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 INTERNATIONAL COMMITTEE ON ELECTROMAGNETIC SAFETY (ICES) OF THE INSTITUTE OF ELECTRICAL AND ELECTRONICS ENGINEERS, INC. (IEEE)

This document solely represents the views of ICES and does not necessarily represent a position of either the IEEE or the IEEE Standards Association (IEEE-SA).

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SUMMARY

Pursuant to Section 1.405 of the Federal Communications Commission's (FCC's) Rules,[1] the International Committee on Electromagnetic Safety (ICES) of the Institute of Electrical and Electronics Engineers (IEEE) 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.[2]

ICES recommends that the Commission adopt the exposure limits for general public exposures found in the IEEE C95.1-2005 standard.[3] These limits, expressed in terms of basic restrictions (specific absorption rate – SAR)[4] and maximum permissible exposure (MPE – incident electric and magnetic fields and power density), are in harmony with the corresponding basic restrictions and "reference levels" of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for frequencies between 30 MHz and 100 GHz, and include a safety factor of 50. Adoption of the IEEE C95.1-2005 basic restrictions for partial-body exposure, 2 W/kg averaged over 10 g of tissue, would place the FCC limits in conformity with the corresponding value used internationally. No existing international standard or guideline supports the 1.6 W/kg averaged over

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[1] 47 C.F.R. §1.405.

[2] *See* Reassessment of Federal Communications Commission Radiofrequency Exposure Limits and Policies, in ET Docket No. 13-84, *and* Proposed Changes in the Commission's Rules Regarding Human Exposure to Radiofrequency Electromagnetic Fields, in ET Docket No. 03-137, FCC 13-39 (Released: March 29, 2013).

[3] IEEE Std C95.1™-2005, which was approved by the IEEE Standards Association Standards Board in October 2005, published in April 2006 and approved for use as an American National Standard by the American National Standards Institute in November 2006, is sometimes referred to as ANSI/IEEE C95.1-2006.

[4] IEEE ICES TC95 has discussed some terminology changes for exposure standards: "basic restriction" will be called "dosimetric reference limit" and "maximum permissible exposure" will be called "exposure reference level" to make the meaning of the terms more obvious.

1 g of tissue basic restriction for partial-body exposure that was adopted by the FCC in 1996. Because adoption of uniform standards is beneficial to consumers, the government, and industry, the World Health Organization promotes global harmonization of safety standards for the use of electromagnetic energy. ICES makes this strong recommendation to the Commission with confidence in the exposure limits of IEEE C95.1-2005. It is the most up-to-date international exposure standard and incorporates many science-based improvements over IEEE C95.1-1991 and the ICNIRP guidelines. Widespread support for the scientific judgments underlying the harmonized ICES and ICNIRP exposure limits is evident from the recent statements by scientific panels and government agencies found in Attachment A below. ICES also fully supports and encourages FCC adoption of the provisions of the IEEE C95.7-2005 standard, which describes RF safety programs designed to complement IEEE C95.1-2005.

ICES also recommends that the Commission adopt the International Electrotechnical Commission assessment standards IEC 62479 (2010), to take advantage of the low power device exclusions agreed to by an international technical committee, and IEC 62209-2 (2010) on SAR measurements for near-body devices. Adoption of these two international standards, taken together, will facilitate a more economical and efficient compliance process.

ICES also recommends using the higher IEC SAR limits based on temperature rise for medical applications and compliance of implanted medical devices rather than the localized SAR exposure limits in ICNIRP guidelines or IEEE C95.1-2005.

I. EXPOSURE LIMITS

In paragraph 207 of the *NOI*, the Commission requests comment on whether the FCC's limits for human exposure to radiofrequency (RF) radiation should be more restrictive, less restrictive, or remain the same.[5] ICES recommends that the Commission adopt the basic restrictions and maximum permissible exposure (MPE) values of IEEE C95.1-2005[6] that were developed by an international committee of more than 125 members representing 25 countries. This recommendation is strengthened by the fact that IEEE standards are developed through an open consensus process with oversight by the IEEE Standards Association under the principles of transparency and due process afforded to all. The IEEE standards development process is further governed by principles of balance, representation across the social spectrum of concerns over safe exposure, and attainment of levels of restrictiveness that are based on the best available science and engineering and, as such, are scientifically defensible. The committee that developed IEEE C95.1-2005 had an extremely wide range of participation by experts in engineering, biology, medicine, measurements, and safety programs.[7] In terms of stakeholders, the committee consists of members of the government, military, academia, industry, and general public.[8]

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[5] *Id.* at para. 207.

[6] IEEE Std C95.1™-2005, IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz.

[7] In 2006, IEEE Std C95.1™-2005 was approved by the American National Standards Institute (ANSI) as an American National Standard.

[8] Representatives of agencies participating in the Federal RF Interagency Working Group, e.g., FCC, FDA,

The committee, which was organized in 1960, has functioned continuously to develop and revise its RF safety standards.[9] The FCC incorporated part of IEEE C95.1-1991[10] into the current federal regulations.[11] The most recent IEEE C95.1 standard (IEEE C95.1-2005) is a revision of the 1991 standard; as such it would be consistent with the prior regulatory process for the Commission to adopt the limits in the 2005 standard. This recommendation is consistent with the recommendation of the IEEE Committee on Man and Radiation (COMAR)[12] that "…*health officials continue to base their policies on RF safety limits recommended by established and sanctioned international organizations such as the Institute of Electrical and Electronics Engineers International Committee on Electromagnetic Safety and the International Commission on Non-Ionizing Radiation Protection, which is formally related to the World Health Organization*."

