

IPEM MR Safety Expert Experience Requirements Applicant Guidance

General guidance

The experience categories and sub-categories are specified in the *IPEM_MRSE_ExperienceRequirements* document which can be downloaded from the IPEM website. There must be at least one piece of evidence per experience category, and you must supply evidence for 16 / 19 (approx. 80%) of the sub-categories. Further detail of the categories and examples are given at the end of this document.

Simulated evidence (e.g., a hypothetical situation) is allowed but must not account for more than 3 of the sub-categories across the whole portfolio.

Evidence must be from your own work, dated and predominantly taken from work carried out over the last five years. Some evidence of practical competency/experience may precede the five years where the work is intermittent in nature. If your portfolio contains a lot of evidence which is considered outdated, it may lead to rejection. Good practice is that all evidence should be dated. Older evidence should not be used multiple times (e.g., in multiple categories, or used again in renewal applications).

The portfolio should be fully digital (paper submissions will **not** be accepted). Evidence can include scanned documents or screenshots, or photographs of relevant items. The portfolio should include the following:

- A comprehensive contents list, detailing and indexing all your items of evidence.
- Complete the *EvidenceTable* providing a cross-reference between the experience sub-category and the submitted evidence. If appropriate, mention which specific parts of your evidence are linked to each sub-category.
- All the documents that you are submitting as your items of evidence. You only have to include a few pages, if that is what is most relevant to your application. Make sure your authorship is clear.
- Authentication (at the end of the *EvidenceTable*), by a suitable referee (e.g. line manager), that the contents truly reflect the extent and nature of your own work.

Evidence may be any of the following:

- Finalised documents
- Review documents with evidence of input either inline within the document (e.g. track changes / comments) or separate document.
- Correspondence (usually emails)
- Meeting minutes with clearly identified contribution by applicant.
- Risk assessments including identification of risks and mitigation measures.
- Reports
- Scanner outputs (e.g. protocol sheets / screengrabs)
- Explanatory notes
- Documented evidence of input – authored documents, reviewed documents, revised documents, correspondence relating to the document, minutes of meetings etc.

Multiple documents (either pdf or .doc) are acceptable or documents can be combined into a single overarching file. If several images or screenshots are being submitted to support a specific evidence category, please combine these into a document for ease of viewing.

Make sure you remove any private or patient-identifiable details where necessary. Blank out (redact) any other information which you do not wish to disclose to the assessors. It is not necessary to redact professional contact details. The content of all portfolios will be kept confidential by the allocated assessors.

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It is not possible to be prescriptive about the exact number of pieces of evidence required for each sub-category as it depends on the breadth and depth of the submitted documentation. As a general guide the evidence submitted should be more than just a single simple statement: it also does not need to be so extensive that it covers every last possible interpretation of the category and sub-category. Evidence from very similar examples is unlikely to add value to your portfolio. The assessors are looking for you to provide evidence of broad engaged experience for each sub-category.

Where an experience category specifies “contribute to” this is a general term that captures almost every aspect of providing advice towards a particular output. Specifically, it includes one or more of the following activities:

- Propose; Initiate; produce
- Review
- Revise

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<p>1. Provide advice on the development and continuing evaluation of a safety framework for the MR environment.</p> <p><i>A safety framework encompasses the manner in which MR safety is assured related to a particular MR service and specifies the requirements for key documents (e.g. local rules, standard operating procedures, risk assessments, checklists, roles, and responsibilities). This category is about the applicant demonstrating that they have experience in establishing the processes required. It is not about the content of the various key documents.</i></p> <p><i>Sub-category 1.1 relates to the processes that an MR service has in place to provide assurance to relevant persons or groups within an organisation that appropriate MR safety management processes are in place and complied with. These MR safety management processes are wide ranging and include but may not be limited to appointment of appropriate persons, provision of local rules and SOPs, risk assessments, physical siting requirements and staff training.</i></p> <p><i>The assurance processes may involve the reporting of safety audit results and safety checklists and may involve groups, committee and/or reports.</i></p> <p><i>Evidence to support this category should be related to the assurance mechanisms and not the production or adherence to the audit documents, local rules, training requirements, appointment of persons etc.</i></p> <p><i>Sub-category 1.2 is not about the production of MR safety documents except where the specific MR document directly deals with specifying the local MR safety framework. It is about developing, revising, reviewing the requirements for specific MR safety documents. It is about the process rather than the content.</i></p>	<p>1.1 Contribute to a local MR safety assurance framework</p>	<ul style="list-style-type: none"> • Input to key safety framework documents that specify assurance mechanisms (e.g. MR safety policy/procedure, MR safety group terms of reference) • Advice on suitable governance structures. • Initiate/propose a live adverse incident reporting mechanism for rapid sharing of MR incidents across MR sites
	<p>1.2 Contribute to requirements for MR safety documents</p>	<ul style="list-style-type: none"> • Input to key safety framework documents (e.g. MR safety policy/procedure, MR safety group terms of reference) that specify what documents and procedures an MR unit should have. • Advice on documentation requirements.

