ICES

International Committee on Electromagnetic Safety

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To: Dr. Jean-Claude Brien, Industry Canada

Subject: ICES Comments on Compliance with Health Canada Safety Code (6) – 2015

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1. Overview

Health Canada (HC) recently published Safety Code (6)-2015, which specifies human exposure limits to electromagnetic fields at frequencies down to 3 kHz. Earlier this year individual members of ICES, speaking as individuals—not speaking for ICES – submitted information on electrostimulation-based limits in response to Health Canada's call for comments during the development period of the standard. Although the opportunity to influence the limits in SC(6)-2015 is over, Industry Canada is now soliciting comments on methods for determining compliance with SC(6)-2015.

A member of ICES (J Patrick Reilly) met with Industry Canada representatives in Ottawa on 23 April 2015 as part of a technical advisory group. A number of issues were discussed, including two that are of particular concern to ICES: 1) The specification of *reference levels* in terms of an "instantaneous RMS" metric specified by HC; and 2) the possibility of specifying relaxed limits for primary exposure of the limbs. Subsequently two draft technical reports were prepared by Reilly— one on each of these subjects.

On 25 June, Reilly was part of a teleconference between Industry Canada and members of ICES (speaking as individuals) regarding HC limits based on peripheral nerve stimulation. The teleconference was chaired by Dr. Jean-Claude Brien of Industry Canada. A brief synopsis of the two technical reports was sent to Dr. Brien, followed by a draft of each report. Dr. Brien stated that the reports are of interest but would carry more weight if they were formally submitted through ICES, rather than by Reilly as an individual.

Following the 25 June teleconference, the ICES leadership agreed to submit the reports as the ICES position. The reports were distributed to the ICES TC95 membership as a ballot for approval and comments. The comments received were incorporated and a recirculation ballot initiated. The following two sections represent the position of ICES regarding Compliance with Health Canada Safety Code (6) – 2015.

2. Scientific basis for increased exposure limits for limbs

2.1 Introduction

Health Canada (HC) Safety Code (SC) (6)-2015 specifies limits on human exposure to electro-magnetic fields (EMF). Limits intended to avoid adverse reactions to electrostimulation (ES) are specified for frequencies below 10 MHz. The HC Basic Restrictions (BRs) on the induced *in-situ* electric field follow those of the International Commission on Non-Ionizing Radiation Protection (ICNIRP). The ICNIRP BRs, in turn, closely follow those of IEEE Standards C95.6™-2002 and C95.1™-2005, except that ICNIRP BRs are more conservative by a factor of roughly 2 – 3.

When testing for compliance, HC follows the practice of ICNIRP and IEEE by specifying limits on the external fields, called *Reference Levels* (RLs) by ICNIRP, and *Maximum Permissible Exposure* (MPE) *values* by IEEE. The RL/MPE values are conservative and intended to ensure compliance with the BRs under stressful case assumptions.

A special exposure case is when the limbs are principally exposed, but with insignificant exposure of the head and torso. An example might apply to an open-MRI attendant who may need to extend his/her arms into the field to interact with the patient. In such cases, the small induction area of the limbs as compared with the torso justifies an increase in the exposure limits compared with whole body exposure. In addition, the absence of CNS tissue in the limbs precludes the need to protect against adverse CNS reactions that could potentially occur with whole body exposure at very low frequencies. CNS considerations are below the lowest frequency of 3 kHz in HC Safety Code (6).

Another example occurs in the case of an Electronic Article Surveillance (EAS – anti-theft) tag deactivation unit where the cashier scans the barcode, and sweeps the scanned item within about 10 cm of the deactivation unit to degauss or turn off the EAS tag.

To accommodate the special case of principal limb exposure, IEEE specifies increased limits for exposure of the limbs based on the relative sizes of the induction areas of torso and limbs. Limb exposure limits appear in Table 3 of IEEE Standard C95.6™-2002, and Table 3 of IEEE C95.1™-2005.

With respect to Tables 3 and 4 of SC(6), HC states (page 7, note 5) regarding RLs for the limbs: "For localized exposure of the limbs, the reference levels for magnetic field strength may be exceeded provided that the basic restrictions in Table 1 are respected within the limbs."

While HC SC(6) does not specify separate RLs for the limbs, this statement suggests that limb exposure limits above those for the whole body can be justified. In fact, this analysis supports a relaxation of the RLs for the limbs.

