

ACCIDENTAL RADIATION OCCURRENCE REPORT

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 enter your own company name under Establishment Identification and Submitter Address, or enter N/A and provide your home or other address.

Contact Information

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

Occupation Title

Email Address*

Establishment Identification (Manufacturer of the radiation-emitting product being reported, if known)

Establishment Name

Division Name

Submitter Address

Address

Telephone Number*

Street*

City*

State*

Zip Code*

Fax Number

INFORMATION REGARDING PRODUCT MANUFACTURER

Product Manufacturer Name (If known)

Product Manufacturer Address (If known)

Street (Line 1)

Street (Line 2)

City

Territory, Province, or State

Country

Zip or Postal Code

Product Model Designation (If known)

Model Name or Number Model Family Designation Brand Name

Please provide any other information known regarding the manufacturer of the product that was involved in the accidental radiation exposure incident.

If you are aware that the manufacturer was informed about the incident, please provide the contact information below.

Contact Information (Including whom you contacted and address)

Date Contacted

PRODUCT INFORMATION

Product Types (Please select the best match (only one). Note that product types are grouped into radiation categories.)

<p>Acoustic Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Therapeutic Ultrasonic Devices (Including diathermy and stimulators)<input type="checkbox"/> Ultrasonic Medical Devices (Miscellaneous) (Including lithotriptors)<input type="checkbox"/> Diagnostic Ultrasound Devices<input type="checkbox"/> Sonic Medical Products (Including hearing aids and vibrators)<input type="checkbox"/> Ultrasound Non-Medical Products (Including jewelry cleaners and intrusion security systems)<input type="checkbox"/> Sonic Non-Medical Products<input type="checkbox"/> Veterinary Diagnostic Ultrasonic Products<input type="checkbox"/> Veterinary Therapy Ultrasonic Products<input type="checkbox"/> Other Sonic or Ultrasonic Product	<p>Microwave EMF Radiation (Continued)</p> <ul style="list-style-type: none"><input type="checkbox"/> Microwave Identification, Safety, Security, and Surveillance Products<input type="checkbox"/> Industrial Dielectric Heaters<input type="checkbox"/> Microwave Medical Products<input type="checkbox"/> Microwave Heating and Drying Products<input type="checkbox"/> Microwave Communication, Data Transmit, and Measurement Products (Including CB radios, cell phones, walkie-talkies, household remote controllers)<input type="checkbox"/> Nuclear Magnetic Resonance Devices<input type="checkbox"/> Household ELF Products (Including electric blankets)<input type="checkbox"/> Other Microwave Product
<p>Ionizing Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Personnel Security Systems (Including backscatter and transmission x-ray systems)<input type="checkbox"/> Cargo Non-Intrusive Security Systems<input type="checkbox"/> Cabinet X-Ray Systems, Non-Medical (Including baggage x-ray systems)<input type="checkbox"/> Industrial X-Ray Systems (Excluding Cabinet)<input type="checkbox"/> Analytical X-Ray Systems, Non-Medical<input type="checkbox"/> High Voltage Vacuum Switches<input type="checkbox"/> Industrial Particle Beam Systems<input type="checkbox"/> TVs and video monitors (Not including flat-screen TVs)<input type="checkbox"/> Medical Diagnostic X-Ray Equipment<input type="checkbox"/> Dental Diagnostic X-Ray Equipment<input type="checkbox"/> Therapeutic X-Ray Systems<input type="checkbox"/> Veterinary X-Ray Systems<input type="checkbox"/> X-Ray Bone Densitometers<input type="checkbox"/> X-Ray Film and Film Processing Materials<input type="checkbox"/> Cabinet X-Ray Systems, Medical<input type="checkbox"/> Medical Accelerators<input type="checkbox"/> Non-Medical Accelerators<input type="checkbox"/> High Voltage Vacuum Tubes<input type="checkbox"/> Cathode Ray Tube (Without Electronics Chassis)<input type="checkbox"/> Cold-Cathode Gas Discharge Tubes<input type="checkbox"/> Other X-Ray Product	<p>Optical Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Medical Laser Products (Including surgical devices and laser therapy)<input type="checkbox"/> Surveying, Leveling, Alignment Laser Products (Including laser pointers, laser levels)<input type="checkbox"/> Laser Light Show/Display Products<input type="checkbox"/> Toy, Novelty, Play Laser Products<input type="checkbox"/> Safety, Security, Surveillance Laser Products (Including night vision systems, traffic speed systems and intrusion detection systems)<input type="checkbox"/> Research, Scientific, Laboratory Laser Products<input type="checkbox"/> Material Processing Laser Products (Including welders, cutters, engravers)<input type="checkbox"/> Data Measurement, Transmit, Control Laser Products (Including fiber optic communication systems, laser vision systems and process control systems)<input type="checkbox"/> Utility/Peripheral Laser Products (Including laser printers, bar code scanners, CD and DVD systems)<input type="checkbox"/> In Vitro and Other Medical Laser Products (Including Veterinary devices)<input type="checkbox"/> Patient Positioning Medical Laser Products<input type="checkbox"/> Other Laser Products<input type="checkbox"/> Sunlamp Products (Including sunlamps and tanning beds)<input type="checkbox"/> Mercury Vapor Lamps<input type="checkbox"/> Ultraviolet Medical Products<input type="checkbox"/> Ultraviolet Commercial/Consumer Products<input type="checkbox"/> Ultraviolet Surveillance & Detection Products<input type="checkbox"/> Ultraviolet Hygiene Products (Including UV sanitizers)<input type="checkbox"/> General Optical Products, Medical (Including surgical lamps)<input type="checkbox"/> General Optical Products, Non-Medical (Including LEDs and fluorescent lamps)
<p>Microwave EMF Radiation</p> <ul style="list-style-type: none"><input type="checkbox"/> Microwave Ovens (Food Prep)<input type="checkbox"/> Microwave Hyperthermia Therapy Devices<input type="checkbox"/> Microwave Diathermy Machines	

