

**Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554**

In the Matter of)
)
Amendment of Parts 2 and 95 of the) **ET Docket No. 09-36**
Commission's Rules to Provide Additional)
Spectrum for the Medical Device)
Radiocommunication Service in the)
413-457 MHz Band)

To: The Commission

Comments of the Society of Broadcast Engineers, Incorporated

The Society of Broadcast Engineers, Incorporated (SBE), the national association of broadcast engineers and technical communications professionals, with more than 5,000 members world wide, hereby respectfully submits its comments in response to the *Notice of Proposed Rule Making*, FCC 09-36, 74 Fed. Reg. 22491, released March 12, 2009 (the Notice). The Notice seeks comments relative to the Commission’s consideration of the feasibility of allowing up to 24 megahertz of spectrum in the 413-457 MHz band to be used on a secondary basis under the Medical Device Radiocommunication Service (MedRadio Service) in Part 95 of the Commission’s Rules. The Notice was issued in response to the September 5, 2007 Petition for Rule Making filed by the Alfred Mann Foundation (AMF) which manufactures and wishes to market wide bandwidth, implantable neuromuscular microstimulation devices using wireless technologies. The Notice proposes to permit these and other devices, referred to collectively as wideband medical micropower networks (MMN) such as the neural stimulators to permit patient mobility following injury or damage to a patient’s neuromuscular and other systems. In the interests of the broadcast and broadcast auxiliary services, SBE states as follows:

I. Introduction

1. SBE's interest in this proceeding is principally with respect to the interference susceptibility of devices which might be utilized in the MedRadio Service pursuant to rules¹ which may be promulgated pursuant to the Notice. The Notice in this proceeding refers to the bands 413-419 MHz, 426-432 MHz, 438-444 MHz and 451-457 MHz, which accommodate a number of incumbent radio services. These include Part 74, Subpart D, Remote Pickup (RPU) stations. RPU stations operate in, among other bands, 450-451 and 455-456 MHz. While some RPU operations are land mobile-like in their operations, RPU remote broadcasts can have long transmit duty cycles and effective radiated powers in the 40-100 watt range. These lawful Part 74 transmissions are likely to interfere with, and therefore pose risks to patients using MMN devices. RPU operation would be co-channel to MMNs in the proposed fourth MMN channel at 451-457 MHz. There is presently reserved spectrum for medical applications in the Part 95 Wireless Medical Telemetry Service (WMTS) rules, precisely oriented toward MMN operation, and neither AMF nor the Notice sets forth any substantiated reason why the existing WMTS allocations and service rules are not sufficient for, if not more appropriate for, MMN operation.² If new spectrum is in fact needed for MMNS, that spectrum needs to be in a range that is not already encumbered by high power, high duty-cycle licensed services. It is inappropriate, and inconsistent with the Commission's obligation to avoid creating an allocation that involves a predictable interference potential, to create a secondary allocation for medical applications

¹ It is unfortunate that the Notice in this proceeding does not contain an Appendix of proposed rules for the operation of MMNs in this service. It is suggested that a Notice of Proposed Rule Making in this case is premature. Those who wish to comment on specific rules that might substantially affect the interference potential or interference susceptibility of these devices are precluded from doing so because the operating parameters of such rules are not specified. The only devices described with any specificity are those of AMF, and other types of devices may have substantially different interference potential and susceptibility.

² AMF argues that the bands above 470 MHz that are available in the Wireless Medical Telemetry Service (WMTS) under Part 95 (which includes, among other bands, 608-614 MHz) are unsuitable because

involving implanted muscle stimulator devices in a band where interference could potentially cause medical harm.

2. Similar circumstances have already occurred. One, in 1973 which required years of work to resolve and resulted in the creation of the WMTS bands, and another, more recent occurrence which resulted in a de-facto secondary status of a licensed television service in protection of unlicensed part 15 devices. It would seem prudent in light of that experience to avoid the same problems that plagued low-power medical devices and require that MMNs utilize the WMTS spectrum, which was established precisely for the purpose of accommodating medical devices such as MMNs. That is a far better solution than the 413-456 MHz band, in which high-power fixed and mobile incumbent radio services might predictably disrupt medical devices implanted in patients.

3. SBE's position is fairly summarized as follows: A sufficiently high degree of interference rejection capability of MMNs has not been demonstrated to date. Actual testing has not occurred, or if any testing has occurred, the results have not been made public. Based on the information that is available, the ability of MMNs to withstand high power, co-channel transmissions from RPUs, military radars, land mobile systems, Amateur Radio and other licensed, mobile and itinerant transmitting facilities without danger to patients is unlikely. There is reasonable risk that operation of MMNs in this band, and in the 455-456 MHz range specifically, would either cause health risks to users or alternatively, result in the *de facto* downgrading of the present allocation status of licensed facilities. For this reason, devices should not now be allowed to operate anywhere in the 413-457 MHz band pursuant to this rulemaking proceeding. SBE agrees in this respect with the National Telecommunications and

radiofrequency signal propagation within the human body is not satisfactory above 470 MHz. This is an

Information Administration, which has stated in this proceeding that: “Measurements are necessary to verify that the interference mitigation techniques will actually protect the MMN Service systems and the individuals that rely on them. To accomplish this, coordinated measurement efforts with the incumbent spectrum users are necessary. The MMN Service devices should be thoroughly evaluated prior to initiating a measurement program with the incumbent spectrum users. The authorization of the MMN Service will be subject to the successful completion of measurements that verify the interference mitigation techniques employed protect MMN Service devices from incumbent systems.”

