CDRH Role in Laser Safety

An Overview of CDRH's Radiological Health Program

2011 Laser Safety Officer Workshop

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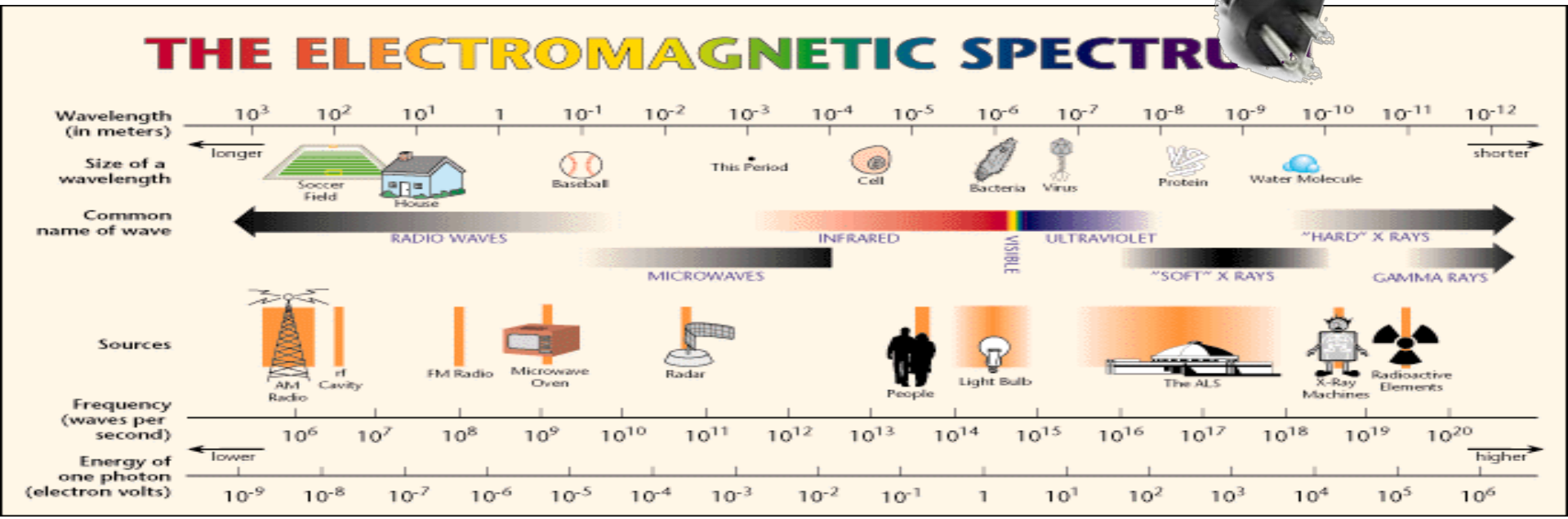
Topics