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<p>2. Provide advice for the development of local rules and procedures to ensure the safe use of MR equipment.</p> <p><i>This category relates to the production and the review & revision of documents which manage MR safety a) in the area where the MR equipment is located b) as applied to the use of MR equipment.</i></p> <p><i>In contrast to Category 1, Category 2 is about the content rather than the process. It is not about the need for a safety framework, it is specifically about the procedures and the documents which manage the safe use of MR equipment.</i></p> <p><i>Local rules and SOPs might be lengthy, and the entire document should not be included. Each piece of evidence should be limited to a few pages, should include proof of authorship (e.g. title page, email), and should only include relevant sections (e.g. where the author had an input).</i></p> <p><i>Category 2.1 relates to the production and the review & revision of MR safety documents.</i></p> <p><i>Category 2.2 is specifically about documented audits of local procedures for compliance with legislation and guidelines.</i></p>	<p>2.1 Contribute to local rules and procedures within the MR unit.</p>	<ul style="list-style-type: none"> • Input into MR local rules. • Input into safety procedures
	<p>2.2 Audit local rules and SOPs for compliance with national guidance and legislation</p>	<ul style="list-style-type: none"> • MR safety audits of working practices and procedures (note: this does not include audits of equipment or facilities) for compliance with legislation and/or guidelines. • Risk assessments of MR safety issues as they relate to local procedures (e.g. BIR EMF Risk Assessments)
<p>3. Provide safety advice on the modification of MR protocols including diagnostic effectiveness linked to safety</p> <p><i>This category is about the modification of MR protocols in order to safely scan particular patients or patient groups, (e.g. change sequence parameters to reduce SAR, acoustic noise, dB/dt) whilst providing acceptable diagnostic effectiveness (e.g. contrast, SNR, artefacts, acquisition time)</i></p> <p><i>For patients with medical implants or devices, changes could be based on restrictions set by implant manufacturers or following local risk assessments when there is either lack of information or manufacturer's conditions are not met.</i></p>	<p>3.1 MR protocol modification for an individual patient.</p>	<ul style="list-style-type: none"> • Sequence parameter modifications to meet MR conditions indicating any image quality considerations e.g. screengrabs, dicom header comparisons, parameter printouts.
	<p>3.2 MR protocol modification for specific patient groups</p>	<ul style="list-style-type: none"> • Assessment (safety, image quality) of testing a modified protocol for safety on a phantom/volunteer.

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<p><i>This category is not about any risk assessment carried out (this is covered in section 4), but about the changes made to MR protocols to enable MR scanning of a specific patient or patient group.</i></p> <p><i>Sub-category 3.1 relates to changes made to an MR protocol that would allow to safely scan a specific patient.</i></p> <p><i>Sub-category 3.2 relates to changes made to an MR protocol that would allow to safely scan a specific patient group. This could be a group of patients with similar implants or devices where equivalent restrictions apply or a particular group of patients e.g. pregnant patients.</i></p>		<ul style="list-style-type: none"> • Review or audit of a modified MR protocol in relation to safety e.g. review a SAR limited protocol in a number of patients
<p>4. Provide safety advice regarding MR procedures for individual subjects and specific subject groups including diagnostic effectiveness linked to safety. This includes advice regarding safety related to implanted devices, metallic foreign bodies, tattoos, and other similar issues.</p> <p><i>This category is about situations that require more than just a simple relay of MR Conditional restrictions from manufacturer to user. The advice may require interpretation and advice on practical ways to adhere to MR conditions, risk assessment and advice on appropriate MR conditions in the absence of advice or when MR conditions cannot be</i></p>	<p>4.1 Provide advice for adhering to MR conditions of implanted medical devices with an MR Conditional label</p>	<ul style="list-style-type: none"> • Advice to MR operator on practical implementation of MR conditions. • policy/procedure for adhering to MR conditions.

