DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

ACCIDENTAL RADIATION OCCURRENCE REPORT

Form Approved:
OMB Number 0910-0025
Expiration Date: July 31, 2020

See Burden Statement on page 5.

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

PSC Publishing Services (301) 443-6740 EF

PRODUCT INFORMATION

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

Acoustic Radiation

- ☐ Therapeutic Ultrasonic Devices (Including diathermy and stimulators)
- ☐ Ultrasonic Medical Devices (Miscellaneous) (Including lithotriptors)
- ☐ Diagnostic Ultrasound Devices
- ☐ Sonic Medical Products (Including hearing aids and vibrators)
- ☐ Ultrasound Non-Medical Products (Including jewelry cleaners and intrusion security systems)
- ☐ Sonic Non-Medical Products
- ☐ Veterinary Diagnostic Ultrasonic Products
- ☐ Veterinary Therapy Ultrasonic Products
- ☐ Other Sonic or Ultrasonic Product

Ionizing Radiation

- ☐ Personnel Security Systems (Including backscatter and transmission x-ray systems)
- ☐ Cargo Non-Intrusive Security Systems
- ☐ Cabinet X-Ray Systems, Non-Medical (Including baggage x-ray systems)
- ☐ Industrial X-Ray Systems (Excluding Cabinet)
- ☐ Analytical X-Ray Systems, Non-Medical
- ☐ High Voltage Vacuum Switches
- ☐ Industrial Particle Beam Systems
- ☐ TVs and video monitors (*Not* including flat-screen TVs)
- ☐ Medical Diagnostic X-Ray Equipment
- ☐ Dental Diagnostic X-Ray Equipment
- ☐ Therapeutic X-Ray Systems
- ☐ Veterinary X-Ray Systems
- ☐ X-Ray Bone Densitometers
- ☐ X-Ray Film and Film Processing Materials
- ☐ Cabinet X-Ray Systems, Medical
- ☐ Medical Accelerators
- ☐ Non-Medical Accelerators
- ☐ High Voltage Vacuum Tubes
- ☐ Cathode Ray Tube (Without Electronics Chassis)
- ☐ Cold-Cathode Gas Discharge Tubes
- ☐ Other X-Ray Product

Microwave EMF Radiation

- ☐ Microwave Ovens (Food Prep)
- ☐ Microwave Hyperthermia Therapy Devices
- ☐ Microwave Diathermy Machines

Microwave EMF Radiation *(Continued)*

- ☐ Microwave Identification, Safety, Security, and Surveillance Products
- ☐ Industrial Dielectric Heaters
- ☐ Microwave Medical Products
- ☐ Microwave Heating and Drying Products
- ☐ Microwave Communication, Data Transmit, and Measurement Products (Including CB radios, cell phones, walkie-talkies, household remote controllers)
- ☐ Nuclear Magnetic Resonance Devices
- ☐ Household ELF Products (Including electric blankets)
- ☐ Other Microwave Product

Optical Radiation

- ☐ Medical Laser Products (Including surgical devices and laser therapy)
- ☐ Surveying, Leveling, Alignment Laser Products (Including laser pointers, laser levels)
- ☐ Laser Light Show/Display Products
- ☐ Toy, Novelty, Play Laser Products
- ☐ Safety, Security, Surveillance Laser Products (Including night vision systems, traffic speed systems and intrusion detection systems)
- ☐ Research, Scientific, Laboratory Laser Products
- ☐ Material Processing Laser Products (Including welders, cutters, engravers)
- ☐ Data Measurement, Transmit, Control Laser Products (Including fiber optic communication systems, laser vision systems and process control systems)
- ☐ Utility/Peripheral Laser Products (Including laser printers, bar code scanners, CD and DVD systems)
- ☐ In Vitro and Other Medical Laser Products (Including Veterinary devices)
- ☐ Patient Positioning Medical Laser Products
- ☐ Other Laser Products
- ☐ Sunlamp Products (Including sunlamps and tanning beds)
- ☐ Mercury Vapor Lamps
- ☐ Ultraviolet Medical Products
- ☐ Ultraviolet Commercial/Consumer Products
- ☐ Ultraviolet Surveillance & Detection Products
- ☐ Ultraviolet Hygiene Products (Including UV sanitizers)
- ☐ General Optical Products, Medical (Including surgical lamps)
- ☐ General Optical Products, Non-Medical (Including LEDs and fluorescent lamps)

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 Street			Telephone Number
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*

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:

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Food and Drug Administration
Office of Chief Information Officer
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"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."