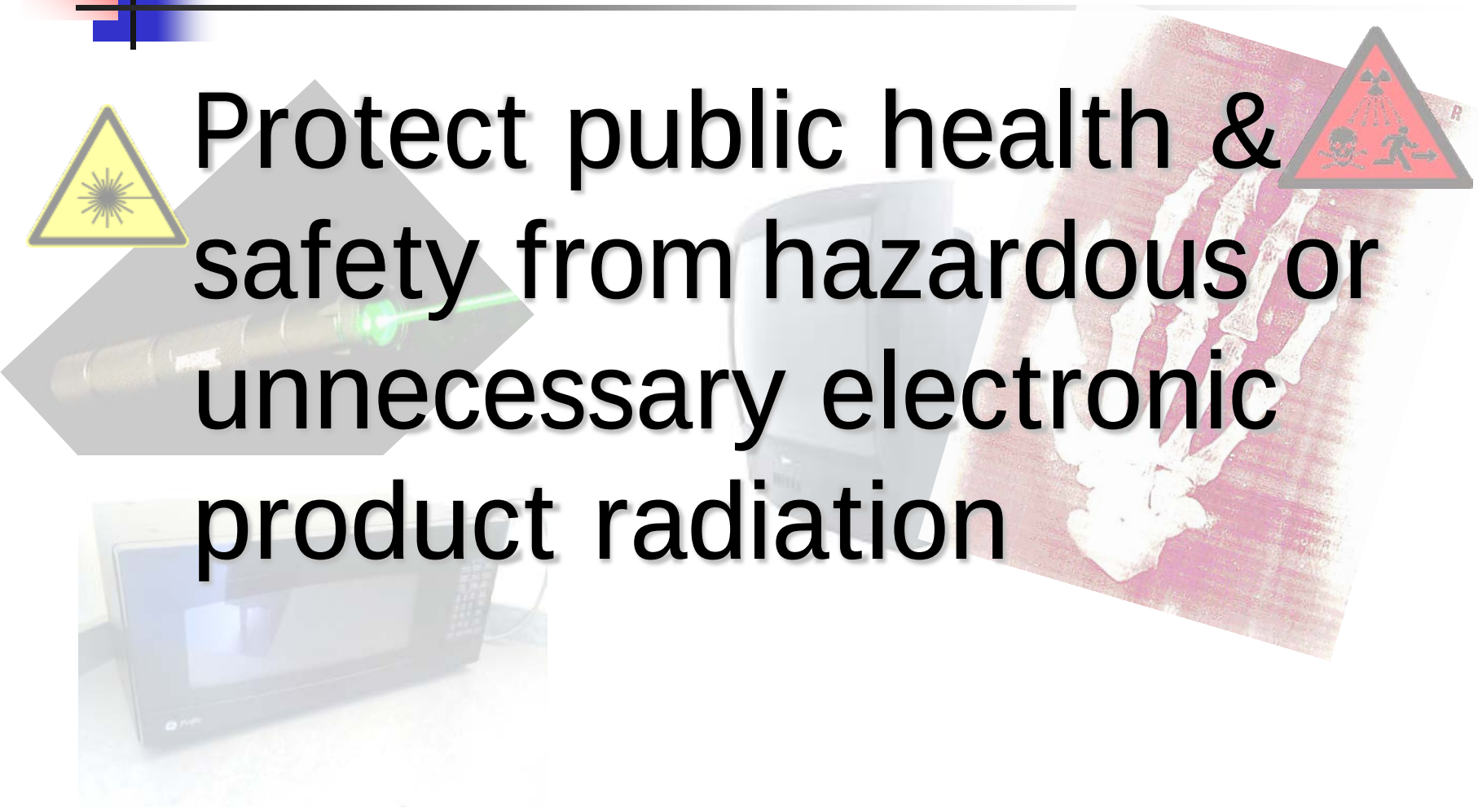
- What is an electronic product?
- Mission & authorities
- Requirements for manufacturers
  - All
  - Some – reports and records
  - Few – specific performance standards
- Enforcement
- Guidance

What is an Electronic Product?

- Contains electronic circuit & emits electronic product radiation

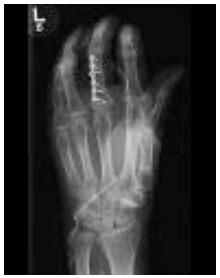


Radiological Health Mission

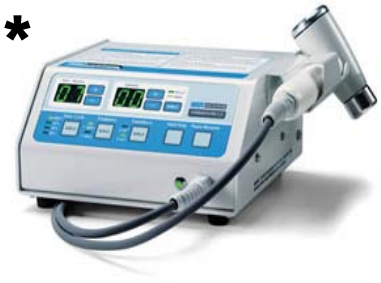


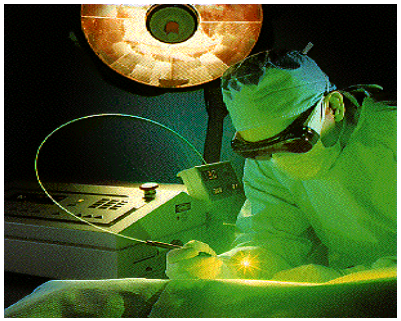
Protect public health & safety from hazardous or unnecessary electronic product radiation

