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REPORT

The Royal Society of Canada Expert Panel:

A Review of Safety Code 6 (2013): Health Canada's Safety Limits for Exposure to Radiofrequency Fields

Spring 2014

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A Review of Safety Code 6 (2013): Health Canada's Safety Limits for Exposure to Radiofrequency Fields

An Expert Panel Report prepared at the request of
the Royal Society of Canada
for Health Canada

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The opinions expressed in this report are those of the authors and do not necessarily represent those of the Royal Society of Canada or the opinion or policy of Health Canada.

Preface

In recent years there has been an explosion in the use of wireless technologies, from smart meters and wireless local area networks to bluetooth devices and both cordless and cellular phones. While delivering incredible convenience and mobility, these technologies have increased human exposure to electromagnetic frequencies ranging from 3 kHz to 300 GHz.

Health Canada is the federal agency responsible for setting limits on the human exposure to such radiofrequency (RF) energy and they do this through 'Safety Code 6'. Back in 1998, Health Canada first commissioned the Royal Society to examine Safety Code 6 and assess whether it was consistent with the scientific literature in setting limits that would protect the public from adverse health risks. This led to a March 1999 Expert Panel report *A Review of the Potential Health Risks of Radiofrequency Fields from Wireless Telecommunication Devices* that has been highly cited over the past 15 years.

While changes have been made to Safety Code 6 over the past 15 years, public concern has not abated over possible health impacts of RF exposure that are within the limits of the code. In 2013, Health Canada, once again approached the Society to commission another independent expert panel.

The expert panel process is a key part of the mission of the Royal Society to *"...advance knowledge, encourage integrated interdisciplinary understandings and address issues that are critical to Canadians".* Royal Society Expert Panels provide independent, timely and authoritative insights and advice to Canadian governments, industry, non-governmental organizations, and citizens regarding subject areas that are in the public interest and that would benefit from a critical assessment of existing knowledge from a range of disciplinary and sectorial perspectives.

It is worth noting that unlike some other National Academies, the Royal Society's Expert Panel reports are not official reports of the society. Rather they are reports to the society. Although we are proud of the products generated by our Expert Panels, they do not necessarily represent the official position of the Royal Society of Canada, nor of the funding organization.

While Health Canada identified the terms of reference and provided necessary funding for the panel, they had no decision over whom we selected to Chair or to sit on the panel, or whom we chose to act as external reviewers of the report. They were not privy to any of the panel discussions and only saw the final report a week before it was released publically. They were given no opportunity to request changes in the report.

We wish to thank the Panel Chair, Dr. Paul Demers and his fellow panelists for volunteering their time and expertise to prepare this report. This represents a huge amount of work on a complex and challenging subject.

We also want to thank the Peer Review Monitor and Peer Reviewers who provided extensive comments, criticisms and suggestions on the first draft of the report. The changes in the report generated by that feedback have greatly improved the quality and value of the document.

Finally, a special thank you to the members of the Royal Society's Committee on Expert Panels, the Oversight Committee that was set up to advise on the administration of this initiative, and the dedicated Royal Society staff that worked with this Expert Panel.

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The Royal Society of Canada would like to acknowledge and sincerely thank the seven peer reviewers who provided valuable, detailed input into the first draft of this report. The following reviewers have permitted the RSC to release their names:

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In the RSC's Peer Review process, a Peer Review Monitor appointed by the Committee on Expert Panels gathers the input from the reviewers and provides this anonymously to the Panel Chair. The Panel is required to communicate with the Peer Review Monitor as to how it will respond to each of the comments, criticisms and suggestions from the reviewers. When the Monitor is satisfied that the Panel has made the necessary changes to the Report, or otherwise addressed the feedback from the reviewers, the Report is prepared for publication and released.

The peer reviewers provided many very constructive comments, but they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before it was released. The identification of reviewers is done to recognize them for their valuable contributions and does not imply that they endorse the report or agree with its content. Responsibility for the final content of this report rests entirely with the Panel.

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1. Public Summary

A large number of industrial and consumer technologies operate using radiofrequency (RF) energy, which consists of electric and magnetic fields. To protect the public from adverse health effects from exposure to radiofrequency fields, Health Canada established Safety Code 6 (SC6) in 1991. It sets recommended limits for safe human exposure to RF energy emitted from devices such as cellular telephones, Wi-Fi equipment, cellular phone towers, radar and radio/TV broadcast antennas. For the general public, by far the most frequent source of exposure is through personal use of cell phones.

Health Canada regularly reviews SC6 to ensure that it is based on the most up-to-date scientific knowledge. In 2013, it proposed several revisions to bring SC6 in line with current knowledge and other international standards and asked the Royal Society of Canada to form an Expert Panel to review the proposed changes to SC6. The Panel was asked to determine whether SC6 limits provide adequate protection from established adverse health effects, whether there are other potential health impacts that should be considered, and whether additional precautionary measures should be recommended. This report outlines the evidence considered by the Panel and presents their response to the questions posed by the Royal Society. In addition, the Panel identified where there are gaps in the current state of knowledge and where further research is warranted.

The Panel considered an "established adverse health effect" as an adverse effect that is observed consistently in several studies with strong methodology. With this definition in mind, the Panel reviewed the evidence for a wide variety of negative health impacts from exposure to RF energy, including cancer, cognitive and neurologic effects, male and female reproductive effects, developmental effects, cardiac function and heart rate variability, electromagnetic hypersensitivity, and adverse health effects in susceptible regions of the eye.

Many of the studies considered reached conflicting conclusions. For example, the Panel reviewed conflicting evidence about effects of exposure to RF energy on cancer, concluding that effects are possible but are not "established" in accordance with its definition of "established health effects". The Panel's conclusion on cancer is in agreement with a recent report from the International Agency for Research on Cancer (IARC, 2013). Similarly, while effects of exposure to RF energy on aspects of male reproductive function have been found, the evidence has not been established to indicate that these translate into fertility or health effects. Problems in study design and inadequate dosimetry make it difficult to interpret the results of many of these reproductive health studies.

Therefore, the Panel has concluded that the balance of evidence at this time does not indicate negative health effects from exposure to RF energy below the limits recommended in the Safety Code. However, research on many of these health effects is ongoing and it is possible that the findings of future studies may alter this balance of evidence. The Panel recommends that Health

Canada should continue to monitor the literature for emerging evidence and that it aggressively pursue scientific research aimed at clarifying the RF energy-cancer issue and at further investigating the question of electromagnetic hypersensitivity, in particular.

Within the constraints of available resources and time, the Panel reviewed the scientific literature on biological effects of radiofrequency fields. This literature includes a number of reports of effects in various biological systems at exposure levels below recommended SC6 limits. In general, these reported low-level effects are often not consistent across similar studies and have no clear implications with respect to human health. Consequently they cannot presently be used to design safety standards. The Panel recommends that Health Canada continue to evaluate this literature as it develops.

Available studies suggest that the basic restrictions recommended in Safety Code 6 do provide adequate protection against known adverse health effects across the radiofrequency range. However, the science of exposure measurement is still developing and further research is required to not only examine the effects of exposure to new and emerging technologies, but also to compare the effectiveness of the recommended reference levels against the findings of new studies. In particular, the Panel recommends that Health Canada should consider studies in which additional data has been collected on child exposure, postured adult and postured child exposure, pregnant female and newborn exposure under grounded and isolated conditions.

During the public consultation, the Panel heard a number of significant concerns about the health effects of RF energy, the increasing levels of public exposure to RF energy, the process used to review the Safety Code, and the need for improved risk communication activities. While the Panel concluded that the human exposure limits in the Safety Code are science-based and do reflect the current state of knowledge regarding health effects, the Panel recommends that Health Canada continue to improve its efforts to inform the public regarding this issue and provide practical advice to concerned consumers on how to reduce their personal or their children's exposure. The Panel also urges Health Canada to investigate the problems of sensitive individuals with the aim of understanding their condition and finding ways to provide effective treatment, develop a procedure for the public to report suspected disease clusters and a protocol for investigating them, and encourage inclusion of basic education on non-ionizing radiation in the curriculum of Canadian medical schools.

2. EXECUTIVE SUMMARY

2.1. Background

The *Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz - Safety Code 6* (SC6), was first established by Health Canada in 1991. Designed to protect workers and the public from radio frequency (RF) energy and to prevent against all known adverse health effects from RF energy in the frequency range of 3 kHz to 300GHz, SC6 sets recommended limits for safe human exposure to RF energy emitted from devices such as cellular phones, Wi-Fi equipment, cellular phone towers, radar and TV/radio broadcast antennas.

The Code provides guidelines for both controlled and uncontrolled environments. Controlled environments are areas "where the RF field intensities have been adequately characterized by means of measurement or calculation and exposure is incurred by persons who are: aware of the potential for RF field exposure, cognizant of the intensity of the RF fields in their environment, aware of the potential health risks associated with RF field exposure and can control their risk using mitigation strategies". An uncontrolled environment is "an area where any of the criteria defining the controlled environment are not met". Generally, controlled environments are limited to areas where only occupational exposure may occur, while the general public is exposed in uncontrolled environments. Larger protection factors[1], and, therefore, stricter maximum exposure limits are set for uncontrolled environments. SC6 sets out maximum exposure limits in terms of both "basic restrictions" and the derived "reference levels," the regulatory limits for exposure. Basic restrictions are defined as "dosimetric limits directly related to established health effects that incorporate safety factors and are expressed in terms of internal electric field strength, specific absorption rate and power density". Reference levels are defined as "an easily measured or calculated quantity (i.e. externally applied electric field strength, magnetic field strength and power density or resulting body current), that, when respected, ensures compliance with the underlying basic restrictions in Safety Code 6."

Guidelines by themselves do not have the force of law or regulation in Canada. However, guidelines in the Code may be adopted and enforced by provinces or other government agencies, as well as industry or other interested parties. SC6 applies directly to all individuals working at, or visiting, federally regulated sites (for example, the Department of National Defense, which is required to conform to SC6, except where compliance is considered detrimental to training and operations of the Canadian Forces). Industry Canada directly uses the Code for equipment certification related to wireless devices, such as cell phones, cell towers (base stations), and broadcast antennae; and it uses the guidelines to develop licensing requirements that manufacturers of wireless communication equipment and service providers must meet. The Code does not cover deliberate exposure to patients by medical practitioners, or to medical personnel

[1] The protection factors for peripheral nerve stimulation are 5-fold (controlled) and 10-fold (uncontrolled). For thermal effects, they are a factor of 10 (controlled) and 50 (uncontrolled).

operating magnetic resonance imaging scanners (MRI's) or other RF-energy-emitting medical equipment[2].

To ensure that the safety limits are based on and reflect new knowledge in the scientific literature, Health Canada conducts an ongoing review of SC6. Considered in these reviews are published scientific studies, authoritative reviews of the scientific literature (internal and external), and Health Canada research. Health Canada states that the current version of SC6 reflects the scientific literature published up to August 2009 and this document replaced the previous version published in 1999. In an effort to harmonize with international standards and guidelines, in particular those proposed by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), Health Canada has reviewed the most recent scientific evidence and proposed a series of revisions to the Code. The proposed revision is referred to in this report as Safety Code 6 (2013) or SC6 (2013).

2.2. The Report

At the request of Health Canada, the Royal Society of Canada (RSC) convened an Expert Panel to conduct a review of SC6 (2013), specifically focusing on emerging evidence on the potential health risks of RF energy from wireless telecommunication devices, as well as other sources of RF exposure in the range of 3 kHz – 300 GHz. The Panel was charged with determining whether the proposed changes to the Code provide adequate protection from established adverse health effects, whether there are other potential health impacts that should be considered, and whether additional precautionary measures should be recommended.

In conducting their review of the evidence, the Panel considered an "established adverse health effect" as an adverse effect that is observed consistently in several studies with strong methodology. To achieve its mandate, the Panel considered not only Health Canada's rationale for the proposed revisions to SC6 (2013), but also recently published peer-reviewed scientific studies and authoritative or comprehensive reviews conducted by academic, governmental and non-governmental organizations (see Section 4). The Panel also accepted external submissions by the general public and concerned stakeholder groups and conducted a public meeting on October 28, 2013 to solicit further input (see Section 8).

The Panel's conclusions and recommendations are presented in this report. The report is organized into ten sections (not including the appendices and the references). The first two sections provide a complete overview of the report, in lay and scientific language. Section 3 introduces SC6 (the current code as well as Health Canada's proposed changes) and provides information on the Panel's mandate and methodology. Section 4 summarizes the main conclusions from previous reviews on the human health impacts from exposure to RF energy and compares the proposed changes with authoritative international standards. Section 5 summarizes

[2] Although RF energy associated with MRI is not covered by SC6 and is, therefore, technically outside the scope of the Panel's review, the Panel did consider this issue in Section 6.5 of this report.

potential sources of exposure to RF energy and describes the biophysical mechanisms of interaction between RF energy and biological systems. Section 6 reviews recent results in RF dosimetry and compares them with the levels being proposed by Health Canada to determine whether the basic restrictions are satisfied. Section 7 provides an overview of potential health risks, including: cancer, hypersensitivity and multiple unexplained physical symptoms, cognitive and neurologic effects, reproductive effects, ocular effects, developmental changes, cardiac functions and heart rate variability, and other biological effects. Section 8 presents an overview of the public consultation process and summarizes the feedback received into four primary areas of concern: health effects, exposure, the review process, and communication of risk. The last two sections discuss the precautionary principle of risk management as it relates to RF energy (Section 9) and present the Panel's conclusions and recommendations (Section 10). Health Canada's proposed SC6 (2013) is provided in the Appendices, along with a complete list of references considered by the Panel.

2.3. Summary of Proposed Changes to Safety Code 6

Thresholds for adverse health effects in SC6 are based upon different biological phenomena observed in the following region of the electromagnetic frequency spectrum: 3 kHz – 300 GHz. Details of the specific changes proposed by Health Canada, along with the rationale for the changes and how the proposed changes compare with international standards, are presented in tabular form and graphically in Section 4 of this Report. A high level summary of the proposed changes is presented here.

3 kHz – 10 MHz: In this frequency range, the threshold for adverse health effects in SC6 (2009) was based upon the avoidance of both peripheral nerve stimulation (PNS) and thermal effects from externally applied electric and/or magnetic fields. The PNS threshold is based on the perception of a tingling sensation. Painful PNS only occurs at even higher electric field strengths in the body. No newly identified adverse health effects have been established in this frequency range since SC6 (2009).

Proposed Basic Restrictions: The avoidance of PNS and thermal effects remains the basis for the proposed basic restrictions in this frequency range. However, basic restrictions for the avoidance of PNS were not specified in SC6 (2009). Health Canada decided that basic restrictions were required in SC6 (2013) between 3 kHz and 10 MHz for the avoidance of PNS. This harmonizes the SC6 (2013) basic restrictions with those presented in ICNIRP (2010) for this frequency range.

Proposed Reference Levels: In setting reference levels for both electric and magnetic fields in SC6 (2013), Health Canada considered two simultaneous criteria: the adoption of separate basic restrictions for PNS and thermal effects, and harmonization with other international standards,

where feasible. With the exception of the SAR-based[3] magnetic field reference levels, the proposed magnetic and electric field reference levels (controlled and uncontrolled) in SC6 (2013) align with the 2010 ICNIRP levels. The 1998 ICNIRP limits are proposed for SAR-based magnetic field reference levels. The resulting reference levels are slightly more restrictive than the SAR-based reference levels in SC6 (2009).

3 kHz – 110 MHz: In this frequency range, the induced and contact current limits in SC6 (2009) were based upon avoidance of PNS (perception and/or pain) at frequencies from 3 – 100 kHz and thermal effects (thermal perception and/or pain) for frequencies from 0.1 – 110 MHz. In SC6 (2013), induced- and contact-current reference levels have been revised to take into account recent dosimetric information and to provide a larger safety margin for the avoidance of painful RF shocks and burns. Proposed contact current limits in SC6 (2013) are based on avoiding the occurrence of finger-touch shocks in the 3 – 100 kHz frequency range.

Proposed Reference Levels: The current version of SC6 (2009) sets basic restrictions for the avoidance of adverse thermal effects from induced and contact currents through the foot at 100 mA and 45 mA for controlled and uncontrolled environments, respectively. IEEE (2005) and ICNIRP (2010, 1998) have established reference levels for contact currents at lower levels, providing an additional margin of safety from the occurrence of such effects. Induced and contact current limits are derived from the basic restrictions. Therefore, these limits have been specified as reference levels in SC6 (2013).

Proposed Reference Levels for Induced Current: In the frequency range 3 kHz to 400 kHz, the proposed induced current reference levels in SC6 (2013) have been revised to avoid the occurrence of thermal perception and increase the safety margin for the avoidance of RF shocks and burns. The proposed uncontrolled induced current reference level of 40 mA for the frequency range of 400 kHz to 110 MHz is based on avoidance of peak spatially-averaged SAR in the ankles.

Proposed Reference Levels for Contact Current: Finger touch forms the basis for the proposed contact current reference levels in SC6 (2013) because it appears to have the lowest perception thresholds. In keeping with the goal of harmonization, the proposed reference levels are identical to those specified by ICNIRP (1998 and 2010).

10 MHz – 6 GHz: In this frequency range, the threshold for adverse effects is based upon the avoidance of tissue heating. Since the last revision of SC6 (2009), no new adverse health effects have been established in this frequency range.

[3] SAR is the acronym for "specific absorption rate". It is the amount of power absorbed by a given mass of tissue, in watts per kilogram of tissue. SAR is a relevant and useful measure of biological damage because exposure to RF energy is associated with excessive heating of tissue.

Proposed Basic Restrictions: Avoidance of adverse thermal effects remains the basis for the basic restrictions in this frequency range. Basic restrictions are proposed for whole-body average SAR and peak spatially-averaged SAR.

Proposed Reference Levels: In the 10 to 65 MHz frequency range, proposed reference levels for uncontrolled- and controlled-environments are equal to 1998 ICNIRP levels. For frequencies from 65 to 100 MHz, the proposed reference levels in SC6 (2013) deviate from 1998 ICNIRP levels by decreasing with increasing frequency to accommodate dosimetry data from studies on children.

Peak Pulsed RF Field Levels: The proposed limits for power density in SC6 (2013) include a note, which limits the temporal peak power density for pulsed RF energy (in the 10 MHz – 300 GHz frequency range) to no more than 1000 times the reference level for power density.

6 GHz – 300 GHz: In this frequency range, no new health effects have been established since the last revision of SC 6 (2009). The avoidance of tissue heating remains the basis for the reference limits in this frequency range and no changes in the basic restrictions are recommended. Proposed reference levels remain unchanged from SC6 (2009).

2.4. Public Input on the Proposed Changes

Although the original terms of reference for the Expert Panel did not require a public forum regarding the proposed changes to SC6, the RSC decided to host a public meeting on October 28, 2013 (in part because it had received interest from a number of public groups regarding this review and its process). The objective of the meeting was to allow the public the opportunity to voice their opinions and perspectives regarding Safety Code 6. A total of 35 people made presentations that day either in person or online. In addition to the public meeting, the Royal Society accepted written comments and submissions from individuals as well as representatives from different groups and agencies.

Fifteen primary topics emerged from the public consultation. In addition to grouping the public input into primary areas and topics of concern, the Panel also contextualized the submissions into eight frames. Framing is a method by which efforts are made to understand the context through which people perceive an issue and is useful for ensuring more effective communication in the future. The results of the public consultation are described in detail in Section 8 of this report. In analyzing the submissions, the Panel noted four primary areas of concern.

Health effects: This topic generated the largest number of public comments. Many participants expressed concerns regarding the potential health impacts from exposure to RF energy at the levels proposed in Safety Code 6 (2013). Presenters described a series of symptoms and conditions that they or their family members had experienced which they associated with exposure to RF energy.

Exposure: Participants expressed concerns about how much exposure exists, where exposures occur, cumulative exposures, issues of distance from sources, and engineering controls to reduce exposure in devices and spaces.

The review process: Participants expressed concerns regarding Health Canada's involvement in the RSC process and requested that the Expert Panel maintain a high level of transparency regarding its selection and review of the scientific literature on health effects. Calls were also made for the RSC to implement a precautionary approach in its review.

Risk Communication: Participants called for greater public awareness campaigns regarding RF energy and requested more information from manufacturers such as better labeling and warnings.

2.5. Key Conclusions of the Panel

In reviewing Health Canada's proposed changes to Safety Code 6, the Panel was asked to address five key questions. The Panel's conclusions are presented in Section 10 and are summarized below.

1. Do the basic restrictions specified in SC6 (2013) provide adequate protection for both workers and the general population from established adverse health effects from RF fields?

SC6 (2013) essentially combines the most conservative aspects of limits previously recommended by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the International Committee on Electromagnetic Safety of the Institute of Electrical and Electronics Engineers (IEEE). The safety factors for PNS are 5-fold (controlled) and 10-fold (uncontrolled). For thermal effects, they are a factor of 10 (controlled) and 50 (uncontrolled). The Panel notes that although the margins of safety in the basic restrictions appear to be quite high, they are difficult to judge with precision. The basic restrictions at the lower end of the frequency range (3 – 400 kHz) were based on thresholds for nerve stimulation obtained by extrapolating data from studies at much lower frequencies and arguments have been raised that the assumptions ICNIRP used in making these extrapolations are overly conservative. Likewise, there are very few data that would be directly useful in setting exposure limits at millimeter wave frequencies (30-300 GHz).

The basic restrictions themselves have a considerable amount of conservatism inherent in them. The whole body limit for SAR in SC6 (2013) for uncontrolled environments corresponds to roughly 10% of the basal metabolic rate of the human body and is equivalent to the thermal load from very slight physical activity. Research suggests that the basic restrictions, even for controlled conditions, are adequate for protection against excessive thermal load to the body from exposure to RF energy (Adair, 2003). See Section 5.2 (specifically, the subsection entitled "thermal sensitivity of biological systems").

2. Are there any other established adverse health effects occurring at exposure levels below the basic restrictions in SC6 (2013) that should be considered for revising the basic restrictions and reference levels in SC6 (2013)?

In Section 7 of this report, the Panel reviewed the evidence for a wide variety of adverse health effects. Although questions remain regarding the risk of cancer, the case for a causal association between cancer and exposure to RF energy is weak (based on limited and conflicting epidemiology and laboratory studies, see Section 7.1). Idiopathic Environmental Intolerance Attributed to Electromagnetic Fields (IEI-EMF), or Electrical Hypersensitivity, also remains an issue of serious concern that deserves further investigation. However, there is no firm evidence for the hypotheses that people with IEI-EMF can perceive RF energy at levels below the limits in SC6 or that there is a causal link between exposure to RF energy and their symptoms. In addition, no cognitive and neurologic, male and female reproductive, developmental, cardiac function and heart rate variability, or other adverse health effects below the basic restrictions in SC6 (2013) have been established. Since research on many of the topics described above continues, the Panel made an extensive search for new studies that might point to adverse effects of exposure to RF energy. The Panel was unable to identify any established adverse health effects occurring at levels below the basic restrictions in SC6 (2013). As shown in Section 4 and Section 7, the Panel's conclusions are in line with almost all recent expert reviews.

3. Is there sufficient evidence upon which to establish separate basic restrictions or recommendations for the eye?

In Section 7.5 of this report, the Panel reviewed the evidence for adverse effects on the eye due to exposure to RF energy. The Panel concluded that recent studies on the exposure of the eye to RF energy do not show adverse effects in potentially susceptible regions (for example, the aqueous humour, lens and vitreous humour) at exposure levels below those proposed in SC6 (2013) for the head, neck and trunk. While there has been controversy about possible links between exposure to RF energy and cataracts going back to the 1960s, recent reviews (e.g., AGNIR, 2012) have concluded that no definite evidence exists linking exposure to RF energy below international limits and cataract in humans. Cataracts can be produced in experimental animals, but only at exposure to levels of RF energy that cause painful heating to the skin around the eye. Therefore, there is insufficient evidence upon which to establish separate exposure limits for the eye.

4. Do the reference levels established in SC6 (2013) provide adequate protection against exceeding the basic restrictions in SC6 (2013)?

The Panel concludes that the SC6 (2013) reference levels provide adequate protection against exceeding the PNS (3 kHz-10 MHz) and power density (6 GHz-300 GHz) basic restrictions. However, the Panel believes that the proposed reference levels do not provide adequate protection against exceeding the SAR basic restrictions (100 kHz- 6 GHz).

In Section 6, the Panel states that available data strongly suggest that the SC6 (2013) electric and magnetic field strength reference levels provide adequate protection against exceeding the SC6 (2013) internal electric field strength basic restrictions between 3 kHz and 10 MHz. Provided that appropriate skin conductivities are used to calculate the induced electric field strengths in anatomically realistic human models, compliance with the reference levels will ensure compliance with the basic restrictions. However, the Panel notes that dosimetry is still developing in this intermediate frequency range. Therefore, the Panel recommends that further studies investigating the characterization of skin conductivity and the variability of the internal electric field strength in different human anatomical models, from exposure to external magnetic and electric fields, be carried out in the near future to further test the suitability of the SC6 (2013) reference levels for this frequency range.

The Panel noted that a number of recent reported SAR studies show that compliance with the SC6 (2013) electric, magnetic field strength and power density reference levels between 100 kHz and 6 GHz will not ensure compliance with the SC6 (2013) SAR basic restrictions. It is important to note that in these cases where a compliant reference level produces a non-compliant SAR basic restriction value, it is very unlikely that the SAR will be at a sufficient level to produce an adverse health effect in humans. However, for the reference level definition statement in SC6 (2013) "compliance with the reference levels will ensure compliance with the basic restrictions in this safety code" to be correct, the proposed SC6 (2013) reference levels must be changed. The Panel recommends that Health Canada review the large number of dosimetry studies that have been produced since the last major revision of SC6 in 1999 and modify the proposed SC6 (2013) reference levels accordingly.

The Panel noted that available studies suggest that the SC6 (2013) electric, magnetic field strength and power density reference levels provide adequate protection against adverse health effects in humans across the 6 GHz to 300 GHz frequency range. However, similar to internal electric field dosimetry between 3 kHz and 10 MHz, dosimetry in the 6 GHz to 300 GHz frequency range is still developing and further research is required to examine the effects of exposure to new and emerging technologies.

5. Should additional precautionary measures be introduced into the human exposure limits in SC6 (2013)? If so, what is recommended and why?

The Panel notes in Section 9 of this report that human exposure limits in SC6 (2013) are science-based limits designed to avoid all known health hazards of exposure to RF energy. The limits were designed, and would be understood by the public, to protect against demonstrated adverse effects with an appropriate safety factor. These limits could be undermined by arbitrary changes that are not based on a careful review of the scientific evidence and identification of hazards. However, other precautionary measures can and should be taken by Health Canada in relation to SC6 (2013). For example, Health Canada should expand their existing risk communication strategy to address consumer need for more information around RF energy, the types of devices

that use RF energy and the levels emitted. In addition, Health Canada should incorporate additional suggestions into their recommendations on practical measures that Canadians can take to reduce their exposure around cell phone use (for example, using an earpiece).

During the public consultation, the Panel heard from numerous individuals who felt that they are sensitive to low levels of RF energy in the environment from a variety of sources, a condition that is technically known as Idiopathic Environmental Intolerance Attributed to Electromagnetic Fields (IEI-EMF) or more popularly as Electromagnetic Hypersensitivity. The Panel notes in Section 7.2 that extensive research has failed to clearly link a person's symptoms with actual exposure to RF energy and that the etiology of the condition remains unknown and perhaps complex. This Panel feels strongly that these individuals need compassion and assistance in overcoming their symptoms. However, because of the very unclear relation between the symptoms and actual exposure to RF energy, the Panel considers that such assistance should be provided by means other than a revision of SC6 (2013). Therefore, the Panel urges Health Canada to investigate the symptoms of IEI-EMF individuals with the aim of understanding the etiology of their condition, developing criteria for differential diagnosis of the condition, and finding ways to provide effective treatment for such individuals.

2.6. Summary of the Panel's Recommendations

Although not explicitly tasked with providing recommendations to Health Canada beyond the five questions above, the Panel has identified a number of gaps in our current knowledge about the impact of exposure to RF energy on human health, as well as the effectiveness of the proposed guidelines. To address these gaps, as well as concerns raised during the public consultation, the Panel offers the following non-binding recommendations to Health Canada.

- Studies investigating the characterization of skin conductivity and the variability of the internal electric field strength in different human anatomical models, from exposure to external magnetic and electric fields, should be carried out in the near future to further test the suitability of the SC6 (2013) reference levels for the 3KHz to 10 MHz frequency range.
- The effectiveness of the SC6 (2013) reference levels should be examined against a larger number of new dosimetry studies than those specified in the SC6 (2013) Rationale. Additional data should be collected on child exposure, postured adult and postured child exposure, pregnant female and newborn exposure under grounded and isolated conditions.
- Dosimetry in the 6 GHz to 300 GHz frequency range is still developing and further research is required to examine the effects of exposure to new and emerging technologies
- Health Canada should aggressively pursue scientific research aimed at clarifying the RF energy-cancer issue. This would allow the government to develop protective measures if the risk were substantiated.
- Health Canada is urged to investigate the symptoms of IEI-EMF individuals with the aim of understanding the etiology of their condition, developing criteria for differential

diagnosis of the condition, and finding ways to provide effective treatment for such individuals.

- Health Canada should develop a procedure for the public to report suspected disease clusters and a protocol for investigating them. This could be based on the US Centers for Disease Control protocol or on the 2011 Alberta protocol (Alberta Health Services, 2011).
- Health Canada should expand their existing risk communication strategy to address consumer need for more information around RF energy, the types of devices that use RF energy and the levels emitted. In addition, Health Canada should incorporate additional suggestions into their recommendations on practical measures that Canadians can take to reduce their exposure around cell phone use (for example, limiting use in areas with low signal strength, and using an earpiece).
- Health Canada should encourage inclusion of basic education on non-ionizing radiation in the curriculum of Canadian Medical Schools.
- Health Canada should pursue research to expand our current understanding of possible adverse effects of exposure to RF energy at levels below SC6 (2013). Several gaps in the evidence are identified in Section 7 of this report.
- Health Canada should evaluate the need for a document to encompass all aspects of safety around magnetic resonance imaging (MRI).

3. INTRODUCTION

3.1. Background

The *Limits of Human Exposure to Radiofrequency Electromagnetic Energy in the Frequency Range from 3 kHz to 300 GHz - Safety Code 6* (SC6), was first established by Health Canada in 1991. Safety Code 6 sets recommended limits for safe human exposure to electromagnetic energy emitted from devices such as cellular phones, Wi-Fi equipment, cellular phone towers and radio/TV broadcast antennas. The Code outlines basic restrictions and reference levels designed to protect workers and the public against all known adverse health effects from radiofrequency (RF) energy in the frequency range of 3 kHz to 300GHz.

The part of the electromagnetic spectrum covered by SC6 is used by a large number of technologies. For example, induction ovens[4] operate at the low end of the spectrum (1 – 400 kHz); household microwave ovens typically operate in the megahertz range (2450 MHz or 2.45 GHz); radio and television stations broadcast their signals at various frequencies ranging from 500 kHz to 1.6 MHz for AM radio, 87 to 108 MHz for FM radio and up to 850 MHz for some television stations; communications transmitters, such as cellular telephones, generally operate between 0.1 and 3 GHz. A more complete description of potential sources of exposure to RF energy is found in Section 5 of this report.

The photons that constitute RF energy are nonionizing[5]. This is very different from ionizing radiation such as X-rays and, consequently, the biophysical interactions of RF energy with the body are very different from those of ionizing radiation. RF energy can propagate through space (in which case it is described as RF radiation) or it can be confined to the immediate vicinity of sources (in which case it is described as RF fields). While the term "radiation" is used frequently in this report, it is used in a technical sense to refer to energy that propagates through space. Radiofrequency energy, as with electromagnetic energy of all sorts, consists of electric and magnetic fields. The particular exposure situation determines whether it is more appropriate to consider exposure in terms of the intensity of RF radiation or of its constituent electric or magnetic fields.

SC6 applies directly to all individuals working at, or visiting, federally regulated sites. The Department of National Defense is required to conform to SC6, except where compliance is considered detrimental to training and operations of the Canadian Forces. The Code is also directly used by Industry Canada for equipment certification related to wireless devices, such as cell phones, cell towers (base stations), and broadcast antennae. Industry Canada uses the guidelines set out in the Code to develop licensing requirements that manufacturers of wireless communication equipment and service providers must meet. It does not cover deliberate exposure

[4] Induction heating takes advantage of ferromagnetism to heat a container and its contents, rather than heating the surrounding air. An alternating electric current produces an oscillating magnetic field that, in turn, excites iron molecules and induces an electric current in the container. This current produces resistive heating, which heats the container and its contents.

[5] That is, their energy is orders of magnitude below a level that can disrupt even the weakest chemical bond.

to patients by medical practitioners, or to medical personnel operating MRI's or other RF-energy-emitting medical equipment.

