

Collaborations

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Learning Objective

Understand how being involved with AAPM and other organizations can also help promote innovative, safe and effective medical devices

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FDA Outreach & Collaboration

- Share information
- Seek input
- Promote collaborations on specific projects



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Food, Drug & Cosmetic Act

- Coordination, research, and outreach are in the law...
 - “plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation” (360ii(a)(2))
 - “maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation” (360ii(a)(3)).

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Collaborations

- The majority of the employees in our divisions are involved in collaborations with federal, state, national, and international groups and individuals across the product areas that we regulate

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Federal and State Agencies

- Exchange product safety information
- Exchange information on regulatory activities
- Participate on grant reviews

BARDA	Biomedical Advanced Research and Development Authority
FAA	Federal Aviation Administration
FCC	Federal Communications Commission
CPSC	Consumer Product Safety Commission
CRCPD	Conference of Radiation Control Program Directors
ISCORS	Interagency Steering Committee on Radiation Standards (ISCORS)
IWGMI	Interagency Workgroup on Medical Imaging
NIH	National Institute of Health
NIST	National Institute of Standards and Technology
NRC	Nuclear Regulatory Commission

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National Organizations

- Product specific workgroups
- Conference attendance / presentations to learn and share information

AAPM	American Association of Physicians in Medicine
ACR	American College of Radiology
ASTRO	American Society for Radiation Oncology
Image Gently	Alliance for Radiation Safety in Pediatric Imaging
NCRP	National Council on Radiation Protection and Measurements
QIBA	Quantitative Imaging Biomarker Alliance
	and many more...

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International Organizations

- Share information on radiation safety and regulations
- Develop radiation safety publications

HERCA	Heads of the European Radiological protection Competent Authorities (HERCA)
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Health (ICRP)
WHO	World Health Organization

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Standards and Trade Associations

- Work on product specific standards
- Single point-of-contact to receive/share information with product manufacturers

AdvaMed	Advancing Medical Technology Association
IEC	International Electrotechnical Commission
MITA	Medical Imaging Technology Alliance

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Discuss examples related to...

- AAPM Committees and IEC Standards
- Radiation/Product Safety
- Research and Development

(note: in the examples, I have underlined how you can be involved, or may be directly impacted)

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AAPM Committees

- FDA attendees coordinate to cover most AAPM committees, and FDA staff chair/co-chair multiple committees
- Government and Regulatory Affairs (GRAC)
- Technology Assessment Committee (TAC)
- Imaging Physics Committee (IPC)
 - Computed Tomography Subcommittee
 - TG 200 - CT Dosimetry Phantoms and the implementation of AAPM Report Number 111
 - TG 233 - Performance Evaluation of Computed Tomography Systems
 - Computer Aided Detection in Diagnostic Imaging (CAD) Subcommittee
 - Mammography Subcommittee
 - Radiography and Fluoroscopy Subcommittee
 - TG 150 - Acceptance Testing and Quality Control of Digital Radiographic Imaging Systems

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AAPM Committees

- Pediatric Imaging Subcommittee
 - TG 251 - Survey of Pediatric Fluoroscopic Exposure Rates
 - TG 252 - Methodology for the development of pediatric techniques for computed radiography and digital radiography
 - TG 261 - Quality control methodology for low-dose dental and maxillofacial CBCT systems
- Tomosynthesis Subcommittee
 - TG 245 - Tomosynthesis Quality Control
- Work Group on Medical Display
 - TG 196 - Requirements and methods for color displays in medicine
 - TG 260 - Considerations for the Use of Handheld Devices for Viewing Medical Images
 - TG 270 - Display QA
- Working Group on Magnetic Resonance Safety
 - and radiation therapy committees...

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International Standards

- Division wants to increase reliance on voluntary consensus standards and issue guidance documents that reference IEC standards or allow conformance to voluntary standards, in lieu of parts of FDA standards
- FDA is engaged with IEC and industry organizations to introduce safety features into the national and international standards for medical (e.g., x-ray, MRI) and non-medical (e.g., laser, microwave) products
- You can be involved in standards development, or related workgroups

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IEC Standards: X-Ray Equipment

- FDA is an active participant in the development of CT, fluoroscopy, and radiography IEC standards
- FDA proposals for updates to standards based on AAPM, ACR, Image Gently and input from other professional organizations include requirements to provide QC instructions to users, structured dose reporting, and pediatric safety features
- FDA is working with CRCPD's H-46 Task Force on IEC Standards to develop a pathway to address the practical implementation issues related to performance testing done by FDA, states, and medical physicists
- FDA is seeking to engage you (regulators, industry, and physicists) to explore how to support performance testing to voluntary consensus standards

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Radiation Safety

- FDA is actively engaged with international organizations (e.g., WHO, IAEA, HERCA) and researchers on issues related to product and radiation safety
- Recent publications:
 - WHO publication "Communicating radiation risks in paediatric imaging" in April 2016
 - Cancer risks in U.S. radiologic technologists working with fluoroscopically-guided interventional procedures (AJR: Amer J Roentgenol May 2016)
 - Long-term Mortality in 43,763 U.S. Radiologists Compared with 64,990 U.S. Psychiatrists (Radiology July 2016)
 - Organ doses from diagnostic medical radiography – trends over eight decades (1930 to 2010) (Health Physics 2016; in press)

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Nationwide Evaluation of X-ray Trends Surveys

