AbstractID: 4208 Title: Refocusing of the Radiological Health Program at the FDA and the 2005 Amendments to the Performance Standard for Diagnostic X-ray Systems

Purpose: This presentation will describe the results of a recently concluded process to refocus the radiological health program activities of the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration and the resulting strategic plan for these activities. The plan calls for CDRH's radiological health program to concentrate efforts on medical devices and electronic products that present the greatest public health risks to patients and members of the public. The program will look for opportunities to increase use and reliance on international, consensus standards to control product performance and focus more efforts on the education and training of the users of medical devices employing radiation and on educating users and consumers regarding the safe use of industrial and consumer products that emit potentially hazardous radiation. The elements of the plan will be described and the opportunities for medical physicists and other stakeholders to assist in its implementation will be described.

The presentation will also briefly summarize the amendments to the federal performance standard for diagnostic x-ray systems (21 CFR 1020.30 -1020.33) that are publishing in June 2005, and which will become effective in June 2006, for all newly manufactured diagnostic x-ray systems. The amendments establish new requirements for both radiographic and fluoroscopic x-ray systems; however, a majority of the new requirements apply to fluoroscopic x-ray systems. These changes to the performance standard were warranted by changes in both the technology and manner of use of fluoroscopic x-ray systems.