS UNDER OAC 3701:1-46-11**

**Regulations:** OAC 3701:1-38-18(A); OAC 3701:1-38-19(A); OAC 3701:1-40-19(D); OAC 3701:1-46-11; OAC 3701:1-46-42.

**Criteria:** Applicants for a specific license to initially transfer byproduct material for certain in vitro clinical or laboratory testing for distribution to persons generally licensed under OAC 3701:1-46-11 must provide sufficient information to satisfy OAC 3701:1-46-42(B)-(E).

**Discussion:** This section outlines the requirements to obtain a license for an applicant requesting authorization to distribute in vitro kits to persons who use them for a variety of clinical tests such as Schillings tests, red cell survival tests, hormone evaluations and thyroid stimulating hormone tests (TSH). An SSD review is not required.

The byproduct material must be prepared for distribution in prepackaged units consisting of any of the following:

- Iodine-131, iodine-125, carbon-14 or selenium-75 not exceeding 370 kilobecquerels (kBq) (10 microcuries (10  $\mu$ Ci)).
- Hydrogen-3 not exceeding 1,850 kBq (50  $\mu$ Ci).
- Iron-59 not exceeding 740 kBq (20  $\mu$ Ci).
- Mock iodine-125 not exceeding 1.85 kBq (0.05  $\mu$ Ci) of iodine-129 and 0.18 kBq (0.005  $\mu$ Ci) of americium-241.

Each prepackaged unit must bear a durable, clearly visible label including the following information:

- The radionuclide and chemical form.
- A statement that the radioactivity does not exceed the limit indicated above for each radionuclide.

- The radiation caution symbol described in OAC 3701:1-38-18(A).
- The words, "Caution - Radioactive Material," and "Not for Internal or External Use in Humans or Animals."

Each package must also have a statement, or a substantially similar statement, that contains the following information on a label affixed to the prepackaged unit or in a leaflet or brochure accompanying the package.

This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material or the radiation there from, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority

(Name of Manufacturer)

**Figure 7.2 Package Label.**

This label or leaflet/brochure must contain adequate information about the precautions to be observed in handling and storing such byproduct material. Regarding Mock Iodine-125 reference/calibration sources, the information must also contain directions on disposing of waste in accordance with OAC 3701:1-38-19(A). Usually, compliance with this requirement is achieved by transfer to an authorized recipient.

In accordance with 3701:1-46-11(F), except for mock iodine-125 sources, these licensees are exempt from the requirements in OAC 3701:1-38, including the requirements on disposal of licensed material. The distribution licensees may wish to inform their customers of this exemption.

Note: The distributor of generally licensed in vitro kits must not transfer materials to a general licensee unless the general licensee has a properly completed HEA 5518, "Registration Certificate - In Vitro Testing with Radioactive Material" on file with ODH. Distributors can verify this information by obtaining a copy of the general licensee's validated Form HEA 5518. An ODH Form HEA 5518 has been validated if it has been assigned a registration number by ODH.

**Response from Applicant:** Submit an actual package label and/or leaflet/brochure for each type of prepackaged kit. These labels and/or leaflet/brochures must contain the information described in the Discussion section above.

**References:** Appendix I contains a checklist for reviewing general distribution license applications for certain in vitro kits licensed under 3701:1-46-11.

## 7.8 ITEM 12: DOMESTIC/FOREIGN CORPORATION

<b>12. Indicate whether licensee is a</b> <input type="checkbox"/> <b>Domestic (in-state)</b> or <input type="checkbox"/> <b>Foreign (out-of-state) corporation</b> If a Foreign corporation, show the Designated Agent		
Name:	Address:	Phone: (    )

Applicants should indicate their corporate designation. Section 1701.01 of the ORC provides the following definitions:

- “Corporation” or “Domestic Corporation” means a corporation for profit formed under the laws of this state.
- “Foreign Corporation” means a corporation for profit formed under the laws of another state.

Applicants that meet the definition of “foreign corporation” should provide the name, address and phone number of their designated agent. A designated agent is required by Section 1703.041 of the ORC.

## 7.9 ITEM 13: CERTIFICATION

<b>13. Application Certification</b> The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that: a. This application is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder. b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief.		
Printed name and title of applicant/official executing this application	Signature	Date

Individuals acting in a private capacity are required to date and sign the application form. Otherwise, representatives of the corporation or legal entity filing the application should date and sign the application form. Representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. As discussed previously in “Management Responsibility,” signing the application acknowledges management’s commitment and responsibilities for the radiation protection program. The department will return all unsigned applications for proper signature.

### NOTES:

- It is a criminal offense to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

## 7.11 ITEM 14: TAX ID NUMBER

**14. Licensee Federal Tax ID number** (If no Tax ID number, then Social Security Number):

The department needs this number in order to process any adjustments to fees, which favor the licensee, such as refunds of overpayments. If the applicant is an individual and does not have a tax ID number, include the Social Security number.

**7.10 ITEM 15: REDUCED FEES CERTIFICATION**

<b>15. License Reduced Fees Certification</b> (Attach financial documentation to indicate qualifications for reduced fees.)		
The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that:		
a. This License Reduced Fees Certification is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder.		
b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief.		
c. The qualifications for reduced fees is based on OAC 3701:1-38-02, paragraph (J), subparagraph ( )		
Printed name and title of applicant/official executing this application	Signature	Date

Applicants should review and determine if the facility to be licensed for radioactive material meets the definitions for reduced license fees as delineated in paragraph (J) of rule 3701:1-38-02 of the OAC. Applicants shall sign the certification and attach all required supporting documentation if the applicant desires a reduction in fees as provided for in the OAC.

## **8 AMENDMENTS AND RENEWALS TO A LICENSE**

It is the licensee's obligation to keep the license current. If any of the information provided in the original application is to be modified or changed, the licensee must submit an application for a license amendment before the change takes place. Also, to continue the license after its expiration date, the licensee must submit an application for a license renewal at least 180 days before the expiration date (OAC 3701:1-40-18(A)).

Applications for license amendment, in addition to the following, must include the appropriate fee. For renewal and amendment requests applicants must do the following:

- Be sure to use the most recent guidance in preparing an amendment or renewal request.
- Submit either the application form or a letter requesting amendment or renewal.
- Provide the license number.
- For renewals, provide a complete and up-to-date application if any outdated documents are referenced or there have been significant changes in regulatory requirements, the department's guidance, the licensee's organization or radiation protection program. Alternatively, describe clearly the exact nature of the changes, additions and deletions.

Licensees wishing to renew their licenses should submit a complete application according to NMS-LIC-16. Department staff's action will be similar to that described for amendments, but will include an extension of the license's expiration date.

Deviations from the suggested wording of responses as shown in this document or submission of alternative procedures may require a custom review.

## **9 DEFICIENCY IN THE APPLICATION**

If, in the process of evaluating an application, it is determined that insufficient information has been submitted, the license reviewer will contact the applicant to obtain the necessary information. Depending on the type and complexity of the information needed, the reviewer may request the additional information through a formal written request or, especially for simple answers and clarifications, via telephone or e-mail. Submittal of an inadequate or deficient application may delay the issuance of the license. The application could be rejected by the department for failure to provide a prompt or timely response to a deficiency in the application.

Applicants may request an extension of time in order to respond to any correspondence or request for additional information about its application, provided the department determines there is good cause and the additional time is reasonable. The request may be in writing or via telephone. Typically, the reviewer notifies the applicant by telephone that an extension has been granted and gives the applicant the new proposed date.

## 10 ISSUANCE OF A LICENSE

Licenses authorizing distribution of generally licensed products or devices under OAC 3701:1-46-30, 46-33, 46-37, 46-40 and/or 46-42 are a separate license from the possession and use license. These separate licenses are commonly referred to as a "general distribution" license. All general distribution licenses include the following information:

- Licensee's name and mailing address.
- License number, docket number and expiration date (all assigned by the department).
- Byproduct material and its chemical and/or physical form.
- Authorized activity.
- Products, model number, and maximum activity per source or device.
- Location(s) from which generally licensed products may be distributed.
- Condition that "this license does not authorize possession or use of licensed material."

The general distribution license also contains a "tie-down" condition that commits the licensee to conducting its program in accordance with the statements, representations and procedures contained in the documents, including any enclosures, submitted by the applicant.

## 11 TERMINATION OF ACTIVITIES

**Regulations:** OAC 3701:1-40-18.

**Criteria:** Termination of distribution activities.

**Discussion:** Pursuant to OAC 3701:1-40-18, general distribution licensees may request termination of their radioactive materials license at any time. Licensees should notify the department within 60 days of their decision to permanently cease licensed activities or the lack of licensed activities for 24 months.

General distribution licensees who intend to terminate their possession and use activities as well are responsible for notifying and providing records to the appropriate NRC or Agreement State authorities concerning the disposition of the possession license and all radioactive material, etc.

A specific license is not terminated until the department takes final action to terminate the license; therefore, an application for license termination does not relieve the licensee from its obligations to comply with ODH regulations and the terms and conditions of the license until the license is terminated in writing by the department.

