June 18, 1999

Ms. Magalie Roman Salas, Secretary
Federal Communications Commission
The Portals, TW-A325
445 12th Street, S.W.
Washington, DC 20554

Re: Ex Parte Presentation
WT Docket 99-66 – Medical Implant Communications Service

Dear Ms. Salas:

We are writing to address the matter of the Commission's proposal to exempt from routine RF exposure evaluation the transmitters that would be used in medical implant devices to be authorized under the rules proposed in WT Docket 99-66. As the record in this proceeding will reflect, we have presented differing points of view on the need for the routine submittal of a showing in support of compliance with the RF exposure guidelines prior to the issuance of a grant of equipment authorization for medical implant transmitters.

After Medtronic had filed its position on the issue, we discussed this matter. The ensuing conversation centered around antenna technologies that could be used on medical implants and how each technology could influence RF exposure of the patient. Although Medtronic has posited a system for which the finite difference time domain (FDTD) modeling conducted by Medtronic shows a substantial margin of compliance, the Medtronic approach may not be the only one employed for medical implant transmitters. A different technology, such as an electrically short antenna, can have strong localized reactive fields. It was also recognized that other manufacturers will develop their own designs and that other technologies could potentially cause SAR levels at or near the current limits. In view of the discussion, we have reached a consensus that it would be appropriate, due to the potential impact of differing technologies on RF exposure, for the Commission to require routine filing of an FDTD computational modeling report with each application for certification of a medical implant transmitter. Filing of this type of report will provide additional assurance that the patient's health and safety are protected and will serve to provide a "yardstick" for determination of the need for the Commission to exercise its authority to require actual SAR measurements. To this end, we are attaching recommended revisions to Section 1.1307 of the Commission's rules and to Section 95.603 of the proposed rules.

We hope that this joint submittal will help to clarify the record in this proceeding and assist the Commission as it works to conclude this rule making.

Respectfully,

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Enclosure
cc: Mr. Eugene Thomson (FCC/WTB) (w/ encl.)

Proposed Revisions to Section 1.1307 of the FCC Rules

Revised language is shown in **bold underlined** text.

§1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

(a) Commission actions with respect to the following types of facilities may significantly affect the environment and thus require the preparation of EAs by the applicant (see §§1.1308 and 1.1311) and may require further Commission environmental processing (see §§1.1314, 1.1315 and 1.1317):

(1) Facilities that are to be located in an officially designated wilderness area.

(2) Facilities that are to be located in an officially designated wildlife preserve.

(3) Facilities that: (i) May affect listed threatened or endangered species or designated critical habitats; or (ii) are likely to jeopardize the continued existence of any proposed endangered or threatened species or likely to result in the destruction or adverse modification of proposed critical habitats, as determined by the Secretary of the Interior pursuant to the Endangered Species Act of 1973.

NOTE:
The list of endangered and threatened species is contained in 50 CFR 17.11, 17.22, 222.23(a) and 227.4. The list of designated critical habitats is contained in 50 CFR 17.95, 17.96 and Part 226. To ascertain the status of proposed species and habitats, inquiries also may be directed to the Regional Director of the Fish and Wildlife Service, Department of the Interior.

(4) Facilities that may affect districts, sites, buildings, structures or objects, significant in American history, architecture, archeology, engineering or culture, that are listed, or are eligible for listing, in the National Register of Historic Places. (See 16 USC 470w(5); 36 CFR Parts 60 and 800.)

NOTE:
The National Register is updated and republished in the Federal Register each year in February. To ascertain whether a proposal affects an historical property of national significance, inquiries also may be made to the appropriate State Historic Preservation Officer, see 16 USC 470s(b); 36 CFR Parts 63 and 800.

(5) Facilities that may affect Indian religious sites.

(6) Facilities to be located in a flood plain. (See Executive Order 11988.)

(7) Facilities whose construction will involve significant change in surface features (e.g., wetland fill, deforestation or water diversion). (In the case of wetlands on Federal property, see Executive Order 11990.)

(8) Antenna towers and/or supporting structures that are to be equipped with high intensity white lights which are to be located in residential neighborhoods as defined by the applicable zoning law.

