Reducing Unnecessary Medical Imaging Exposure

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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…”
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/DeviceRegulationsandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm](http://www.fda.gov/MedicalDevices/DeviceRegulationsandGuidance/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
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.

Initiative Scope

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

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
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
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: