



*Reducing Unnecessary
Medical Imaging Exposure*

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Center for Devices and Radiological Health

April 30, 2010



Objectives

- FDA's role in ensuring patient safety through regulation of the medical imaging industry
- How FDA rules are formed and updated
 - How you can influence regulations and guidance
- FDA current and planned activities
 - Most important things that the FDA wants to see with regard to CT safety?

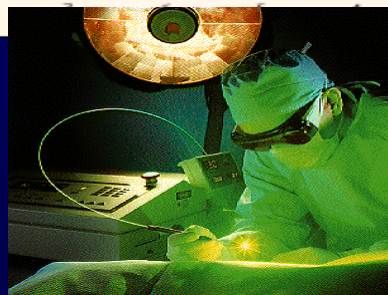
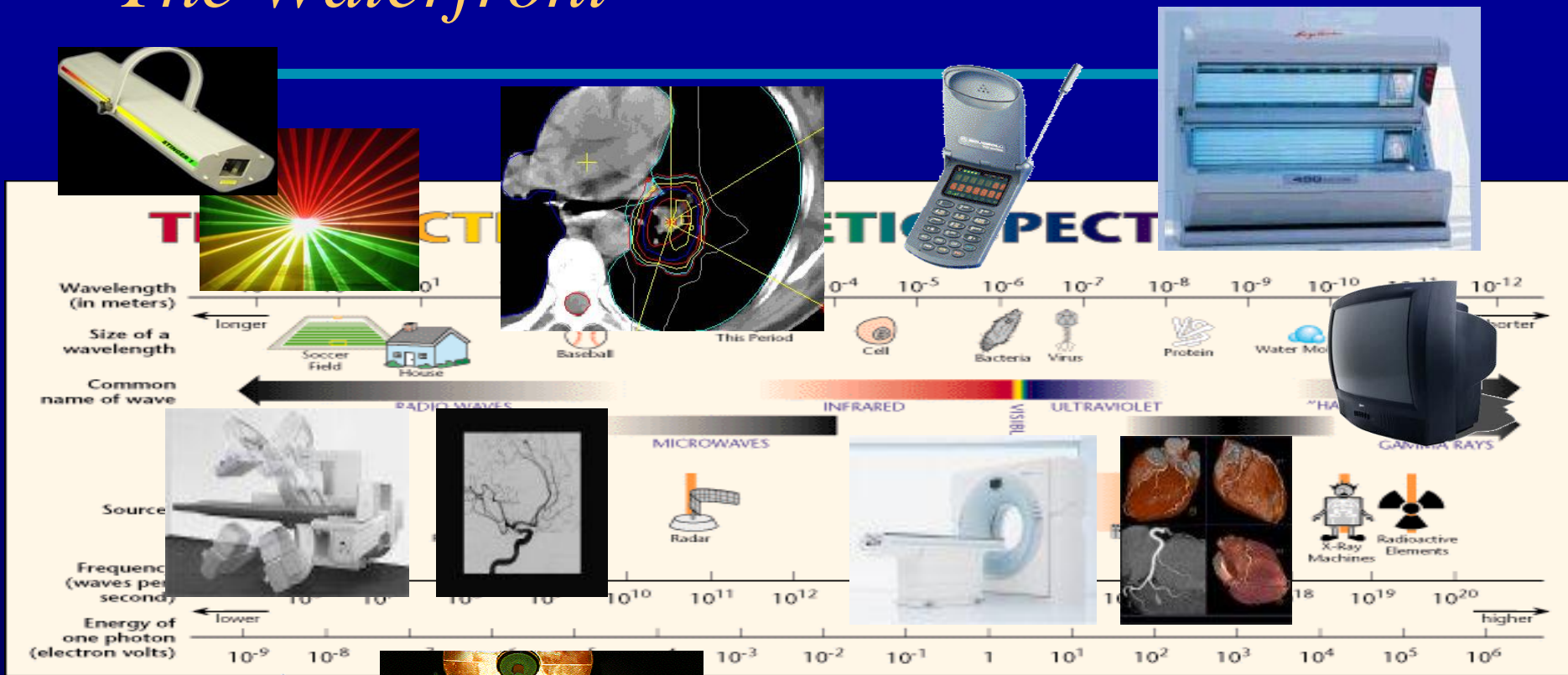


FDA/CDRH Mission

“To protect and promote the public health by assuring the safety, effectiveness, and quality of medical devices, and assuring the safety of radiation-emitting products...”



