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Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

AAPM 2012 Annual Meeting:
Medical Physics in Federal and State Governments
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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

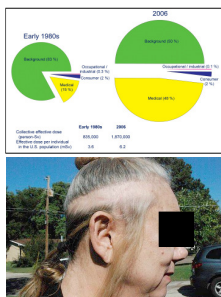


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FDA Medical Imaging Initiative

- 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



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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

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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

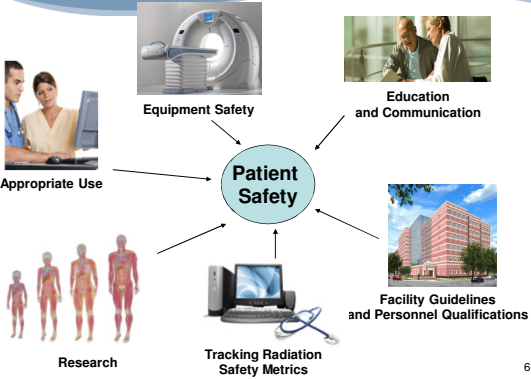
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The diagram illustrates the factors influencing Patient Safety. A central circle labeled "Patient Safety" is surrounded by six boxes, each with an arrow pointing towards the center. The boxes are: "Appropriate Use" (top left, with an image of a doctor and patient), "Equipment Safety" (top, with an image of a CT scanner), "Education and Communication" (top right, with an image of two people talking), "Facility Guidelines and Personnel Qualifications" (bottom right, with an image of a hospital building), "Tracking Radiation Safety Metrics" (bottom, with an image of a computer monitor and stethoscope), and "Research" (bottom left, with an image of human figures).

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**Multiple parts working together:
CT Dose Check example**

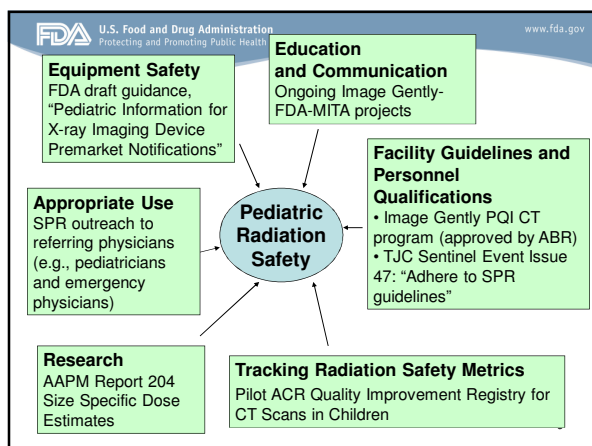
- Equipment safety feature:** NEMA XR-25 Computed Tomography Dose Check standard
- Education and Communication:** AAPM WGCTNP "Recommendations Regarding Notification and Alert Values for CT Scanners: Guidelines for Use of the NEMA XR 25 CT Dose Check Standard"
- Facility Guidelines and Personnel Qualifications:**
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)


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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





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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: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm300850.htm>
 - **Comment period through September 7, 2012:** search for Docket No. FDA-2012-D-0384 on <http://www.regulations.gov>.
- 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>
- FDA Pediatric X-ray Imaging webpage:** <http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/ucm298899.htm>

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More information on overall Initiative

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

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

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