



The Royal Australian and New Zealand
College of Radiologists®

The Faculty of Clinical Radiology

Faculty of Clinical Radiology Submission on the Draft Clinical Evidence Guidelines – Medical Devices

About the Royal Australian and New Zealand College of Radiologists

The Royal Australian and New Zealand College of Radiologists (RANZCR) is the peak body advancing patient care and quality standards in the clinical radiology and radiation oncology sectors. It represents over 3,500 members in Australia and New Zealand.

RANZCR's role is to drive the appropriate, proper and safe use of radiological and radiation oncological medical services. This includes supporting the training, assessment and accreditation of trainees; the maintenance of quality and standards in both specialties; and workforce mapping to ensure we have the specialists available to support the sectors in the future.

Structure of RANZCR

RANZCR consists of two faculties, each representing a different speciality.

The Faculty of Clinical Radiology is the bi-national body for setting, promoting and continuously improving the standards of training and practice in diagnostic and interventional radiology for the betterment of the people of Australia and New Zealand.

Clinical radiology relates to the diagnosis or treatment of a patient through the use of medical imaging. Diagnostic imaging uses plain X-ray radiology, computerised tomography (CT), magnetic resonance imaging (MRI), ultrasound and nuclear medicine imaging techniques to obtain images that are interpreted to aid in the diagnosis of disease. In addition to their diagnostic role, clinical radiologists also provide treatments and use imaging equipment in an interventional capacity.

The Faculty of Radiation Oncology is the peak bi-national body advancing patient care and the specialty of radiation oncology through setting of quality standards, producing excellent radiation oncology specialists, and driving research, innovation and collaboration in the treatment of cancer.

Radiation oncology is a medical specialty that involves the controlled use of radiation to treat cancer either for cure, or to reduce pain and other symptoms caused by cancer.



Introduction

The Royal Australian and New Zealand College of Radiologists (RANZCR) welcomes the opportunity to comment on the draft Clinical Evidence Guidelines – Medical Devices.

RANZCR appreciates that the Guidelines are directed towards vendors and sponsors of medical devices; however, we have reviewed the Guidelines from the perspectives of clinical radiologists using these devices, or managing them in special circumstances, where the clinical radiologist is primarily responsible for the safety of the patient.

Members of RANZCR are affected by these guidelines in four fields of activity:

1. The approval and use of devices for diagnostic radiological procedures;
2. The approval and use of devices for interventional radiological procedures;
3. The approval and use of devices for the delivery and modification of radiation therapy;
4. The assessment of the safety of MRI scanning (and to a much lesser extent CT scanning) in patients with implanted or on-planted medical devices.

In the context of magnetic resonance imaging (MRI) exposure of medical devices, RANZCR appreciates the detailed attention paid to this matter in the consultation draft, and the invitation to specifically comment on this area.

The assessment of medical device safety in the context of MRI scanning occurs at two levels:

1. General assessment of the device's fitness for exposure to MRI, leading to marketing approval; this is primarily the role of the TGA
2. Specific assessment of a particular device implanted in a specific individual, proposed to be scanned with a particular MRI scanner; this is primarily the role of the MRI radiologist at the MRI site in question.

New devices for approval

Testing of the safety of active medical implants in the MRI environment has been bedevilled for years by the marked variations in endpoints, such as lead tip heating and changes in pacing threshold, with seemingly minor variations in lead length, angulation, positioning, or coupling. The advent of computing power sufficient to allow high-resolution modelling of these effects for a large number of scenarios in reasonable time frames, and their validation against pre-clinical measurements, have been major advances. These advances have enabled assessment of a much wider range of implant positions and orientations than would be a feasible in a clinical trial.

