

Review

MR System Operator: Recommended Minimum Requirements for Performing MRI in Human Subjects in a Research Setting

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This article is intended to provide guidelines for the *minimum* level of safety and operational knowledge that an MR system operator should exhibit in order to safely perform an MR procedure in a human subject in a research setting. This article represents the position of the International Society for Magnetic Resonance in Medicine (ISMRM) regarding this important topic and was developed by members of this society's MR Safety Committee.

Key Words: MR safety; research; human; education; training; guidelines

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DESCRIPTION

THE CONTENT of this article is intended to provide an outline of the guidelines for the *minimum* level of

safety and operational knowledge that a magnetic resonance (MR) system operator should exhibit in order to safely scan a human subject in a research setting.

RATIONALE

This article represents the position of the International Society of Magnetic Resonance in Medicine (ISMRM) regarding this important topic and was developed by members of this society's MR Safety Committee.

These guidelines are meant to specifically focus on potential MR safety-related matters to ensure that operation of the research facility is carried out in a safe manner for the subject undergoing the MR procedure, associated researchers, and healthcare providers. All the requirements for the MR system operator relating to the quality, efficiency, and/or efficacy of the research to be performed must be defined by the principal investigator responsible for the specific research project under consideration.

Furthermore, these guidelines cover the minimum requirements to ensure basic safety, and do not cover other issues related to invasive procedures, interventional procedures, or the administration of MRI contrast agents, which require special consideration and are beyond the scope of this article.

Finally, this article only provides an *outline* for the minimum standards that MR sites should consider in order to set up their MR safety plan; this article therefore does not intend to mandate how MR system operators obtain the necessary education and training but rather establishes the baseline of MR safety topics in which the operators must be proficient. Therefore, it is the individual site's responsibility to define how, by whom, and by what sources the MR system operator obtains the necessary safety-related knowledge, acknowledging that specific details and requirements may vary between centers, countries, etc.

DEFINITIONS AND RESPONSIBILITIES

Given the difference in existing nomenclature and to avoid any possible misunderstanding, the

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The full list of members of the 2013–2014 ISMRM Safety Committee is available as Supporting Information.

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following definitions are applicable throughout this article:

- Principal investigator (PI): the person who is scientifically responsible for the research being conducted. In reality, several people may share this responsibility.
- MR Medical Director/MR Research Director/Safety Officer (MRMD/MRRD/SO): the person who is responsible for the safe operations of the MR facility in which the study is conducted.
- MR system operator: the individual operating an MR system to perform an investigation on a human subject as part of a research project.
- Subject: the human subject voluntarily undergoing an MR procedure. Subjects may be colleagues or externally recruited. Further, the subjects may be healthy or have a health condition. However, insofar as the objective of the MR procedure is not being performed to establish a medical diagnosis the subject is not a patient.

While operating within the MR facility, the PI and the MR system operator are responsible for all aspects of the MR examination including but not limited to maintaining the overall safety of subjects, staff, and equipment within the MRI environment. However, regardless of the nature of the MRI investigation (ie, whether it is a clinical facility, research site, or an industrial operation), an MR Research Director or Medical Director (as determined by local regulatory requirements) is required (as is advised by the American College of Radiology for all clinical MRI facilities (1)), who will be the one ultimately responsible for ensuring that the safety provisions of the MR facility meets the recommended guidelines/standards. In addition, the MRMD/MRRD/SO is responsible, among others, for ensuring the existence of site policies relating to complaint reporting, unexpected radiological findings, human subject privacy requirements (data protection), and the traceability of subjects.

It is highly recommended that human MR scanning not be performed by the operator alone, but rather that another individual (ideally, another MRI safety trained and responsible individual) be present and available during the time that the subject is in the scanner bore; this person will act as support personnel in the event of an emergency, including the case when this affects the MR system operator.

MINIMAL REQUIREMENTS FOR MR SYSTEM OPERATORS

When developing a program for the education and training that constitutes the minimal requirements for MR system operators, the following topics should be considered:

Qualifications and Training

The program must define the minimum qualifications for training and education of the MR system operator. This must include being familiar with the specifics of the safety section in the Instructions for Use of the

MR system, as well as the site-specific policies on MR safe practices policies and guidelines.

MR Operating Mode

The MR system operator must be able to determine the International Electrotechnical Commission / Food and Drug Administration (IEC/FDA) Operating Mode for the MR sequence protocol to be used (2):

- Normal Operating Mode: mode of operation of the MR equipment in which none of the outputs have a value that would be anticipated to cause physiological stress to subjects.
- First Level Controlled Operating Mode: mode of operation of the MR equipment in which one or more outputs reach a value that may cause physiological stress to subjects, which needs to be controlled by medical supervision. Note: the MRMD/MRRD/SO can waive the required medical supervision requirement if only healthy adults are scanned.
- Second Level Controlled Operating Mode: mode of operation of the MR equipment in which one or more outputs reach a value that can produce significant risk for subjects, for which explicit ethical approval is required according to local requirements.

“Higher-Risk” Subjects

The MR system operator should identify a possible “higher-risk” category for subjects to be studied, given their potential for increased MR safety concerns. For example, pediatric patients, patients with mental deficiencies or communication difficulties, various disease processes, language barriers, etc., for which a more specialized training and expertise might be required. It is highly recommended that an MR technologist/radiographer, who is trained and certified according to national/state/regional regulations to perform MR examinations, be utilized to perform the duties of “MR system Operator” for such higher-risk category subjects.