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<p><i>adhered to. It includes advice regarding safety related to implanted devices, metallic foreign bodies, tattoos, and other similar issues.</i></p> <p><i>Sub-category 4.1 is about advising where complying with MR conditions requires some practical guidance either because the MR system does not offer direct control of the MR safety condition or because complying with the condition requires a detailed review of scanner field levels and/or other outputs.</i></p> <p><i>Sub-category 4.2 includes those situations of thinking through the likely risks involved with these types of non-medical device situations but determining the relative risk with scanning based on knowledge of their construction or composition, evidence, location, and types of scans performed.</i></p> <p><i>Sub-category 4.3 includes those situations where medical devices are unlabelled or the stated MR conditions cannot practically be complied with whilst maintaining diagnostic effectiveness. Examples are not expected to include situations that are quick to assess such as completely plastic implants but rather demonstrate the thought processes around determining if an MR Unlabelled implant is safe to scan using MRI safety theory and current experience. NB "MR Unlabelled" is a term used by the MHRA, and indicates devices which have no MR-specific labelling.</i></p> <p><i>Sub-category 4.4 is concerned with the scanning of subject groups where repeated safety situations are likely to occur and so generalised guidance is warranted (e.g. persons with foreign bodies, pregnancy, particular implant categories etc). Note that this sub-category is not for individualised assessments, covered in earlier sub-categories.</i></p>	<p>4.2 Provide advice for non-medical implants and body adornments.</p>	<ul style="list-style-type: none"> • Risk assessment of patient with a non-medical implant or body adornment • Advice for person with a non-medical implant or body adornment on scanning a patient based on risk vs benefit. • Input into policy/procedure for scanning persons with non-medical implants and/or body adornments.
	<p>4.3 Provide advice for MR Unlabelled medical devices or MR Conditional devices where the MR conditions cannot be met.</p>	<ul style="list-style-type: none"> • Risk assessment of patient with an MR Unlabelled medical device • Advice for person with an MR Unlabelled medical device on scanning a patient based on risk vs benefit
	<p>4.4 Provide advice for specific subject groups</p>	<ul style="list-style-type: none"> • Input into a risk assessment or policy/procedure for scanning a specific subject group (e.g. persons with foreign bodies, pregnancy etc)
<p>5. Provide advice on MR Safety training programs and MR Quality Assurance programs.</p> <p><i>This category concerns advice on training staff for MR safety. Evidence should show that you can identify appropriate training needs for different groups of staff who need to access an MR installation. Show evidence that you can develop training materials or update</i></p>	<p>5.1 Review and revise training needs for different staff groups, and/or produce appropriate training material</p>	<ul style="list-style-type: none"> • Definitions of different staff groups and classification of training needs • Policy/procedure document for induction of new staff, showing MR training needs. • Online or classroom training materials different groups of MR staff (identify your own contribution or updates)

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<p><i>existing training material. It will not be considered sufficient to show that you were the trainer in MR training sessions, using material created by others. Use category 8.1 to show evidence of training sessions where you have maintained and improved your own knowledge of MR safety.</i></p> <p><i>Adverse incidents can range from persons harmed by projectile events to “near misses”, Investigation of adverse incidents is essential to understand the root cause and provide feedback to update safety procedures and safety training programs.</i></p> <p><i>This category includes quality assurance programs for MR; a QA program is considered essential to verify diagnostic performance of a scanner. Evidence should show that you can define or audit a QA program. Where appropriate the program should be tuned to the particular usage of the scanner, e.g., radiotherapy planning.</i></p>		<ul style="list-style-type: none"> • Written audit report of a training program
	5.2 Provide advice on adverse incident investigations	<ul style="list-style-type: none"> • Report or email concerning an adverse incident. • Excerpt from incident reporting management tool • Report showing how an adverse incident lead to an update of safety procedures and/or training
	5.3 Propose or audit an MR QA program.	<ul style="list-style-type: none"> • Correspondence showing advice on how a QA program should be set up for a new MR installation. • Set up of QA program. • Written evaluation of an existing QA program, showing positive points and areas for improvement.
<p>6. Provide safety advice regarding the selection, procurement, siting and installation of the MR system and related equipment.</p> <p><i>This category is about providing MR safety advice and guidance relevant to the selection and procurement of MR systems, such as enhanced safety features. It is also about being part of the team tasked with designing a suitable MRI department factoring MR safety in the design, from the earlier scoping phase of site choice to detailed design plans. In addition, it is concerned with giving advice prior to and during the installation phase and highlighting potential safety issues. Modifications of MR departments and their surroundings are also relevant to this category, as is MR safety advice on the procurement, selection and use of related equipment, such as an MR Conditional anaesthetic machine.</i></p> <p><i>Sub-category 6.1 is about consideration of MR safety issues when procuring equipment which may include the MR system itself but also extends to procurement of ancillary</i></p>	6.1 Contribute to the specification or selection of MR systems or related equipment	<ul style="list-style-type: none"> • Select safety related documentation from procurement process with named involvement. • Input into specification or selection of MR ancillary equipment e.g. anaesthetic machines, infusion pumps, ferromagnetic detection systems. • Input into specification for safety related features of an MR system
	6.2 Contribute to design and siting and/or installation of an MR system	<ul style="list-style-type: none"> • Advice given on the scoping exercise for the siting of a new MRI department • Production of initial draft plans of MRI department