Medical Electronic Products



- Medical diagnostic x-ray systems*
- Sunlamps*
- Ultrasound therapy*
- Laser therapy and surgical devices*
- Radiation therapy
- Microwave or ultrasound diathermy devices
- Microwave blood warmers or sterilizers
- Ultraviolet dental curing devices

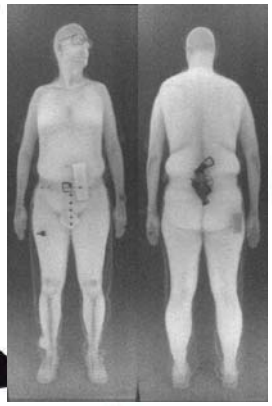




* subject to performance standards

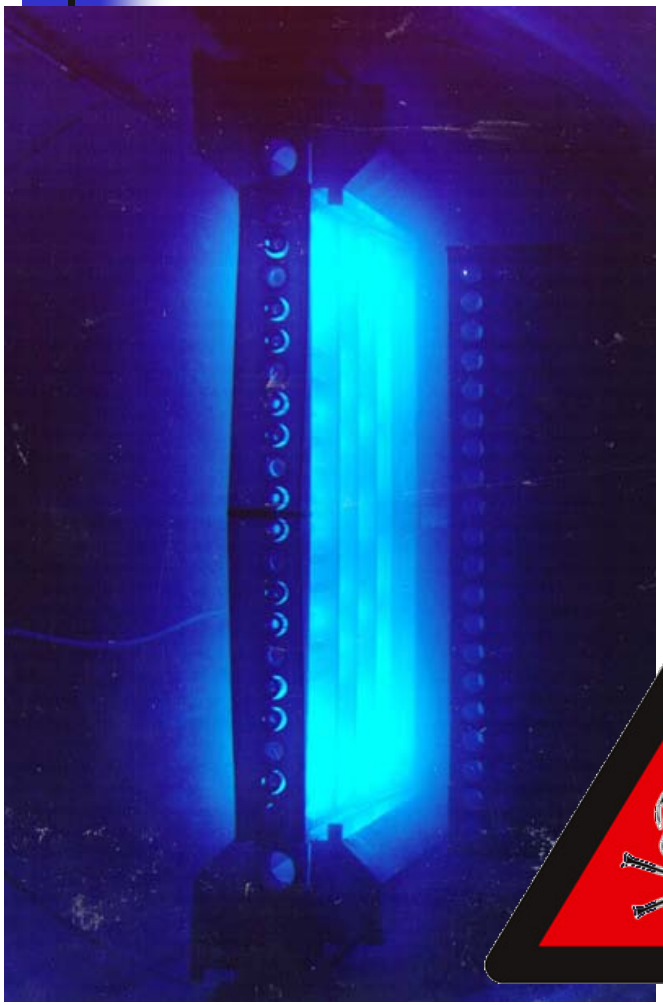
Non-Medical Electronic Products

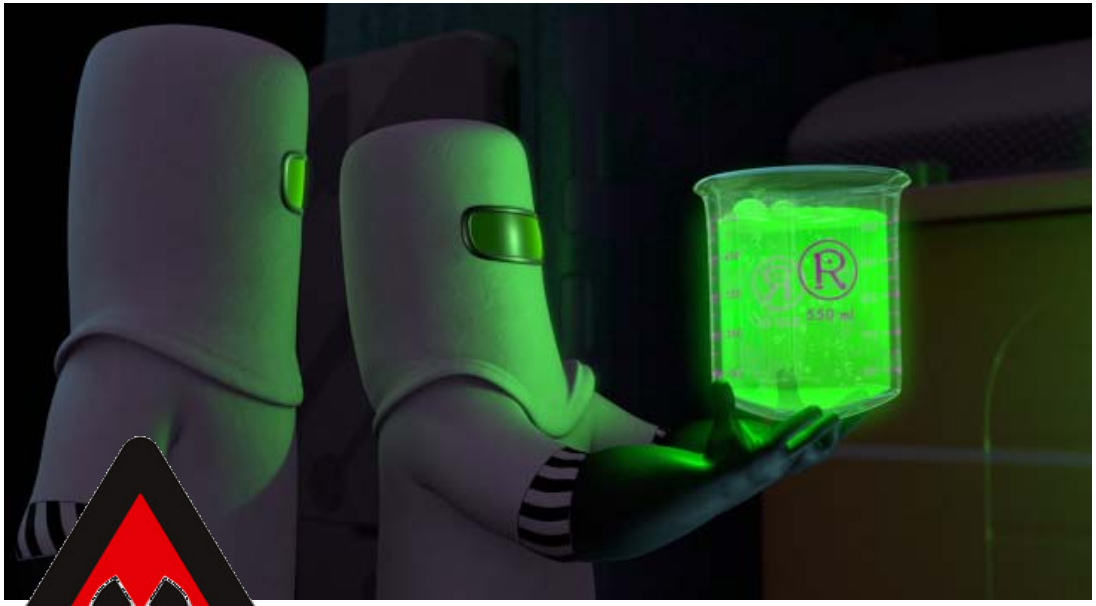
- Laser products (Pointers, CD players, light shows, welding lasers)*
- Televisions receivers*
- Cordless and cellular telephones
- Baggage x-ray security systems*
- Full-body x-ray security systems
- Microwave ovens*
- Metal halide lighting*
- Industrial radio frequency (RF) sealers of plastics and laminates
- Light emitting diodes



* subject to performance standards

Radioactive Material = **Not** an Electronic Product





U.S. Regulation of Radiation

- Radioactive material (ionizing)
  - Licensed by Nuclear Regulatory Commission
- Electronic products (ionizing & non-ionizing)
  - **FDA** = regulation of **manufacturers**
- State regulators & OSHA = regulation of **use**

Law and Regulations

- Electronic Product Radiation Control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act
  - United States Code (USC) Title 21, Chapter 9, Subchapter V, part C, sections 360hh – 360ss

- Title 21 Code of Federal Regulations (CFR) 1000 – 1050

Separate Authorities: Electronic Products vs. Medical Devices

- Non-medical electronic products = radiological health requirements only
