DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

ACCIDENTAL RADIATION OCCURRENCE (ARO) QUARTERLY SUMMARY REPORT

Form Approved: OMB No 0910-0025
Expiration Date: February 26, 2026
See Burden Statement on page 2.

FOR FDA USE ONLY ON INITIAL REGISTRATIONS

Registration Date (MM/DD/YYYY)

FDA

Note: Items with an asterisk (*) require a *response*.

SUBMITTER INFORMATION

If you are not submitting this report representing the manufacturing establishment for the radiation-emitting product causing the problem, you may submit individual occurrences using FDA FORM 3649.

Contact Last Name*	Contact First Name*	Occupation Title*	
Email Address*	Fax Number	Telephone Number*	
Street Address*	City*	State*	Zip Code*

SUMMARY REPORT INFORMATION

Summary Report Year *(YYYY)**	Quarter *(Select one)**
	☐ Quarter 1 (Jan 1st to Mar 31st) ☐ Quarter 2 (Apr 1st to Jun 30th)
	☐ Quarter 3 (Jul 1st to Sept 30th) ☐ Quarter 4 (Oct 1st to Dec 31st)

INFORMATION REGARDING PRODUCT MANUFACTURER

Product Manufacturer Name*

Street Address *(Line 1)**	Street Address *(Line 2)**		
City*	Territory, Province, or State*	Country*	Zip or Postal Code*

SUMMARY ARO TABLE CONTENT*

In addition to this form, the ARO Summary Table should be submitted to RadHealthCustomerService@fda.hhs.gov. The ARO Summary matrix must include the following columns in the following order:

1. Event ID (*your firm's unique identification alpha-numerical for each event*)
2. Model (*e.g., model name, number, family designation, brand name, and/or Unique Device Identifier [UDI]*)
3. Premarket Application Number, if applicable (*e.g., 510[k], PMA, etc.*)
4. Product Classification Code, if known (*cite the primary product code first if there is more than one*)
5. Brief Product Description
6. Location of Occurrence (*e.g., establishment name, address, telephone, and email address of the event location*)
7. Person(s) involved (*e.g., name and contact information [address, telephone, and/or email] of individuals involved in the event [e.g., device operators, patients, etc.], if available*)
8. Type of reportable event †‡◊ (*e.g., death, serious injury, malfunction, other*)
9. Type of ARO (original or supplement)
10. Description of event
11. Date of event
12. Hazard(s) to person(s) involved
13. Root cause determination
14. Actions taken/planned mitigation
15. Other important information

† Deaths and serious injuries are to be reported in individual ARO reports using FORM FDA 3649.

‡ Any event reportable under 21 CFR Part 803 shall be reported under 21 CFR Part 803.

◊ A manufacturer need not file a separate report under this section if an incident involving an accidental radiation occurrence is associated with a defect or noncompliance and is reported pursuant to 21 CFR 1003.10.

PSC Publishing Services (301) 443-6740 EF

SUMMARY ARO ANALYSIS*

Tracking and Trending Analysis

Provide a description of the trending analysis performed and conclusions drawn from the analysis. Occurrences may be grouped to identify the most common circumstances and potential cause(s), including but not limited to, design changes, manufacturing, or user. Planned mitigation(s) with an assessment of effectiveness, or a justification for why mitigation is not necessary, must be associated with each occurrence or grouping of similar occurrences. *(If your analysis includes images or figures, please submit your analysis as a separate document with this form and your ARO Summary Table to RadHealthCustomerService@fda.hhs.gov.)*

Feel free to send in medical documentation regarding the incident and injuries.

Please send this completed FORM FDA 3649S to RadHealthCustomerService@fda.hhs.gov.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

–DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW–

The burden time for this collection of information is estimated to average 2 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."