Guidelines by themselves do not have the force of law or regulation. However, provinces or other government agencies, as well as industry or other interested parties may adopt Safety Code 6. To provide guidance on how to achieve recommended levels and to assist users in understanding and assessing the safety of electromagnetic exposures in working and living environments, Health Canada publishes a companion document to SC6, the *Technical Guide for Interpretation and Compliance Assessment of Health Canada's Radiofrequency Exposure Guidelines*.

SC6 provides maximum exposure limits in terms of both "basic restrictions" and the derived "reference levels," the regulatory limits for exposure. Basic restrictions are defined as "dosimetric limit directly related to established health effects that incorporate safety factors and are expressed in terms of internal body currents or specific absorption rate (100 kHz to 6 GHz)" (SC6, 2013). Reference levels are defined as "an easily measured or calculated quantity (i.e. externally applied electric field strength, magnetic field strength and power density or resulting body current), that, when respected, ensures compliance with the underlying basic restrictions in Safety Code 6."

Health Canada conducts an ongoing review of SC6 to ensure that the safety limits are based on and reflect new knowledge in the scientific literature. Considered in these reviews are published scientific studies, authoritative reviews of the scientific literature (internal and external), and Health Canada research. The current version of SC6 reflects the scientific literature published up to August 2009 and replaced the previous version published in 1999.

In an effort to harmonize with international standards and guidelines, in particular those proposed by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) in 2010, Health Canada has reviewed the most recent scientific evidence and proposed a series of revisions to the Code, referred to in this report as Safety Code 6 (2013) or SC6 (2013).

3.2. The Expert Panel

At the request of Health Canada, the Royal Society of Canada (RSC) convened an Expert Panel to conduct a review of Safety Code 6 (2013), specifically focusing on emerging evidence on the potential health risks of radiofrequency fields from wireless telecommunication devices, as well as other sources of exposure to RF energy in the range of 3 kHz – 300 GHz. The Panel was charged with addressing the following questions:

1. Do the basic restrictions specified in Safety Code 6 (2013) provide adequate protection for both workers and the general population from established adverse health effects from RF fields?

2. Are there any other established adverse health effects occurring at exposure levels below the basic restrictions in Safety Code 6 (2013) that should be considered for revising the basic restrictions and reference levels in SC6 (2013)?
3. Is there sufficient scientific evidence upon which to establish separate basic restrictions or recommendations for the eye?
4. Do the reference levels established in Safety Code 6 (2013) provide adequate protection against exceeding the basic restrictions in Safety Code 6 (2013)?
5. Should additional precautionary measures be introduced into the human exposure limits in Safety Code 6 (2013)? If so, what is recommended and why?

Because a number of the proposed changes in SC6 (2013) were based on refinements in dosimetry, Health Canada suggested that the larger proportion of the membership should have expertise in the engineering aspects of Safety Code 6. The RSC convened a Panel of eight members from Canada, the United Kingdom, the Netherlands and the United States with a wide range of expertise relevant to the questions submitted, including dosimetry, biology, medicine, epidemiology, risk communication and policy.

3.3. The Panel's Methodology

The Panel was provided with a copy of the new proposed Safety Code 6 (2013), as well as a more extensive document, which provided the rationale for the revised code. Health Canada did not participate on, or communicate with the Panel, except to answer questions regarding the proposed code. The Panel's mandate was to examine Health Canada's proposed changes in light of recent expert reviews regarding the adverse health effects of exposure to RF energy. It was not expected to do a comprehensive analysis of the literature. There have been a large number of authoritative or comprehensive reviews relevant to the tasks of the Panel in recent years (see Section 4 of this report). These reviews have been conducted by both governmental and non-governmental organizations and academics. In fulfilling its mandate, the Panel began with these authoritative or comprehensive reviews and then conducted searches of the peer-reviewed literature using both standard search engines, such as Medline, and specialized databases such as EMF portal (www.emf-portal.de) to identify any relevant peer-reviewed literature published subsequent to the authoritative reviews. The Panel also accepted submissions by the general public and concerned stakeholder groups and conducted a public meeting on October 28, 2013 to solicit further input. The public meeting process, along with a synopsis of the major topic areas covered by the submissions, is summarized in Section 8 of this Report.

3.4. Proposed Changes to Safety Code 6

The purpose of Safety Code 6 is to provide guidance for maximum human exposure to electromagnetic radiation across the frequency range 3 kHz – 300 GHz. The thresholds for adverse health effects in the Safety Code are based upon different biological phenomena observed in the following regions of the frequency spectrum: 3 kHz – 10 MHz (i.e., electric and

magnetic fields), 3 kHz – 110 MHz (i.e., induced and contact current), 10 MHz – 6 GHz (i.e., electric fields, magnetic fields and power density), and 6 GHz – 300 GHz (i.e., electric fields, magnetic fields and power density). Health Canada's proposed revisions to the Code reflect new scientific knowledge and are intended to harmonize, wherever practical, with international standards, such as those presented in Section 4 in this report.

Safety Code 6 provides guidelines for both controlled and uncontrolled environments. A controlled environment is defined as "a condition or area where exposure is incurred by persons who are aware of the potential for RF exposure and are cognizant of the intensity of the RF energy in their environment, where exposures are incurred by persons who are aware of the potential health risks associated with RF exposure and whom can control their risk using mitigation strategies." An uncontrolled environment is defined simply as "a condition or area where exposures are incurred by persons that do not meet the criteria defined for the controlled environment" (Safety Code 6, 2013). Generally, controlled environments are limited to areas where only occupational exposure may occur, while uncontrolled environments encompass areas where the general public is exposed. Larger protection factors, and, therefore, stricter maximum exposure limits are set for uncontrolled environments.

The specific changes proposed by Health Canada, along with the rationale for the changes and how the proposed changes compare with international standards, are presented in tabular form and graphically in Section 4 of this Report. Proposed basic restrictions are summarized in Table 4.2-1, while all proposed reference levels for controlled and uncontrolled environments are presented in Table 4.2-2 and Table 4.2-3. Proposed reference levels for electric fields, magnetic fields and power density in controlled and uncontrolled environments are presented graphically in Figure 4.2-1, Figure 4.2-2 and Figure 4.2-3. For ease of comparison with international standards, Health Canada's proposed changes are presented in these tables and figures alongside the recommendations of the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the Institute for Electrical and Electronics Engineers (IEEE).

A high level summary of the proposed changes is presented here.

3 kHz – 10 MHz:

The threshold for adverse health effects in SC6 (2009) was based upon the avoidance of both peripheral nerve stimulation (PNS), and thermal effects from externally applied electric and/or magnetic fields. No newly identified adverse health effects have been established in this frequency range since SC6 (2009).

Proposed Basic Restrictions

The avoidance of PNS and thermal effects remains the basis for the proposed basic restrictions in this frequency range. However, basic restrictions for the avoidance of PNS were not specified in SC6 (2009). Health Canada has proposed basic restrictions for the avoidance of PNS. This

harmonises the SC6 (2013) basic restrictions with those presented in ICNIRP (2010). See Table 4.2-1.

Proposed Reference Levels

In setting reference levels for both electric and magnetic fields in SC 6 (2013), Health Canada considered two simultaneous criteria: the adoption of separate basic restrictions for PNS and thermal effects, and harmonization with other international standards, where feasible.

Magnetic Fields: For protection against PNS, the ICNIRP (2010) magnetic field strength reference levels (uncontrolled and controlled) are proposed for adoption in Safety Code 6 (2013). For SAR-based magnetic field reference levels, the sloped portion of the ICNIRP (1998) limits, extended back to 100 kHz (uncontrolled) or beginning at 100 kHz (controlled) are proposed for Safety Code 6 (2013). The resulting reference levels are slightly more restrictive than the SAR-based reference levels in Safety Code 6 (2009). See Table 4.2-2; Table 4.2-3 and Figure 4.2-2.

Electric Fields: Over the frequency range 3 kHz to 10 MHz, the ICNIRP (2010) electric field strength reference levels (uncontrolled and controlled) are proposed for adoption in Safety Code 6 (2013). See Table 4.2-2; Table 4.2-3 and Figure 4.2-1.

3 kHz – 110 MHz:

Induced- and contact-current reference levels in Safety Code 6 (2013) have been revised to take into account recent dosimetric information and to provide a larger safety margin for the avoidance of painful RF shocks and burns. In Safety Code 6 (2009), the induced and contact current limits were based upon avoidance of PNS (perception and/or pain) at frequencies from 3 – 100 kHz and thermal effects (thermal perception and/or pain) for frequencies from 0.1 – 110 MHz. Proposed contact current limits in Safety Code 6 (2013) are based on avoiding the occurrence of finger-touch shocks in the 3 – 100 kHz frequency range.

Proposed Reference Levels

The current version of Safety Code 6 (2009) set basic restrictions for the avoidance of thermal effects from induced and contact currents in one foot at 100 mA and 45 mA for controlled and uncontrolled environments, respectively. Other international organizations (for example, ICNIRP (2010, 1998) and IEEE, (2005)) have established reference levels for contact currents at lower levels, providing an additional margin of safety from the occurrence of such effects. Induced and contact current limits are derived from the basic restrictions; therefore, these limits have been specified as reference levels in SC6 (2013). See Table 4.2-1.

Proposed Reference levels for Induced Current

3 kHz to 400 kHz: ICNIRP (1998) does not specify reference levels for induced current in limbs at frequencies below 10 MHz, while ICNIRP (2010) makes no recommendations for induced

current reference levels up to 10 MHz. The proposed induced current reference levels in SC6 (2013) have been revised in this frequency range to avoid the occurrence of thermal perception and increase the safety margin for the avoidance of RF shocks and burns.

400 kHz to 110 MHz: The proposed uncontrolled induced current reference level of 40 mA for this frequency range is based on avoidance of peak spatially-averaged SAR in the ankles. See Table 4.2-2 and Table 4.2-3.

Proposed Reference Levels for Contact Current

Contact current is usually termed an indirect effect of exposure to RF energy. The factor that makes contact current potentially hazardous is the current flowing through parts of the body with narrow cross-section (e.g., fingers, wrists, ankles) that can give rise to large current densities and limb SARs. Since finger touch appears to have the lowest perception thresholds, it forms the basis for the proposed contact current reference levels in Safety Code 6 (2013). In keeping with Health Canada's goal of harmonization, the proposed contact current reference levels in Safety Code 6 (2013) are identical to those specified in ICNIRP (1998) and ICNIRP (2010). See Table 4.2-2 and Table 4.2-3.

10 MHz – 6 GHz:

The threshold for adverse effects is based upon the avoidance of tissue heating and basic restrictions are proposed for whole-body average SAR and peak spatially-averaged SAR. Since the last revision of Safety Code 6 (2009), no new adverse health effects have been established in this frequency range.

Proposed Basic Restrictions

Avoidance of thermal effects remains the basis for the basic restrictions in this frequency range. See Table 4.2-1.

Proposed Reference Levels

The proposed uncontrolled- and controlled-environment reference levels were established at levels equal to those of ICNIRP (1998) in the 10 to 65 MHz frequency range. However, for frequencies from 65 to 100 MHz, the proposed reference levels in Safety Code 6 (2013) deviate from those of ICNIRP (1998) by decreasing with increasing frequency to accommodate the dosimetry data from studies on children, providing more protection.

Peak Pulsed RF Field Levels

Safety Code 6 (2009), IEEE C95.1 (2005) and ICNIRP (1998) all contained provisions to limit the intensity of individual or infrequent RF field pulses. This is to avoid pressure waves in the head from rapid thermo-elastic expansion of tissues caused by absorption of RF field pulses typical of those produced by radar, which might lead to auditory sensations in the individual (the

"microwave hearing" effect) (Foster and Finch, 1974). To harmonize with international standards, the proposed limits for power density include a note, which limits the temporal peak power density for pulsed RF energy (in the 10 MHz – 300 GHz frequency range) to no more than 1000 times the reference level for power density. See Table 4.2-2 and Table 4.2-3.

6 GHz – 300 GHz:

Since measurements of whole-body SAR and peak spatially-averaged SAR are not readily achievable or appropriate in this frequency range due to the superficial nature of energy deposition within tissue, reference levels for electric- and magnetic-fields and power density form the basis of the human exposure limits in this frequency range. Since the last revision of Safety Code 6 (2009), no new health effects have been established in this frequency range. Therefore, the avoidance of thermal effects remains the basis for the reference limits in this frequency range and no changes in the basic restrictions are recommended by Health Canada. Proposed reference levels remain unchanged from Safety Code 6 (2009). See Table 4.2-2 and Table 4.2-3.

4. Authoritative Reviews and Standards

In reviewing and updating SC6 (2009), Health Canada's objective was two-fold: to ensure that the safety limits are based on and reflect new knowledge in the scientific literature and to harmonize with other international standards and guidelines, wherever feasible. This section summarizes the main conclusions from previous reviews on the human health impacts from radiofrequency exposure and compares the proposed changes with authoritative international standards—specifically, those published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the International Committee on Electromagnetic Safety of the Institute of Electrical and Electronics Engineers (IEEE). An overview of potential adverse health effects is presented in Section 7 of this report.

4.1. Authoritative Reviews on Human Health Impacts due to RF Exposure

Numerous high calibre reviews have been produced since the release of the 1999 report by the Royal Society of Canada on the health risks of radiofrequency fields resulting from wireless telecommunication devices. Some of these reviews were produced by the International Agency for Research on Cancer (IARC, 2013), European Commission (EFHRAN, 2012; Mudgal et al., 2011; Pärt and Jarosinska, 2013; SCENIHR 2009b), the USA (President Cancer Panel, 2010), Japan (Telecommunication Bureau, 2001), and South America (Latin American Expert Committee, 2010). Others were produced by respected national organizations (BUWAL, 2003; CCARS, 2011; Japan Telecom Bureau, 2001; L'ANSES, 2013; NIPH, 2012; NRBP, 2004; SSK, 2011; SSM, 2013; The Hague, 2013; Victoria Dept. of Health, 2012). This section of the report presents a high level summary of the most pertinent conclusions.

There is a consensus among these major international reviews that there is no conclusive and strong evidence that exposure to low levels of electromagnetic radiation as stated by the current guidelines would pose any risk of adverse outcomes to humans (AGNIR 2012; EFHRAN 2012; ICNIRP 1998, 2011; Pärt and Jarosinska, 2013). Adverse outcomes considered in these reviews include, but are not limited to: cancer initiation or promotion; genotoxicity; ocular effects; cognitive impairments; neurophysiological functions; cardiovascular, immune, hematologic, endocrine, auditory, or reproductive systems; pregnancy; fetal development; and generalized hypersensitivity symptoms. Section 7 of this report provides an overview of the potential adverse health risks considered by the Expert Panel in relation to the proposed Safety Code 6 (2013).

Some reviews reported possible occurrences of adverse outcomes in relation to radiofrequency fields such as brain tumours, acoustic neuromas, and sperm abnormalities (e.g., EFHRAN, 2012; BUWAL, 2003). The most recent authoritative review of the carcinogenicity of RF energy was published in 2013 by the International Agency for Research on Cancer (IARC, 2013). Although this review concluded that there is limited evidence linking exposure to RF radiation with cancer, an IARC Working Group categorized radiofrequency fields as a possible carcinogen to humans (group 2B). Section 7 provides a more complete summary of the Working Group's evaluation.

Despite the lack of strong and conclusive evidence of an association between the use of mobile phones and development of cancer, some of those major reviews suggested that a precautionary approach might be warranted (e.g., BUWAL, 2003; L'ANSES, 2013; Pärt and Jarosinska, 2013). This approach comprises reducing environmental exposure to radiofrequency fields, through the use of mobile phones with low specific absorption rate (SAR), minimizing the use of mobile phones by children, and reducing the levels in areas where people are heavily exposed to radiation. The Panel's response to the question of whether additional precautionary measures should be introduced into Safety Code 6 (2013) is found in Section 9.

Even with the lack of conclusive evidence, many reviews point out that the data analyzed from exposure to radiofrequency fields in the past 13 to 15 years cannot be used to rule out any possible adverse health outcomes, and hence there is still a need for continuing research on the possible occurrence of such outcomes.

4.2. Authoritative Standards to Protect Against Exposure to RF Radiation

The two main international scientific organizations that publish recommendations on limiting exposure to electromagnetic radiation are the International Commission on Non-Ionizing Radiation Protection (ICNIRP) and the International Committee on Electromagnetic Safety of the Institute of Electrical and Electronics Engineers (IEEE). As discussed below, while the rationale for the limits in draft SC6 (2013) is based on both ICNIRP and IEEE, the recommended numerical limits generally follow the more conservative of the two, ICNIRP.

Basic Restrictions

The recommended limits based on the effects induced in the human body by exposure to external electromagnetic radiation are called basic restrictions. In the frequency range covered by SC6 (2013), both ICNIRP and IEEE base their recommendations on the prevention of excessive nerve stimulation and excessive heating of the body or parts of the body. For frequencies between 3 kHz and 10 MHz, basic restrictions are set for the induced electric field strength and are designed to prevent stimulation of excitable membranes in cells, which, at sufficient levels of exposure can become painful and also affect normal cardiac function.

The basic restrictions proposed by Health Canada and how they compare to ICNIRP (2010) and IEEE (2005) recommendations are set out below in Table 4.2-1. For electric field strength in the frequency range 3 kHz to 10 MHz, proposed basic restrictions are identical to those of ICNIRP (ICNIRP, 2010). The basic restrictions in the IEEE standard are higher, since it uses a higher threshold value for peripheral nerve stimulation and applies a smaller safety factor to account for individual variability in sensitivity (IEEE, 2002). For frequencies between 100 kHz and 6 GHz, basic restrictions are set for Specific Absorption Rate (SAR), the amount of power absorbed by a given mass of tissue, in watts per kilogram of tissue. The basic restrictions for SAR in SC6 (2013) are identical to those in both ICNIRP and IEEE recommendations (IEEE, 2005; ICNIRP,

1998); with the exception of the local SAR restriction for head and trunk, which is 20% lower because of refinements in dosimetry. The basic restrictions for local SAR also apply to a smaller volume (1 g in SC6 (2013) versus 10 g in ICNIRP and IEEE) making them more conservative for near-field exposure to sources of RF energy such as cellular telephones.

Table 4.2-1: Basic Restrictions

A. Electric field strength (V/m RMS), frequencies 3 kHz to 10 MHz

	SC6 (2013)	*ICNIRP (2010)*	*IEEE (2005)*
Controlled environment	2.7×10^{-4} f	2.7×10^{-4} f	6.3×10^{-4} f *
Uncontrolled environment	1.35×10^{-4} f	1.35×10^{-4} f	2.9×10^{-4} f
f is the frequency in Hz			
*Formula shown is for frequencies from 3.35 kHz to 10 MHz. For frequencies from 2 to 3.35 kHz, the basic restriction is 2.1 V/m			

B. SAR (W/kg), frequencies 100 kHz to 3 GHz

	SC6 (2013)	*ICNIRP (2010)*	*IEEE (2005)*
Whole body, controlled environment	0.4	0.4	0.4
Whole body, uncontrolled environment	0.08	0.08	0.08
Head and trunk, controlled environment	8	10	10
Head and trunk, uncontrolled environment	1.6	2	2
Limbs, controlled environment	20	20	20
Limbs, uncontrolled environment	4	4	4

Reference levels

Reference levels are set in terms of the strength of the electric and magnetic field outside the body, which can be more easily measured than the internal electric field strength and SAR. Designed by engineering methods with conservative assumptions, reference levels are set so that compliance with reference levels will ensure that the basic restrictions are not exceeded. However, the standards allow exposures at levels above the reference levels, provided that the basic restrictions are not exceeded. Reference levels for RF energy with frequencies between 3 kHz and 10 MHz are derived from the basic restrictions for internal electric field strength to prevent nerve stimulation. As shown in Table 4.2-1 and Table 4.2-2, these reference levels are identical for SC6 (2013) and ICNIRP (2010), but higher for IEEE due to its higher basic restrictions and different dosimetric considerations (IEEE, 2005). Reference levels for RF energy

with frequencies between 100 GHz and 300 GHz are derived from the basic restrictions for SAR to prevent excessive heating.

For electric fields with frequencies up to 10 MHz, proposed reference levels in SC6 for controlled conditions are lower than those of ICNIRP in order to obtain the same frequency dependence as in uncontrolled conditions (see Table 4.2-2, and Figure 4.2-1). One reason why the 1998 ICNIRP occupational reference levels for electric fields are higher was to connect them to the reference levels derived from nerve stimulation (ICNIRP, 1998), but these have since been reduced in the 2010 ICNIRP guidelines (ICNIRP, 2010). The electric field reference levels up to 10 MHz are even higher (i.e., less conservative) for IEEE, due to its higher basic restrictions for electrical stimulation and different dosimetric considerations (IEEE, 2005).

The reference levels for uncontrolled conditions in SC6 (2013) and ICNIRP are identical, but those of IEEE are again higher (see Table 4.2-3 and Figure 4.2-1). For magnetic fields with frequencies up to 10 MHz, reference levels in SC6 (2013) are identical to those of ICNIRP (1998). Like the electric field reference levels, the magnetic field reference levels up to 10 MHz are higher for IEEE, due to its higher basic restrictions for electrical stimulation and different dosimetric considerations (see Table 4.2-2, Table 4.2-3, and Figure 4.2-2).

For frequencies higher than 10 MHz, ICNIRP and IEEE reference levels for electric and magnetic field strength and power density are largely identical. The main exception is the higher IEEE power density reference levels for controlled conditions. In contrast, reference levels proposed in SC6 (2013) show an initial "dip" between 65 and 100 MHz and then a less steep increase with frequency with mostly lower values than ICNIRP and IEEE (see Table 4.2-2, Table 4.2-3, Figure 4.2-1, Figure 4.2-2 and Figure 4.2-3). The stated reason for this is to guarantee that basic restrictions will not be exceeded for children, based on recent dosimetric literature. The proposed reference levels in SC6 (2013) for controlled conditions show the same frequency dependence as those for uncontrolled conditions to account for workers of small stature and to maintain the same ratio between controlled and uncontrolled conditions with increasing frequency.

Contact current can occur when a person's skin (usually on the finger) makes contact with an insulated conductive object that has been energized in an electric field. Induced current can flow through the foot to ground in the presence of an external electric field. For frequencies up to 100 kHz, contact or foot current may result in tingling or painful shocks. Between 100 kHz and 110 MHz, they may result in excessive heating and tissue damage (burns). There are situations where there is compliance with electric field reference levels, but contact current may still occur. SC6 (2013) sets separate reference levels for contact current and induced current through the foot. Reference levels for contact currents in SC6 (2013) and ICNIRP guidelines (1998, 2010) are identical. They are slightly higher for controlled conditions and slightly lower for uncontrolled conditions in IEEE guidelines (IEEE, 2005). Reference levels for induced current through the

foot at frequencies between 100 kHz and 110 MHz are identical in ICNIRP and IEEE guidelines, but slightly lower in draft SC6 (see Table 4.2-2 and Table 4.2-3).

Table 4.2-2: Reference levels for controlled environments

A. Based on induced electric field (frequencies from 3 kHz to 10 MHz)

Frequency	Electric field strength (V/m RMS)			Magnetic field strength (A/m RMS)		
	SC6 (2013)	ICNIRP (2010)	IEEE (2005)	SC6 (2013)	ICNIRP (2010)	IEEE (2005)
0.003 - 0.00335 MHz	170	170	1842	80	80	1640/f
0.00335 - 0.1 MHz	170	170	1842	80	80	490
0.1 - 5 MHz	170	170		80	80	490
5 - 10 MHz	170	170		80	80	

B. Based on SAR, power density (frequencies from 100 kHz to 300 GHz)

Frequency	Electric field strength (V/m RMS)			Magnetic field strength (A/m RMS)			Power density (W/m^2 RMS)		
	SC6 (2013)*	ICNIRP (2010)	IEEE (2005)	SC6 (2013)*	ICNIRP (2010)	IEEE (2005)	SC6 (2013)*	ICNIRP (2010)**	IEEE (2005)
0.1 - 1 MHz		610	1842	1.6 / f	1.6 / f	16.3 / f			
1 - 10 MHz	193 / $f^{0.5}$	610 / f	1842 / f	1.6 / f	1.6 / f	16.3 / f			
10 - 30 MHz	61.4	61	1842 / f	0.163	0.16	16.3 / f		10	
30 - 65 MHz	61.4	61	61.4	0.163	0.16	16.3 / f		10	
65 - 100 MHz	493 / $f^{0.5}$	61	61.4	1.309 / $f^{0.5}$	0.16	16.3 / f	645.5 / f	10	
100 - 300 MHz	15.6 $f^{0.25}$	61	61.4	0.0414 $f^{0.25}$	0.16	0.163	0.6455 $f^{0.5}$	10	10
300 - 400 MHz	15.6 $f^{0.25}$	61		0.0414 $f^{0.25}$	0.16		0.6455 $f^{0.5}$	10	f /30
400 - 2000 MHz	15.6 $f^{0.25}$	3 f 0.5		0.0414 $f^{0.25}$	0.008 $f^{0.5}$		0.6455 $f^{0.5}$	f / 40	f /30
2000 - 3000 MHz	15.6 $f^{0.25}$	137		0.0414 $f^{0.25}$	0.36		0.6455 $f^{0.5}$	50	f /30
3000 - 6000 MHz	15.6 $f^{0.25}$	137		0.0414 $f^{0.25}$	0.36		0.6455 $f^{0.5}$	50	100
6000 - 15000 MHz	137	137		0.364	0.36		50	50	100
15000 - 150000 MHz	137	137		0.364	0.36		50	50	100
150000 - 300000 MHz	0.354 $f^{0.5}$	137		9.40×10^{-4} $f^{0.5}$	0.36		3.33×10^{-4} f	50	100

f is the frequency in MHz
*For frequencies from 6 GHz to 300 GHz, the reference level also forms the basic restriction
**For frequencies from 10 GHz to 300 GHz, the reference level also forms the basic restriction

C. Contact currents and induced current in limbs

Frequency	Contact current, touch (mA)			Induced current through foot (mA)		
	SC6 (2013)	ICNIRP	IEEE*	SC6 (2013)	ICNIRP**	IEEE***
0.003 - 0.1 MHz	400 f	400 f	500 f	225 f	100	1000 f
0.1 - 0.4 MHz	40	40	50	225 f	100	100
0.4 - 10 MHz	40	40	50	90	100	100
10 - 110 MHz	40	40	50	90	100	100

f is the frequency in MHz
*Reference level for grasp contact is two times the value listed
**Induced current in any limb (arm or leg)
***Reference level for induced current through both feet is two times the value listed.

Table 4.2-3: Reference levels for uncontrolled environments

A. Based on induced electric field (frequencies from 3 kHz to 10 MHz)

Frequency	Electric field strength (V/m RMS)			Magnetic field strength (A/m RMS)		
	SC6 (2013)	ICNIRP	IEEE	SC6 (2013)	ICNIRP	IEEE
0.003 - 0.00335 MHz	83	83	614	21	21	547/f
0.00335 - 0.1 MHz	83	83	614	21	21	163
0.1 - 5 MHz	83	83		21	21	163
5 - 10 MHz	83	83		21	21	

B. Based on SAR, power density (frequencies from 100 kHz to 300 GHz)

Frequency	Electric field strength (V/m RMS)			Magnetic field strength (A/m RMS)			Power density (W/m^2 RMS)		
	SC6 (2013)*	ICNIRP	IEEE	SC6 (2013)*	ICNIRP	IEEE	SC6(2013)*	ICNIRP**	IEEE
0.1 - 0.15 MHz		87	614	0.73 / f	5	16.3/f			
0.15 - 1 MHz		87	614	0.73 / f	0.73 / f	16.3/f			
1 - 1.34 MHz	$87 / f^{0.5}$	$87 / f^{0.5}$	614	0.73 / f	0.73 / f	16.3/f			
1.34 - 10 MHz	$87 / f^{0.5}$	$87 / f^{0.5}$	823.8 / f	0.73 / f	0.73 / f	16.3/f			
10 - 30 MHz	27.5	28	823.8 / f	0.073	0.073	16.3/f		2	
30 - 65 MHz	27.5	28	27.5	0.073	0.073	$158.3/f^{1.668}$		2	
65 - 100 MHz	$221 / f^{0.5}$	28	27.5	$0.585 / f^{0.5}$	0.073	$158.3/f^{1.668}$	129.1 / f	2	
100 - 400 MHz	$6.97 f^{0.25}$	28	27.5	$0.0185 f^{0.25}$	0.073	0.0729	$0.129 f^{0.5}$	2	2
400 - 2000 MHz	$6.97 f^{0.25}$	$1.375 f^{0.5}$		$0.0185 f^{0.25}$	$0.0037 f^{0.5}$		$0.129 f^{0.5}$	f/200	f/200
2000 - 6000 MHz	$6.97 f^{0.25}$	61		$0.0185 f^{0.25}$	0.16		$0.129 f^{0.5}$	10	10
6000 - 15000 MHz	61.4	61		0.163	0.16		10	10	10
15000 - 100000 MHz	61.4	61		0.163	0.16		10	10	10
100000 - 150000 MHz	61.4	61		0.163	0.16		10	10	$(90 f_G - 7000) / 200$
150000 - 300000 MHz	$0.158 f^{0.5}$	61		$4.21\times10^{-4} f^{0.5}$	0.16		$6.67\times10^{-5} f$	10	$(90 f_G - 7000) / 200$

f is the frequency in MHz

*For frequencies from 6 GHz to 300 GHz, the reference level also forms the basic restriction

**For frequencies from 10 GHz to 300 GHz, the reference level also forms the basic restriction

C. Contact currents and induced current in limbs

Frequency	Contact current, touch (mA)			Induced current through foot (mA)		
	SC6 (2013)	*ICNIRP*	*IEEE*	*SC6 (2013)*	*ICNIRP**	*IEEE***
0.003 - 0.1 MHz	200 f	200 f	167 f	100 f	45	450 f
0.1 - 0.4 MHz	20	20	16.7	100 f	45	45
0.4 - 10 MHz	20	20	16.7	40	45	45
10 - 110 MHz	20	20	16.7	40	45	45

f is the frequency in MHz

*Induced current in any limb (arm or leg)

**Reference level for induced current through both feet is two times the value listed

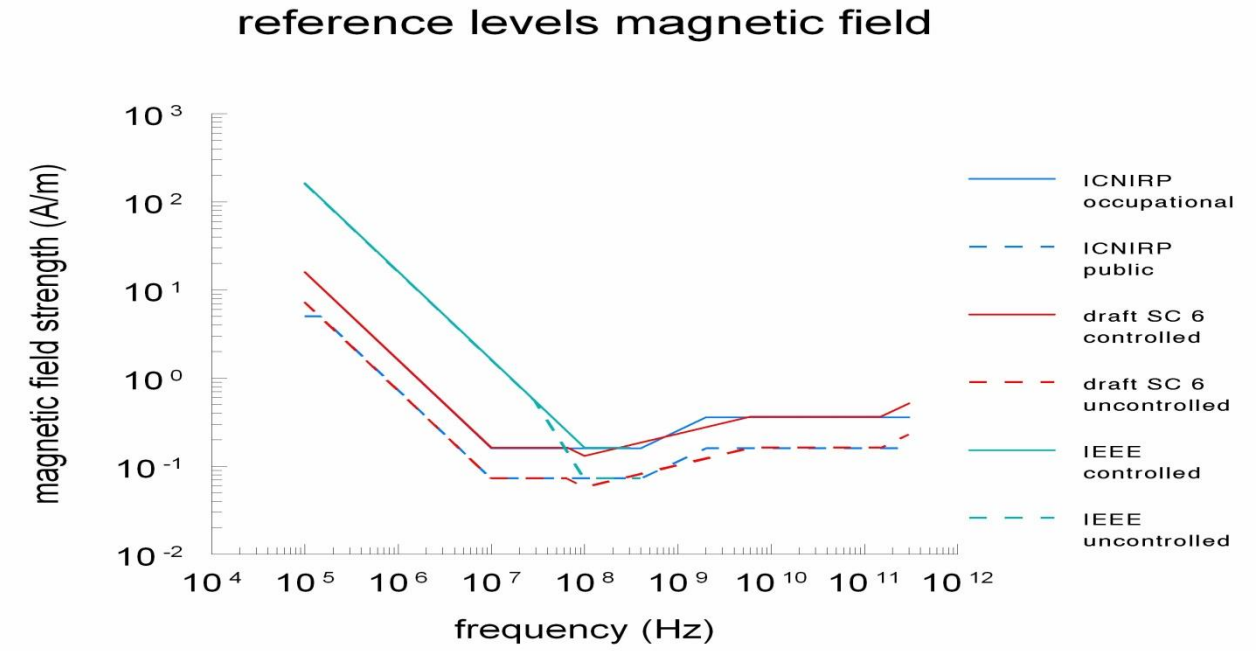

Figure 4.2-1: Comparison of electric field reference levels in SC6 (2013) with international standards

