

Ohio Department of Health

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

ODH Use Only Application Tracking Number

(1) APPLICANT 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 Dated
Date received ODH Use Only	Date assigned ODH Use Only

(2) TYPE OF ACTION REQUESTED

Review of a Source Device	Application is for a New Device Amendment to registration number	Dated	Model number(s)
Amendment Request			

Last full evaluation recent enough to consider only changes. **ODH Use Only**

SS&D Review for

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]

(4) GENERAL DESCRIPTION AND CONSTRUCTION SUMMARY

Any Changes? If “No”, go to Section 5
 If a new device or there are changes, information is in Attachment

	Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)
	Shielding efficiency and integrity
	Was a FDA 510(k) provided for medical devices?
	Safety interlocks, guards, etc. to prevent access to beam or high radiation levels
	On-Off indicators (describes description, qty., location)
	Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances
	If the applicant is requesting to register more than one source/device on a certificate, are designs similar enough to do so?
	Identifies overall operation of the product
	Identifies the primary components and safety features
	Identifies type of installation including method of attachment for fixed gauges
	Identifies means of relocation for a portable device
	Identifies the primary construction materials used for structure and integrity and for safety features
	Corrosion between unlike materials (e.g., aluminum and steel, depleted uranium and steel)
	Identifies the accessibility of radiation beam during use
	Identifies means of providing containment, security and shielding of the radiation source including shutters or other moveable shielding
	Identifies operation of on/off or shielded/exposed indicators
	Identifies design features that protect the product from abuse or tampering
	The identification of the components of the product and safety features includes a description of each’s purpose, function and operation
	Includes an overall drawing of the of the product identifying primary components and safety features and indicating the overall dimensions

(5) DETAILED DESIGN AND CONSTRUCTION FOR SOURCE/DEVICE

Any Changes? If “No”, go to Section 6
 If a new device or there are changes, information is in Attachment

See “ANSI and Other Standards” list for appropriate references for particular source/device designs (e.g. radiography, brachytherapy, etc.)

	Includes complete annotated engineering design and/or construction drawings of all critical safety components, specification sheets, materials lists, and/or detailed written descriptions
	Parts critical to safety include those parts or components that provide primary containment, safety, and shielding of the radioactive material or sealed source
	Drawings of safety critical parts and components identified and are fully dimensioned with tolerances
	Indicates the materials of construction or refers to a drawing number and revision date (or number)
	Indicates fabrication and assembly methods
	Drawing and descriptions of non-safety critical components or parts that contribute to the safety and/or integrity of the of the product are provided
	Drawings contain sufficient information to determine how the components contribute to the safety and/or integrity of the source/device
	Drawings indicate how the component is integrated with other components of the product, and determine if the non-safety critical components could degrade the effectiveness of the safety critical components
	The assembly methods (e.g., welds, bolts, screws), including size, materials, and spacing, and materials of construction of the device are sufficient to withstand normal use and likely accident conditions. These include being subjected to corrosive environments, vibration, impact, puncture, compressive loads, explosion, flooding, excessive high or low temperatures, and drastic changes in temperature (i.e., thermal cycling), and cycling of the on/off mechanism.
	If construction includes use of dissimilar materials, the materials are compatible and corrosion is not likely to occur because of contact between the unlike materials (e.g., corrosion is likely when you have direct contact between aluminum and steel, or depleted uranium and steel). In addition, the materials will not cause corrosive environments without direct contact (e.g., Teflon can break down when subjected to radiation and cause a corrosive environment for certain metals).
	The assembly methods would have no detrimental effects on the product during its fabrication (e.g., heat from welding a holder directly to the sealed source; securing the sealed source by tightening a screw or bolt against the wall of the sealed source).

(6) ADDITIONAL DETAILED DESIGN AND CONSTRUCTION FOR DEVICES

Any Changes? If “No”, go to Section 7 Applicable? If “No”, go to Section 7

If an applicable product and it is either a new device or there are changes, information is in Attachment

See “ANSI and Other Standards” list for appropriate references for particular source/device designs (e.g. radiography, brachytherapy, etc.)

