MR Safety Advice 2023

Update on MR safety standards

In the past year the following international MR safety standards have been updated.

IEC 60601-2-33

In Aug 2022, version 4 of IEC 60601-2-33, the international standard for basic safety and essential performance requirements of MR equipment to provide protection for the patient and the magnetic resonance worker, was published. Some of the changes introduced here were covered in an advice sheet produced for MR safety week 2022. Note the original version of this BIR article contained an incorrect suggestion that there will have to be a change in the ICNIRP guidelines or a change in the CEMFAW legislation for the UK to adopt 0.9 mT rather than 0.5 mT for the extent of the MR Environment. An erratum has been issued to clarify that while there remains an action level of 0.5 mT under CEMFAW legislation in the UK that requires employers to perform an occupational risk assessment and put control measures in place, this is separate from the definition of the MR Environment. Note, the recently updated example BIR MRI risk assessment for EMF is designed to help with this CEMFAW requirement.

ASTM F2503

In May this year an update was published for ASTM F2503, the international standard that defines MR safety labelling, i.e. MR Safe, MR Conditional and MR Unsafe and defining the term 'MR Environment'. For clinical MRI staff there are perhaps two changes to note. Firstly, there is a small change to the definition of the MR Environment, replacing the inclusion of a specific value (previously 0.5 mT) for the static magnetic field threshold with simply the mention of the B0 Hazard Area, a new term introduced in the recent update of IEC 60601-2-33 that defines the space around the MR equipment where the static magnetic field can cause harm. Essentially, ASTM F2503 now points to the IEC standard for defining what static magnetic field should be associated with the B0 Hazard Area, currently 0.9 mT (as discussed in the 2022 advice sheet).

The updated definition of the MR Environment is now "the three dimensional volume surrounding the MR magnet that contains both the Special Environment (Faraday shielded volume) and the B0 Hazard Area (space around the MR equipment where the static magnetic field can cause harm). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories, and for which access control is part of the risk mitigation. **Adapted from IEC 60601-2-33**"

Additionally, the updated ASTM F2503 standard introduces a lengthy table of potential MR conditions and suggested wording. The aim of this is to help improve the wording used on MR Conditional labelling. As a reminder, this standard is not just for medical devices, but for any items that are to be brought into the MR Environment. Consequently, this section may be helpful for people involved in local decisions to label equipment as MR Conditional. For now, this table is part of the non-mandatory section of the standard, so nobody is obligated to use it when following this standard. However, this is a long-term effort. It will take some time for this to filter through to MR Conditional labelling that we see for devices implanted in patients referred for MRI scans.

In the meantime, people are encouraged to highlight examples of poor MR Conditional labelling to the MHRA that people feel may negatively impact on MR safety. The MHRA have powers to force manufacturers to update labelling if they deem appropriate.

Join the BIR today at www.bir.org.uk

The British Institute of Radiology
Audrey House
16-20 Ely Place
London
EC1N 6SN

T : +44(0)20 3668 2220

E : admin@bir.org.uk

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