The Waterfront

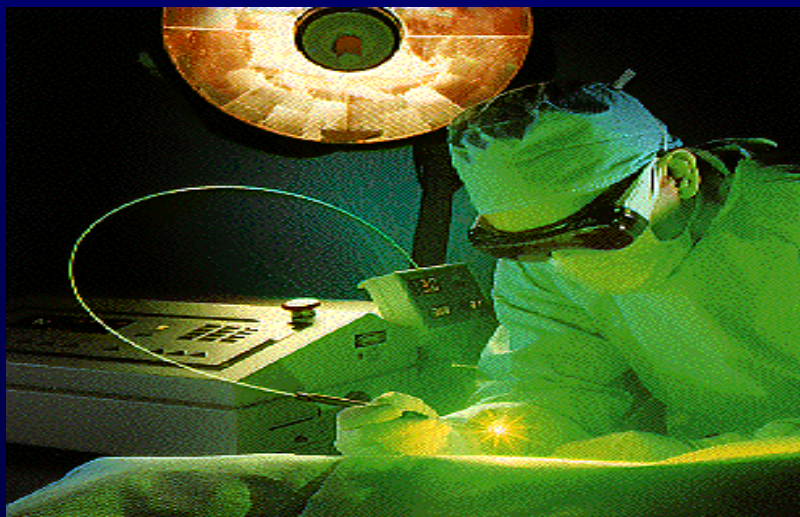


Any product that can emit any form of radiation



Radiation-Emitting Medical Devices

- Medical devices that use radiation are subject to multiple laws:
 - Medical Device Amendments
 - Electronic Product Radiation Control (EPRC)
 - Mammography Quality





Medical Device Authorities

- Establishment registration
- Device listing
- Quality systems
- Premarket clearance
- Corrections and Removals
- Medical Device Reporting (MDR)



EPRC Authorities

- Performance standards
- Certification to standards
- Quality control testing
- Submission of reports
- Notification of defects/noncompliance
- Accidental Radiation Occurrences



Regulations and Guidance

Developing or updating the CFR





Regulations and Guidance

- Special controls
 - Guidance document
 - Information needed for premarket review
 - Labeling, testing or data to address unique risks
- Consensus standards
 - May be recognized or referenced in guidance



Regulations and Guidance

- Have an idea? Share it!
- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm>
- FDA > Medical Devices > Industry Assistance
 - “Guidance Documents”