	Mounting integrity and security of sealed source in the device is described in detail
	The fixed shielding will not move nor easily become dislodged from the device.
	The mounting of the sealed source is such that the sealed source will not unintentionally move during use nor become dislodged from the device, and the mounting sufficiently secures the sealed source against access by unauthorized users.
	The device can be locked in the closed condition (source fully shielded) and cannot be locked in the open condition.
	The device contains indicators that clearly identify whether the source shielding is in the open or closed position. If colors are used to identify the open or closed conditions, red should be used for the open condition where exposure could occur and green should be used for the closed condition where the source is “safe” in the shielded position.
	Sufficient safety interlocks, barriers, or guards are included to prevent access to the radiation beam and prevent exposures in excess of those specified in the regulations (the inclusion of barriers or guards should be included as reviewer notes to alert license reviewers).
	If pneumatic or hydraulic systems are used, there are appropriate filters, relief valves, and operating pressures.
	The operation is designed to be fail-safe, that is, loss of power or a failure in the system would cause the shutter to return to, or remain in, the fully shielded position.
	Tamper-resistant hardware or assembly methods are used in the design of the device. Typically, this is required for devices used by general licensees and persons exempt from licensing
	The device is hermetically sealed from foreign materials or moisture if needed.
	The materials of construction (e.g., adhesives, lubricants, and gaskets) will not be detrimentally affected by exposure to radiation or expected conditions of use.
	All moving parts have adequate spacing to ensure they will not bind during use. The tolerances of the spacing between the parts should be such that likely changes (e.g., from bending, temperature changes causing expansion or contraction, introduction of foreign materials) will not cause binding that may lead to unintentional exposure of the source

(7) CERTAIN PRODUCTS AND APPLICATIONS REQUIRING ADDITIONAL REVIEW CRITERIA

Any Changes? If “No”, go to Section 8 Applicable? If “No”, go to Section 8

If an applicable product and it is either a new device or there are changes, information is in Attachment

	Self-luminous products also meet the requirements of OAC 3701:1-40-12 and OAC 3701:1-46-25 [10 CFR 32.22 et seq.]
	Gas and aerosol detectors also meet the requirements of OAC 3701:1-40-13 [10 CFR 30.20] and OAC 3701:1-46-27 [10 CFR 32.26 et seq.]
	Certain generally license measuring, gauging or controlling devices under 3701:1-46-05 [10 CFR 31.5] also meet the requirements of OAC 3701:1-46-05, -30 [10 CFR 31.5 and 32.51]
	Generally licensed luminous devices for use in aircraft under OAC 3701:1-46-07 [10 CFR 31.7] also meet the requirements of OAC 3701:1-46-33 [10 CFR 32.53]
	Generally licensed Sr-90 ice detection system under OAC 3701:1-46-10 [10 CFR 31.10] also meet the requirements of OAC 3701:1-46-40 [10 CFR 32.61]
	Sources and devices designed for use in radiography operations under chapter 3701:1-48 [10 CFR 34] also meet the requirements of OAC 3701:1-48-05, -06, -07 [10 CFR 34.20 through 34.23]
	Sources used in well logging operation under chapter 3701:1-49 [10 CFR 39] also meet the requirements of OAC 3701:1-49-10 [10 CFR 39.41]
	Sources used in irradiator operations under chapter 3701:1-52 [10 CFR 36] also meet the requirements of OAC 3701:1-52-07 [10 CFR 36.21]

(8) CONDITIONS OF USE

Any Changes? If "No", go to Section 9

If a new device or there are changes, information is in Attachment

Expected working life of the source/device (years, operations)
Where is the source/device intended to be used?
Who are the users of the source/device going to be and how will they be trained?
How will the source/device be used?
What are the frequency and duration of occasions when a person may be near the source/device
For devices, the possibility of being used in another component or device
Actions to be taken when source/device reaches the end of its working life

Environmental conditions of use	Normal use & handling	Storage/ transportation	Likely accident conditions
Temperature range, with or w/out cycling			
Vibration			
Atmosphere – corrosion, humidity, weather			
Light (UV, sunlight)			
Puncture – impact			
Crushing			
External Pressure			
Falls/ drop impact			
Explosion			
Flooding			
Electrical/Air quality			
On/off cycling			
Bending/Torsion – with or w/out cycling			

(9) SEALED SOURCE(S)