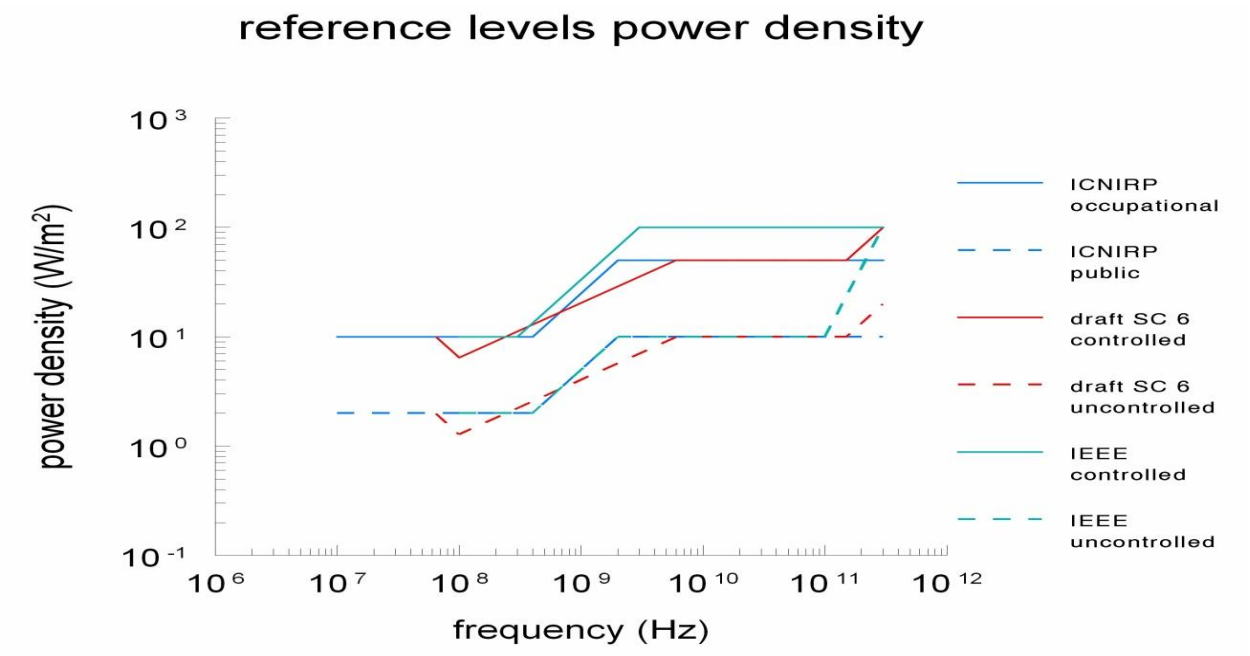

Figure 4.2-2: Comparison of magnetic field reference levels in SC6 (2013) with international standards

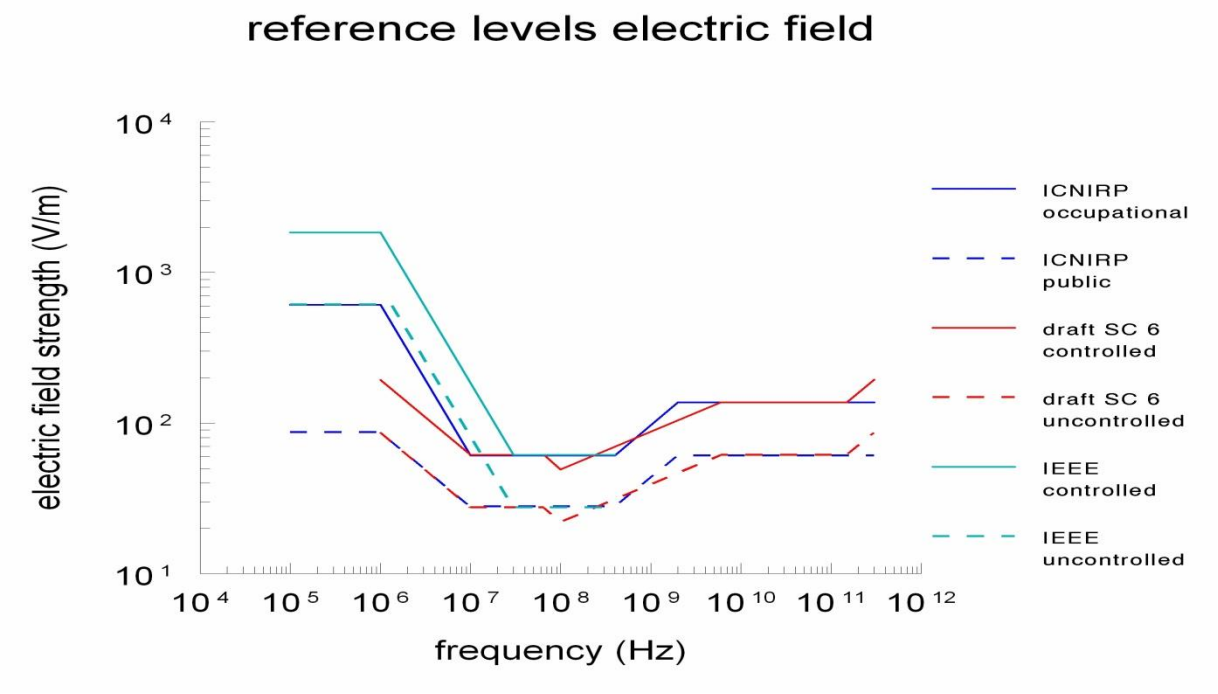

Figure 4.2-3: Comparison of power density reference levels in SC6 (2013) with international standards

5. Sources of Exposure & Mechanisms of Interaction

A large number of technologies use devices that operate in the part of the electromagnetic spectrum covered by SC6 (2013). To provide context for the Panel's conclusions, this section of the report presents an overview of the ways in which exposure to the public and to workers can occur. As the limits proposed in SC6 to control human exposure to RF energy are based on biological data, this section also provides some background relevant to the process of setting standards on the underlying biophysical mechanisms of interaction between RF energy and biological systems.

5.1. Sources of Exposure

Safety Code 6 covers the very broad frequency range from 3 kHz to 300 GHz. Industry Canada refers to this entire range as the radiofrequency (RF) band, a terminology that will be used in this report (Joint Government/Industry Committee for Industry Canada, 2005). A subset of this frequency range, 300 MHz – 300 GHz, is conventionally termed the microwave band; the lower end of this frequency band (3-30 kHz) if often referred to as the subradiofrequency band.

The RF band of the electromagnetic spectrum is used by a large number of technologies, with many RF generating devices in operation, at widely varying power levels. Industry Canada provides a comprehensive overview of the uses of the electromagnetic spectrum, as summarized below in Table 5.1-1.

Table 5.1-1: Classes of RF Emitting Devices

Commercial Mobile (cellular, PCS, AWS)
Land Mobile
Amateur Service
Public Safety
Broadcasting
Satellite Services
Space Science Services
Aeronautical Services and Applications
Maritime Mobile Service
Radiodetermination (terrestrial) Service
Licence-Exempt Devices (including Industrial-Scientific-Medical)

Source: (Industry Canada, 2010)

Much of this equipment operates at low power levels, or the RF energy is confined with little potential exposure to workers or the general public (as long as the equipment is working properly). However, in some occupational settings, some high-powered equipment is present that has significant potential to cause overexposure to workers in accident scenarios or if the

equipment is not operated or installed properly (see Table 5.1-2). One of the major applications of SC6 is to ensure the safety of workers who operate such equipment under normal conditions.

Table 5.1-2: High Powered RF Sources with Potential to Create Overexposure to Workers

Source of Exposure	Operating Power/ Frequency Range (power output or effective radiated power)	Potential for Exposures Approaching or Exceeding SC6 Limits
RF Induction Heaters	1-400 kHz; 2-500 kW	Significant to workers operating equipment
RF Industrial Heating Equipment (heat sealers, plastic welders, dielectric heaters)	Typically operate at frequencies in the industrial-scientific-medical (ISM) bands at 13.56 MHz, 27.12 MHz, and 40.68 MHz; kW power	Significant to workers operating equipment
Industrial microwave ovens, microwave dryers	Typically operate in the 0.915, 2.450 or 5.8 GHz ISM bands at 100s of kW	Generally low as long as the equipment is operating properly; significant under fault conditions or if interlocks are disabled.
Broadcast transmitters (FM, TV)	87-108 MHz (FM); mostly in the kW range but some stations > 100 kW 470-854 MHz (TV); mostly in the kW range but some stations > 500 kW	Significant to workers climbing towers while station is transmitting
Broadcast transmitters (AM)	0.5-1.6 MHz; generally in the kW range	Significant in immediate proximity to transmitting tower. Severe hazard from contact currents if a person touches a tower while grounded. Significant potential exposure to contact currents from large conductive objects such as construction cranes in vicinity of tower.
Communications transmitters (cellular telephone, paging, emergency services, land mobile	Various frequencies, generally between 0.1-3 GHz; cellular base stations operate at effective radiated powers generally below 10 kHz	Significant in the main beams close to the antenna, low otherwise.

Industrial-Scientific-Medical (ISM)

The Canadian Table of Frequency Allocations currently provides 12 frequency bands between 6.7 MHz and 246 GHz for “license exempt” devices used for industrial, scientific and medical purposes, not including telecommunications. Two bands in particular, centered at 915 and 2450 MHz, are widely used for industrial heating applications and, in the home, for household

microwave ovens. Microwave ovens for domestic use operate at power levels of approximately 500 W.

A vast number of low-powered equipment used in ordinary consumer environments also utilize these same two frequency bands: Wi-Fi routers, Bluetooth enabled devices for remotely controlled appliances, and many Smart Meters. Industry Canada estimates that as many as 250 million wireless devices of this sort are presently in use in Canadian households (Industry Canada, 2010a), and this number will undoubtedly increase greatly in coming years. However, these devices characteristically use digital communications technologies that transmit pulses at low peak power (typically much less than 1 watt effective radiated power[6]) at very low duty cycles (typically much less than 1%) and their average power output is characteristically far below 1 watt.

Broadcasting

A large number of broadcast transmitters operate in Canada, including traditional analog AM, FM and TV as well as newer digital broadcasting systems. The power output of these transmitters varies greatly, with some commercial broadcasters transmitting up to a megawatt effective radiated power. Figure 5.1-1 summarizes the operating frequency and effective radiated power of 8200 licensed broadcasting facilities as summarized on Industry Canada's website. Each point in the figure indicates a different broadcasting station.

By design, these facilities transmit RF signals to the population and hence are a source of exposure to RF energy, both to workers and to the general public at large. At nearly all locations accessible to the public, the RF signal levels from even high-powered transmitters are far below SC6 limits, although close to the radio towers, RF field levels might approach SC6 limits in areas of public access. Antennas used for commercial broadcasting are typically mounted high on towers, in part because of the need to transmit signals over long distances. Tower workers, who often climb towers on which a number of different transmitters might be located, face significant potential exposures to RF energy, and accidents resulting in burns or serious thermal injury to such workers are occasionally reported.

[6] "Effective radiated power" is a measure of the output of a transmitter that takes into account the gain and power input to an antenna.

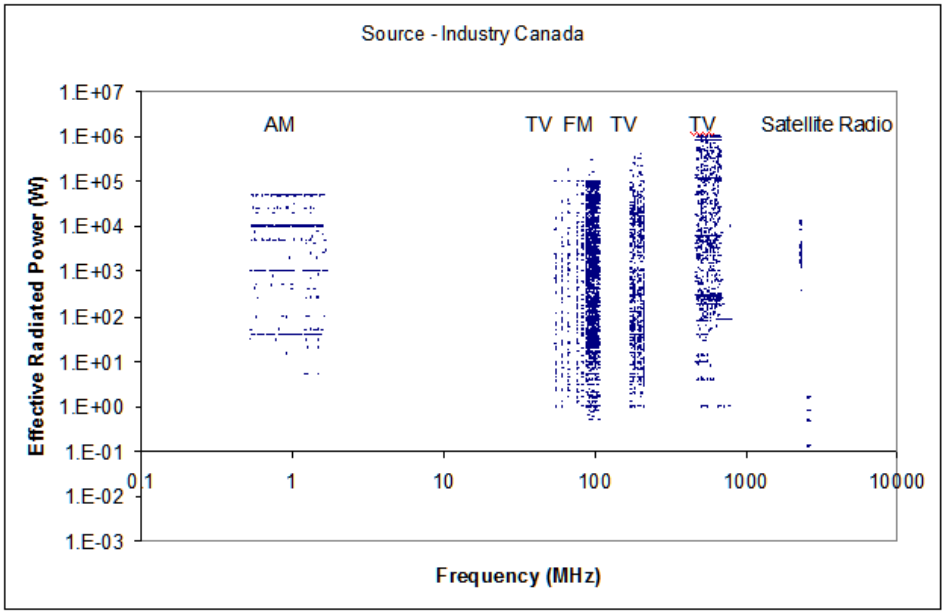

Figure 5.1-1: Operating Frequency and Effective Radiated Power of Broadcast Transmitters in Canada. Each dot indicates a different radio station or transmitter.

Commercial Mobile

This class of service encompasses commercial cell phone systems. According to Industry Canada, there were approximately 15 million subscribers to major cellular phone providers in Canada in 2010; the numbers have undoubtedly increased since then. These subscribers are served by approximately 18,000 cellular base stations throughout Canada for the various cellular telephone services (cellular, PCS, and AWS), many of them co-located on the same structure with other transmitters of various sorts. Cellular base stations operate at effective radiated powers of a few thousand watts; the antennas are typically located on towers or, in urban and suburban areas, on rooftops or facades of buildings. At areas of public access, the RF signal levels are ordinarily far below SC6 limits; however levels of exposure to RF energy may exceed occupational limits close (typically within a few meters) and directly in front of the transmitting surfaces of the antennas.

Other RF sources

Many other transmitters are present in Canada. This includes municipal police and emergency systems, land-mobile systems, and amateur radio operation. The power output of these systems varies widely, but typically is a few hundred watts or less.

RF Transmitters in Toronto

The sheer number of RF transmitters, and their wide range in power output, is illustrated by examination of the Industry Canada database for Toronto[7]. A search of the database for transmitters operating at frequencies between 1 and 19,000 MHz identified more than 17,000 radio "stations" (i.e. discrete transmitters) within a radius of 10 km from City Hall, the majority of which are associated with cellular telephone systems. (Since cellular base stations may contain a number of "stations" as the term is used by Industry Canada, the number of discrete sites that transmit RF energy is far smaller). Other transmitters included police and emergency services, various other municipal systems, a variety of commercial communications systems, as well as radio and TV broadcasting stations.

Most of the transmitters listed in the database operate at low power levels. However, the Industry Canada database lists 60 broadcast stations within 10 km of city hall, some transmitting at power levels up to a million watts. The CN tower, in the city center, has what its website describes as transmitters for "all major Broadcast, AM, FM and DAB Radio stations as well as wireless service providers" in Canada.[8] The Industry Canada database indicates that the cumulative transmitter power from all transmitters on the tower is 1.4 million watts. A 2002 survey of the area showed that RF field levels at street level in the city ranged up to 5% of SC6 limits (Nguyen et al., 2002). An even earlier survey[9] done in 1977 found that levels of exposure to RF energy inside the building were well within the limits in effect then. In a few generally inaccessible places near the transmitting equipment in areas off limits to the general public (for example, in tight spaces behind equipment cabinets), RF field levels were above SC6 limits, but the potential for overexposure to workers in such locations was low. This Panel is aware of no more recent surveys. However, it is clear that levels of exposure to RF energy in publicly accessible places in Canada is highly variable and in some places more than a tiny fraction of SC6 (2013) limits.

While these various sources of RF energy serve different purposes, they all share the electromagnetic spectrum. Indeed, many different systems use the very same frequency range (as with ISM equipment) or operate in nearby frequency ranges to each other. Some of these systems operate at high power levels and have the potential of producing significant levels of exposure (compared to the present SC6 limits) to workers or members of the public. Other systems, including a vast number of devices in use in non-occupational settings, operate at comparatively much lower power levels and the potential levels of RF exposure to members of the public are very low compared to the present SC6 limits. Given the diverse and rapidly changing nature of technology, it would be difficult to establish a consistent set of exposure limits on a technology-by-technology basis. Moreover, changes to SC6 to address safety concerns related to a particular technology, if not very carefully considered, may have unintended consequences for other

[7] http://www.ic.gc.ca/eic/site/sd-sd.nsf/eng/home
[8] http://www.cntower.ca/en-ca/about-us/communications/broadcasters.html
[9] Report on the Safety from Electromagnetic Radiation In and Around the CN Tower, Toronto. Report 77-EHD-7, Department of National Health and Welfare, 1977.

technologies as well, some of which may be important for health and safety. Safety Code 6 is intended to set limits to RF exposure to protect against all identified hazards, regardless of the technology.

5.2. Biophysical Mechanisms of Interaction

As with many exposure limits, the limits in SC6 for human exposure to RF energy must be based on biological data. However, some understanding of the underlying biophysical mechanisms of interaction between RF energy and biological systems is needed as well. Mechanistic considerations are relevant to the standards setting process in two ways: (i) through the extrapolation from limited data to develop generally applicable exposure limits and (ii) by developing generalizable knowledge and assessing the external validity of experimental results. These two situations are explained further below.

a. Extrapolation from limited data to develop generally applicable limits

Exposure limits must be established over a very wide range of frequencies (3 kHz to 300 GHz, which varies by a factor of 100 million), wide range of modulation characteristics, polarization and other parameters. By contrast, biological effects studies are performed at best under a few exposure conditions with particular biological preparations. Some theoretical understanding or conceptual framework is needed to allow one to predict exposure conditions that are likely to be adverse to humans under a wide range of potential exposure scenarios. For example, setting exposure limits for ionizing radiation relies on the understanding that biological damage results from disruption of chemical bonds and the creation of free radicals. This informs the concept of relative biological effectiveness, which provides a way to compare biological effects of a very wide range of ionizing radiation.

Because electromagnetic fields in the frequency range considered by SC6 have insufficient energy[10] in their photons to disrupt chemical bonds, they fall into the category of nonionizing radiation. The mechanisms by which they interact with matter are quite different than those of ionizing radiation such as X-rays. The most obvious biological damage from exposure to RF energy is associated with excessive heating of tissue. This leads to the use of the specific absorption rate (SAR) as the most relevant and useful measure of exposure. The SAR is the amount of power absorbed by a given mass of tissue, in watts per kilogram of tissue, and is fundamentally a measure of heating potential of the exposure. Other measures of exposure may be significant also, but heating at some level will always be present.

[10]At 1 GHz, the energy of a photon of RF energy is 0.02% of the mean thermal energy kT, and approximately 0.01% of the energy of the weakest hydrogen bond. RF energy falls below the infrared energy range and its quantum energy is correspondingly below that of infrared energy. Strictly in terms of heating potential, the reference levels in SC6 for the general public for microwave radiation (10 W/m^2 between 6 and 150 GHz) are considerably lower than the levels of infrared radiation that a consumer might commonly experience in the bathroom with a heat lamp installed in the ceiling, and far lower than a consumer might experience while in close proximity to an infrared radiant heater. Safety limits for both RF energy (at least at frequencies at which electrical stimulation of tissue is not a factor) and infrared energy have essentially the same goal, to protect against thermal hazards from excessive heating of tissue.

b. Developing generalizable knowledge and assessing the external validity of experimental results

Some understanding, even if tentative, of the biophysical mechanism that produces an observed effect can be tremendously useful in assessing its significance and predicting the conditions under which it can occur. For example, the microwave auditory effect[11] had been known since the 1960s and probably, as anecdotal reports, for many years before that. A plausible mechanistic explanation for the effect in 1974 led to extensive research by a number of groups that quickly clarified the nature of the effect and its possible physiological significance (Foster and Finch, 1974).

Established mechanisms

The mechanisms of interaction between electric and magnetic fields and biological systems have been studied for many years. Indeed, much of biophysics during the 20th century is related to attempts by scientists to understand the interaction between electric or magnetic fields with biological systems. The work by Peter Debye on electrically induced forces on molecular dipoles (1913) and the Hodgkin-Huxley model for nerve excitation (1952) together have spurred many thousands of scientific studies involving mechanisms of interaction of electric fields with biological systems. A theoretical paper by Pauly and Schwan (1959) on electrical potentials induced across a cell membrane in an external RF field has been cited more than 300 times according to the Web of Science. A search of the Web of Science for papers on dielectrophoresis[12] and cells yielded more than 1200 papers. A search for papers on electroporation[13] and cells yielded nearly 6500 citations.

The theories for these effects are well developed and are now found in elementary textbooks in biophysics. In general, very high field strengths are needed to produce such effects and, consequently, the theories discussed above are not directly useful in setting exposure limits or in understanding the reported effects of RF energy at low exposure levels. This does not rule out the possibility of a new mechanism of interaction being discovered that produces significant effects at low exposure levels, but it suggests that such a mechanism would be different from any that are already well established.

One major conceptual problem in developing theories for mechanisms by which relatively weak RF energy might cause biological effects is the so-called thermal noise limit (Adair, 2003). All matter is subject to random thermal agitation and random thermal effects will swamp the response of a biological system to an applied field unless the fields are sufficiently strong to overcome them. Moreover, energy is transported throughout the system, an effect technically known as dissipation, which limits the amount of energy that can be added to a structure within a

[11]The microwave auditory effect is defined as the auditory sensations experienced when a person's head is exposed to pulsed RF energy.
[12]This refers to forces induced on cells by externally applied radiofrequency fields.
[13]This refers to creating pores in cell membranes by applied radiofrequency fields.

biological system by an applied field. Finally, the response of the system to an applied force depends on its dynamic properties, which implies that the response depends on the frequency of the field. While many theories have been proposed over the years that attempt to explain how weak RF energy might affect biological systems, they typically have remained controversial because of failure to properly account for dissipative or other effects (Adair, 2003; Foster, 2000; Challis, 2005; Moulder, 2005; Repacholi, 2012; Vecchia, 2009). Some investigators have suggested that modulated[14] RF energy might somehow be "demodulated" at cellphone frequencies to produce low frequency stimuli, but no credible biophysical theory has been proposed that might account for such effects (Foster and Repacholi, 2009). It has not even been well specified in biophysical terms what "demodulation" would refer to in this case.

One interaction mechanism that has received extensive discussion in recent years is related to the ability of many avian species to sense the inclination of the Earth's magnetic field, apparently through visual cues (e.g., Wiltschko et al., 2002). This ability (which is apparently used for navigation by migratory birds) can be disrupted by exposing the birds to very weak alternating magnetic fields (tens of nanoTesla, a tiny fraction of limits in SC6) at a very specific frequency close to 1 MHz. A credible theory has emerged for the biophysical mechanism for this detection ability and its disruption by comparatively weak RF energy. The theory posits that the Earth's magnetic field affects the rate of photochemical reactions involving free radicals that occur within specialized photopigments in the bird's retina (e.g., Ritz et al., 2009). Careful review of behavioral data suggests that the radical pairs must have very specific properties for this explanation to work (Xu et al., 2013). In particular, they must have extraordinarily long coherence times (lifetimes), which also imparts a sensitivity to RF energy only over a very narrow frequency range near 1 MHz. Assuming the theory to be correct, many details of this process remain to be understood and the pathway leading to the animal's detection of the orientation of the Earth's magnetic field remains unknown.

This phenomenon, while scientifically very interesting, has no apparent relevance to human biology since it pertains to a specialized sensory mechanism found in migratory birds but not so far demonstrated in humans. However, assuming that the theory is correct, it provides an example of a biophysical mechanism of interaction that can result in a biological effect of RF energy at unexpectedly low exposure levels, albeit under very specialized circumstances.

Thermal sensitivity of biological systems

It is well known that biological systems are sensitive, to a greater or lesser extent, to thermal changes. Possible direct effects from electric or magnetic fields on a biological structure occur in the presence of the heating that necessarily accompanies the absorption of electromagnetic energy in the structure. A number of different thermal processes in physiology and biophysics have been intensively studied, with varying relevance to setting exposure limits. These include

[14]Modulation refers to the process of introducing variations in amplitude or frequency into a continuous signal, which is needed to allow the signal to carry information.

the following: temperature dependence of biochemical reactions, burns and thermal injury, thermal pain, and thermoregulatory consequences of whole body heating. Each of these processes is briefly described below. The topic of non-thermal effects is discussed later in this section and in Section 7.8 of this report.

Temperature dependence of biochemical reactions

All biological reactions are thermally sensitive. Most reactions exhibit a Q10 of about 2. Q10 is a measure of the rate of change of a biological or chemical system as a consequence of increasing the temperature by 10°C. Therefore, a Q10 of 2 means that the rate of reaction doubles with a 10°C increase in temperature. However, some biological processes are far more sensitive to temperature changes. For example, between 24 and 36°C, the membrane conductance of TRPV4 channels exhibits a Q10 of 19.1 (Foster and Glaser, 2007). Some animals possess specialized sense organs that are even more sensitive to heat. For instance, some species of snakes can perceive temperature increases of 0.003 to 0.01°C via their pit organs. This high sensitivity is achieved by a combination of highly thermo-sensitive membranes, together with neural summation of the outputs of multiple thermo-receptor cells. Humans can perceive increases in skin temperature of less than 0.1°C induced by brief pulses of RF energy (Foster and Glaser, 2007). Such effects have no apparent implications for human health.

Burns and thermal injury

Extensive data are available on thermal damage to tissue, and the concept of thermal dose is well established in the thermobiology community (Dewhirst et al., 2003; Yarmolenko et al., 2011). The accepted measure of thermal dose is CEM43, which is the equivalent number of minutes that a preparation must be held at 43°C to produce a given thermal injury (Dewhirst et al., 2003). CEM43 is defined as

$$CEM\,43 = \Delta t R^{43-T_c}$$

where: Δt is the time of exposure at temperature T_c (in degrees C) The base R is taken to be 0.25 for T<43°C and 0.5 for T > 43°C. This exponential relation implies that thermal damage can be produced by rather small temperature increases provided that the exposure is sufficiently long. For example, a CEM43 of 40 minutes (a typical thermal dose that is sufficient to produce visually apparent thermal damage to mammalian tissue) would be achieved by holding the tissue at 43°C for 40 min or at 40°C for about 40 hr. In theory, an arbitrarily small temperature increase in temperature maintained for a very long time would produce some level of thermal damage. However, thermal repair mechanisms are not taken into account in CEM43 and there is little experimental support for projecting thermal doses measured over short periods to predict thermal damage from small temperature increases maintained for very long periods (Foster and Morrissey, 2011). Moreover, the diurnal variation in body temperature is a degree or so, which

suggests that RF heating at levels considerably below 1°C would not have much health significance.

Thermal pain

The occurrence of thermal pain from exposure to RF energy has been characterized for humans in terms of a threshold skin temperature of about 44°C (for brief exposures to microwave energy). A simple thermal model can successfully predict thermal pain thresholds for exposure to RF energy over a broad range of frequencies (Walters et al., 2000).

Thermoregulatory consequences of whole body heating

The thermoregulatory responses in animals and humans exposed to RF energy have been studied, including human studies at levels considerably above present SC6 guidelines. A good thermal model exists that is useful in predicting the exposure conditions at which significant thermoregulatory responses occur (Foster and Adair, 2004).

There are, however, important gaps in knowledge that introduce uncertainty in thermally based exposure guidelines. The thermal injury data in the literature are scattered due to a lack of standardized testing procedures and other problems. In addition, the thermal dose required to produce thermal injury in various human tissues is not precisely determined. Consequently, while SC6 (2013) and other related guidelines would seem to be highly protective against thermal injury, the safety margins cannot be defined with precision.

It is known that raising the temperature of tissue to 43°C for some minutes is sufficient to produce observable thermal damage and raising it to a slightly lower temperature for much longer times will produce similar effects (Dewhirst et al., 2003). The maximum temperature increase produced in tissue at exposure levels comparable to SC6 limits for occupational exposure is generally below 1°C (and typically a few tenths of a degree), which is within the range of diurnal variation in body temperature in humans (ICNIRP, 2009). At the exposure limits for the general public, the corresponding increase in localized temperature would be a few tenths of a degree after extended exposure (tens of minutes). This would imply a safety factor well in excess of 10 for general public exposure. Studies involving whole body exposures to physically fit adult subjects show that they can tolerate exposures of 1 W/kg for extended periods (45 minutes) in warm environments (31°C) with increases in body temperature of less than 0.5 C. This suggests that occupational exposure limits for whole body exposure (0.4 W/kg) have safety factors of roughly 2 or more, for long term (hour) exposures in warm environments. Under extreme environmental conditions (high temperatures or humidity, extreme work intensity), the safety factors might conceivably be smaller, but such extreme conditions would probably be excluded by occupational safety rules apart from RF exposure limits.

Non-Thermal Effects

The proposed code defines "non-thermal effect" as "biological effects resulting from exposure to RF fields, that are not due to tissue heating". In other words, the distinction between thermal and non-thermal effects depends on the biophysical mechanism responsible for it. As discussed above, there are a number of well-established biological effects of RF energy that do not involve heating and are non-thermal in this mechanistic sense. Examples include electrical excitation of nerve and muscle (the limiting hazard in SC6 at the lower end of the applicable frequency range) as well as electrical breakdown of cells by intense RF energy, which is widely used in biotechnology and for some medical treatments. The disruption of the ability of birds to sense the orientation of the earth's magnetic field by a relatively weak RF field is another non-thermal effect, albeit one that is poorly understood at present.

In public discussions of the possible health effects of RF energy, the term "non-thermal" is often used in a different sense—namely as an effect that occurs at low exposure levels, of which a number have been reported in the scientific literature. However, unless the biophysical mechanism for a reported effect is known, it is not possible to decide whether it is "thermal" or "non-thermal" in any mechanistic sense. For example, de Pomerai et al (2000) reported that exposure of nematodes (a kind of worm) to RF energy at low levels resulted in a detectable induction of heat shock protein, which the authors described as a "non-thermal" effect. The group later discovered that the effect was actually caused by small temperature increases in the preparation during exposure and was, in fact, a thermal effect. The authors subsequently retracted their paper (de Pomerai, 2006). As another example, the microwave auditory effect is known to be caused by exceedingly tiny temperature increases produced in the head by pulsed microwaves (Foster and Finch, 1974) and is a thermal effect. However, until the mechanism for the effect was clarified, it could have been plausibly described as "non-thermal".

As a practical matter in designing safety limits, the distinction between thermal and non-thermal effect is not very useful or easy to draw. Scientific arguments about whether a reported effect is thermal or non-thermal are not particularly relevant to the problem of setting exposure limits. The more important problem is to evaluate evidence as it relates to possible health hazards, regardless of mechanism. For further discussion of this issue, see Section 7.8 on low level and "non-thermal" effects.

5.3. Reviews Considered by the Panel

The authoritative reviews listed in Section 4 of this report were reviewed for their conclusions about possible biophysical mechanisms that might lead to hazardous effects of RF exposure at levels allowable by draft SC6. These reviews have not identified any mechanisms (apart from heating) as plausible candidates for producing observable biological effects from exposure to RF energy at levels that would be allowed by the proposed SC6. However, these reviews often noted the longstanding controversies that have existed on the topic.

For example, IARC points to the lack of an established mechanism for low level effects, while allowing for the possibility that mechanisms might be uncovered in the future:

> [T]issue heating is the best-established mechanism for RF radiation-induced effects in biological systems. However, there are also numerous reports of specific biological effects from modulated RF-EMF, particularly low-frequency modulated fields. Mechanistic studies will be needed to determine how effects that are reproducible might be occurring… Although it has been argued that RF radiation cannot induce physiological effects at exposure intensities that do not cause an increase in tissue temperature, it is likely that not all mechanisms of interaction between weak RF-EMF (with the various signal modulations used in wireless communications) and biological structures have been discovered or fully characterized… Alternative mechanisms will need to be considered and explored… While the debate continues on whether or not non-thermal biological effects occur as a result of exposures to low-intensity RF radiation, it may be difficult to specify observed effects as non-thermal because of the high sensitivities of certain physiological responses to small increases in temperature." (IARC, 2013; p. 104)

By contrast, the BioInitiative Report described theoretical mechanisms for weak RF energy effects that have been developed over the years by a number of investigators, chiefly in Eastern Europe (BioInitiative Working Group, 2012). These theories remain largely untested and have not been shown to be useful in predicting the occurrence of biologically significant effects.

A review of the literature (a search of "mechanisms of interaction" on EMF-Portal, www.emf-portal.de, for the years 2010-2013) uncovered 42 papers on a diverse range of topics. Most of these were related to effects at power line frequencies (50/60 Hz), which are outside the scope of SC6. A review by Torgomyan and Trchounian (2013) describes effects of millimeter wave radiation (chiefly, 51-73 GHz) on bacteria and summarizes the investigators' theories about mechanisms responsible for the observed effects. So far, the reported effects have not been independently confirmed, their health significance remains unclear, and the theories themselves remain speculative.

Conclusion of the Panel

An extensive body of knowledge exists on mechanisms of interaction between electric and magnetic fields and biological systems, and research on this topic has progressed for more than a century. While a number of theories for biophysical mechanisms have been proposed over the years as explanations for biological effects to low level exposure to RF energy (such as would be allowed under SC6), none has gained widespread acceptance. Consequently, previous authoritative reviews have not considered these theories to be useful for setting exposure guidelines beyond those set by considering thermal effects. This Panel concludes that no new developments have occurred since these previous reviews that would change that conclusion.