- Electronic products which are medical devices = **BOTH** radiological health and medical device requirements
- Medical devices which
  - Do not emit radiation or
  - Use radioactive material

  = only medical device requirements

Establish Program of Control: Protect Public Health & Safety from Electronic Product Radiation

- Develop & administer performance standards
  - Radiation safety reports, product tests, manufacturer inspections
- Plan, conduct, coordinate, and support: Research, development, training, & operational activities to:
  - Minimize emission of radiation
  - Reduce exposure to radiation

Performance Standards

- Develop for specific products
- Address
  - Test and measurement of emissions
  - Warning signs, indicators, and labels
  - Installation, operation, and use instructions
- Consider
  - Scientific and medical data
  - Existing consensus standards
  - Reasonableness and technical feasibility
  - Uniformity and reliability of test and measurement equipment

Performance Standards

- 21 CFR 1020.10 Television Receivers
- 21 CFR 1020.20 Cold-cathode Discharge Tubes
- 21 CFR 1020.30 Diagnostic X-ray Systems & their major components
  - 21 CFR 1020.31 Radiographic equipment
  - 21 CFR 1020.32 Fluoroscopic equipment
  - 21 CFR 1020.33 Computed tomography (CT) equipment
- 21 CFR 1020.40 Cabinet X-Ray Systems
- 21 CFR 1030.10 Microwave Ovens
- **21 CFR 1040.10 Lasers and Laser Systems**
  - **21 CFR 1040.11 Specific Laser Products**
- 21 CFR 1040.20 Sunlamps and Sunlamp Products
- 21 CFR 1050.10 Ultrasonic Therapy Products
- 21 CFR 1040.30 High-intensity Mercury Vapor Discharge Lamps