**Response from Applicant:** General distribution licensees who are required to submit material transfer reports under OAC 3701:1-46-32 or OAC 3701:1-46-36 are required to file material transfer reports when discontinuing activities authorized under the license. The report must include transfers since the period previously reported until the date of the last transfer. If no transfers of byproduct material have taken place, then the report should so indicate

# Appendix A

## State of Ohio Application for a License for Radioactive Material

## Ohio Department of Health Application for a License for Radioactive Material

<b>This is an application for:</b> <input type="checkbox"/> <b>Initial License</b> <input type="checkbox"/> <b>Renewal or</b> <input type="checkbox"/> <b>Amendment of License Number:</b>			
<b>1. Name of Licensee</b> (Person or firm proposing to conduct the activities described below.)		<b>2. Address of Licensee</b> (Mailing address of licensee. This may be a PO Box.)	
<b>3. Location(s) of Use or Storage</b> (May not be a PO Box, an actual street address is required. Use additional pages if necessary.)			
a. Address:			
b. Address:			
c. Address:			
<b>4. Licensee Contact Person</b> If consultant or other non-employee, so indicate <input type="checkbox"/>			
Name:	Phone: (    )	Fax: (    )	E-Mail:

Submit detailed information for items 5 through 11 on separate 8-1/2" x 11" plain paper.  
See examples and instructions provided for type and scope of information requested.

<b>5. Radioactive Material</b>		
a. Element and Mass Number (e.g., Hydrogen-3)	b. Physical / Chemical Form (e.g., sealed source, liquid, metal foil)	c. Maximum Activity (in SI units)
<b>6. Purpose for which radioactive material will be used</b>		
<b>7. Radiation Safety Officer</b> (Include training and experience.)		
<b>8. Training Program</b> (Include topics to be covered, frequency of training, and recipients.)		
<b>9. Facilities and Equipment</b> (attach documentation and diagram of locations of use and storage.)		
<b>10. Radiation Protection Program</b> (Include personnel monitoring, instrumentation, and procedures.)		
<b>11. Waste Disposal / Waste Management</b> (List methods to be used by name or reference.)		
<b>12. Indicate whether licensee is a</b> <input type="checkbox"/> <b>Domestic (in-state)</b> or <input type="checkbox"/> <b>Foreign (out-of-state) corporation</b> If a Foreign corporation, show the Designated Agent		
Name:	Address:	Phone: (    )
<b>13. Application Certification</b> The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that: a. This application is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder. b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief.		
Printed name and title of applicant/official executing this application	Signature	Date
<b>14. Licensee Federal Tax ID number</b> (If no Tax ID number, then Social Security Number):		
<b>15. License Reduced Fees Certification</b> (Attach financial documentation to indicate qualifications for reduced fees.) The applicant stated herein, or any official executing this application on behalf of the applicant, certifies that: a. This License Reduced Fees Certification is prepared in conformity with Chapter 3748 of the Revised Code and rules adopted thereunder. b. All information contained herein, including supplements and attachments is true and correct to the best of our knowledge and belief. c. The qualifications for reduced fees is based on OAC 3701:1-38-02, paragraph (J), subparagraph (    )		
Printed name and title of applicant/official executing this application	Signature	Date
Return completed application to: Ohio Department of Health Radiation Protection 246 North High Street Columbus, Ohio 43215	Make payment instrument payable to: <b>Treasurer, State of Ohio</b> Ohio Department of Health Accounts Receivable Unit P.O. Box 15278 Columbus, Ohio 43215	

HEA5133 (Rev. 03/2006)

## Appendix B

### An Example of a Sealed Source and Device (SSD) Registration Certificate for Generally Licensed Products

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(CORRECTED PAGE 1, April 12, 2005)

NO: OH-1090-D-101-B

Date: December 7, 1999

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DEVICE TYPE: Transmission Gauge

MODEL: TG-5 (Previously Models TG-5 and C-7 under ABB  
Process Automation)

MANUFACTURER/DISTRIBUTOR:

Automation and Control Technology (ACT)

**6141 Avery Road**

**P.O. Box 3667**

**Dublin, OH 43016**

SEALED SOURCE

MODEL DESIGNATION:

ACT Model S-18

ISOTOPE:

Sr-90

MAXIMUM ACTIVITY:

3.7 GBq (100 mCi)

LEAK TEST FREQUENCY:

6 months

PRINCIPLE USE:

(E) Beta Gauge

CUSTOM DEVICE:

\_\_\_\_ Yes \_\_\_X\_\_\_ No

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

DESCRIPTION:

The model TG-5 device is designed for gauging physical characteristics of processed materials. The device is designed with the source housing and the detector housing within a single outer housing. The processed material passes through a tube in the center block within the device. The maximum diameter of the tube is 2 cm (0.8 inch).

The device is installed at fixed locations by the manufacturer or another specific licensee of the NRC or Agreement State that is licensed to do so. The device may be installed into existing manufacturing equipment or onto a frame or scanner that is incorporated in the manufacturing process. The device may also be mounted in laboratory or other similar locations.

The dimensions of the device range from 197 to 233 mm (7.8 to 9.2 inches) long by 92 mm (3.6 inches) wide by 149 to 166 mm (5.9 to 6.5 inches) high. The device consists of an outer shell, the sealed source, shutter mechanism, detector, and various electronic components. A drawing of the device is shown in Attachment 1.

The center block is made of sintered tungsten and has a minimum thickness of 22.2 mm (0.87 inches).

The source holder is screwed to the shutter assembly facing the center of the block. The beta beam produced when the shutter is opened goes through the pass tube (perpendicular to the tube axis) containing the process material, into the detector. The detector is screwed to the opposite side of the center block from the source holder.

The shutter is made of 1.5 mm (0.06 inches) of stainless steel. The shutter is moved by a solenoid and is held in the closed position by a spring, unless the solenoid is actively holding the shutter open. (Fail safe design.)

The center block is attached to a base plate. The base plate is fabricated from aluminum, steel or sintered tungsten and has a minimum thickness of 6.3 mm (0.25 inches). The base plate is the means of attaching the device to the process equipment or mounting frame. In a typical installation configuration, the base plate and the process equipment shield the highest dose rate side of the device. (See external radiation levels.)

The outer enclosure, a five-sided box, is cast from aluminum or fabricated from steel. It has minimum wall thickness of 1.5 mm (0.06 inches). It is mechanically fastened to the enclosure and is locked to prevent unauthorized access or removal of the source material.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

DESCRIPTION continued:

**The shutter “fire lock” is a soldered spring that will open to hold the shutter in the closed position in the event of a catastrophic fire that would be hot enough to melt the solder.**

The device is operated as a part of a computer controlled measurement and control system. The computer control system may be in a remote location. The system software and logic determines if the conditions are appropriate (material to be measured is present, process material is moving, etc.) for the shutter to open. The operator cannot override the system logic and open the device shutter mechanism.

Lights on the front of the device indicate the shutter position as determined by an optical sensor. A red light indicates that the shutter is open or is not in its fully closed position. A green light indicates that the shutter is fully closed.

The ACT source model S-18 is approved for use only in the Model TG-5. The source is not registered on separate certificates. Amersham Corporation manufactures the source to ACT specifications. Amersham model numbers for the sources used are SIFW517 and SIFW518.

The ACT model TG-5 is the same as ABB model TG-5, which replaced the ABB model C-7.

LABELING:

The device is labeled in accordance with 10 CFR 20.1901 as referenced in Ohio Administrative Code (OAC) 3701-39-021. The labels contain the radiation symbol, isotope, activity, model number, serial number, name of the distributor, and the words “CAUTION-RADIOACTIVE MATERIAL”.

When distributed to persons generally licensed, the device is additionally labeled in accordance with 10 CFR 32.51 as referenced in OAC 3701-39-021.

General license labels are 2.5” high x 3” wide (6 cm x 8 cm). A copy of the label is shown in Attachment 2.

Radiation warning labels are 2.5” high by 3” wide (6 cm x 8 cm). A copy of the label in English (and other languages) is shown in Attachment 2.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

LABELING continued:

Labels made of anodized aluminum are screwed on and have the information die stamped. Self-adhesive labels have the information typed in and may be covered by a laminate. ACT will choose a label sufficient to withstand the environment in which the device is installed. The label has a yellow background with black lettering and a magenta trefoil symbol.

The "Caution-Radioactive Material" label is attached to the device, and if necessary, will be attached to the mounting assembly containing the device so that it is clearly visible after the device is installed. The label information will contain the isotope, activity, assay date, serial number, model number, test interval and distance specification.

The manufacturer's name is displayed on other labels and emblems are attached to the supporting structures of the device.

The ACT source is engraved and stamped with the isotope, activity, serial number and date of manufacture.

DIAGRAM:

Device diagram – Attachment 1

Label diagram – Attachment 2

CONDITIONS OF NORMAL USE:

The device is designed and manufactured for measuring the density of materials in a continuous process. The predominant continuous process measured with the TG-5 is cigarette rod measurements. Other examples of applications would include yarn and rope making machines. Operating temperatures for the device is limited to 0-40 degree C (32-104 degree F) due to the electrical components. Vibration, shock and corrosion will be typical of those associated with the above processes.

The ACT model S-18 sealed source used in the device was tested by its manufacturer and achieved an ANSI N542-1977 classification of 77C65544. The source manufacturer also indicates that the source met special form requirements.

