IEEE C95.1 RADIO FREQUENCY SAFETY STANDARD: TEMPERATURE ISSUE

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SUMMARY: A brief history of the C95.1 RF safety standard is provided followed by an explanation of the rationales for whole-body and localized exposures in the IEEE C95.1-2005 standard. During the latter stages of the development of the 2005 standard, the possibility of using temperature rise in tissues as a basis for limiting localized exposure was discussed but due to lack of information and time constraints, the issue was deferred for the next revision. Results of the FDA Thermal Workshop held in January 2010 will stimulate discussion on the possibility of using temperature as a basis for localized RF exposure limits.

AIMS: To collect scientific information on the temperature effects on various tissues for setting RF exposure limits to protect against thermal injury in tissues due to localized exposure to RF energy.

History and rationales: The first RF safety standard was published by the United States of America Standards Institute in 1966 (USAS C95.1-1966) [1]. Based on a simple thermal model, a 10 mW/cm^2 power density limit was set which was frequency independent from 10 MHz to 100 GHz. The revision of the 1966 standard, American National Standards Institute – ANSI C95.1-1974 [2], contained limits on E^2 and H^2 to address near-field exposures. In addition to limits on external exposure fields, the 1982 revision (ANSI C95.1-1982) [3] was based on the internal dosimetric quantity "specific absorption rate" (SAR), which was introduced to set limits for both whole-body and localized exposures. The exposure field limits were based on the envelope of a family of resonance curves for various size human models, from infants to adults, exposed to RF fields at various frequencies under plane-wave conditions and produced the same whole-body averaged SAR, which resulted in frequency dependent power density and field limits. The frequency range of the 1982 standard is 300 kHz to 100 GHz. The committee agreed that the most sensitive and reproducible potentially adverse health effect is disruption of food-motivated behavior demonstrated in several species of animals over a wide range of frequencies that consistently occurred at a whole-body-average SAR of about 4 W/kg. A safety factor of 10 was applied resulting in a 0.4 W/kg limit for whole body exposure. The spatial peak average SAR for localized exposure was 8 W/kg averaged over any 1 g of tissue and over any time period of 0.1 h. The committee agreed that 8 W/kg (equal to 20 times 0.4 W/kg) was appropriate based on human model and animal dosimetry studies. In 1989 the ANSI committee became an IEEE committee and the next revision of the standard was published as IEEE C95.1-1991 [4]. Whereas the earlier C95.1 standards were single tier, the 1991 standard had two tiers – an upper tier for exposures in controlled environments and a lower tier for exposures in areas that were not controlled, e.g., for the general public. The frequency range was also broader extending from 3 kHz to 300 GHz. The latest revision IEEE C95.1-2005 [5] published in April 2006, indicates in the introduction that "*in the frequency range of 100 kHz to 300 GHz, the rules protect against adverse health effects associated with heating.*" The basis for whole-body-averaged SAR remains the same, i.e., behavioral effects at 4 W/kg, an exposure which is associated with a 1 ^oC core temperature rise in animals, as in the 1982 version. The localized SAR in the 2005 standard is based on

thermal damage to the lens of the eye, and limits have been changed to 10 and 2 W/kg averaged over 10 g of tissue (eye ball mass) for the two tiers. The literature review supporting the C95.1-2005 standard included review of effects at levels producing no significant temperature increase but it was judged to be not useful for standards development.

Temperature issues: During the revision of C95.1, the working group prepared an outline in 1999 that included an item "*Relationship of temperature increase to SAR.*" The Risk Assessment Working Group of the Subcommittee conducted a survey in 2001 with the following question: "*While it would seem that a temperature based standard, for both body average and local tissues, would be more directly related to potential injury from RF fields, does the present scientific database provide sufficient support for deriving such a standard?* " In the 2001 meeting minutes [6], the following statements were recorded. "*Localized SAR limits are ultimately intended to protect against excessive local temperature rises, sustained over sufficient time.*" "*Moreover, the limits for whole body exposure seem designed to protect against excessive total thermal load to the body, whereas those for partial body exposure should probably be designed to protect against excessive local heating (local temperature rise). That would call for a different rationale for the spatial averaging limits entirely.*" "*If one moves to a thermal base for local or partial body protection then one can theoretically determine the limit below which it is impossible to elevate the temperature to a critical level.*" The minutes also state that "*it is not only necessary to know the maximum tolerable temperature rise for prolonged exposures, but also to know how long intermittent excursions of higher temperatures can be safely tolerated.*" Currently SAR is the basic restriction, but the final resultant temperature rise is dependent on many other factors, such as heat diffusion and blood flow. Under temperature controlled conditions, studies show that SAR even at a very high level cannot produce effects. Thus the ultimate quantity related to an effect is tissue temperature – not SAR. The question of why not use temperature as the basic restriction for localized exposure was raised in 2005, but because the standard was in subcommittee ballot, the proposal was deferred to the next revision. During the 2007 Winter meeting, the Subcommittee approved the motion "*to pursue the investigation of relationships between localized tissue temperature increase and peak spatial-average SAR (100 kHz to 3 GHz) or power density (3 GHz to 300 GHz) as a basis for revising a decision on the need to revise the localized exposure limits at frequencies from 100 kHz to 300 GHz.*"

CONCLUSION: Currently, the most sensitive established adverse health effects at RF frequencies above 100 kHz are related to tissue heating. During revision meetings, the question was raised as to why not use temperature directly as a basis to set RF exposure limits to protect against known adverse thermal effects. Gaps of knowledge on thermal injury first need to be addressed and the recent FDA Thermal Workshop will help to provide such knowledge.

REFERENCES:

[1] USAS C95.1-1966 "Safety Level of Electromagnetic Radiation with Respect to Personnel." United States of America Standards Institute.

[2] ANSI C95.1-1974 "Safety Level of Electromagnetic Radiation with Respect to Personnel." American National Standards Institute.

[3] ANSI C95.1-1982 "Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 300 kHz to 100 GHz." American National Standards Institute.

[4] IEEE C95.1-1991 “IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz” .
[5] IEEE C95.1-2005 “IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz” .
[6] ICES approved meeting minutes are posted at www.ices-emfsafety.org.