Mandatory Radiation Safety Performance Standards

- Product specific performance standards

  [Title 21 CFR 1020 - 1050]

  - Applicability identified in 1st paragraph of each specific standard
- General performance standard is required when applicable specific performance standard exists [Title 21 CFR 1010]
  - Certification by manufacturer
  - Identification labeling
  - Variance or exemptions from performance standards

Before Entry into Commerce

- Design & manufacture products which can be used **safely**
- Submit radiation safety report to FDA (if required)

And when a specific performance standard applies:

- Design & manufacture products to comply with all applicable performance standards
- Manufacturer **self-certifies** product meets requirements of all applicable performance standards – Does **not** mean FDA approval
  - Certification must be based on mfr's quality control & testing program
  - Certification label or tag permanently affixed to product

Many different types of product & radiation!

Different combinations of requirements for radiation safety reports and records.

TABLE 1—RECORD AND REPORTING REQUIREMENTS BY PRODUCT

Products	Manufacturer						Dealer & Distributor
	Product reports § 1002.10	Supplemental reports § 1002.11	Abbreviated reports § 1002.12	Annual reports § 1002.13	Test records § 1002.30(a)[1]	Distribution records § 1002.30(b)[2]	Distribution records §§ 1002.40 and 1002.41
DIAGNOSTIC X-RAY[3] (1020.30, 1020.31, 1020.32, 1020.33)							
Computed tomography	X	X		X	X	X	X
X-ray system[4]	X	X		X	X	X	X
Tube housing assembly	X	X		X	X	X	
X-ray control	X	X		X	X	X	X
X-ray high voltage generator	X	X		X	X	X	X
X-ray film changer			X		X	X	
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			X		X	X	X
Beam-limiting devices	X	X		X	X	X	X
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X		X	X	X	X
Cephalometric devices manufactured after February 25, 1978			X		X	X	
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978			X		X	X	X
CABINET X RAY (§ 1020.40)							
Baggage inspection	X	X		X	X	X	X
Other	X	X		X	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY							
Medical			X	X	X	X	
Analytical			X	X	X	X	
Industrial			X	X	X	X	
TELEVISION PRODUCTS (§ 1020.10)							
<25 kilovolt (kV) and <0.1 milliroentgen per hour (mR/hr IRLC[5,6]			X	X[6]			
≥25kV and <0.1mR/hr IRLC[5]	X	X		X			
≥0.1mR/hr IRLC[5]	X	X		X	X	X	
MICROWAVE/RF							
MW ovens (§ 1030.10)	X	X		X	X	X	
MW diathermy			X				
MW heating, drying, security systems			X				
RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2–500 megahertz)			X				
OPTICAL							
Phototherapy products	X	X					
Laser products (§§ 1040.10, 1040.11)							
Class I lasers and products containing such lasers[7]	X			X	X		
Class I laser products containing class IIa, II, IIIa, lasers[7]	X			X	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers[7]	X	X		X	X	X	X
Class IIIb and IV lasers and products containing such lasers[7]	X	X		X	X	X	X
Sunlamp products (§ 1040.20)							
Lamps only	X						
Sunlamp products	X	X		X	X	X	X
Mercury vapor lamps (§ 1040.30)							
T lamps	X	X		X			
R lamps			X				
ACOUSTIC							
Ultrasonic therapy (1050.10)	X	X		X	X	X	X
Diagnostic ultrasound			X				
Medical ultrasound other than therapy or diagnostic	X	X					
Nonmedical ultrasound			X				