Any Changes? If “No”, go to Section 10

If a new product or there are changes, information is in Attachment

	Source is evaluated IAW ANSI N43.6 (N542) protocols
ANSI N43.6 (N542) rating	
Is source ANSI classification sufficient (from ANSI N43.6-2007):	
	Radiography – Unprotected 43515
	Radiography - In Device 43313
	Medical – Radiography 32312
	Medical – Teletherapy 53524
	Gamma Gauges – Unprotected 43333
	Gamma Gauges – In Device 43232
	Gamma Gauges, Low Energy Gamma Gauges, or X-ray fluorescence 33222
	Oil Well Logging 56522
	Portable Moist/Density 43333
	Neutron Applications 43323
	Gamma Irradiators (II, III) 43424
	Gamma Irradiators (IV) 53424
	Gamma Irradiators (I) 43323
	Static Eliminators 22222
	Smoke Detectors 32222
Is the source doubly encapsulated?	
Identify the chemical form of the radionuclide	
Identify the binding/encapsulation mechanism of the radionuclide substrate	
	Sealed sources contain appropriate internal void spacing to ensure accurate leak testing results, if applicable. Void spacing should allow for any thermal expansion differentials between the materials of construction.
	“Long” source(s) subjected to bend test
	Source is tested to verify integrity under conditions of use extremes
Source is tested to verify source design will withstand corrosive environments	
Is the sealed source substrate and chemical form dispersible?	
	Well logging and irradiator sources must be non-dispersible and non-soluble.

(10) DEVICES

Any Changes?

If "No", go to Section 11

Applicable?

If "No", go to Section 11

If applicable and there are changes, or if this is a new applicable device, information is in Attachment

	Sealed source meets the minimum ANSI N43.6 classification for device
	Sealed source meets minimum ANSI N43.6 classification for the normal conditions of use
	Device tested IAW applicable industry and consensus standards
	Testing performed sufficiently simulates expected conditions of use, transportation, storage, etc.
	Testing performed simulates likely accident conditions radiation levels do not change more than 20%, RAM is contained and not dispersed.
	Guidance used from a standard of a comparable device

(11) SPECIAL DESIGN FEATURES

Any Changes?

If "No", go to Section 12

Applicable?

If "No", go to Section 12

If applicable and there are changes, or if this is a new applicable device, information is in Attachment

	Identifies the design features that protect the device from abuse
	Identifies means to control the hazard from indirect or scattered radiation
	Identifies means to discourage/prevent unauthorized access to the source
	Describes accessibility of the radiation beam during use, including the size of openings or air gaps that could allow any part of a human body to enter the radiation beam, and any protective measures, additional guards, or installation requirements designed to prevent accessibility of the radiation beam during use.

(12) LABELING

Any Changes?

If "No", go to Section 13

If a new product or there are changes, information is in Attachment

	The locations of the labels are readily visible to the users
	The materials of label construction, label dimensions, and means of writing on label are identified and adequate
	The colors of the labels are identified
	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)
	The means of attaching labels are expected to last the life of the device
	The labels are expected to be remain legible over the life of the device
	Copies, photos, or diagrams of the labels were provided
	Verify that the labeling does not misinterpret, misrepresent, or lead the user into violating any applicable regulations

(12.1) Specific labeling criteria

Any Changes? If “No”, go to Section 13 Applicable? If “No”, go to Section 13

If applicable and there are changes, or if this is a new applicable device, information is in Attachment

	Self-luminous products under OAC 3701:1-40-12 [10 CFR 30.19] also meet the labeling requirements of 10 CFR 32.25
	Gas and aerosol detectors under OAC 3701:1-40-13 [10 CFR 30.20] also meets the labeling requirements of 10 CFR 32.29
	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]
	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]
	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]
	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]
	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]
	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]

(13) DESIGN ANALYSIS - PROTOTYPE TESTING/HISTORICAL USE

Note: If the product is registered for use by a custom user, prototype testing may not be required.