The ANSI N538-1977 classification of the model TG-5 as determined by ACT is ANSI 13-455-675-R6 for the typical mounting configuration. The device operating limits are restricted by the electronic components and not the source or source assembly.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

CONDITIONS OF NORMAL USE: (continued)

The expected useful life of the device is 10-25 years. The manufacturer states that many have been in use for more than 25 years.

PROTOTYPE TESTING:

The model TG-5, and the predecessor model C-7, was produced by ABB Industrial, which split off the division making these devices, and who is now called ACT. The model has been used in industry for more than 25 years without any safety-related incidents.

The ACT model S-18 sealed source used in the device was tested by its manufacturer and achieved an ANSI N542-1977 classification of 77C65544. The source manufacturer also indicates that the source met special form requirements.

The ANSI N538-1977 classification of the device model TG-5 as determined by ACT is ANSI 13-455-675-R6 in the typical mounting configuration.

EXTERNAL RADIATION LEVELS:

Table 1 is the maximum external radiation levels from the device in a typically mounted configuration. The manufacturer states that the radiation levels were determined using procedures specified in ANSI N538-1979. The levels are for the TG-5 containing a 100 mCi (**3.7 GBq**) Sr-90 source and fitted with an empty 9 mm (0.35 inch) diameter pass tube going through the center block.

Table 2 is external radiation levels coming from the back of the device that is normally mounted against the process equipment and is not an accessible surface.

Table 1 – Typical mounting configuration, front and sides

		Maximum Radiation Level			
Distance		Shutter Open		Shutter Closed	
(cm)	(inches)	(uSv/hr)	(mRem/hr)	(uSv/hr)	(mRem/hr)
5	2	300	30	44	4.4
30	12	42	4.2	7	0.7
100	39	1	0.1	0	0

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

PROTOTYPE TESTING continued:

Table 2 – Back side normally not accessible

		Maximum Radiation Level			
Distance		Shutter Open		Shutter Closed	
(cm)	(inches)	(uSv/hr)	(mRem/hr)	(uSv/hr)	(mRem/hr)
5	2	580	58	580	58
30	12	35	3.5	35	3.5
100	39	6	0.6	6	0.6

The above radiation levels represent the maximum dose rates. Upon field installation, there may be additional shielding from surrounding process equipment and mounting frames to which the device is attached.

When installed at a general licensee facility, the radiation levels will be controlled with external shielding, barriers, and location such that the dose at continuously occupied workstations will not exceed 2.5 uSv/hr (0.25 mR/hr).

QUALITY ASSURANCE AND CONTROL:

ACT maintains a quality assurance and control program, which has been deemed acceptable for licensing purposes by the Department. A copy of the program is on file with the Department.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

The device may be distributed to specific or general licensees of the NRC or an Agreement State.

Handling, storage, use, transfer, and disposal: To be determined by the licensing authority.

When the device is distributed to general licensees, persons specifically licensed by the NRC or an Agreement State shall initially test it for external radiation levels, required labels, and leakage/contamination of radioactive material.

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SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE continued:

Servicing of the device, including installation and removal, of mechanisms essential to its inherent safety features shall be performed by persons specifically licensed by the NRC or and Agreement State. Examples of inherent safety mechanisms include, but are not limited to, external shielding, barriers, and shutter mechanisms.

Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 as referenced in Ohio Administrative Code 3701-39-021 or an Agreement State equivalent.

The device shall be leak tested at 6 month intervals using techniques capable of detecting 185 Bq (5 nanocurie) of removable contamination.

When installed at general licensee facilities, the radiation levels shall be controlled such that the dose rate at continuously occupied workstations will not exceed 2.5 uSv/hr (0.25 **mRem**/hr).

The maximum diameter of the pass tube is 2 cm (0.8 inches).

The Model S-18 sealed source is approved by the Department for use in the TG-5. The source is not registered on a separate certificate.

This registration sheet and the information contained within the references shall not be changed without the written consent of the Department. Conditional consent is granted for ministerial changes (excluding name/address changes) and refinements of policy and procedure documents, and the QA/QC program providing that any changes retain or add more stringent requirements.

SAFETY ANALYSIS SUMMARY:

Automation and Control Technology, Inc (ACT) has submitted sufficient information to provide reasonable assurance that:

**For specifically and generally licensed devices**

Based on a review of the Model TG-5, and the information cited below, we conclude that the device is acceptable for licensing purposes.

Furthermore, we conclude that the device would be expected to maintain its containment integrity for normal conditions of use and accidental conditions that might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

SAFETY ANALYSIS SUMMARY continued:

**For generally licensed devices**

Persons not trained in radiological protection can safely operate the device.

Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing. Under ordinary conditions, it is unlikely that any person will receive in any one year a dose in excess of:

- 5 mSv (0.5 Rem) TEDE to the whole body,
- 15 mSv (1.5 Rem) LDE to the lens of the eye, or
- 50 mSv (5 Rem) SDE to a distal extremity or the skin averaged over a 1 cm<sup>2</sup> area.

Under accident conditions associated with handling, storage, and use of the device, it is unlikely that any person would receive a radiation dose in excess of the limits to the appropriate organ as specified in the following chart:

<u>PART OF BODY</u>	<u>DOSE</u>
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.15 Sv (15 Rem)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 cm <sup>2</sup> (0.15 in <sup>2</sup> )	2.0 Sv (200 Rem)
Other organs	0.50 Sv (50 Rem)

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SAFETY EVALUATION OF DEVICE  
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DEVICE TYPE: Transmission Gauge

REFERENCES:

The following supporting documents for the TG-5 are hereby incorporated by reference and are made a part of this registry document:

- ACT's application dated July 28, 1999, with enclosures,
- Letter dated October 8, 1999, with enclosures,
- Letter dated October 21, 1999, with enclosures,
- E-mail dated November 16, 1999

ISSUING AGENCY:

Ohio Department of Health  
Bureau of Radiation Protection

Date: \_\_\_\_\_ Reviewer: \_\_\_\_\_

Date: \_\_\_\_\_ Concurrence: \_\_\_\_\_

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
 SAFETY EVALUATION OF DEVICE  
 (Corrected copy – August 13, 2001)

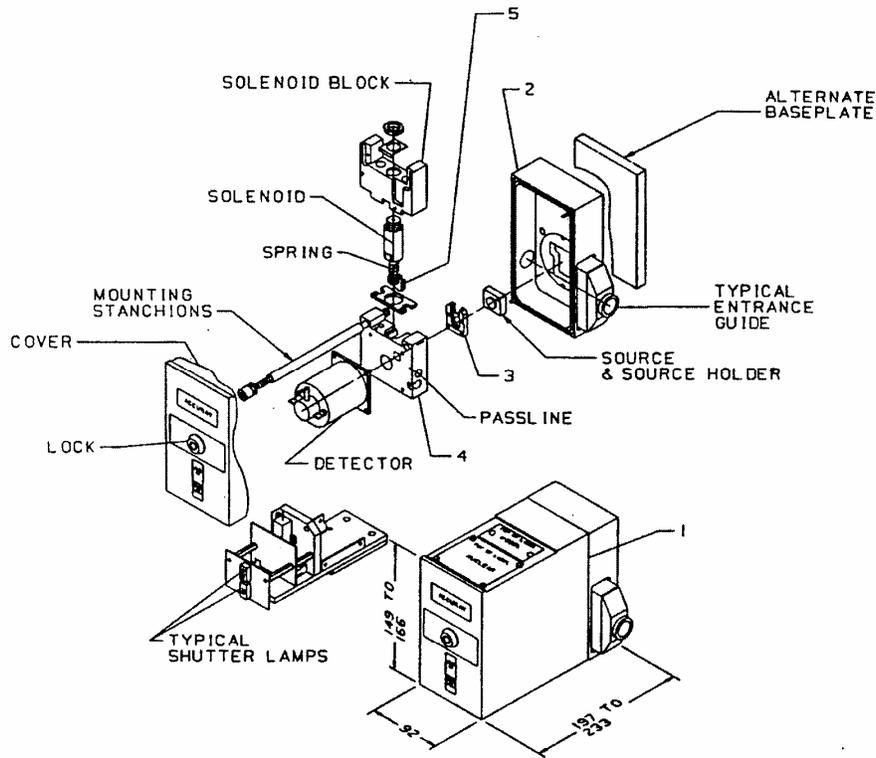
NO: OH-1090-D-101-B

Date: December 7, 1999

Attachment 1

DEVICE TYPE: Transmission Gauge

Device drawing



Model TG-5

<u>Item No.</u>	<u>Description</u>
1	Enclosure
2	Base Plate
3	Shutter Guide
4	Center Block
5	Shutter Blade

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(Corrected copy – August 13, 2001)

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Date: December 7, 1999

Attachment 2

DEVICE TYPE: Transmission Gauge

Sample Labels

<b>CAUTION</b>	
RADIOACTIVE MATERIAL	
	MODEL _____
	DATE MEAS. _____
	TEST INTERVAL _____
REMOVAL OF THIS LABEL IS PROHIBITED	
DO NOT CONTINUOUSLY OCCUPY THE	
AREA WITHIN	OF THIS DEVICE