The FCC peak spatial-average specific absorption rate (SAR) limits were based on concepts for limiting localized exposure first proposed in 1982 by the ANSI C95 Committee (ANSI C95.1-1982).[13] (The peak spatial-average SAR limit specified in the 1982 standard, which did not distinguish between limits for occupational exposure and exposure of the general public, is 8 W/kg averaged over 1 g of tissue.) In 1986 the National Council on Radiation Protection and Measurements (NCRP Report No 86)[14] reaffirmed the ANSI C95.1-1982 SAR value and introduced an additional safety factor of 5 for protection of the general public, thereby establishing levels one-fifth of the 1982 ANSI value. These values were reaffirmed in IEEE C95.1-1991 (whereby a peak spatial-average limit of 1.6 W/kg averaged over 1 g was defined for the general public). A subsequent extensive review of the latest scientific literature by the ICES committee deemed it appropriate to revise the IEEE C95.1-1991 recommendations; the revised values, which are consistent with the ICNIRP values,[15] and based on similar scientific principles, were approved by

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NIOSH and OHSA, participated in the development of C95.1-2005.

[9] In 1960, the American Standards Association approved the initiation of the Radiation Hazards Standards project under the co-sponsorship of the Department of the Navy and the Institute of Electrical and Electronics Engineers, Inc. Prior to 1988, C95 standards were developed by Accredited Standards Committee C95, and submitted to the American National Standards Institute (ANSI) for approval and issuance as ANSI C95 standards. Between 1988 and 1990, the committee was converted to IEEE Standards Coordinating Committee 28 (SCC 28) under the sponsorship of the IEEE Standards Board. In 2001, the IEEE Standards Association Standards Board approved the name "International Committee on Electromagnetic Safety (ICES)" for SCC 28 to better reflect the scope of the committee and its international membership. In accordance with policies of the IEEE, C95 standards are issued and developed as IEEE standards, and submitted to ANSI for approval as an American National Standard.

[10] IEEE Std C95.1™-1991, IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz.

[11] 47 CFR §1.1310.

[12] COMAR Technical Information Statement: Expert reviews on potential health effects of radiofrequency electromagnetic fields and comments on the BioInitiative Report. Health Phys. 97(4):348 –356, 2009.

[13] ANSI Std C95.1-1982, American National Standard Safety Levels with Respect to Radio Frequency Electromagnetic Fields, 300 MHz to 100 kHz.

[14] *Biological Effects and Exposure Criteria for Radio Frequency Electromagnetic Fields*, NCRP Report No. 86, National Council on Radiation Protection and Measurements, Bethesda, MD (1986).

[15] ICNIRP (International Commission on Non-Ionizing Radiation Protection), Guidelines for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz). Health Physics 74(4): 494-522, 1998.

the IEEE-SA Standards Board and published in April 2006 (IEEE C95.1-2005). Both IEEE C95.1-2005 and the 1998 ICNIRP guidelines (reaffirmed in 2009)[16] recommend 2.0 W/kg averaged over 10 g of tissue as a limit for localized exposure of the general public, and 10 W/kg averaged over 10 g of tissue for occupational exposure. Today, there are no international standards or guidelines that support a partial-body exposure basic restriction of 1.6 W/kg, averaged over 1 g of tissue, adopted by FCC in 1996.

The rationale for the change in partial-body SAR limits from 1.6 and 8 W/kg averaged over 1 g of tissue to 2 and 10 W/kg averaged over 10 g of tissue for general public and occupational exposure, respectively, is explained in Annex C, Section C.2.2.2.1 of IEEE C95.1-2005. As explained below, the 1991 SAR basic restrictions for partial-body exposure were based on dosimetry considerations alone; however the 2005 limits are based on a significantly improved understanding of RF and thermal dosimetry and biological/health effects.

a) **Origin of the 1.6 W/kg / 1 g limit in IEEE C95.1-1991:** Prior to C95.1-1991, the committee that developed the ANSI C95.1-1982 standard identified behavioral disruption in laboratory animals as the most sensitive, repeatable physiological endpoint considered potentially adverse to human health, with a threshold of 4 W/kg expressed in terms of whole-body average (WBA) SAR. A safety factor of 10 was applied to define the basic restrictions from which the MPE was derived, i.e., 0.4 W/kg for whole-body exposure. Unlike ANSI C95.1-1982, the 1991 standard had two tiers of limits. By incorporating an additional safety factor of 5 (yielding a total safety factor of 50), a lower tier for whole-body exposure was established in IEEE C95.1-1991 applicable to the general public in the uncontrolled environment (0.08 W/kg). The earlier peak spatial average SAR values (averaged over 1 g of tissue) for partial body, or localized exposures for controlled (8 W/kg) and uncontrolled (1.6 W/kg) environments were based on the 20:1 ratio of spatial peak to WBA SAR, empirically derived from experimental dosimetry data available in the late 1970s. The 1 g averaging mass was consistent with the achievable resolution of thermographic measurements at the time, i.e., rooted in engineering considerations for dosimetry, not biological or health criteria.

