Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	
Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies	)	ET Docket No. 13-84
Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields	)	ET Docket No. 03-137

Comments of the Cardiac Rhythm Management Device Committee (CRMD) / Working Group WG02 on EMC Protocols of the Association for Advancement of Medical Instrumentation (AAMI)

This document solely represents the views of the AAMI CRMD / WG02 membership, and does not necessarily represent a position of AAMI or FDA.

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INTRODUCTION

The Association for Advancement of Medical Instrumentation (AAMI) CRMD committee is responsible for development of a number of performance standards for implantable devices used to treat cardiac arrhythmia and heart failure. The committee also serves as the US Technical Advisory Group to International Standards Organization (ISO) TC150/SC6/JWG1, which is responsible for development of international standards for active implantable cardiac devices. These committees worked closely in the development of ISO 14117:2012, which is the guiding electromagnetic compatibility standard for all implantable cardiac devices. This standard is currently being revised under the auspices of AAMI by a working group WG02 reporting to the standing AAMI CRMD committee. Membership of the working group consists of experts from all cardiac device manufacturers, allied manufacturers, independent experts, and the FDA.

SUMMARY

We recommend that the Commission carefully consider its responsibility to "protect the public without imposing an undue burden on industry", and adopt harmonized human exposure levels as low as deemed possible thereby limiting the impact upon those persons having active implantable cardiac devices, in addition to the potential impact for biological effects for all patients who might encounter these fields.

Given the critical nature of the 0-100 kHz frequency band in question, we strongly recommend that the Commission consider development of either rules or guidelines for emitter manufacturers to which the low frequency spectrum applies.

We further recommend that such guidance be developed collaboratively in conjunction with the AAMI CRMD / WG02, as they possess considerable knowledge concerning the effects of low frequency emissions upon implantable cardiac devices as well as potential risk mitigation methods that manufacturers might apply. We ask the Commission to establish an ongoing liaison role with the AAMI CRMD / WG02.

We urge the Commission to reconsider the need for rulemaking in regards to SAR exposure for conductive implants. Should the Commission still feel there is a need to do so, we strongly recommend the Commission to establish rules or guidance on this topic only after collaboration with the ISO TC150/SC6/JWG 2 committee (author of ISO TS 10974). We ask the Commission to establish an ongoing liaison role with the JWG 2.

DETAILS

Pursuant to Section 1.405 of the Federal Communications Commission's (FCC's) Rules, the AAMI CRMD Committee /Working Group WG02 hereby submits comments in response to the *Further Notice of Proposed Rule Making* (FNPRM) and *Notice of Inquiry (*NOI) issued by the Commission in the above-captioned proceeding.

I. EXPOSURE LIMITS (Regarding paragraph 207-209 of the NOI)

The EMC standard ISO 14117:2012 *"Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices"* [1] establishes immunity requirements for

cardiac devices when patients are exposed to EM fields from 0 Hz to 3 GHz. This spectrum is divided into several bands, with different testing approaches provided for each band, appropriate to the type of fields and field absorption characteristic in the human body. To establish the immunity levels, the authors of ISO 14117 and its predecessors (e.g., AAMI PC69 [2], ISO 14708-2 [3], ISO 14708-6 [4]) utilized information from a variety of known emitters, as well as the reference levels established by ICNIRP 1998[5]. The MPE (reference) values from ICNIRP 1998 were multiplied by a safety factor and used to predict the level at which interference might be expected at the sensing ports of cardiac devices. These levels form the basis of conformance tests that have been in place since the year 2000. In that time, hundreds of thousands of patients have received devices tested to these limits, which are implied within the existing standard to provide a level of safety for patients as they go about their lives in the general public environment.

Any standard or rulemaking that concerns MPE, whether in the US or elsewhere, is of importance to the authors of ISO 14117, and ultimately to the patients whose safety is assured through conformity with it. By themselves, MPE levels are not the concern of the authors of ISO 14117. However, if the MPE levels are in turn used by standards organizations or rule-making bodies to set the allowable emissions of equipment subject to such rules, then it may reasonably be expected that at some point in the future, there will be a higher level of fields in either the general public or occupational environments.

