August 9, 2013

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852.

Citizen Petition

The undersigned submits this petition under 21U.S.C Chapter 9 Subchapter V, Part C, section 360kk of the Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to amend 21CFR section 1030, microwave and radio frequency emitting products, to include Nuclear Magnetic Resonance Imaging, product code LNH and LNI. Defined in Sec. 892.1000. Suggest 1030.30 for Nuclear Magnetic Resonance Imaging system performance standards.

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).

Nuclear Magnetic Imaging devices are class II devices. Authority to regulate performance standards for Nuclear Magnetic Resonance Imaging systems 21 U.S.C. 351, 352, 360, 360e-360j, 360hh-360ss, 371, 381.

A. Action requested to amend 21CFR section 1030 to include 1030.30, performance standards for Nuclear Magnetic Resonance Imaging, to include the following proposed language.

(1) (a) Applicability.

The provisions of this standard are applicable to Nuclear Magnetic Resonance Imaging manufactured after August 14, 1984.

(b) Definitions –

(1) 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

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spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information). Nuclear Magnetic Imaging devices are used in the healing arts.

(2) RF shielded room means the room in which the Magnet, sub-assemblies and patient couch of Nuclear Magnetic Imaging device is installed and operated in.

(3) Door means the movable barrier which prevents access to the shielded room during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the shielded room.

(4) Safety interlock(s) means a device(s), system(s) or peripherals which is intended to prevent generation of microwave energy when access to the shielded room to prevent the generation of microwave energy to the human body that exceeds power, SAR limits or other conditions outside the normal safe operating of the Nuclear Magnetic Resonance Imaging system.

(5) Service adjustments or service procedures means those servicing methods prescribed by the manufacturer for a specific product model.

(7) External surface means the outside surface of the shielded room, surface of the magnet, patient couch, cabinets or enclosures in the shielded room provided by the manufacturer as part of the Nuclear Magnetic Resonance Imaging system.

(8) Industrial, scientific, and medical (ISM) equipment. Equipment or appliances designed to generate and use locally RF energy for industrial, scientific, medical, domestic or similar purposes, excluding applications in the field of telecommunication. Typical ISM applications are the production of physical, biological, or chemical effects such as heating, ionization of gases, mechanical vibrations, hair removal and acceleration of charged particles.

(9) Scan increment means the amount of relative placement/displacement of the patient with respect to the Nuclear Magnetic Imaging device between successive scans measured along the direction of such placement/displacement.

(10) Scan sequence means a preselected set of two or more scans performed consecutively under preselected Nuclear Magnetic Resonance Imaging conditions of operations.

(11) Radio frequency (RF) energy. Electromagnetic energy at any frequency in the radio spectrum from 9 kHz to 3 tHz (3,000 gHz).

(12) RF Amplifier is defined as Radio frequency amplifier that produces RF electrical energy at any frequency from 9 kHz to3 tHz (3.000 gHz).

(13) RF coils are defined as coils that receive electromagnetic energy at any radio frequency in the spectrum from 9 kHz to 3 tHz (3,000 gHz).

(14) RF Processing is defined as any devices or peripherals that produces a radio frequency signal in the spectrum from 9 kHz to 3 tHz (3,000 gHz) supplied to the RF amplifier.

(15) Specific Absorption Rates SARS is defined as the mass normalized rate at which RF electromagnetic energy is coupled to all biological tissue and is indicated in units of watts per

kilogram (W/kg). The relative amount of RF radiation that an individual encounters during an MR procedure is designated as the whole-body-averaged SAR.

(c) Requirements –

(1) Power density limit. A means shall be provided to measure the power density limits, measured in watts, in the RF Processing and RF Amplification of RF electrical energy at its maximum limit for all transmitting coils matching the magnetic static field multiplied by the gyromagnetic ratio for RF energy transmission for a proper calculation of the Specific Absorption Rate of the transmitting coil.

(2) Safety interlocks:

(i) The shielded room housing the Nuclear Magnetic Resonance Imaging system shall have a minimum of two operative safety interlocks. At least one operative safety interlock on a fully assembled Nuclear Magnetic Resonance Imaging system shielded room shall not be operable by any part of the human body, or any object with a straight insertable length of 10 centimeters. Such interlock must also be concealed, unless its actuation is prevented when access to the interlock is possible. Any visible actuator or device to prevent actuation of this safety interlock must not be removable without disassembly of the Nuclear Magnetic Resonance Imaging system or its door.

(ii) Failure of any single mechanical or electrical component of the Nuclear Magnetic Resonance Imaging system shall not cause all safety interlocks to be inoperative.

(iii) Service adjustments or service procedures on the Nuclear Magnetic Resonance Imaging system shall not cause the safety interlocks to become inoperative or the microwave radiation emission to exceed the power density limits of this section as a result of such service adjustments or procedures.