In theory, calculation of the *in-situ* field induced in the limbs should allow one to justify exposure to environmental fields above the whole body limits in SC(6) Tables 3 and 4. However, it would be preferable to develop effective limits for the external field for the limbs that can be readily tested with an approved meter. Otherwise, an assessment of the BRs may be required, which may be difficult for regulatory agencies to determine.

2.2 Calculations

2.2.1 Induction principles

To develop a quantitative comparison of the maximum induced electric field (E-field) in the torso vs. the limbs by an external magnetic field, consider an *Induction Factor*, $F_{I,}$

$$F_I = E_i /(dB/dt)_e \qquad (1)$$

where E_i is the maximum induced electric field, and $(dB/dt)_e$ is the time derivative of the incident magnetic flux density in a direction perpendicular to a defined cross section of a body part. The units of F_I are volts-per-meter (V/m) per tesla-per-second (T/s), i.e., [(V/m)/(T/s)]. The intent is to determine F_I separately for the limbs and the torso. The ratio of those F_I measures can be considered an allowable enhancement factor for exposure of the limbs relative to that of the torso derived from the relative sizes of those body parts. That ratio is referred to as a *Limb Enhancement Factor* (L_{EF}), i.e.,

$$L_{EF} = F_I \text{ (torso)}/F_I \text{ (Body part)} \qquad (2)$$

In developing its low-frequency limits based on ES, IEEE-ICES used an *Ellipsoidal Uniform Conductivity* (EUC) induction model, consisting of an elliptical shape fitted to the maximum cross-section of the whole body, the torso, or the leg. An exact solution to the induced electric field (E-field) in an ellipsoidal shape was derived by Durney and Colleagues[1] (1975), and expressed in applied form by Spiegel[2] (1976). For a concise representation of the pertinent equations, the reader is directed to Reilly (1998)[3], pp. 362-366.

Based on the EUC model for uniform exposure by a time-varying magnetic field perpendicular to the cross section of interest, the induction factor at the outer limits of the major and minor axes is readily obtained from Eq. (9.21) of Reilly (1998) as:

[1] Durney, CF et al. (1975). Long wavelength analysis of plane wave irradiation of a prolate spheroid model of a man. *IEEE Trans. Microwave Theory*, 23(2); 245-253

[2] Spiegel, RJ (1976). Magnetic coupling to a prolate spheroid model of a man. *IEEE Trans Pwr. App. Sys.* 96(1): 208-212.

[3] Reilly, JP (1998). *Applied Bioelectricity*. Springer, (New York, Berlin).

$$F_I\,(b) = a^2 b/(a^2 + b^2) \qquad (3)$$

$$F_I\,(a) = b^2 a/(a^2 + b^2) \qquad (4)$$

where $F_I(a)$ is the induction factor determined at the outer limit of the semi-major axis, *a*, and F_I (b) is determined at the outer limit of the semi-minor axis, *b*. In Eqs. (3) and (4), *a* and *b* are expressed in meters, and the units for F_I are [(V/m)/(T/s)]. The maximum induced E-field occurs at the outermost limit of the minor axis is given by Eq. (3).

2.2.2 Quantitative solution

Table 1 lists anthropometric dimensions[4,5] for elliptical cross sections of three body segments approximately fitted with equivalent ellipses: a) arm, from shoulder sleeve out-seam to wrist; b) leg, from gluteal furrow to ankle; and c) torso neck to gluteal furrow. From the perspective of magnetic induction, case c) would be a worst-case scenario. Table 1 lists dimensions applying to the median adult male or female and for the 95 percentile largest adult male or female.

Table 2 determines F_I from the data in Table 1 using Eqs. (3) and (4). For convenience of numerical notation[6], F_I values in Table 2 are given in [(mV/m)/(T/s)].

Table 3 tabulates the "Limb Enhancement Factor," L_{EF}, determined by the ratio of F_I of the torso to F_I of the indicated body part. The L_{EF} values can be interpreted as multiples by which exposure limits for the limbs can be increased relative to whole body exposure, based solely on the relative sizes of the body parts.

The L_{EF} values in Table 3 are comparable to a corresponding factor of 1.91 for the leg in IEEE Standard C95.6™-2002, and a factor of 3.0 for the "limbs" in EU Directive 2013/35/EU.