Any Changes? If “No”, go to Section 14

If a new product or there are changes, information is in Attachment

(13.1) Prototype Testing

	Prototype is a complete representation of final product
	Prototype includes all safety features, shielding, safety markings
	Prototype includes all accessory features and/or mounting
	Prototype was constructed from same materials as the final product
	Prototype was constructed to the same dimensions and tolerances as the final product
	Prototype was tested for normal operating conditions
	Prototype was tested for likely accident conditions
	The test methods and conditions for the source and device (if applicable) meet or exceed conditions of use
	Tests results are included
	Source model ANSI N43.6 (N542) classification
	If applicable, device model ANSI N43.8 (N538) classification
	Source/device likely to maintain its integrity when subjected to normal and likely accident conditions

AND/OR

(13.2) Engineering Analysis

	Parts and systems subjected to analysis
	Analysis done by calculation
	Analysis done by modeling
	Analysis done by sample testing
	Analysis done by evaluation
	Industry/consensus standard used
	Engineering evaluation demonstrates that source/device would had passed test if it had been subjected to test.
	Conclusions supported with supporting documentation/ calculations
	Source/device likely to maintain its integrity when subjected to normal and likely accident conditions

AND/OR

(13.3) Operational History/Comparative History

	Operational history includes identical device (excluding accessory equipment that has no effect on the safety or integrity of the product)
	Comparative history includes similar or equivalent source/device to the one being requested
	Used in equivalent or more severe conditions of normal use
	Operational history includes environmental and operating conditions
	Operational history includes number of cycles per year, number of years in service
	Operational history includes results of known accidents and accident conditions
	Operational history includes results and root causes of any known product failures
	Source/device likely to maintain its integrity when subjected to normal and likely accident conditions
Years of use and manufacture/distribution	

(13.4) Special requirements for prototype tests

Any Changes? If "No", go to Section 14 Applicable? If "No", go to Section 14

If applicable and there are changes, or if this is a new applicable device, information is in Attachment

	Passes prototype tests listed in OAC 3701:1-46-33, -45 [10 CFR 32.53 and 32.101] for "Luminous Safety Devices for Use in Aircraft" under chapter 3701:1-46 [10 CFR 31.7] general license
	Passes prototype tests listed in OAC 3701:1-46-40, 47 [10 CFR 32.61 and 32.103] for "Ice Detection Devices Containing Sr-90" under chapter 3701:1-46 [10 CFR 31.10] general license
	Passes prototype tests listed in OAC 3701:1-48-05 [10 CFR 34.20] for sources and devices used under OAC 3701:1-48 [10 CFR 34] radiography operations
	Passes prototype tests listed in OAC 3701:1-49-10 [10 CFR 39.41] for sources and devices used under chapter 3701:1-49 [10 CFR 39] well logging operations
	Passes prototype tests listed in OAC 3701:1-52-07 [10 CFR 36.21] for sources used under chapter 3701:1-52 [10 CFR 36] irradiator operations

(14) NMED REVIEW- ODH Use Only

New Product? If "Yes", go to Section 15

	Check NMED for reported events involving source and/or device
	Current application addresses applicable issues from reported incidents

(15) RADIATION PROFILES

Information is included in Attachment

	Radiation profile measured with the source/device containing the maximum radionuclide activity
	Radiation profiles made for all radionuclides used
	Radiation profiles are extrapolated to maximum radionuclide activity based on actual dose rate measurements
	Radiation profiles are calculated values
	Survey instrument identified (type, window thickness, sensitivity, etc.)
	The survey instrument was applicable for the radiation measured (type, beam/detector sizes, appropriate dose conversion used energy measured)
	Survey was performed with a calibrated instrument?
Did any correction factors need to be considered for gamma energy beam vs calibration energy?	
	Dose rates identified as deep (1000 mg/cm ² or less) for gamma, include shallow/skin (7 mg/cm ²) for beta (or alpha) emitters when appropriate
	Survey conditions include usage environment, scatter (product in beam), and use of guards and shields
	Measurements made at distance from source/surface per ANSI N43.8 (N538) (at 5, 30 and 100 cm)
	Contact/surface shallow dose rate measured/ calculated for sources – applicable for potential finger contact doses
	Measurements made with the shutter open and closed (source unshielded/ shielded)
	Gamma radiation surveys are consistent with inverse square law.
	Non-gamma radiation surveys have not been calculated using inverse square law.
	Remote Handling Tools are needed
Localized shielding is needed or recommended	

(15.1) Specific dose rate limits

Any Changes?

If “No”, go to Section 16

Applicable?