b) **Origin of the 2.0 W/kg / 10 g limit:** During revision of the IEEE C95.1-1991 standard, ICES concluded that the biologically based ICNIRP rationale using health effects on the eyes was more appropriate for a health related standard than the purely dosimetry-based rationale in IEEE standards C95.1-1982, C95.1- 1991, and C95.1, 1999 Edition.[17] ICNIRP uses a 10 g SAR averaging mass to correlate the SAR with RF-induced localized heating of the eye (about a 10 g mass) and other parts of the head with equivalent mass. The limit of 10 W/kg averaged over 10 g is supported by results from animal experiments showing that this value is at least 10 times below the SAR threshold for inducing cataracts (100 W/kg). The cataractogenic threshold in humans is also determined to be 100 W/kg deposited in the approximately 10 g mass of the eyeball. For the lower tier limit, a safety factor of 50 was applied to obtain a limit of 2 W/kg averaged over 10 g of tissue. In addition to this biological rationale, at least three

[16] Statement on the Guidelines for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz). Health Physics 97(3):257-259, 2009.

[17] IEEE Std C95.1™-1999 Edition (Incorporating IEEE Std C95.1™-1991 and IEEE Std C95.1a™-1998), IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz.

computational studies[18,19,20] have shown that averaging SAR over 10 g correlates better with localized temperature rise than averaging over 1 g. A mass of 10 g is therefore more appropriate for averaging SAR in tissue.

While exposure limits found in the ICNIRP guidelines and IEEE C95.1-2005 are essentially the same for the general public, there are some differences, which ICES considers improvements over IEEE C95.1-1991 and the ICNIRP guidelines. For example:

1. SAR in the pinnae follows the same exposure limits as those for extremities. (Already adopted by FCC in the *Report and Order*, paragraph 47.)
2. For frequencies greater than 3 GHz, the MPE is expressed in terms of the incident power density. To provide a transition in the frequency range 3 GHz to 6 GHz, compliance with IEEE C95.1-2005 may be demonstrated by evaluation of either incident power density or local SAR. Two recent publications[21,22] have shown that 6 GHz is a better choice for the transition to incident power density as compared to 10 GHz used in the ICNIRP guidelines.
3. In IEEE C95.1-2005, the peak spatial-average SAR is averaged over any 10 g of tissue in the shape of a cube, whereas in the ICNIRP guidelines, averaging is over any 10 g of contiguous tissues. All current international measurement standards are based on cubic mass and not on contiguous tissue mass. [IEEE 1528-2003,[23] IEC 62209-1: 2005,[24] and IEC 62209-2:2010[25]]. Pragmatically, it is virtually impossible to standardize contiguous tissue mass of arbitrary shape.

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[18] Hirata A., Fujiwara O. The correlation between mass-averaged SAR and temperature elevation in the human head model exposed to RF near-fields from 1 to 6 GHz. Phys Med Biol. 54:7227-7238, 2009.

[19] Razmadze A., Shoshiashvili L., Kakulia D., Zaridze R., Bit-Babik G. and Faraone A. Influence of specific absorption rate averaging schemes on correlation between mass-averaged specific absorption rate and temperature rise. Bioelectromagnetics 29(1): 77-90, 2009.

[20] McIntosh RL., and Anderson V. SAR versus VAR, and the size and shape that provide the most appropriate RF exposure metric in the range of 0.5-6 GHz. Bioelectromagnetics 32(4): 312-321, 2011.

[21] McIntosh RL and Anderson V, SAR versus S_{inc}: What is the appropriate RF exposure metric in the range 1-10 GHz? Part II: Using complex human body models. Bioelectromagnetics 31(6):467-478, 2010.

[22] Hirata A, Laakso I, Oizumi T, Hanatani R, Chan KH, and Wiart J. The relationship between specific absorption rate and temperature elevation in anatomically based human body models for plane wave exposure from 30 MHz to 6 GHz. Phys Med Biol. 58(4):903-21, 2013.

[23] IEEE Std 1528™-2003, IEEE Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Head from Wireless Communications Devices: Measurement Techniques. (Revision approved by the IEEE SA Standards Board June, 2013.)

[24] IEC 62209-1, Edition 1.0 (2005-02-18), Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices—Human models, instrumentation, and procedures - Part 1: Procedure to determine the specific absorption rate (SAR) for hand-held devices used in close proximity to the ear (frequency range of 300 MHz to 3 GHz). International Electrotechnical Commission, Geneva, Switzerland.

[25] IEC62209-2, Edition 1.0 (2010-03-30), Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures—Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz). International Electrotechnical Commission, Geneva, Switzerland.

4. For both general public and occupational exposures above 100 kHz, the basic restrictions in IEEE C95.1-2005 are protective against excessive heating due to absorption of RF energy. To achieve the same total energy at the limiting SAR for exposures of the general public or workers, different averaging times are specified with respect to the different SAR limits. For general public exposures at frequencies above 5 GHz, the values for time averaging have been modified to more accurately reflect thermal time constants. At 300 GHz, the averaging time is consistent with that of the laser standards, e.g., ANSI Z136.1-2007,[26] IEC 60825-1 (2003).[27] This improvement over previous standards advances the scientific basis for protection from RF exposure and represents an improvement over the uniform 6 min averaging time found in the ICNIRP guidelines.
5. For frequencies greater than 3 GHz, partial-body exposure evaluation in terms of power density is based on an area that is a function of wavelength. Guidelines are provided for evaluating partial-body exposure in terms of power density at these higher frequencies where SAR is not applicable. This is an important improvement for evaluating compliance for partial-body exposures. No other standard (other than the laser standards) includes this concept.
6. ICES also developed IEEE C95.7-2005,[28] which was designed to complement IEEE C95.1-2005. The IEEE C95.7-2005 standard includes information and guidance for engineering and administrative controls as well as for the use of personal protective equipment, placement of appropriate RF safety signage, designation of restricted access areas, the use of personal RF monitors, and RF safety awareness training. This standard is designed to provide guidance for controlling exposure and for preventing hazards associated with RF sources. ICES notes that the Commission's proposals in the *FNPRM* closely mirror many of the recommendations contained in this standard, and ICES fully supports and encourages FCC adoption of the provisions of this standard.