At this point two issues arise. First, the safety of patients having implanted devices tested to the current device standards may no longer be assured. Secondly, to ensure safety in the future without imposing undue cautions or warnings, (and attendant reduction in Quality of Life or QoL), devices would need to meet a higher immunity standard. Unfortunately, due to the very nature of cardiac devices, the signals they are designed to sense, and the desire to implement more features in a smaller device size, device design for higher immunity levels, especially at frequencies below 30 MHz is a difficult challenge. These implantable devices are designed to sense low amplitude (microvolts-millivolts) intrinsic cardiac signals in the frequency range from 0-500Hz. Accurate sensing of these cardiac signals is critical for the appropriate operation of these devices and patient safety.
It is therefore more likely that the sole outcome of an environment posing an increased interference potential will be that manufacturers will have to provide considerably more cautionary and warning language to their patients. Such an outcome leads to deterioration in patient QoL due to anxiety and restriction of movement in their daily lives that is as deleterious as their underlying heart disease.

In regards to the Commission's question as to whether the exposure levels should be more restrictive, less restrictive, or remain the same, our working group has no comment for frequencies above 300 kHz where harmonized levels have already been established. We do however strongly support the concept that the Commission harmonizes its MPE levels with those specified within either the IEEE C95.1:2005[8] standard, or the ICNIRP 1998 Guidelines. Such harmonization will allow our working group to revise its immunity requirements (for frequencies above 300 kHz) with greater confidence that they will apply with equal efficacy on a global scale.

Clearly, there is a tradeoff here between patient safety / QoL and the needs of the non-medical manufacturing and general public. We recommend that the Commission carefully consider its responsibility to "protect the public without imposing an undue burden on industry", and adopt harmonized MPE levels as low as deemed possible under this tradeoff.

We further recommend that the Commission establishes a liaison level of participation with the AAMI CRMD / WG02 in order to determine ways to mitigate the problems outlined above. The Commission could provide guidance, to be developed in conjunction with AAMI CRMD / WG02, which would instruct equipment manufacturers as to possible design or use mitigations. Examples of such mitigations include avoidance of amplitude modulation, choosing burst rates that are well above 5 Hz thereby avoiding mimicry of cardiac activity, control over the exposure duration (either by design, labeling or signage), and shielding. These mitigations can significantly reduce the safety risk to persons having cardiac implants, and our working group would welcome the opportunity to collaboratively develop with the Commission such guidance.

II. FREQUENCY RANGE (paragraph 229 of the NOI)

As previously stated, implantable cardiac devices perform critical physiological sensing of heart rhythm in the frequency range of 0 to 500Hz, at voltages between 10 μV and a few mV. This bandwidth is required in order to capture signal components that represent all periods and types of cardiac activity. The devices are generally designed to ignore signals above 1 kHz to the maximum extent possible. Due to their miniature design, these devices rely upon digital filtering to accomplish out of band rejection at low frequencies (up to 30 MHz), above which analog filtering becomes feasible and necessary. For frequencies between 0 and 100 kHz, cardiac devices are extremely vulnerable to emitters with high magnetic fields, in particular sources that employ pulse or duty cycle modulation at low frequencies. Given the critical nature of the frequency band in question, we recommend that the Commission should consider development of either rules or guidelines for emitter manufacturers to which the low frequency spectrum applies.

We understand that there are no current restrictions in this frequency range. Therefore, it is entirely possible that equipment is brought to the market that is FCC compliant, while at the same time presenting a risk to persons with cardiac devices. Once such risks become reality, medical device manufacturers must then react to protect the safety of their patients. This reaction can lead to the aforementioned additional warnings to patients, incorporation of design changes in future implantable devices, and collaboration with the equipment manufacturers. Collaboration with equipment manufacturers is on a voluntary basis and usually long after the product has reached the marketplace, by which time it is difficult to effect a change. By providing guidance to equipment manufacturers, the Commission can reverse this state of affairs from one of reactive to proactive collaboration between medical device manufacturers and manufacturers of potentially harmful emitters.

We recommend that these rules or guidelines be developed collaboratively in conjunction with the AAMI CRMD / WG02, as we possess considerable knowledge concerning the effects of low frequency emissions upon implantable cardiac devices as well as potential risk mitigation methods that manufacturers might apply. The FDA, medical device manufacturers, and manufacturers of potentially harmful emitters must equally engage with the FCC to develop low frequency limits that are in-line with physiological sensing constraints.

