FDA Updates "Bonn Call for Action" Activities

The U.S. Food and Drug Administration (FDA) released in March an update on its efforts in response to the "Bonn Call for Action," a list of 10 priorities for radiation protection. The list was created at a December 2012 meeting organized by the International Atomic Energy Agency and the World Health Organization and hosted in Bonn by the government of Germany. The meeting was attended by 536 participants from 77 countries and 16 organizations, including the FDA. Each item on the Bonn Call for Action was considered essential for strengthening radiation protection over the next decade and was subdivided into several subactions. The recent FDA report summarizes specific areas in which the FDA has identified, advocated for, and implemented solutions to improve radiation usage in medicine and strengthen radiation protection, both in the United States and in cooperative international collaborations. The 10 points of the call for action (not in prioritized order) include goals to:

1. Enhance implementation of the principle of justification.

2. Enhance implementation of the principle of optimization of protection and safety, including ensuring the establishment, use of, and regular update of diagnostic reference levels for radiologic procedures, including interventional procedures, especially for children; and developing and applying technological solutions for patient exposure records, harmonizing dose data formats provided by imaging equipment, and increasing utilization of electronic health records.

3. Strengthen manufacturers' roles in contributing to the overall safety regime, including ensuring improved safety of medical devices by enhancing radiation protection features; supporting development of technical solutions for reduction of radiation exposure of patients (as well as of health workers) while maintaining clinical outcomes; enhancing provision of tools and support for training that is specific to different medical devices; reinforcing conformance to applicable standards of equipment with regard to performance, safety, and dose parameters; strengthening cooperation and communication between manufacturers and other stakeholders, such as health professionals and professional societies; and supporting usage of platforms for interaction between manufacturers and health and radiation regulatory authorities.

4. Strengthen radiation protection education and training of health professionals, including prioritizing radiation protection education and training for health professionals globally; and targeting professionals using radiation in all medical and dental areas, including new technology implementation.

5. Shape and promote a strategic research agenda for radiation protection in medicine, including assessment of low-dose health risks from internal and external radiation sources; exploring variations in radiation sensitivity and hypersensitivity; exploring the possibilities of biomarkers specific to ionizing radiation; advancing research in specialized areas of radiation effects; and promoting research to improve methods for organ dose assessment.

6. Increase availability of improved global information on medical exposure and occupational exposure in medicine, including improving collection of dose data and trends on medical exposures globally (especially in low- and middle-income countries) by fostering international cooperation; and improving data collection on occupational exposures in medicine.

7. Improve prevention of medical radiation incidents and accidents, including implementing and supporting voluntary educational safety reporting systems for learning from safety-related events in medical uses of radiation; working toward inclusion of all medical modalities using ionizing radiation in voluntary safety reporting, with an emphasis on brachytherapy, interventional radiology, and therapeutic nuclear medicine in addition to external beam radiotherapy; and ensuring prioritization of independent verification of safety at critical steps.

8. Strengthen radiation safety culture in health care, including establishing patient safety as a strategic priority and recognizing leadership as a critical element in this process; fostering closer cooperation between radiation regulatory authorities, health authorities, and professional societies; fostering closer cooperation on radiation protection between different disciplines of medical radiation applications; and supporting integration of radiation protection aspects in health technology assessment.

9. Foster an improved radiation benefit–risk dialog, including increasing awareness about radiation benefits and risks among health professionals, patients, and the public; and supporting risk communication skills of health care providers and radiation protection professionals.

10. Strengthen implementation of safety requirements globally, including development of practical guidance for implementation of the International Basic Safety Standards in health care; and establishment of sufficient legislative and administrative frameworks for protection of patients, workers, and the public at the national level.

The complete FDA update on activities in support of the Bonn Call for Action is available at: http://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationSafety/RadiationDoseReduction/UCM439602.pdf.

U.S. Food and Drug Administration