ORIGINAL

THELEN, MARRIN, JOHNSON & BRIDGES
ATTORNEYS AT LAW
805 15TH STREET, N.W.
WASHINGTON, D.C. 20005-2207
(202) 962-3000
FAX (202) 842-0830

SAN FRANCISCO
OAKLAND
ORANGE COUNTY
SAN JOSE

LOS ANGELES
HOUSTON
HONG KONG
NEW YORK

Direct Dial No.
(202) 962-3060

RECEIVED

JAN 2 9 1992

Federal Communications Commission
Office of the Secretary

January 29, 1992

Ms. Donna Searcy
Secretary
Federal Communications Commission
1919 M Street, NW, Room 222
Washington,DC 20554

Re: Amendment of Section 18.121
of the Commission's Rules

Dear Ms. Searcy:

Enclosed please find the original and nine copies of the Petition for Rulemaking of the Magnetic Resonance Section of the National Electrical Manufacturers Association in the above-referenced proceeding.

Should there be any questions, please do not hesitate to contact the undersigned.

Yours very sincerely,

Lawrence J. Movshin

LJM/att
Enclosures
cc (w/enc.): Dr. Thomas Stanley
Mr. Robert L. Cutts
Mr. Julius Knapp
Mr. David Means
Mr. L. Art Wall
Mr. Richard Engelmann

No. of Copies rec'd 0+9
List A B C D E

RECEIVED

JAN 2 9 1992

Federal Communications Commission
Office of the Secretary

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20054

In the Matter of	)	
	)	
Amendment of § 18.121 of the	)	
Commission's Rules to Exempt	)	RM No. _____
Non-consumer Magnetic	)	
Resonance Diagnostic Systems	)	
From The Technical Standards	)	
and the Reporting Requirements	)	
of the Commission's Rules	)	

TO: THE COMMISSION

PETITION FOR RULEMAKING
OF THE MAGNETIC RESONANCE SECTION
OF THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

Dale R. Schmidt
Counsel

NATIONAL ELECTRICAL
MANUFACTURERS ASSOCIATION
2101 L Street, N.W.
Suite 300
Washington, D.C. 20037
(202) 457-1973

By: Lawrence J. Movshin, Esq.
Robert L. Hoggarth, Esq.

THELEN, MARRIN, JOHNSON & BRIDGES

805 15th Street, N.W.
Suite 900
Washington, D.C. 20005
(202) 962-3000

Its Attorneys

January 29, 1992

TABLE OF CONTENTS

	Page
SUMMARY	i
INTRODUCTION	2
I. Description of Magnetic Resonance Diagnostic Systems	3
II. Non-consumer MR Diagnostic Systems Pose No Threat Interference To Authorized Telecommunication Services	6
III. The Commission Should Exempt Non-consumer Medical Magnetic Resonance Diagnostic Systems From the Administrative Requirements of Part 18.	10
CONCLUSION	14
APPENDIX A: NEMA MEMBERS	

13451

SUMMARY

The Magnetic Resonance Section of the National Electrical Manufacturers Association ("NEMA") hereby petitions the Commission to initiate a rulemaking to exempt non-consumer medical magnetic resonance ("MR") diagnostic systems from the technical standards and record keeping requirements of Part 18 of the Commission's rules. Such an exemption, through amendments to Sections 18.107 and 18.121 of the Commission's Rules would remove burdensome regulations from MR manufacturers who currently face the ambiguities of compliance with complex regulatory testing and record keeping requirements.

Given the nature and use of MR technology, compliance with these requirements is clearly unnecessary for the protection from interference of other spectrum users. The design, installation, and sensitivity of performance of MR devices already provides ample assurance of non-interference with authorized telecommunication services, without imposing requirements for potentially costly, difficult testing to verify compliance with Part 18 specifications. Moreover, the use of MR systems is confined to discrete areas in hospitals and other medical facilities where authorized telecommunication services are not likely to be found, and where discrete shielding and protective designs are already imposed.