2.3 Recommendations

Based on electrostimulation reactions, Reference Levels for the limbs can exceed those derived for the whole body, without exceeding the BRs. To be consistent

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[4] Source: C C Gordon (1988). *1988 Anthropometric Survey of U.S. Army personnel: Methods and Statistics*. Tech. Report NATICK/TR-89/044. U.S. Army Natick Research & Dev. Cent., Natick Mass. U.S. NTIS Document Tracking # AD-A225 094

[5] The maximum dimensions of the body parts used here for EUC calculations do not occur at the mid-point of the fitted ellipses. Taking a conservative approach, the minor axis dimension of the arm is taken as the circumference of the arm at the bicep divided by π, of the leg as the breadth of the thigh, and of the torso as the breadth of the upper torso below armpits. The length of the arm or leg has been measured to the wrist or ankle, thereby excluding the hand or foot. This procedure was considered reasonable in the light of the very restricted cross sections of ankle and wrist, and the preponderance of low conductivity tissue (mainly ligaments & bone) in those body parts.

[6] E_i is expressed in Table 2 in millivolts-per-meter (mV/m), rather than volts-per-meter as in Eqs. (1) – (5).

with the use of RLs in testing for compliance with HC Safety Code (6), it is recommended that RLs for arm and leg exposure be increased from the limits for the whole body using the factors in Table 3. Considering that the RLs and MPEs of ICNIRP and IEEE assume exposure a large adult male, limb relaxation factors based on a 95% male can be justified. Exposure of a large adult man provides a conservative case because of the larger induced E-field as compared with a small size woman or child. This would result in recommended relaxation factors of 2.9 for the arms, and 1.9 for the legs. With slight numerical rounding, enhancement factors of 3.0 for the arms and 2.0 for the legs would closely represent enhancement factors for all the cases tested here.

Table 1—Fitted ellipse dimensions for various body segments of adults. Table entries are semi-major (a) and semi-minor (b) axes of fitted ellipses through central cross sections of the body parts. Dimensions are in cm.

Body Part	Males				Females			
	50%		95%		50%		95%	
	a	b	a	b	a	b	a	b
(a) Arm	30.0	5.35	32.7	6.13	27.3	4.46	30.0	5.11
(b)Leg	37.3	8.38	40.8	9.5	34.1	7.91	37.4	9.00
(c) Torso	35.3	20	37.9	22.8	33.1	17.5	35.9	19.9

Table 2—Induction Factors, F_I, for body parts expressed in [(mV/m)/(T/s)]

Body Part	Males		Females	
	50%	95%	50%	95%
(a) Arm	51.9	59.2	43.4	49.7
(b) Leg	79.8	90.1	75.1	85.1
(c) Torso	151	167	137	152

Table 3—Allowable limb enhancement factor, $L_{EF} = F_I$ (Torso)/ F_I (Body part)

Body Part	Males		Females	
	50%	95%	50%	95%
(a) Arm	2.92	2.83	3.15	3.07
(b) Leg	1.90	1.86	1.82	1.79
(c) Torso	1.00	1.00	1.00	1.00

3. Comments on Health Canada RMS quantities as exposure metrics

3.1 Introduction

This section discusses the metric "*Instantaneous RMS*" appearing in Health Canada (HC) Safety Code (6). Since an RMS measurement requires an averaging period (the *M* in *RMS* stands for the *mean* over an averaging period), the specification of *Instantaneous RMS* seems to be ambiguous. To resolve such ambiguity, HC issued a "Technical Guide" that clarifies the intent of that term.

The Technical Guide's clarification as applied to amplitude-modulated carrier waveforms used in some products such as anti-theft devices, seems reasonably consistent with the other SC(6) tables based on continuous sinusoidal waveforms. For broadband signals, however, there appear to be technical problems with interpretation of the HC specifications that could lead to inconsistencies in determining compliance with broadband EMF exposures, such as might be produced by the switched gradient fields of MRI scanners.

3.2 Applicability of the RMS metric for nerve stimulation

An RMS metric is meant to characterize the heat-producing capacity of a time-varying current or voltage. While it might be appropriate in characterizing thermal effects, an RMS metric may be a very poor descriptor of a signal's potential for electrostimulation (ES). Considering that fact, how does one justify the use of RMS metrics in standards designed to avoid adverse ES effects?

An RMS metric is a poor indicator of the potential for ES *unless the waveform is defined in detail*. In cases related to ES limits, the RMS metric is simply a surrogate for amplitude. And since the ES effects of stimulation by sinusoidal waveforms is well known through experiments and computational models, one can usefully stipulate ES-based limits for sinusoidal stimulation in terms of RMS values.