To date, marketed active implanted medical devices (AIMDs) in Australia have undergone extensive modelling studies with pre-clinical validation, as well as conventional clinical trials (usually single-arm). Given the expense and limitations of clinical trials, industry is developing a range of pre-clinical tests, many of which are defined in an ISO Technical Specification (ISO TS 10974, 2012), designed to ensure that the design of active devices prevents or minimises adverse interaction with electromagnetic fields encountered in MRI. This document continues to evolve, with version 2 of the *Technical Specification* due probably early in 2017, and an eventual mature ISO Standard expected, possibly in 2019-20. It is said that the mature Standard will probably differ little from the second edition of the Technical Specification, but presumably this cannot be guaranteed. Test methods for gradient-induced heating and gradient field induced electrical potentials (which could lead to inappropriate tissue stimulation) are

understood to have now been agreed (but will not be disclosed until the publication of the second edition), and there is ongoing work to define the levels of uncertainty associated with these and other tests proposed in the *Technical Specification*.

Another way to control the risks from exposure of active devices to MRI is to limit the electromagnetic field exposures generated by the MRI system so that devices can be designed to be tolerant of known exposure values. This has been provided for as an option in the MRI equipment standard (IEC 60601-2-33), as the 'Fixed Parameter Option', but as yet there has been limited uptake of this by MRI equipment vendors.

An important source of safety data following device approval is post-market surveillance. This potentially provides access to a much larger pool of subjects and device configurations than a clinical trial. Conversely, complete and accurate data collection is more difficult. Clinical surveillance of patients undergoing MRI scans in the post-market period is likely to be less rigorous than that in a pre-market clinical trial, with greater potential risk to subjects if an unexpected problem is encountered.

To maximise the usefulness and validity of post-market surveillance, a comprehensive formal registry (or series of registries) would need to be considered, raising questions about how such registries would be governed and funded.

Registries would provide a reliable source of data on the implant(s) present in a given subject.

While an expanded role for post-market surveillance seems highly desirable, the unavailability, as yet, of the revised version of the pre-clinical testing Technical Specification suggests that it may be premature to abandon the requirement for pre-marketing clinical test data at this point. This may change once the second edition of the Technical Specification becomes available.

A transition to relying on post-market surveillance, only, for clinical data may be dependent on greater knowledge of, and experience with, the pre-clinical testing methods, and possibly more systematic documentation of MRI scans performed in the early phases of post-market surveillance.

Assessing approved devices at the scanner

In daily MRI practice, the clinical radiologist faces three main issues in dealing with medical devices that have been implanted in or on patients:

1. Which implant(s) is / are present?
2. What are the MRI safety characteristics of the implant(s)?
3. Are the characteristics of the device compatible with a safe examination in my MRI system?

1. Which implant(s) is / are present?

The determination of the presence of an implant is mainly a matter of history taking and reference to medical records. Determining the specific type and model of an implant may be much more difficult. Historically, implant identification has mainly relied on its written documentation in the patient's medical record—assumed to be correct, though the record is sometimes not complete (e.g. model number not fully specified), not accessible, or no longer extant.

The patient may be given a card or medallion with information identifying the implant (as suggested in the draft Guidelines, p.105). While this can be very helpful, compliance by both providers and patients is incomplete, and the identifier is frequently not available when needed.

Some implants (e.g. MRI-conditional pacemakers) have more recently been designed with metal markers allowing their identification in vivo by radiography. Such a solution may not be feasible for all types of medical device.

Linking of the device details (even down to the level of a unique product identifier) to a universal health identifier (perhaps the Individual Healthcare Identifier) in a widely accessible electronic medical record would perhaps be the most reliable source of implant identification. If a more systematic approach to post-marketing surveillance, for example, by the use of device registries, were adopted, such registries could also be a reliable way to verify the identity of an implant.

2. What are the MRI safety characteristics of the implant(s)?

This question has become easier to answer with the advent of the Internet. Many vendors now make their instructions for use (IFU), including those pertaining to MRI, available on their websites. There are also third-party websites that aggregate this information, saving users the need to navigate multiple vendor sites (some of these third-party sites charge small fees). There is potential for the *National Product Catalogue* to be a further third-party resource; however there is very little awareness of this catalogue in clinical radiology practice, and its completeness as a reference for MRI safety information has not been tested.

