

The FDA and the Bonn Call for Action: Update on the Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging

In December 2012, the International Atomic Energy Agency sponsored, and the World Health Organization co-sponsored an International Conference on Radiation Protection in Medicine: Setting the Scene for the Next Decade". The meeting, held in Bonn, Germany, was hosted by the Government of Germany through the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. The meeting was attended by 536 participants from 77 countries and 16 organizations, including FDA. The conference resulted in a list of priorities for radiation protection in medicine for the next decade, called the Bonn Call for Action.

The Bonn Call for Action is divided into ten principal actions, each of which is considered essential for strengthening radiation protection over the next decade. Each action is further subdivided into several sub-actions. As a regulatory agency, FDA shares in the responsibility for strengthening radiation protection of patients and health workers with other national and international agencies, researchers, educators, medical institutions, professional societies and individual practitioners. All parties are important in identifying, advocating for and implementing solutions to improve radiation usage in medicine and strengthen radiation protection.

Some of the actions proposed by the Bonn conference are outside of FDA's role and authority. Many of the actions, however, are areas where FDA has made efforts and contributions. The following list of selected actions and sub-actions highlights areas where FDA is participating actively to implement the Bonn Call for Action.

1. *Enhance the implementation of the principle of justification*

FDA staff are participating in drafting the International Commission on Radiological Protection's (ICRP) guidance on justification in medicine. FDA staff have also made substantial contributions to Federal Guidance Report No. 14 (Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures), which discusses justification extensively and recommends the use of clinical decision support technology.

2. *Enhance the implementation of the principle of optimization of protection and safety*

Ensure establishment, use of, and regular update of diagnostic reference levels for radiological procedures, including interventional procedures, in particular for children;

FDA, in cooperation with the Conference of Radiation Control Program Directors (CRCPD), has conducted the Nationwide Evaluation of X-Ray Trends (NEXT) surveys for many years. The 2008-2009 survey of cardiac catheterization facilities resulted in publication of possible initial U.S. national diagnostic reference level (DRL) values for certain interventional cardiology procedures (Med Phys 2012; 39:6276-6286). The 2014-2015 survey of dental facilities will provide similar data for dental radiology.

FDA has worked with the American College of Cardiology (ACC) to incorporate radiation dose data in procedure data submitted to the ACC's National Cardiovascular Data Registry, and is working with the Society of Interventional Radiology to accomplish the same purpose. The goal is establishment of an infrastructure for development of national DRLs for the U.S. FDA staff have contributed to National Council on Radiation Protection and Measurements (NCRP) Report No. 172 on DRLs, and are also participating actively in drafting ICRP guidance on DRL development and use.

Develop and apply technological solutions for patient exposure records, harmonize the dose data formats provided by imaging equipment, and increase utilization of electronic health records.

As part of FDA's Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging, FDA worked with industry (the Medical Imaging & Technology Alliance (MITA)), the International Electrotechnical Commission (IEC) and the American Association of Physicists in Medicine (AAPM) to harmonize radiation dose data formats and encourage the automatic output of complete radiation dose reports from imaging devices through Radiation Dose Structured Reports.

FDA staff participate in AAPM Task Group 246 (Patient dose from diagnostic radiation) to develop methods for recording organ dose in structured reports from CT scanners and fluoroscopes.

3. *Strengthen manufacturers' role in contributing to the overall safety regime*

Ensure improved safety of medical devices by enhancing the radiation protection features in the design of both physical equipment and software and to make these available as default features rather than optional extra features;

FDA is actively engaged with standards development organizations (IEC) and industry organizations (MITA) to introduce safety features into the national and international standards for medical devices. These include CT Dose Check, access controls for CT devices, and a user quality control mode for fluoroscopy equipment, all of which were developed by industry with input from FDA.

Support development of technical solutions for reduction of radiation exposure of patients, while maintaining clinical outcome, as well as of health workers;

FDA held a public meeting in 2012 on Device Improvements for Pediatric X-Ray Imaging, and has continued to interact with industry and other stakeholders.

FDA scientists work with industry and other stakeholders to develop methods and tools for the evaluation of new technologies that are intended to reduce radiation exposure. The goals of this work are to ensure that pathways to market are streamlined, that new

technologies are safe and effective, and that accurate information about the performance of these technologies is available.

Enhance the provision of tools and support in order to give training for users that is specific to the particular medical devices, taking into account radiation protection and safety aspects;

FDA provided both advice on content and financial support for Image Gently's educational project on Promoting Safe Use of Fluoroscopic Devices in the Pediatric Population, which developed online modules for technologist training. FDA also assisted in the development of Image Gently's online modules for vendor-specific instructions and training on proper use of certain CT scanner features.

In cooperation with ACR, FDA conducted research that demonstrated suboptimal implementation of the CT Dose Check features on current CT devices, and published these findings (J Am Coll Radiol 2014;11:989-994) in an effort to promote use of this safety feature.