(iv) Microwave radiation emission in excess of the limits specified in paragraph (c)(1) of this section shall not be caused by insertion of an insulated wire through any opening in the external surfaces of a fully assembled Nuclear Magnetic Resonance Imaging system into the shielded room, waveguide, or other microwave-energy-containing spaces while the door is closed, provided the wire, when inserted, could consist of two straight segments forming an obtuse angle of not less than 170 degrees.

(v) A means of monitoring one or both of the required safety interlocks shall be provided which shall cause the Nuclear Magnetic Resonance Imaging system to become inoperable and remain so until repaired if the required safety interlock(s) should fail to perform required functions as specified in this section. Interlock failures shall not disrupt the monitoring function.

(vi) A Means shall be provided so that the operator can terminate the RF energy exposure at any time during a scan, or series of scans under the RF system control, of greater than one-half second duration. Termination of the RF energy exposure shall necessitate resetting of the Nuclear Magnetic Resonance Imaging system conditions of operation prior to the initiation of another scan.

(3) Measurement and test conditions.

(i) A means shall be provided for measuring and testing:

(a) Signal-to-Noise Ratio - all volume coils provided with the system

(b) Geometric Distortion - body coil

(c) Image Uniformity - all volume coils provided with the system

(d) Slice Profile/Thickness/Spacing - body coil

(e) Characterization of Special Purpose Coils - all coils designed with spatially dependent sensitivity

(ii) A means shall be provided to test the system high contrast spatial resolution using the body coil, spin echo sequence and suitable phantom. This test shall demonstrate that the spatial resolution is limited by the pixel size.

(iii) A means shall be provided to measure and test the RF amplifier of a Nuclear Magnetic Resonance Imaging system, operating at its maximum output, with relationship to all transmitting RF coil(s). Measurements shall be made on the RF transmitting coil(s) of a Nuclear Magnetic Resonance Imaging system, operating at its maximum output.

(iv) A means shall be provided to measure and test the shielded door fully closed as well as with the door fixed in any other position which allows the Nuclear Magnetic Resonance Imaging system to operate. Measurements shall be made with the proper matching impedance, attenuation and wattage of the testing load in relationship to the transmitting RF coil(s).

(4) Scan increment accuracy. The deviation of indicated scan increment from actual scan increment may not exceed 1 millimeter. Compliance shall be measured as follows: The determination of the deviation of indicated versus actual scan increment shall be based on measurements taken with a mass 100 kilograms or less, on the patient support device. The patient support device shall be incremented from a typical starting position to the maximum incrementation distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

(5) User instructions. Manufacturers of Nuclear Magnetic Resonance Imaging system to which this section is applicable shall provide, or cause to be provided, with each Nuclear Magnetic Resonance Imaging system, radiation safety instructions which:

(i) Occupy a separate section and are an integral part of the regularly supplied users' manual, and are located so as to elicit the attention of the reader.

(ii) Are as legible and durable as other instructions with the title emphasized to elicit the attention of the reader by such means as bold-faced type, contrasting color, a heavy-lined border, or by similar means.

(iii) Contain the following wording:

this section for a properly functioning system of the same model. The representative images shall be of two forms as follows:

(iv) Photographic copies of the images obtained from the image display device.

(10) A means shall be provided to display and preserve image testing data stored in digital form on a storage medium compatible with the Nuclear Magnetic Resonance Imaging systems on the image display device.

f) Control and indication of conditions of operation

(1) Visual indication. The Nuclear Magnetic Resonance Imaging systems conditions of operation to be used during a scan or a scan sequence shall be indicated prior to initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of the Nuclear Magnetic Resonance Imaging systems conditions of operation shall be visible from any position from which scan initiation is possible.

(13) Timers. (i) Means shall be provided to terminate the RF exposure automatically by either deenergizing the RF source or shuttering the RF beam in the event of equipment failure affecting data collection. A visible signal shall indicate when the RF exposure has been terminated through these means and manual resetting of the Nuclear Magnetic Resonance Imaging systems conditions of operation shall be required prior to the initiation of another scan.

(ii) Means shall be provided so that the operator can terminate the RF exposure at any time during a scan, or series of scans under RF system control, of greater than one-half second duration. Termination of the RF exposure shall necessitate resetting of the Nuclear Magnetic Resonance Imaging systems conditions of operation prior to the initiation of another scan.

(14) A means shall be provided to test and measure the method for the calculation of SARS measurement and values.

(iv) Include additional radiation safety precautions or instructions which may be necessary for particular Nuclear Magnetic Resonance Imaging system designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(15) Service instructions. Manufacturers of Nuclear Magnetic Resonance Imaging systems to which this section is applicable shall provide or cause to be provided to servicing dealers and distributors and to others upon request, for each Nuclear Magnetic Resonance Imaging system model, adequate instructions for service adjustments and service procedures, and, in addition, radiation safety instructions which:

(i) Occupy a separate section and are an integral part of the regularly supplied service manual and are located so as to elicit the attention of the reader.