RANZCR notes that Essential Principle 13 requires vendors to provide appropriate IFU, and also applauds the recommendation that “All devices that might be used in the MRI environment **should** be assigned a label of ‘MR Safe’, ‘MR Conditional’ or ‘MR Unsafe’” (p.103), as per the ASTM definitions [emphasis added]. We have long advocated that all devices that might enter an MRI scan room should have MRI safety testing information available, and that this should eventually become a mandatory requirement.

It is also noted that there is still provision for a category of ‘Safety in MRI not evaluated’, albeit with significant restrictions on its use. Clinical experience is that a large proportion of devices in this category are legacy devices for which testing has not been performed, perhaps for economic reasons, but which on first principles may well be at least conditionally safe. Prudence dictates that a device for which ‘safety in MRI has not been evaluated’ should be treated as MR unsafe. Clinical MRI scans are still being cancelled for this reason, though in many cases there is probably little real risk.

RANZCR urges the TGA to continue to exert pressure on vendors to provide testing information, and, where this is not forthcoming, as much relevant information (such as device composition) as possible in the IFU, so that an informed risk-benefit assessment can be made before a potentially very valuable scan is cancelled.

The IFU for all marketed devices should be readily available, preferably online, to assist clinical safety assessments. Consideration should be given to the feasibility of using the *National Product Catalogue* as a repository of IFU.

3. Are the characteristics of the device compatible with my MRI system?

Once the MRI safety characteristics of a device have been established, it is the responsibility of the MRI site to assess whether the site can meet the conditions (if any) specified for the device. This may require a knowledge of, inter alia, the distributions of the main (B0) magnetic field around the magnet bore, and of the spatial gradient of the magnetic field, as well as the characteristics of the systems' time-varying gradient fields. Control of the RF field exposure is largely handled by the MRI system's software (which automatically limits the estimated Specific Absorption ratio (SAR) in the patient, and/or the B1 rms value). The international standard for clinical MRI systems specifies that the MRI system's IFU should include plots of the distribution of the B0 field, its spatial gradient, and of the distribution of the gradient magnetic field (IEC 60601-2-33 ed 3.1, subclause 201.7.9.3.101), and provision of this information should certainly be required for new systems being installed in Australia. Again, there are legacy systems for which this information may not be readily available, at least not in the detail now required.

Sites should ensure that they have the best available understanding of the safety characteristics of their system.

It is noted that the management of RF-induced heating is under active discussion in the industry, particularly due to the inhomogeneity of RF-induced heating at higher field strengths.

Conclusion

While RANZCR notes the great advances in modelling studies and pre-clinical testing of devices for their safety in the MRI environment, it does not consider that these testing methods are yet sufficiently well established and disseminated to obviate the need for clinical experience before regulatory approval. With the imminent publication of the second edition of ISO 10974, this may change.

RANZCR also notes the development of the 'Fixed Parameter Option' by MRI system vendors, and suggests that vendors be encouraged to make this option available in Australia.

RANZCR supports a more systematic program of post-marketing surveillance of Active Implantable Medical Devices, particularly in relation to the exposure of these devices to MRI.

Such a program could be designed to allow it to help confirm the identity of the implant(s) in an individual patient.

RANZCR has long been concerned about the lack of MRI safety testing information, or available safety testing information, for many marketed implanted devices (active or inactive). It encourages the TGA to move towards making provision of such testing information a mandatory requirement for device approval in the medium term. The feasibility of using the *National Product Catalogue* as a repository for IFU should be explored.

RANZCR notes the requirements for the 'Instructions For Use' to be provided by MRI system vendors in the latest edition (3.1) of IEC 60601-2-33, and requests that the TGA ensure that these requirements are met by MRI systems marketed in Australia.

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Questions and contact

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