The World Health Organization (WHO) recognizes the following two documents that specify safety limits for human exposure to electric, magnetic and electromagnetic fields:[29] 1) the IEEE C95.1-2005 standard (published in 2006), and 2) the International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines published in 1998 (reaffirmed in 2009). Both specifications include high margins of safety. Because adoption of uniform standards is beneficial to consumers, the government and industry, WHO promotes harmonization of EMF standards globally. There is significant value in having consistent safety limits worldwide. Not only do different safety limits unnecessarily complicate international trade, differing values tend to lessen public confidence in the safety limits. It is therefore appropriate for the Commission to adopt the contemporary peak spatial-average SAR basic restrictions found in the ICNIRP guidelines and IEEE C95.1-2005. We urge the Commission to adopt the ICNIRP and IEEE C95.1-2005 SAR values of 2 W/kg averaged over 10 g of tissue for exposure of the general public and 10 W/kg

[26] ANSI Z136.1-2007, American National Standard for Safe Use of Lasers.

[27] IEC60825-1, Edition 2.0 (2007-03-30), Safety of laser products—Part 1: Equipment classification and requirements. International Electrotechnical Commission, Geneva, Switzerland.

[28] IEEE Std. C95.7™-2005 IEEE Recommended Practice for Radio Frequency Safety Programs, 3 kHz to 300 GHz.

[29] World Health Organization (WHO), "Electromagnetic fields and public health: mobile phones," Fact sheet N°193 June 2011, http://www.who.int/mediacentre/factsheets/fs193/en/index.html.

averaged over 10 g of tissue for exposure in controlled environments.

In addition to addressing established adverse health effects, ICES also extensively reviewed the literature dealing with the biological effects ascribed to exposure to low-level fields, i.e., at or below the corresponding basic restrictions in the frequency range 3 kHz to 300 GHz, which ICES describes as low-level effects and which others call "non-thermal" or "athermal" effects. The resulting ICES position on the existence of low levels effects is: "*Despite more than 50 years of RF research, low-level biological effects have not been established. No theoretical mechanism has been established that supports the existence of any effect characterized by trivial heating other than microwave hearing*[30]. *Moreover, the relevance of reported low-level effects to health remains speculative and such effects are not useful for standard setting*." (Annex C.1.2, page 82 of IEEE C95.1-2005.)

The breadth of international and national consensus on the ICES and ICNIRP limits recently was demonstrated in a report by Rowley and colleagues [31] who reported on standards for wireless communications among 229 countries, territories, dependencies and sub-national regions. Of these, 102 had adopted the ICNIRP guidelines for mobile networks and 115 had adopted the ICNIRP guidelines for mobile devices. In contrast, 9 agencies had adopted current FCC limits for mobile networks and 13 had adopted FCC limits for mobile devices. The rules adopted by the remainder were unknown or employed unique limits.

In summary, ICES urges the Commission to adopt the exposure limits for general public exposures found in IEEE Standard C95.1-2005. These limits, expressed in terms of basic restrictions (SAR) and reference levels (MPEs), are in harmony with International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines for frequencies between 30 MHz and 100 GHz. These limits incorporate many science-based improvements over IEEE C95.1-1991 and the ICNIRP guidelines. Adoption of IEEE C95.1-2005 basic restrictions would place the FCC limits in conformity with the internationally harmonized partial-body limit of 2 W/kg averaged over 10 g of tissue. No existing international standard or guideline supports the partial-body exposure basic restriction of 1.6 W/kg, averaged over 1 g of tissue that was adopted by FCC in 1996. The scientific judgments of ICES are consistent with those reached by other scientific expert groups and government agencies around the world as cited in IEEE C95.1-2005 Annex B.2, page 35, and Attachment A (for the last three years) at the end of this document.

II. ASSESSMENT STANDARDS

In paragraph 114 of the *FNPRM,* the Commission proposed various power thresholds for exempting transmitters from being evaluated for RF exposure.[32] ICES believes these power thresholds should be based on those already developed by the International Electrotechnical

[30] As noted in IEEE C95.1-2005, the phenomenon of microwave hearing in humans is a well-established biological effect with no known adverse health consequence. Although the effect has been induced at low levels, it is caused by thermoexpansion pressures from exposure to very short RF pulses.

[31] Rowley J., Joyner K., Zollman P. & Larsson LE. Radiofrequency exposure policies relevant to mobile communication devices and antenna sites. BioEM 2013, 10-14 June, Thessaloniki, Greece.

[32] *Id* at para. 114.