Reinforce the conformance to applicable standards of equipment with regard to performance, safety and dose parameters

FDA has mandatory performance standards for most radiology medical devices. These help to ensure patient safety. In addition, FDA recognizes relevant IEC standards for these devices. FDA is an active participant in the development and revision of these IEC standards. Manufacturers may use conformance to these standards as a way to demonstrate device safety.

Strengthen cooperation and communication between manufacturers and other stakeholders, such as health professionals and professional societies

FDA works actively with industry (MITA), state regulators (CRCPD), European regulators (Heads of the European Radiological protection Competent Authorities (HERCA)), and professional societies (AAPM, American College of Radiology (ACR), American Society for Radiation Oncology (ASTRO), and ACC) to facilitate communication among the various groups on matters related to medical device safety and radiation safety.

Support usage of platforms for interaction between manufacturers and health and radiation regulatory authorities and their representative organizations

FDA meets regularly with MITA to discuss matters of mutual interest and concern, and has an agreement with HERCA that permits discussion of matters of mutual interest. FDA has been an active participant in MITA's development of CT and fluoroscopy safety standards, including National Electrical Manufacturers Association (NEMA) standards XR-25, XR-26, XR-27 and XR-28. FDA, in a coordinated effort with HERCA, MITA and COCIR (the European Coordination Committee of the Radiological, Electromedical and

Healthcare IT Industry), is attempting to avoid duplication of effort in interactions between regulators and industry.

4. Strengthen radiation protection education and training of health professionals

Prioritize radiation protection education and training for health professionals globally, targeting professionals using radiation in all medical and dental areas

FDA has provided financial support and subject matter experts for an NCRP report, currently in preparation, on radiation protection in dentistry. FDA staff have served as co-authors of NCRP and ICRP documents on DRL use, radiation protection for fluoroscopy performed outside the radiology department, and radiation protection in cardiology. FDA staff are also active participants in the development of other NCRP and ICRP documents on radiation protection in medicine. These documents are intended to educate health professionals in radiation protection and radiation management in medical and dental imaging.

FDA participates in various professional organizations' efforts in education and quality assurance for radiation therapy and nuclear medicine devices, including linear accelerators, brachytherapy devices, proton beams, SPECT, and PET systems.

Pay particular attention to the training of health professionals in situations of implementing new technology.

This is a particular point of emphasis in Federal Guidance Report No. 14 (Federal Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, forthcoming), for which FDA made substantial contributions.

6. Increase availability of improved global information on medical exposures and occupational exposures in medicine

Improve collection of dose data and trends on medical exposures globally, and especially in low- and middle-income countries, by fostering international co-operation;

FDA is an active participant in the NEXT surveys, which collect radiation dose data for specific medical and dental imaging procedures in the U.S. The 2014-2015 survey is collecting data on dental radiology in the U.S.

FDA has worked with the ACC to incorporate radiation dose data collection as part of the National Cardiovascular Data Registry. FDA staff participate actively in a number of International Atomic Energy Agency (IAEA) and World Health Organization (WHO) projects that are intended to provide information on patient and occupational exposures in medicine.

FDA staff participated in IAEA's ISEMIR (Information System on Exposure in Medicine, Industry and Research) project to develop a global database on occupational exposure in interventional cardiology.

Improve data collection on occupational exposures in medicine globally, also focusing on corresponding radiation protection measures taken in practice

FDA staff participated in the IAEA ISEMIR (Information System on Occupational Exposure in Medicine, Industry and Research) project on interventional cardiology occupational exposures, the results of which were reported in IAEA TECDOC No. 1735 in 2014. FDA staff have also participated in developing several ICRP documents that provide recommendations on reducing occupational exposures.

7. *Improve prevention of medical radiation incidents and accidents*

Implement and support voluntary educational safety reporting systems for the purpose of learning from the return of experience of safety related events in medical uses of radiation;

FDA participates in AAPM, ASTRO, and American Society of Radiologic Technologists (ASRT) annual meetings and on specific subcommittees that evaluate safety concerns and appropriate use recommendations for radiation oncology. More recently, FDA has begun to participate in ROSSI (Radiation Oncology Stakeholder's Safety Initiative). FDA is currently in discussions with MITA regarding the upcoming RT-2 standards that will address interoperability, quality assurance, and certifications for radiation oncology.

Work towards inclusion of all modalities of medical usage of ionizing radiation in voluntary safety reporting, with an emphasis on brachytherapy, interventional radiology, and therapeutic nuclear medicine in addition to external beam radiotherapy;

FDA currently reviews Medical Device Reports (MDR) of adverse events related to medical devices, including radiology devices. Many MDR submissions are required by regulation, but FDA encourages voluntary submission of these reports as well. These MDRs describe adverse events associated with, among others, fluoroscopy systems, CT scanners, radiation therapy devices including linear accelerators, proton beam and brachytherapy devices, and nuclear medicine systems, including SPECT and PET systems.