II. There are Alternatives That Would Better Suit This Application.

4. The Notice proposes to allow MMN devices for the treatment of persons with nerve damage. These devices have the laudable goal of improving the quality of life for persons suffering from spinal cord injuries, strokes, and traumatic brain injuries; they offer the possibility of more effective treatment for wounded war veterans. The proposed 451-457 MHz segment is allocated now to non-government land mobile radio (LMR) services. The 455-456 MHz band is assigned to Part 74, Subpart D, Remote Pickup (RPU) stations; a fact not mentioned in the Notice.

5. SBE is concerned about the potential for RPU operations to so severely interfere with a MMN, such that persons utilizing such devices would be put at risk. Although this risk is probably low during initial deployment of MMN devices, there is no geographic limit to the use of such devices. They are not confined to hospitals and other medical care facilities, and as such geographic separation cannot be relied on as an interference mitigation factor. If the devices eventually are proven effective and become widely used, then the potential for harm to patients

unsupported allegation that SBE finds unpersuasive.

from co-channel RPU operations would be increased, and would be unpredictable. The licensed radio service would have absolutely no ability to protect the patient, because RPU operation is mobile and the locations unpredictable. Since this would involve the control of medical devices implanted inside a human being, the position taken in the Notice that MMN use of these bands would be on a secondary basis and therefore not protected against interference, is neither reasonable nor practical. It is improper to create an allocation for MMN that is not in a band in which interference protection from incumbent services can be predicted, precisely because of the obvious safety issue to a patient whose MMN devices could either be falsely triggered, or become inoperable due to co-channel interference. Thus, at least the 451–457 MHz allocation, if not the entire 413-457 MHz band is inappropriate, because of the interference that MMN devices could receive from RPU operations. Indeed, the Commission has acknowledged this in the Notice, at paragraph 17, where it asks about the suitability of this band “for use by medical micro-power networks or other similar bandwidth intensive medical implant networks *that require a high degree of operational reliability.*” No portion of the 413-457 MHz band offers that assurance due to high-power incumbent operations such as RPUs. AMF itself has stated that the bands between 450 and 470 MHz are unsuitable due to the fact that the band is “congested and populated with commercial, high-power transmitters that could preclude reliable operation of lower-power, wireless medical implant devices.” Why in the face of these admissions the Commission proposes use of the 451-457 MHz band nevertheless is a mystery.

6. SBE's concern about sharing spectrum with a “secondary” medical use is based on the recent controversy involving Part 15 medical telemetry devices operating on previously guaranteed-vacant TV channels. For example, prior to the recent DTV transition, if a community had full-service analog TV stations on Channels 8 and 10, it was guaranteed that

there would be no high-power, full-service TV stations on Channels 7, 9 or 11 in that community. Some medical equipment providers unwisely took advantage of that fact and deployed Part 15 medical telemetry devices on those vacant adjacent TV channels. This was apparently helpful to patients in coronary care units, for example, who were now freed from a tangle of hard-wired connections, because a body-worn Part 15 RF telemetry device could monitor their vital signs. However, in 1987, when the first DTV stations began to operate on these previously precluded adjacent channels, interference to the Part 15 medical telemetry device was caused.³ Because of the patient safety issue, the Commission was forced to require primary, full-service DTV stations to first check with local health care facilities (HCFs) to ensure that the new DTV channel was not being used by a Part 15 medical telemetry system, even though Part 15 of the FCC rules is clear that a Part 15 use must accept interference from licensed users. A consequence was that every DTV construction permit (CP) was issued with a HCF condition, requiring the permittee to bear the burden of first identifying and checking with local HCFs, and, in some cases, delaying commencement of its DTV operations until the HCF had moved the medical telemetry devices to a different frequency. This requirement, in practice, caused a primary, licensed operator to protect at-sufferance users, giving priority to an unlicensed service.

7. A similar event had already taken place, which required years to remedy. In 1973, secondary use of the 460-470 MHz band was permitted by low-power medical devices was authorized. This necessitated restrictions in the power levels permitted for licensed land mobile radio stations, and even so, interference resulted to the medical devices from normally operating land mobile facilities. The Commission, in response to this interference, established the WMTS

³ The cause of WFAA-DT, N08/D09/FCD08, in Dallas, TX, was probably the most high-profile example.

in 1999. There was required a long period of migration of low-power medical devices from the 460-470 MHz band to the WMTS frequencies in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands. Those operations that remained in the UHF band became secondary to the land mobile service.

8. It is important as a potential safety issue that the Commission not allow another incompatible medical use of RF spectrum on an unprotected, secondary, basis. The Commission should not become an active partner in the use of RF spectrum on a secondary basis for a medical application.

