

## Ohio Department of Health

Bureau of Environmental Health and Radiation Protection Sealed Source and Device Transfer Review Checklist

**ODH Use Only** Application Tracking Number

**(1) APPLICANT INFORMATION**

Distributor Name and Address	
Manufacturer Name and Address	
Name, Title, Telephone Number and email address of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the Department	
<b>Ohio Registration # - ODH Use Only</b>	
Applicant's Ohio License Number	Application Dated
Company Name of Prior Registrant	Previous Registration Number
Date received <b>ODH Use Only</b>	Date assigned <b>ODH Use Only</b>

**(2) TYPE OF ACTION REQUESTED**

Transfer of a  Source                      Device	Model number(s)
---	-----------------

**(3) SUMMARY DATA**

Leak Test Frequency	6 month	Other	Months
Radionuclides and Maximum Activities (including loading tolerance)  Attach additional pages if necessary	Not required	Model #	Radionuclide
			Maximum activity

Serial number of last device manufactured by prior company before transfer to new company	
Number of completed units transferred	
Change of ownership information includes: Transfer of products      Records Custody      Servicing Arrangements	
<input type="checkbox"/>	New label picture or diagram included
Effective date of label change	
<input type="checkbox"/>	Commitment that no changes have been made to product since last amendment registration or initial registration
<input type="checkbox"/>	No change in prior commitments of old company
<input type="checkbox"/>	QA Program submitted?

**(4) GENERAL DESCRIPTION AND CONSTRUCTION SUMMARY - Ask ODH if this needs to be submitted**

<input type="checkbox"/>	Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)
--------------------------	---

**(5) LABELING – Will need photo or diagram of label**

<input type="checkbox"/>	The locations of the labels are readily visible to the users
<input type="checkbox"/>	The materials of label construction, label dimensions, and means of writing on label are identified and adequate
<input type="checkbox"/>	The colors of the labels are identified
<input type="checkbox"/>	Contents: - meet rules and regulations as specified below – typically include Manufacturer, Model #, Serial #, Isotope, Activity, Date of Assay, Trefoil, “CAUTION – RADIOACTIVE MATERIAL” (Depleted Uranium information must be included)
<input type="checkbox"/>	The means of attaching labels are expected to last the life of the device
<input type="checkbox"/>	The labels are expected to be remain legible over the life of the device
<input type="checkbox"/>	Copies, photos, or diagrams of the labels were provided
<input type="checkbox"/>	Verify that the labeling does not misinterpret, misrepresent, or lead the user into violating any applicable regulations

**(5.1) Specific labeling criteria**

Applicable?      If “No”, go to Section 6

<input type="checkbox"/>	Self-luminous products under OAC 3701:1-40-12 [10 CFR 30.19] also meet the labeling requirements of 10 CFR 32.25
<input type="checkbox"/>	Gas and aerosol detectors under OAC 3701:1-40-13 [10 CFR 30.20] also meets the labeling requirements of 10 CFR 32.29
<input type="checkbox"/>	Certain generally licensed measuring, gauging or controlling devices under OAC 3701:1-46-05 [10 CFR 31.5] also meet the labeling requirements of OAC 3701:1-46-30 [10 CFR 32.51]
<input type="checkbox"/>	Generally licensed luminous devices for use in aircraft under OAC 3701:1-46-07 [10 CFR 31.7] also meet the labeling requirements of OAC 3701:1-46-34 [10 CFR 32.54]
<input type="checkbox"/>	Generally licensed Sr-90 ice detection systems under OAC 3701:1-46-10 [10 CFR 31.10] also meet the labeling requirements of OAC 3701:1-46-40 [10 CFR 32.61]
<input type="checkbox"/>	Sources and devices designed for use in radiography operations under chapter 3701:1-48 [10 CFR 34] also meet the labeling requirements of OAC 3701:1-48-05 [10 CFR 34.20]
<input type="checkbox"/>	Sources used in well logging operation under chapter 3701:1-49 [10 CFR 39] also meet the labeling requirements of OAC 3701:1-49-05 [10 CFR 39.31]
<input type="checkbox"/>	<i>Sources and devices used for medical use under OAC 3701-39-02.1 [10 CFR 35] also meet the labeling requirements of OAC 3701:1-46-44 [10 CFR 32.74]</i>

**(6) QUALITY ASSURANCE**

QA checklist or information is in Attachment

**(7) AUTHORIZED SIGNATURE (ONLY REQUIRED IF APPLICANT COMPLETES CHECKLIST)**

---

<b>Authorized Signature</b>	<b>Date</b>
-----------------------------	-------------

**(8) REVIEWER INFORMATION SUMMARY – ODH Use Only**

---

<b>Primary Reviewer</b>	<b>Date Completed</b>	<b>Total Hours</b>
-------------------------	-----------------------	--------------------

---

<b>Concurrence Reviewer</b>	<b>Date Completed</b>	<b>Total Hours</b>
-----------------------------	-----------------------	--------------------

---

<b>Trainee Reviewer</b>	<b>Date Completed</b>	<b>Total Hours</b>
-------------------------	-----------------------	--------------------