(b) In addition to the actions listed in paragraph (a) of this section, Commission actions granting construction permits, licenses to transmit or renewals thereof, equipment authorizations or modifications in existing facilities, require the preparation of an Environmental Assessment (EA) if the particular facility, operation or transmitter would cause human exposure to levels of radiofrequency radiation in excess of the limits in §§1.1310 and 2.1093 of this chapter. Applications to the Commission for construction permits, licenses to transmit or renewals thereof, equipment authorizations or modifications in existing facilities

must contain a statement confirming compliance with the limits unless the facility, operation, or transmitter is categorically excluded, as discussed below. Technical information showing the basis for this statement must be submitted to the Commission upon request.

(1) [See Bulletin OET 65 and 65A] The appropriate exposure limits in §1.1310 and §2.1093 of this chapter are generally applicable to all facilities, operations and transmitters regulated by the Commission. However, a determination of compliance with the exposure limits in §1.1310 or §2.1093 of this chapter (routine environmental evaluation), and preparation of an EA if the limits are exceeded, is necessary only for facilities, operations and transmitters that fall into the categories listed in Table 1, or those specified in paragraph (b)(2) of this section. All other facilities, operations and transmitters are categorically excluded from making such studies or preparing an EA, except as indicated in paragraphs (c) and (d) of this section. For purposes of Table 1, "building-mounted antennas" means antennas mounted in or on a building structure that is occupied as a workplace or residence. The term "power" in column 2 of Table 1 refers to total operating power of the transmitting operation in question in terms of effective radiated power (ERP), equivalent isotropically radiated power (EIRP), or peak envelope power (PEP), as defined in §2.1 of this chapter. For the case of the Cellular Radiotelephone Service, Subpart H of Part 22 of this chapter; the Personal Communications Service, Part 24 of this chapter and the Specialized Mobile Radio Service, Part 90 of this chapter, the phrase "total power of all channels" in column 2 of Table 1 means the sum of the ERP or EIRP of all co-located simultaneously operating transmitters owned and operated by a single licensee. When applying the criteria of Table 1, radiation in all directions should be considered. For the case of transmitting facilities using sectorized transmitting antennas, applicants and licensees should apply the criteria to all transmitting channels in a given sector, noting that for a highly directional antenna there is relatively little contribution to ERP or EIRP summation for other directions.

Table 1. - Transmitters, Facilities and Operations Subject to Routine Environmental Evaluation

Experimental Radio Services (Part 5)	Power > 100 W ERP (164 W EIRP)
Multipoint Distribution Service (Subpart K of Part 21)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1640 W EIRP Building-mounted antennas: power > 1640 W EIRP MDS licensees are required to attach a label to subscriber transceiver or transverter antennas that: (1) provides adequate notice regarding potential radiofrequency safety hazards, e.g., information regarding the safe minimum separation distance required between users and transceiver antennas; and (2) references the applicable FCC-adopted limits for radiofrequency exposure specified in §1.1310.
Paging and Radiotelephone Service (Subpart E of Part 22)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1000 W ERP (1640 W EIRP) Building-mounted antennas: power > 1000 W ERP (1640 W EIRP)
Cellular Radiotelephone Service (Subpart H of Part 22)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 1000 W ERP (1640 W EIRP) Building-mounted antennas: total power of channels > 1000 W ERP (1640 W EIRP)

Personal Communications	(1) Narrowband PCS (Subpart D): Services (Part 24)non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 1000 W ERP (1640 W EIRP) Building-mounted antennas: total power of all channels > 1000 W ERP (1640 W EIRP) (2) Broadband PCS (Subpart E): non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 2000 W ERP (3280 W EIRP) Building-mounted antennas: total power of all channels > 2000 W ERP (3280 W EIRP)
Satellite Communications (Part 25)	All included
General Wireless Communications Service (Part 26)	Total power of all channels > 1640 W EIRP
Wireless Communications Service (Part 27)	Total power of all channels > 1640 W EIRP
Radio Broadcast Services (Part 73)	All included
Experimental, auxiliary, and special broadcast and other program distributional services (Part 74)	Subparts A, G, L: power > 100 W ERP Subpart I: non-building-mounted antennas: height aboveground level to lowest point of antenna < 10 m and power > 1640 W EIRP Building-mounted antennas: power > 1640 W EIRP ITFS licensees are required to attach a label to subscriber transceiver or transverter antennas that: (1) provides adequate notice regarding potential radiofrequency safety hazards, e.g., information regarding the safe minimum separation distance required between users and transceiver antennas; and (2) references the applicable FCC-adopted limits for radiofrequency exposure specified in §1.1310.
Stations in the Maritime Services (Part 80)	Ship earth stations only
Private Land Mobile Radio Services Paging Operations (Part 90)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1000 W ERP (1640 W EIRP) Building-mounted antennas: power > 1000 W ERP (1640 W EIRP)
Private Land Mobile Radio Services Specialized Mobile Radio (Part 90)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 1000 W ERP

