

Ohio Department of Health

Sealed Source and Device Application

General information

Name and Complete Mailing Address of the Applicant				
Name, Title, Telephone Number and Email Address of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the Department				
Applicant's Ohio License Number			Application is for a	
			Sealed Source	Device
The Applicant is the	Manufacturer	Distributor	Manufacturer and Distributor	Custom User
If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer				
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor				
Provide the Name, Complete Mailing Address, and Function of Other Companies Involved				
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Calibration Source, etc.)				
Primary Use Code			Secondary Use Code (If Applicable)	
For Use by				
	Specific Licensees	General Licensees	Both Specific and General Licensees	
Leak Test Frequency				
	Not required	6 months	Other If other, specify frequency and provide justification	

Type of action requested

	New Item	Amendment to Registration#	Transfer of Registration #
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Description of Request

For devices - list sealed source(s) to be used (For amendments to a current registration; list changes only; attach additional sheets if needed)

Device Model Number	Sealed Source Manufacturer	Sealed Source Model #	Radionuclide	Maximum Activity*

* For nominal sources include tolerance

Application for source or device manufacture and/or distribution and use is governed by, and meets the following OAC rules

Default – most items	OAC 3701:1-46-49 [10 CFR 32.210]
GL for certain measuring, gauging or controlling devices	OAC 3701:1-46-05 and -30 [10 CFR 31.5, 32.51]
Medical use	OAC 3701:1-46-44 [10 CFR 32.74]
Self-luminous products	3701:1-40-12 [10 CFR 30.19], OAC 3701:1-46-25 [10 CFR 32.22]
Exempt gas and aerosol detectors (Exclusively NARM)	OAC 3701:1-40-13 [10 CFR 30.20], OAC 3701:1-46-27 [10 CFR 32.26]
Luminous safety devices in aircraft	OAC 3701:1-46-33, -34, -35, -48 [10 CFR 32.53, 32.54, 32.55, 32.110]
Ice detection devices using Sr-90	OAC 3701:1-46-40, -41, -47, -48 [10 CFR 32.61, 32.62, 32.103, 32.110]
Radiography equipment	OAC 3701:1-48-05, -06, -09 [10 CFR 34.20, 34.21, 34.22, 34.27]
Well logging equipment	OAC 3701:1-49-05, -07 [10 CFR 39.31, 39.35]
Irradiators	OAC 3701:1-52-07, -22 [10 CFR 36.21, 36.59]

Trade secret information

Is any information “Trade Secret”?	If “Yes” is form Trade Secret Request (HEA5519) included?
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Attachment information - Indicate enclosed attachment name/number that the information is in, if applicable. If not applicable or the item is currently registered and there are no changes, indicate N/A

Attachment Name	Item
	General product description
	List of safety-related basic components and their purpose
	Labels used on device
	Detailed drawings and description
	Leak test - diagram of leak test locations, frequency, user instructions
	Identify normal (designed) conditions of use and environmental conditions
	Prototype testing and results, and ANSI classifications as appropriate
	Radiation profiles at maximum loading for each radionuclide and configuration
	Quality Assurance and Quality Control procedures
	Certification of DOT package test results if applicable
	Documents sent to item purchaser
	For medical sources/devices, copy of FDA 510(k) or PMA certifications

(7) CERTIFICATION AND AUTHORIZED SIGNATURE

The applicant understands all statements and representations made in this application and ensuing correspondence, are binding upon the applicant, are incorporated by reference into the license and the record keeping requirements are identified in OAC 3701:1-46-12. The applicant and any official executing this certification on behalf of the applicant certify that this application is prepared in conformity with OAC 3701:1-40 et. seq., and that all information contained herein is true and correct to the best of my knowledge and belief.

Printed Name	Title
Authorized Signature	Date