13451

There have been no recorded interference complaints related to MR devices, demonstrating the ability of the industry to design products to high standards of performance without FCC imposed constraints. Moreover, the Food and Drug Administration has established an extensive regulatory framework which already polices the manufacture and operation of MR systems. The same factors that convinced the Commission to exempt non-consumer ultrasonic ISM equipment apply equally to non-consumer MR diagnostic systems, and therefore a similar exemption should be provided in the rules.

RECEIVED

JAN 2 9 1992

Federal Communications Commission
Office of the Secretary

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20054

In the Matter of	)	
	)	
Amendment of § 18.121 of the	)	
Commission's Rules to Exempt	)	RM No. _____
Non-consumer Magnetic	)	
Resonance Diagnostic Systems	)	
From The Technical Standards	)	
and the Reporting Requirements	)	
of the Commission's Rules	)	

TO: THE COMMISSION

PETITION FOR RULEMAKING
OF THE MAGNETIC RESONANCE SECTION
OF THE NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION

Dale R. Schmidt
Counsel

NATIONAL ELECTRICAL
MANUFACTURERS ASSOCIATION
2101 L Street, N.W.
Suite 300
Washington, D.C. 20037
(202) 457-1973

By: Lawrence J. Movshin, Esq.
Robert L. Hoggarth, Esq.

THELEN, MARRIN, JOHNSON & BRIDGES

805 15th Street, N.W.
Suite 900
Washington, D.C. 20005
(202) 962-3000

Its Attorneys

January 29, 1992

SUMMARY

The Magnetic Resonance Section of the National Electrical Manufacturers Association ("NEMA") hereby petitions the Commission to initiate a rulemaking to exempt non-consumer medical magnetic resonance ("MR") diagnostic systems from the technical standards and record keeping requirements of Part 18 of the Commission's rules. Such an exemption, through amendments to Sections 18.107 and 18.121 of the Commission's Rules would remove burdensome regulations from MR manufacturers who currently face the ambiguities of compliance with complex regulatory testing and record keeping requirements.

Given the nature and use of MR technology, compliance with these requirements is clearly unnecessary for the protection from interference of other spectrum users. The design, installation, and sensitivity of performance of MR devices already provides ample assurance of non-interference with authorized telecommunication services, without imposing requirements for potentially costly, difficult testing to verify compliance with Part 18 specifications. Moreover, the use of MR systems is confined to discrete areas in hospitals and other medical facilities where authorized telecommunication services are not likely to be found, and where discrete shielding and protective designs are already imposed.

There have been no recorded interference complaints related to MR devices, demonstrating the ability of the industry to design products to high standards of performance without FCC imposed constraints. Moreover, the Food and Drug Administration has established an extensive regulatory framework which already polices the manufacture and operation of MR systems. The same factors that convinced the Commission to exempt non-consumer ultrasonic ISM equipment apply equally to non-consumer MR diagnostic systems, and therefore a similar exemption should be provided in the rules.

TABLE OF CONTENTS

	Page
SUMMARY	i
INTRODUCTION	2
I. Description of Magnetic Resonance Diagnostic Systems	3
II. Non-consumer MR Diagnostic Systems Pose No Threat Interference To Authorized Telecommunication Services	6
III. The Commission Should Exempt Non-consumer Medical Magnetic Resonance Diagnostic Systems From the Administrative Requirements of Part 18.	10
CONCLUSION	14
APPENDIX A: NEMA MEMBERS	

13451

Appendix A

The NEMA Magnetic Resonance Section member companies have voted, in accordance with the by-laws of NEMA, to submit this petition to the Commission. The Section Member Companies are:

ADVANCED NMR SYSTEMS, INC.	Wilmington, MA
BRUKER MEDICAL INSTRUMENTS, INC.	Bellerica, MA
ELSCINT, LTD.	Hackensack, NJ
GE MEDICAL SYSTEMS	Milwaukee, WI
HITACHI MEDICAL SYSTEMS AMERICA, INC.	Twinsburg, OH
PHILIPS MEDICAL SYSTEMS, INC.	Shelton, CT
PICKER INTERNATIONAL, INC.	Highland Heights, OH
RESONEX, INC.	Sunnyvale, CA
SIEMENS MEDICAL SYSTEMS, INC.	Iselin, NJ
TOSHIBA AMERICA MEDICAL SYSTEMS	South San Francisco, CA

Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20054

In the Matter of	)	
	)	
Amendment of § 18.121 of the	)	
Commission's Rules to Exempt	)	RM No. _____
Non-consumer Magnetic	)	
Resonance Diagnostic Systems	)	
From The Technical Standards	)	
and the Reporting Requirements	)	
of the Commission's Rules	)	

PETITION FOR RULEMAKING

The Magnetic Resonance Section of the National Electrical Manufacturers Association ("NEMA"),[1/] by its attorneys and pursuant to Commission Rule § 1.401 hereby requests the Commission to initiate rulemaking proceedings to amend Part 18 of the Rules by adding a definition in Section 18.107 for "Magnetic resonance diagnostic equipment", and by amending Section 18.121 to exempt non-consumer magnetic resonance (hereinafter "MR") diagnostic systems from the technical standards and administrative requirements of Part 18.

Amending Section 18.121 would remove burdensome regulations from MR manufacturers, who currently face the ambiguities of compliance with complex regulatory testing and record keeping requirements which are unnecessary in view of the nature and use of MR technology. As demonstrated below,

---

1/ The Magnetic Resonance Section member companies who have participated in the preparation of this petition are listed in Appendix A.

the design, installation, and sensitivity of performance of MR systems provide ample assurance of non-interference with authorized telecommunication services without requiring costly and difficult testing to verify compliance with Part 18 specifications. There have been no recorded complaints of interference with authorized telecommunications services related to MR devices and many of the factors which influenced the Commission to exempt non-consumer ultrasonic ISM equipment apply equally to MR devices.[2/]

INTRODUCTION

The first magnetic resonance ("MR") studies began over 40 years ago. MR was initially applied by physicists, and later by chemists, biologists and biochemists, to study molecular structure and interactions. MR systems have been operated at universities and in both private and government research laboratories for many years. Research into the use of MR for

---

2/ NEMA proposes amending Section 18.107 by adding a definition for magnetic resonance diagnostic equipment to read:

> *Magnetic resonance diagnostic equipment.* A category of ISM equipment in which the RF energy is used to create images and data representing spatially resolved density of transient atomic resonances within the human or animal body.

NEMA also proposes to amend 18.121 as follows:

> Non-consumer ultrasonic ISM equipment **and systems employing magnetic resonance diagnostic** equipment, as defined under Section 18.107, that are used for medical, diagnostic and monitoring applications ,

human diagnostic studies began in the 1970's; many MR systems are now in operation in medical facilities nationwide, and MR has become a critical element in medical diagnostic practice. Development of MR systems continues today closely monitored by the Food and Drug Administration ("FDA") under its charter to protect public safety.

The use of MR technology is most widely recognized in the medical application of magnetic resonance imaging ("MRI") devices in hospitals, and the uses of the technology continue to expand. MRI devices are used today to diagnose brain and spine conditions, monitor blood flow, detect and examine many forms of cancer and evaluate organs for transplant. MR diagnostic devices produce highly resolved and diagnostically useful thin slice images and data revealing the human internal anatomy and pathology.

I. Description of Magnetic Resonance Diagnostic Systems

The MRI procedure is quite simple. In a hospital or other medical diagnostic facility, the patient lies on an imaging bed positioned inside a large magnet. The region of medical interest -- the head, body organ, or extremity -- is positioned in the most uniform region of the magnetic field. Within the patient, a small percentage of atoms with gyromagnetic nuclei will align with the magnetic field of the magnet and will precess. Gradient coils, which are mounted between the magnet and the patient, are used to control the

localized magnetic field values around the patient and to code spatial position. Short (millisecond) pulses of radiofrequency energy from coils surrounding or adjacent to the body region under examination are used to align and synchronize the precession of resonating atoms in the patient. For a short time (less than a few seconds), while the resonant groups of atoms within the patient are synchronized in phase, and as they dephase, the sensitive radiofrequency coils surrounding or adjacent to the patient receive the minute radiofrequency energy signals. The signals are then amplified, digitized, processed, and transformed by a data processing system for reconstruction into images or data representing spatially resolved density of the transient atomic resonances within the patient's body.