(ii) Are as legible and durable as other instructions with the title emphasized so as to elicit the attention of the reader by such means as bold-faced type, contrasting color, a heavy-lined border, or by similar means.

(iii) Contain the following wording:

Precautions To Be Observed Before And During Servicing To Avoid Possible Exposure To Excessive Microwave Energy

(a) Do not operate or allow the Nuclear Magnetic Resonance Imaging system to be operated with the RF shielded door open.

(b) Make the following safety checks on all Nuclear Magnetic Resonance Imaging systems to be serviced before activating the RF system or other microwave sources, and make repairs as necessary: (1) Interlock operation, (2) proper door closing, (3) seal and sealing surfaces (arcing, wear, and other damage), (4) damage to or loosening of hinges and latches, (5) evidence of abuse.

(c) Before turning on RF power for any service test or inspection within the microwave generating compartments, check the Nuclear Magnetic Resonance Imaging system static conditions.

(d) Any defective or misadjusted components in the interlock, monitor, door seal, and microwave generation and transmission systems shall be repaired, replaced, or adjusted by procedures described in this manual before the Nuclear Magnetic Resonance Imaging system is released to the owner.

(iv) Include additional radiation safety precautions or instructions which may be necessary for particular Nuclear Magnetic Resonance Imaging system designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(16) Warning labels. Except as provided in paragraph (c)(6)(iv) of this section, microwave Nuclear Magnetic Resonance Imaging systems shall have the following warning labels:

(i) A label, permanently attached to or inscribed on the Nuclear Magnetic Resonance Imaging system, which shall be legible and readily viewable during normal Nuclear Magnetic Resonance Imaging system use, and which shall have the title emphasized and be so located as to elicit the attention of the user. The label shall bear the following warning statement:

Precautions For Safe Use To Avoid Possible Exposure To Excessive Microwave Energy

DO NOT Attempt to Operate This Nuclear Magnetic Resonance Imaging system With:

(a) Object Caught in Door.

(b) Door That Does Not Close Properly.

(c) Damaged Door, Hinge, Latch, or Sealing Surface.

(ii) A label, permanently attached to or inscribed on the external surface of the Nuclear Magnetic Resonance Imaging system, which shall be legible and readily viewable during servicing, and

which shall have the word "CAUTION" emphasized and be so located as to elicit the attention of service personnel. The label shall bear the following warning statement:

(iii) The labels provided in accordance with paragraphs (c)(6)(i) and (ii) of this section shall bear only the statements specified in that paragraph, except for additional radiation safety warnings or instructions which may be necessary for particular Nuclear Magnetic Resonance Imaging system designs or models, as determined by the Director, Center for Devices and Radiological Health or the manufacturer.

(iv) Upon application by a manufacturer, the Director, Center for Devices and Radiological Health, Food and Drug Administration, may grant an exemption from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such exemption shall be based upon a determination by the Director that the microwave Nuclear Magnetic Resonance Imaging system model for which the exemption is sought should continue to comply with paragraphs (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). An original and two copies of applications shall be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

(a) The specific microwave Nuclear Magnetic Resonance Imaging system model(s) for which the exemption is sought.

(b) The specific radiation safety warning(s) from which exemption is sought.

(c) Data and information which clearly establish that one or more of the radiation safety warnings in paragraph (c)(6)(i) of this section is not necessary for the specified microwave Nuclear Magnetic Resonance Imaging system model(s).

(d) Such other information and a sample of the applicable product if required by regulation or by the Director, Center for Devices and Radiological Health, to evaluate and act on the application.

B. Statement of grounds

The health effects of microwave energy on the human body are well known and documented. The regulatory control of microwave energy for Nuclear Magnetic Resonance Imaging systems is the responsibility of the Food and Drug Administration, see 47 CFR part 18.

To date there are no performance standards for Nuclear Magnetic Resonance Imaging systems in 21CFR. 21CFR has a section for microwave energy devices, section 1030 which currently regulates the performance standards for microwave ovens only.

C. Environmental impact

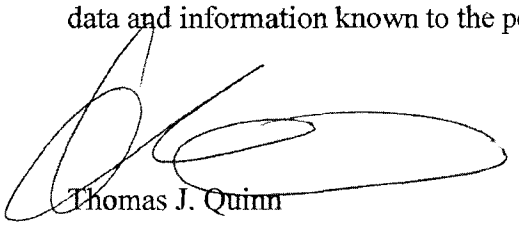
(A) No known environmental impact

D. Economic impact

No known economic impact.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.



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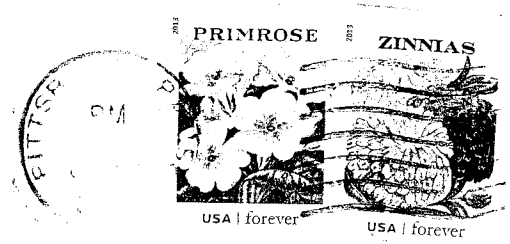

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