6. DOSIMETRIC ISSUES

Electromagnetic field dosimetry has advanced significantly since the last major revision of Safety Code 6 in 1999 (Health Canada, 1999). Accurate assessment of induced internal electric fields or SAR in living humans is only possible through computational modelling. Modelling allows the internal fields in heterogeneous human phantoms[15] produced by exposure to RF energy to be directly assessed.

The main objective of this section of the report is to determine whether the proposed new reference levels in SC6 (2013) ensure that the basic restrictions are satisfied. To answer this question, recent results in RF field computational dosimetry have been reviewed (see Sections 6.2 and 6.3) and representative results have been compared with the proposed reference levels in SC6 (2013) (see Section 6.4).

6.1. Background

The proposed SC6 (2013) describes basic restrictions, dosimetric quantities intended to protect against adverse biological effects from human exposure to RF energy in the frequency range from 3 kHz to 300 GHz. Derived reference levels are also described in SC6 (2013). These quantities are specified in terms of external unperturbed electric and magnetic field strength, power density, induced and contact currents. It is intended that compliance with the reference levels will guarantee compliance with the basic restrictions at a particular frequency, regardless of the exposure situation. This can be checked, for example, by taking values of whole-body SAR for a particular exposure configuration and calculating the electric field value required to produce the whole-body SAR basic restrictions stated in SC6 (2013). That is, 0.4 W kg^{-1} for controlled environments and 0.08 W kg^{-1} for uncontrolled environments between 100 kHz and 6 GHz (see Table 2 in SC6 2013). If the calculated electric field value is above the reference level for the worst-case exposure situation at that frequency, the SC6 (2013) reference level value is a conservative estimate of the basic restrictions. This is the desired situation. If the calculated electric field value is below the reference level for the worst-case exposure situation at that frequency, the SC6 (2013) reference level value is not a conservative estimate of the basic restrictions and the reference level does not guarantee compliance with the basic restrictions.

6.2. Dosimetry related to electric and magnetic fields (3 kHz – 10 MHz)

Exposure to external electric and magnetic fields in the intermediate frequency (3 kHz-10 MHz) range can induce electric fields within the body. These fields may cause stimulation effects on peripheral nerves (Weinberg et al., 2012). The way in which the field is absorbed in humans at intermediate frequencies is highly dependent on whether the incident radiation is an electric or magnetic field. For exposure to an *external electric* field, the human body will significantly perturb this field. At low to intermediate frequencies, the human body is a good conductor. Non-

[15]Human phantoms are human models used in computational dosimetry.

uniform charges are induced on the surface of a human and this leads to induced electric fields inside the body many orders of magnitude smaller than the external applied electric field. For exposure to an *external magnetic* field, the human body does not perturb this field. The magnetic permeability of human tissue is the same as that of air. Therefore, the magnetic field within the body is also the same as that in air. These magnetic fields will be absorbed according to Faraday's Law of Induction, inducing electric fields and currents within the body.

The primary dosimetric measure of electromagnetic field absorption between 3 kHz and 10 MHz is the induced electric field. An expert group in 2004 investigated the potential health effects of physiologically weak electric fields induced by electromagnetic field exposure (McKinlay and Repacholi, 2003). This group suggested that induced electric fields in the body rather than induced current densities averaged over 1 cm^2 may be a more appropriate dose quantity for effects based on voltage-gated ion channels and that the averaging volume should be based on a minimum of 1000 interacting cells (approximately 1 mm^3 in most nerve tissue). At the time of the McKinlay et al. expert group, the highest available resolution in numerical phantoms was 2 mm. Therefore, the averaging region was chosen as a 2 mm cube.

The numerical methods used to calculate induced electric fields in the body tend to use voxelised[16] human models made up of cubes. These cubes have sharp corners, and the maximum single voxel electric field value is susceptible to errors due to these sharp corners, particularly where there is a large contrast in conductivity between neighbouring voxels and where single isolated voxels occur embedded in another tissue. To arrive at a more satisfactory estimate of the maximum electric field and avoid, in part, errors introduced by voxel discretisation and staircasing at sharp corners, the 99th percentile electric field value was introduced (Dawson et al., 1997, 2001, 2002). The 99th percentile field value represents the value exceeded in only 1% of cubic cells within the human model. Thus, in the ICNIRP guidelines (2010) and in SC6 (2013), the 99th percentile value of the induced electric field was selected as the dosimetric quantity used in basic restrictions up to 10 MHz, as thresholds of the excitable tissue stimulation are defined by these electric fields and the related spatial variation. However, until 2010, the majority of dosimetric studies at low and intermediate frequencies focussed on the induced current density in the body as this measure was often used in exposure guidelines (e.g., ICNIRP, 1998). Therefore, there are only a relatively small number of studies concerned with the calculation of induced electric fields in the body.

Similarly, guidelines intended to protect against the effects of peripheral nerve stimulation from exposure to electromagnetic fields have only recently been introduced (ICNIRP, 2010; SC6, 2013). Because of this, the dosimetry on which the SC6 (2013) peripheral nerve stimulation basic restrictions are based is still developing and authoritative conversions between external electric and magnetic fields and the internal induced electric field for a range of different exposure situations are still to be established.

[16]A voxel is a three dimensional, volume analogue of a pixel.

Different reference levels exist in SC6 (2013) for human exposure to external electric and magnetic fields between 3 kHz and 10 MHz. Therefore, the dosimetry relating to exposure to external electric fields *vs*. external magnetic fields will be discussed separately below.

a. Applied Electric Fields

The highest internal electric fields in the body are obtained when the body is in perfect contact with the electric ground through both feet (Dawson et al., 2001; Dimbylow, 2005a; Findlay, 2013). The further away from the ground that the body is located, the lower the induced electric field in tissues. The maximum ratio of internal fields for grounded to free space human models is approximately 2 for the same applied field. The highest 99th percentile electric field values tended to occur in tissues that had low conductivity values—namely, bone, tendon, skin and fat.

When calculating internal electric fields, it is important to use the appropriate tissue conductivities. If tissue conductivities were multiplied by a constant factor, say 2.0, the induced electric field value in a particular tissue will be halved. In general, lower induced electric fields are associated with higher tissue conductivities. The exceptions to this are locations of the body associated with concave curvature (e.g., the tissue surrounding the armpits) where the absorbed electric field is enhanced (Dimbylow, 2005a; Kavet et al., 2001).

Studies investigating the induced electric fields in children from exposure to external electric fields are limited. However, Hirata et al. (2001) calculated internal electric fields for a simplified model of a 5-year old child of 1.10 m and 18.7 kg.

The way in which changes in posture, anatomy, age and pregnancy influenced human absorption of an incident electric field has been investigated (Dimbylow and Findlay, 2010). A standing, arms above the head posture and to a lesser extent, an arms horizontally outstretched posture have a masking effect on the head that reduces the electric field absorption within head tissues. Absorption of the external electric field tends to increase in the heart muscle and other organs within the torso due to the influx of current from the arms when adopting these postures.

The most conservative posture for compliance with guidelines is the standing, arms down by the side posture. No consistent pattern for electric field absorption as a function of age was found for the child models. Additionally, the stage of pregnancy has little effect on the absorption of applied electric fields. Absorption in the foetus was calculated, although again no clear pattern emerged as this was highly dependent on the position of the foetus within the pregnant model. Variations can also occur in calculated 99th percentile induced electric field values when different human models are used (Dimbylow, 2005a; Findlay, 2013).

b. (ii) Applied Magnetic Fields

Heterogeneous, anatomically realistic models of the human body have been employed to evaluate the absorption of incident magnetic fields using the scalar potential finite difference (SPFD) method (Dawson et al., 2001; Dimbylow, 2005a; Dimbylow and Findlay, 2010) and the

impedance method (Gandhi et al., 2001). Induced electric fields have been calculated in various organs and tissue types from exposure to a uniform 1 μT magnetic field orientated front to back at 60 Hz (Kavet et al., 2001). Comparable studies, calculated at 50 Hz and normalised to 1 mT, have also been performed (Dimbylow, 2005a).

Similar to the results obtained for incident electric fields, it is not unusual for the highest 99th percentile values for magnetic field exposure to be found in bone (Dimbylow, 2005a). Also similar to exposure to external electric fields, the magnitude of the values calculated will depend on the human model used. The 99th percentile electric field values from exposure to a 1 mT magnetic field orientated front to back differed between calculated induced electric field values in human models, often significantly (Dimbylow, 2005a; Kavet et al., 2001). Although values tend to be calculated at 50/60 Hz, differences in fields calculated in different models will also exist at 3 kHz (low frequency limit of SC6) and above as the induced electric field value can be linearly scaled in frequency regions where there is little change in tissue conductivity.

These differences exist because height, mass and general shape (including anatomy) can influence the 99th percentile induced electric field value. Caputa et al. (2002) used a larger sized model to investigate this. This large size model had a mass 40% larger than the other two average sized models employed in this study. It was found that the maximum induced electric field values for the whole body were also approximately 40% greater than the two average sized models, whilst the 99th percentile values increased between 34 and 41%. However, this correspondence did not extend to the induced electric fields in specific organs and tissues. Small organs (such as the testes) or thin organs (such as the skin or spinal cord) indicated larger differences in induced electric field strengths that could be due to differences in the shape and size of these organs in the different human models.

More recently, Bakker et al. (2012) calculated induced electric fields in anatomical models of two adult models and six child models from exposure to uniform magnetic fields. The results showed that the induced electric fields were within the ICNIRP (2010) basic restrictions in almost all cases. However, it was demonstrated that there was a maximum overexposure of 79% in peripheral nerve tissues for the occupational reference levels. This was mainly due to the low values of skin conductivity used (0.002 S m^{-1}) from Gabriel et al. (1996b). It has since been shown that these low values of skin conductivity are not suitable for exposure assessment with respect to peripheral nerve stimulation according to ICNIRP (2010) and a value of 0.1 S m^{-1} should be used (Schmid et al., 2013), as adopted by SC6 (2013).

In summary, peripheral nerve stimulation dosimetry between 3 kHz and 10 MHz is currently a developing area as guidelines intended to protect against the effects of peripheral nerve stimulation from exposure to electromagnetic fields have only recently been introduced (e.g., ICNIRP, 2010). Internal electric field calculations have been performed from exposure to external electric and magnetic fields. However, the range of anatomically realistic body models used in these simulations is limited. As a result, the relationship between external field reference

levels and internal basic restrictions defined by SC6 (2013) were derived from published data using just a few human anatomical models, often scaled from 50/60 Hz calculations to the 3 kHz to 10 MHz frequency range.

In the future, more electromagnetic field studies utilising a wider variety of high resolution adult, child, pregnant and postured anatomically realistic body models are required to increase the knowledge base of peripheral nerve stimulation dosimetry and improve safety guidelines for human exposure to external electric and magnetic fields.

6.3. Dosimetry related to electric, magnetic fields and power density (10 MHz – 300 GHz)

Specific absorption rate (SAR) is the dosimetric quantity commonly used in the assessment of electromagnetic field exposure of the body from a radiofrequency field. The SAR has the units of Watts per kilogram and, therefore, is averaged over a certain mass. Typically, whole-body SAR and peak localised SAR values are used in exposure guidelines. Averaging over the whole-body is self-explanatory, but the localised SAR can be averaged over various masses and volumes. SAR has been used by Health Canada in SC6 (2013) for defining the basic restrictions between 100 kHz and 6 GHz.

As SAR is used in exposure guidelines as a surrogate of temperature rise in tissues, it is important that an averaging mass is chosen that correlates closely with local temperature elevation. In the past, guidelines have stated that the localised SAR should be averaged over a 1 g (Health Canada, 2009; IEEE, 2002), 10 g (Health Canada, 2009; ICNIRP, 1998; IEEE, 2005) and 100 g (NRBP, 1993) mass in the shape of a cube (Health Canada, 2013; IEEE, 2005) or contiguous region (ICNIRP, 1998). Of these averaging masses, the peak 10 g averaging mass correlated well with maximum temperature elevation in the 30 MHz to 6 GHz frequency range (Hirata et al., 2013). The same study stated that while the peak 10 g SAR value averaged over a contiguous region correlated well with local temperature elevations over the same frequency range, the correlation of the peak 10 g SAR value averaged over a cube with temperature rise is problematic above 4 GHz.

SAR calculations for plane-wave radiofrequency exposure of anatomically realistic male adult models have been numerous since 1999 (Dimbylow, 2002; A-K Lee et al., 2006; Mason et al., 2000; Nagaoka et al., 2004). Generally, SAR values calculated in the various phantoms are similar. The differences that do occur are usually due to small changes in the height, mass, anatomy and dielectric properties used.

Anatomically realistic female voxel models have been developed (Dimbylow, 2005a; W. Liu et al., 2005; Mazzurana et al., 2004; Nagaoka et al., 2004). As these models tend to be shorter than their male equivalents, the whole-body SAR resonance of female models from plane wave exposure occurs at a higher frequency (Dimbylow, 2005b, 2006; Sandrini et al., 2004). Note that SAR resonance is related to the height of the human. It typically occurs when the height is 0.5 (isolated exposure) or 0.25 (grounded exposure) of the wavelength of the incident field. Pregnant

female models have been produced, including those representing nine gestational ages (Wu et al., 2006), a truncated body model of a mother with a 28-week old foetus (Hand et al., 2006) along with hybrid models at 28 weeks (Nagaoka et al., 2006), 26 weeks (Nagaoka et al., 2007) and the mathematical representations representing a mother and foetus at 8, 13, 26 and 38 weeks gestation (Dimbylow, 2006). Whole-body SAR in these models has been calculated between 20 MHz and 3 GHz (Dimbylow and Bolch, 2007). The difference between whole-body SAR in the pregnant and non-pregnant NAOMI models increased from eight weeks gestation to approximately15% lower in the pregnant female at 28 weeks. Nagaoka et al. (2007) examined the plane wave exposure of a pregnant Japanese model (26 weeks gestation) under isolated conditions. It was found that the whole-body SAR calculated differed by only a very small amount when compared to the non-pregnant model. Calculations of SAR were also carried out using the University of Florida newborn female model (Dimbylow et al., 2010). It was reported that a primary resonance occurs at approximately 400 MHz, with a secondary resonance at 900 MHz.

Human models in postures other than the standing, arms down to the side position have been developed. Examples of these include: arms outstretched horizontally to the side and above the head (Findlay and Dimbylow, 2005) and seated (Allen et al., 2003, 2005; Findlay and Dimbylow, 2005, 2006). Results showed that the whole body SAR resonance changed when a posture other than the conventional standing, arms down position was adopted. The primary resonance occurred at approximately 70 MHz in the sitting posture, 80 MHz with the arms stretched out horizontally to the side and 60 MHz with the arms vertically above the head.

Anatomically realistic child voxel models have been produced. Studies of child exposure previously used scaled adult models (Dimbylow, 2005b; Findlay and Dimbylow, 2006; Findlay et al., 2009; Wang et al., 2006). However, new paediatric voxel models based on CT imaging child datasets have emerged for the application to electromagnetic dosimetry (Christ et al., 2010; Dimbylow and Bolch, 2007). The Dimbylow study used a 9-month old male, 4- and 8-year old females, and 11- and 14-year old males based on ionising dosimetry phantoms acquired by the University of Florida (C. Lee et al., 2006). These models are more representative of child anatomy than the rescaled adult models. Results generally agreed well with the scaled adult version as close to the resonant frequency these values are dependent on model height. However, at frequencies above 1 GHz, it was shown that a higher resolution was required to accurately represent field–tissue interactions in these models.

Recently, a limited number of surface-based computational human models have emerged for the purposes of ionising and non-ionising dosimetry (Christ et al., 2010; Findlay, 2013; C. Lee et al., 2010). Surface-based phantoms combine the advantages of stylised and anatomically realistic voxel models. They are flexible, allowing changes to organ position and posture to occur, but they also present accurate models of the human anatomy and can be voxelised to a desired resolution. Hence, dose estimations for small organs such as the eye are improved.

Previous to SC6 (1999), localised head exposure studies tended to use adult heads. There are now a number of dosimetric studies examining child head exposure. These investigations either suggest no significant difference in SAR between adult and child models (Christ and Kuster, 2005; Fujimoto et al., 2006; Keshvari and Lang, 2005; A-K. Lee et al., 2007; Martinez-Burdalo et al., 2004; Wiart et al., 2007) or a slightly higher SAR in the heads of children (Anderson, 2003; Fernandez et al., 2005; Wiart et al., 2008). In particular, Wiart et al. (2008) calculated that the SAR in 1 g of peripheral brain tissue was higher in the child models between 5- and 8- years old, but there was no difference in the SAR for child models older than this when compared to adult models from exposure to handsets operating at 900, 1800, 2100 and 2400 MHz. The differences were attributed to lower thicknesses of the pinna, skin and skull in the five to eight-year old models. Beard et al. (2006) reported that peak 1g averaged SAR in a child model was higher than that of an adult at 835 MHz, but lower than an adult at 1900 MHz. The SAR in the head is highly dependent on the model used, dielectric properties, distance of the antenna to the tissue being examined and the type of handset. The majority of the SAR values reported for child heads are below the SC6 (2013) localised SAR basic restriction of 2 W kg^{-1}. The few studies that report SAR higher than this value are for exposure situations that would not normally occur (e.g., holding a very high power antenna directly against the eye).

Dosimetric research has been published on the potential adverse health effects of Smart Meters (CCST, 2011; EPRI, 2010; Maine CDC, 2010). The EPRI study estimated the maximum exposure to a Smart Meter 1 W representative antenna at a distance of 30 cm as 18 µW cm^{-2}. This value is significantly below ICNIRP (1998) and SC6 (2013) limits. This study concluded that even if a meter malfunctioned and transmitted constantly, this 100% duty factor would produce exposure levels well below international limits.

A number of studies have investigated the SAR produced by Wi-Fi devices (Findlay and Dimbylow, 2010; Joseph, Frei et al., 2010; Joseph et al., 2013; Joseph, Verloock et al., 2010; Parazzini et al., 2010). The various exposure scenarios tested result in SAR values significantly below SC6 (2013) basic restrictions. For example, a peak 10 g SAR value of 0.817 W kg^{-1} has been calculated in a 10-year old child model when exposed to a Wi-Fi antenna (Findlay and Dimbylow, 2010). When a representative 1% duty cycle is used, this corresponds to a time-averaged SAR of 8.17 mW kg^{-1}, a factor of nearly 250 below the basic restriction of 2 W kg^{-1} found in SC6 (2013).

Conclusion of the Panel

To summarize, electromagnetic field dosimetry in the 10 MHz to 300 GHz frequency range has progressed significantly during the last decade and provided a sound basis for understanding the way in which RF energy interacts with the human body. Advances in model development now ensure that the range of anatomically realistic human phantoms extends beyond the male adult and presently includes female, pregnant female and child models of varying age and size. Higher resolution models derived from surface-based representations of the body are also now available.

These more detailed models are particularly important for simulations at frequencies above 1 GHz. New models have considerably improved our understanding of human exposure to far and near field irradiation at radio frequencies not only for standing adult males (the basis for the previous SC6 guidelines) but also for children, females and a number of different body postures.

Anatomically realistic human phantoms and appropriate numerical methods have been used to quantify whole and partial body SAR for a wide range of exposure configurations. Numerical dosimetry will continue to have a major role in the future to further characterize the interaction of RF energy with human tissues and improve safety guidelines for existing and new technologies in the radiofrequency range. It is recommended that this future research be carried out using more detailed, anatomically accurate human models together with improved tissue dielectric properties, increasing the resolution of the results.

6.4. Reference levels and basic restrictions

Since the last major revision of SC6 in 1999, dosimetric numerical methods and models have improved considerably. This is acknowledged in SC6 Rationale (2013), which states "recent developments in electromagnetic dosimetry using MRI-derived voxel models of the human body have shown that for certain body dimensions and frequencies, the basic restriction of whole-body SAR may be exceeded at reference levels corresponding to SC6 (2009) and ICNIRP (1998)".

A number of developments in human models for non-ionising calculations since 1999 are described in Section 6.2 and Section 6.3, above. A representative list of these human model studies is found in Appendix II. Due to these developments in electromagnetic dosimetry, SC6 (2013) has introduced new reference levels for the 3 kHz-10 MHz and 10 MHz-300 GHz frequency ranges. The purpose of this section is to determine if the proposed changes in the SC6 (2013) reference levels provide adequate protection against exceeding the SC6 (2013) basic restrictions, by examining the implications of using the human models such as those described above.

a. Electric and Magnetic Fields (3 kHz – 10 MHz)

i. Applied Electric Fields

The proposed SC6 (2013) basic restriction for the induced electric field between 3 kHz and 10 MHz is $2.7 \times 10^{-4}\ f$ and $1.35 \times 10^{-4}\ f$ V m^{-1} for controlled and uncontrolled environments respectively, where f is the frequency in Hertz. These limits are intended to protect humans against peripheral nerve stimulation. SC6 (2013) recommends determining the induced electric field as an average of the electric field in a 2 x 2 x 2 mm^3 volume in any tissue or organ and proposes external electric field reference levels of 170 V m^{-1} for a controlled environment and 83 V m^{-1} for an uncontrolled environment.

Dosimetric assessment studies of induced electric fields in heterogeneous, anatomically realistic human models from exposure to external electric fields are few. Therefore, SC6 (2013) has been

limited to using just two studies to assess the validity of the proposed external electric field reference levels (specifically, Dimbylow, 2005a and Kaune et al., 1997). It is recommended that dosimetric values obtained from calculations using ellipsoid models (Kaune et al., 1997) are discounted as more recent induced electric field calculations in heterogeneous, anatomically realistic models of the human body have demonstrated that these are unrepresentative of electric field absorption in humans (Dimbylow, 2005a; Dimbylow and Findlay, 2010; Findlay, 2013; Hirata et al., 2001).

Therefore, the validity of the SC6 (2013) electric field reference level between 3 kHz and 10 MHz has been tested using one set of induced electric field values in one publication (Dimbylow, 2005a) for one human model calculated at 50 Hz (SC6 Rationale 2013). This presents problems, as the maximum 99th percentile value is highly dependent on a number of factors, including:

- tissue conductivity (Dawson et al., 2001)
- the human model used (Caputa et al., 2002)
- the grounding condition applied to the model (Dimbylow, 2005a)
- posture (Dimbylow and Findlay, 2010)
- the short-circuit current (Dimbylow, 2000) which is determined by body height and weight, orientation of the incident field (Dimbylow, 2005a), and
- the age of the human model (Hirata et al., 2001).

The value is also dependent on differences in complex external shape of the human and internal organ shapes as the induced electric field value can change significantly due to the concave curvature of a particular feature on the body or organ. Additionally, the 99th percentile value is dependent on the numerical method used. Methods used for electromagnetic dosimetry include: scalar potential finite difference (SPFD), finite differences (FD) in the frequency domain, finite-difference time-domain (FDTD) and finite element (FE). Each has its advantages and limitations. A review of the accuracy of various dosimetric measures and codes can be found in Dawson et al. (2001) and Stuchly and Dawson (2000).

The induced currents in the body from exposure to an external electric field can increase if the posture of the body is changed from the standing, arms down to the side pose commonly used in electric field dosimetry. For example, if the arms are held vertically above the head or horizontally out to the side, the induced currents can increase by up to 30% (Dimbylow and Findlay, 2010). The result will also be a larger induced electric field in peripheral nerve tissues.

Another unintended consequence of defining the SC6 (2013) internal electric field strength basic restriction in any tissue or organ is that the maximum value tends to occur in bone where there are no peripheral nerves (Dimbylow, 2005a; Findlay, 2013). The maximum 99th percentile induced electric field value in all tissues and organs of the NAOMI adult female voxel phantom at 50 Hz was calculated as 49.4 mV m^{-1} in bone for an applied electric field value of 1 kV m^{-1}. Dimbylow (2005a) and Findlay (2013) used the surface-based male MAXWEL human model to

calculate induced electric fields from exposure to uniform external electric fields. It was found in this work that the maximum 99th percentile induced electric field also occurred in bone at 50 Hz, but this value was considerably lower at 15.7 mV m^{-1} per kV m^{-1}. The difference was attributed to the different human model used. These values can be scaled to produce estimated values of the maximum 99th percentile induced electric field in the 3 kHz to 10 MHz frequency range as the tissue conductivity values do not change significantly with frequency.

Figure 6.4-1, below, shows the values required to produce the SC6 (2013) basic restrictions on internal electric field strength in the adult female NAOMI model (Dimbylow, 2005a) and male MAXWEL model (Findlay, 2013), alongside the SC6 (2013) proposed reference level in the 1 KHz – 100 kHz range. Using values from these two studies, it can be seen that the SC6 (2013) reference levels provide a conservative estimate of the basic restrictions for exposure in this frequency range.

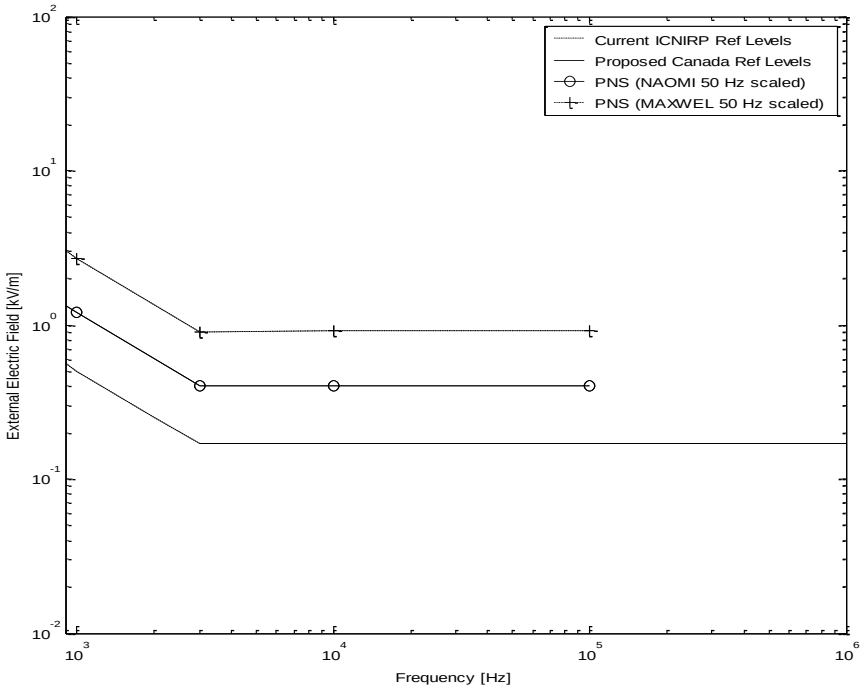

Figure 6.4-1: External electric field strength values required to produce the proposed controlled environment basic restriction for PNS as a function of frequency for the female adult NAOMI (Dimbylow 2005) and male adult MAXWEL (Findlay, 2013) phantoms and a skin conductivity of 0.1 S m^{-1}.

The current flowing through the body from an applied external electric field depends on the size and surface of the body and not the internal structure. The induced current density is then multiplied by the conductivity of the tissue to calculate the induced electric field. Because these currents are independent of internal body structure, reducing the conductivity of the skin will produce a corresponding increase in the induced electric field. Therefore, the conductivity of the

skin is an extremely important value when considering human exposure to low and intermediate frequency exposure to external electric fields.

The skin conductivity used for the calculations presented in Figure 6.4-1 was 0.1 S m^{-1}. Skin in these models is treated as a composite tissue consisting of skin and subcutaneous fat and a conductivity value for composite skin of 0.1 S m^{-1} has been suggested (Dimbylow, 2005). However, Gabriel et al. (1996, 1996a, 1996b) recommend lower skin conductivities of 0.00043 S m^{-1} for wet skin and 0.0002 S m^{-1} for dry skin, values used by (Bakker et al., 2012) in low frequency calculations for the Virtual Family (Christ et al., 2010) human models from exposure to external magnetic fields.

Figure 6.4-2, below, shows the external electric field values required to produce the SC6 (2013) basic restrictions on internal electric field strength, alongside the SC6 (2013) proposed reference level in the 1 KHz – 100 kHz range. These values have been scaled from values for the NAOMI human model (Dimbylow, 2005a) and MAXWEL model for the Gabriel et al. dry and wet skin cases (C. Gabriel et al., 1996; S. Gabriel et al., 1996a, 1996b). It is evident that the SC6 (2013) does not provide a conservative estimate of the PNS basic restriction if the Gabriel values of dry and wet skin conductivity are used. As described previously, however, these low values of skin conductivity are not suitable for exposure assessment with respect to peripheral nerve stimulation according to SC6 (2013) because skin in human models is currently treated as a composite of skin and subcutaneous fat. Therefore, a value of 0.1 S m^{-1} should be used (Schmid et al., 2013).

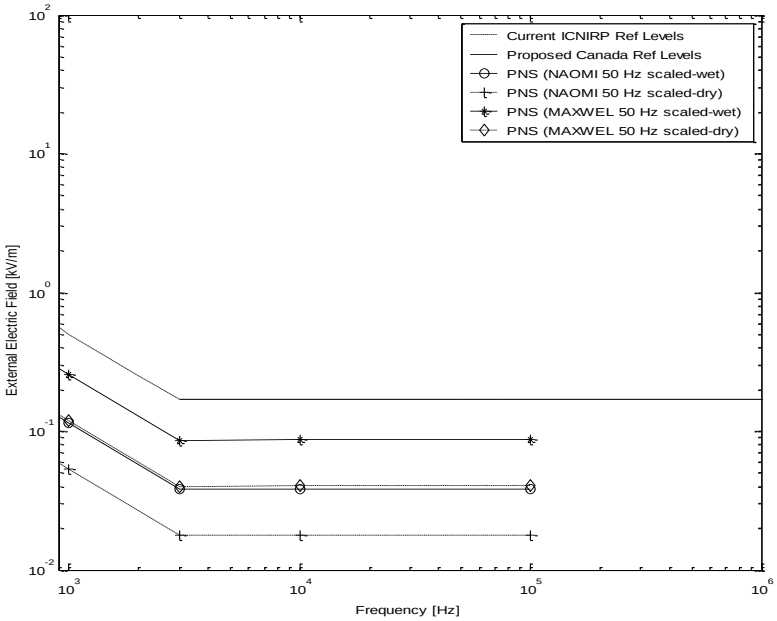

Figure 6.4-2: External electric field strength values required to produce the proposed controlled environment basic restriction for PNS as a function of frequency for the female adult NAOMI (Dimbylow 2005) and male adult MAXWEL (Findlay 2013) phantoms with wet and dry skin conductivities.

ii. Applied Magnetic Fields

SC6 (2013) recommends a basic restriction of 2.7 x 10^{-4} f for controlled environments and 1.35 x 10^{-4} f V m^{-1} for uncontrolled environments between 3 kHz and 10 MHz, where f is the frequency in Hertz. SC6 (2013) recommends determining the induced electric field as an average of the electric field in a 2 x 2 x 2 mm^3 volume in any tissue or organ. SC6 (2013) also proposes external magnetic field reference levels of 80 A m^{-1} in a controlled environment and 21 A m^{-1} in an uncontrolled environment.

More dosimetric assessment studies of induced electric fields in heterogeneous, anatomically realistic human models are available for exposure to external magnetic fields than for external electric field exposure. This is because the human body does not perturb the external field during magnetic field exposure and the resultant internal electric fields induced in tissues can be calculated more easily. SC6 (2013) has used the Dimbylow (2005a), Kaune et al. (1997), Caputa et al. (2002) and Bakker et al. (2012) studies to assess the validity of the proposed external magnetic field reference levels. Again, as mentioned above in section (i), subsection (a) *"Electric and Magnetic Fields (3 kHz – 10 MHz), Applied Electric Fields"*, it is recommended that dosimetric values obtained from calculations using ellipsoid models (Kaune et al., 1997) be discounted as more recent induced electric field calculations in heterogeneous, anatomically realistic models of the human body have demonstrated that these are unrepresentative of electromagnetic field absorption in humans.

Figure 6.4-3, below, shows the magnetic flux density values required to produce SC6 (2013) controlled environment basic restrictions on induced electric field as a function of frequency. These values are for the NAOMI adult phantom when exposed to an external magnetic field at 50 Hz (Dimbylow, 2005a), scaled to the higher frequencies. It can be seen that the SC6 (2013) reference levels provide a conservative estimate of the SC6 (2013) basic restrictions for all frequencies considered between 1 kHz and 100 kHz in this representative study.

