Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is distributed for comment purposes only.

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You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

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When final, this guidance will supersede FDA's Guidance entitled "Guidance for Industry: Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices," dated November 14, 1998.

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Food and Drug Administration
Center for Devices and Radiological Health

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Division of Radiological Health

Office of Science and Engineering Laboratories (OSEL)
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2015-D-2148. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

1. Introduction

This draft guidance provides the Food and Drug Administration's (FDA) Center for Devices and Radiological Health detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD). This document is a recommendation of how to comply with certain requirements contained in 21 CFR 807.87 and is intended to be used in conjunction with information regarding the content and format of a 510(k) premarket notification. For more information about the content and format of a 510(k), see FDA's guidance entitled "Format for Traditional and Abbreviated 510(k)s" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM084396.pdf). The approach outlined in this guidance document is intended to facilitate the timely review and marketing clearance of MRDDs.

This updated guidance document reflects regulatory decisions made by the Agency, updates to standards, and legislative changes adopted by the Agency since the issuance of the previous version of this document.[1]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance documents means that something is suggested or recommended, but not required.

[1] http://www.fda.gov/RegulatoryInformation/Guidances/ucm073817.htm.

2. Scope

This document is applicable to MRDDs as defined in 21 CFR 892.1000:

> **21 CFR 892.1000: Magnetic resonance diagnostic device.**
>
> (a) *Identification*. A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).
>
> (b) *Classification*. Class II.

MRDDs are Class II medical devices that require premarket notification and an agency determination of substantial equivalence prior to marketing. Three product codes are currently used to identify these devices:

LNH – Nuclear Magnetic Resonance Imaging System
LNI – Nuclear Magnetic Resonance Spectroscopic System
MOS - Magnetic Resonance Specialty Coil

The principal components of current MRDDs include the main magnet, shim and gradient systems, radiofrequency transmitter and receiver, transmit and receive coils, power supplies, computer and software. This draft guidance document is applicable to premarket notifications for magnetic resonance imaging (MRI) and magnetic resonance spectroscopy (MRS) systems, components, and modifications to systems and components which have a significant impact on safety or effectiveness of the magnetic resonance diagnostic device and trigger the need for premarket review of a 510(k) prior to marketing. The information in this guidance document is also applicable to the MRI system components of dual-modality devices, such as PET/MRI systems.

3. Relevant Standards

FDA recognized standards may be used to help demonstrate substantial equivalence in a premarket application. For more information regarding recognition and use of consensus standards, see FDA's guidance entitled "Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm). Please refer to FDA's Recognized Consensus Standards Database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm) for the currently recognized versions.

3.1. NEMA Standards

Standards promulgated by the National Electrical Manufacturers Association (NEMA) provide standardized test methods for the assessment of performance and safety parameters for MRDDs. The NEMA standards only prescribe standard measurement methods and do not specify acceptance criteria; acceptance criteria should be specified and will be evaluated by FDA on a case-by-case basis depending on the intended use and specific technological characteristics of the device. NEMA test methods recognized by FDA include:

- MS 1 - Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images
- MS 2 - Determination of Two-dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images
- MS 3 - Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
- MS 4 - Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices
- MS 5 - Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging
- MS 6 - Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI)
- MS 8 - Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems
- MS 9 - Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
- MS 10 - Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging Systems
- MS 11 – Determination of Gradient-Induced Electric Fields in Diagnostic Magnetic Resonance Imaging
- MS 12 - Quantification and Mapping of Geometric Distortion for Special Applications

3.2. IEC 60601-2-33

The International Electrotechnical Commission (IEC) 60601-2-33 ("Medical Electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis"*)* is the international standard for the safety of magnetic resonance equipment intended for medical diagnosis. The NEMA standards for measuring acoustic noise (NEMA MS 4:2006) and SAR (NEMS MS8: 2008) have been incorporated into the IEC

standard. However, the IEC standard does not address performance issues, such as SNR, image uniformity, geometric distortion and slice thickness.

3.3. Other Applicable Standards

- UL 94 Tests for Flammability of Plastic Materials for Parts in Devices and Appliances - This standard applies to the flammability of plastics used in various MRDD components, e.g., pads, coil enclosures, etc.

