DEPARTMENT OF HEALTH AND HUMAN SERVICES	Form Approved:
Food and Drug Administration Center for Devices and Radiological Health	OMB Control Number 0910-0025 Expiration Date: February 28, 2026
CONSUMER ACCIDENTAL RADIATION OCCURRENCE REPORT (FORM FDA 3649C)	*See Burden Statement on page 3.*

If you are reporting an event related to a medical device, please use the MedWatch Online Voluntary Reporting Form: https://www.accessdata.fda.gov/scripts/medwatch/

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

Contact Name *(Title, first name, last name)*	

Email Address

			Telephone Number

Product Manufacturer Name *(If known)*

Radiation Product Type: <<drop down menu>>
------ <<default option>>
Optical (e.g., laser pointers, ultraviolet hygiene products, night vision systems)
Microwave (e.g., microwave ovens, cell phones, electric blankets)
Ionizing (e.g., diagnostic x-ray equipment, tube television)
Acoustic (e.g., sonic and ultrasonic devices)
Unknown

Product: *Please provide any information to identify the product, such as product brand, model name, where you bought it (e.g., weblink), any description about the product.**

Event: Please describe the event, e.g., What happened? How did it happen? Was anyone injured? What was the injury? What action has been taken to care for the person affected? *

Any other Important Information *you would like to provide (e.g., any contact history with the manufacturer, relevant ARO reports submitted previously, other references, etc.)?*

Feel free to send in medical documentation or other supporting documents (including photos) regarding the incident and injuries to RadHealthCustomerService@fda.hhs.gov. Please refer to this ARO report when you submit the documents.

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

The Paperwork Reduction Act of 1995 provides that an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0025. The time required to complete this information collection is estimated to average 15 minutes per response. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden to PRAStaff@fda.hhs.gov.