

# 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



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

Name (Printed/Type)	Title
Signature	Date