- ISO 10993-1 - Biological evaluation of medical devices – Part 1: Evaluation and Testing within a Risk Management Process. This standard applies to patient-contacting materials in MRDDs.

- NEMA PS 3.1 - 3.18 DICOM (Digital Imaging and Communications in Medicine) - This standard specifies formats for the digital exchange of medical images.

- AAMI/ANSI 60601-1 - Medical electrical equipment - Part 1: General Requirements for Basic Safety and Essential Performance

- IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests

4. Describing Your Device in a 510(k) Premarket Notification

When submitting a 510(k) premarket notification for a magnetic resonance diagnostic device, you must include the information required under 21 CFR 807.87. You should identify your device by regulation and product code and include the information below.

4.1. Indications for Use

You should describe with particularity, as described below, the Indications for Use (IFU) for your device. The device labeling, training materials, performance claims, and promotional materials should all be consistent with the IFU.

Specific clinical indications (e.g., disease identification or rule-out, diagnosis or prognosis with respect to disease staging or severity, and prevention or reduction in morbidity and/or mortality associated with particular diseases) are beyond the scope of this document. While the Agency handles each such application on an individual basis, the Agency believes that clinical studies are often necessary to support such specific clinical indications. Prior to the submission of any such application, you are encouraged to contact the Agency to discuss the level of supporting evidence required and clinical trial study design.

MRDDs often contain protocols recommended for specific applications (e.g., adult abdomen, pediatric brain, etc.). For MRDDs, these specific protocols do not necessarily create a new specific indication for the MRDD, provided that disease-specific or diagnostic claims are not made. For

example, a "Liver Perfusion" protocol would be acceptable under a general IFU, but a "Liver Cirrhosis Staging" protocol would likely be interpreted as a new specific indication.

The Indications for Use for coils and accessory devices should specify the MRI system with which the devices are intended to be used. The level of detail necessary will depend upon the individual device and the MRI systems with which it is intended to be used. For example, FDA generally believes that specifying the manufacturer and field strength of the MRI system with which a radiofrequency (RF) coil is compatible is appropriate.

4.2. Device Description

You should provide a comprehensive description of your device in the premarket notification, that includes information about the principal components of the system, a brief description of the purpose of each component, and a diagram illustrating their interconnections. SI Units are generally preferred. The following information should be provided for the principle system components:

4.2.1. **Magnet** – A full description of the main magnet including:

- Field strength and type of magnet (superconducting, resistive or permanent)
- Dimensions of the patient-accessible bore space
- Type of installation (fixed, mobile, interventional, or transportable)
- Design characteristics of the magnet, including weight, bore size, cryogens and boil-off rates (if applicable), bore dimensions, type of shielding, shimming method
- Performance characteristics of the magnet, including decay characteristics of the magnetic field in the event of a quench, fringe field maps (including 0.5 mT, 1 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT and 200 mT contours), temporal field stability (ppm/hr), and spatial homogeneity

4.2.2. **Gradient System** – A full description of the gradient system including:

- An illustration of the system with dimensions
- Information on shielding and cooling
- Maximum gradient amplitude (per axis) in T/m, rise time (ms), slew rate (T/m/s)
- A description of how cardiac and peripheral nerve stimulation control is implemented

- Information about which operating modes are implemented on the system (Normal, First Level Controlled, Second Level Controlled) and how control between the different modes is implemented

4.2.3. **Radiofrequency System** – A description of the architecture of the RF transmit-receive system should be provided. The number of transmit and receive channels, amplifier peak power and duty cycle should be specified.

FDA recommends that all MRDDs retain the ability to operate in quadrature transmit mode. Please include a description of how the user identifies and selects quadrature transmit mode on your system.