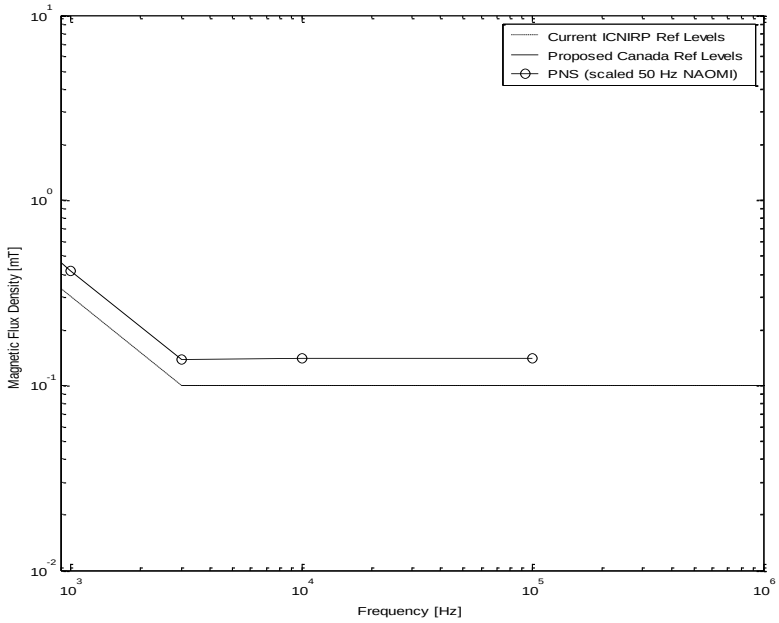

Figure 6.4-3: External magnetic flux density values required to produce the proposed controlled environment basic restriction for PNS as a function of frequency for the female adult NAOMI phantom (Dimbylow 2005) and a standard skin conductivity of 0.1 S m^{-1}.

b. Electric Fields, Magnetic Fields and Power Density (10 MHz – 300 GHz)

i. Adult Models

Isolated and Grounded Exposure

Anatomically realistic adult male phantoms existed prior to the last major revision of SC6 in 1999 (Dawson et al., 1997; Gandhi et al., 1992; Tinniswood et al., 1998). As a result, versions of SC6 since this date have included reference levels that take into account dosimetric studies using models such as these and, hence, are conservative for adult males at frequencies in the RF energy range.

Calculations of whole-body SAR using female voxel phantoms due to plane-wave exposure have also been carried out (Dimbylow, 2005a; Nagaoka et al., 2007; Sandrini et al., 2004). The slightly higher thickness of the subcutaneous fat layer in females than in males leads to a higher whole-body SAR in the female model (Sandrini et al. 2004). However, the SC6 (2013) reference levels continue to provide a conservative estimate of the basic restrictions for these female models.

ii. Child Models

Isolated Exposure

The proposed SC6 (2013) uncontrolled and controlled reference levels for power density are presented in Figures 14 and 15 of the SC6 Rationale (2013), along with power density values from several recent studies (Conil et al., 2008; Dimbylow and Bolch, 2007; Kaune et al., 1997; Nagaoka et al., 2008). As can be seen in these figures, the new SC6 (2013) reference levels are conservative for the 100 MHz and 2 GHz regions, which were previously problematic for child models exposed to RF energy under isolated conditions (Dimbylow, 2002).

Grounded Exposure

Problems remain with the SC6 (2013) reference levels for child models exposed under grounded conditions in the 50-100 MHz frequency range. This is due to the proposed reference levels being validated against only the isolated studies listed above. To illustrate, the electric field values required to produce a whole-body SAR of 0.08 W kg^{-1} for 10-year old, 5-year old and 1-year old child models under grounded conditions (Dimbylow, 2002) are shown in Figure 6.4-4 alongside the SC6 (2013) and ICNIRP (1998) reference levels.

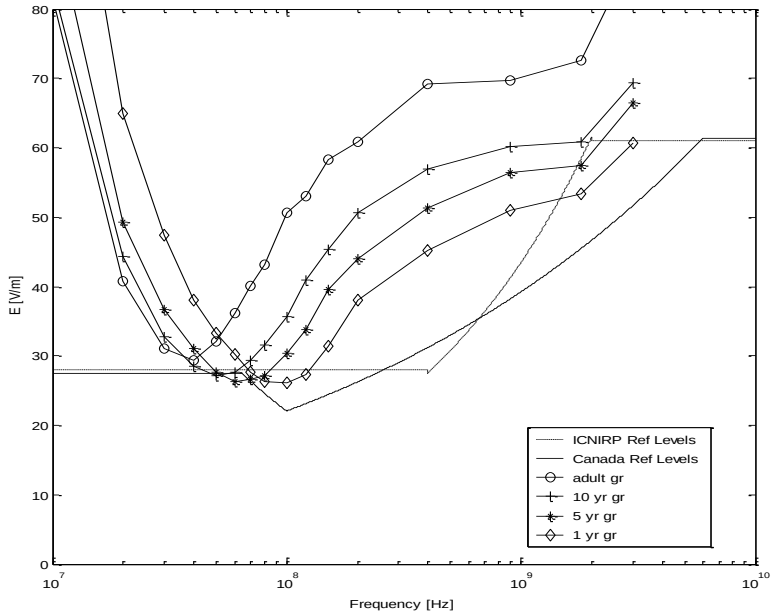

Figure 6.4-4: Electric field strength values required to produce Health Canada SC6 (2013) basic restrictions on WBSAR for male NORMAN adult and child models under grounded conditions (Dimbylow, 2002) in uncontrolled environments between 10 MHz and 10 GHz.

It can be seen that in the 60 MHz region the reference levels do not provide a conservative estimate of the basic restrictions. The electric field required to produce a whole-body SAR value

of 0.08 W kg^{-1} in the 5-year old model is 26.4 V m^{-1}, below the SC6 (2013) reference level of 27.5 V m^{-1} for an uncontrolled environment. Therefore, the 5-year old model could be exposed to an electric field of 27 V m^{-1} at 60 MHz, in compliance with the SC6 reference level of 27.5 V m^{-1} at this frequency. However, the whole-body averaged SAR value for this field value is 0.084 W kg^{-1} for the 5-year old model, exceeding the SC6 (2013) basic restriction of 0.08 W kg^{-1} by 5%.

Secondary reference levels[17] limiting current flowing through a single foot to ground are 90 mA for controlled environments and 40 mA for controlled environments as defined in SC6 (2013). Despite being set to avoid another issue, these induced current restrictions should ensure compliance with basic restrictions for the above-noted grounded cases. However, the intention of these induced current reference levels is to protect against localised heating in the limbs and not against whole-body averaged SAR (SC6 Rationale 2013). As a result, Health Canada cannot say definitively that secondary reference levels limiting limb current flow would definitely cover this.

iii. Postured models

A number of postured models have been developed recently for use in electromagnetic dosimetry (Allen et al., 2003, 2005; Dimbylow and Findlay, 2010; Findlay and Dimbylow, 2005, 2006; Findlay et al., 2009; A-K Lee and Choi, 2012; Nagaoka et al., 2008; Uusitupa et al., 2010) and calculations have demonstrated that posture can affect the way in which incident RF energy is absorbed in the body.

Isolated Exposure

Figure 6.4-5 presents an example of plane-wave exposure using 7-year old child models in the standing, arms vertically above the head and sitting postures under isolated conditions (Findlay et al., 2009). The figure shows the electric field values required to produce the SC6 (2013) whole-body SAR basic restriction of 0.08 W kg^{-1}. SC6 (2013) and ICNIRP (1998) reference levels are also presented for comparison. SC6 (2013) does not guarantee that compliance with reference levels will ensure compliance with basic restrictions for postures at some frequencies. Figure 6.4-5 shows that the SC6 (2013) reference levels are not conservative for the standing, arms up posture child model in the 60-100 MHz region.

[17]Secondary reference levels are those set to avoid another issue.

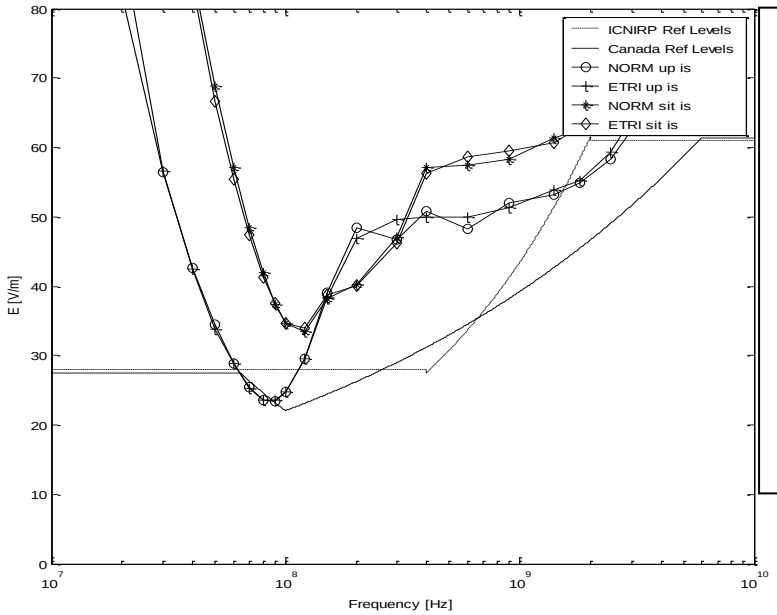

Figure 6.4-5: Electric field strength values required to produce Health Canada SC6 (2013) basic restrictions on WBSAR for 7-year old ETRI and NORMAN child models in the standing (arms up) and sitting postures under isolated conditions for uncontrolled environments between 10 MHz and 10 GHz (Findlay et al., 2009).

Similarly, Figure 6.4-6, below, shows the electric field values required to produce whole-body SAR basic restrictions for the ETRI child and adult models in the standing, arms vertically upwards posture under isolated conditions (A-K Lee and Choi, 2012). The SC6 (2013) reference levels are not conservative in the 60 to 100 MHz frequency range for the adult and 7-year old models. The reference levels are also not conservative for the 1-year old model at frequencies of 2 and 3 GHz (and beyond).

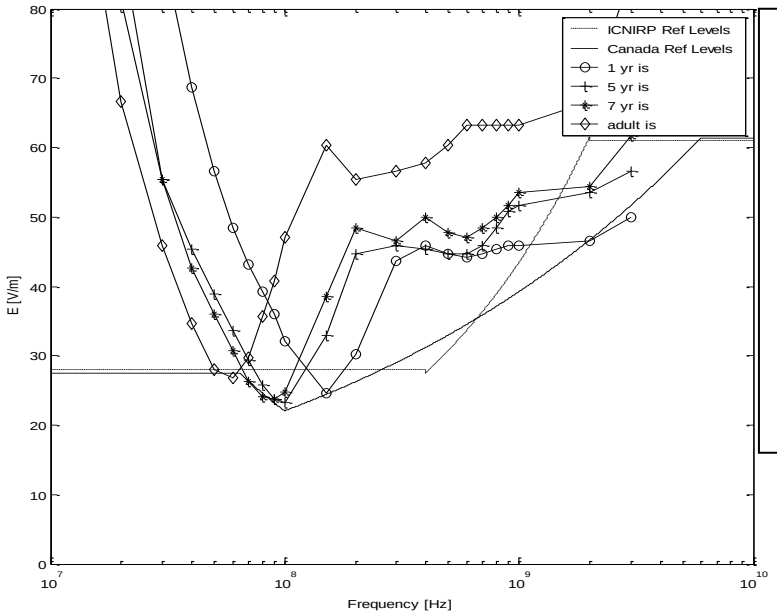

Figure 6.4-6: Electric field strength values required to produce Health Canada SC6 (2013) basic restrictions on WBSAR for male adult and child models in the standing (arms up) postures under isolated conditions for uncontrolled environments between 10 MHz and 10 GHz (A-K Lee et al., 2012).

Grounded Exposure

Figure 6.4-7 shows the electric field values required to produce the limiting whole-body SAR for adult and child models in a standing, arms vertically above the head posture under grounded conditions (A-K Lee and Choi, 2012) and the SC6 (2013) reference levels. In this figure, the plot representing the electric field value required to produce the uncontrolled whole-body SAR basic restriction in the standing, arms up posture is below the reference level for the adult, 7-year old and 5-year old models in the 30-80 MHz region. Therefore, compliance with the SC6 (2013) reference levels does not guarantee compliance with the SC6 (2013) basic restrictions.

It is possible that the secondary reference levels limiting current flowing through a single foot to ground will prevent the basic restriction on whole-body SAR from being exceeded. However, in the absence of calculated ankle currents for these child models in various postures, this cannot be guaranteed.

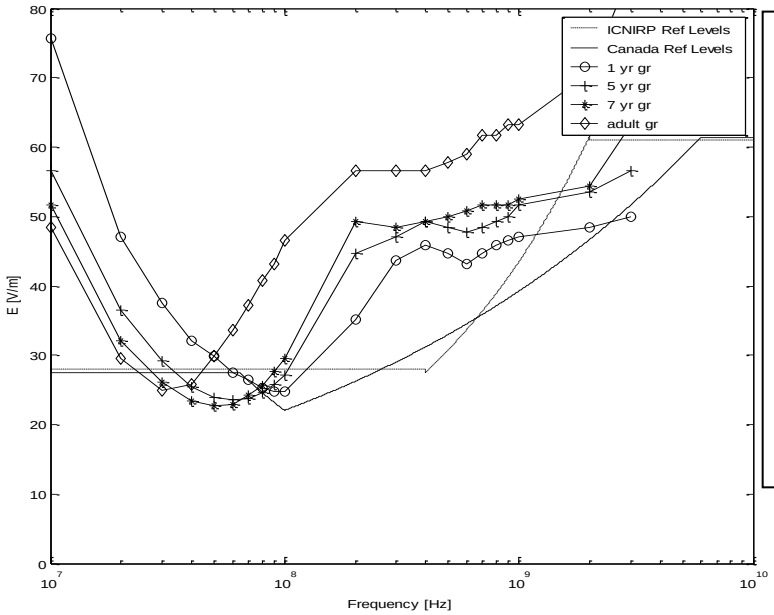

Figure 6.4-7: Electric field strength values required to produce Health Canada SC6 (2013) basic restrictions on WBSAR for male adult and child models in the standing (arms up) postures under grounded conditions for uncontrolled environments between 10 MHz and 10 GHz (A-K Lee et al., 2012).

iv. Pregnant Models

Isolated and Grounded Exposure

FDTD simulations of exposure of pregnant female models in the radiofrequency range have been reported (Dimbylow, 2007; Nagaoka et al., 2007; X. Xu et al., 2007). Figure 6.4-8 presents the electric fields required to produce whole-body SAR basic restriction values in an uncontrolled environment for a pregnant female model (26 weeks gestation) under isolated and grounded conditions (Dimbylow et al., 2009). The SC6 (2013) and ICNIRP (1998) reference levels are

shown for comparison. The figure demonstrates that the SC6 (2013) reference levels provide a conservative estimate of the basic restrictions for calculated whole-body SAR values at all frequencies studied.

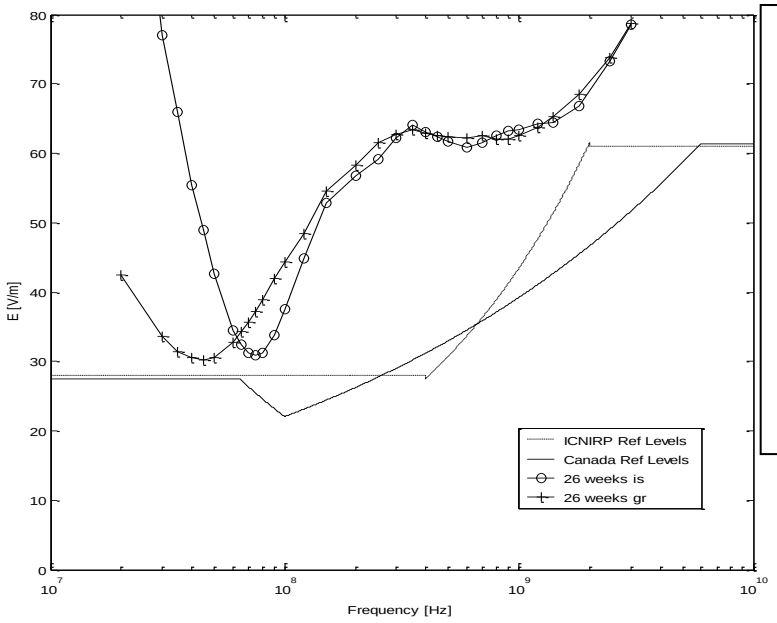

Figure 6.4-8: Electric field strength values required to produce Health Canada SC6 (2013) basic restrictions on WBSAR for an adult pregnant female (26 weeks gestation) under isolated and grounded conditions for uncontrolled environments between 10 MHz and 10 GHz (Dimbylow et al., 2009).

v. Foetal Models

Isolated Exposure

Voxel models of the human foetus within a pregnant female have been developed (Dimbylow, 2007; Nagaoka et al., 2007; X. Xu et al., 2007). These models were used to investigate foetal SAR exposure to radiofrequency fields (Dimbylow et al., 2009).

Figure 6.4-9 presents the electric fields that would be required to produce the proposed SC6 (2013) uncontrolled environment peak localised SAR restriction of 2 W kg^{-1} over 10 g in the foetus. The foetal and pregnant female models used were the Rensselaer Institute, NICT and HPA phantoms at 13, 26 and 38 weeks. The electric fields shown in this figure for each frequency are the minimum values over all irradiation situations (Dimbylow et al., 2009). These values show that the SC6 (2013) reference levels are a very conservative predictor of localised SAR basic restrictions in the foetus.

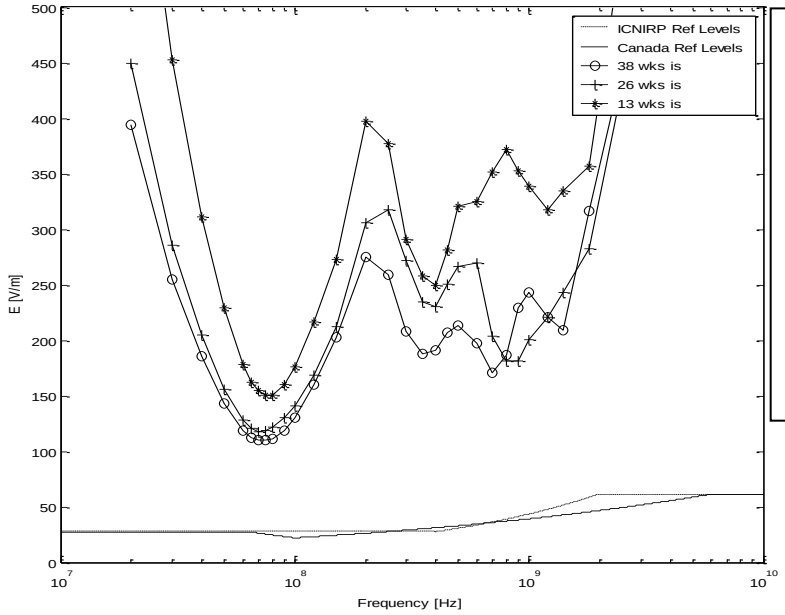

Figure 6.4-9: Electric field strength values required to produce Health Canada SC6 (2013) basic restrictions on WBSAR for foetus models under isolated conditions for uncontrolled environments between 10 MHz and 10 GHz (Dimbylow et al., 2009).

vi. Newborn Models

Isolated Exposure

C. Lee et al. (2007) developed a female newborn model for the purposes of ionizing dosimetry. This was then adapted for electromagnetic field exposure calculations (Dimbylow et al., 2010). The electric field values required to produce the limiting condition for whole-body SAR of 0.08 W kg^{-1} have been calculated for this newborn model and compared with SC6 (2013) and ICNIRP (1998) reference levels. The results are displayed in Figure 6.4-10.

The SC6 (2013) reference levels are not a conservative predictor of whole-body SAR at all frequencies in this frequency range. At 250 MHz, the newborn could be exposed to an electric field value of 27.5 V m^{-1}, in compliance with the SC6 (2013) reference level of 27.7 V m^{-1}. However, at this frequency the whole-body SAR for the newborn model would be 0.107 W kg^{-1}, exceeding the SC6 (2013) basic restriction of 0.08 W kg^{-1} by 33%. This demonstrates that the reference levels do not ensure compliance with basic restrictions in this case. It can be seen that the reference levels are also breached between 700 MHz and 2 GHz for the newborn.

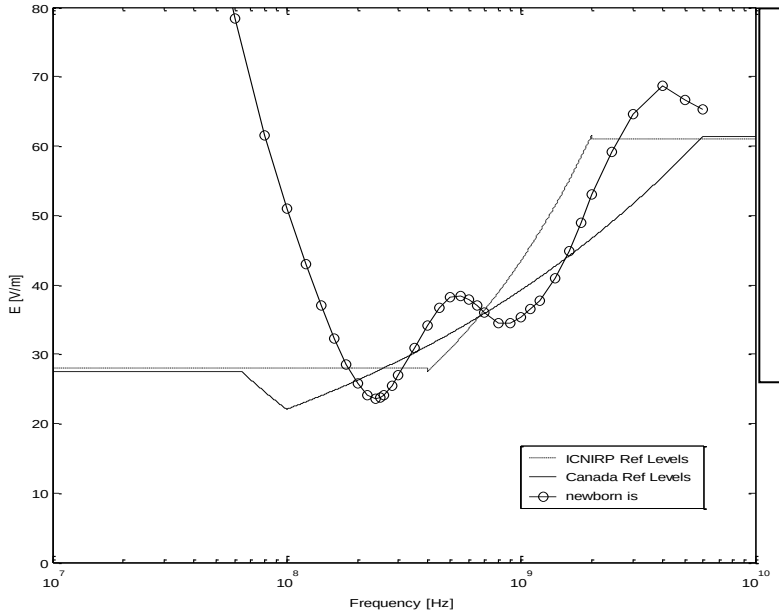

Figure 6.4-10: Electric field strength values required to produce Health Canada SC6 (2013) basic restrictions on WBSAR for a newborn model under isolated conditions for uncontrolled environments between 10 MHz and 10 GHz (Dimbylow, 2010).

vii. Localised Exposure

The proposed SC6 (2013) will retain the present limits in SC6 (2009) for peak localised SAR. In two respects (lower peak SAR and smaller averaging volume), the proposed SC6 (2013) limits are more conservative than either the current ICNIRP (2010) or IEEE C95 (2005) limits.

There is one issue, however, that is not addressed in either the Rationale or the draft SC6 (2013). Neither explicitly states how the pinna (the cartilaginous outer structure of the ear) is to be considered in the limits (i.e., is it included with the rest of the head or is it regarded as an extremity like any other limb). This is significant with respect to compliance testing of mobile phone handsets and other transmitters that are used close to the head. ICNIRP limits (which are in effect in most European countries and elsewhere) include the pinna with the rest of the head. In the U.S., the Federal Communications Commission (FCC) has recently ruled that the pinna is to be regarded for purposes of compliance assessment as being an extremity and subject to the higher peak SAR limit that applies to limbs (FCC, 2013).

During mobile phone usage, the feedpoint of the antenna is typically located close to the pinna, producing a comparatively high SAR in that structure compared to elsewhere in the head. Depending on how the pinna is to be considered in the limits, phones that may be compliant with FCC limits may consequently fail to meet SC6 limits, even though the peak SAR limits in the head and limbs and averaging masses are the same. This has been the source of considerable controversy in the technical literature (Gandhi and Kang, 2002).

Introducing a third set of limits on peak SAR (in addition to FCC and ICNIRP limits) will increase compliance costs by requiring additional testing of handsets. Moreover, most SAR testing is conducted using "phantom" hardware models that are filled with tissue-equivalent liquid, following a detailed set of protocols (IEEE, 2013). This does not permit a measurement of the peak SAR in the pinna.

Whether the benefits in terms of added safety in introducing a third set of limits in SC6 are sufficient to offset the additional costs of compliance assessment is warranted is a value judgment beyond the mandate of this Panel. However, SC6 (2013) needs to clarify whether the pinna is to be subjected to the same limits as the rest of the head and, if it is, how the SAR in the pinna should be measured.

viii. Other

As shown in Table 6.4-1, below, inconsistencies exist in the SC6 (2013) reference levels. It can be unclear as to what the reference level is at a particular frequency. For example, it is difficult to ascertain the electric field reference level at 10 MHz. If the 1-10 MHz expression is used ($193 / f^{0.5}$) the value is 61.0 V m^{-1}, whereas it is 61.4 V m^{-1} if the 10-65 MHz value is used. Because there are a number of other similar situations that arise in the SC6 (2013) reference levels, the Panel recommends increased precision in the reference level formulae.

Table 6.4-1: Inconsistencies in SC6 (2013) reference levels

Frequency	Environment	Electric Field (V m^{-1})	Magnetic Field (A m^{-1})
10 MHz	controlled	61.0 or 61.4	0.160 or 0.163
65 MHz	controlled	61.4 or 61.1	0.163 or 0.162
65 MHz	uncontrolled	27.5 or 27.4	-

Conclusion of the Panel

To summarize, recent investigations suggest that the SC6 (2013) electric and magnetic field strength reference levels provide protection against the SC6 (2013) internal electric field strength basic restrictions between 3 kHz and 10 MHz. In this frequency range, these studies demonstrate that compliance with the reference levels will ensure compliance with the basic restrictions, if appropriate tissue dielectric property values are used. However, the number of available studies in this area is limited. Hence, more electromagnetic field studies at frequencies between 3 kHz and 10 MHz, utilising the current range of anatomically realistic human models, are recommended to further test the suitability of the SC6 (2013) reference levels.

In the 100 kHz to 6 GHz frequency range, recent SAR dosimetry studies demonstrate that the SC6 (2013) reference levels do not always provide adequate protection against exceeding the

SC6 (2013) basic restrictions. A number of authoritative studies utilising adult and child anatomically realistic human models under grounded and isolated exposure conditions show that compliance with the SC6 (2013) reference levels will not ensure compliance with the SC6 (2013) SAR basic restrictions for some frequencies. It is important to note that in these highlighted cases where a compliant reference level produces a non-compliant SAR basic restriction value, it is very unlikely that the SAR will be at a sufficient level to produce an adverse health effect in humans. This is because the deviations tend to be relatively minor and the proposed SAR basic restrictions include margins of safety.

However, for the reference level definition statement made in Section 2 of SC6 (2013)—namely "compliance with the reference levels will ensure compliance with the basic restrictions in this safety code"—to be correct, there is a requirement to change the proposed SC6 (2013) reference levels. The Panel recommends that Health Canada review the large number of dosimetry studies, in addition to those referenced in this report, which have been produced since the last major revision of SC6 in 1999 and modify the proposed SC6 (2013) reference levels accordingly.

6.5. Magnetic Resonance Imaging

In the preface to Safety Code 6 (2013), there is a statement that SC6 does not apply to the deliberate exposure for treatment of patients or to exposure of medical personnel operating RF-energy emitting medical equipment such as magnetic resonance imaging (MRI) equipment.

With respect to MRI, the patient and worker are exposed to static magnetic fields, static magnetic field gradients, time changing gradient magnetic fields and RF fields that are ELF (extremely low frequency) modulated. As SC6 only covers frequencies above 3 kHz, it is not relevant for static and gradient magnetic fields around and in MRI devices. For time changing gradient magnetic fields, they are just below the 3 kHz threshold. Therefore, SC6 is only relevant to the exposures in the RF frequency range. Currently, patient and worker exposures are dictated by the equipment design and facility design. The MRI vendor community follow the International Electrotechnical Commission guidelines document IEC 60601-2-33:2010. This results in patient exposures to RF energy similar to the SC6 (2013) SAR basic restriction in a controlled environment. Given that the RF energy exposure is a near field exposure, the RF fields decrease dramatically with distance from the RF-transmission coils. This results in the MRI worker standing next to or briefly leaning into the magnet bore being protected from SAR exceeding basic restrictions (Capstick et al., 2007). Given the importance of site design for MRI worker safety and the lack of a federal document, provincial guidelines have evolved (e.g., Ontario Health Technology Advisory Committee recommendations on MRI environment safety in Ontario[18] (April 18, 2006).

There are other medical devices wherein the patient may potentially be exposed to peripheral nerve stimulation (PNS) or SAR values that far exceed SC6 basic restrictions. Transcranial magnetic field stimulation (TMS) induces central nervous system stimulation with devices that

[18] See http://www.health.gov.on.ca/english/providers/program

produce approximately 2 Tesla in 100 μs i.e. 20,000T/sec and hence have frequencies of about 10 kHz which fall within the domain of SC6 (Terao and Ugawa, 2002). The reference levels for workers may be exceeded under some circumstances (Karlström et al., 2006). Thermal ablation devices that use RF energy destroy tissue by local "burning" that clearly also exceed SC6 SAR basic restriction levels (Zhang et al., 2013). Worker exposure for TMS and RF-ablation again will have to be controlled by equipment design and not reference levels. Significant RF fields may also be generated by diathermy and hyperthermia equipment (see, for example: Martin et al., 1990; Kikuchi et al., 1993).

Conclusion of the Panel

Given that MRI safety encompasses far more than exposure to RF energy and that the last Health Canada document regarding MRI safety dates back to 1987 (Safety Code 26; 87-EHD-127), the Panel recommends that Health Canada evaluate the need of a more relevant document to encompass all aspects of MRI safety. At the same time, Health Canada could examine safety issues for workers associated with other medical devices such as TMS and RF-ablation equipment.

7. Reported Adverse Health Effects

7.1. Cancer

The most recent authoritative review of the carcinogenicity of radiofrequency electromagnetic fields (RF) in the 30 kHz to 300 GHz range was published in 2013 by the World Health Organization's International Agency for Research on Cancer (IARC) (IARC, 2013). Although other reviews and commentaries were examined (BioInitiative Working Group, 2012; Davis et al., 2013; Samet et al., 2014; Swerdlow et al., 2011), the IARC review was the most comprehensive in its summary and evaluation of the epidemiological literature. We further reviewed papers published subsequent to the IARC meeting in May 2011.

IARC's Evaluation of Carcinogenic Risks to Humans

The IARC Working Group (WG) examined epidemiological evidence from cohort, case–control, and time-trend studies published prior to May 2011. These studies focused on three sources of human exposure: occupational (e.g., high-frequency dielectric and induction heaters, and high-power pulsed radars), environmental (e.g., mobile-phone base stations, broadcast antennae, smart meters, and medical applications), and personal (e.g., mobile phones, cordless phones, Bluetooth devices, and amateur radios). However, the IARC evaluation was largely based on the evidence on central nervous system (CNS) tumours and cell phones, primarily focusing on the multi-centric INTERPHONE study (INTERPHONE Study Group, 2010, 2011) and a series of Swedish case-control studies conducted by Hardell and colleagues (Hardell et al., 2011), which were found to be the most compelling and informative.

The INTERPHONE study, which was coordinated by IARC, is the largest investigation to date of the association between brain tumours and mobile phone use. The study includes data collected on 2708 cases and 2972 controls between 2000 and 2004 in Australia, Canada, Denmark, Finland, France, Germany, Israel, Italy, Japan, New Zealand, Norway, Sweden, and the United Kingdom. The WG focused on the results from the two pooled analyses that have been published (INTERPHONE Study Group, 2010, 2011), rather than the results from individual studies. The pooled analysis found an overall 20% reduced risk of gliomas among "regular users"[19] of mobile phones (odds ratio (OR)=0.8, 95% CI=0.7-0.9) and no trends of increasing risk with "time, in years, since start of use" or "cumulative call time" (not including hands free devices). However, a moderately elevated risk (40%) was observed in the highest decile of cumulative exposure (>1640 hours, OR=1.4, 95% CI=1.0-1.9), which was only marginally significant. Increased risks were also observed for tumours of the temporal lobe (where exposure is thought to be highest)(>1640 hours, OR=1.9, 95% CI=1.1-3.2) and for having a tumour on the same side as the phone was commonly held (referred to as ipsilateral exposure). Among people with the highest

[19]Defined as those with an average of at least one call per week for a period of 6 months or more.

cumulative exposure, an increased risk for acoustic neuromas[20] was also observed, but no increase in risk was observed among long-term cell phone users (>10 years).

Additional analyses from the Interphone Study Group were also reviewed by the WG. In an alternate analysis using the lowest category of users as the reference group, a stronger association between gliomas and years since first use was observed (INTERPHONE Study Group, 2011). In a sub-analysis of data from five Interphone countries, an increasing risk of glioma with increasing dose (as measured in joules per kilogram) was also observed (Cardis et al, 2011). In addition, investigators from the Interphone Study Group conducted validation studies to assess the potential impact of misclassification of exposure and selection bias (Cardis et al., 2011; Vrijheid et al., 2009; Vrijheid et al., 2006).

Hardell and colleagues have published many population-based case-control studies of cancer and mobile/cordless phone use, but the IARC WG focused on the most recent paper, which presented results of a pooled analysis of two studies of gliomas conducted in Sweden between 1997 and 2003, which included 1148 cases and 2438 controls (Hardell et al., 2011). The study reported an overall 30% increased risk among "ever users", which appears to include anyone who had a personal subscription to a cell phone network, (OR=1.3, 95% CI=1.1-1.6) and increasing trends for "time, in years, since start of use" and for "cumulative call time", with the highest levels of exposure showing a doubling to a tripling of risk. Increased risks were also observed for ipsilateral exposure. Similar increased risks were also observed for cordless phones. In an earlier study, Hardell and colleagues observed an overall increased risk of acoustic neuromas associated with "ever use" and increasing trends with cumulative exposure (Hardell et al., 2006).