Commission (IEC). ICES recommends the Commission consider Tables A.1 and B.1 of IEC 62479 (2010).[33] Table A.1, "Example values of SAR-based P_{max} for some cases described by ICNIRP, IEEE C95.1-1999 and IEEE C95.1-2005," shows the power levels that can be excluded because even if all power were absorbed by the 1 g or 10 g tissue mass, the corresponding SAR limits could not possibly be exceeded. In Table B.1, "Some typical frequency bands of portable wireless devices and corresponding low-power exclusion levels P_{max}' predicted using Equations (B.1) through (B.9)," alternative low power exclusions are listed for various technologies, bandwidths, frequencies and distance between the device and the human body, with levels much higher than those shown in Table A.1. Annex B of IEC 62479 explains in detail the "Derivation of alternative low-power exclusion levels for wireless devices used close to the body." Annex B also describes formulae derived by researchers[34, 35] from the USA and Austria to establish P_{max}' values for the 300 MHz to 6 GHz frequency range for devices that are operated within 25 mm of the body. The algorithm found in Annex B is generally applicable to many popular mobile telephone system standards (e.g., GSM, CDMA, PCS), and land mobile radios and wireless local area network (WLAN) devices. The formulae have been shown to be conservative for a wide variety of antennas typically used on portable wireless devices, such as dipoles, monopoles, planar inverted-F antennas (PIFAs), and inverted-F antennas (IFAs). However, the formulae may not apply for wireless devices having antennas whose directivity is significantly greater than that of a half-wavelength dipole antenna (i.e., 2.1 dBi). Further details are given in IEC 62479 where Table B.1 lists some typical portable wireless devices and corresponding alternative low power exclusion levels P_{max}' for separation from the body by 5 and 25 mm. Other distances can be calculated using the formulas provided. The following description is from IEC 62479 (2010), based on the work of Ali et al.[34] and Sayem et al.[35] where further details are available.

Based on a systematic study of canonical dipole antennas of different lengths and at different distances from a flat phantom, a simple equation (B.1) was developed for predicting alternative higher values of the low-power exclusion levels, P_{max}':

$$P_{max}' = \exp[As + Bs^2 + C\ln(BW) + D] \qquad \text{(B.1)}$$

where s is the closest distance between the wireless device and the user's body, BW is the free-space antenna bandwidth, and A, B, C and D are third-order polynomials of frequency. The bandwidth corresponds to $|S_{11}| \leq -7$ dB, which is the reciprocal of the radiation quality factor, defined as the ratio between the stored and the radiated energies of an antenna. In Equation (B.1), s is expressed in mm and BW is expressed in percent (e.g., enter 10 in the equation if the bandwidth is 10%). Two sets of formulas of A, B, C, D were derived for both 2 W/kg averaged over 10 g limit and 1.6 W/kg averaged over 1 g limit. Table B.1 in IEC 62479 (2010) shows some typical frequency bands of portable wireless devices and corresponding low-power exclusion levels P_{max}' for two separation

[33] IEC 62479, Edition 1.0 (2010-06-16), Assessment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz), International Electrotechnical Commission, Geneva, Switzerland.

[34] Ali, M., Douglas, M.G., Sayem, A.T.M., Faraone, A. and Chou, C-K. Threshold power of canonical antennas for inducing SAR at compliance limits in the 300- 3000 MHz frequency range. IEEE Trans. Electromag. Compat. 49(1): 143-152, 2007.

[35] Sayem, A.T.M., Douglas, M. G., Schmid, G., Petric, B. and Ali, M. Correlating threshold power with free-space bandwidth for low directivity antennas. IEEE Trans. Electromag. Compat. 51(1): 25-37, 2009.

distances (5 and 25 mm). Other distances can be calculated using the formulas provided.

Tables A.1, B.1 and related formulas in IEC 62479 (2010) can eliminate the need for testing in those cases where the SAR cannot physically exceed exposure limits. Since this standard is already adopted internationally, ICES endorses acceptance of the provisions of IEC 62479 (2010). In contrast, the FCC 1 mW exclusion and the calculated levels in Table 2 of the subject Order and Report are overly conservative and not as practical for use with modern wireless devices. Adoption of the provisions of IEC 62479 (2010) will eliminate many instances of unnecessary, costly, and time-consuming compliance tests. It is useful to note from Table A.1 of IEC 62479 (2010) the significant difference between the exclusion level of 1.6 mW associated with IEEE C95.1-1991 and the more recent value of 20 mW based on IEEE C95.1-2005 and the ICNIRP guidelines. In order to resolve this large difference, ICES again urges the Commission to adopt the peak spatial-average SAR value of 2 W/kg averaged over 10 g of tissue, which will result in an exclusion power of 20 mW in harmony with the rest of the world.

Similarly, the FCC should also adopt the provisions of IEC 62209-2 (2010).[36] In this standard, a single tissue-equivalent liquid in the phantom is specified for frequencies ranging between 30 MHz and 6 GHz for testing devices in close proximity to the human body. This liquid is the same as the head simulating tissue in IEC 62209-1, and different from the body simulating liquid in FCC OET Bulletin 65 Supplement C, which was derived from extrapolations from the head tissue by FCC (not verified by others). If the FCC adopts IEC 62209-2, as has other parts of the world, it would eliminate unnecessary double testing of products in two different tissue stimulants for devices used in the USA and devices used in the rest of world. The large safety factor built into the exposure standards assures that small differences in the SAR values do not substantively affect protections to public health and safety provided by the standards. Finally, global harmonization yields benefits that would be unavailable by preserving the status quo.

In summary, the FCC should adopt the provisions of international assessment standards IEC 62479 (2010) and IEC 62209-2 (2010); specifically the international low power device exclusion values and the use of a single tissue simulating liquid. Both of these changes will facilitate a more efficient and economical compliance process.