If “No”, go to Section 16

If applicable and there are changes, or if this is a new applicable device, information is in Attachment

	Meets dose rate limits identified in OAC 3701:1-46-25 [10 CFR 32.22] for self-luminous products used under the OAC 3701:1-40-12 [10 CFR 30.19] exemption
	Meets dose rate limits identified in OAC 3701:1-46-27 [10 CFR 32.26] for gas and aerosol detectors used under the OAC 3701:1-40-13 [10 CFR 30.20] exemption
	Meets dose rate limits identified in OAC 3701:1-46-30 [10 CFR 32.51] for certain measuring, gauging, and controlling devices used under the OAC 3701:1-46-05 [10 CFR 31.5] general license
	Meets dose rate limits identified in OAC 3701:1-48-05 [10 CFR 34.20 and 34.21] for devices used under chapter 3701:1-48 [10 CFR 34] radiography operations

(16) QUALITY ASSURANCE

Any Changes in approved QA plan?

If “No”, go to Section 17

If a new product or there are changes, QA checklist and information is in Attachment

(17) INSTALLATION, SERVICING, AND SAFETY INSTRUCTIONS TO USERS

Any Changes? If “No”, go to Section 18

If a new product or there are changes, information is in Attachment

Type of installation – fixed, portable, movable, fixed installation but portable source housing	
	Inherent shielding, inaccessibility of radiation
	Beam access: size of air gap/opening to beam use of interlocks, locks, additional shielding or barriers
	Instructions to user for user installations
	Mounting instructions and integrity
	Interlock installation instructions
	Installation of guards and barriers
	Initial dose rate survey required?
	Emergency response instructions to limit exposures to radiation
	GL mounting procedures include: Mount in location compatible with “Normal Conditions of Use” in SSD Mount in location compatible with “Limitations ...” in SSD On/Off mechanism must be locked in “Off” position
	Relocation instruction
	Maintenance – instructions and limits
	Repair – instructions and limits
	Leak test – instruction on frequency and technique
	Calibration – instructions
	Shutter test (on/off test) w/ instruction on frequency and technique
	Routine testing of interlock operation
	Identification of equipment malfunction and return to “safe position”
	For distribution to OAC 3701:1-46-05 [10 CFR 31.5 General Licensees]: Verify that the NRC Regions and Agreement State listing is up-to-date for copies of all pertinent rules and instructions IAW OAC 3701:1-46-05, -30 [10 CFR 32.51 and 32.51a]
	Shipping instructions
	End of use/ service life instructions
	Disposal instructions and options

(18) TRANSPORTATION (OAC Chapter 3701:1-50 [10 CFR 71])

Any Changes? If “No”, go to Section 19

If a new product or there are changes, information is in Attachment

“A2” activity limit (normal form)	
“A1” activity limit (special form)	
	Is the sealed source certified special form 3701:1-50-01 [10 CFR 71.75] (otherwise is normal form)?
	Does the source / device need to be shipped in a Type A or Type B container?
	Does the manufacturer state that the device meets the criteria of a Type A container?
	Is the transportation container certified as a Type B container (certificate of compliance number, and expiration date)?
	Is the source shipped separate from the device and installed at the site of use?
	Is the device/source secured during shipment and transportation?
	Can the device/source be stored in the shipping container?

(19) SERVICING

Any Changes? If "No", go to Section 20

If a new product or there are changes, information is in Attachment

The following activities may be performed by the persons indicated.

If N/A, indicate N/A in comments section

Activity	By a general licensee	Only by a specific licensee	Will be offered by applicant	Comments
Initial Mounting				
Installation				
Relocation				
Maintenance				
Repair				
Source Exchange				
Calibration				
Leak Testing				
Radiation Survey				
Training				

(20) FOREIGN VENDORS

Any Changes? If "No", go to Section 21 Applicable? If "No", go to Section 21

If applicable and there are changes, or if this is a new applicable device, information is in Attachment

Drop Ship? (QA inspection by?)
Where and by whom is source installed
Leak test and radiation surveys
QA in the US

(21) AUTHORIZED SIGNATURE

Authorized Signature

Date

(22) REVIEWER INFORMATION SUMMARY – ODH Use Only

_____ Initial Reviewer	_____ Date Completed	_____ Total Hours
_____ Concurrence Reviewer	_____ Date Completed	_____ Total Hours
_____ Trainee Reviewer	_____ Date Completed	_____ Total Hours