In consideration of these facts, IEEE-ICES constructed the low frequency ES-based limits in IEEE Standards C95.6™-2002 and C95.1™-2005 in terms of RMS values for exposure by continuous sinusoidal fields so as to be comparable with limits above 100 kHz, where thermal effects are of greater concern.

A complication arises if the exposure waveform is not a continuous sine wave, such as pulsed sinusoidal waveforms or other broadband signals. The IEEE Standards deal with such waveforms by requiring compliance with one of two tests based on the frequency or temporal characteristics of the *in situ* waveform, in addition to the RMS limits in the general tables for continuous sinusoidal exposure.

3.3 HC RMS specifications for frequencies below 10 MHz

3.3.1 HC Safety Code (6) statements

The following statements regarding RMS measurements appear in HC Safety Code (6) with respect to frequencies below 10 MHz. Statement numbers have been added here as a convenience for further reference in this note.

(SC1) "Instantaneous root mean square (RMS) values apply. In the case of RF fields with amplitude modulation, the RMS values during the maximum of the modulation envelope shall apply." [*Note below Table 1in HC SC(6)-2015*]

(SC2) "At no point in time shall the RMS values for electric fields exceed the reference levels with an instantaneous reference period. In the case of RF fields with amplitude modulation, the RMS value during the maximum of the modulation envelope shall be compared to the reference level." [*Notes for Tables 3 and 4 in HC SC(6) —Note 1(as applied to the electric field)*].

(SC3) "At no point in time shall the RMS values for magnetic fields exceed the reference level with an instantaneous reference period. In the case of RF fields with amplitude modulation, the RMS value during the maximum of the modulation envelope shall be compared to the reference level." [*Notes for Tables 3 and 4 in HC SC(6) —Note 1(as applied to the magnetic field)*].

3.3.2 HC Technical Guide statements

Related statements appear in the HC Technical Guide (TG), apparently to resolve ambiguities that may be encountered in the above statements of Safety Code (6).

(TG1) "The term 'instantaneous RMS' denotes the square root of the average of the square of the field strength waveform when averaged over a single cycle of the carrier. The instantaneous RMS value of a modulated waveform, when plotted over time, traces out the RMS 'envelope.' The temporal maximum of the RMS envelope of the field strength waveform will be defined as the 'Maximum RMS' of the field strength waveform." [*Section 4.2.4 titled "Exposure Assessment Determined by Type of Reference Level (NS vs. SAR-Based*)"; *paragraph 2, page 10*]

(TG2) "Below 10 MHz, SC(6)-2015 contains two categories of reference levels (RLs)—one set of which is based on prevention of nerve stimulation (NS). The code identifies these types of RLs as having an instantaneous reference period. This means that the appropriate parameter of the field strength to be compared with NS-based RLs is the Maximum RMS for amplitude modulated field strengths. In the case of unmodulated, periodic, non-sinusoidal field waveforms, the recommended procedure is outlined in the section below. It should be emphasized that the RL values from Tables 3 and 4 of SC(6)-2015 apply to the temporal maximum of the RMS envelope that is 0.707 times the signal peak." [*Section titled 3 kHz – 10 MHz, page 11*].

(TG3) "Examples of periodic, non-sinusoidal waveforms are square waves, trapezoidal, triangular, or saw-tooth waveforms. Also included are periodically repeating exponential-rise or decay field strength waveforms that would result from square wave excitation of an inductive or capacitive load."

"The procedure for assessing this type of waveform is to measure or compute the peak-to-peak amplitude of the waveform over its entire period. The 'Effective Maximum RMS' value of the waveform that is to be compared with the NS-based reference level is equal to the peak-to-peak amplitude of the waveform divided by the factor $2\sqrt{2}$, which equals 2.83. The value of Effective Maximum RMS of such periodic, non-sinusoidal waveforms is to be treated the same as the Maximum RMS value of amplitude-modulated sinusoidal waveforms throughout the remainder of this statement." [*Section titled "Assessment of periodic, non-sinusoidal …", page 12*].

3.4. Interpretation difficulties regarding RMS metrics in HC Safety Code (6)

In assessing the HC clarifications concerning "instantaneous RMS," one must distinguish between the properties of the exposure waveform with regard to the following categories:

A. Broadband vs. narrowband waveforms: Clarification of the HC RMS metric should distinguish narrow band vs. broadband waveforms;

B. B(t) vs. dB/dt. Electrostimulation effects are more closely related to the time rate of change of flux density[7], *dB/dt,* than the waveform of flux density, *B(t)*.