III. MEDICAL IMPLANTS

In paragraph 125 of the *FNPRM*, the Commission cites a "worst-case" example of RF-transmitting medical implants that have a high potential for most of their energy being absorbed in one gram of tissue.[37] Furthermore, in paragraph 168, the Commission states that it proposes to apply only the 1 mW blanket exemption to implanted medical devices.

ICES notes that neither IEEE C95.1-1991 nor IEEE C95.1-2005 is intended for exposure of

[36] IEC 62209-2 Edition 1.0 (2010-03-30), Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices – Human models, instrumentation, and procedures – Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz). International Electrotechnical Commission, Geneva, Switzerland.

[37] *Id.* at para. 125.

patients by, or under the direction of, physicians and medical professionals. In its 1998 guidelines, ICNIRP also clarifies its position: "*Compliance with the present guidelines may not necessarily preclude interference with, or effects on, medical devices such as metallic prostheses, cardiac pacemakers and defibrillators, and cochlear implants.*"[15]

ICES urges the Commission not to use the general public peak-spatial SAR limit for medical implants. It is an inappropriate use of the standard and guidelines and would severely limit beneficial applications of medical implants for improved healthcare.

We note that FDA[38] has adopted the IEC temperature limits for compliance of MRI scanning, rather than relying on just the SAR as a limiting factor because excessive temperature is acknowledged as a definite cause of harm that must be prevented for medical diagnostics and medical implants, whereas SAR of itself is not a relevant factor in clinical circumstances. IEC 60601-2-33 provides SAR values that were derived in a manner such that localized temperatures will not result in tissue damage. IEC 60601-2-33 also states that higher temperatures and higher local SAR values may be accepted for specific tissues if there is no unacceptable risk for the patient.[39]

In summary, for compliance in medical applications ICES recommends use of the (higher) SAR values based on temperature rise derived by the IEC, not the SAR exposure limits in ICNIRP or IEEE C95.1-2005.

IV. CONCLUSION

In response to the *Further Notice of Proposed Rule Making* (FNPRM) and *Notice of Inquiry* (NOI) issued by the Commission, the International Committee on Electromagnetic Safety (ICES) of the Institute of Electrical and Electronics Engineers urges the Commission to adopt up-to-date, internationally recognized, electromagnetic exposure and assessment standards. Those standards supplant out-of-date localized exposure limits that no existing international standard organization supports. Specifically, ICES recommends that the Commission adopt the IEEE C95.1-2005 exposure limits. These limits are harmonized with International Commission on Non-Ionizing Radiation Protection guidelines in terms of basic restrictions (SAR) and reference levels (MPEs) as applied to exposures of the general public at frequencies between 30 MHz and 100 GHz. IEEE C95.1-2005 contains many science-based improvements over the IEEE C95.1-1991 and ICNIRP guidelines. In particular, we therefore urge the Commission to adopt the widely endorsed ICNIRP and IEEE C95.1-2005 peak spatial-average SAR value of 2 W/kg averaged over 10 g of tissue for localized exposures among the general public, and 10 W/kg averaged over 10 g of tissue for occupational exposures in controlled environments. In addition, ICES fully supports and

[38] Food and Drug Administration, "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices," Nov. 14, 1998.

[39] IEC Standard 60601-2-33 Edition 3 (2010-03-10), Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis. International Electrotechnical Commission, Geneva, Switzerland.

encourages FCC adoption of the provisions of the IEEE C95.7-2005 standard, which describes RF safety programs designed to complement IEEE C95.1-2005.

ICES also urges the adoption of international assessment standards IEC 62479 (2010) that defines low power device exclusions agreed upon by an international technical committee, and IEC 62209-2 (2010) that provides technical guidance on SAR measurements for transmitting devices operated close to the body. Adoption of these two international standards will make the compliance process more efficient and economical without any adverse impact on human safety. For medical products, ICES recommends that compliance be determined using SARs based on temperature rise as determined by the IEC rather than the SAR exposure limits in ICNIRP or IEEE C95.1-2005.

Respectfully submitted,

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Attachment A: Expert Reviews

Statements from Governments and Expert Panels Concerning Health Effects and Safe Exposure Levels of Radiofrequency Energy (Examples from last 3 years)

1. Spain's Comité Cientifico Asesor en Radiofrecuencias y Salud (CCARS) (2011)
   http://ccars.es/en
   - "According to various agencies, there is no scientific justification for a reduction in current exposure limits for RF EMF."

2. UK Health Protection Agency
   (2011) http://www.hpa.org.uk/NewsCentre/NationalPressReleases/2011PressReleases/110531electomagneticfields/
   - "HPA advice is that there is no clear scientific evidence of a cancer risk from exposure to radiofrequencies at levels below international guidelines but the possibility remains."

3. UK National Health Service (2011)
   http://www.nhs.uk/news/2011/05May/Pages/iarc-mobile-phones-brain-tumour-cancer.aspx
   So do mobile phones definitely cause cancer?
   - "No. The IARC's classification means there is some evidence linking mobile phones to some types of brain cancer but that this evidence is too weak to draw strong conclusions."