<b>ATTENZIONE</b>	
MATERIALE RADIOATTIVO	
	MODELLO _____
	ISOTOPO _____
	ATTIVITA _____
	DATA MISURA _____
E'PROIBITO TOGLIERE QUESTA TARGA	

REGULATORY CONDITIONS	
THE RECEIPT, POSSESSION, USE, AND TRANSFER OF THIS DEVICE ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT AND THE REGULATIONS OF THE U.S. NRC OR A STATE WITH WHICH THE NRC HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY.	
ABANDONMENT OR DISPOSAL PROHIBITED UNLESS TRANSFERRED TO PERSONS SPECIFICALLY LICENSED BY NRC OR AN AGREEMENT STATE.	
OPERATION PROHIBITED IF THERE IS INDICATION OF FAILURE OF, OR DAMAGE TO CONTAINMENT OF RADIOACTIVE MATERIAL. INSTALLATION, DISMANTLING, RELOCATION, REPAIR OR TESTING SHALL BE PERFORMED BY PERSONS SPECIFICALLY LICENSED BY NRC OR AN AGREEMENT STATE.	
DEVICE SHALL BE TESTED FOR LEAKAGE OR RADIOACTIVE MATERIAL AND PROPER FUNCTIONING OF THE ON-OFF MECHANISM AND INDICATOR, IF ANY, AT INTERVALS SPECIFIED ON THE ATTACHED YELLOW CARD.	
THIS LABEL SHALL BE MAINTAINED ON THE DEVICE IN A LEGIBLE CONDITION. REMOVAL OF THIS TAG IS PROHIBITED.	
035715-002	

<b>ATENCION</b>	
MATERIAL RADIOACTIVO	
	MODELO _____
	ISOTOPO _____
	ACTIVIDAD _____
	FECHA MEDIDA _____
- SE PROHIBE QUITAR ESTE ROTULO -	
-NO PERMANEZCA INNECESARIAMENTE CERCA DE ESTE EQUIPO-EL MANTENIMIENTO DE ESTE EQUIPO REQUIERE DE PERSONAL CALIFICADO Y PREVIAMENTE AUTORIZADO.	

<b>CAUTION</b>	
RADIATION WHEN ENERGIZED	
	MODEL _____
	VOLTAGE _____
	CURRENT _____
REMOVAL OF THIS LABEL PROHIBITED	
DO NOT CONTINUOUSLY OCCUPY THE	
AREA WITHIN	OF THIS DEVICE
WHEN ENERGIZED.	

<b>DANGER</b>	
RADIATION—RAYONNEMENT	
	MODEL _____
	DATE MEAS. _____
	TEST INTERVAL _____
REMOVAL OF THIS LABEL IS PROHIBITED	
DO NOT CONTINUOUSLY OCCUPY THE	
AREA WITHIN	OF THIS DEVICE
035639-008-A	

## Appendix C

# Information Needed for Transfer of Control Application

### **Information Needed for Transfer of Control Application**

Licensees must provide full information and obtain the director's prior written consent before transferring ownership or control of the license; some licensees refer to this as "transferring the license." Call the Bureau of Radiation Protection Decommissioning section at (614)644-2727 for further information.

## Appendix D

### Trade Secret Request Declaration



## Instructions and Limitations of “Trade Secret Request Declaration”

During the course of an application for a Sealed Source and Device Registration certificate, certain information and details about a product design and its fabrication methods are needed for the evaluation, but are also considered “trade secrets” by the applicant. The evaluation and issuance of an SS&D registration is integrated into a license renewal process. Items that are identified, stamped, and justified, as trade secrets are not subject to public disclosure.

This form is to be used to justify the trade secret status of each document claimed by the applicant. If, after review, the Bureau determines that the information qualifies as a trade secret, such information will be treated as confidential by the Bureau. The applicant will be notified if a request for a document’s status as a trade secret is denied.

Rule 3701:1-40-14(H) of the Administrative Code states:

*“Information provided by a licensee or applicant for a license or license renewal that constitutes a “trade secret” as defined in section 1333.61 of the Revised Code is not subject to public disclosure in accordance with sections 1333.61 to 1333.69 of the Revised Code.”*

Division (D) of section 1333.61 of the Revised Code states:

*“ ‘Trade secret’ means information, including the whole or any portion or phase of any scientific or technical information, design, process, procedure, formula, pattern, compilation, program, device, method, technique, or improvement, or any business information or plans, financial information, or listing of names, addresses, or telephone numbers, that satisfies both of the following:*

- (1) It derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use.*
- (2) It is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.”*

### Instructions

- 1. In the first column, enter the document number or drawing number as it is identified in your QA/QC program.**
- 2. In the second column, enter the descriptive name of the document or drawing.**
- 3. In the third column, state the reason why the document is a “trade secret”. The justification must clearly identify that it meets the definition of a trade secret in ORC 1333.61. (A copy of the definition is listed above.) A justification of trade secret status may be made for a series of documents in the application that have the same justification instead of reiterating the same reason several times. However, each document must be listed individually.**

The term “*document*”, as used in this form, means a supporting drawing, process or design specification, brochures, manuals, or procedures as it relates to a portion of the item for which a source or device registration is sought.

## Appendix E

Review Checklist for General  
Distribution License Application;  
Certain Measuring, Gauging or  
Controlling Devices (OAC 3701:1-46-  
32)

**ITEM 1: ACTION TYPE**

ACTION TYPE:	ADMINISTRATIVE
<input type="checkbox"/> New	<input type="checkbox"/> Current Guidance Used
<input type="checkbox"/> Amendment	<input type="checkbox"/> References in Application Based on Current Regulations
<input type="checkbox"/> Renewal	<input type="checkbox"/> All Attachments Referenced Included
	<input type="checkbox"/> Signature on Application

**ITEM 2: LEGAL IDENTITY**

Name:	
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**ITEM 3: ADDRESSES**

MAILING ADDRESS:	LOCATION OF DISTRIBUTION ADDRESS:

**ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

CONTACT PERSON:	
TELEPHONE NUMBER:	

**ITEMS 5 AND 6: MATERIAL TO BE DISTRIBUTED**

Item	Isotope	Mfg/Model No.	Maximum Quantity Per Device	Purpose of Device	SSD Registry Number
List as Stated in Application					
Defined in SSD Registry Certificate for a Generally Licensed Device?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

**ITEMS 7, 8, 9, AND 11: NOT APPLICABLE**

**ITEM 10: RADIATION SAFETY PROGRAM**

<b>Issue</b>	<b>Suggested Response</b>	<b>Provided?</b>
Transfer Reports	“We will provide annual transfer reports in accordance with OAC 3701:1-46-32(A) and (B).”	Yes / No
Record Keeping	“We will maintain records in accordance with OAC 3701:1-46-32(C).”	Yes / No
Information to Customers	“We will provide the appropriate information to customers in accordance with OAC 3701:1-46-31.”	Yes / No

## Appendix F

### Review Checklist for General Distribution License Application: Luminous Safety Devices for Use in Aircraft (OAC 3701:1-46-33)

**ITEM 1: ACTION TYPE**

ACTION TYPE:	ADMINISTRATIVE
<input type="checkbox"/> New	<input type="checkbox"/> Current Guidance Used
<input type="checkbox"/> Amendment	<input type="checkbox"/> References in Application Based on Current Regulations
<input type="checkbox"/> Renewal	<input type="checkbox"/> All Attachments Referenced Included
	<input type="checkbox"/> Signature on Application

**ITEM 2: LEGAL IDENTITY**

Name:	
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**ITEM 3: ADDRESSES**

MAILING ADDRESS:	LOCATION OF DISTRIBUTION ADDRESS:

**ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

CONTACT PERSON:	
TELEPHONE NUMBER:	

**ITEMS 5 AND 6: MATERIAL TO BE DISTRIBUTED**

Item	Isotope	Mfg/Model No.	Maximum Quantity Per Device	Purpose of Device	SSD Registry Number
List as Stated in Application					
Defined in SSD Registry Certificate for a Generally Licensed Device?	Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

**ITEMS 7, 8, 9, AND 11: NOT APPLICABLE**

**ITEM 10: RADIATION SAFETY PROGRAM**

Issue	Suggested Response	Provided?
Transfer Reports	“We will provide annual transfer reports in accordance with OAC 3701:1-46-36.”	Yes / No

## Appendix G

Review Checklist for General  
Distribution License Application:  
Americium-241 in the Form of  
Calibration or Reference Sources  
(OAC 3701:1-46-37)

**ITEM 1: ACTION TYPE**

ACTION TYPE:	ADMINISTRATIVE
<input type="checkbox"/> New	<input type="checkbox"/> Current Guidance Used
<input type="checkbox"/> Amendment	<input type="checkbox"/> References in Application Based on Current Regulations
<input type="checkbox"/> Renewal	<input type="checkbox"/> All Attachments Referenced Included
	<input type="checkbox"/> Signature on Application

**ITEM 2: LEGAL IDENTITY**

Name:	
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**ITEM 3: ADDRESSES**

MAILING ADDRESS:	LOCATION OF DISTRIBUTION ADDRESS:

**ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

CONTACT PERSON:	
TELEPHONE NUMBER:	

**ITEMS 5 AND 6: MATERIAL TO BE DISTRIBUTED**

Item	Isotope	Maximum Quantity Per Device	Purpose of Device
Manufactured as defined in OAC 3701:1-46-37.	Am-241	185 KBq (5 µCi)	Distribution for use under a GL of OAC 3701:1-46-08
Manufactured as defined in OAC 3701:1-46-37.	Radium	185 KBq (5 µCi)	Distribution for use under a GL of OAC 3701:1-46-08

**ITEMS 7, 8, 9, AND 11: NOT APPLICABLE**

**ITEM 10: RADIATION SAFETY PROGRAM**

Issue	Suggested Response	Provided?
<p>Labeling for Americium-241 OAC 3701:1-46-38</p>	<p>Submit an actual label that contains sufficient information relative to safe use and storage of the source and statement or substantially similar statement, with the following:</p> <p>The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.</p> <p>CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS AMERICIUM-241.</p> <p>DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.</p> <p>Name of manufacturer or initial transferor</p>	<p>Yes No</p>
<p>Labeling for Radium OAC 3701:1-46-38</p>	<p>Submit an actual label that contains sufficient information relative to safe use and storage of the source and statement or substantially similar statement, with the following:</p> <p>The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.</p> <p>CAUTION-RADIOACTIVE MATERIAL-THIS SOURCE CONTAINS RADIUM.</p> <p>DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.</p> <p>Name of manufacturer or initial transferor</p>	<p>Yes No</p>

Issue	Suggested Response	Provided?
Leak Testing for sources >3.7 KBq (0.1 μCi) OAC 3701:1-46-39	A dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcuries) of americium-241 or radium prior to transferring the source to a general licensee under OAC 3701:1-46-08.	<div style="text-align: center;">             Yes      No           </div>

## Appendix H

### Review Checklist for General Distribution License Application: Strontium-90 in Ice Detection Devices (OAC 3701:1-46-40)

**ITEM 1: ACTION TYPE**

ACTION TYPE:	ADMINISTRATIVE
<input type="checkbox"/> New	<input type="checkbox"/> Current Guidance Used
<input type="checkbox"/> Amendment	<input type="checkbox"/> References in Application Based on Current Regulations
<input type="checkbox"/> Renewal	<input type="checkbox"/> All Attachments Referenced Included
	<input type="checkbox"/> Signature on Application

**ITEM 2: LEGAL IDENTITY**

Name:	
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**ITEM 3: ADDRESSES**

MAILING ADDRESS:	LOCATION OF DISTRIBUTION ADDRESS:

**ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

CONTACT PERSON:	
TELEPHONE NUMBER:	

**ITEMS 5 AND 6: MATERIAL TO BE DISTRIBUTED**

Item	Isotope	Maximum Quantity Per Device	Purpose of Device
Manufactured as defined in OAC 3701:1-46-40.	Sr-90	1.85 MBq (50 µCi)	Distribution for use under a GL of OAC 3701:1-46-10

**ITEMS 7, 8, 9, AND 11: NOT APPLICABLE**

**ITEM 10: RADIATION SAFETY PROGRAM**

<b>Issue</b>	<b>Suggested Response</b>	<b>Provided?</b>
Visually Inspect	“We will visually inspect each device in accordance with OAC 3701:1-46-41(A).”	Yes / No
Leak Test	“We will test each device for contamination in accordance with OAC 3701:1-46-41(B).”	Yes / No
Random Sample	“We will conduct random sampling in accordance with OAC 3701:1-46-41(C).”	Yes / No
Defective or Rejected Devices	“We will not distribute defective or rejected devices in accordance with OAC 3701:1-46-41(E).”	Yes / No

# Appendix I

## Review Checklist of General Distribution License Application: Certain *In Vitro* Clinical or Laboratory Testing (OAC 3701:1-46-42)

**ITEM 1: ACTION TYPE**

ACTION TYPE:	ADMINISTRATIVE
<input type="checkbox"/> New	<input type="checkbox"/> Current Guidance Used
<input type="checkbox"/> Amendment	<input type="checkbox"/> References in Application Based on Current Regulations
<input type="checkbox"/> Renewal	<input type="checkbox"/> All Attachments Referenced Included
	<input type="checkbox"/> Signature on Application

**ITEM 2: LEGAL IDENTITY**

Name:	
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**ITEM 3: ADDRESSES**

MAILING ADDRESS:	LOCATION OF DISTRIBUTION ADDRESS:

**ITEM 4: PERSON TO BE CONTACTED ABOUT THIS APPLICATION**

CONTACT PERSON:	
TELEPHONE NUMBER:	

**ITEMS 5 AND 6: MATERIAL TO BE DISTRIBUTED**

Item	Isotope	Maximum Quantity Per Device	Purpose of Device
Manufactured as defined in OAC 3701:1-46-42(B)(1).	Iodine-125	370 KBq (10 µCi)	Distribution for use under a GL of OAC 3701:1-46-11
Manufactured as defined in OAC 3701:1-46-42(B)(2).	Iodine-131	370 KBq (10 µCi)	Distribution for use under a GL of OAC 3701:1-46-11
Manufactured as defined in OAC 3701:1-46-42(B)(3).	Carbon-14	370 KBq (10 µCi)	Distribution for use under a GL of OAC 3701:1-46-11
Manufactured as defined in OAC 3701:1-46-42(B)(4).	Hydrogen-3	1.85 MBq (50 µCi)	Distribution for use under a GL of OAC 3701:1-46-11
Manufactured as defined in OAC 3701:1-46-42(B)(5).	Iron-59	740 KBq (20 µCi)	Distribution for use under a GL of OAC 3701:1-46-11
Manufactured as defined in OAC 3701:1-46-42(B)(6).	Selenium-75	370 KBq (10 µCi)	Distribution for use under a GL of OAC 3701:1-46-11
Manufactured as defined in	Cobalt-57	370 KBq	Distribution for use under a

Item	Isotope	Maximum Quantity Per Device	Purpose of Device
OAC 3701:1-46-42(B)(8).		(10 $\mu$ Ci)	GL of OAC 3701:1-46-11
Manufactured as defined in OAC 3701:1-46-42(B)(7).	MOCK Iodine-125		Distribution for use under a GL of OAC 3701:1-46-11
	Iodine-129	1.85 KBq (0.05 $\mu$ Ci)	
	Americium-241	1.85 Bq (0.005 $\mu$ Ci)	

**ITEMS 7, 8, 9, AND 11: NOT APPLICABLE**

**ITEM 10: RADIATION SAFETY PROGRAM**

Issue	Suggested Response	Provided?
Labeling OAC 3701:1-46-42(C)	<p>Submit an actual package label that contains the following:</p> <ul style="list-style-type: none"> <li>• The radionuclide and chemical form.</li> <li>• A statement that the radioactivity does not exceed the limit indicated above for each radionuclide.</li> <li>• The Radiation Caution Symbol described in OAC3701:1-18-(A).</li> <li>• The words, “Caution - Radioactive Material,” and “Not for Internal or External Use in Humans or Animals.”</li> </ul>	<div style="border: 1px solid black; width: 100px; height: 100px; position: relative;"> <span style="position: absolute; top: 50%; left: 50%; transform: translate(-50%, -50%); font-size: 2em;">/</span> </div>

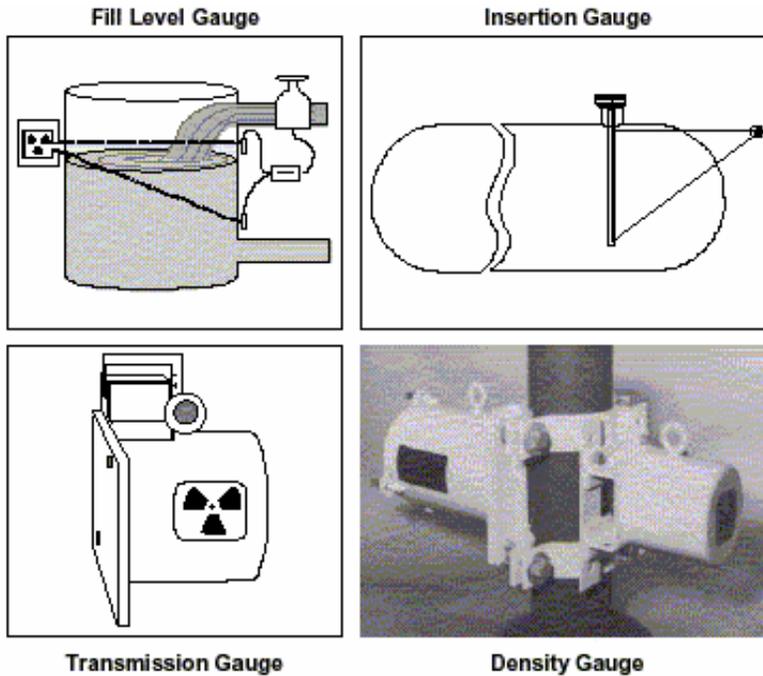
Issue	Suggested Response	Provided?
<p>Label/Leaflet Byproduct Material OAC 3701:1-46-42(C)(1)</p>	<p>Submit an actual package label (or leaflet/brochure to accompany package) that contains a statement or a substantially similar statement with the following:</p> <p>“The radioactive material may be received, acquired, possessed and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the United States Nuclear Regulatory Commission or of a state with which the commission has entered into an agreement for the exercise of regulatory authority.”</p> <p>(Name of manufacturer)</p>	<p>Yes No</p>
<p>Label/Leaflet Accelerator Material OAC 3701:1-46-42(C)(2)</p>	<p>Submit an actual package label (or leaflet/brochure to accompany package) that contains a statement, or a substantially similar statement with the following:</p> <p>“The radioactive material may be received, acquired, possessed and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories or hospitals and only for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of a NARM licensing state.”</p> <p>(Name of manufacturer)</p>	<p>Yes No</p>
<p>Label/Leaflet MOCK I-125 Kits OAC 3701:1-46-42(E)</p>	<p>Submit and actual package label (or leaflet/brochure to accompany package) that contains directions on disposing of waste in accordance with OAC 3701:1-38-19(A).</p>	<p>Yes No</p>