These two sets of case-control studies both used self-reported cell phone use as the measure of exposure. A validation study conducted by investigators associated with the Interphone Study found that there can be considerable random and systematic errors associated with data collected in this way (Cardis et al., 2011; Vrijheid et al., 2009; Vrijheid et al., 2006). They noted the potential for non-differential information bias, which generally reduces the strengths of associations, as well as the potential for recall bias, which generally operates in the opposite direction. The IARC WG also noted that participation rates for Interphone study were low, raising the possibility of selection bias. The WG concluded that other case-control studies available at the time of their review were not informative.

A large Danish cohort study (420,095 individuals) examined the risk of many forms of cancer among mobile phone subscribers (Schuz et al., 2006). The study found no excess risk of gliomas or other tumours in the follow-up period, which ended in 2002. The authors also investigated the risk of acoustic neuromas and found no evidence of an increased risk. Concerns have been raised regarding the use of subscription information as a surrogate for use of cell phones, as was done in this study.

[20]Acoustic neuroma is the common term applied to vestibular schwannoma, a non-malignant intracranial tumour.

The IARC WG also reviewed several studies of time trends in CNS tumours relative to the increasing prevalence of cell phone use under the assumption that if there is a large increase in cancer risk accompanied by large increases in cell phone use, the impact should be observable in the overall rates of cancer. Although these types of ecological studies are difficult to draw conclusions from, the WG observed that there has not been "any documented increase in the rates of tumours of the brain," but noted that most studies only examined rates prior to the early 2000's.

The IARC WG did examine other studies of occupational and environmental exposure. Their review of occupational studies was limited to those in which workers' exposure to RF energy was specifically documented or assessed, although few assessed cancer risk relative to measured levels of exposure. For brain cancer, the findings of the case-control studies suggested a moderate increase in the risk of brain cancer from occupational exposure to RF energy, although chance and confounding risk factors could not be ruled out as likely explanations for the association. All but two of the eight cohort studies observed relative risks were close to or below unity in the highest exposure category. One of the two positive studies had only a single brain cancer death, while the other found only a small, non-statistically significant excess. One additional cross-sectional study observed an excess risk but had methodological problems. The WG concluded that, due to exposure misclassification and the potential for confounding, there was no clear evidence of an association between brain cancer and occupational exposure to RF energy. The WG also considered studies of leukaemia and lymphoma. Although the data suggested a weak association with occupational exposure to RF energy and leukaemia/lymphoma, the results were difficult to interpret due to limited exposure assessment and the lack of adjustment for potential confounding factors. They noted that studies of other cancer sites were of inadequate quality and that the results were too inconsistent to draw conclusions.

Few high quality studies of environmental exposure to RF had been conducted. In these studies, exposure was assessed on the basis of proximity to fixed site transmitters of radiofrequency signals. For brain cancer and leukaemia/lymphoma, the WG considered ecological and case-control studies. Although some of these studies showed slight elevations in risk, the WG concluded that, on balance, the evidence did not support a positive association between these cancers and exposure to RF energy from fixed transmission sources. They found that the interpretation of these studies was limited by the potential for exposure misclassification and by small study size. They looked at studies of other cancers and exposure to RF energy, but found them uninformative due to methodological limitations.

Based on epidemiological evidence, the IARC Working Group concluded that there was

> "limited" evidence for the human carcinogenicity because "positive associations have been observed between exposure to radiofrequency radiation from wireless phones and glioma and acoustic neuroma." The term "limited" is used by IARC when "a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence" (IARC, 2013).

IARC classifies carcinogenicity into categories. IARC Group 1 is reserved for definite human carcinogens, while Group 2A is probable human carcinogens. Based largely on the limited epidemiologic evidence for an association between cell phones, gliomas, and acoustic neuromas, IARC classified radiofrequency fields as "possibly carcinogenic to humans" (Group 2B). In regards to the evaluation of human evidence, there were some dissenting opinions. A minority of the Working Group felt that the evidence for humans was inadequate, citing the differences in the results of the Interphone and Hardell studies, the negative findings of the Danish cohort study, and the lack of correlation between cancer incidence rates and mobile phone use.

Studies Published Since IARC Monograph

Several important studies have been published in the few years following the IARC evaluation. Frei and colleagues extended the period of follow-up of the large Danish cohort study to 2007 (Frei et al., 2011). The cohort was reduced to 358,403 individuals for whom socioeconomic status was available, but the extended follow-up greatly increased the power of the study to examine the risk of cancer among long-term cell phone users (>10 years). Overall, the study found no evidence for an increased risk of central nervous tumours, but did not report on findings for acoustic neuromas. The concerns regarding the use of subscription information as a surrogate for use of cell phones noted for the earlier follow-up of this cohort remain.

Mobile phone use and the risk of brain neoplasms were also examined in another large prospective study that included 791,710 UK women (Benson et al., 2013). Participants were asked twice about their mobile phone use (in a survey conducted between 1999 and 2005 and in another conducted in 2009) and cancer incidence was examined through 2009. Overall, no increased risk was observed among ever users for CNS tumours or other major cancer sites. Among long-term cell phone users (>10 years), there was no increase in risk for gliomas, but a large increased risk of acoustic neuroma. They also reported a pooled result combining their data with that of the Danish cohort, which together show only a very small non-significant excess of acoustic neuroma. In a letter to the editor, de Vocht (2013) challenged this approach because of the differences in the way exposure to cell phones was assessed. In a random effects meta-analysis, he found a 43% increased risk that was not statistically significant.

Hardell et al. (2013) have also published a new case-control study with a new, more recent set of 593 malignant brain tumour cases and 1368 controls (2007-2009). Overall, the study observed a 70% increased risk for both mobile and cordless phones, with larger risks for the temporal lobe. Evidence of dose-response with cumulative exposure was observed for analogue and 2G mobile phones as well as for cordless phones. Because the study was restricted to malignant brain tumours, there were no acoustic neuromas included.

Pettersson and colleagues (2014) very recently published a case-control study of acoustic neuromas in Sweden. The study included 451 cases and 710 controls that completed a mailed questionnaire. No excess was observed among mobile phone users overall, and the study found

little evidence of an excess risk except for an increased risk for the highest quartile of calling time. No excess risk was observed among long-term (>10 years) users or on the same side of the head as mobile phone use. Odds ratios decreased when only histologically confirmed cases were included.

Using relative risks reported in the Interphone and the Hardell case-control studies, Little and colleagues compared projected rates of glioma incidence with rates observed in the United States for 1992–2008, the period coinciding with a substantial increase in mobile phone use (Hardell et al., 2011; INTERPHONE Study Group, 2010; Little et al., 2012). Their analysis used data from 12 high-quality US cancer registries. Age-specific incidence rates of glioma remained nearly constant over this time period even as mobile phone usage increased dramatically. Using data from Nordic country cancer registries, Deltour et al. (2012) used a similar approach to investigate time trends for glioma incidence rates. No clear trends were observed and the authors concluded that the incidence rates were not compatible with the high relative risks observed in some case-control studies.

The results of studies published since the IARC Monograph meetings appear to be relatively consistent with the IARC Working Group's classification of radio frequency fields, specifically from cell phones, as a possible human carcinogen. Lagorio and Röösli (2014) recently published a meta-analysis, which included all mobile phone studies published through 2012 (but not the more recent studies by Benson et al., 2013, Hardell et al., 2013, and Petterson et al., 2014). The authors concluded that a causal association is not supported by the current literature and that much of the heterogeneity in results was generated by the Orebro studies by Hardell and colleagues. Some researchers, such as the ICNIRP Standing Committee on Epidemiology, have concluded that the trend in the evidence is against the hypothesis that mobile phones cause brain tumours (Swerdlow et al., 2011), while others have argued that the evidence is stronger and that precautionary measures should be taken (Davis et al., 2013). Unfortunately, the measures of exposure used in the epidemiologic studies, based on duration of use in years or cumulative use based on estimated hours, do not translate well into data that can be compared to make specific recommendations regarding SC6.

Some researchers, affiliated with the IARC Working Group have called for more epidemiologic research to resolve the uncertainty surrounding this issue (Samet et al., 2014). In particular, they point to the need for additional large cohort studies with access to detailed cell phone records. One such study, called COSMOS, is currently underway in five European countries (Schuz et al., 2011). In addition, another large, collaborative international case-control study is underway focused on examining the risk in children (the Mobi-kids study). The Panel agrees with this call for further research in this area.

Safety Code 6: Treatment of Laboratory Studies Relevant to Carcinogenesis

In developing the latest version of Safety Code 6, Health Canada monitored new laboratory studies published since the previous version of SC6 in 2009, considering

> …scientific literature with respect to possible biological effects of RF fields… [including] the potential for acute and chronic RF field exposures to elicit possible effects on a wide range of biological endpoints including…rodent lifetime mortality; tumor initiation, promotion and co-promotion; mutagenicity and DNA damage… (Safety Code 6)

Health Canada concluded that:

> Despite the advent of numerous additional research studies on RF fields and health, the only established adverse health effects associated with RF field exposures in the frequency range from 3 kHz to 300 GHz relate to the occurrence of tissue heating and peripheral nerve stimulation (PNS) from short-term (acute) exposures. At present, there is no scientific basis for the occurrence of acute, chronic and/or cumulative adverse health risks from RF field exposure at levels below the limits outlined in Safety Code 6. The hypothesis of other proposed adverse health effects occurring at levels below the exposure limits outlined in Safety Code 6 suffer from a lack of evidence of causality, biological plausibility and reproducibility and do not provide a credible foundation for making science-based recommendations for limiting human exposures to low-intensity RF fields. (Safety Code 6)

Recent reviews (Foster and Moulder, 2013; Habash et al., 2009; Juutilainen et al., 2011; McNamee and Chauhan, 2009; Repacholi et al., 2012; Verschaeve et al., 2010; IARC, 2013; ICNIRP, 2009a; SCENIHR, 2009b; Swerdlow et al., 2011; Valberg, van Deventer, & Repacholi, 2007; Vecchia et al., 2009) almost unanimously agree with Health Canada's conclusions. The only exception is the BioInitiative Report (BioInitiative Working Group, 2012), which carries little weight in this area of risk assessment because it ignores most of the relevant recent cancer-related *in vivo* studies (for example, H. Lee et al., 2011; Paulraj and Behari, 2011; Saran et al., 2007; Shirai et al., 2007; Smith et al., 2007; Sommer et al., 2007; Tillmann et al., 2007, 2010; Zook and Simmens, 2006) and because it relies on studies without mentioning that they have failed confirmation attempts (for example, the findings of the Repacholi et al (1997) study which were not confirmed by Oberto et al. (2007) or Utteridge et al., 2002). See Verschaeve (2012) and COMAR (2009) for a summary of this and other reviews of the field.

The number of new laboratory studies of RF energy that are directly relevant to cancer risk assessment is quite small. They are summarized below, along with studies with indirect relevance to cancer risk assessment. Doses in SAR are shown where they were reported. For *in vivo* studies, a SAR below 400 mW/kg (0.4 W/kg) would be an exposure below the SC6 basic restrictions. For cellular studies and/or where exposures are given only as power density (mW/cm^2), it is very difficult to determine whether the exposure levels are above or below the SC6 basic restrictions. Note that in a number of studies, no dosimetry was provided.

Studies of Life-time Mortality and Tumour Initiation

Prior to 2009, studies of normal animals exposed to non-thermal levels of RF energy found no consistent evidence of lifespan shortening or cancer initiation. For reviews of these studies, see IARC (2013), Juutilainen et al. (2011), Moulder et al. (2005), and Repacholi (1997). Only two peer-reviewed studies have appeared since 2009. Bartsch et al. (2010) exposed rats to RF energy at 900 MHz (at 15-130 mW/kg) and found no evidence for increased cancer. Tillmann et al. (2010) exposed pregnant mice to 1966 MHz RF energy (at 1.1-4.6 W/kg) and found no evidence for increased cancer.

Studies in Transgenic and Tumour-Prone Animals

Repacholi et al. (1997) reported that exposure to 900 MHz RF energy (at 0.1-1.4 W/kg) increased the incidence of lymphoma in lymphoma-prone mice. Further studies failed to confirm this finding (Oberto et al., 2007; Utteridge et al., 2002). H. Lee et al. (2011) found no effects of 849 MHz and 1950 MHz RF energy (at 4 W/kg) on body weight, survival or tumour incidence in lymphoma-prone AKR/J mice. No work has been done since 2007 on other transgenic mouse models.

Studies of Tumour Promotion and Co-Promotion

Prior to 2009, studies of normal animals exposed to non-thermal RF energy found no consistent *in vivo* evidence that RF energy had epigenetic activity (i.e., promotion or co-promotion). For reviews of these studies, see IARC (2013), Juutilainen et al. (2011), Moulder et al. (2005), and Repacholi (1997). Paulraj and Behari (2011) studied RF energy in a skin tumour promotion model and found no effects at 112 MHz (0.75 W/kg) or 2450 MHz (0.1 W/kg). Using a novel co-carcinogenesis model, Tillmann et al. (2010) exposed pregnant mice to RF energy at 1966 MHz (at 0.1-0.4 W/kg) plus a chemical carcinogen and found an increase in two types of cancer in their offspring. There have been no published studies with lymphoma promotion models since 2001, none in mammary tumour promotion models since 2008, and none in brain tumour promotion models since 2007.

Studies of Genotoxic and Epigenetic Activity

When agents are found to be carcinogenic in animals, studies of their potential to cause genotoxic and or epigenetic injury can assist in relating those studies to human risk assessment; and when there are no relevant animal studies, assessment of genotoxic and/or epigenetic potential can help prioritize agents for assessment in animal models. However, when agents are not shown to be carcinogenic in animal models, as is the case for "low level" RF energy, studies of genotoxic and/or epigenetic potential are of little use for risk assessment, as the false negative rate (i.e., "positive" results for laboratory studies with negative evidence of carcinogenicity in humans) for these assays are high (Brusick et al., 1998).

According to the 2013 IARC review:

> Several published reviews concluded that: (i) the existing data are not sufficiently strong to suggest that RF radiation is directly genotoxic; (ii) exposure to RF radiation probably does not enhance the damage induced by known genotoxic agents; and (iii) some of the reported "adverse effects" may be attributed to hyperthermia induced by RF radiation (IARC, 2013)

Other recent reviews have largely supported this conclusion (Habash et al., 2009; Hintzsche & Stopper, 2012; Repacholi et al., 2012; Vecchia et al., 2009; Verschaeve, 2005; Verschaeve et al., 2010). The exception is Ruediger (2009) who concluded that there was

> "…evidence that [RF fields] can alter the genetic material of exposed cells *in vivo* and *in vitro*… [and that] this genotoxic action may be mediated by microthermal effects in cellular structures, formation of free radicals, or an interaction with DNA-repair mechanisms."

Studies of genotoxic and epigenetic activity in humans and experimental systems, published since 2009, are considered below.

Studies of genotoxic and epigenetic activity in humans published since 2009

Three studies of the genotoxic potential of RF energy in humans have been published since 2009. None showed significant effects. Hintzsche and Stopper (2010) found no difference in the frequency of micronuclei (a measure of genotoxic injury) in buccal cells of mobile phone users and non-users. Ros-Loor et al. (2012) found similar negative genotoxicity results in mobile phone users. Yildirim et al. (2010) reported no evidence of genotoxicity in people living near mobile phone base stations. There have been no studies since 2009 of DNA damage in workers occupationally exposed to RF energy.

Studies of genotoxic and epigenetic activity in experimental systems published since 2009

As in earlier studies, the post-2009 studies contain a mix of reports indicating possible genotoxic and epigenetic activity and others showing no evidence of either. There is a wide mix of endpoints (many of which are indirect) and exposure conditions (e.g., different frequencies, modulation schemes, power, exposure duration). There are also methodological weaknesses in many studies (e.g., lack of dosimetry, lack of sham-exposed controls, non-standard assays) (Foster and Moulder, 2013; IARC, 2013; Repacholi et al., 2012). Thermal artifacts are of particular concern in the *in vitro* studies, as temperature control is difficult (and in some cases undocumented) and heat itself is suspected to be genotoxic (Dewhirst et al., 2003; Kheifets et al., 2003). Overall, no firm conclusions can be drawn from these newer studies that would affect risk assessment for humans.

The studies that provide some evidence for genotoxic activity of RF energy include:

- Kesari et al. (2010) exposed rats to 2450 MHz RF energy (0.11 W/kg) and found evidence for genotoxic injury in their brain cells.

- Şekeroğlu et al. (2012) exposed rats to 1800 MHz RF energy (at 0.37-0.49 W/kg) and found evidence for genotoxicity in their blood cells.
- Karaca et al. (2012) exposed rat brain cells to 10.7 GHz RF energy (at 0.725 W/kg) and found evidence for genotoxicity.
- Avendaño et al. (2012) exposed human sperm to a WiFi-connected laptop computer (unknown SAR) and found evidence for genotoxicity.
- Pesnya and Romanovsky (2013) exposed onions to a GSM mobile phone (unknown SAR) and found evidence of genotoxicity.
- Kumar et al. (2013) exposed rats to 10 GHz RF energy (at 0.14 W/kg) and found evidence of genotoxicity in their blood cells.

The studies that provide indirect evidence for genotoxic and/or epigenetic activity of RF energy include:

- Panagopoulos and Margaritis (2010a, 2010b) exposed fruit files to a mobile phone (unknown SAR) and found decreased reproduction that they interpreted as evidence of DNA damage.
- Kumar et al. (2010) exposed rats to 10 (at 0.14 W/kg) or 50 GHz (at 0.14 W/kg) RF energy and found hematological changes they interpreted as evidence of genotoxic and epigenetic activity.
- Schrader et al. (2011) exposed cells to 900 MHz (at 11.5 W/kg) and found alterations in the mitotic apparatus that might indicate genotoxicity. Hintzsche et al. (2011) found similar effects at 10.6 GHz (at a power density of 0.04-4.3 mW/cm2).
- Atasoy et al. (2012) exposed rats to a 2436 MHz Wi-Fi gateway (unknown SAR) and found hematological changes they interpreted as evidence of genotoxicity.

The studies that found mixed evidence for genotoxic and/or epigenetic activity of RF energy include:

- Markovà et al. (2010) exposed human cells to 905, 915 and 1947 MHz RF energy (at 0.037-0.039 W/kg) and found evidence that suggested inhibition of DNA repair in some studies, but not in others.
- C. Liu et al. (2013) exposed rat cells to 1800 MHz RF energy (at 1-4 W/kg) and found evidence of genotoxic injury at the highest SAR in some, but not all, assays.
- S. Xu et al. (2013) exposed cells to 1800 MHz RF energy (at 3 W/kg) and found evidence for possible genotoxic activity in some, but not most, cell types.

The studies that found no evidence for genotoxic and/or epigenetic activity of RF energy include:

- Luukkonen et al. (2010) exposed human tumor cells to 872 MHz RF energy (at 5 W/kg) and found no evidence of DNA strand breaks.

- Zhijian et al. (2010) exposed human cells to 1800 MHz RF energy (at 2 W/kg) and found no indication of DNA damage.
- Franzellitti et al. (2010) found no DNA damage in cells exposed to 1800 MHz RF energy (at 2 W/kg)
- Falzone et al. (2010) exposed human sperm to 900 MHz RF energy (at 2.0 and 5.7 MHz) and found no evidence for genotoxic activity.
- Hintzsche et al. (2012) exposed cells to 900 MHz RF energy (SAR uncertain) and found no evidence of genotoxicity.
- Bourthoumieu et al. (2011) exposed cells to 900 MHz RF energy (at 0.25-4 W/kg) and found no chromosome aberrations.
- Hintzsche et al. (2012) exposed cells to 10,600 GHz RF energy (at a power density of 0.04 – 2 mW/cm2) and found no evidence of genotoxicity.
- Zeni, Sannino, Romeo, et al. (2012) reported that exposure of human cell to 1950 MHz RF energy (at 0.15-1.25 W/kg) reduced their genotoxic response to subsequent exposure to a chemical carcinogen.
- Zeni, Sannino, Sarti, et al. (2012) exposed cells to 1950 MHz RF energy (at 10 W/kg) and found no evidence of genotoxic activity.

Conclusion of the Panel

The authoritative reviews considered by the Panel find that a causal association between cancer and exposure to RF energy is possible (based on the IARC definition for Group 2B). This Panel agrees with that assessment. The present review also considered numerous studies that appeared after these authoritative reviews were completed. None of the newer studies materially affect the conclusions of the authoritative reviews. However, a weight-of-evidence evaluation shows that the current evidence for a causal association between cancer and exposure to RF energy is weak. The epidemiological evidence is largely limited to a weak association of prolonged mobile phone use with increased incidence of glioma and acoustic neuroma. The epidemiological associations are not strong and the various studies are inconsistent with each other. Animal studies of RF energy and cancer have provided no consistent evidence that exposure to RF energy below SC6 (2013) limits causes or promotes cancer. Extensive *in vitro* studies have generated inconsistent evidence that RF energy has genotoxic or epigenetic potential. No viable biophysical mechanism has been proposed for carcinogenic effects for exposure below the levels of SC6 that are supported by results in experimental systems (Moulder et al., 2005; Repacholi et al., 2012; Vecchia et al., 2009).

The most critical issue for this Panel to establish is whether there is evidence of adverse health effects, regardless of whether the mechanisms are known. Unfortunately, the interpretation of existing epidemiological studies is limited by problems with exposure assessment. Several large international epidemiologic studies are underway and at least one very large government-sponsored animal exposure study is still in progress in the US. Thus, additional time and research

will be required for a more thorough assessment of the possibility of a causal connection between cancer and the RF energy. If exposure to RF energy is actually associated with cancer risk, the relevant measure of dose, and the dose-response, are both unknown. Therefore, if an association is substantiated, more detailed dose-response studies will be needed to determine the exposure levels of greatest risk. If substantial cancer risks are demonstrated in a future study, then increasing the safety margin of SC6 would be warranted, although the Panel concludes that the current evidence is not strong enough to warrant doing so at present.

7.2. Hypersensitivity and MUPS (Medically Unexplained Physical Symptoms)

Background

There is a group of people who experience a variety of physical symptoms of ill health, which they attribute to exposure to electromagnetic fields at strengths below the limits in international guidelines. This phenomenon is often called "electrosensitivity" or "electrical (electromagnetic) hypersensitivity", but a 2004 workshop of the World Health Organization (WHO) proposed the term "Idiopathic Environmental Intolerance with attribution to EMF" (IEI-EMF), which is more neutral with respect to causality (ICNIRP, 2006). There has so far been a lack of a validated, mutually accepted case definition and diagnostic instrument for IEI-EMF. A recent systematic review found that the predominant criteria used to identify IEI-EMF are: self-report of being (hyper)sensitive to EMF; attribution of physical symptoms to at least one EMF source; absence of medical, psychiatric or psychological disorder capable of accounting for these symptoms; symptoms should occur soon (up to 24 hours) after the individual perceives an exposure source or exposed area. Reported hypersensitivity to EMF can be either generalized (attributed to various EMF sources) or source-specific (Baliatsas et al., 2012).

In the earliest references to IEI-EMF, which were available at the time of the previous review of SC6, the predominant symptoms reported were skin reactions such as redness, itching, burning or dryness after working with video display units. The case-control and double-blind experimental studies available at the time did not find a clear causal relationship with EMF exposure (Levallois et al., 2002). There were also indications for a more generalized syndrome of complaints attributed to a wider range of EMF sources and frequencies, which was also observed in later studies. Besides skin reactions, the symptoms include: fatigue, dizziness, headache, tinnitus, sweating, muscle and joint pain, burning sensations in the eyes, ear, nose and throat complaints, gastrointestinal disturbances and sleep problems (Genuis and Lipp, 2012; Hagstrom et al., 2013; Johansson, 2006; Kato and Johansson, 2012; Ziskin, 2002). These symptoms are not specific for IEI-EMF, but also occur in different combinations in a variety of other syndromes with other attributions. Examples of these are multiple chemical sensitivities, chronic fatigue syndrome, fibromyalgia and irritable bowel syndrome. Since the symptoms in question are non-specific and not directly attributable to organic disease, they are generally called "medically unexplained symptoms" (MUS) or "medically unexplained physical symptoms" (MUPS) (Brown, 2007; Rief and Broadbent, 2007; van der Feltz-Cornelis et al., 2012).

The prevalence of IEI-EMF varies from country to country. At the time of the previous review of SC6, surveys in various European countries indicated a prevalence between "few per million" to "tenths of a percent". Countries also varied in the degree to which complaints were associated with sources at the workplace or at home (Aringer et al., 1996). More recent surveys report a higher prevalence for IEI-EMF, varying from 2 to 13 percent of the general population (C. Baliatsas et al., 2012; Genuis and Lipp, 2012; Mortazavi et al., 2011; Röösli, 2008; M. Tseng et al., 2011; van Rongen et al., 2009). Apart from genuine differences between the populations investigated, these variations could also be influenced by the number of identification criteria used and how strictly they are applied (Baliatsas et al., 2012). There is a wide variety in symptom severity between individuals with IEI-EMF, from perception or minor symptoms without functional impairment in daily life to severe impairment with loss of employment (Aringer et al., 1996; M. Tseng et al., 2013). The type of sources, which is deemed to be the main cause of symptoms, also varies between individuals. Sources can roughly be subdivided into the following categories: sources producing power frequency (50-60 Hz) EMF such as power lines and electrical appliances, high-frequency transients (3-150 kHz, also called "dirty electricity") and radiofrequency sources (3 kHz-300 GHz) such as video display units, wireless home electronics and mobile phone masts (Genuis and Lipp, 2012).

Association in general population

With regard to a possible causal link between exposure to EMF and MUPS, three types of questions can be asked: are MUPS related to objectively measured EMF exposure in the general population; are individuals with IEI-EMF able to detect low-level EMF; does EMF exposure cause MUPS in individuals with IEI-EMF? With regard to association between EMF and MUPS in the general population, a recent meta-analysis of cross-sectional and cohort studies conducted by Baliatsas et al. (2012) found no significant association between actual exposure to EMF and headache, concentration problems, fatigue, dizziness, headache or sleep problems. Findings in individual studies are inconsistent, but generally studies with more advanced exposure characterization are less likely to find significant associations. Perceived exposure to EMF is associated with headache and concentration problems, but associations with other symptoms are non-significant or inconsistent (Baliatsas et al., 2012). While earlier reviews were more equivocal (Röösli, 2008; Seitz et al., 2005), a more recent systematic review concludes that the bulk of observational studies do not support an association between exposure to RF energy and MUPS or health-related quality of life. Those studies that do find an association tend to rely more on distance to the RF-emitting source, which does not correlate well with actual exposure levels (Röösli and Hug, 2011). A more recent study not covered by the reviews does not change these conclusions (Frei et al., 2012). One limitation of these observational studies is that exposure gradients (i.e., the contrast between low to high-exposed) can be small and some misclassification between high and low-exposed may occur (Röösli and Hug, 2011). Systematic reviews of randomized and blinded provocation experiments conclude that short-term exposure to RF energy, either from close-by sources such as mobile phones or far field sources such as

mobile phone masts, does not cause MUPS. In the minority of cases where an association is reported, there is no consistent pattern or direction of symptoms (Röösli, 2008; Röösli and Hug, 2011). Some case studies and intervention studies have suggested an association between high frequency voltage transients ("dirty electricity") and MUPS, but methodological problems with blinding and exposure assessment make it difficult to draw any firm conclusions from these (de Vocht, 2010).

Ability to perceive low-level EMF

The ability of individuals with IEI-EMF to consciously detect the presence of low-level RF energy has been tested with randomized double-blinded laboratory tests and a randomized blinded field test with a mobile phone base station. Participants with IEI-EMF were unable to detect the RF energy more accurately than chance (Röösli, 2008; Röösli et al., 2010; Seitz et al., 2005). Occasionally, analyses on the individual level can identify participants who accurately report symptoms during randomized and blinded exposure to RF energy with a consistency that is unlikely to be due to chance. When the performance cannot be reproduced in a subsequent replication experiment, it is possible that the participant responded to subtle cues of the actual exposure condition (Röösli and Hug, 2011). However, it cannot be excluded that there are individuals with IEI-EMF who are genuinely hypersensitive to EMF but are lost in group averaging or have not been experimentally tested yet.

Exposure to RF Energy & MUPS in EHS

Systematic reviews of the experimental literature conclude that, taken together, individuals with IEI-EMF do not show an increase in MUPS after short-term, randomized and blinded exposure to RF energy, either from close-by sources such as mobile phones or far field sources such as mobile phone masts. This includes laboratory exposure studies and intervention studies in the living environment (Röösli et al., 2010; Röösli and Hug, 2011; Rubin, and Wessely, 2005; Rubin et al., 2010; van Rongen et al., 2009). The balance of the evidence also does not indicate a consistent effect of RF on indicators of autonomic arousal such as blood pressure, heart rate and pupillary reflexes in IEI-EMF (Röösli et al., 2010; Rubin et al., 2011). More recent individual studies not covered by the reviews do not change these conclusions (Kwon et al., 2012; Mortazavi et al., 2011; Wallace et al., 2012) or provide insufficient information to draw conclusions (Havas and Marrongelle, 2013). On the other hand, there is some evidence that MUPS can be triggered in IEI-EMF by the conviction of being exposed to EMF, regardless of whether actual exposure has taken place (Röösli and Hug, 2011; Rubin et al., 2005; Rubin et al., 2010) or by media attention to adverse health effects of EMF (Witthöft and Rubin, 2013).

Limitations

There are several limitations to the studies on IEI-EMF performed so far. One possibility that has been insufficiently investigated is that there may be subgroups of individuals with different sensitivities with regard to frequency or intensity of the stimulus or with regard to the presence or

absence of other pathological conditions, which could underlie the symptoms. In experimental studies, there has also been a focus on individuals with IEI-EMF who claim to respond relatively quickly to EMF exposure. Some individuals with IEI-EMF claim to experience symptoms only after more chronic exposure to EMF or with longer intervals after exposure (Baliatsas et al., 2012; Genuis and Lipp, 2012; Havas and Marrongelle, 2013; Rubin et al., 2011; Rubin et al., 2005). Future research should therefore try to differentiate between these possibilities. There is a relative lack of experimental or intervention studies with long-term exposure and exposure in the living environment where multiple sources and frequencies of RF energy are present at the same time (Genuis and Lipp, 2012; Havas, 2006; Rubin et al., 2011; Rubin et al., 2010). One reason may be that it is difficult to conduct such experiments in a randomized, double blinded way. It also seems logical to investigate the possible association between MUPS and high-frequency voltage transients in the home environment (for example, by blinded placement of filter units) (de Vocht, 2010). In the absence of clear evidence for a causal relationship between IEI-EMF and MUPS, there is also a need for more research into effective ways of treating the symptoms and reducing disability (de Graaffa and Bröer, 2012; Rubin et al., 2006; Ziskin, 2002).

Taken together, research in the past ten years does not provide firm evidence for the hypotheses that people with IEI-EMF can perceive RF energy at levels below the limits in SC6 or that there is a causal link between exposure to RF energy and their symptoms.

7.3. Cognitive and neurologic effects

The most recent comprehensive review of the cognitive and neurological effects of RF energy is based on a systematic search of Pub Med and ISI Web of Science for peer-reviewed journal articles between 1998 and the end of 2009 (Regel and Achermann, 2011). Like previous reviews (e.g., Cook et al., 2006), the authors found many methodological differences and flaws but found no consistent negative effects.

An important development in behavioural neuroscience in the past 25 years has been the demonstration that the brain is far more sensitive to experience than was previously believed, a phenomenon referred to as brain plasticity. Brain plasticity can be studied at many levels ranging from behaviour to molecular measures (see Table 7.3-1). The choice of level will depend upon the question being posed and the species being studied. There is no “correct” or “best” level. Studies need to be done at many levels to thoroughly understand how environmental events such as electromagnetic waves might influence brain activity and behaviour.

Table 7.3-1: Levels of analysis of brain structure and function

Behaviour
Neural imaging (e.g., fMRI, PET)
Maps – invasive and non-invasive
Physiology (e.g., electroencephalogram, event related potentials)
Neuronal morphology
Genetics and epigenetics
Proteins and other molecules

One important distinction in examining brain plasticity is the difference between acute and chronic changes in the brain. Plastic changes may be transient (such as the effects of a flash bulb on visual acuity), persist somewhat longer (such as short-term memories), or be chronic (such as long-term memories). As we examine the effect of any experience, such as exposure to electromagnetic waves, we must distinguish between these different outcomes. One variable that will influence the nature of plastic changes in the brain is the duration and intensity of an experience. Long-lasting, intense, experiences can be expected to produce greater changes in brain plasticity than brief, mild, experiences.

One complexity to analyzing experience-dependent changes in brain and behaviour is that experiences normally have behaviourally-specific effects (Kolb and Whishaw, 2009). Thus, the analysis of the effects of electromagnetic waves must be made on a variety of behavioural measures rather than on a single task. Demonstrating that there are no effects of an experience on a specific behaviour does not allow generalizations to behaviour in general.