	(1640 W EIRP)
	Building-mounted antennas: Total power of all channels > 1000 W ERP (1640 W EIRP)
Amateur Radio Service (Part 97)	Transmitter output power > levels specified in §97.13(c)(1) of this chapter
Local Multipoint Distribution Service (Subpart L of Part 101)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1640 W EIRP
	Building-mounted antennas: power > 1640 W EIRP LMDS licensees are required to attach a label to subscriber transceiver antennas that: (1) provides adequate notice regarding potential radiofrequency safety hazards, e.g., information regarding the safe minimum separation distance required between users and transceiver antennas; and (2) references the applicable FCC-adopted limits for radiofrequency exposure specified in §1.1310 of this chapter

(2) Mobile and portable transmitting devices that operate in the Cellular Radiotelephone Service, the Personal Communications Services (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services (ship earth stations only) and the Specialized Mobile Radio Service authorized under Subpart H of Parts 22, 24, 25, 26, 27, 80, and 90 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§2.1091 and 2.1093 of this chapter. Unlicensed PCS, unlicensed NII and millimeter wave devices are also subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§15.253(f), 15.255(g), and 15.319(i) and 15.407(f) of this chapter. **Equipment authorized for use in the Medical Implant Communications Service (MICS) as a medical implant transmitter (as defined in Appendix I to Subpart E of Part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in §2.1093 of this chapter by finite difference time domain computational modeling or laboratory measurement techniques. Where a showing is based on computational modeling, the Commission retains the discretion to request that specific absorption rate measurement data be submitted.** All other mobile, portable, and unlicensed transmitting devices are categorically excluded from routine environmental evaluation for RF exposure under §§2.1091 and 2.1093 of this chapter except as specified in paragraphs (c) and (d) of this section.

(3) In general, when the guidelines specified in §1.1310 are exceeded in an accessible area due to the emissions from multiple fixed transmitters, actions necessary to bring the area into compliance are the shared responsibility of all licensees whose transmitters produce, at the area in question, power density levels that exceed 5% of the power density exposure limit applicable to their particular transmitter or field strength levels that, when squared, exceed 5% of the square of the electric or magnetic field strength limit applicable to their particular transmitter. Owners of transmitter sites are expected to allow applicants and licensees to take reasonable steps to comply with the requirements contained in §1.1307(b) and, where feasible, should encourage co-location of transmitters and common solutions for controlling access to areas where the RF exposure limits contained in §1.1310 might be exceeded.

(i) Applicants for proposed (not otherwise excluded) transmitters, facilities or modifications that would cause non-compliance with the limits specified in §1.1310 at an accessible area previously in compliance must submit an EA if emissions from the applicant's transmitter or facility would result, at the area in question, in a power density that exceeds 5% of the power density exposure limit

applicable to that transmitter or facility or in a field strength that, when squared, exceeds 5% of the square of the electric or magnetic field strength limit applicable to that transmitter or facility.

(ii) Renewal applicants whose (not otherwise excluded) transmitters or facilities contribute to the field strength or power density at an accessible area not in compliance with the limits specified in §1.1310 must submit an EA if emissions from the applicant's transmitter or facility results, at the area in question, in a power density that exceeds 5% of the power density exposure limit applicable to that transmitter or facility or in a field strength that, when squared, exceeds 5% of the square of the electric or magnetic field strength limit applicable to that transmitter of facility.

(4) Transition Provisions. Applications filed with the Commission prior to October 15, 1997, (or January 1, 1998, for the Amateur Radio Service only), for construction permits, licenses to transmit or renewals thereof, modifications in existing facilities or other authorizations or renewals thereof require the preparation of an Environmental Assessment if the particular facility, operation or transmitter would cause human exposure to levels of radiofrequency radiation that are in excess of the requirements contained in paragraphs (b)(4)(i) through (b)(4)(iii) of this section. In accordance with §1.1312, if no new application or Commission action is required for a licensee to construct a new facility or physically modify an existing facility, e.g., geographic area licensees, and construction begins on or after October 15, 1997, the licensee will be required to prepare an Environmental Assessment if construction or modification of the facility would not comply with the provisions of paragraph (b)(1) of this section. These transition provisions do not apply to applications for equipment authorization or use for mobile, portable and unlicensed devices specified in paragraph (b)(2) of this section.