## Appendix J

Guidance for OAC 3701:1-46-05  
General Licensees (Q&A)

**1. What is a generally licensed (GL) device?**

Generally licensed (GL) devices contain radioactive material and are typically used to detect, measure or control the density, level or chemical composition of various items. Examples of such devices are gas chromatographs, density gauges, fill-level gauges and static elimination devices. One of the more widely used devices is self-luminous exit signs.



**Figure J.1 Fixed Gauging Devices** *Certain nuclear gauges can be possessed under a general license (OAC 3701-46-05).*



**Figure J.2 Gas Chromatograph Units** *Certain gas chromatograph units (detector cells) used for analysis of chemical composition can be possessed under a general license (OAC 3701-46-05).*



**Figure J.3 Tritium Exit Signs** Certain tritium exit signs can be possessed under OAC 3701-46-05 (typical devices contain 25 Ci of tritium per sign).

**2. What is an OAC 3701:1-46-05 general licensee?**

A general licensee is a company or person who uses or stores a GL device. The device is obtained through an authorized transfer from the device manufacturer/distributor or by a change of company ownership whereby the device remains in use at a particular location. If you have received a device through unauthorized means, contact your regulatory authority immediately (see Question 14).

**3. What is the reporting to ODH of generally licensed devices?**

ODH requires that certain generally licensed devices authorized in OAC 3701:1-46-05 be reported each year. Reporting of the device depends upon the type and quantity of radioactive material in the device (see Question 4). Reporting involves completing "GL Device Inventory Form," and submitting it to ODH (see Questions 4 and 6 below).

**4. Which GL devices are subject to reporting to ODH?**

Devices that are subject to reporting to ODH are generally licensed devices used and/or stored in ODH jurisdiction that contain, at the time of manufacture, 370 MBq (10 mCi) of Cesium-137, 3.7 MBq (0.1 mCi) of Strontium-90, 37 MBq (1 mCi) of Cobalt-60, 3.7 kBq (0.1  $\mu$ Ci) of Radium, or 37 MBq (1 mCi) of Americium-241 or any other transuranic, i.e., Element with atomic number greater than uranium (92).

Tritium exit signs and gas chromatographs are not subject to reporting.

**5. How do I know if I have a GL device?**

If you have a device as described in Question 1 above; look at the device for any and all labels.

GL devices should have labels containing such words as:

“Caution-Radioactive Material;” “The receipt, possession, use and transfer of the device are subject to a general license”; **OR** identification of the radioactive material, such as “5 millicuries of Cesium-137” or “1 mCi of Am-241.”

Review any paperwork (such as manuals or brochures) that you received with the device. It can provide you with information on the radioactivity contained within the device and whether the device is subject to ODH regulations. If you are still unsure, contact the manufacturer or distributor of the device for help. If the manufacturer is not available, contact ODH (see Question 14).

Possession or use of similar devices may require a specific license. Manufacturers or distributors cannot transfer specifically licensed devices to customers who do not have a specific license to possess such a device. The customer should apply to ODH or the appropriate Agreement State or the NRC for such a license.

#### **6. How do I know if I have a GL device that is subject to reporting?**

The device manufacturer should be able to answer questions regarding the reporting of any devices you have purchased. However, you could look at the identification of the radioisotope and quantity of radioactive material listed on a label on the device. If the device contains at least 370 megabecquerels (MBq) (10 millicuries (mCi)) of Cesium-137, 3.7 MBq (0.1 mCi) of Strontium-90, 37 MBq (1 mCi) of Cobalt-60, 37 MBq (1 mCi) of Americium-241, 37 MBq (1 mCi) of Curium-244 or any other transuranic, then it is subject to reporting to ODH. The ODH will contact you when reporting is required.

#### **7. What are the requirements for a GL device?**

GL devices used within ODH’s jurisdiction are subject to the ODH regulations listed in OAC 3701:1-46-05. General licensees are required to appoint a responsible individual who will know about the requirements and have the authority to carry out the necessary duties to comply with the regulatory requirements. These requirements are summarized as follows:

##### **Routine Maintenance**

- Maintain labels.
- Comply with the instructions and precautions provided on the labels including any referenced documents such as operating and service manuals.

- Perform leak tests every six months in accordance with manufacturer's instructions (unless in storage or otherwise indicated on the label) and maintain this record for three years.
- Perform shutter tests every six months in accordance with manufacturer's instructions (unless in storage or otherwise indicated on the label) and maintain this record for three years.

#### **Requirements if the Device Becomes Damaged or Fails a Shutter or Leak Test**

- Suspend operation of the device.
- Have the device repaired or properly disposed of by the manufacturer or distributor or other specifically licensed person.
- Provide to ODH, within 30 days, a brief description of the event and remedial actions taken. If contamination is measured as greater than 185 Bq (0.005 microcuries) or is likely to have resulted from the event, develop and submit a plan to ODH for ensuring the premises and environs are acceptable for unrestricted use.

#### **Additional Actions to be Taken in the Case of Significant Damage to the Device**

- Immediately secure the area and keep people away from the device until the situation is assessed and radiation levels are known. If equipment is involved, isolate it until it is determined there is no contamination present. Perform first aid for any injured individuals but remove them from the area only when medically safe to do so.
- Arrange for a radiation survey to be conducted as soon as possible by a knowledgeable person using an appropriate radiation detector (survey meter). This person could be a representative of a manufacturer or distributor, a local emergency responder, a consultant or a licensee employee using a radiation survey meter. To accurately assess the radiation hazard, it is essential that the person performing the survey be competent in the use of a radiation survey meter.
- In addition to any required notification of ODH, you may report any incident to ODH by calling (614)644-2727, which is staffed 24 hours a day. Local authorities may also be able to provide assistance.

**Reporting Requirements (Applicable to All OAC 3701:1-46-05 General Licensees)**

**Table J.1 General Licensee Reporting Requirements**

Type of Report	Contents of Report	Frequency
Transfer or disposal OAC 3701:1-46-05(C)(8)(b)	Identification of device by manufacturer's (or initial transferor's) name, model number and serial number; name, address and license number of recipient; and date of transfer.	Within 30 days of transfer, disposal or export.
Transfer report for change of ownership (where device remains in use at a particular location) OAC 3701:1-46-05(C)(9)(a)	Manufacturer's (or initial transferor's) name, model number and serial number; name and address of the transferee; and name, title and phone number of the responsible individual of the transferee.	Within 30 days of transfer.
Report if device becomes damaged or fails a shutter or leak test OAC 3701:1-46-05(C)(5)	Brief description of the event and remedial actions taken and a plan (if contamination is measured or likely) for ensuring the premises and environs are acceptable for unrestricted use.	Within 30 days of occurrence.
Report name change of licensee OAC 3701:1-46-05(C)(13)	Name of new general licensee.	Within 30 days of occurrence.
Report of change of mailing address of the location of use. OAC 3701:1-46-05(C)(13)	New mailing address where device is used or stored.	Within 30 days after moving the device.
Report of incidents or lost or stolen devices OAC 3701:1-46-05(C)(10)	The following information: (A) Description of the radioactive material. (B) Description of the circumstances under which the loss or theft occurred. (C) Disposition of the radioactive material. (D) Radiation exposure to individuals. (E) Actions taken to recover the material. (F) Actions taken to prevent recurrence.	Immediate telephone report if quantity >1,000 times value in Appx A of OAC 3701:1-38-18.  30-day telephone report if quantity >10 times value in Appx A of OAC 3701:1-38-18.  30 days after telephone report submit a written report.

**Requirements for Certain GL Devices Subject to Possession Reporting**

**Table J.2 Reporting Requirement for Certain GL Devices**

Type of Report	Contents of Report	Frequency
Report of Possession	<p>The following information and any other information specifically requested by ODH:</p> <p>(A) Name and mailing address.</p> <p>(B) Information about each device: the manufacturer or initial transferor, model number, serial number, radioisotope and activity.</p> <p>(C) Name, title and telephone number of the responsible individual.</p> <p>(D) Address where the device(s) is/are used and/or stored.</p> <p>(E) Certification that the information concerning the device(s) has been verified through a physical inventory and checking of the label.</p> <p>(F) Certification by the responsible individual that he/she is aware of the requirements of the general license.</p>	Annual
Bankruptcy	Notification of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the U.S. Code.	Immediately following the filing of a voluntary or involuntary petition for bankruptcy.