Finally, it is important to recognize that just because an experience produces a significant, and possibly large, behavioural effect does not necessarily mean that there will be a long-lasting change in brain and behaviour. For example, although psychoactive drugs such as alcohol or caffeine clearly change brain function, these drugs do not have long-term effects on the brain unless taken to excess. In contrast, many psychoactive drugs do produce long-lasting effects on brain structure and function, even in low doses (Robinson & Kolb, 2004), and these changes can have a significant impact on how the brain responds to subsequent experiences, a phenomenon referred to as metaplasticity.

One overriding principle is that chronic behavioural change is related to specific gain and elimination of synapses within ensembles of connections. While the ultimate cause of the synaptic change is related to gene expression and related molecular events, it is the synaptic change that is most related to behaviour.

Thus, a review of the effects of electromagnetic waves on the brain must distinguish between acute and chronic effects, examine multiple behaviours, and measure brain-behavioural changes

at multiple levels and vary intensity and duration of the wave exposure. To date, few studies in the literature have done this.

Neurophysiological effects

Several reviews have summarized the effects of exposure to electromagnetic waves on electroencephalography (EEG) and related measures including event-related potentials (ERP) and evoked potentials (EP). Studies have examined resting EEG, sleep EEG (see below), and experience-related ERPs and EPs. Although the effects are small, and mostly transient, there do appear to be many studies showing effects but it is difficult to identify any consistent result across studies (Cook et al., 2006; Cook et al., 2002; Kaprana et al., 2008; Rubin et al., 2011; van Rongen et al., 2009). Many studies report high intersubject variability and it has been suggested that studies should separate participants based upon individual or personality differences (e.g., Stevens, 2001). The Panel is unaware of any such studies to date. Marino and Carrubba (2009) noted that most studies had negative results but concluded that the bulk of studies had methodological flaws and that the pathophysiology of EMFs as measured by brain electrical activity remains unanswered.

Sleep EEG

Perhaps the most consistent neurophysiological effect of exposure to RF energy is on sleep EEG. Although many studies fail to find effects (e.g., Fritzer et al., 2007; Wagner et al., 1998; 2000), other studies, especially those conducted by the Niels Kuster and Peter Achermann laboratories, have found short-term changes in sleep EEG related to exposure to mobile phone-like RF energy in laboratory experiments (e.g., Lustenberger et al., 2013; Regel et al., 2007; Schmid, Loughran, et al., 2012; Schmid, Murbach, et al., 2012). Despite these EEG changes, there is no indication of any impact on the subjective overall sleep quality or on cognitive performance. Schmid et al (2012) reported high inter-subject variability in sleep EEG but did find alterations in some study participants although the EEG effects were not related to changes in waking cognitive performance. Epidemiological studies have also not found any adverse effects of exposure to RF energy on sleep quality (e.g., Danker-Hopfe et al., 2010; Mohler et al., 2012).

Cognitive effects

Studies have examined a wide variety of cognitive/behavioural measures (e.g., memory, attention, perception and executive function (i.e., frontal lobe function)). There do not appear to be any consistent effects and the current conclusion is that EMF waves do not interfere significantly with cognitive functions (Cook et al., 2006; Rubin et al., 2011; van Rongen et al., 2009).

Molecular effects

There are very few studies of molecular effects of electromagnetic waves. The best-studied effect is changes in the blood brain barrier (BBB). A change in permeability of the BBB could have

significant consequences for brain function and, thus, this is an important issue. Although some studies have reported small changes, the overall conclusion is that radiofrequency electromagnetic waves at levels below the proposed limits in SC6 do not alter the permeability of the BBB (Stam, 2010).

Conclusion of the Panel

Although some small transient effects of exposure to RF energy on cognitive and neurological functioning have been reported, there is little consistency across studies and high inter-subject variability. While the intensity of exposure in the studies varies widely, a number of the studies were designed to mimic cell phone levels of exposure, which could occur below the levels of SC6. Extensive studies examining multiple behaviours and measuring brain-behavioural changes at multiple levels with varying intensity and duration of the wave exposure are needed.

7.4. Male and female reproductive effects

Male reproductive system

Most of the previous major reviews concluded that there was a lack of convincing evidence for negative impacts of exposure to radiofrequency fields below SC6 levels on the reproductive process in animals (e.g., Expert Group on Health Effects of Electromagnetic Fields, 2007; ICNIRP, 2009b; SSK, 2011; SSM, 2010). Other reports concluded that there is insufficient evidence of RF-related impact on testicular morphology or functions (e.g., Latin American Experts Committee, 2010; NIPH, 2012; SSM), 2013), or on sperm quality (NIPH, 2012). However, specific reproductive effects of exposure to low-level RF energy (3KHz – 300 GHz) have been reported. These effects include: low testosterone levels (AGNIR, 2012; SSM, 2013), significant sperm abnormalities (AGNIR, 2012; SSM, 2013), sperm count increase (SSM, 2013), or decrease, low fructose levels in semen, clumping of sperms leading to decreased sperm motility and frequency and duration of ejaculation (AGNIR, 2012). The Panel notes that some of the reported changes were changes in parameters without impacting spermatogenesis, such as thinning of the germinal epithelium, or smaller diameters of the seminiferous tubules (AGNIR, 2012). It is difficult to interpret the results of most of the studies that reported these significant health impacts on testicular function because of problems in study design, particularly regarding inadequate dosimetry and control of confounding sources of heat (AGNIR, 2012). In particular, the poor dosimetry in many studies makes it difficult to identify the levels at which effects may occur.

Because they are particularly vulnerable to increases in temperature (which subsequently impacts fertility), the testes have long been considered to be an organ at particular risk from excessive exposure to RF energy (AGNIR, 2003; Ahlbom et al., 2004; Latin American Experts Committee, 2010). The threshold temperature increase of the testes that will lead to significant reduction in sperm quality is not well established, but evidence suggests that it is above 1°C (Wang et al., 1997). The use of a mobile phone or carrying the phone in the pocket or hanging from the belt

could not produce such temperature changes. However, use of a laptop computer has been reported to cause scrotal temperature increases of about 2°C, in part because of the heating effect of the computer due to its power consumption (and not due to radiofrequency fields) when placed close to the body and in part because the user tends to keep his legs together when using a laptop in his lap, placing the scrota in closer contact with the legs (Sheynkin et al., 2011).

Many major reviews reported that specialized studies could not provide sufficient and strong evidence of negative impacts of RF energy on male fertility, sperm count, or sperm quality in human studies (e.g., EFHRAN, 2012; AGNIR, 2003, 2012; Ahlbom et al., 2004; Latin American Experts Committee, 2010; NIPH, 2012; SCENIHR, 2007; SSM, 2013; Stewart, 2000). The SSM (2010, 2013) reported a possible association between mobile phone use and altered sperm qualities (in particular, morphology and motility) and pointed to the importance of monitoring the changes in fertility in relation to the different levels of exposure to mobile phones. The review by AGNIR (2012) reported a study, considered by the review to be of limited quality, which concluded a disturbed sperm morphology, decreased motility and low count in association with increased daily use of mobile phones. AGNIR concluded that despite the lack of convincing evidence, the negative impacts on male reproductive system due to exposure to radiofrequency fields cannot be ruled out at this point.

Female reproductive system

It is well established that raising the core body temperature by more than about 1.5°C for extended times during critical periods of gestation has teratological effects in laboratory animals and can be presumed to produce similar effects in humans as well (Miller et al., 2002). To produce such temperature increases in a human would require RF exposures considerably above the present SC6 limits. There is no good quality and conclusive evidence of adverse effects due to RF exposure at levels below the proposed SC6 (2013) guidelines on the female reproductive system or on pregnancy (AGNIR, 2012; EFHRAN, 2012; Latin American Experts Committee, 2010; NIPH, 2012; SCENIHR, 2007; SSM, 2013; Stewart, 2000). No negative impacts were reported on animal reproductive behaviour as to the number of offspring, or incidence of stillbirths or miscarriages (SSK, 2011).

While some reviews reported on the occurrence of negative impacts on pregnancy due to exposure to radiofrequency fields (AGNIR, 2003, 2012), others concluded that the incidence of such impacts on pregnancy is “virtually limited” to certain occupations such as physiotherapists (AGNIR, 2003; SCENIHR, 2007). However, a Norwegian study of naval personnel recently reported an increase in the risk of preeclampsia and perinatal mortality associated with acute paternal exposure to radiofrequency fields during the three months prior to gestation (Baste et al., 2012; SSM, 2013), but the authors note that the correlation with levels of exposure was weak and need confirmation. The exposures levels were not specified, but were reported to be below ICNIRP guidelines and were from radar, transmitters, and antennae on fast patrol boats.

Conclusion of the Panel

At present, the balance of evidence indicates that exposure to radiofrequency fields below the guidelines set in SC6 (2013) does not have negative impacts on reproductive systems and functions. However, in view of the mixed results in the previous work, further research aimed at addressing questions raised by some of the previous studies should be a top priority. Particular care should be taken to ensure adequate study design and dosimetry in future studies, which were lacking in many of the previous studies that reported effects from exposure to RF energy.

7.5. Effects on the eye

Background

In its review of Health Canada's SC6 (1999), the Royal Society of Canada Expert Group stated:

> "The panel noted that whereas exposure limits for the head, neck and trunk given in Safety Code 6 also apply to the eye, Safety Code 6 suggests that even lower exposures for the eye are desirable. Because of the unique physiological characteristics of the eye, the panel recommends that the exposure limits given in Safety Code 6 for the eye be reviewed as new scientific information becomes available. Due to the lack of exposure duration limits, the expert panel recommends the lowering of the dose to the eye of RF workers to that recommended for the general public (1.6 W/kg) as an interim measure." (RSC, 1999)

In subsequent versions of SC6 (1999, 2009), Health Canada did not explicitly state separate basic restrictions for the eye, adding the following note in the section on basic restrictions: "Although it is not a requirement of the code, it is suggested that whenever possible, the organ-averaged SAR for the eye should not exceed 0.4 W/kg in the controlled environment and 0.2 W/kg in the uncontrolled environment".

For the proposed revisions to SC6 (2009), Health Canada state in their Rationale (2013): "Overall, there is an inadequate body of scientific evidence upon which to support the causality of adverse health effects of RF energy on the human eye at exposure levels below the peak spatially averaged SAR limits in SC6 (2013)." Similar conclusions have been stated in ICNIRP (1998; 2010), and IEEE C95.1 (2005). Therefore, Health Canada proposes to remove the statement regarding the eye described above from SC6 (2013), the implication being that the basic restrictions for the eye are the same as the head.

This section reviews recent research into the exposure of the eye to radiofrequency fields to determine if the SC6 (2013) SAR basic restrictions for the head, neck and trunk provide adequate protection against adverse health effects in the eye.

Experimental Studies

The UK's Advisory Group on Non-ionising Radiation in 2003 stated that a number of experimental studies into cataract formation were conducted in the 1960s and 1970s (AGNIR,

2003). These investigations were of variable quality and did not provide quantitative data on exposures. Some studies suggested that minor defects of the posterior pole of the lens are found more frequently in workers exposed to microwave radiation, but this was not a consistent finding and the changes reported were of doubtful clinical relevance (AGNIR, 2003).

In its 1998 guidelines, the ICNIRP presented the possibility of microwave-induced cataract formation in rabbit eyes at lenticular temperatures of 41-43°C, based on research carried out by Guy et al. (1975). This investigation used power densities of 1500 W m^{-2} for durations up to 100 minutes. Kramar et al. (1978) found no cataract formation in the eyes of monkeys when exposed at power densities of 1800 W m^{-2} for a frequency of 2.45 GHz, although facial burns were observed. To put these power densities into context, the SC6 (2013) reference level limit for power density at 2.45 GHz, averaged over six minutes, is 6.4 W m^{-2}, significantly below the power densities being used in these investigations.

More recent dosimetric studies have investigated eye exposure to electromagnetic fields at power density values comparable to the proposed SC6 (2013) reference levels for localised head, neck and trunk exposure (Buccella et al., 2007; Cvetkovic et al., 2011; Flyckt et al., 2007; Hirata, 2005; Hirata et al., 2013; Laakso, 2009; Papaioannou and Samaras, 2011; Wainwright, 2007). In these studies, no adverse health effects were predicted on the eye at these reference level values.

The SAR in the eye in a model of a human head was calculated from exposure to 900 MHz, 2.4 GHz and 5.8 GHz radiofrequency fields (Hirata et al., 2000). The SAR averaged over a 10 g region was found to be small compared to various international standards. Furthermore, the maximum temperature rise in the eye for exposure to these high frequency fields calculated was 0.26°C (at 5.8 GHz). This is small compared to the threshold temperature rise of 3.0°C for cataract formation.

Wainwright (2007) investigated electromagnetic exposure to the eye using models of handsets operating at 380 MHz (TETRA), 900 MHz and 1800 MHz (used for GSM[21] handsets) to determine exposure configurations that could be tolerated without causing an eye temperature rise of greater than 1°C. A temperature rise of between 0.017°C and 0.55°C was calculated in the eye of the NORMAN voxel model for representative exposure scenarios using helical and monopole phone antennas. The position of the maximum temperature rise was always found in or very close to the lens. However, there was no significant difference between the maximum rise in the lens and the whole eye.

The temperature rise in the eyes of realistic Japanese male and female models for plane-wave exposure between 600 MHz and 5 GHz has also been investigated (Hirata et al., 2007). Computational results showed that the SAR was a good predictor of temperature rise in the eye.

[21] Global System (or Standard) for Mobile, a standardized international system for digital mobile telecommunication. (GSM (n.d.), Oxford Dictionary. Retrieved on March 1, 2014 from http://www.oxforddictionaries.com/definition/english/gsm)

The ratio of maximum temperature in the lens to eye averaged SAR was almost uniform at 0.112-0.147°C per W kg^{-1} in the frequency region between 600 MHz and 3 GHz.

The temperature elevation in the lens, skin surrounding the eyes and core temperature has recently been investigated in human and rabbit models for plane wave and localised exposure at 3000 W m^{-2} and 2.45 GHz (Hirata et al., 2013). It was found that the core temperature for cataract formation was not reached and the skin temperature around the eye reached its pain threshold temperature of 43°C before the lens reached its threshold of 41°C. This suggests that skin temperature elevation is dominant for radiofrequency exposure of the human eye and supports experimental evidence of facial burns in monkeys before cataract formation (Kramar et al., 1978)

Authoritative reviews conducted by the IEEE and ICNIRP concluded that there is little evidence to suggest adverse health effects in the eye from exposure to RF energy below the limits presented in the proposed SC6 (2013). In addition to these reviews, other organisations and expert groups have concluded that there was no definitive evidence of any effects (e.g., increased incidence of cataracts) on the lens of the eye from exposure to RF energy within guideline levels proposed by international organisations (AGNIR, 2003, 2012).

Summary

Animal Studies

Studies on animals have provided no convincing evidence for an association with ocular damage from exposure to RF energy at levels below SC6 (2013) limits. Biological effects measured have included: disturbed vision, cataracts, eye irritation, or impact on the aqueous or vitreous humor (ICNIRP, 2009b; Latin American Experts Committee, 2010; NIPH, 2012). Whereas Stewart (2000) described reports of anesthetized primates as being vulnerable to ocular damage from exposure to low levels of radiofrequency fields, they found no such effects in unanesthetized monkeys, a conclusion also reached by the ICNIRP (2009b) which stated that primates were less vulnerable to thermally induced cataracts compared to rabbits, especially while not being anesthetized during the exposure to radiofrequency fields.

Human Studies

Apart from early controversy about cataracts in humans exposed to low level RF energy, recent reviews conclude that there is not sufficient evidence to support a causal association between exposure to radiofrequency fields and ocular damage at levels below SC6 (2013) limits (Latin American Experts Committee, 2010). However, the 2004 ICNIRP report suggested that the lens is susceptible to thermal damage after even a single acute exposure, which is a potential mechanism for RF-induced cataract (Ahlbom et al., 2004). The thresholds for such damage are not clear. Studies in animals suggest that temperatures exceeding 41°C would be required to

produce corneal damage (Elder, 2003), which would require exposure to RF energy at levels far above the SC6 (2013) limits.

Conclusion of the Panel

The available evidence on exposure of the human eye to RF energy at levels below those proposed in SC6 (2013) strongly suggest that no adverse health effects occur. Even at power density values orders of magnitudes above the reference level limits stated in SC6 (2013), experimental and numerical studies report that the parts of the eye potentially susceptible to radiofrequency radiation (i.e., the aqueous humour, lens and vitreous humour) show no signs of significant temperature elevation and no cataract formation is observed.

The Panel notes that one unanswered issue is related to possible effects of exposure to RF energy on visual acuity. The eye is unique biologically in that it has stem cells and high vascularity in the retina. Changes to either could significantly alter visual acuity. There appear to be no studies of visual acuity (e.g., Snellen acuity, Vernier acuity), which would be critical in determining whether exposure to RF energy alters visual functioning.

7.6. Developmental Changes (Neuronal Growth, Connectivity)

There are few systematic reviews of exposure to RF energy on brain development and behaviour (e.g., Feychting, 2011) even though the WHO has identified studies on the effects of RF on the developing brain to be a high priority research area.

Brain development reflects a series of stages that can be seen as being broadly divided into two phases. In most mammals the first reflects a genetically determined sequence of events *in utero* that can be modulated by maternal environment. The second phase, which is both pre- and postnatal in humans, is a time when the connectivity of the brain is very sensitive not only to the environment but also to the patterns of brain activity produced by experiences. More importantly, however, it is now recognized that epigenetic changes, which can be defined as changes in developmental outcomes, including regulation of gene expression, are based upon mechanisms other than DNA itself. For example, gene expression can be altered by specific experiences and this, in turn, can lead to organizational changes in the nervous system. Such epigenetic changes can sometimes cross generations.

The brain is acutely sensitive to both internal and external experiences throughout development (Kolb et al., 2012). One complexity here is that as the brain develops, some early perturbations that have negative effects are compensated for, whereas brain dysfunctions not detectable early in life may begin to appear later, and especially in adolescence (Kolb and Whishaw, 2009). Indeed, this is easily seen in the fact that most mental disorders first appear in adolescence (Paus et al., 2008).

The Panel notes that, just as in the study of cognitive and neurological effects of electromagnetic waves in adult brains, there must be multiple measures at many levels of analysis. This has not

yet been done. Thus, although it is reasonable to expect that experiences such as exposure to electromagnetic waves might influence brain development either in utero or postnatally, there are surprisingly few studies. The most recent and extensive review is by Feychting (2011) who concluded that methodological limitations in available studies, confounding, and selection bias prevents conclusions about the causal effects of electromagnetic wave exposure in children and adolescents on behavioural tests. van Rongen et al. (2009) reached a similar conclusion in their review of both electrophysiological and behavioural effects in children.

As noted earlier, the brain is especially sensitive to prenatal experiences but there are too few data on the effects of electromagnetic waves on the developing foetus to allow any conclusions. Such studies are technically difficult because it would be very hard to single out electromagnetic waves as a causal factor in neurodevelopmental disorders. The best strategy would likely be to expose the developing brain of laboratory animals (e.g., rats, mice) to electromagnetic waves that could be varied in duration and intensity but this does not appear to have been done to date.

Conclusion of the Panel

There is no evidence that either pre- or postnatal exposure of the developing brain to RF energy has cognitive or neurological sequelae. There are, however, very few studies systematically examining this question and the Panel agrees with the WHO that this should be seen as a high priority field of study.

7.7. Cardiac functions and heart rate variability

Previous Expert Reviews

The Panel examined the conclusions of previous expert reviews on the effects of exposure to RF energy on cardiac function and heart rate variability. Particular attention was paid to the following: the most significant recent reviews (2009 or later) identified by Verschaeve (2012); the latest version of a report by the Swedish Radiation Safety Authority (2013); and two reviews covering literature published mostly before 2000 on the topic (Black and Heynick, 2003; Jauchem, 1997).

The following biological effects were examined: blood pressure changes, changes in the electrocardiogram (ECG), heart rate, or changes in heart rate variability (HRV) associated with exposure to RF energy. Heart rate variability refers to the comparatively small variations in time (of the order of 10%) between successive heart beats, which reflects control mechanisms of the heart rate by the autonomic nervous system (Task Force of the European Society of Cardiology the North American Society of Pacing Electrophysiology, 1996).

All of these reviews, with the exception of the BioInitiative Working Group (2012), came to broadly similar conclusions about possible effects of exposure to RF energy on cardiac function. Overall, the reviews found no clear evidence for cardiovascular effects of exposure to RF energy for humans or animals at levels below current or proposed SC6 limits. At higher exposure levels,

the previous studies noted a range of effects that can be attributable to thermoregulatory responses. As the reviews noted, a few studies reported effects of some sort on cardiovascular function, but the reviews did not consider them to be convincing evidence of health hazards from exposure to RF energy because of technical concerns with the studies or other reasons. The general tenor of the conclusions of all of these reports (apart from the much stronger conclusions of the BioInitiative Report) is similar to that of the RSC review (1999): "when the intensity of exposure is low enough that overt heating of tissue does not occur, the nature of the biological response is much less clear."

More Recent Studies

The Panel searched the EMF-Portal (http://www.emf-portal.de) for human and animal studies examining the effects of exposure to RF energy on cardiovascular function published since 2010. The search yielded the ten papers summarized below.

- Havas and Marrongelle (2013) studied the effects of RF exposure on heart rate variability in the human cardiovascular system and found a significant (doubling or more) increase in heart rate in a large fraction of exposed subjects.
- Meral et al. (2014) exposed guinea pigs to GSM-type exposure (pulsed 890-915 MHz, pulses at 217 Hz, SAR stated to be 0.95 W/kg, 12 hr/day for 30 days) and found no significant ECG effects.
- Parazzini et al. (2013) measured heart rate variability in humans after rest and sit-to-stand protocol (GSM 900 MHz mobile phone/sham exposure) and reported no statistically significant effect due to GSM exposure on the nonlinear dynamics of heart rate variability.
- Alhusseiny et al. (2012) measured electro-cardiographic parameters in patients with ischemic heart disease or history of other heart disease and healthy controls and concluded that mobile phone radiofrequency (placed at belt level) prolongs the QT interval in human beings and interferes with voltage criteria of ECG records in male patients with myocardial ischemia.
- Colak et al. (2012) measured the cardiovascular effects of placing 3G (1.9 GHz – 2.2 GHz) mobile phones beneath the cages of Wistar rats (40 min/day, 22 days) and found no significant effects on blood pressure, heart rate and ECG parameters.
- Barutcu et al. (2011) measured the cardiovascular effects of GSM mobile phone (frequency not stated) placed against the chests of human subjects and found that short-time exposure to electromagnetic fields emitted by mobile phone does not affect cardiac autonomic modulation in healthy subjects.
- Kwon et al. (2011) measured the cardiovascular effects (heart rate, heart rate variability, respiratory rate) on ten subjects with self-reported electromagnetic hypersensitivity (EHS) and ten subjects without EHS under both sham and real exposures (1.95 GHz, mobile

communication system, WCDMA waveform, 1.95 W/kg) and found no physiological changes in either group.

- Turker et al. (2011) measured oxidative stress in the hearts ofof Wistar rats exposed to 2.45 GHz, whole body SAR 0.143 W/kg (range 0.008-4.2 W/kg), 60 min/day for 28 days and reported changes in the effects of selenium and L-carnitine on changes in vitamin E concentrations induced in the rats' heart.
- Parkar et al. (2010) measured effects on cardiovascular system (heart rate, blood pressure, oxygen saturation, different haematological parameters and lipid profile) in humans using 900 MHz cell phone for a one-minute call (no measurement of RF exposure) and reported a significant increase in the peak heart rate of exposed subjects who had used cell phone for more than four years, as well as mild alteration of lipid profile.
- Yilmaz and Yildiz (2010) measured the cardiovascular effects (heart rate variability) of GSM 900 mobile phones placed against the heads of human subjects and found a significant effect of high-level EMF exposure on the complexity of cardiac system behaviour.

The studies reviewed reported either no effects (e.g., Barutcu et al., 2011; Kwon et al., 2011; Parazzini et al., 2013) or, at most, small effects of exposure to RF energy (e.g., the subtle changes in the statistical properties of the variability observed by Yilmaz and Yildiz, 2010). Most of the studies had significant technical limitations (e.g., inadequate exposure assessment) and lacked blinding and other elements of good study design. It is unclear whether the small reported effects were due to the subjects' use of the phones or to exposure to RF energy directly.

The noticeable exception was the Havas and Marrongelle study (2013), which reported large changes in the heart rate (a doubling or more) of subjects when the base station of a cordless DECT phone was brought close to them. The reason for this apparent disagreement in study findings is unclear at present. The study designs of these different studies differed considerably. The study appears to have uncovered a very large biological effect from exposures far below SC6 (2013) limits. However, there are reasons to question the reliability of the results. The study employed a commercial heart rate variability (HRV) instrument (Intellewave, Ronkonkoma, NY), which displayed the heart rate but not the electrocardiogram from which the heart rate had been calculated by the device. Consequently, artifacts in the measurement could easily have been overlooked. To determine the heart rate and HRV reliably, the instrument has to reliably identify the QRS waves in the ECG, and it is sensitive to electromagnetic interference from external sources. (The manual for the instrument cautions the user to keep the subject "away from powered electrical equipment or other sources of electromagnetic interference"). These results need to be independently confirmed in a study with better design, including independent measurement of the ECG and heart rate to rule out possible artifacts.

Conclusion of the Panel

The authoritative reviews considered by the Panel failed to find clear evidence for a health or safety hazard related to cardiovascular effects from exposure to RF energy at levels below the proposed SC6 (2013) limits. While some of the studies covered by these earlier reviews reported adverse health effects from exposure to RF energy, the authoritative reviews did not consider these reports to be convincing evidence, either because of technical limitations or due to lack of apparent health significance of the effects. This Panel agrees with that assessment.

The present review also considered ten more recent studies that appeared after the previous authoritative reviews were completed. These studies reported either no adverse health effects from exposure to levels of RF energy below the proposed SC6 (2013) limits or modest effects with no apparent health significance. Several of the studies had apparent technical weaknesses that make their interpretation difficult. In particular, Havas and Marrongelle (2013) reported a doubling or more in heart rate of subjects when the base station of a cordless DECT telephone (of the sort that can be inexpensively purchased from an office supply store) was brought near the subjects. That study should be followed up by independent studies employing more rigorous design to confirm its findings.

7.8. Low-Level and "Non-Thermal" Effects

The Panel had a range of opinions regarding the strengths and/or weaknesses of some individual studies and the potential significance of some observed biological effects, such as brain glucose metabolism and EEG, that may be referred to as "Low-Level" or "Non-Thermal". However, the Panel was in consensus in regards to overall weight of evidence regarding the absence of established adverse health effects occurring below the levels proposed in SC6 (2013).

The Panel notes that a number of biological effects of exposure to RF energy have been reported at levels below SC6. While these low-level effects are sometimes characterized as "non-thermal", that term is ambiguous in several respects.

The terms thermal and non-thermal have been used in at least three different senses at different times. The previous Royal Society of Canada expert panel review of SC6 (1999) defined non-thermal effects as follows:

> "Thermal effects often occur when sufficient RF energy is deposited to cause a measurable increase in the temperature of the sample in question (e.g., more than 0.1 C). … Non-thermal effects are those occurring when the energy deposited in the sample is less than that associated with normal temperature fluctuations of the biological system being studied."

A second definition, adopted in SC6 (2013) is: "Biological effect… resulting from exposure to RF fields, that are not due to tissue heating". Thirdly, the term is often used, particularly in public discussions, to refer to effects reported for exposure levels below SC6 or ICNIRP limits.

The implications of these definitions vary greatly. The first definition refers to the magnitude of the temperature increase produced by exposure. By this definition, the microwave auditory effect (Foster and Finch 1974), which is produced by small (micro-degree) temperature increases in the head, would be considered "non-thermal" despite its thermal mechanism. The second definition refers to the mechanism by which an effect is produced. Numerous biological effects of RF energy are well known to result from non-thermal mechanisms, such as electroporation of cell membranes (Joshi et al., 2010). This latter effect requires very high field strengths, which would be thermally damaging if sustained, but still would be classified as non-thermal in terms of mechanism. The third definition refers to an effect observed at low exposure levels, whose mechanism is frequently unknown.

Given this definitional ambiguity, the distinction between "thermal" and "non-thermal" is inherently ambiguous without careful qualification and the question "whether non-thermal effects exist" cannot be answered without clarifying which definition one has in mind. More importantly, the distinctions between thermal and non-thermal effects, in and of themselves, are of little practical use in establishing safety guidelines, which are based on avoiding hazardous effects of exposure to RF energy regardless of underlying mechanism.

For a variety of reasons, many low-level effects are difficult to interpret and, hence, are subject to different interpretations, even by experts. Many of the reported effects are also poorly understood. Moreover, in many cases the external validity of a study may be in question. That is, the study may not be measuring what the investigators think it is. Even when reports of low-level effects are presumed to be correct, their implication for human health may be subject to significantly different interpretations by different scientists.

As a case in point, the following discussion considers two studies that reported an effect from low-level (below SC6) exposures and some of the problems with interpreting them. Members of this Panel themselves disagree on the validity of the results of the studies.

In 2011, Volkow et al. at the National Institutes of Health in Bethesda, Maryland reported that exposure to RF energy emitted by a mobile phone held against the head for 50 minutes increases the rate of glucose metabolism (a measure of brain activity) in the brains of volunteer subjects. The study employed positron emission tomography (PET), a technique with which that laboratory is highly experienced. Shortly thereafter, Kwon et al. (2011), at the University of Turku, Finland reported, in a similar study, the opposite result: decreases in glucose metabolism in the brain following exposure to RF energy from a mobile phone.

The effects reported in both studies were statistically significant according to the authors' analysis, but overall were small[22]. Neither author claimed that the observed differences in brain glucose metabolism were biologically significant or hazardous to the subjects. Volkow et al.

[22]The increases in glucose metabolism reported by Volkow et al. (about 7%) are similar to those resulting from modest levels of brain activation. For example, visual stimulation results in a 10-50% increase in glucose metabolism in the visual cortex (Phelps et al., 1981). Kwon et al. do not indicate the magnitudes of the changes that they observed.

(2011): “This finding is of unknown clinical significance”. Kwon et al. (2011): “The observed suppressive effect on glucose metabolism does not necessarily entail any adverse influence of GSM [a widely used access technology for cell telephony] exposure on brain function because no behavioural effects were found in the present or in many other previous studies”.

While the studies’ objectives were similar, they differed in many respects. The later study, by Kwon et al., had important improvements in design compared to the earlier study. Kwon et al. explained, “the present study has several methodological advantages, especially accurate SAR assessment, well-controlled exposure setup, measurement of temperature in the head region, and objective monitoring of the subject’s alertness state. Proper dosimetry is crucial in microwave exposure studies….”

While they agreed on the inability to use either study in setting exposure limits, different members of this Panel disagreed on their significance. Two experts on the Panel were not convinced about the biological significance of the findings; a third thought that the studies demonstrated a real effect of RF fields on the brain; the remaining Panel members had no comments on the issue. Since the mechanism for the reported effects is presently unknown, there is no way to tell whether they are thermal or non-thermal (in the mechanistic sense). Moreover, the Volkow study has been criticized on technical grounds (AGNIR 2012). As AGNIR (2012) noted in a critical review of these studies, “Further research on the effects of RF fields on brain metabolism is therefore required to reach a firm conclusion. In addition, it remains unclear whether changes in brain metabolism of the size found in these experiments are relevant to health or not.”

Even if these two reports were interpreted as indicating adverse effects to humans, there is, at this time, no practical approach to recommend exposure limits based on these studies. This situation arises because it is not known how the reported effects scale with exposure parameters. For thermal damage, the detriment increases with the rate at which power is dissipated in tissue (i.e., SAR). However, there is no reason to expect that non-thermal (in a mechanistic sense) effects would scale in the same way (i.e., with SAR). One would need a metric of exposure that is predictive of the effect. To obtain that data, one would need dose-response information spanning a range of exposure parameters. That information is lacking in the Volkow and Kwon studies and typically in many other studies reporting low-level effects.

7.9. Possible Effects on Stress Protein Expression

The possible effects of RF exposure on stress protein expression have been the subject of considerable research and discussion. Experiments have involved a wide variety of exposure levels, including some below the limits proposed in SC6 (2013), with no apparent consistency in results. Overall, the literature is mixed, with some studies reporting that exposure to RF energy increased the expression of heat shock or other proteins, and other studies reporting no effects.

Several reviews of this literature have been published (Cotgreave, 2005; ICNIRP, 2009; IARC, 2013; AGNIR, 2012).