Magnetic resonance diagnostic systems are composed of three major sections; a) the magnet and magnetic gradients, b) the spectrometer, and c) the data processing, control and display equipment. The magnets used for magnetic resonance diagnostic devices are designed to produce a uniform stable magnetic field. Magnet types include permanent, resistive (copper conductor electro magnet), and superconducting (liquid helium temperature). The magnetic gradient system and power supplies produce a controlled change of magnetic field within the uniform volume of the magnet. The magnetic gradient system is operated at audio frequencies and is not a potential source of radiofrequency emission.

The spectrometer is the acquisition system for the magnetic resonance diagnostic device. It is a series of analog and digital components designed to produce radiofrequency pulses and magnetic resonances in the patient. The spectrometer receives that RF signal generated within the patient as resonances decay due to dephasing. The signals collected are conditioned and digitized for reconstruction into images and data.

The spectrometer is generally located within an RF shielded enclosure, which is designed to shield the sensitive coils from external RF signals so that the very weak magnetic resonance emissions from the patient can be detected and analyzed. The MR system operates alternately in a transmit and receive mode during the time a patient is being examined. The RF shield provides an effective barrier on the outside of the enclosure to the RF emissions inside the enclosure during the transmit mode of operation. Since magnetic resonance depends upon detecting the minute signals generated by the precession of atoms within the patient's body, the patient and coil must be enclosed with shielding of 60 to 80 dB. This RF shielding is bi-directional, thus protecting not only the <u>internal</u> environment from <u>outside</u>-generated signals, but also protecting the <u>external</u> environment from the potential for interference from <u>internally</u>-generated RF emissions from the coil, tuning and matching circuits and other components that are within the shielding.

The remaining components of the spectrometer are rack mounted in metal cabinets which are situated outside of the RF enclosure. The components outside the RF enclosure are connected to the coils inside the RF enclosure by shielded cables which pass through penetration filters or wave guides built into the RF enclosure. The penetration filters or wave guides provide access to the RF enclosure for the cabling in a manner that preserves the integrity of the RF shielding.

Finally, the system includes a computer and array processor which controls the acquisition, analysis, and reconstruction of data into diagnostic images and spectra. These components are generally located outside of the RF enclosure, although they are also well shielded to prevent interference with the computer and array processor.

II. Non-consumer MR Diagnostic Systems Pose No Threat of Interference To Authorized Telecommunication Services

The Commission has consistently recognized that the primary intent of its Part 18 regulations is the protection of licensed communications services and facilities. Where it has been demonstrated that, by reason of the design or nature of anticipated use, the imposition of specific emission limits and compliance testing requirements is unnecessary to achieve this objective, the Commission has consistently exempted classes or types of products from such requirements. In such cases, the agency has instead relied on a generic non-interference requirement to meet its objectives. Most notably, for example,

in response to the comments of NEMA and others in 1985, the Commission in 1986 (in Docket 85-303) exempted non-consumer medical ultrasonic diagnostic and monitoring equipment from the technical standards and certain administrative requirements of Part 18. In that case, the agency concluded that the absence of interference complaints, the controlled medical environment in which such devices were typically found, and the existence of comprehensive health and safety regulations otherwise imposed on such devices, demonstrated that the public interest would be served by such an exemption. The agency also noted that the exemption would enhance the benefits to be derived by society from the application of ultrasonics in the field of medicine by reducing the design and marketing costs of such monitoring and diagnostic equipment.

For virtually identical reasons, a similar exemption is warranted for MR diagnostic devices. MR diagnostic systems are non-consumer devices that are primarily located in the RF-noise controlled environment of hospitals and medical clinics, where potential emissions of the system are not likely to create harmful interference to the operation of authorized telecommunication services. As a general matter receivers associated with such services are not likely to be found in the vicinity of MR devices. Furthermore, hospitals and clinics are typically constructed of reinforced concrete and steel according to building codes, which provide an additional, significant level of shielding from MR diagnostic and other

medical devices to authorized telecommunication services. These factors were the primary bases for the Commission's decision to exempt medical computing devices from compliance of Subpart J of Part 15 [Section 15.103(e)] and medical diagnostic ultrasonic ISM equipment from the technical and administrative requirements of Part 18 (Section 18.121).