**8. Can I relocate my device(s) from one location to another?**

Some GL devices have been approved for installation and relocation by the general licensee; however, this does not apply to all GL devices. You should contact the manufacturer or distributor to determine if your device(s) has been approved for relocation/installation by the general licensee.

**9. Is there reciprocity for GL devices?**

No, there is no reciprocity provision applicable to general licensees. If a general licensee obtains a device in an Agreement State or NRC-regulated state and wishes to use the device within ODH's jurisdiction, it must do so under OAC 3701:1-46-05.

In this case, the general license in OAC 3701:1-46-05 applies automatically without application for license or other permission as long as the device has been

manufactured and distributed appropriately. The general licensee is subject to the provisions of OAC 3701:1-46-05.

The general license in OAC 3701:1-46-05 applies only within ODH's jurisdiction. General licensees intending to move from one jurisdiction to another should contact the applicable regulatory authority, ODH, NRC or the particular Agreement State before moving to determine the applicable regulations in their jurisdictions. All jurisdictions do not have a comparable general license and specific provisions of the general license may vary among jurisdictions.

**10. I am an NRC or Agreement State general licensee. Does ODH allow me to use my GL device at temporary job sites within ODH jurisdiction?**

No, all portable devices containing radioactive material used within the State of Ohio must be specifically licensed. [OAC 3701:1-46-05(E)]

**11. Would an Agreement State allow me to use my GL device at temporary job sites within that Agreement State's jurisdiction?**

All portable devices containing radioactive material used within the State of Ohio must be specifically licensed. For other devices that may be transported from one Agreement State to another or from ODH jurisdiction to an Agreement State, use of the device comes under the regulations of the Agreement State where the device is being used. Be sure to know the requirements in the area where you are using the device by contacting the particular Agreement State. Some Agreement States currently require that the device be registered or specifically licensed before it can be used in that state.

**12. How can I get rid of a GL device?**

GL devices can only be transferred (for disposal or to obtain a replacement device) to: (1) a person holding a specific license under OAC 3701:1-40, or equivalent NRC or Agreement State regulations such as the device manufacturer; or (2) a person holding a specific license that authorizes waste collection such as a waste broker.

In the case of a change of ownership where a GL device remains in use at a particular location, the new owner will be the new general licensee. The seller must provide copies of OAC 3701:1-38-21(A) and (B), 40-21, 46-02, 46-05, and any safety documents identified in the device label to the new general licensee.

**13. Can I keep a device I am not using?**

GL devices not in use can be stored for only two years. After two years, the device must be properly transferred. During this period of non-use, the shutter must be locked in the closed position. Devices kept in standby for future use are excluded

from the two-year time limit if the general licensee performs a quarterly physical inventory of the device while it is in standby.

**14. Who can answer additional questions?**

Call the device manufacturer, who should be able to assist you. If the manufacturer is no longer in business, or you cannot contact the manufacturer, call the ODH at (614)644-2727.

**15. What other requirements apply?**

Persons who possess devices listed in OAC 3701:1-46-05 are exempt from the requirements of OAC 3701:1-38, with the exception of the provisions in OAC 3701:1-38-02, 21(A) and (B). They are subject to the following sections of OAC 3701:1-46: 46-02 through 46-10, 40-08(D), 40-16(A) to (E), 40-19 through 21.

**16. My company has a specific license for use of radioactive material and also has generally licensed devices. Do I have to include these devices on my inventory of radioactive materials?**

No, you do not have to include GL devices on your inventory that is required by your specific license. However, many companies have chosen to keep track of their devices through periodic inventory along with their specifically licensed material.

## Appendix K

### Guidance on Self-Luminous Exit Signs (Q&A)

## 1. What is a self-luminous exit sign?

A self-luminous exit sign is a non-electrical product that uses radioactive tritium gas to produce light. Specifically, the signs contain light sources that consist of glass tubes, internally coated with phosphor and filled with tritium gas. Tritium (H-3) is an isotope of hydrogen that emits low-energy beta radiation in the form of electrons. These electrons excite the phosphor, causing the glass tubes to continuously emit light.

A self-luminous sign is a generally licensed (GL) device because it contains radioactive material.



**Figure K.1 Self-Luminous Exit Sign** *Certain self-luminous, tritium exit signs can be possessed under OAC 3701-46-05 (typical devices contain 25 Ci of tritium per sign).*

## 2. Do I need to apply for a license to use a self-luminous exit sign?

No. Self-luminous exit signs are generally licensed by ODH. Any company, institution or individual conducting business can use self-luminous exit signs without a specific license from ODH. The companies, institutions or individuals do not have to apply for a license; they are automatically considered "general licensees" of ODH and must follow the ODH requirements for use of the signs.

The distributors of self-luminous exit signs are; however, specifically licensed by ODH.

## 3. What is an OAC 3701:1-46-05 “general licensee?”

Any company, institution or person conducting business who uses, stores or possesses a self-luminous exit sign acquired in an authorized manner is a general licensee, that is, a licensee by rule and subject to certain ODH rules.

## 4. What are the obligations of a general licensee?

As a general licensee using a self-luminous exit sign, you must appoint an individual responsible for fulfilling the regulatory requirements listed in OAC 3701:1-46-05. In general, these requirements are:

- You cannot remove the labeling or radioactive symbol on the sign.

- You cannot abandon a self-luminous exit sign.
- You must properly dispose of a self-luminous exit sign by transferring it to a manufacturer or radioactive waste broker specifically licensed by ODH, NRC or an Agreement State.
- Any lost, stolen or broken sign(s) must be reported to ODH.
- You cannot give away or sell the self-luminous exit sign to another individual, company or institution unless the device is to remain in use at a particular location; for example in a transfer of ownership of a building. In this case, you are obligated to pass on a copy of the regulatory requirements to the new general licensee (owner) and you must notify ODH.
- You must inform ODH of a company name change or change of address.
- You are required to make certain reports. These reports are summarized in the following table.

**Table K.1 Reporting Requirements**

Type of Report	Contents of Report	Frequency
Transfer or disposal OAC 3701:1-46-5(C)(8)(b)	Identification of device by manufacturer's (or initial transferor's) name, model number and serial number; name, address and license number of recipient; and date of transfer.	Within 30 days of transfer, disposal or export.
Transfer report for change of ownership (where device remains in use at a particular location) OAC 3701:1-46-5(C)(9)(a)	Manufacturer's (or initial transferor's) name, model number and serial number; name and address of the transferee; and name, title and phone number of the responsible individual of the transferee.	Within 30 days of transfer.
Report if device becomes damaged or fails a shutter or leak test OAC 3701:1-46-05(C)(5)	Brief description of the event and remedial actions taken and a plan (if contamination is measured or likely) for ensuring that the premises and environs are acceptable for unrestricted use.	Within 30 days of occurrence.
Report name change of licensee OAC 3701:1-46-05(C)(13)	New name of general licensee.	Within 30 days of occurrence.

Type of Report	Contents of Report	Frequency
Report of change of mailing address of the location of use OAC 3701:1-46-05(C)(13)	New mailing address where device is used or stored.	Within 30 days after moving the device.
Report of incidents or lost or stolen devices OAC 3701:1-46-05(C)(10)	The following information:  (A) Description of the radioactive material. (B) Description of the circumstances under which the loss or theft occurred. (C) Disposition of the radioactive material. (D) Radiation exposure to individuals. (E) Actions taken to recover the material. (F) Actions taken to prevent recurrence.	Immediate Telephone report if quantity >1,000 times value in Appx A of OAC 3701:1-38-18.  30-day telephone report if quantity >10 times value in Appx A of OAC 3701:1-38-18  30 days after telephone report submit a written report.

**5. How do I identify a self-luminous exit sign?**

All Self-luminous Exit signs are required to have a permanent label affixed to the sign that identifies it as containing radioactive material. The label will contain the words “Caution Radioactive Material” and may also include the radiation symbol.



In addition, the label will include the name of the manufacturer (or initial transferor), the product model number, the serial number and the quantity of tritium contained.

## **6. How can I tell if it is working?**

Because self-luminous exit signs will not appear to be lit in ambient light conditions, they must be viewed in darkness to evaluate their performance. When viewed in the dark, all letters should be visible. If the letters are clearly legible and uniformly lit, the sign is functioning properly.

If the luminance appears to be uniformly low, check the UL label to determine the expiration date of the sign. If the sign has passed its expiration date, it no longer meets the luminance requirements of the applicable fire or building code. Contact the manufacturer for replacement and disposal information.

If any letter(s) or part(s) of letters are not lit when viewed in the dark, the sign is not functioning properly. This may mean that the sign has been damaged and that one or more of the internal light sources has been damaged. In this instance, contact the manufacturer immediately for return instructions.