PRODUCT INFORMATION (Continued)

Product Description

Description of product and its intended use

ACCIDENTAL RADIATION OCCURRENCE INFORMATION

Location of Occurrence

Please provide the physical location where the Accidental Radiation Occurrence took place (e.g., at a residence, a factory, a tanning salon, school, restaurant, airport, etc.). If you do not know the exact address, provide responses to the best of your ability, or enter "Unknown."

Location or Establishment Name

Specific Section of Location or Establishment (If applicable)

Address			Telephone Number	
Street				
City		State	Zip Code	Fax Number
Date of Event*	From	To	Web Address	

Persons Involved

Number of people exposed in the Accidental Radiation Occurrence*	Number of people adversely affected*	Number of unexposed people who were involved*	Number of potentially exposed people who have not exhibited any adverse reactions*
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Type of reportable event Death Serious Injury Malfunction Other _____ .

Description of the nature and magnitude of exposure and/or injuries

ACCIDENTAL RADIATION OCCURRENCE INFORMATION (Continued)

Description of the Radiation Occurrence

Is this a new Accidental Radiation Occurrence (ARO) report or a supplement to a previous ARO report filed by you or your organization?
(Please select one.)*

New ARO report

Supplement to previous ARO report (Enter date of previous report below.)

Date of previous ARO report, if applicable (mm/dd/yyyy) (Required entry* only if "Supplement to previous ARO report" is selected.)

Description of circumstances surrounding the accidental radiation occurrence (Please include a description of the activities leading up to the event and actions that occurred during the event, as well as any suspected causes of the occurrence.)*

Actions Taken

The actions described below are those taken to control, correct, or eliminate the causes and to prevent reoccurrence. If unknown, you may state "Unknown" below.

Description of specific actions, to date, taken by the manufacturer in response to the Accidental Radiation Occurrence*

ACCIDENTAL RADIATION OCCURRENCE INFORMATION (Continued)

Actions Taken (Continued)

Description of future actions to be taken by the manufacturer, if known, in response to the Accidental Radiation Occurrence (*If this is a preliminary ARO report from the manufacturer, please indicate that further investigation is ongoing.*)*

If this involved a medical device, has a Medical Device Report (MDR) been submitted to FDA?*

Yes No N/A Unknown

Other Important Information (Please enter below)

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

**Please mail this completed FORM FDA 3649
to the address to the right:**

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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
PRASStaff@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.”*