The argument is no less compelling in the case of MR diagnostic equipment. As noted above, the MR device's operation is dependent on the spectrometer's ability to read very weak radio signals. As a result, such devices must be carefully shielded to prevent any electrical interference from outside sources and the leakage of the system's own emissions. Thus, the physical design of the typical MR diagnostic system is "self-protecting", both in avoiding outside interference sources and in keeping any radiated emission internal to the system.

Moreover, MR devices are comprehensively regulated from a health and safety standpoint by the FDA which regulates radiofrequency levels produced by MR devices. MR diagnostic devices are regulated by the FDA Center for Devices and Radiological Health as a Class II device. See 21 C.F.R. Section 892.1000(a). MR system manufacturers are required by the FDA to meet good manufacturing practices and are subject to FDA inspection. See 21 C.F.R. Section 820 et. seq. Under the FDA regulatory process, each manufacturer must maintain a product locator file. Each manufacturer must also maintain

records that include the installed location of every MR device manufactured by the company. Thus, in the unlikely case that corrective action to the design or any part of the system should become necessary, an MR system is easily located. Additionally, the FDA imposes labeling requirements on MR manufacturers which include recommending maintenance schedules to MR operators.

The FDA has provided guidelines for medical patient safety relative to emanations produced by MR devices and other medical equipment. Products that produce emanations that exceed the guidelines must provide specific proof of safety to the FDA. As a result, the system designer is necessarily sensitized to RF suppression techniques.

There are other factors generic to the design and manufacture of MR devices that warrant favorable consideration of an exemption from comprehensive regulation. For example, extensive preventive maintenance schedules are imposed on the installation and operation of such devices. MR Diagnostic systems receive frequent and periodic inspections and maintenance to insure proper operation and prevent downtime that can be very costly to MR diagnostic device owners. FDA requirements for labeling of MR systems require MR manufacturers to recommend a maintenance schedule in the instructions provided to all MR system operators. Regular maintenance and servicing of MR systems helps identify any potential problems before they become serious.

MR manufacturers are also required by the FDA to provide instructions and means for the MR system operator to perform periodic quality assurance tests to check MR system performance. Because MR systems are so highly susceptible to outside interference and any reduction in RF or EMI shielding seriously reduces the performance of the system, deterioration of RF or EMI shielding at an MR site is usually first detected as a degradation of the system performance. It is thus unlikely to become so serious as to pose a threat of objectionable interference to other spectrum users.

III. The Commission Should Exempt Non-consumer Medical Magnetic Resonance Diagnostic Systems From the Administrative Requirements of Part 18

Absent an exemption, the burden of compliance with the technical and administrative requirements of the rules can be enormous. By virtue of their size, weight, shielding and power requirements, MR systems are operable only in specially prepared locations. This makes traditional open field testing of MR systems and compliance with Section 18.311 of the Rules totally impractical. Simply to replicate the power and shielding requirements of a particular location -- appropriate to simulating the use of the device in a "typical" configuration -- would be very costly in capital expenditures and, no less costly, require many hours of installation and preparation time prior to the testing. Moreover, testing in factory locations where the MR systems are manufactured is not

sufficiently representative of how the MR system will perform after installation with RF shielding at the operating site.[3/] While the general emanation characteristics of the product can be determined in the laboratory, the only relevant test facility which can be used, as a practical matter, for verification testing mandated by the agency's regulations is the installed user site.