- Collaboration among FDA, CRCPD, and ACR
 - Captures radiation exposure data using phantoms from a nationally representative sample of U.S. clinical facilities for specific examinations
 - Publishes the state of the practice of diagnostic radiology
 - November 2015 – Publication of CT Survey (dosimetry for 17 adult and pediatric exams)
 - June 2016 – Summary publication for Cardiac Catheterization Fluoroscopy
 - Upcoming – Dental Radiography (currently analyzing collected data)
- You can help with data collection and analysis

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<http://www.crccd.org/Pubs/NEXT.aspx>

Magnetic Resonance Imaging

- MR Burn Prevention Poster (October 2015)
- Collaboration with members of the International Society for Magnetic Resonance in Medicine
- Incorporates knowledge from review of most frequent adverse events (submitted by you as a facility/manufacture)
- You can download/print a copy



<http://www.ismrm.org/mr-safety-links/mri-burn-prevention-poster/>
<http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/>

Radiation Oncology

- Exchange information with ASTRO, NRC, and federal agencies related to adverse events and device failures
- FDA Participation in IEC Subcommittee 62C Radiation Therapy:
 - Discussed key changes in the 4th edition of LINAC standard, IEC 60601-2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV
 - Discussion of amendment and new editions of IEC 61217 (Coordinates & Scales) 62083 (Treatment planning systems), 62274 (Record & Verify) and 61168 (Simulator performance)
- Your participation and reporting of adverse event is important to identifying trends and enhance safety standards

FDA Guidance Documents

- Provide another means for stakeholder input, and consistency
 - FDA's Guidance for the submission of 510(k)'s for Solid State X-ray Imaging Device recommends a list of tests to be performed for digital radiographic systems with solid state x-ray imagers in premarket submissions (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/vcm073780.htm>)
 - TG150 (Acceptance Testing and Quality Control of Digital Radiographic Imaging Systems) is currently working on a AAPM report for a list of recommended acceptance and routine tests for digital radiographic systems
- Your collaboration/comments promote use of the latest science and consistency in premarket testing and clinical quality control

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FDA Public Advisory Panel Meetings

- FDA holds public advisory panel meetings to seek feedback from panel experts, patients, members of the public, and regulated industry
 - Example: FDA Public Workshop - Advancing the Development of Biomarkers in Traumatic Brain Injury, March 3, 2016
- You can apply to be a member of the Radiological Advisory Committee (<http://www.fda.gov/AdvisoryCommittees/default.htm>)
- You can present as a member of the public at these meetings, or send comments regarding the meeting materials and/or draft guidance documents

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FDA Communications

- You can sign-up to you to receive important FDA news and information as it become available (e.g., Recalls and Safety Alerts, Medical Devices, Radiological Health, FDA Press Releases)
- Note: options for medical and non-medical radiation emitting electronic products that FDA regulates (e.g., lasers, microwaves, sunlamps)
- FDA also publishes notices of guidance documents, upcoming meetings, and proposed regulations in the Federal Register

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/GetEmailUpdates/default.htm?source=govdelivery>

Product Development

- FDA's mission to protect and promote public health depends on safe and effective products coming to the market

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Pre-Submissions

- FDA/CDRH's pre-submission program allows you (researchers or manufacturers) to request feedback from the FDA on proposed regulatory pathway and protocols
 - (also for study risk determination, information, and submission issue meetings)
- Consider for devices with novel or specific intended uses
- Guidance: Request for Feedback on Medical Device Submissions
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>

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Grant Reviews

- Our division *occasionally* receives a request to provide feedback on the application and/or regulatory pathway discussion for grant proposals for innovative therapeutic and diagnostic devices
 - Examples: BARDA and NIH grants
- Our feedback provides grant applicants with a better understanding the regulatory pathway for new products

(Industry and researchers can submit pre-submissions directly to FDA/CDRH to request feedback on protocols intended to support a FDA regulatory submission)

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Quantitative Imaging Biomarkers Alliance

- Collaboration to create consistent, reliable, valid and achievable quantitative imaging results across imaging platforms, clinical sites, and time
- Accelerating development and adoption of hardware and software standards to achieve accurate and reproducible quantitative results from imaging methods
- FDA is well represented across the committees and has lead related research projects
- You can become involved to support the research and development

<https://www.rna.org/qiba/>

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Research Collaborations

- Supports the evaluation of safety and effectiveness of products
 - Phantom development for breast imaging
 - TG245 Tomosynthesis Quality Control (Steve Glick, co-chair)
 - Computed aided diagnosis and methodologies for algorithm assessment
 - Computer Aided Detection in Diagnostic Imaging (CAD) Subcommittee (Berkman Sahiner, SC Chair)
 - Virtual imaging clinical trials for regulatory evaluation (VICTRE)
 - TG234 - Task Group on Virtual Tools for the Evaluation of New 3D/4D Breast Imaging Systems (Kyle Myers, TG Co-chair)
 - CT iterative reconstruction – object assessment of image quality and dose reduction
- You can collaborate, or download imaging system simulation tools and statistical analysis software for reader or algorithm assessment that CDRH makes public (<https://github.com/DIDSR>)

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Summary

- FDA engages in multiple efforts to seek public input, and collaborate with federal, state, national, international groups, and individuals
- Being involved with AAPM and other organizations and sharing your research/physics/clinical expertise helps promote safe and effective medical devices

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Contact Information and Resources

Division of Radiological Health

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Device Advice: Comprehensive Regulatory Assistance

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>

CDRH-Division of Industry and Consumer Education (DICE)

DICE@fda.hhs.gov

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1. Pre-market
2. Post-market
3. Regulatory research
4. Collaborations

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