III. CONDUCTIVE IMPLANTED OBJECTS (paragraph 230 of the NOI)

The Commission has posed two questions in regards to conductive implanted objects, the first being whether present volume-averaged SAR limits are protective for the more localized SAR that may

occur near the tip of a conductive object such as an implanted wire. Secondly, the Commission asks whether "high levels of RF exposure may cause internal injury at the site of conductive implants".

Our response to the latter question is clearly yes, as has been documented in several cases where patients with implanted devices (and leads) were exposed and subsequently injured due to the high RF fields associated with MRI systems. These cardiac devices had not specifically been designed and labeled as conditionally approved for MR exposure. In the literature, during MRI, there are examples of pacemakers not designed for the MR environment having inhibited (immediately life threatening for a pacemaker dependent patient), devices have been permanently damaged, devices have been reset, and distal electrodes have overheated. Inhibition occurs when the pacemaker detects EMI as a normal cardiac rhythm and then shuts off (to avoid rate competition and also to save battery life).

As to the former question on the protective nature of present SAR limits, exposure to other sources of high levels of RF energy is a very complex question that, fortunately, has been addressed by other standards development organizations and groups. For example, IEC 60601-2-33 [9] provides SAR values that were derived in a manner such that localized temperatures will not result in tissue damage. Also, ASTM standard F2182-11[10] governs the measurement of heating (e.g., orthopedic devices). Finally, ISO TS 10974:2012 [11], sets forth information for the compatibility between MRI exposure and active implantable medical devices.

These standards documents have all been developed in response to the needs of the medical device regulatory agencies, including the FDA.
We urge the Commission to reconsider the need for rulemaking in regards to SAR exposure for conductive implants. Should the Commission still feel there is a need to do so, we strongly recommend the Commission establish rules or guidance on this topic only after collaboration with the ISO TC150/SC6/JWG 2 committee (author of ISO TS 10974). There should be an ongoing liaison role between the Commission and the JWG 2, composed of over 100 experts in the area of interaction between conductive implants and modeling and prediction of the effects due to RF exposure.

IV. TRANSMITTER POWER EXEMPTION THRESHOLD (paragraphs 121-126 of the FNPRM)

Implantable cardiac devices almost universally are equipped with telemetry radios. However, due to the inherent need to provide maximum battery life, such radios are intentionally designed to have low output power and limited range. We support the Commissions' establishment of a 1 mW exemption level in that it would simplify regulatory approval steps for all device manufacturers. We further recommend however that the Commission consider increasing the exemption level to the highest possible value consistent with SAR limits based upon IEEE standard and ICNIRP guidelines, as long as MPE levels are consistent with internationally adopted standards for cardiac device immunity (e.g., ISO 14117). This additional margin may in the future allow cardiac devices to be exempted at higher power levels if necessary, either for enhanced range, data rate, or where a rechargeable power source is available. This will benefit not only manufacturers with reduced regulatory burden, but also patients who may enjoy higher levels of functionality.

V. REFERENCES

[1] ISO 14117:2012 Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices
[2] AAMI PC69:2007 Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators
[3] ISO 14708-2:2005 Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers
[4] ISO 14708-6:2010 Implants for surgery — Active implantable medical devices — Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)
[5] ICNIRP Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic fields (up to 300 GHz). Health Physics, 74(4): 494–522, 1998.
[6] ICNIRP GUIDELINES FOR LIMITING EXPOSURE TO TIME-VARYING ELECTRIC AND MAGNETIC FIELDS (1 HZ – 100 kHZ) PUBLISHED IN: HEALTH PHYSICS 99(6):818-836; 2010
[7] IEEE C95.6:2002 - IEEE Standard for Safety Levels With Respect to Human Exposure to Electromagnetic Fields, 0-3 kHz
[8] IEEE C95.1:2005, IEEE Standard for Safety Levels with Respect to Human Exposure to Radio-Frequency Electromagnetic Fields, 3 kHz to 300 GHz
[9] IEC 60601-2-33:2010 Medical Electrical Equipment - Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis
[10] ASTM F2182-11:2011 Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
[11] ISO TS 10974:2012 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device