9. There is no indication that the scope of the risk to patients who would be receiving potentially interference-susceptible MMN devices has been properly evaluated. The Notice proposes to put normal Part 15-type disclaimers on the devices, but these are meaningless once the devices have been implanted. Notices that the devices “are required to accept interference, even that which might cause undesired operation” are completely useless in this context. The notification to patients proposed at paragraphs 53 and 54 of the Notice is an abdication of the Commission’s obligation to make spectrum allocations based on technical evaluation and a finding that the interference potential is predictably low. Merely stating to patients that there is no “guarantee” that the device will not malfunction is unacceptable. If testing shows that the band is unsuitable for MMN devices, it should not be allocated for them. Patients are due more consideration than the cursory disclaimer proposed in the Notice. They deserve careful allocation planning such as that proposed in this proceeding by NTIA, involving actual tests, measurements, and RF compatibility studies.

10. The AMF Petition for Rulemaking claims that its system would use "redundant coding" to avoid interference from co-channel federal government operations (for the 413-419 MHz,

426-432 MHz, and 438-444 MHz bands) and from land mobile operations (for the 451-457 MHz band). However, no technical details regarding the redundant coding scheme are provided. Further, while land mobile operations have intermittent duty cycles, RPU operations can transmit continuously for several hours when a remote broadcast is in progress. Even if MMN operation is restricted for some reason to medical care facilities, a remote broadcast set up in the parking lot of the local hospital, as part of a "Walkathon for Heart" or similar promotion would place the RPU operation in close geographic proximity to MMN patients. Such operation could generate a strong co-channel interfering signal that could be present for hours. The point is that there are limits to what redundant coding can do in the presence of a strong co-channel interfering signal. An MMN implanted device will have an ERP of -7 dBm while typical RPU base stations may have 46 to 50 dBm ERP. Perhaps multiple layers of redundant coding would protect MMNs from *adjacent-channel* RPU operations at 450-451 MHz, but practical applications have shown that no amount of redundant coding will protect a 451-457 MHz MMN from *co-channel* RPU operations at 455-456 MHz.

11. SBE notes that NTIA has also expressed skepticism regarding the proposal and some of AMF's claims. In its early February 27, 2009, docket comments, NTIA submitted a letter that included the following points:

11A. That there may be "electromagnetic compatibility issues associated with the proposed MMN Service medical devices and current and future [federal] systems operating in the band."

11B. "Given the types of incumbent federal systems that are allocated in the 413-450 MHz band, the interference effects of high powered systems on the MMN Service devices and ultimately the individuals in whose body the devices operate must be considered. While interference is scenario dependent, scenarios are possible where a recipient of MMN Service implants could be in close proximity, or in the field of view, and illuminated by a high-

powered radar system, resulting in unknown and potentially devastating effects to the individual."

11C. "The effectiveness of an error detection and correction coding technique is highly dependent on the type of interfering signal and needs to be evaluated as part of this rulemaking proceeding."

11D. "An error detection and correction coding technique that works well for a low duty cycle pulsed radar signal may prove to be ineffective for analog or digital LMR [land mobile radio] signals."

11E. "There are no analytical techniques that can be employed to assess the effectiveness of an interference mitigation technique. Measurements are necessary to verify that the interference mitigation techniques will actually protect the MMN Service systems and the individuals that rely on them."

12. The lack of details regarding the AMF redundant coding scheme, mean that NTIA concerns may not have been addressed in this proceeding. SBE agrees with all of the points raised by NTIA. SBE does not want to see broadcasters having to choose between covering a news event using their 455-456 MHz RPU communications and disrupting an MMN system. The only way to ensure this is not to implement the proposed fourth MMNS band at 451-457 MHz.

III. Conclusion

13. Because the interference susceptibility of MMN devices generally is not known, it would be improper to create a co-secondary allocation for MMNs anywhere in the 413-457 MHz band, and especially in the 451-457 MHz band at this time. The Broadcast Auxiliary Service has a practical inability to protect patients wearing RF-susceptible MMNs from interference from ongoing ubiquitous, mobile RPU operations in the 450-455 MHz band, and the people of the United States who depend on broadcast radio and television stations for important news and

information cannot be deprived of those sources due to imprudent spectrum allocation decisions made in haste. There has been no testing of these devices to date relative to interference susceptibility, or at least no public results have been provided of any testing that has been accomplished. The Commission cannot just slough off the interference potential to patients who demand and deserve in these devices “a high degree of reliability” with mere notices that nearby RF energy may disrupt operation of the devices. That is improper spectrum management and no comfort at all to the patients who depend on the devices. Absent any testing showing a high degree of reliability of these devices in the presence of RF energy from unrestricted operation by incumbent licensees in the band in question, MMN operation cannot be allowed at all in the subject bands. MMN operation anywhere in the 413-457 MHz band would have to be conditioned on the ability to withstand and function properly in the presence of all high-power signals normally found in that band. This capability would have to be demonstrated by MMN proponents in advance and until that is done, this proceeding is premature.

Respectfully submitted,

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