4.2.4. **RF Coils** – For each RF coil included with the system:

- Type of coil (transmit, receive, transmit/receive).
- Description of the hardware characteristics of the coil (e.g., geometry, materials, dimensions, construction details, etc.)
- A description of the coil design (e.g., linear, quadrature, phased array, multi-transmit)
- Intended use (resonant nucleus, frequency(ies), anatomical region of interest)
- Schematic of the coil design including the location of individual coil elements
- Circuit diagrams
- For receive-only coils, a description of the decoupling method(s) employed

4.2.5. **SAR Management and Control System**

- A comprehensive description of the SAR management and control system, including how whole-body averaged (avg-WB), partial body (PB), and local (10g-averaged) SAR control is implemented.
- Information about which operating modes are implemented on the system (Normal, First Level Controlled, Second Level Controlled) and how control between the different modes is implemented
- The specification for accuracy and uncertainty in the console-reported SAR values

4.2.6. **Imaging Protocols** – A complete description of the pre-programmed protocols available on the MRDD should be provided. This list should be organized by target anatomy, and should include the following information for each protocol:

- A list of the pulse sequences included in each protocol (e.g., spin echo, gradient echo, fast spin echo, 2D/3D), including the contrast characteristics (e.g., T1, T2, weighting, fat saturation), k-space trajectory (spiral, Cartesian, etc.) and associated options (shimming, parallel imaging, saturation pulses, etc.) for each pulse sequences

- Coil preference for the protocol (if any)

- Whether the protocol is intended to be used in combination with exogenous contrast media

- Additional accessory equipment required (e.g., respiratory and/or cardiac gating, elastography drivers, etc.)

- For novel pulse sequences, a pulse sequence diagram should be provided.

4.2.7. **Image Processing** - A full description and the intended use of each image processing module, including:

- Inputs to the module, their data formats, and methods of input (e.g., feed from other modules, manual input)

- Core algorithms employed

- Level of user interaction (e.g., automated, semi-automated and manual, whether results can be edited or need to be reviewed by the user)

- Outputs from the module, their data formats, and how they are displayed

4.2.8. **Software** - In general, FDA considers software used in MRDDs to be of "Moderate" level of concern. The 510(k) application should include software documentation consistent with a moderate level of concern as specified in the FDA guidance documents entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm) and "Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm).

4.2.9. **Additional Information** – The following additional information about your MRDD should also be provided:

- Physiological monitoring accessories included with the system (EKG leads, pulse oximeters, etc.)

- A description of the patient table including dimensions, positioning accuracy and maximum supported weight

5. Electrical, Mechanical, Structural, and Related System Safety

FDA recommends you evaluate the safety aspects of your device according to the following FDA-recognized consensus standards:

- AAMI/ANSI 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests

6. Physical Laboratory Testing

To demonstrate the substantial equivalence of your MRDD, FDA recommends that you provide the performance testing specified below. A number of the tests specified below can be performed in accordance with FDA-recognized consensus standards.

When performance testing involves phantoms that have been validated and are publicly available (e.g., the ACR MRI Accreditation Large Phantom), a simple reference to the phantom used is adequate; for custom-made phantoms, a complete description of the phantom should be provided and its use justified.

6.1. Performance

6.1.1. **Imaging** – Image quality metrics for a magnetic resonance diagnostic device should measure signal-to-noise ratio, geometric distortion, image uniformity, slice thickness, and spatial resolution. The measurement method used should be specified for all performance test results. Results and pre-determined pass/fail acceptance criteria should be reported for all image quality metrics.

- **Signal to Noise Ratio (SNR)** – The measured SNR value as well as pre-determined pass/fail acceptance criteria should be reported for all coils included with the system.

- **Geometric Distortion** – Distortion measured in all three slice orientations (sagittal, coronal and transverse) as well as pre-determined pass/fail acceptance criteria should be reported.

- **Image Uniformity** – Image uniformity measurements and/or gray-scale uniformity maps as well as pre-determined pass/fail acceptance criteria should be reported for all coils included with the system.

- **Slice Thickness** – Full-width-half-maximum (FWHM) values as well as pre-determined pass/fail acceptance criteria should be reported.

- **Spatial Resolution** – High contrast spatial resolution of the system should be demonstrated using suitable phantoms for the clinical pulse sequence protocols using the smallest field of view (FOV).