4. US National Cancer Institute (2011)
   http://www.cancer.gov/newscenter/pressreleases/2011/IARCcellphoneMay2011
   NCI Statement: International Agency for Research on Cancer Classification of Cell Phones as "Possible Carcinogen"
   - "Interphone, considered the major study on cell phone use and cancer risk, has reported that overall, cell phone users have no increased risk of the most common forms of brain tumors -- glioma and meningioma. In addition, the study revealed no evidence of increasing risk with progressively increasing number of calls, longer call time, or years since beginning cell phone use. For the small proportion of study participants who reported spending the most total time on cell phone calls, there was some increased risk of glioma, but the researchers considered this finding inconclusive. Furthermore, a large population-based cohort study in Denmark has found no evidence of increased risk of brain tumors. It is noteworthy that brain cancer incidence and mortality rates in the population have changed little in the past decade."

5. WHO (June, 2011)
   Fact Sheet #193 Electromagnetic fields and public health: mobile phones
   http://www.who.int/mediacentre/factsheets/fs193/en/index.html
   Are there any health effects?

- "A large number of studies have been performed over the last two decades to assess whether mobile phones pose a potential health risk. To date, no adverse health effects have been established as being caused by mobile phone use."
- "WHO will conduct a formal risk assessment of all studied health outcomes from radiofrequency fields exposure by 2012."

6. ICNIRP (July 2011)
   Mobile Phones, Brain Tumours and the Interphone Study: Where Are We Now?
   http://ehp03.niehs.nih.gov/article/info%3Adoi%2F10.1289%2Fehp.1103693
   - "In summary, Interphone and the literature overall have methodological deficiencies but do not demonstrate greater risk of either glioma or meningioma with longer or greater use of mobile phones, although the longest period since first use examined is <15 years."
   - "Although there remains some uncertainty, the trend in the accumulating evidence is increasingly against the hypothesis that mobile phone use can cause brain tumours in adults."

7. International Epidemiology Institute (2011)
   http://jnci.oxfordjournals.org/content/early/2011/07/27/jnci.djr285.full
   - "There have been other recent studies presenting brain tumor incidence trends among adults and children over the last 20 years in the United States; the United Kingdom; New Zealand; and Denmark, Norway, Sweden, and Finland. It is especially encouraging that these nationwide time-trend studies are uniformly and remarkably consistent in showing no evidence of increases in brain tumors over recent calendar years, up to and including 2009 in Sweden. Increases would have been expected if radio frequency waves were causally associated with brain cancer, given the steady and marked rise in the use of cell phones throughout the world since the 1980s."

8. National Cancer Institute (2011)
   Fact Sheet: Cell Phones and Cancer Risk
   http://www.cancer.gov/cancertopics/factsheet/Risk/cellphones
   - "Studies thus far have not shown a consistent link between cell phone use and cancers of the brain, nerves, or other tissues of the head or neck."
   - "..to date there is no evidence from studies of cells, animals, or humans that radiofrequency energy can cause cancer."

9. Health Canada (2011)
   Wi-Fi Equipment
   http://www.hc-sc.gc.ca/ewh-semt/radiation/cons/wifi/index-eng.php
   - "Based on scientific evidence, Health Canada has determined that exposure to low-level RF energy, such as that from Wi-Fi equipment, is not dangerous to the public."

10. Health Canada (2011)
    Safety of Cell Phones and Cell Phone Towers
    http://www.hc-sc.gc.ca/hl-vs/alt_formats/pacrb-dgapcr/pdf/iyh-vsv/prod/cell-eng.pdf

- "The IARC classification of RF energy reflects the fact that some limited evidence exists that RF energy might be a risk factor for cancer. However, the vast majority of scientific research to date does not support a link between RF energy exposure and human cancers."
- "With respect to cell phone towers, as long as exposures respect the limits set in Health Canada's guidelines, there is no scientific reason to consider cell phone towers dangerous to the public."

11. Health Council of the Netherlands (2011)
    Radiofrequency electromagnetic fields and children's brains
    http://www.gezondheidsraad.nl/en/news/infleuence-radiofrequency-telecommunication-signals-children-s-brains
    - "Available data do not indicate that exposure to radiofrequency electromagnetic fields affect brain development or health in children."

12. EU Commission's DG Health and Consumers (2011)
    Public Health (22-11-2011) Electromagnetic Fields and Health: The Way Forward
    http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=1198
    - "The nocebo effect (an ill effect caused by the suggestion or belief that something is harmful) is a major contributor to electrohypersensitivity"

13. UK Independent Advisory Group on Non-Ionizing Radiation (AGNIR) (2012)
    Health effects from radiofrequency electromagnetic fields.
    http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1317133826368
    - "In summary, although a substantial amount of research has been conducted in this area, there is no convincing evidence that RF field exposure below guideline levels causes health effects in adults or children."

14. UK Biological Effects Policy Advisory Group (BEPAG) of the Institution of Engineering and Technology (2012)
    http://www.theiet.org/factfiles/bioeffects/emf-position-page.cfm?type=pdf
    - "that the balance of scientific evidence to date does not indicate that harmful effects occur in humans due to low-level exposure to EMFs."
    - "In summary, the absence of robust new evidence of harmful effects of EMFs in the past two years is reassuring and is consistent with our findings over the past two decades. The widespread use of electricity and telecommunications has demonstrable value to society, including health benefits. BEPAG is of the opinion that these factors, along with the overall scientific evidence, should be taken into account by policy makers when considering the costs and benefits."

15. US Government Accountability Office (2012)
    Exposure and testing requirements for mobile phones should be reassessed.
    http://www.gao.gov/products/GAO-12-771

- "Scientific research to date has not demonstrated adverse human health effects of exposure to radio-frequency (RF) energy from mobile phone use, but research is ongoing that may increase understanding of any possible effects."