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<p><i>equipment such as anaesthetic equipment, interventional equipment, infusion pumps and patient accessories.</i></p> <p><i>Sub-category 6.2 is about the planning or design phase of a new MRI project, such as MR safety advice related to proposed sites and designs and guidance on requirements of the new department/installation.</i></p>		<ul style="list-style-type: none"> • Input into MRI department planning in relation to MR safety aspects (e.g. extent of MR controlled access area, quench pipe issues, floor demarcation zones) • Input into MR safety signage requirements. • Emails discussing quench pipe and quench pipe exhaust. • Lecture given to design team on MR safety requirements • MR safety guidance given as part of the MR design team (e.g., minutes or emails detailing advice) • Advice given on proposed modifications of an MRI department and its environs (e.g., email advice to Estates department)
<p>7. Provide safety advice as part of acceptance testing and, prior to the first clinical or human research use of the MR equipment, provide advice regarding performance testing procedures and testing following any major maintenance procedure.</p> <p><i>This category is about performing Acceptance Testing including an MR Safety Audit of the MRI facility post installation completion. Acceptance testing will ensure that the system is operating within accepted specifications, e.g., IPEM Report 112 and therefore does not represent a risk to patient safety in terms of poor system performance. The MR safety audit could include checking the correct MR safety limits are configured, ensuring the oxygen sensor alarm and extract fan are correctly operating, correct MR safety labelling of ancillary equipment, correct signage, verification of the quench pipe route and exit, checking the 0.5 and 3.0 mT contours. The safety audit may be a checklist of</i></p>	<p>7.1 Contribute to safety related acceptance tests of an MR unit.</p>	<ul style="list-style-type: none"> • Input into development of MR unit acceptance safety check process. • MR safety site report with reference to MHRA guidelines, identifying areas of deficiency. • Measurements of the actual magnetic fringe field outside of the MR Environment. • Verification of the actual magnetic field isocontour for ancillary equipment on the floor of the MRI magnet room • Follow-up emails of on-going issues

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<p>requirements for the site. Advice should also be given on basic QA procedures to ensure equipment is operating properly before patient examinations are undertaken.</p> <p><i>It is not about reviewing a site's MR safety documentation</i></p> <p><i>Sub-category 7.1 is about the post-installation phase of a new MRI system and the related infrastructure, auditing against safety guidelines and providing input for on-going issues.</i></p> <p><i>Sub-category 7.2 is about auditing a site against relevant guidelines and issuing advice based on the results of the audit. These audits may occur regularly for the lifetime of the MR system / unit.</i></p> <p><i>Acceptance testing is a broad activity typically incorporating both system performance and safety measures. This category should show evidence of experience related to safety. Where detailed safety related measurements have been performed these should be included.</i></p>	<p>7.2 Contribute to regular post installation MR unit safety checks.</p>	<ul style="list-style-type: none"> • Input into development of MR unit safety check process. • MR safety site report with reference to MHRA guidelines, identifying areas of deficiency.
<p>8. Establish and maintain links with any appropriate district, regional, and/or professional bodies.</p> <p><i>This category is about linking up with professional colleagues to further develop your own knowledge and understanding of MR safety issues, as well as contributing to MR safety developments within the wider MR community.</i></p> <p><i>Sub-category 8.1 is about attendance and subsequent reflections on learning for formal MR safety scientific or educational events, as well as more active contributions to such events.</i></p> <p><i>Sub-category 8.2 is about contribution to MR safety conversations within specialist groups outside of your local institution. Examples of this second sub-category may include groups at a district/regional level, or at a national/international level via professional bodies. It may include formal membership of specialist groups as well as examples of correspondence (either directly or via mailbases) on MR safety related matters.</i></p>	<p>8.1 Attend/contribute to MR safety update / training events organised by national or international professional bodies</p>	<ul style="list-style-type: none"> • Attendance certificate and reflections on learning for relevant national/international meetings, e.g. IPEM MR Safety update, ISMRM safety workshop/virtual meeting. • Abstracts/copies of presentations or other contributions to relevant national/international MR safety meetings
	<p>8.2 Active engagement with relevant specialist groups, professional bodies, or other relevant organisations.</p>	<ul style="list-style-type: none"> • Dates of membership of relevant groups/committees within professional bodies/other relevant organisations. Where relevant, description of your role or examples of your contribution within these groups. • Contributions to MR safety conversations on the MR physics mailbase

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		<ul style="list-style-type: none"> Responses to international / national / regional MR-safety related consultation documents.

Reference

Calamante et al, JMRI 2016.



Calamante et al
2016.pdf

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