Safety Topics

To ensure the minimal requirements for MR safety, the training/education program for MR system operators should include the following safety-related topics:

MR System Considerations

A number of issues related to the MR system must be carefully considered, including those related to the static magnetic field, magnet quench, radiofrequency issues, MR safety zones, and equipment preparation:

- i. Static magnetic field considerations: the presence of the static magnetic field has a number of associated safety related issues, including:
 - Magnetic field spatial gradient (or static field gradient): interpretation of manufacturer’s data.
 - Translational forces/projectile effects.
 - Torque/rotational forces.
 - Lenz’s forces.

- Magneto-hydrodynamic effect considerations (for higher field studies).
- Flow potentials (if ECG triggering/gating is required).
- ii. Quench and cryogen safety considerations.
- iii. Radiofrequency (RF) issues, predominantly as they relate to the potential for thermal injury and the prevention of excessive heating.
- iv. MR safety zones, as described by the American College of Radiology (1), controlling access to the MRI environment, including site access restriction for research team and/or other ancillary personnel.
- v. Equipment preparation:
 - Coils and cables in good condition, straight cords.
 - Verifying conditions satisfied for any/all MR conditional equipment or devices in use.
 - Nonstandard components (investigational devices, non-CE-marked devices, etc.) identified by their labels; conditions and restrictions for using such devices understood and obeyed.

Consideration for the Subject and Ancillary Personnel

A number of issues related to the subject undergoing an MR procedure and any ancillary personnel must be carefully considered, including those related to providing adequate information and instructions, screening, subject preparation, monitoring, and incidental imaging findings:

- i. Information and instruction:
 - Explaining the examination.
 - Ensuring compliance with local Institutional Review Board/Ethics board requirements for written/documented informed consent.
 - Possible side effects or sensations, including: acoustic noise, dizziness, nausea, metallic taste, anxiety, claustrophobia, possible temperature elevations, focal or diffuse.
 - Pregnancy, obesity, other special conditions or considerations.
- ii. Written documentation of screening of scan subject, as well as screening of research team and/or other ancillary personnel entering safety zones 3 or 4:
 - Exclusion criteria and contraindication policy.
 - Prior surgery (anything ferromagnetic and/or electrically conductive implanted or left temporarily in body).
 - Trauma history (possible ferromagnetic embedded foreign objects).
 - Tattoos, piercings, body art.
 - Any external objects that may be ferromagnetic and/or have electrically conductive properties.
 - Conditions that may compromise the thermoregulatory system.
- iii. Subject preparation: the following factors should be considered with regard to the preparation of the subject for the MR procedure:
 - Proper attire (ie, gown).
 - Hearing protection.
 - Proper positioning and padding.
 - Explain alarm features and operation (eg, squeeze ball).

- Prevention of excessive heating and burns: avoiding skin-to-skin or skin-to-bore contact, avoiding large-diameter electrically conductive loops especially if involving or contiguous with subject tissue, etc.
- iv. Subject monitoring should include two-way verbal communication, and visual supervision (direct and/or electronic).
- v. Study Monitoring: a number of factors should be taken into account when monitoring the MR procedure, including:
 - Specific absorption rate (SAR) limitations.
 - B0 restrictions.
 - dB/dt limitations.
 - Acoustic noise limitations.
 - Understanding the MR safety consequences of modifications of each operator controllable parameter (eg, thermal issues related to MR hardware and pulse sequence design; peripheral nerve stimulation issues related to dB/dt, etc.).
- vi. Incidental and/or unanticipated imaging findings:
 - Prospectively defined presence or absence of clinical interpretation review of obtained imaging or study data.
 - Protocols for communication between radiologist, scan subject and their physician, if/as applicable.
 - Consent forms and documentation of unanticipated study findings.

Emergency Situations

A number of issues related to emergency situations must be carefully considered, including those related to medical emergencies, anticipatable adverse events, magnet quench, non-MRI related emergencies, and local response procedures:

- i. Medical emergencies: there should be prospectively defined responses to anticipatable medical emergencies, including but not limited to: myocardial infarction/angina, seizure, panic attack, thermal injuries/burns, reactions to administered drugs.
- ii. Prospectively defined response to anticipatable adverse events (eg, neurological stimulation or neuromuscular excitation from the research MR study sequence(s), projectile event, etc.).
- iii. Quench:
 - Predefined conditions that do or do not require an intentional quench.
 - Prospectively defined quench responses.
- iv. Non-MRI related emergencies:
 - Fire alarm.
 - Building evacuation.
 - Security-related emergency.
- v. Familiarity with local response procedures so that adequate required support can be ensured in a timely manner.

Room Setup and Infection Control

Consistent with site specific policies, the following issues should be considered:

- Clean linen.
- Gowning of research subjects.
- Sanitary use of all equipment.
- Room air exchange considerations following subjects potentially with certain infectious diseases.
- Cleaning and proper disposal of waste, including predefined procedures when hazardous materials or biological materials (animals, cadavers, etc.) are involved.
- Room conditions (temperature, humidity, bore air flow).

In conclusion, ensuring the MR safety of the research facility for the subject being scanned and other personnel is of paramount importance. The outline described in this article provides essential elements that should be carefully considered when developing a program for the training and education for MR system operators in a research setting. It should be emphasized, however, that these guidelines constitute only the *minimal* requirements for MR safety

and that any local implementation of such a program must be part of, and adopted to, a site-specific policy concerning the scanning of human subjects.

SUGGESTED READING

A list of suggested reading material, which represents peer review and/or committee/societal/regulatory agency publications of relevance to the current content, is included as Supporting Information.

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