AbstractID: 8356 Title: FDA Guidelines for Magnetic Resonance Equipment Safety

There are two types of safety issues associated with magnetic resonance (MR) diagnostic devices, site safety issues and safety issues associated with the equipment itself. Recently, several tragic accidents have focused attention on site safety issues. However, equipment safety issues are also becoming increasingly important. Advances in MR technology over the last decade have resulted in a significant increase in the speed of MR imaging procedures and an expansion in the range of clinical applications. In order to achieve this increase in speed and capability it has been necessary to increase the amount of energy applied to the patient. For example, increased signal can be obtained at higher static magnetic field strengths resulting in increased speed, and fields up to 3 tesla are now in clinical use. However, imaging at higher field strength and faster imaging techniques require more radio frequency (RF) power, which increases the amount of heating experienced by the patient. Techniques such as fat suppression, spatial presaturation and magnetization transfer contrast, which improve diagnostic capability, also require the application of additional RF power. Some rapid imaging techniques (e.g. echo planar) require a train of rapid gradient pulses that can produce nerve and muscle stimulation. Also, an increasing number of patients who are candidates for MR procedures have implanted medical devices, and the potential hazard for such patients has increased as MR technology has advanced. The increase in MR equipment capability requires that equipment safety guidelines be in place to ensure the safety of patients and staff. At the same time the guidelines should not be unnecessarily restrictive so as to impede the progress of MR technology, which can result in diagnostic benefit to patients.

This course will begin with a brief introduction to the basic physics associated with the interaction between the patient and MR equipment. The parameters used to describe the capabilities of the equipment and the strength of the interactions with the patient will be described. This will be followed by a detailed discussion of current guidelines of the International Electrotechnical Commission (IEC) and Food and Drug Administration (FDA) for the safety performance of MR equipment. These guidelines include safety design characteristics for MR equipment and acceptable levels of patient exposure. Compliance with the IEC standard (IEC 60601-2-33) is required for marketing in Europe and the FDA safety guidelines have been harmonized with this standard. The current version of IEC 60601-2-33 was published in 1995. However, a revision was recently completed and will be published this year. The revised version includes many significant changes, especially with regard to limits for gradient output, which will be described in detail in this course.

The course will conclude with a discussion of the potential hazards during MR procedures for patients with implanted medical devices. The standardized methods that have been developed by the American Association for Testing and Materials (ASTM) for determining the interaction of implanted medical devices with MR equipment will be discussed.