Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

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Outline

• Overview: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging
• Spotlight on 2 FDA priority areas:
  – Implementation of CT Dose Check
  – Pediatric radiation safety

FDA Medical Imaging Initiative

• NCRP Report 160
• Investigation of CT perfusion events and letter to MITA
• 2010 public meeting
  – Improved equipment safety
  – Better trained operators
  – Enhanced quality assurance practices
Initiative Goals

• Right exam, right time (Justification)
  – Exams using ionizing radiation should be performed only when medically indicated
  – Key players: referring physicians, patients, payers (e.g., CMS)

• Right dose (Optimization)
  – Radiation doses should be as low as reasonably achievable while providing necessary clinical information
  – Key players: imaging team (physicist, technologist, imaging physician or dentist), device manufacturers, FDA and other regulators, accreditation organizations

Partnerships Required

• FDA’s regulatory authority applies to manufacturers and equipment

• FDA’s ability to address appropriate or proper use and operator qualifications is limited

• Bring stakeholders together to promote awareness and collaboration
Multiple parts working together:
CT Dose Check example

- **Equipment safety feature**: NEMA XR-25 Computed Tomography Dose Check standard
- **Education and Communication**: AAPM WGCTNP "Recommendations Regarding Notification and Alert Values for CT Scanners: Guidelines for Use of the NEMA XR 25 CT Dose Check Standard"
- **Facility Guidelines and Personnel Qualifications**: Example from Michigan state regulation: "CT Operator Check of Dose Indicator/Dose Indices" ([http://www.michigan.gov/lara/0,4601,7-154-35299,28142-35791,35798-259055---00.html](http://www.michigan.gov/lara/0,4601,7-154-35299,28142-35791,35798-259055---00.html))

CT Dose Check, continued

- **Tracking radiation safety metrics**: ACR dose registry (AAPM suggested CT Dose Check notification values used preliminary data)
- **Research**:
  - How are checks used in practice?
    - Example: D. Zamora et al., 2012 AAPM Annual Meeting, TU-G217BCD-09, Integration of Recent NEMA (MITA) XR-25 CT Dose-Check Standard into Clinical Practice
  - Importance of grouping dose data by patient size, if possible making use of automatic scanner size estimation: AAPM TG220

Appropriate Use
SPR outreach to referring physicians (e.g., pediatricians and emergency physicians)

- **Equipment Safety**: FDA draft guidance, "Pediatric Information for X-ray Imaging Device Premarket Notifications"
- **Pediatric Radiation Safety**
- **Facility Guidelines and Personnel Qualifications**: Image Gently PQI CT program (approved by ABR) • TJC Sentinel Event Issue 47: "Adhere to SPR guidelines"
- **Research**: AAPM Report 204 Size Specific Dose Estimates
- **Tracking Radiation Safety Metrics**: Pilot ACR Quality Improvement Registry for CT Scans in Children
More information on pediatric dose reduction

- Draft Guidance for Manufacturers and FDA staff:
  - "Pediatric Information for X-ray Imaging Device Premarket Notifications" (published May 10, 2012) available at:

- Public Workshop: Device improvements for Pediatric X-ray Imaging (July 16, 2012)
  - Slides and archived webcast available at:
    - http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm301989.htm
  - See the questions about the guidance in section IV of the FR notice for the workshop: http://www.gpo.gov/fdsys/pkg/FR-2012-05-10/pdf/2012-11262.pdf


More information on overall Initiative

Major update (released May 9, 2012) to activities under the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging