

Ohio Department of Health

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

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 ODH Use Only	Date assigned ODH Use Only

(2) QA INFORMATION

(2.1) Externally Audited QA Programs

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

	The final product is leak tested
	Final radiation profile is performed
	Tests to 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 include

	Verification the final product is leak tested
	Verification a final radiation profile is performed
	Verification that the manufacturer verified that source activities are IAW specifications, or direct verification that source activities are IAW specifications
	Organization – structure and responsibilities
	Personnel – training and qualifications
	Equipment – Verify equipment used for measuring, testing, or inspecting are controlled, calibrated, and maintained
	Inventory procedures – Include provisions for material shelf life, inspection points, and segregation of non-conforming items
	Inspection and Testing –Applicant should have written procedures for verifying the manufacturer's 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 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 the manufacturer(s)
	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; REQUIRED ONLY IF APPLICANT USES CHECKLIST)

Authorized Signature

Date

(4) REVIEWER INFORMATION SUMMARY – ODH Use Only

Primary Reviewer	Date Completed	Total Hours
Concurrence Reviewer	Date Completed	Total Hours
Trainee Reviewer	Date Completed	Total Hours