ICNIRP
INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION

# Public Consultation Template - ICNIRP Draft RF Guidelines, Appendix A, Appendix B

## Comments to be uploaded until 9.10.2018

Dear Contributor,

Thank you for participating in the public consultation of the ICNIRP draft guidelines.
Please note that it is important that ICNIRP understands exactly the points that you are making. To facilitate our task and avoid misunderstandings, please:

- be concise
- be precise
- provide supporting evidence (reference to publication, etc.) if available and helpful.

**How to complete the comments table:**

Please use 1 row per comment. If required, please add extra rows to the table.
This response document asks you to provide your 'comment', your 'proposed change', and the 'context' to this comment and proposed change. What is meant by these is the following:

**Comment:** A brief statement describing the issue that you have identified (and that you would like ICNIRP to take into account in the final version of the guidelines).
**Proposed Change:** A brief statement describing how you would like the document changed to account for this issue.
**Context:** A brief statement identifying relevant documents in support of your comment and proposed change.

**Please, provide your details below as per the online form and the provision of the privacy policy**

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|---|---|---|
| Last name, first name: Carrillo, MD, MBA; Dr. Roger | Email address: | Affiliation (if relevant): Heart Surgeon, Palmetto General Hospital, Miami, FL USA. |
| If you are providing these comments officially **on behalf** of an organization/company, please name this here: Chair, ISO TC 150 / SC6 (Active Implants); Co-Chair AAMI Cardiac Rhythm Management Device Committee (AAMI-PC) | | |
| ☒ I hereby agree that, for the purpose of transparency, **my identity (last and first names, affiliation and organization where relevant) will be displayed** on the ICNIRP website after the consultation phase along with my comments.<br>☐ I want my comments to be displayed anonymously. | | |

| | Document (Guidelines, App A, App B) | Line Number # | Type of comment (General/ Technical/ Editorial) | Comment. Proposed change. Context. |
|---|---|---|---|---|
| **1** | Guidelines | 22-41 | General | The purpose of the guidelines is stated as being „high level of protection for all people against known adverse health effects from direct, non-medical exposures to both short- and long-term, continuous and discontinuous radiofrequency EMFs". Later in the purpose and scope section (starting on line 38), it is stated that „Radiofrequency EMF may also interfere with electrical equipment, which can affect health indirectly by causing equipment to malfunction. This is referred to as electromagnetic compatibility, and is outside the scope of these guidelines (for further information, see ISO14117 and IEC 60601-1-2)."<br>These statements are contradictory and partially incorrect:<br>1. People with active implantable medical devices are in fact no different from persons without such an implant, in that the "equipment" they bear is for all intents and purposes a permanent part of their physiology, one which they cannot simply turn off or ignore. The interference from EMF that can occur with these implants may lead to adverse health effects, some of which can be life threatening.<br>2. Citing the two standards above (ISO 14117 and IEC 60601-1-2) as examples of "equipment" that is out of scope of the guidelines represents a misunderstanding of these two very different standards. IEC 60601-1-2 addresses electromagnetic compatibility (EMC) of medical electrical equipment and systems, and is *correctly* cited in the context above, in the sense that it does not apply to active implantable medical devices (AIMDs) themselves. It does however apply to the non-implantable parts of AIMD systems, such as a body-worn insulin pump controller.<br>In contrast, ISO 14117 is concerned with EMC of implanted pacemakers and defibrillators (ICD), which as pointed out *are not* "equipment", but rather a vital part of a living human being that is needed to improve their quality of life. Similar standards apply to neurostimulators, cochlear implants, implanted infusion pumps and circulatory assist devices. These active implantable medical device standards establish EMC requirements to allow for proper and intended device operation, and take into account current EMF exposure guidelines as well as state-of-the-art device designs. The EMF exposure levels proposed greatly exceed the EMC requirements established for active implantables medical devices, and thus increase the likelihood of interactions that may occur, creating an increased safety risk for people with active implantable medical devices.<br>The guidelines must consider the effects of EMF on persons bearing active implantable medical devices with the same level of concern as for any other person.<br>Today, there are over 6 million patients worldwide (a conservative estimate) bearing a pacemaker or ICD, and similar numbers of patients with neurostimulators. This represents a large and growing segment of the population who should be considered in the establishment of guidelines for EMF exposure in both the general public and occupational exposure environments. These same concerns have been conveyed to the US Federal Communications Commission as part of its ongoing rulemaking efforts to establish similar exposure limits at low frequencies (i.e. below 300 kHz). For reference, please see the documents submitted by AAMI (Association for the Advancement of Medical Instrumentation) as part of an ex parte filing at the following links: |

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| **3** | Document ? | Line number | Type of comment | Insert your comment.<br>Insert your proposed change.<br>Explain the context of your comment. |
| **4** | Document ? | Line number | Type of comment | Insert your comment.<br>Insert your proposed change.<br>Explain the context of your comment. |
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