## **7. What should I do if a sign is broken or damaged?**

Most signs that are broken do not cause a release of tritium. If a sign is excessively damaged, the tritium gas could be released and would dilute rapidly in the air. Keep in mind that for this to occur, the outer frame and inner protective housing would also have to be damaged. The area should be evacuated and ventilated to avoid unnecessary exposure to the radioactive material. The material does not pose any immediate health hazard to workers at the location or members of the public. However, the sign would be expected to have relatively high levels of tritium on it and should be properly handled. Do not move the sign into other areas to avoid spreading contamination prior to disposal.

Contact the manufacturer for directions on proper handling of the damaged sign, as well as proper shipping and disposal. If you do not know who the manufacturer is, carefully look on the sign itself for the name and phone number of the manufacturer. If you still cannot identify a manufacturer, call ODH to request assistance in dealing with the broken sign.

Typically, manufacturers will advise a procedure such as the following: Wear rubber gloves and eye protection because you may come in contact with broken glass and/or radioactive material. Wipe the entire surface of the sign with a paper towel. Wrap the sign, paper towel and gloves in a plastic bag (i.e., garbage bag) and tape it closed. Wash your hands with soap and water. Wrap the sign a second time in a plastic bag (i.e., garbage bag) and tape it closed. Wash your hands with soap and water. Place each sign in a sturdy carton. Use filler materials to assure a tight, rattle-free fit. Tape the seal flaps and seams. Label the carton: "RADIOACTIVE." Place this package into a second sturdy cardboard carton and include a piece of paper with the following words: "This package conforms to the conditions and limitations specified in 49 CFR 173.424 for radioactive material, excepted package-instruments or

articles, UN2910.” Use filler materials to assure a tight fit. Tape the seal flaps and seams. DO NOT label this outer carton "RADIOACTIVE." Before shipping, contact the manufacturer whose name appeared on the sign label. Make a report to ODH (see the table of reporting requirements in Question 4).

**8. Can broken signs contaminate buildings and require cleanup?**

Yes. If the sign is severely damaged and mishandled, the contamination can be spread throughout a room or building - wherever the sign traveled. If contamination occurs, appropriate cleanup is required by a person specifically authorized by ODH for this activity. Keep in mind that for this to occur, the outer frame and inner protective housing would have to be damaged and the sign mishandled. To avoid spreading contamination, follow the instructions in the previous question.

**9. Do I need a license to sell self-luminous exit signs?**

It depends on whether the exit signs are stocked for sale. If you intend to maintain an inventory of exit signs for sale to customers, you must obtain a specific ODH license for distribution. You do not need a license if you sell signs to individual customers and obtain the signs through a specifically licensed distributor. You must provide this distributor with the customer's name, address and the name of the responsible individual (see Question 4) prior to shipment.

**10. Can I throw a self-luminous exit sign in the trash?**

No. It is unlawful to abandon or dispose of self-luminous exit signs except by transfer to a manufacturer or other person specifically licensed by ODH. Most manufacturers will accept the return of any self-luminous exit signs.

It is important that these signs be properly disposed of and that they not be abandoned because they can end up damaged. They can also end up in the hands of individuals who do not know that they are radioactive and may inadvertently contaminate themselves.

**11. Can I give away or sell a self-luminous exit sign to someone else?**

No, you cannot transfer the sign to someone else. The only exception is when the sign remains in use at a particular location such as when a building is sold. In the specific case of a change of ownership with a GL device remaining in use at a particular location, the new owner will become the new general licensee. You are then obligated to provide a copy of the regulatory requirements to the new general licensee and you must notify ODH.

**12. My company has a specific license for use of radioactive material and also has self-luminous exit signs. Do I have to include the signs in my inventory of radioactive materials?**

No, you do not have to include GL devices on your inventory that is required by your specific license. However, many companies have chosen to keep track of their devices through periodic inventory along with their specifically licensed material.

**13. To whom can I go with additional questions?**

Call the device manufacturer, who should be able to assist you. If the manufacturer is no longer in business, or you cannot contact the manufacturer, call the ODH.

**14. What other requirements apply?**

Persons who possess devices listed in OAC 3701:1-46-05 are exempt from the requirements of OAC 3701:1-38, with the exception of the provisions in OAC 3701:1-38-02, 21(A) and (B). They are subject to the following sections of OAC 3701:1-46: 46-02 through 46-10, 40-08(D), 40-16(A) to (E), 40-19 through 21.

# Appendix L

General License Device Inventory Form  
for Possession of Certain Devices Listed  
in  
OAC 3701:1-46-05

## GL DEVICE REPORTING REQUIREMENTS

The regulation requiring the reporting of certain GL devices is summarized below, per Ohio Administrative Code 3701:1-46-05 and 3701:1-38-02, which states in part, as follows:

### **Ohio Administrative Code 3701:1-46-05(C)(12):**

- (a) Shall report, in accordance with paragraphs (C)(12)(b) and (c) of this rule, devices containing at least 370 MBq (10 mCi) of Cesium-137, 3.7 MBq (0.1 mCi) of Strontium-90, 37 MBq (1 mCi) of Cobalt-60, 3.7 kBq (0.1 :Ci) of Radium, or 37 MBq (1 mCi) of Americium-241 or any other transuranic, i.e., element with atomic number greater than Uranium (92), based on the activity indicated on the label. Each address for a location of use, as described under paragraph (C)(12)(c)(iv), represents a separate general license.
- (b) If in possession of a device meeting the criteria of paragraph (C)(12)(a) of this rule, shall report these devices annually to the director and is subject to the fees in paragraph (u) of rule 3701-38-02.1 of the Administrative Code. Reporting must be done by verifying, correcting, and/or adding to the information contained in a request provided by the director. The information must be submitted to the director within thirty days of the date of the request for information or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of paragraph (C)(12)(a) of this rule is subject to the bankruptcy notification requirement in chapter 3701:1-40 of the Administrative Code.
- (c) In reporting the devices, the general licensee shall furnish the following information and any other information specifically requested by the director:
  - (i) Name and mailing address of the general licensee.
  - (ii) Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity (as indicated on the label).
  - (iii) Name and telephone number of the responsible person designated as a representative of the general licensee under paragraph (C)(11) of this rule.
  - (iv) Address at which the device(s) are used and/or stored.
  - (v) Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.
  - (vi) Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

**Ohio Administrative Code 3701:1-38-02:**

- (U) Licensees with general licenses requiring an annual report to the director shall submit the report with a fee of four hundred twenty dollars within thirty days of mailing an invoice by the department and are subject to late penalties in paragraph (I) of this rule. If a facility has a specific license which is in a category that would include the generally licensed material, the facility may add the generally licensed material to the specific license and will not be charged the additional fee for that generally licensed material. Annual reports are required for devices under a general license containing radionuclides at or above activities listed as follows:

<b>Radionuclide</b>	<b>Activity</b>
Cesium 137 (Cs 137)	370 MBq (10mCi)
Strontium 90 (Sr 90)	3.7 MBq (0.1mCi)
Cobalt 60 (Co 60)	37 MBq (1mCi)
Radium 226 (Ra 226)	3.7 kBq (0.1mCi)
Americium 241 (Am 241 or any other transuranic (element with atomic number > Uranium 92, based on the activity indicated on the label)	37 MBq (1mCi)

**GENERAL LICENSE  
DEVICE INVENTORY FORM**

*(Please read accompanying instructions before completing this form.)*



Paragraph (C)(12)(b) of Rule 3701:1-46-05 of the Administrative Code, requires those in possession of a device meeting the criteria of paragraph (C)(12)(a) of Rule 3701:1-46-05, report these devices annually to the Director.

**Submit both pages of this form to the address below within thirty (30) days of receipt.**

**Ohio Department of Health  
Attn: Jill Rabold  
246 N. High Street  
Bureau of Radiation Protection/7<sup>th</sup> Floor, 35 Bldg.  
Columbus, Ohio 43266-0118**

<b>1. NAME</b> <i>(Firm proposing to conduct the activities described below)</i>		<b>2. INDIVIDUAL RESPONSIBLE</b>	
<b>3. ADDRESS OF LICENSEE</b> <i>(Mailing address or other location where licensee may be located)</i>		<b>4. TELEPHONE NO.</b> <i>(Include Area Code)</i>	<b>5. FACSIMILE NO.</b> <i>(Include Area Code)</i>
		<b>6. EMAIL ADDRESS</b>	<b>7. TAX ID NUMBER</b>
<b>8. LOCATION OF USE</b> <i>(If different from address listed in item 3. No P.O. boxes, please)</i>			
<b>9. CERTIFICATION</b>			
I, THE UNDERSIGNED, HEREBY CERTIFY THAT:			
<ul style="list-style-type: none"> <li>a. All information in this report is true and complete.</li> <li>b. The information concerning the devices(s) has been verified through a physical inventory and checking of label information.</li> <li>c. I understand that Ohio Department of Health regulations require that any change in the information furnished by a registrant on this registration certificate be reported to the Bureau of Radiation Protection within 30 days from the effective date of such change.</li> <li>d. I have read and understand the provisions of the applicable regulations (Rule 3701:1-46-05 of the Administrative Code); and I understand that I am required to comply with those provisions as to all radioactive material which I receive, acquire, possess, use, or transfer under the general license for which this inventory is filed with the Bureau of Radiation Protection.</li> </ul>			
<b>PRINTED OR TYPED NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>	