- **Image contrast validation** – The image contrast behavior for new pulse sequences should be validated using suitable phantoms. For example, fat saturation pulse sequences should demonstrate adequate fat signal suppression in a phantom composed of fat and water. The accuracy of quantitative outputs should be verified and validated.

6.1.2. **Spectroscopy –** No standardized tests have been developed for magnetic resonance spectroscopy performance. FDA recommends the following performance testing for systems with spectroscopy scan protocols. All test results should be accompanied by a description of the test methods used, including the pulse sequences and coils utilized, and the geometry and composition of all phantoms. The target anatomical region and the RF hardware used should be specified. Phantom testing should include performance characteristic such as:

- **Spatial Localization Accuracy** – Comparison of desired and actual volume

- **Spectral Resolution** – Full-width-half-maximum of the water resonance using the clinical protocols (e.g., single voxel or chemical shift imaging)

- **Signal-to-noise ratio** – Ratio of peak amplitude to standard deviation of background for key metabolites (e.g., N-Acetyl aspartate or lactate)

- **Solvent suppression –** Ratio of area of solvent peak with and without suppression

- **Decoupling** – Comparison of SNR with and without decoupling

- **Spectral Data Processing** – Validation of spectral post-processing techniques

6.2. Safety

Safety testing of a MRDD should address acoustic noise, gradient-induced electric fields, RF energy deposition and biocompatibility and flammability of patient-contacting materials.

6.2.1. **Acoustic Noise** – The measurement method used (e.g., maximum gradient acoustic noise or maximum clinical acoustic noise) should be specified. Unweighted peak sound pressure level (Lpeak) and the time integral of the A-weighted sound pressure level ($L_A$eq) should be reported.

6.2.2. **Gradient-induced Electric Fields** – The maximum electric field (in V/m) induced by the time-varying gradient magnetic fields should be measured and reported. The uncertainty boundaries of the induced electric field measurements should be specified.

6.2.3. **RF Energy Deposition** – Whole-body averaged, -head averaged , and/or partial body SAR should be measured for volume -transmit coils as appropriate. The test method used (e.g., pulse energy or calorimetry) should be specified. Both the measured and the scanner-displayed SAR values should be reported. For surface transmit coils, local 10g-averaged SAR values should be measured and reported. Uncertainty boundaries should be specified for all reported SAR values.

Isocontours of the electric field ($\vec{E}$) and the magnetic field ($\vec{H}$) in the unloaded state should also be provided for the body coil.

For multi-channel transmit coils, a discussion of how the peak local (10g-averaged) SAR values compare to quadrature volume coil values should be included. This discussion should encompass the entire patient population and anatomical scan landmarks for which the device is indicated. If computational models are used to support the scientific rationale of substantial equivalence, these models should be accompanied by validation and uncertainty data. Peak local 10-g averaged SAR values in quadrature coils operating at whole-body averaged SAR equal to 2W/kg are known to be significantly higher than the local 10-g averaged SAR limits set forth in IEC 60601-2-33. However, given the long history of safe use of the quadrature whole body coils, FDA considers the peak local 10-g averaged SAR values of these coils (while conforming to the current whole-body and whole-head SAR limits) to be an acceptable safety benchmark.

6.2.4. **Heating of RF Surface Coils** – To ensure patient safety and prevent burns to patients undergoing MR exams, you should measure the temperature rise of all receive-only coils included with the system. The results reported to FDA should include an assessment of why the measured temperature rise is acceptable and does not pose a risk to patients. FDA recommends that temperature be measured at locations in the coil pre-determined to be the local hot spots, and that this test be conducted for the coil in the normal operating condition, and for the single fault condition of the coil left in the bore of the magnet unplugged.

6.2.5. **Biocompatibility** – Biocompatibility data should be provided for new materials or materials that have invasive uses. Biocompatibility data need not be provided for external RF coil assemblies and other MRI components which are not intended to contact the body. Biocompatibility data also need not be provided for materials intended to contact intact skin if the final finished form of the patient-contacting materials have the same materials and manufacturing process as the predicate device. In such cases, the use of the material in a legally marketed predicate device should be demonstrated.

