FDA Radiological Health Program Update

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Center for Devices and Radiological Health
FDA Radiological Health
Mission and Goals

- Protect the public from hazardous or unnecessary electronic product emissions
- Refine our programs to address today’s public health problems
FDA Initiatives

- Focus on equipment and procedures that expose patients to high radiation doses
- Use regulatory and non-regulatory mechanisms to have manufacturers build their equipment with radiation safety and dose reduction in mind.
- Educate the public on the risks and benefits of radiation emitting products and devices
- Reinforce professionals knowledge of radiation safety and dose reduction
Accomplishments

- Fluoroscopy amendments published
- Reduction of effort on low risk products
- Increasing effort on high risk products
Fluoroscopy amendments

- Amendments to the “Performance Standard for Diagnostic X-Ray Systems and their Major Components
  - Published June 10, 2005
  - Effective Date June 10, 2006

- New requirements affect equipment manufactured as of June 10, 2006
Fluoroscopy amendments

- Assure the x-ray beam
  - Is where the user thinks it is
  - Has the intensity the user thinks it has
  - Has an intensity that is limited (for fluoroscopy only)

- Assures the user is continually informed about the exposure rate and cumulative dose

- Allows cumulative dose to be recorded and included as part of a comprehensive Quality Assurance program
Reduced effort

- **Low risk products**
  - Reduced reporting and imports review requirements on laser, television, and microwave oven products that pose little risk of personal exposure.

- **Examination of installed equipment**
  - Reducing field tests of installed equipment

- **MQSA survey radiation measurements**
  - Over 100,000 measurements show no problems with dose.
  - Accept annual medical physicist and triennial accreditation body measurements in lieu of FDA inspection measurement
Increased effort

- High risk products
  - Focus report and imports review on high risk products

- Manufacturer inspections
  - Redirecting investigational resources toward manufacturing facilities to address equipment problems at their source
Next steps

- Electronic reporting
- Web site redesign
- Training programs
- Dose monitoring
Next steps

- Electronic reporting
  - Developing software that will enable manufacturers to submit required reports electronically
  - Increasing process efficiency
  - Improving FDA ability to identify and triage information for review and action
Next steps

- Web site redesign
  - Developing new look and content for FDA/CDRH electronic product radiation control web page

- Training programs
  - Developing on-line training for FDA and State inspectors
  - Information covers general health physics, medical imaging equipment testing
Next steps

- Dose monitoring
  - Planning a pilot study to capture medical imaging dose information
    - Coordinate with MedSun hospitals
    - Focus on CT procedures
    - Partner with other organizations to expand pilot beyond FDA/CDRH
Thank you

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- Radiological Health Web Page
  http://www.fda.gov/cdrh/comp/eprc.html
- New Initiatives Web Page
  http://www.fda.gov/cdrh/radhlth/initiative.html