Devices vs. Electronic Products Before Entry into Commerce

- Medical device - requires FDA action
  - Premarket notification – requires clearance as substantially equivalent
  - Premarket application – requires approval
- Electronic product – requires manufacturer actions
  - Submit radiation safety report (some products)
  - Certify products meet requirements of performance standards (when applicable)
- Medical device which is also an electronic product – manufacturer shall comply with both types of requirement (premarket submission, radiation safety report & manufacturer certification)

Radiation Safety Reports

- Document evidence of manufacturer's quality control & testing program
  - Product technical specifications & test data
  - Procedures for quality control checks & compliance tests
  - Labels & information for users
- Report review can reveal safety problems
- Reports provide reference for inspection of manufacturers

Accidental Radiation Occurrence (ARO) Reports

- 21 CFR 1002.20

- Report accidental radiation occurrences
  - Manufacturers shall report
  - Others may report – are encouraged
  - Report to CDRH – electronically or paper

Accidental Radiation Occurrence (ARO) Reports

- Manufacturers shall investigate & report when there are reasonable grounds for suspecting an incident occurred
- Report must include description of the incident, location, product identification, analysis of cause, number of people involved, actions to prevent re-occurrence
- Exceptions
  - When an MDR is required (product is also a device and event meets criteria for mandatory MDR)
  - When the manufacturer submits notification of a product which has a failure to comply or defect

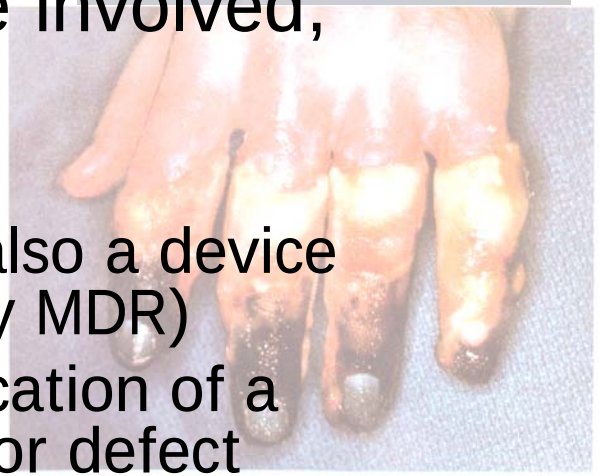


Fig. 10. The victim's left hand on 8 March 1992.
Reproduced with permission from:
Health Physics journal, Volume 65, Number 2, August 1993

ARO Report Form

- **Submitter Information**
- **Information Regarding Product Manufacturer**
- **Product Information (check-off list)**
- **Occurrence Information**
  - **Location**
  - **Persons involved**
  - **Action taken**

ARO Form

- Form location:
  - http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM236066.pdf

CDRH goes paperless

Electronic Submission of Reports & Correspondence

eSubmitter software

http://www.fda.gov/cdrh/cesub/

FDA Electronic Submission Gateway

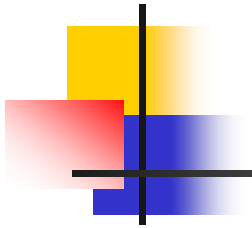
http://www.fda.gov/esg/ESG

Importation

- Electronic Products are not allowed entry into the United States when there is the appearance:
  - Products fails to comply with an applicable performance standard
  - Products subject to a performance standard are not certified
- Form FDA 2877 *Declaration for Imported Electronic Products Subject to Radiation Control Standards* required
  - Form requires declaration of compliance status (Certified?)
  - Form requires evidence radiation safety report was submitted to FDA
- When reports are received by FDA an acknowledgement is sent which includes a unique accession number
  - Accession Numbers are **NOT** an approval
  - Acknowledgement may take 6 weeks for paper submission
  - Acknowledgment for electronic submissions within 48 hours if sent on CD & less than 1 hour if sent through ESG!

Requests

- Manufacturers may request exemption from reporting and record keeping requirements
- Manufacturers may request variance from requirements of performance standards for future production
- Federal agencies may request exemption from some or all requirements of performance standards for products intended for federal government use
- Complaints about competitors



Defects and Failures to Comply

Defect Definition

A radiation safety defect exists in products:

- Which do not use emission of radiation to accomplish their purpose when the product:
  - Emits radiation which creates a risk of injury, or
  - Fails to meet design radiation emission specifications, or
- Which rely on the radiation emission to accomplish their purpose when the product:
  - Fails to meet its design specifications for radiation emission
  - Emits radiation that is unnecessary which creates a risk of injury
  - Fails to accomplish its intended purpose
- Defect applies to risks caused as a result of design, production, or assembly

Failure to Comply Defined

- Failure of compliance: When a product does not meet requirements of an applicable performance standard [Title 21 CFR 1010 – 1050] as a result of design, production, or assembly
  - User's product neglect or abuse outside scope of FDA authority

Defect or Failure to Comply Requires Notification

- FDA or manufacturer required to notify upon discovery
- When discovered manufacturer shall:
  - Notify FDA, dealers, distributors, and purchasers
  - Describe product, number affected, expected use, explain problem (defect or failure to comply), hazard evaluation, corrective action plan, and date discovered
- Customer notification & manufacturer corrective action plan subject to FDA review
- Exemption from notification (and correction) may be requested
  - Must provide evidence no significant risk to public health
- If FDA notified manufacturer, manufacturer may refute failures to comply and defects
  - Must provide evidence problem does not exist

Repurchase, Repair or Replacement

- Corrective action required when notification required
- Manufacturer shall correct at **no cost** to the purchaser
- Manufacturer shall submit corrective action plan for FDA review and approval
  - **Repurchase** = Refund product cost
  - **Repair** = Bring the product into compliance with performance standards or correct defect or
  - **Replace** product with a like product which complies or has no defect
- FDA may deny plan, approve plan, or approve plan with conditions

When Products Fail to Comply - Additional Actions

- Manufacturer may not enter new products which fail to comply into commerce
- Corrective actions affect only products already distributed
- Before resuming entry into commerce
  - Manufacturer must correct product design or procedures to assure new products comply
  - Manufacturer must submit an updated radiation safety report which documents design or procedure changes

Enforcement Options - Program Disapproval

- FDA may disapprove a manufacturer's quality control & testing program when not adequate or does not exist
- Manufacturer's w/ disapproved program may not certify products
- Manufacturers w/ disapproved program may not enter any products subject to performance standards into commerce
- FDA must rescind program disapproval before manufacturer can resume product certification & entry into commerce

Enforcement Options - Punishments

- Civil monetary penalties

- Injunction

- Criminal penalties

Guidance

- A Laser Notice is “Guidance”
- Guidance does not create or confer rights or operate to legally bind FDA or the public
- Usually are written to explain specific details of a regulation or agency’s current thinking on a subject

Notable Laser Notices

- # 13 – laser kits must comply when assembled
- # 14 – lasers manufactured and used in-house
- # 31 – investigational medical laser; significant risk
- # 34 – medical laser delivery system interlocks
- # 37 – walk-in workstations
- # 38 – importation for investigation and evaluation
- # 41 – exemption for inherently Class I lasers
- # 42 – distributor incorporates certified Class I
- # 44 – user instruction for medical lasers
- # 50 – conformance with comparable IEC Standards
- # 52 – DoD exemption
- # 54 – exempts certain product reporting for Class I

Sources of Information

- FDA website http://www.fda.gov/Radiation-EmittingProducts/default.htm
  - General information available as "Industry Assistance" including:
    - Getting a product to market
    - Laws and Regulations
    - Industry guidance
    - Addresses for reports and recordkeeping
    - Importing and Exporting products
  - For product specific information, use the "A-Z List of Regulated Products & Procedures"