6.3. Performance Data for Device Modifications

It is not necessary to repeat all of the above tests for every new component or system modification since not all test results are affected by each change to the system. Below are examples of the relevant tests that FDA recommends be submitted for major system modifications:

6.3.1. **Magnet** - SNR, geometric distortion, image uniformity, acoustic noise

6.3.2. **Gradient System** - Geometric distortion, image uniformity, slice thickness, acoustic noise

6.3.3. **RF Transmit Coil** - SNR, image uniformity, RF energy deposition, coil heating, biocompatibility and/or flammability as appropriate

6.3.4. **RF Receive Coil** - SNR, image uniformity, coil heating, biocompatibility and flammability, as appropriate

6.3.5. **Pulse Sequence** – SNR and appropriate contrast behavior, acoustic noise (if anticipated to exceed the current system threshold)

7. Clinical Images

Sample clinical images should be provided for all coils, pulse sequences and imaging protocols introduced in the submission. Images should be provided to the Agency in electronic DICOM format. Any patient identifiers should be removed prior to submitting images to FDA. FDA requests that all images be accompanied by a description of the target anatomical site, scan parameters employed, and the total imaging time.

For new coils, you should provide images using a standard pulse sequence (such as T1W or T2W) with slices covering the entire intended field of view of the coil. Images in all three imaging planes should be provided.

For new pulse sequences or imaging protocols, FDA recommends that you provide images demonstrating that the intended image contrast is achieved.

All sample clinical images submitted to the Agency should be accompanied by a statement from a U.S. Board Certified radiologist indicating that images are of diagnostic quality.

8. Labeling

You must include in the 510(k) submission labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). For a magnetic resonance diagnostic device, such labeling should include the following items:

8.1. Device Labeling

Labeling on all RF coils (with the exception of the integrated body coil) should clearly identify the coil as either a transmit/receive or a receive-only coil.

8.2. Summary Specification Sheet

The Summary Specifications Sheet should provide a description of the system configuration and components and provide a summary of available applications. The Summary Specifications Sheet should include the following information:

8.2.1. **Magnet** – Field strength and type of magnet (superconducting, resistive or permanent), patient-accessible bore size, type of installation (fixed, mobile, interventional, or transportable), design characteristics of the magnet, including weight, bore size, cryogens and boil-off rates (if applicable), type of shielding, shimming method, performance characteristics of the magnet, including decay characteristics of the magnetic field in the event of a quench (time from full field to 20mT), temporal field stability (ppm/hr), spatial homogeneity and information about maximum |B|, |grad|B||, and |B|.|grad|B||, in patient-accessible values

8.2.2. **Gradient System** – Maximum gradient amplitude (per axis) in T/m, rise time (ms), slew rate (T/m/s), and information on shielding and cooling. Peak acoustic output (peak and A-weighted).

8.2.3. **RF Subsystem** – Resonant frequency(ies), the number of transmit and receive channels, amplifier peak power and duty cycle. Operating modes employed on the system (Normal, First Level Controlled, Second Level Controlled).

8.2.4. **RF Coils** – For each coil supplied with the system, the type of coil (transmit, receive, transmit/receive), coil design (e.g., linear, quadrature, phased array, multi-transmit), and intended use (resonant nucleus, frequency(ies), anatomical region of interest)

8.2.5. **Imaging Protocols** – A list of protocols and/or pulse sequences provided with the system

8.2.6. **Patient Table** – Dimensions and maximum supported patient weight

8.2.7. **Post processing features** – A summary of the post-processing features available on the system, including the software version.

8.2.8. Additional Accessories provided with the system (e.g., physiological monitoring accessories such as EKG leads, pulse oximeters, respiratory and/or cardiac gating, elastography drivers)

8.3. User Manual

The User or Operator's Manual for a MRDD must address (1) the contraindications, warnings, precautions, and general risks associated with the device, and (2) contain a statement that "Caution: Federal law restricts this device to sale by or on the order of a physician" as required by 21 CFR Part 801. Moreover, the User or Operator's Manual for a MRDD and should contain the following information, as applicable:

8.3.1. **Indications for Use** – The indications for use statement in the User Manual should be identical to the Indications for Use statement in FDA Form 3881 and the 510(k) Summary, if provided.