(i) For facilities and operations licensed or authorized under Parts 5, 21 (Subpart K), 25, 73, 74 (Subparts A, G, I, and L), and 80 of this chapter, the "Radio Frequency Protection Guides" recommended in "American National Standard Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 300 kHz to 100 GHz", (ANSI C95.1-1982), issued by the American National Standards Institute (ANSI) and copyright 1982 by the Institute of Electrical and Electronics Engineers, Inc., New York, New York shall apply. With respect to Subpart K of Part 21 and Subpart I of Part 74 of this chapter, these requirements apply only to multipoint distribution service and instructional television fixed service stations transmitting with an equivalent isotropically radiated power (EIRP) in excess of 200 watts. With respect to Subpart L of Part 74 of this chapter, these requirements apply only to FM booster and translator stations transmitting with an effective radiated power (ERP) in excess of 100 watts. With respect to Part 80 of this chapter, these requirements apply only to ship earth stations.

(ii) For facilities and operations licensed or authorized under Part 24 of this chapter, licensees and manufacturers are required to ensure that their facilities and equipment comply with IEEE C95.1-1991 (ANSI/IEEE C95.1-1992), "Safety Levels With Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz." Measurement methods are specified in IEEE C95.3-1991, "Recommended Practice for the Measurement of Potentially Hazardous Electromagnetic Fields--RF and Microwave." Copies of these standards are available from IEEE Standards Board, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331. Telephone: 1-800-678-4333. The limits for both "controlled" and "uncontrolled" environments, as defined by IEEE C95.1-1991, will apply to all PCS base and mobile stations, as appropriate.

(iii) Applications for all other types of facilities and operations are categorically excluded from routine RF radiation evaluation except as provided in paragraphs (c) and (d) of this section.

(5) Existing transmitting facilities, devices and operations: All existing transmitting facilities, operations and devices regulated by the Commission must be in compliance with the requirements of paragraphs (b)(1) through (b)(3) of this section by September 1, 2000, or, if not in compliance, file an Environmental Assessment as specified in §1.1311.

(c) If an interested person alleges that a particular action, otherwise categorically excluded, will have a significant environmental effect, the person shall submit to the Bureau responsible for processing

that action a written petition setting forth in detail the reasons justifying or circumstances necessitating environmental consideration in the decision-making process. (See §1.1313.) The Bureau shall review the petition and consider the environmental concerns that have been raised. If the Bureau determines that the action may have a significant environmental impact, the Bureau will require the applicant to prepare an EA (see §§1.1308 and 1.1311), which will serve as the basis for the determination to proceed with or terminate environmental processing.

(d) If the Bureau responsible for processing a particular action, otherwise categorically excluded, determines that the proposal may have a significant environmental impact, the Bureau, on its own motion, shall require the applicant to submit an EA. The Bureau will review and consider the EA as in (c) above.

(e) No State or local government or instrumentality thereof may regulate the placement, construction, and modification of personal wireless service facilities on the basis of the environmental effects of radio frequency emissions to the extent that such facilities comply with the regulations contained in this chapter concerning the environmental effects of such emissions. For purposes of this paragraph:

(1) The term "personal wireless service" means commercial mobile services, unlicensed wireless services, and common carrier wireless exchange access services;

(2) The term "personal wireless service facilities" means facilities for the provision of personal wireless services;

(3) The term "unlicensed wireless services" means the offering of telecommunications services using duly authorized devices which do not require individual licenses, but does not mean the provision of direct-to-home satellite services; and

(4) The term "direct-to-home satellite services" means the distribution or broadcasting of programming or services by satellite directly to the subscriber's premises without the use of ground receiving or distribution equipment, except at the subscriber's premises or in the uplink process to the satellite.

Recommended Revision to proposed Section 95.603(f)

Language proposed to be added is shown in **bold underlined** text.

§ 95.603 Certification required.

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(f) Each Medical Implant Communications Service transmitter (a transmitter that operates or is intended to operate in the MICS) must be certificated except for medical implant transmitters that are not marketed for use in the United States, but which otherwise comply with the MICS technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad. **Medical implant transmitters (as defined in Appendix I to Subpart E of Part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §§1.307 and 2.1092 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request that specific absorption rate measurement data be also submitted.**