

Ohio Department of Health

Sealed Source and Device Registration Application

Applicant's license number

Applicant is a Manufacturer Distributor Custom user

Applicant's licensed name and address

Name			Phone ()		
Address			FAX ()		
City	State	ZIP	Web site		

Applicant's contact person

Name			Phone ()		
Address			FAX ()		
City	State	ZIP	E-mail		

Distributor information

Manufacturer information (list if different than distributor)

Name			Name		
Address			Address		
City	State	ZIP	City	State	ZIP

If the applicant is a Custom user, provide the name and complete mailing address of the distributor in the distributor information section above

Application is for

- sealed source OR device
 new registration or amendment to # _____

Model number

If a device—

List all manufacturer and model sealed sources that may be used in the device

Manufacturer	Model

Radionuclide and maximum activity to be used

Radionuclide	Maximum activity (if nominal, also list tolerances)

Name used in industry to identify product _____

Principle use code [] []

Source/device is for use by

- specific licensees only general licensees only both general or specific licensees

Leak test frequency

- leak test not required six months Other (specify and justify) _____
- _____

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

Static elimination device and ion generating tube	3701:1-46-04, (-05, -06, 30, -31, -32)
Certain measuring, gauging or controlling devices	3701:1-46-05, -06, -30, -31, -32
Luminous safety devices for use in aircraft	3701:1-46-07, -33, -34, -35, -36, -45, -48
Am-241 or radium in the form of calibration or reference sources	3701:1-46-08, -37, -38, -39, -46
Sr-90 in ice detection devices	3701:1-46-10, -40, -41, -47, -48
Certain items containing byproduct or accelerator produced material	3701:1-40-09, 3701:1-46-16, -17, -18, -29, -48
Self luminous products containing H-3, Kr-85, or Pm-147	3701:1-46-25, -26
Gas and aerosol detectors	3701:1-46-27, -28
Sources or devices for medical use	3701:1-46-44
Registration of specifically licensed sources and devices	3701:1-46-49
Radiography equipment	3701:1-48-05, -06, -09 [10 CFR 34.20, 34.21, 34.22, 34.27]
Well logging equipment	3701:1-49-05, -07 [10 CFR 39.31, 39.35]
Sealed sources for irradiators	3701:1-52-07, -22, 3701:1-46-49
SNM calibration and reference sources	3701:1-56-02, -06

Expected working life

Provide the following information and indicate enclosed attachment name/number that the information is located in
Attachment name/#

	Trade Secret Request (HEA5519) if needed
	General product description
	List of safety-related basic components and their purpose (ref FMEA [Failure Mode and Events Analysis] techniques and OAC 3701:1-38-23)
	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 device purchaser
	For medical sources/devices, copy of FDA 510(k) or PMA certifications

Certification

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.

Certifying Officer Printed/Typed

Name	Title
Signature	Date