8.3.2. **Screening of patients for MRI** – The User Manual should include recommended patient screening procedures and should clearly specify patients for whom exams are contraindicated and patients for whom special procedures must be followed. You may wish to refer to the standardized definitions of MR Safe, MR Conditional, and MR Unsafe defined by ASTM F2503.

8.3.3. **Emergency Procedures** – Instructions for the end user should include emergency procedures for removing a patient rapidly from the MRDD.

8.3.4. **Excessive Noise –** If noise within the MRDD can exceed 99 dBA, user instructions should state the specifications of the hearing protection required for patients. The User Manual should also specify the noise level at the control panel and whether hearing protection is required or recommended for operators.

8.3.5. **Controlled Access Area –** Instructions should state that the user is responsible for establishing a controlled access area around the MRDD outside of which the magnetic field does not exceed 5 gauss. Recommendations for the size and shape of this area based on the fringe field of the MRDD in all three dimensions should be specified, accompanied by a sketch.

The need for the controlled access area should be explained. Recommendations should be given on how the controlled access area should be identified (e.g., markings, barriers or signs) and that the area should be labeled "Danger - High Magnetic Field" at all entries.

The User Manual should state the dangers of introducing equipment (such as patient monitoring, life support and emergency care equipment) not recommended for use in the controlled access area into the controlled access area. The User Instructions should also explain that even MR Conditional devices or equipment may be capable of causing injury if the specific conditions of safe use are not followed.

The value and location of maximal |B|, |grad|B||, and |B|.|grad|B|| in patient-accessible areas should be provided.

8.3.6. **Liquid Cryogens** – For those MRDDs that use cryogens, the user instructions should include information about the potential hazards of cryogens, procedures to be

followed after gas release, precautions against lack of oxygen, use of non-magnetic containers for cryogens, and procedures to be followed if flammable materials are found near cryogen containers.

Instructions should provide information on maintenance and inspection of the magnet and minimum cryogen levels, and specify the frequency at which cryogen levels should be checked by the user.

8.3.7. **Operating Modes** – The operating modes of the system should be clearly explained.

8.3.8. **Emergency Shutdown** – User Instructions should clearly explain the operation of the emergency field shutdown unit and when it is appropriate to use this feature.

8.3.9. **Fire Precautions** – User Instructions should recommend that the end user discuss fire precautions with the local fire department and that site-specific emergency procedures be established.

8.3.10. **Quality Assurance** – Instructions should describe the quality assurance procedures recommended for the user, including specifications of phantoms that should be used. The frequency of all recommended QA procedures should be specified.

8.3.11. **Maintenance –** Instructions should include the recommended maintenance schedules for the equipment, including whether they should be performed by the user or company service personnel.

8.3.12. **Cleaning and Disinfection –** Instructions for cleaning and disinfection should be included for components which come into contact with the patient or are intended for invasive use and are reusable (e.g., endocavitary coils).

8.4. Site Planning Information

The site planning information should contain the following recommendations and information:

8.4.1. **Audio and Visual Contact with Patient** – Provision should be made in the design of the scan room and equipment to enable audio and visual contact with the patient during the examination.

8.4.2. **Magnetic Fringe Field** – Magnetic field plots describing the 3D magnetic field created by the MRDD in a typical installation should be provided. Each plot should contain at least the iso-magnetic field contours with values of 0.5 mT, 1 mT, 3 mT, 5 mT, 10 mT, 20 mT, 40 mT and 200 mT, as well as a distance scale and a superimposed outline of the magnet.

8.4.3. **Liquid Cryogens and Cryogenic Gases** – For superconducting magnets, the design of a venting system connected to an area outside the examination room that has been designed to withstand a quench should be provided.

8.4.4. **Decay Characteristics of Magnetic Field –** For superconducting and resistive magnets the decay characteristics of the magnetic field in the event of a quench or emergency field shut-down should be provided. These characteristics should indicate the time from activation of the emergency field shut-down unit to the moment at which the field strength in the center of the magnet has fallen to 20 mT. Instructions should also be given regarding where and how to install the actuator of the emergency field shutdown unit.