FDA also has a reporting program, the Medical Product Safety Network (MedSun), through which it works with the clinical community to identify and solve problems with the use of medical devices. More than 200 hospitals provide voluntary reports to FDA of safety issues related to medical devices. Both MDR reports and MedSun submissions are included in FDA's Manufacturer and User Facility Device Experience (MAUDE) database,

which is can be searched by the public

(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> .

Ensure prioritization of independent verification of safety at critical steps, as an essential component of safety measures in medical uses of radiation

FDA works actively to promote safety through activities such as participating in the revision of the ACR guidance document on safe MRI practices and the revision of the ACR technical standard for management of the use of radiation in fluoroscopic procedures.

8. *Strengthen radiation safety culture in health care*

Establish patient safety as a strategic priority in medical uses of ionizing radiation, and recognize leadership as a critical element of strengthening radiation safety culture

FDA staff continue as primary contributors to the draft Federal Guidance Report No. 14 (Radiation Protection Guidance for Diagnostic and Interventional X-Ray Procedures). While this report's intended audience is federal facilities, the recommendations represent safety practices important to all facilities.

Foster closer co-operation between radiation regulatory authorities, health authorities and professional societies

FDA meets regularly with industry, state regulators, professional societies and other stakeholders to improve communication among all interested parties and advance radiation safety and awareness in health care.

FDA has met with members of the Heads of the European Radiological protection Competent Authorities (HERCA) to develop a closer working relationship and promote convergence of regulatory efforts. FDA and HERCA have signed both a Memorandum of Understanding and a Confidential Disclosure Agreement to aid in these efforts.

Foster closer co-operation on radiation protection between different disciplines of medical radiation applications as well as between different areas of radiation protection overall, including professional societies and patient associations;

FDA staff participate in meetings of professional associations of diagnostic radiologists, radiation oncologists, interventional cardiologists, medical physicists and health physicists to exchange information and foster cooperation among these specialists.

Support integration of radiation protection aspects in health technology assessment;

FDA consolidated its regulatory authority over radiology devices and radiation-emitting electronic products in late 2012. Programs were reorganized to bring together staff and functions related to premarket review, adverse event analysis, compliance and

enforcement work and outreach efforts within a single office and division of the Center for Devices and Radiological Health. The reorganization streamlined operations and helped improve awareness of issues related to these devices in order to make better informed decisions across the lifecycle of this equipment. Problems are more readily identified and solutions are more rapidly implemented as a result of the new structure. Our current focus is assessing how to best manage adverse event reviews and incorporate a variety of sources of internal and external data into a signal management program.

9. Foster an improved radiation benefit-risk-dialogue

Increase awareness about radiation benefits and risks among health professionals, patients and the public

FDA staff have participated in WHO's Global Initiative on Radiation Safety in Health Care Settings since 2008, and serve on the Core Group of Experts. One of the goals of this initiative is to raise awareness of the safe use of radiation in medicine among health authorities, health policy makers, health care providers, patients and public.

Support improvement of risk communication skills of health care providers and radiation protection professionals – involve both technical and communication experts, in collaboration with patient associations, in a concerted action to develop clear messages tailored to specific target groups;

FDA staff serve on WHO's Core Group of Experts and as contributors to WHO's document on Communicating Radiation Risks in Pediatric Imaging to Support a Risk-Benefit Dialogue.

10. Strengthen the implementation of safety requirements globally

Develop practical guidance to provide for the implementation of the International Basic Safety Standards in health care globally;

FDA staff serve as members of NCRP Scientific Committees, ICRP working parties and WHO's Global Initiative on Radiation Safety in Healthcare Settings, as well as consultants to the IAEA. These organizations develop reports and publications providing such guidance (see below).

Further the establishment of sufficient legislative and administrative framework for the protection of patients, workers and the public at national level, including enforcing requirements for radiation protection education and training of health professionals, and performing on-site inspections to identify deficits in the application of the requirements of this framework.

FDA staff are active participants in drafting NCRP reports on radiation protection in dentistry, evaluating and communicating radiation risks for research involving human subjects, and administrative policies for managing substantial dose procedures and tissue reactions from fluoroscopically-guided interventions. FDA staff are also active participants in drafting ICRP documents on occupational protection issues in fluoroscopically guided procedures and diagnostic reference levels for diagnostic and interventional imaging.

FDA staff participated in the revision of the Healing Arts portion of CRCPD's Suggested State Regulations.

FDA has developed and conducted a training course for FDA inspectors on special issues related to x-ray imaging devices. Sessions include a general equipment overview, a description of FDA mandatory and voluntary consensus standards, and tips on issues to focus on in an x-ray equipment manufacturer inspection.