16. Swedish Council for Working Life and Social Research (2012)
    Radiofrequency electromagnetic fields and risk of disease and ill health– Research during the last ten years
    http://www.fas.se/pagefiles/5303/10-y-rf-report.pdf

    "Extensive research for more than a decade has not detected anything new regarding interaction mechanisms between radiofrequency fields and the human body and has found no evidence for health risks below current exposure guidelines. While absolute certainty can never be achieved, nothing has appeared to suggest that the since long established interaction mechanism of heating would not suffice as basis for health protection."

17. Norwegian Institute for Public Health (2012)
    Low-level radiofrequency electromagnetic fields – an assessment of health risks and evaluation of regulatory practice.
    http://www.fhi.no/eway/default.aspx?pid=238&trg=MainLeft_5895&MainArea_5811=5895:0:15,2829:1:0:0:::0:0&MainLeft_5895=5825:99168::1:5896:1:::0:0

    - "The studies have been performed on cells and tissues, and in animals and humans. The effects that have been studied apply to changes in organ systems, functions and other effects. There are also a large number of population studies with an emphasis on studies of cancer risk."
    - "The large total number of studies provides no evidence that exposure to weak RF fields causes adverse health effects."

18. European Commission (2012)
    European Health Risk Assessment Network on Electromagnetic Fields Exposure (EFHRAN). Report on priorities of health risk management and communication on EMF exposure. 2012 Nov. http://efhran.polimi.it/

    - the public's perception of possible health risks due to EMF exposure levels within international guidelines does not necessarily reflect the scientific community's assessment that there is a lack of evidence that could support this suggestion.
    - This "should suggest to policy and health authorities in Europe…that they need to invest in improving communication strategies related to EMF, allowing Europeans to have access to high quality and referenced information about the scientific state of the art on EMF and health issues.

19. Swedish Scientific Council on Electromagnetic Fields (2013)

    2013:19 – Recent Research on EMF and Health Risk (Eighth report from SSM's Scientific Council on Electromagnetic Fields, 2010), Swedish Radiation Safety Authority
    http://www.stralsakerhetsmyndigheten.se/Global/Publikationer/Rapport/Stralskydd/2013/S

SM-Rapport-2013-19.pdf

- Subsequent to the last Council report published in 2010, IARC in 2011 classified radiofrequency electromagnetic (RF) fields as possibly carcinogenic to humans (Group 2B) based on an increased risk for glioma and acoustic neuroma (vestibular schwannoma) associated with wireless phone use. Since then, numerous epidemiological studies on mobile phone use and risk of brain tumours and other tumours of the head (vestibular schwannomas, salivary gland) have been published. The collective of these studies, together with national cancer incidence statistics from different countries, is not convincing in linking mobile phone use to the occurrence of glioma or other tumours of the head region among adults. Although recent studies have covered longer exposure periods, scientific uncertainty remains for regular mobile phone use for longer than 13-15 years. It is also too early to draw firm conclusions regarding children and adolescents and risk for brain tumours, but the available literature to date does not indicate an increased risk.
- While the symptoms experienced by patients with perceived electromagnetic hypersensitivity are real and some individuals suffer severely, studies so far have not provided evidence that exposure to electromagnetic fields is a causal factor. In a number of experimental provocation studies (mostly with radiofrequency fields), persons who consider themselves electromagnetically hypersensitive as well as healthy volunteers have been exposed to either sham or real fields, but symptoms have not been more prevalent during real exposure than during sham exposure in the experimental groups. Several studies have indicated a nocebo effect, i.e. an adverse effect caused by an expectation that something is harmful.

20. American Cancer Society (2013)
Updates info on cell phone towers http://www.cancer.org/cancer/cancercauses/othercarcinogens/athome/cellular-phone-towers

    - "Cell phone towers are not known to cause any health effects. But if you are concerned about possible exposure from a cell phone tower near your home or office, you can ask a government agency or private firm to measure the RF field strength near the tower (where a person could be exposed) to ensure that it is within the acceptable range."

21. International Agency for Research on Cancer (2013)
Monograph 102 "non-ionizing radiation, part 2: radiofrequency electromagnetic fields" http://monographs.iarc.fr/ENG/Monographs/vol102/index.php

    - There is *limited evidence* in humans for the carcinogenicity of radiofrequency radiation. Positive associations have been observed between exposure to radiofrequency radiation from wireless phones and glioma, and acoustic neuroma.
    - There is *limited evidence* in experimental animals for the carcinogenicity of radiofrequency radiation.
    - Radiofrequency electromagnetic fields are *possibly carcinogenic to humans (Group 2B).*

- The comparative weakness of the associations in the INTERPHONE study and inconsistencies between its results and those of the Swedish study led to the evaluation of *limited evidence* for glioma and acoustic neuroma, as decided by the majority of the members of the Working Group.

[Note: The task of IARC is to classify the possibility of effects, while the other expert reviews are on established health effects.]

22. Health Council of the Netherlands (2013)
Mobile phones and cancer. Part 1: Epidemiology of tumours in the head.

http://www.gr.nl/en/publications/environmental-health/mobile-phones-and-cancer-part-1-epidemiology-tumours-head

"[T]he final conclusion from this systematic analysis is then: there is no clear and consistent evidence for an increased risk for tumours in the brain and other regions in the head in association with up to approximately 13 years use of a mobile telephone, but such risk can also not be excluded. It is not possible to pronounce upon longer term use."