

The Future of FDA's Radiological Health Program

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Message

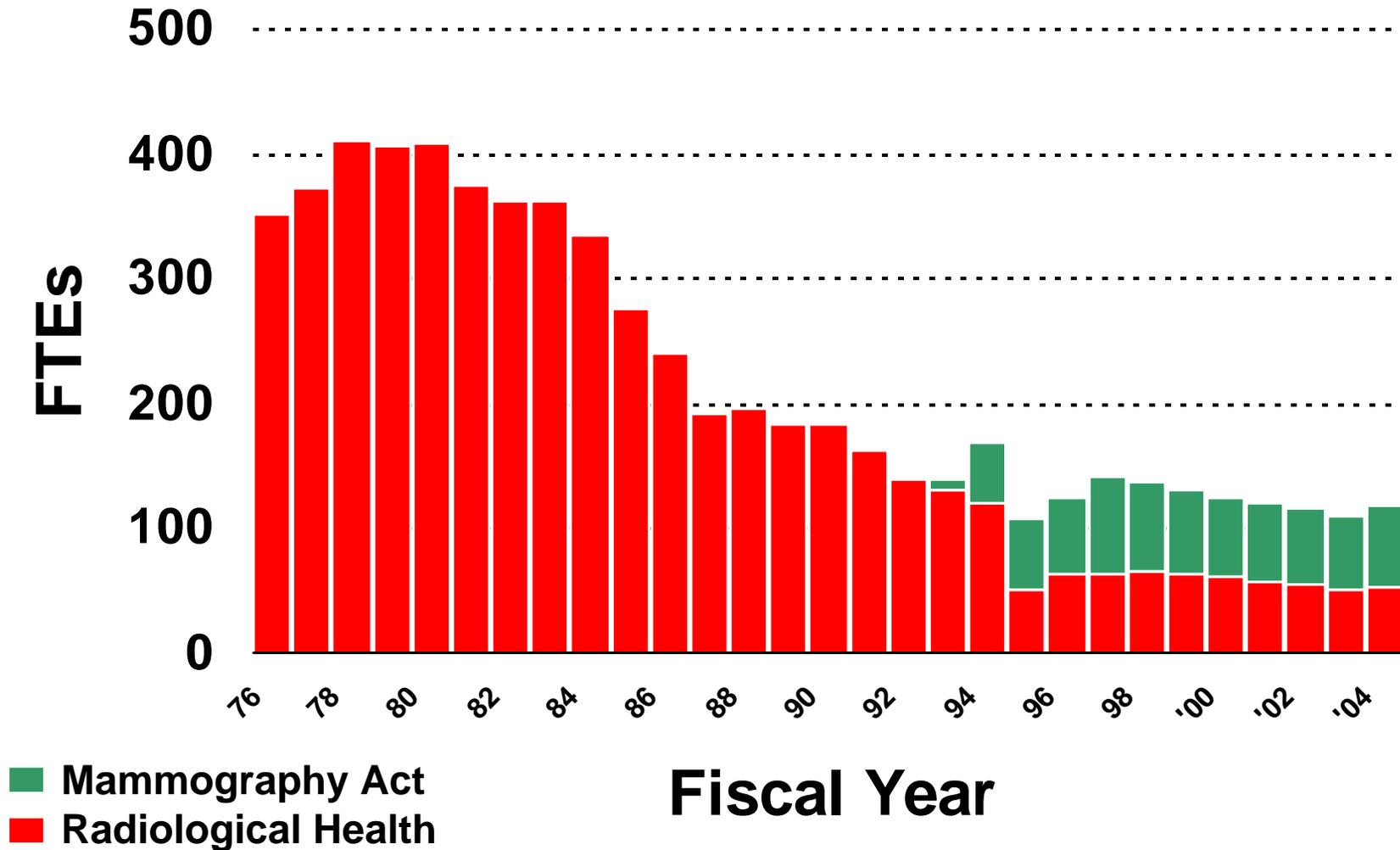
- CDRH has been working to reconceive its radiological health program
- Public health problems and issues have changed, but our mission remains
- We have a plan to address today's public health challenges into the future

What's Changed Since 1968?

- Product environment
 - Markets are global
 - Manufacturing processes have advanced
 - Effective international voluntary standards in place
- Public health needs
 - Product problems have been or can be addressed
 - Issues are more related to product use
- CDRH resources
 - Focus on medical devices
 - Radiological health staff and expertise declining

CDRH FTE History

Fiscal Years 1976-2004



CDRH Program Mission

- To protect the public from hazardous or unnecessary electronic product emissions.
 - Maintain awareness of radiation emitting products and their manufacturers.
 - Assess radiation emission levels and conditions of use for various products.
 - Understand effects of emissions and potential risk to health for various products.
 - Provide public health guidance and direction.
 - Encourage manufacturers to comply with appropriate standards.
 - Pursue enforcement action as necessary.

Program Elements

- Standards
- Monitoring
- Education
- Research
- Program Management

Standards



- Goal
 - Use of performance standards that are enforceable and appropriate for today's technology.
 - Increased use and reliance on consensus standards.
 - Establishment of processes to assure conformance with mandatory and consensus standards as appropriate.

Standards



- Activities

- Increase participation in development of international and national consensus standards.
 - Focus on dose intensive equipment
- Allow conformance to consensus standards by guidance, followed by adopting standard by reference.
 - CT, ultrasound, and other diagnostic x-ray
- Pursue legislative changes to allow adoption and enforcement of voluntary consensus standards.
- Base enforcement actions on risk.

Monitoring



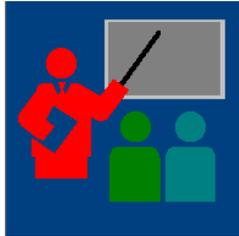
- Goal
 - Maintain awareness of radiation emitting electronic products and manufacturers
 - Assess electronic product emissions and conditions of use
 - Understand effects of emissions and exposure risk

Monitoring



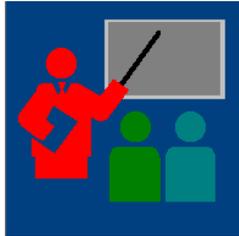
- Activities
 - Require only essential manufacturer reporting.
 - Move from routine field and lab tests to for-cause testing and manufacturer inspections.
 - Eliminate measurement of dose during MQSA inspections
 - Phase out routine laboratory and field testing in favor of for-cause testing
 - Phase out instrument calibration in favor of maintaining instrumentation expertise and measurement capabilities
 - Emphasize assessment of use and exposures by harvesting data rather than direct measurement.

Education



- Goal
 - A public able to make informed choices about exposure in the medical, occupational and home setting
 - Users able to minimize their own exposures and those of people they expose
 - Manufacturers able to understand their responsibilities and sensitive to radiation risk issues
 - FDA and State radiation control programs that assist users in minimizing radiation exposure/risk

Education



- Activities
 - Create a coordinated education program
 - Partner to disseminate information and create training opportunities
 - Invest in the web as an educational tool
 - Redesign the radiological health portion of the CDRH web page

Benefits Expected

- Aligns CDRH efforts with current and evolving public health needs
- Expands focus on patient and consumer experience
- Allows for a more targeted approach to regulation
- Increases information dissemination and training
- Improves coordination across the radiological health community

Questions

- Contact

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- Information on the web at

<http://www.fda.gov/cdrh/radh1th/initiative.html>

- Public meeting 10/31/05 – 11/1/05

<http://www.fda.gov/cdrh/radh1th/meeting-103105.html>