

# Ohio Department of Health

## Bureau of Environmental Health and Radiation Protection Sealed Source and Device Quality Assurance (QA) Checklist for Manufacturer/Distributors

**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	
Sealed Source and Device Registration Number (if this is an amendment to a current registration)	
Applicant's Ohio License Number	Application Dated
Date received <b>ODH Use Only</b>	Date assigned <b>ODH Use Only</b>

**(2) QA INFORMATION SUBMITTED?**

**(2.1) Externally Audited QA Programs**

Operates under an FDA GMP or an ISO 9001 program w/ commitments to ensure

	Materials of construction and final assembly meet design specifications
	The final product is leak tested
	Final radiation profile is performed
	Tests verify that product operates as intended including all safety functions
	Visual and mechanical inspection of components that are considered critical to safety and are expected to be susceptible to failure under extreme or unusual conditions

**OR**

**(2.2) QA procedures submitted ensure**

	The materials of construction and the final assembly were verified to meet the design specifications [required]
	Verification the final product is leak tested [required]
	Verification a final radiation profile is performed [required]
	A visual and mechanical inspection of components that are considered critical to safety and are expected to be susceptible to failure under extreme or unusual conditions is performed [required]
	Dimensions and tolerances are in accordance with specifications
	Source activities are in accordance with specifications
	Organization – structure and responsibilities
	Personnel – training and qualifications
	Equipment – Equipment used for measuring, testing, or inspecting should be controlled, calibrated, and maintained

	Material and Service Procurement – Procurement of materials or services must be controlled to ensure conformance with specifications
	Inventory procedures – Include provisions for materials in production process, material shelf life, in-process material, inspection points, and segregation of non-conforming items
	Production Procedures and Processes – Procedures should contain all necessary instructions, including machinery, equipment, and qualifications of the worker to perform the task including inspection and hold points
	Inspection and Testing –Applicant should have written procedures for in-process inspection and testing of materials, production processes, and final inspection and testing of the device
	Nonconforming Materials – Applicant should have written procedures to ensure that materials and devices that do not conform to the specifications are identified and separated from production and distribution
	Packaging and Transportation – Written procedures should ensure that all materials and devices shipped are packaged and transported according to the regulations and specifications governing the material – ensure that all appropriate manuals, instructions, and documentation accompany the shipment
	Deviations and Complaints – Applicant should have procedures for evaluating and recording deviations – records should be kept and contain the device type model number, serial number, nature and date of complaint, corrective action taken, and root causes of failure
	Audits –Applicant should have procedures for auditing and evaluating its QA program and for auditing their suppliers
	Records and Documentation – Applicant maintains all appropriate records and files, including test results, inspection records, audits, and written procedures.

**(2.3) Specific QA requirements**

Applicable?                    If “No”, go to Section 3

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

	Generally licensed Luminous Safety Devices Used In Aircraft under OAC 3701:1-46-07 [10 CFR 31.7] meet the QA requirements identified in OAC 3701:1-46-35, -48 [10 CFR 32.55 and 32.110]
	Generally licensed Sr-90 in ice detectors under OAC 3701:1-46-10 [10 CFR 31.10] meet the QA requirements of OAC 3701:1-46-40, -41, -48 [10 CFR 32.61, 32.62 and 32.110]

**(3) AUTHORIZED SIGNATURE** Applicant; only required if applicant fills out checklist

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**Authorized Signature**

**Date**

**(4) 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>