

FDA Radiological Health Program Update

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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/radhltth/initiative.html>