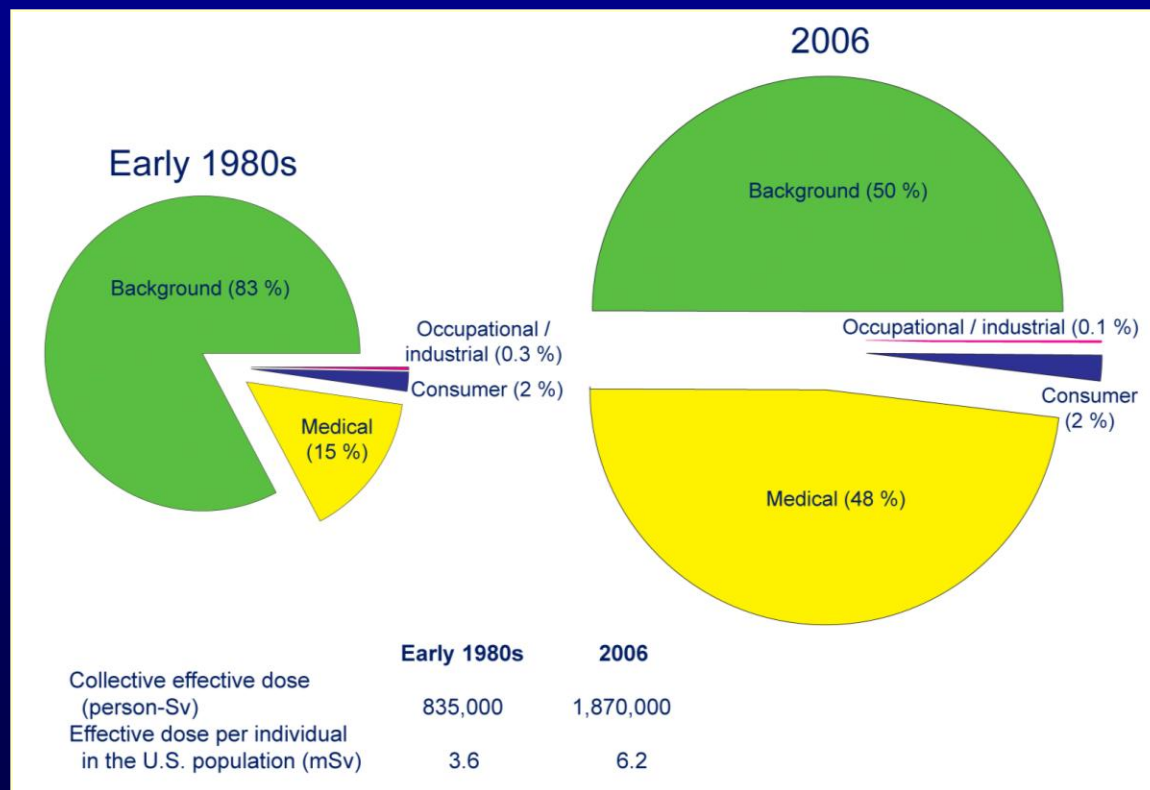
FDA Initiative

- *Each patient should get the right exam, at the right time, with the right dose*
- Exam justification
 - Ensure that only medically necessary examinations are performed
- Dose optimization
 - Minimize the individual's exposure to radiation for each exam while maintaining image quality



Initiative Motivation

Over the past three decades, there has been an increase in the U.S. population's total exposure to ionizing radiation, largely due to medical imaging.

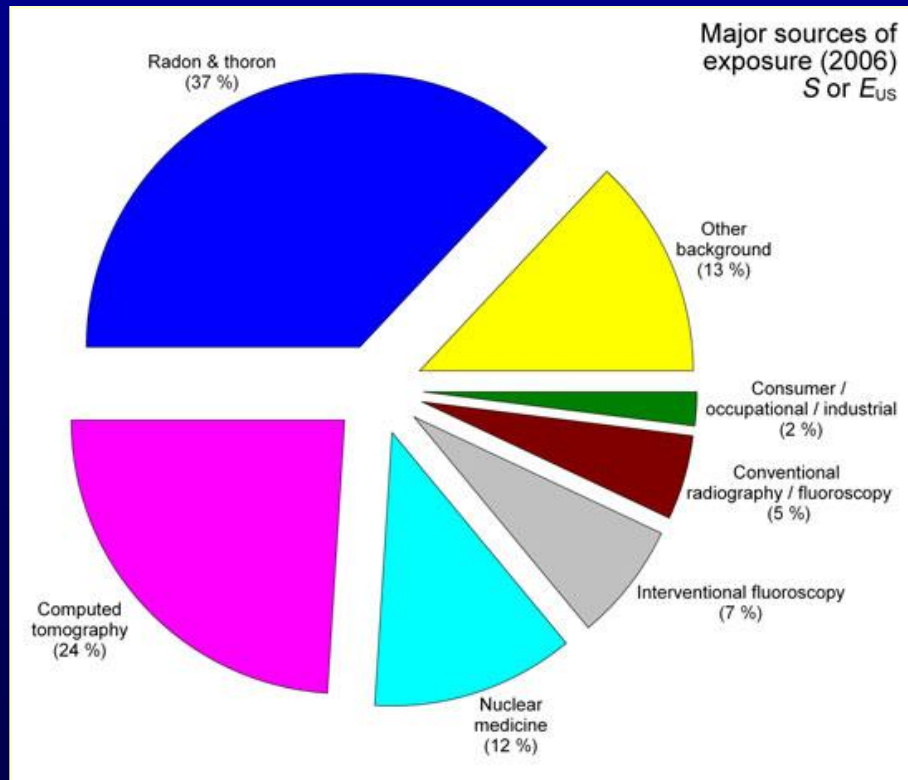


(Source: National Council on Radiation Protection & Measurements. *Report 160: Ionizing Radiation Exposure of the Population of the United States*. March 3, 2009.)



Initiative Scope

In 2006, the majority of medical imaging exposure was from CT, nuclear medicine, and interventional fluoroscopy.



(Source: National Council on Radiation Protection & Measurements. *Report 160: Ionizing Radiation Exposure of the Population of the United States*. March 3, 2009.)



Initiative Scope

- High-dose medical imaging procedures
 - Computed tomography
 - Interventional fluoroscopy
 - Nuclear medicine



Initiative Goals

- Promote Safe Use of Medical Imaging Devices
- Support Informed Clinical Decision Making
- Increase Patient Awareness



Promote Safe Device Use

- Establish safety requirements for CT and fluoroscopic devices
 - Dose display, recording, reporting
 - Access controls
 - Alerts
 - Dose-optimized default settings
 - Training for users



Promote Safe Device Use

- Partner with CMS to enhance facility quality assurance practices
 - Refine accreditation criteria, interpretive guidelines and conditions of participation
 - Incorporate dose optimization and justification
- Promote efforts to develop diagnostic reference levels locally and nationally





Support Clinical Decision Making

- Establish recordkeeping requirements for CT and fluoroscopic devices
 - Linking dose information with patient records
 - Transmission of imaging data to local or national database
 - Incorporation of exam ordering systems
- Promote efforts to develop appropriate referral criteria





Increase Patient Awareness

- Provide patients with tools to track their personal medical imaging history

X-RAY RECORD CARD

Name: _____

Health Ins.Co.: _____

Policy No.: _____

For additional cards, write to FDA, HFZ-220, 1350 Piccard Dr.,
Rockville, MD 20850

**HELP REDUCE
X-RAY RISKS & COSTS**

- Feel free to ask your doctor how an x-ray will help with the diagnosis and treatment.
- Don't refuse an x-ray if there's a clear need for it. Remember, the risk is small.
- Ask if a gonad shield can be used for yourself and for your children during x-rays of the abdomen.
- Tell the doctor or x-ray personnel if you are, or might be pregnant, before having an x-ray of the abdomen.
- Don't insist on an x-ray if the doctor explains there is no need for it.

DATE	TYPE OF EXAM	REFERRING PHYSICIAN	ADDRESS WHERE X-RAYS ARE KEPT



Future State

- A new Radiology Clinic is built in the US
- Purchases a new CT system
- Gains accreditation to perform CT and other advanced medical imaging exams





Facility QA

- Staff are trained to properly use equipment and its dose reduction features
- The facility routinely reviews utilization data, assesses dose protocols to ensure exams are justified and that dose is optimized





Patient awareness

- Patients come for exams with a medical imaging history card in hand
- Staff are trained to discuss risks and benefits of medical imaging procedures and answer patient questions



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Equipment features

- Hospital exam ordering system in place to evaluate exam appropriateness
 - Based on referral criteria established by facility, medical professional organizations
- Imaging protocols and settings are reviewed
 - System requires verification of settings, controls access to changes and tracks modifications made by staff





Equipment features

- The system automatically retrieves information from hospital data systems and/or other dose registry
 - Verifies that settings and dose are within expected range
 - Alerts users when outside the range or if the patient recently had another medical imaging exam





Equipment features

- During each exam, the system automatically collects imaging settings and dose data
 - Transmits data to hospital information systems, the patient's electronic health record and a National Dose Registry





Nothing worth doing is easy

More information at:

<http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/ucm199904.htm>