However, as the Commission has learned in considering the applicability of design regulations to other types of medical diagnostic equipment (and the experience of MR manufacturers confirms) medical facility environments are not conducive to RF interference testing; indeed, this high/tech environment makes verification testing of a particular device nearly impossible. In order to make meaningful measurements in the ambient environment, it is necessary to eliminate other potential sources of RF interference. However, in a patient care facility, many RF radiating devices cannot be taken out of service (without endangering patient well being) to perform RF interference tests. Thus, unless the MR system is sufficiently

---

3/ Limitations in manufacturing plants such as the availability of space and the ambient levels often make it infeasible to conduct laboratory test at the point of manufacture without extensive and costly modifications to facilities as well as lengthened production cycles which result in increased product costs. For example, for manufacturer testing, floor space can cost as much as $10-60 per square foot. Since MR systems are quite large, a test site could require 50,000 square feet of space.

remote from patient care areas, meaningful tests are nearly impossible.

Moreover, even in those unusual circumstances where on-site testing is possible, the uniqueness of the facility, complexity of the equipment, and different configurations of room layout typically make any results that are obtained unique to the one installation; such results cannot reasonably be relied on to characterize for verification testing purposes the emanation profile of the system in a different environment. Since the rules arguably require such assurance, user site testing of such MRI systems could be required in each installation. This is an economic burden of immense proportions.

NEMA member's experienced in compliance testing estimate that the costs of verification of MR systems can range from $10,000 to $100,000 per MR system. This is due, in part, to the complexity of the systems and the difficulty in performing such tests. In addition, the low product volume of individual models and the variations between installations markedly affects the costs that are ultimately passed on to the purchaser of each MR system. Quite clearly, requiring verification testing imposes an enormous burden on the industry.

In the face of this burden, is there any public benefit to maintaining these requirements on MR systems? The answer is clearly no. NEMA is not aware of any complaint of objectionable interference which has been lodged against an MR

system. Given the design of such systems, with their highly integrated shielding techniques, it is highly unlikely that such objectionable interference would occur. Indeed, the MR system is far more likely to be susceptible to, rather than the creator of, such interference.

Operating in the medical environment, highly regulated for safety characteristics by the FDA, and so sensitized to the issue of interference for its own integrity, the MR system designer has every incentive to assure that RF emissions are well controlled. Imposing specific regulations -- and even more burdensome testing and reporting requirements -- does not create or heighten that sensitivity. Instead, it substantially burdens the manufacturer with difficult, time consuming and costly burdens, without in any way improving the already non-hostile radiofrequency environment for these devices. As the Commission noted in exempting ultrasonic devices, the cost and time savings that result from such an exemption can be better invested in the research, development and distribution of these devices which have become such an important part of our healthcare industry.

CONCLUSION

In view of the foregoing, the Magnetic Resonance section of the National Electrical Manufacturers Association hereby requests that the Commission initiate a rulemaking proceeding to amend Sections 18.107 and 18.121 of the Commission's Rules by creating an additional exemption to its technical and

administrative requirements for non-consumer Magnetic Resonance Diagnostic Systems.

Dale R. Schmidt
Counsel

NATIONAL ELECTRICAL
MANUFACTURERS ASSOCIATION
2101 L Street, N.W.
Suite 300
Washington, D.C. 20037
(202) 457-1973

By: Lawrence J. Movshin, Esq.
Robert L. Hoggarth, Esq.

THELEN, MARRIN, JOHNSON & BRIDGES

805 15th Street, N.W.
Suite 900
Washington, D.C. 20005
(202) 962-3000

Its Attorneys

January 29, 1992

Appendix A

The NEMA Magnetic Resonance Section member companies have voted, in accordance with the by-laws of NEMA, to submit this petition to the Commission. The Section Member Companies are:

ADVANCED NMR SYSTEMS, INC.	Wilmington, MA
BRUKER MEDICAL INSTRUMENTS, INC.	Bellerica, MA
ELSCINT, LTD.	Hackensack, NJ
GE MEDICAL SYSTEMS	Milwaukee, WI
HITACHI MEDICAL SYSTEMS AMERICA, INC.	Twinsburg, OH
PHILIPS MEDICAL SYSTEMS, INC.	Shelton, CT
PICKER INTERNATIONAL, INC.	Highland Heights, OH
RESONEX, INC.	Sunnyvale, CA
SIEMENS MEDICAL SYSTEMS, INC.	Iselin, NJ
TOSHIBA AMERICA MEDICAL SYSTEMS	South San Francisco, CA