The RMS clarifications in the *HC Technical Guide* appear to reasonably handle compliance issues related to narrowband waveforms. Clarifications applying to broadband waveforms do not appear to be technically correct because of misapplication of the *B(t)* waveform when *dB/dt* should be used.

3.4.1 Broadband vs. narrowband waveforms

The waveform in Fig. 1 is an example of a so-called "narrow-band" signal, consisting of a "carrier" at frequency f_c, modulated by a rectangular on/off signal. The Sensormatics anti-theft waveform, with parameters listed in Fig. 1, is an example. A spectrum analysis of such a signal would reveal a frequency distribution of energy clustered in a narrow band centered at $f = f_c$. T is the repetition time of the waveform, and would comprise the averaging period in a "true" rms measurement.

Figure 2 shows examples of "broad-band" signals. These are realistic examples of waveforms that have been used for the switched-gradient field of MRI scanners[8] (Reilly, 1998, Fig. 9.14). Spectrum analysis of such signals would reveal a distribution of energy extending down to zero frequency (DC).

3.4.2 B(t) vs. dB/dt as an exposure signal

The reaction of a nerve to an ES waveform can be quite different for narrow- versus broad-band signals. For one thing, a *B(t)* waveform can be monophasic, as indicated by examples (a), (b), and (d) of Fig. 2, whereas *dB/dt* is necessarily biphasic and charge-balanced (zero net charge). Furthermore, the duration of

[7] HC Safety Code (6) defines magnetic field limits in terms of Magnetic Field Strength, H in units of A/m; the units used in the IEEE standard is Magnetic Flux Density, B in units of tesla (T), which is related to magnetic field strength by $B = \mu H$, where μ is the permeability of the medium. The permeability of air (μ_0) is $4\pi \times 10^{-7}$ Henry per meter (H/m). The value of μ for biological tissue differs little from that of air. In this technical note, the B units are used.

[8] Both Health Canada and the IEEE state that their exposure limits do not apply to patients undergoing medical procedures. Neither group precludes application of its limits to the attendants who administer those procedures.

waveform features of the two waveforms can be quite different. In example (a) the waveform of *B(t)* is prolonged relative to the non-zero periods of *dB/dt*. Such distinctions can have a large influence on how one would model nerve excitation.

When speaking about a magnetic field stimulus, it is important to distinguish between flux density as a function of time, *B(t),* and its time derivative, *dB/dt*. From the perspective of a neuron, the important stimulus is the induced electric field $E_i(t)$ within the medium surrounding the neuron, and that waveform would, except for a factor affecting amplitude, follow *dB/dt*, not *B(t)*. This result follows from *Faraday's Law*.

If the waveform of interest is a sine wave, both *B(t)* and *dB/dt* would have sinusoidal waveforms, but with a difference in relative phase. However, if the stimulation waveform were a broadband signal, such as one of the signals illustrated in Fig. 2, the *B(t)* and *dB/dt* waveforms would be significantly different, and it would be important to design a compliance test[9] based on the waveform of *dB/dt*, rather than *B(t)*.

For non-sinusoidal waveforms, the *HC Technical Guide* specifies a compliance test based on the waveform of *B(t)*, rather than *dB/dt*. Confusion in the application of the correct applicable function under test could result in an error in compliance assessment. The magnitude and direction of the error due to misapplication of *B(t)* would depend on the specifics of the waveform under consideration.

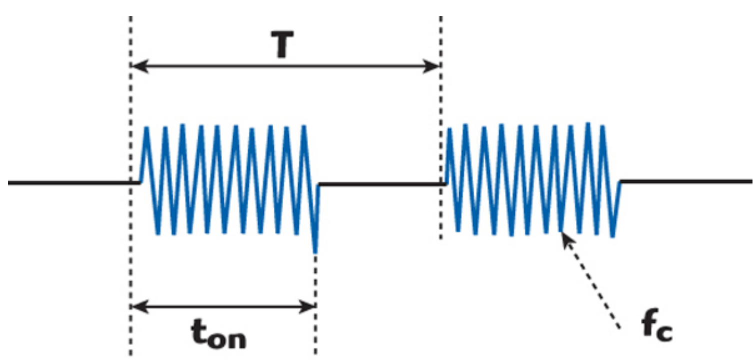

Figure 1—Example of a rectangular wave modulated at a carrier frequency f_c. For the Sensormatics anti-theft device waveform, f_c = 58 kHz, t_{on} = 1.6 ms , and T = 16.6 ms.

[9] In connection with limits based on ES effects, compliance tests for non-sinusoidal waveforms are specified in terms of the *dB/dt* waveform in Section 5.2.4.1.2 of IEEE Standard C95.6™-2002, and in Section 4.1.2.4.1.2 of IEEE Standard C95.1™-2005.

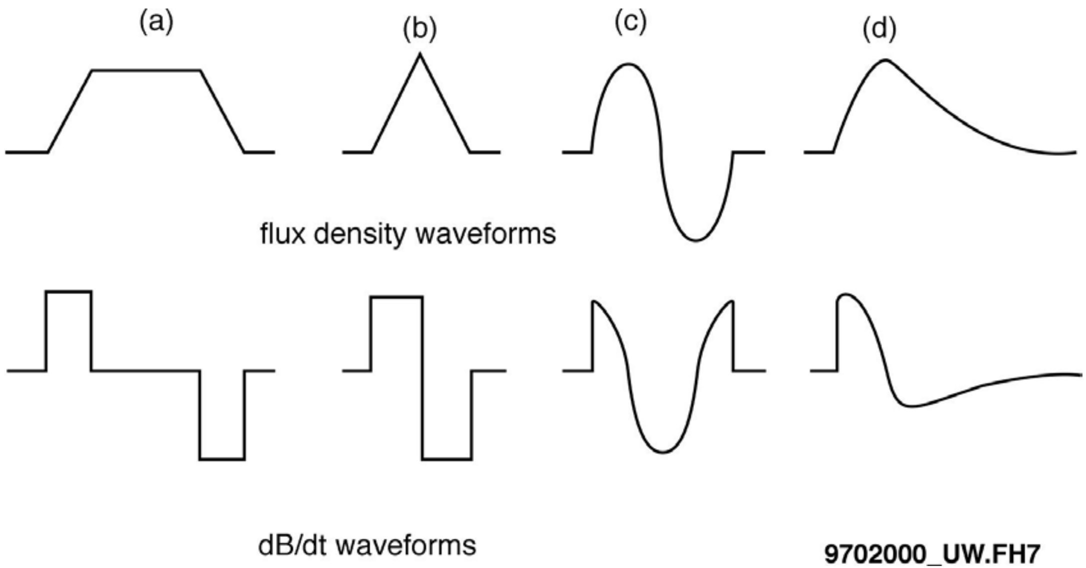

Figure 2—"Broadband" waveforms of flux density, *B(t)* (upper), and its time-derivative *dB/dt*, that have been used as MRI switched gradient fields. The repetition period, *T*, in MRI scans could be greater than the "on-time" of the waveform. Note that examples (a), (b), and (d) of the flux density waveforms, *B(t)*, are monophasic, while all the *dB/dt* waveforms are biphasic and charge-balanced (zero net charge). (From Reilly, 1998, Fig. 9.14).

3.5 Summary and discussion.

Health Canada Safety Code (6)-2015 specifies electric and magnetic field exposure limits using a metric it describes as *Instantaneous RMS*. A strict definition of an RMS quantity requires a finite averaging period, and that would be inconsistent with the HC specification of an instantaneous averaging period. The HC specification seems to be inconsistent or ambiguous in this regard.

The intended meaning of *Instantaneous RMS* is clarified in a Health Canada Technical Guide, which is available to the general public on request. The Technical Guide directly addresses the presumed inconsistency in Safety Code (6), with separate interpretations for continuous sine waves, or amplitude-modulated waveforms (as in Fig. 1), and broadband waveforms (as in Fig. 2).

Guidance in the Technical Guide regarding "instantaneous RMS" metrics would lead to a compliance test for amplitude-modulated sine waves that was consistent with the safety code limits for continuous sine waves. However, for certain broadband waveforms, the Technical Guide clarifications may lead to conclusions regarding compliance that are inconsistent with the limits for continuous sinewaves. A major factor leading to this inconsistency is that HC describes a functional definition based on the temporal behavior of flux density, *B(t)*, whereas ES principles suggest that the waveform of interest is its time derivative, *dB/dt*.

The discrepancy mentioned here is unlikely to be of significance for amplitude-modulated waveforms with a sinusoidal carrier as used in some products, such as anti-theft devices. However, the issue could be significant for exposure to certain broadband waveforms, such as used in the switched-gradient field of MRI scanners.