- Cotgreave (2005) reviewed 13 studies related to RF energy exposure and expression of heat shock proteins and another 14 studies related to expression of genes or proteins other than heat shock proteins.
- An IARC Working Group reviewed 25 studies related to RF exposure and expression of heat shock proteins, mostly since 2005. The IARC review concluded:

The [IARC] Working Group noted that a small number of studies reported altered expression of HSPs in certain cell lines. However, it was not clear whether these responses were specific to the cell line, the frequency, the modulation or model used, or were false-positives, e.g. artefacts caused by irregularities in the exposure system. The majority of studies conducted in cultured human cells to date have found no evidence that exposure to RF radiation under non-thermal conditions elicits alterations in the expression of HSP genes or proteins. (IARC, 2013; p. 351)

- The Advisory Group on Non-Ionizing Radiation (UK), which reviewed 21 studies, concluded:

In general, there is no coherent pattern of exposure conditions or in vitro cell system that consistently shows effects of exposure to RF fields below international guideline levels. The reported studies are still mostly diverse in terms of exposure and biological system tested; furthermore the reported effects lack independent verification. Even in cases where there are several studies using similar cell types, as in the case of lymphocytes, the results for the effect of RF field exposure are conflicting. (AGNIR, 2012; p. 106)

Since 2010, approximately a dozen additional papers have appeared on expression of heat shock protein and other proteins following exposure to RF energy. The results have also been mixed. One difficulty in this line of research is that the expression of heat shock protein (the endpoint most commonly examined in studies on biological stress response) is very sensitive to small temperature changes, with detectable effects resulting from temperature changes below 1 C (AGNIR, 2012). Control of confounding heat exposure in some of the studies may simply have been inadequate to prevent detectable changes in expression of heat shock protein. If exposure to RF energy alone at levels below the proposed SC6 (2013) limits produces changes in protein expression apart from those caused by minor heating effects, previous studies have not convincingly shown such effects.

The Panel did not identify any striking results in recent literature that would have substantially changed the conclusions of previous reviews on this issue.

8. Concerns Expressed during the Public Consultation

The original Safety Code 6 review proposal did not include soliciting input from the public. However, the Royal Society of Canada decided to host a public meeting on the proposed changes to Safety Code 6 in part because they had received interest from a number of public groups regarding this review and its process. The objective of the meeting was to allow the public the opportunity to voice their opinions and perspectives regarding Safety Code 6. This section summarizes the public consultation process and the input received.

8.1. The Public Meeting, Invitations and Organization

The meeting was held on October 28th, 2013 at the University of Ottawa and 35 people made presentations that day either in person or online. No specific speakers were recruited and the public meeting was advertised via the RSC Officer for Expert Panels and the College. The first 25 speaking spots were offered on a first-come, first-serve basis. A further ten spots were filled purposively to ensure that there was adequate representation from people across the country and from different organizations. Members of the Royal Society of Canada, along with members of the Expert Panel, attended the public meeting.

One group in particular, Canadians for Safe Technology, sent in a large number of comments and requests to speak. In order to accommodate this group, the RSC offered its CEO an extended speaking period in order to represent the concerns of his group. Presentations were made in both English and French and translators were provided. The meeting was also attended by members of the public and over the course of the day there were between 50-60 people in attendance. An on-line video conference system was set up to allow for people who weren't able to attend to view the proceedings. Approximately 100 people signed on to the system over the course of the day.

Along with the public meeting, the Royal Society accepted written comments and submissions from the public. Many people who were not able to attend sent in letters, research papers, newspaper articles and other documents for the Panel to review. Submissions came from individuals as well as representatives from different groups and agencies.

8.2. Analysis of Public Input

Notes were taken by the Expert Panel members in attendance during the oral presentations and were circulated between all members after the session. RSC organizers collected written submissions and then made these available to the Panel members. The public comments, both oral and written, were then collated, reviewed, read and re-read, coded and then organized into topic and thematic areas. Codes were generated *in situ* using the participants' presentations rather than using *a priori* codes. This approach was taken to allow for the expression of concerns specific to this public meeting and its content area. Topics areas were created to cover every possible category and no "other" categories were generated. Once the topics areas were set, the

results were sent back to the Expert Panel for review. Topics were then distilled down into specific areas of concern that reflect the overall sentiments from the meeting.

8.3. Results

Fifteen primary topics emerged in the consultation. They are described in more detail in Section 8.4, below. The topic that generated the largest number of public comments was "health effects from exposure to RF", in which presenters described a series of symptoms and conditions that they or their family members had experienced which they associated with exposure to RF energy. Regarding RF specifically, most presenters' discussions focused on their concerns about the potential health impacts from specific devices such as Smart Meters, transmission equipment such as towers and antennas and to a lesser extent, cell phones. There was also a series of focused presentations regarding Wi-Fi, particularly in schools. Less frequently mentioned were other RF-energy emitting devices such as baby monitors, microwaves, TVs and radios.

Overall, the fifteen topics distill down to four major areas:

1. **Concern about health effects:** many participants expressed concerns regarding the potential health impacts from exposure to RF energy at levels found in Safety Code 6.
2. **Concern about exposure:** participants expressed concerns about exposure, including how much exposure exists, where exposures occur, cumulative exposures, issues of distance from sources, engineering controls to reduce exposure in devices and spaces.
3. **Concern about the review process:** participants expressed concern that Health Canada was involved in the RSC process and requested that the scientific panel maintain a high level of transparency regarding its selection and review of the scientific literature on health effects. Calls were also made for the RSC to implement a precautionary approach in its review.
4. **Desire for more information:** participants called for greater public awareness campaigns regarding RF energy including what it is, how people are exposed, how to reduce exposures, potential health effects from exposure, etc. There were also requests for more information from manufacturers such as better labeling and warnings.

The topics raised by the participants were framed in a variety of ways, reflecting how the participants perceive or make sense of Safety Code 6 and exposure to RF energy. An analysis of this framing was undertaken and a summary is provided in Section 8.5.

8.4. Summary of Main Topics

This section summarizes the details of the fifteen main topics, which emerged from the public consultation:

a. Health effects from exposure to RF Energy

A large number of participants reported experiencing health effects from exposure to RF energy in general or RF devices in particular. Many symptoms were reported including migraines, tremors, dizziness, nausea, confusion, heart health problems, heart attacks, skin problems and brain cancer. Participants described their symptoms using a range of terms including: electro-hypersensitivity, electromagnetic field hypersensitivity, EHS, ES, microwave sickness, radar sickness and radio-wave sickness. Participants represented themselves, their family members and/or their patients. Physician and patient organizations also wrote to support people reporting these conditions and to emphasize a call for more attention to these symptoms. Most participants described how significantly exposure to RF energy has impacted their lives, their families, their schooling and/or their ability to make a living. Some people were clearly distressed as they spoke about how their condition was impacting their life. Often people described developing symptoms after a particular exposure event or after an RF device had been introduced in their community or workplace.

There were also some discussions by participants on the difficulties and frustrations people have had finding a doctor who would recognize these symptoms, receiving a diagnosis and finding an effective treatment. Many lauded the physicians who finally helped them relieve their symptoms. Some participants also noted struggling against the sentiments of others, such as their employers, friends, and family, who felt their symptoms don't exist or were not caused by exposure to RF energy.

Academic papers, reports, media announcement and peer reviewed literature were submitted to the Panel on a wide range of health impacts. Many of these were oriented toward either biological changes at low dose exposures, fertility issues and cancer clusters. Some papers described idiopathic environmental intolerance attributed to electromagnetic fields (IEI-EMF).

b. Critiques of Safety Code 6 and protection of vulnerable populations

Many submissions stated that Safety Code 6 was not scientifically established in a manner that protected sensitive sub-populations, such as children, foetuses, seniors, and those reporting electro-sensitivity. Instead, it was stated by a number of participants, that the research used to set the current RF limit was done with adult men and for the exposure levels of those who work at or visit federal facilities. This exposure scenario was seen as not appropriate for setting environmental exposure limits for those who may be more vulnerable to RF energy due to their physiology or health status.

c. Concerns regarding the siting of RF technologies

There were clearly articulated concerns regarding the processes involved in the siting of cell and microwave towers, base stations, masts and antennas. These concerns included the lack of involvement in the site selection process and a lack of dialogue between the companies and

residents. Participants often cited specific telecommunication companies such as Bell and Shaw, by name. Concerns focused on having the towers or antennas too close to people's homes and, specifically, to bedrooms, as well as aesthetic concerns about towers.

d. Concerns regarding Smart Meters

Some participants mentioned Smart Meters for water and power as specific technologies of concerns. Mandatory installation of smart meters was described as problematic. Many people felt there was a lack of data and research on Smart Meter exposure, particularly the issue of pulsing, looking at average versus peak exposure measures in research. Calls were made for more monitoring of the RF energy given off by Smart Meters installed in homes and more options for people who do not want these technologies in their homes.

e. Concerns regarding the implementation, use and promotion of Wi-Fi in schools

Parents and teachers reported concerns regarding the use and promotion of Wi-Fi in schools. Parents described a range of symptoms being experienced by their children at school and after school. Some parents noted that their classrooms had been measured for levels of RF energy. Some school districts and boards are actively promoting Wi-Fi use in schools and encouraging students to bring devices from home. It was reported that this situation would increase students' exposure to other RF technologies such as cell phones. Parents were concerned that they have not been told about the implementation of Wi-Fi in schools and that they are not told where the router(s) are situated in a building. Some people stated that they would like to see "White Zones" where there was no Wi-Fi for those who wish to not be exposed during school hours.

f. Complaints directed towards Health Canada

Some specific criticisms were directed towards Health Canada. Safety Code 6 was described as a regulatory limit that was "lagging behind" countries like France, Switzerland, Belgium and Sweden. Critiques were noted regarding Health Canada's lack of dialogue and response to those suffering from IEI-EMF. Some participants described Health Canada as blocking transparency about the Safety Code 6 process and documentation. Specific mentions were made that information about health effects from exposure to RF energy has been taken off of the Health Canada website. Additionally, some people felt that Health Canada was dictating how the RSC went about its review of Safety Code 6 and was manipulating the data set of evidence for the RSC's review. Complaints that Health Canada provides people with documents that are heavily redacted, decreasing trust, were also made.

g. Concerns that Safety Code 6 doesn't take into account cumulative exposures or near field exposure scenarios or pulses/modulation

Many participants mentioned the vast number of wireless devices that exist in homes, including baby monitors, cordless phones, microwaves, cell phones, gaming systems, smart appliances,

blue tooth devices, etc. They feel that, overall, there is a cumulative exposure that is not being considered by Safety Code 6, which they perceive was developed for federal workplace exposure levels. Several participants also suggested the Panel should reconsider the averaging provisions in its estimation of exposure.

In terms of near field exposures, critiques were presented that because Safety Code 6 relies on averaging of exposure, it does not specifically address peak exposure, which may exert different health effects as the level of exposure is higher.

h. Desire for greater public education on radio-frequency devices, exposure and potential health effects.

Requests were made for greater government-sponsored public awareness campaign regarding the potential hazards and safe use of wireless devices. Input from the Canadian Radiocommunications Information and Notification Service (CRINS) indicated that their organization has seen a rise in the number of people seeking information on exposure to RF energy and Wi-Fi in particular.

i. Requests to consider harm reduction initiatives for RF devices as part of policies or Safety Code 6

Suggestions were presented to the Panel to consider the promotion of technologies that emit lower RF energy or that turn off when not in use to reduce ambient exposure. It was also suggested that there be better labeling on RF energy-emitting products to help educate consumers about exposure. Participants also suggested that people distance themselves from their technologies, and use headsets or speaker functions to reduce cell phone exposure or revert to cables. A range of opinions were offered on what safe distances were. Suggestions were also made to encourage manufacturers to make and design products that emit lower levels of RF energy.

j. Submissions indicating that Wi-Fi is a beneficial technology and that there are no compelling health reasons to restrict its use.

A small number of recommendations were made to the Panel that they keep the review to mainstream, peer reviewed research. Some people submitted studies of public spaces where exposure measures were undertaken and shown to be below Safety Code 6, generally schools and hospitals.

k. Statements that IEI-EMF is not a true condition

A small number of articles and statements were submitted on this topic suggesting that IEI-EMF symptoms can be attributed to other health problems.

l. Requests that the Panel consider a wider range of studies, beyond those using thermal effects as a health outcome.

Participants submitted or suggested research papers that they felt the Panel should review. This included calls for the Panel to specifically include the BioInitiative Report (2012), along with specific papers from the peer-reviewed literature, government reports from military exposure, and the current US FCC review of Wi-Fi. Many people felt that Health Canada has wilfully ignored biological effects data in its setting of Safety Code 6.

m. Critique of the Royal Society of Canada process

Some participants suggested the RSC process hasn't been transparent, that it has been unduly influenced by Health Canada and the Panel does not include a medical doctor. Other suggestions included: the Public Health Agency of Canada should be involved, along with other health organizations in Canada (e.g., the Canadian Medical Association); the RSC should adopt the US National Toxicology Program weight of evidence protocols; and the RSC should disclose the objectives, assumptions, scope and range of research questions used by the Panel.

n. Calls for the implementation of the Precautionary Principle/Approach

Many participants suggested that due to the lack of data and/or scientific consensus on the relationship between chronic low level exposures and health effects, the Precautionary Principle should be applied to reduce allowable exposure levels in the current Safety Code 6. Specifically, the RIO definition[23] is often used for the Precautionary Principle when it is mentioned.

o. Parallels between our current understanding of RF and other historical exposures, like asbestos

Many statements were made that the scientific trajectory of RF energy will be like that of asbestos, DDT, smoking, environmental tobacco smoke. That is, exposure to RF energy will eventually be shown to be dangerous. These comments were generally made in conjunction with calls for the precautionary approach to be taken.

8.5. Framing

Framing can be useful to understand the context through which people perceive an issue and can be used to improve future risk communication strategies. Along with the specific areas of concern, the participants' submissions, and the manner in which their concerns were contextualized, reflected the following eight frames:

[23]The RIO definition is articulated in Principle 15 of the United Nations' Rio Declaration on Environment and Development (1992). See https://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm.

1. **Lack of Safety/People are in Danger:** Safety Code 6 is not safe, is out-dated, is not protecting Canadians and is leaving children and those most vulnerable at risk.
2. **Questions of Morality/Ethics:** Safety Code 6 should be changed because it's the right thing to do. For example, is it ethically acceptable to knowingly expose children to compounds in schools that are classified by IARC as "possible carcinogens"? People are being exposed without their consent. We have a duty to protect our children.
3. **Negligence: lack of government responsibility:** Health Canada is not doing its duty to protect the health of Canadians and hold up its obligation to public health.
4. **Injustice: the lack of transparency is unfair:** Citizens have a right to know more about the dangers of exposure to RF energy, such as how and where they are exposed.
5. **Elitism in science:** Experts are ignoring the evidence that is building up about the health effects of low-level exposure to RF energy.
6. **Industry/Government Collusion:** Government is aiding the telecom companies for financial gains and is supporting the telecom industry at the expense of Canadian's health.
7. **Tainted evidence/research:** Telecommunication companies control the research findings and the results of these studies always show "no health effects".
8. **People/groups' outrage is unwarranted:** A small subset of the written submissions suggested that public exposures to RF energy are very low and that people who are upset or are ill came to be so from other exposures/causes.

In general, many of these frames were negative in tone, reflecting a fairly high level of distrust in the government and the process in which it perceives that Safety Code 6 has evolved. The frames also illustrate conflicting opinions about the health effects of exposure to RF energy.

8.6. The Panel's Response to the Public Input

The Panel carefully considered all of the submissions received by the public and interested stakeholders. It took note of the health effects literature submitted to ensure that any studies meeting the Panel's criteria for inclusion in the review were captured and considered. A number of concerns expressed in the public meeting fell outside the scope of the Panel's mandate. To ensure that the public's concerns are heard, however, the Panel has prepared a synopsis of the fifteen primary topic areas and submitted them to Health Canada for consideration of further action.

As part of its mandate, the Panel was asked whether additional precautionary measures should be introduced into Safety Code 6. Therefore, the Panel carefully considered the submissions and calls to implement the Precautionary Principle. The factors considered by the Panel, as well as its recommendations in this regard, are presented in Section 9 of this report.

The Panel heard, and are sympathetic to, the concerns of individuals who felt that they are sensitive to exposure to low levels of RF energy. Most of the individuals who reached out to the Panel were clearly affected severely by the condition, in some cases being unable to lead normal

lives. The Panel feels strongly that these individuals need compassion and assistance in overcoming their symptoms. However, it considers that such assistance should be provided by means other than a revision of Safety Code 6 because of the very unclear relationship between the symptoms and actual exposure to RF energy (see Section 7.2 for the evidence reviewed by the Panel). The Panel, in its recommendations to Health Canada, urges the government to investigate the symptoms of IEI_EMF individuals with the aim of understanding the etiology of their condition, developing criteria for differential diagnosis of the condition, and finding ways to provide effective treatment for affected individuals (see Section 10).

9. Applying the Precautionary Principle

There are many definitions for the Precautionary Principle and many more interpretations. Within the Panel, there was a range of opinions regarding the level of evidence needed before precautionary actions should be taken. However, there was a consensus regarding the fact that there is insufficient data available at this time with which to make a scientific recommendation to lower the limits proposed in SC6.

The Panel was also in agreement that the decision to apply the Precautionary Principle is a question of risk management, as opposed to a question of risk assessment. In other words, the decision to apply the Precautionary Principle is a policy decision to be made by organizations with the legislative mandate to create policy, regulations and/or guidelines. It is not a decision to be made by an Expert Panel with a mandate to provide scientific advice.

"Precautionary" approaches to managing risks have been known for many years, as shown in adages such as "err on the side of caution". As an identifiable doctrine, the precautionary principle (PP) only emerged in the late 1970s in the form of statements in a number of international treaties and treaty declarations (Foster et al., 2000). Different formulations of the PP vary greatly in emphasis and in practical implications. Their general thrust is that one should take reasonable precautions to deal with plausible threats, even if there is no firm scientific proof of the existence of a problem (Resnik, 2003). A range of actions can be taken under a precautionary approach, ranging from banning a new technology to simply continuing to study the scientific literature pending clearer understanding of a risk.

As illustrated in Figure 9.0-1, the European Commission's position on the use of the Precautionary Principle is that government should first identify a potentially hazardous effect, and "all effort" should then be made to "evaluate the available scientific information", "leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact on the environment, or health..." (Commission of the European Communities, 2000).

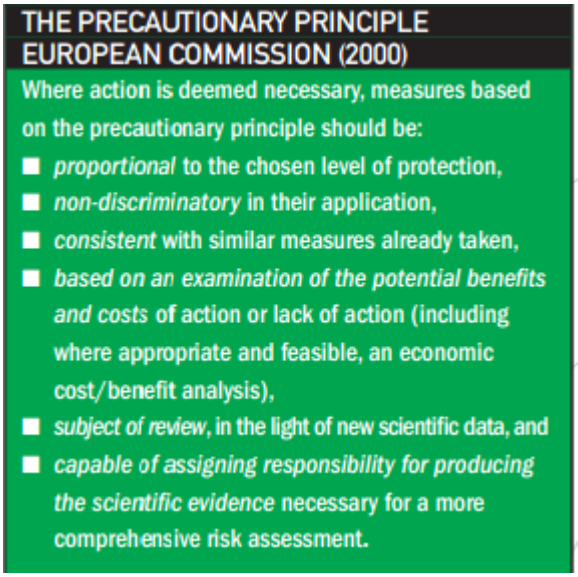

Figure 9.0-1: The Precautionary Principle
(Source: Commission of the European Communities, 2000)

The EC commentary emphasizes that precautionary approaches are meant to supplement science-based risk management. The World Health Organization (WHO) advises "If regulatory authorities react to public pressure by introducing precautionary limits in addition to the already existing science-based limits, they should be aware that this undermines the credibility of the science and the exposure limits." The EC commentary emphasizes that precautionary measures should be considered provisional, and be coupled with a commitment to gain sufficient knowledge about a suspected problem to allow the development of science-based limits.

9.1. Setting Exposure Limits *vs*. Adopting the Precautionary Principle

In Canada, the federal and provincial governments (or designated governmental agencies) have the legislated authority to set and enforce compliance with exposure limits for potentially toxic agents. These limits are based on scientific evidence, but also take into account other factors, such as the capacity of technology to measure exposure and the capacity to comply. Exposure limits are designed to avoid adverse effects with appropriate safety factors or uncertainty factors. The limits may be revised either upwards or downwards as scientific understanding of a potential hazard evolves, but the basis remains protection against established adverse effects of exposure.

Health Canada defines adverse effect as "a change in morphology, physiology, growth, development or lifespan of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increase in susceptibility to the harmful effects of other environmental influences." This same Health Canada document[24] adds: "expert judgement is required to distinguish adverse effects from those effects that merely reflect

[24] http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/spn2008-01/index-eng.php#primer

the ability of an organism to adapt to a biological or chemical insult." In this sense, a biological effect of exposure to RF energy (which is reported on the basis of a difference between an exposed and a control preparation) is not necessarily an adverse effect.

The Panel notes that a number of biological effects of RF energy have been reported in studies of various biological systems at levels below SC6. However, the Panel, as with the great majority of expert assessments consulted by the Panel, did not regard these reports as useful for setting exposure limits because of the lack of a clear link to health effects. While different experts on the Panel varied in their interpretations of the biological significance of particular reported effects, the Panel agreed that uncertainties about reported low-level effects (below SC6 limits) should be resolved with further research.

Therefore, the Panel recommends that Health Canada continue a careful analysis of the evolving scientific evidence on exposure to RF energy. The Panel also suggests that Health Canada actively pursue research to help elucidate the possible link between mobile phones and brain cancer or other health problems that have been the source of public anxiety. This type of data could provide a better scientific understanding of prospective health impacts, particularly in the areas where the database is weak or incomplete.

9.2. Precautionary Policies for RF Protection

Most countries throughout the world have adopted RF exposure limits based on ICNIRP (1998) or IEEE C95.1 (2005). These limits are generally similar to the present SC6. However, assessing exposure limits is only one facet or measure that can be considered precautionary. Some countries have adopted a variety of precautionary measures, typically in the form of special restrictions on the siting of cellular base stations near "sensitive" areas such as schools (e.g., Switzerland). Other countries have adopted RF exposure guidelines at frequencies used by cell base stations (but not necessarily other frequencies) that are reduced from ICNIRP limits by an arbitrary factor (e.g., India). In "Establishing A Dialogue On Risks From Electromagnetic Fields", the WHO adopted the PP as found in the Maastricht Treaty: "taking prudent action when there is sufficient scientific evidence (but not necessarily absolute proof) that inaction could lead to harm and where action can be justified on reasonable judgments of cost-effectiveness".

In Canada, several different precautionary approaches for RF exposure have been taken (in part, to address public health concerns). For example, Toronto has adopted a policy that it calls "prudent avoidance" in the siting of cellular base stations. This policy is defined by the city as encouraging "the adoption of individual or societal actions to avoid unnecessary exposures to radio frequencies that entail little or no cost." In her 1999 memo, Dr. Sheela V. Basrur, the Medical Officer of Health at the time, explained that the city had been requested by citizens to "restrict the siting of base transmitter antennas a certain distance from schools and day-care centres and away from residential areas." However, she noted, "Given the density of Toronto, the mixed land use, and the existing network of antennas, it would be difficult to implement such an

approach" (Basrur, 1999). Moreover, there are obvious difficulties in defining what constitutes "unnecessary exposures". In practice, Toronto has implemented its prudent avoidance policy by simply reducing RF exposure guidelines by a factor of 100 from SC6 for wireless base stations (but not for other transmitting facilities). In addition, the Toronto Board of Health has also recommended (November 2013) that Health Canada

> "…continue to use prudence and to actively review health evidence including most recent scientific research and studies and to allow public and expert consultation pertaining to human exposure to RFs and to revise Safety Code 6 whenever appropriate to protect human health".

Other Canadian cities have considered and rejected prudent avoidance policies. For example, in a report dated May 2013 addressed to the city of Caledon, Dr. David L. Mowat, the Medical Officer of Health of Peel, concluded

> "There is no evidence in the scientific literature at this time to suggest that there are any negative health effects associated with exposure to radiofrequency energy from mobile phone base stations. Although this exposure is widespread there is no evidence of potential harm and it would not be appropriate to apply the precautionary principle in this case."

Considered with respect to the WHO and EC recommendations, prudent avoidance and reducing exposure limits for cellular base stations have limitations. Considering the RF bio-effects literature as a whole, the most suggestive areas of research on potential hazards are associated with mobile phone use, for which user exposures far exceed those from mobile base stations. It is inconsistent to establish separate limits for exposure to RF energy from cellular base stations, while other transmitters are present with higher potential exposures to the public.

Conclusion of the Panel

Health Canada currently advises parents to

> "…reduce their children's RF exposure from cell phones since children are typically more sensitive to a variety of environmental agents….Precautions to limit exposure to RF energy from cell phone towers are unnecessary because exposure levels are typically well below those specified in health-based exposure standards."

In addition, Health Canada currently provides a range of options to reduce exposure to RF energy, particularly for cell phone users. These can be found on various Health Canada websites, including the Healthy Canadians portal. Such efforts should continue and be kept relevant. Education on mitigating exposure to RF energy will improve Canadians' ability to control their own exposures should they decide that this is important for them and their families.

There are many agencies that offer "common sense" approaches for those wishing to reduce their exposures to RF. In Canada, for example, the National Collaborating Centre for Environmental Health (NCCEH) recently generated a "tool kit" for environmental health professionals dealing

with RF related issues[25]. Chapter 14 of this "tool kit" outlines a range of activities, including engineering controls, substitution, administrative controls and protective equipment that can be recommended to individuals who wish to reduce their current RF exposure. Such suggestions include: switching to hard wired devices when possible (for example, using corded phones rather than cell phones or cordless phones); using devices that implement power saving or non-idling functions; or distancing yourself from RF devices using options such as headsets, speaker phones and text-messaging. The NCCEH report cautions that attempts at shielding RF, such as earpiece pads and antenna caps, have been found to be ineffective and could actually increase people's exposure. As a result, the NCCEH does not recommend such strategies.

The Panel recognizes that there has been pressure on the Canadian government to recommend precautionary measures around exposure to RF energy. However, this Panel believes that the application of the Precautionary Principle should properly be decided by Health Canada based on its policies of risk management, consistent with the way it is applied in other analogous situations. Outside of a change in SC6 guidelines, a range of precautionary measures might be considered, which would be consistent with WHO and EC guidelines for the use of the Precautionary Principle. These include requests for Health Canada to continue a careful analysis of the evolving scientific evidence, actively pursuing research to help elucidate the possible link between mobile phones and brain cancer or other health problems that have been the source of public anxiety, or offering guidelines for the public to limit exposure to RF energy (e.g., "hands free" kits). According to WHO and EC guidelines, precautionary measures are to be considered temporary measures and such measures (as well as SC6 guidelines) can be revised in the future if a better scientific understanding of a prospective health threat emerges.

Such risk management strategies would need to incorporate not only scientific assessment, but also take into consideration public opinion, socioeconomic concerns and issues of geography and accessibility. A broader dialogue with Canadians that included the risks and benefits of RF technologies could assist government agencies in setting acceptable options for management of RF exposures in the future.

[25] http://www.bccdc.ca/NR/rdonlyres/9AE4404B-67FF-411E-81B1-4DB75846BF2F/0/RadiofrequencyToolkit_v4_06132013.pdf

10. Conclusions and Recommendations of the Expert Panel

10.1. Conclusions of the Expert Panel

This section sets out the Expert Panel's responses to the specific questions posed by the RSC, along with any recommendations identified in the course of this review.

Do the basic restrictions specified in SC6 (2013) provide adequate protection for both workers and the general population from established adverse health effects from RF fields?

SC6 (2013) is designed to protect against two kinds of established health effects: (1) in the 3 – 100 kHz band, the basic restrictions were set to avoid peripheral nerve stimulation (PNS) by induced fields within the body from external electric and magnetic fields; (2) in the 100 kHz – 10 MHz frequency range, they were set to avoid both peripheral nervous system and thermal effects. The basic restrictions for contact current were set to avoid shock and burns.

SC6 (2013) is essentially similar to IEEE C95.1 (2005) and ICNIRP (1998, 2010), combining the most conservative aspects of these earlier limits. The rationale for setting the basic restrictions has been extensively discussed in the documentation that accompanied these limits. This discussion applies to SC6 (2013) as well.

This Panel notes that the margins of safety in the basic restrictions, while they appear to be quite high, are difficult to judge with precision. The basic restrictions at the lower end of the frequency range (3 – 400 kHz) were based on thresholds for nerve stimulation obtained by extrapolating data from studies at much lower frequencies and arguments have been raised that the assumptions that ICNIRP used in making these extrapolations are overly conservative (see, for example, Kavet et al, 2012). Likewise, there is very little data that would be directly useful in setting exposure limit at millimeter wave frequencies (30 – 300 GHz).

On the other hand, the basic restrictions themselves have a considerable amount of conservatism inherent in them. For example, the limits for whole body SAR (0.4 and 0.08 W/kg for controlled and uncontrolled environments) were based on animal studies that showed behavioural disruption (behavioural changes, from switching from an assigned task to a behaviour characteristic of thermoregulatory behaviours by the exposed animals) at exposures above 4 W/kg whole body SAR (Foster and Morrissey, 2011). However, the human thermoregulatory system is considerably more efficient than those in the species used in the animal studies. The whole body limit for SAR in SC6 (2013) for uncontrolled environments corresponds to roughly 10% of the basal metabolic rate of the human body, and is equivalent to the thermal load from very slight physical activity. In an extended series of studies by Adair and Black (2003), human volunteers were exposed to RF energy at several frequencies (100, 450, 2400 MHz) for extended times (45 minutes) at different environmental temperatures (24°C, 28°C, 31°C) and whole body SAR up to 1 W/kg (more than twice the basic restriction for controlled environments and more than 12 times that for uncontrolled environments in SC6 (2003)). At the two lowest ambient temperatures, the

subjects experienced minimal or no increases in core body temperature; at the highest ambient temperature, the average core temperature of the group had increased by 0.15°C. This suggests that the basic restrictions, even for controlled conditions, are adequate for protection against excessive thermal load to the body from exposure to RF energy. One might imagine circumstances involving heavy work load and extreme environmental conditions where the basic restrictions on whole body SAR might be insufficiently protective, but those work conditions would undoubtedly be excluded by any reasonable occupational safety rules (apart from exposure limits for RF energy) in any event.

This Panel also notes that the few injuries that have been reported from overexposure to RF energy have generally been the result of workplace accidents or equipment failures resulting in RF energy exposures far above any reasonable exposure limit. Protecting individuals against such injuries would require safe work rules and safe design of equipment, which are separate from exposure limits such as SC6.

Are there any other established adverse health effects occurring at exposure levels below the basic restrictions in SC6 (2013) that should be considered for revising the basic restrictions and reference levels in SC6 (2013)?

The Panel reviewed the evidence for a wide variety of potential health effects. Although there remain questions regarding the risk of cancer, the case for a causal association between cancer and exposure to RF energy is weak. IEI-EMF, or electromagnetic hypersensitivity, also remains an issue of serious concern that deserves further investigation. However, there is no firm evidence for the hypotheses that people with IEI-EMF can perceive RF energy at levels below the limits in SC6 or that there is a causal link between exposure to RF energy and their symptoms. In addition, there are no established adverse health effects for exposures below the basic restrictions in SC6 (2013) with respect to cognitive and neurologic systems, male and female reproduction, development, cardiac function and heart rate variability. Although research on many of the potential health effects described above continues, the Panel was unable to identify any established adverse health effects occurring at levels below the basic restrictions in SC6 (2013).

Is there sufficient evidence upon which to establish separate basic restrictions or recommendations for the eye?

Recent studies on exposure of the eye to RF energy do not show adverse health effects in its potentially susceptible regions (i.e., the aqueous humour, lens and vitreous humour) at exposure levels below those proposed in SC6 (2013) for the head, neck and trunk. Therefore, it is recommended that SC6 (2013) not contain separate basic restrictions or recommendations for the eye.

Evidence exists of adverse health effects in the eye (e.g. increased incidence of cataracts) from exposure to RF energy. However, this only occurs at power density values far in excess of limits

proposed in SC6 (2013), after skin temperature around the eye has reached its pain threshold and facial burns have been observed.

Do the reference levels established in SC6 (2013) provide adequate protection against exceeding the basic restrictions in SC6 (2013)?

Available data strongly suggest that the SC6 (2013) electric and magnetic field strength reference levels provide adequate protection against the SC6 (2013) internal electric field strength basic restrictions between 3 kHz and 10 MHz. If appropriate skin conductivities are used to calculate the induced electric field strengths in anatomically realistic human models, compliance with the reference levels will ensure compliance with the basic restrictions. However, induced electric field strength dosimetry is still developing in this intermediate frequency range. Therefore, it is recommended that further studies investigating the characterisation of skin conductivity and the variability of the internal electric field strength in different human anatomical models, from exposure to external electric and magnetic fields, are carried out in the near future to further test the suitability of the SC6 (2013) reference levels for this frequency range.

Recent reported SAR dosimetry studies show that compliance with the SC6 (2013) electric, magnetic field strength and power density reference levels between 100 kHz and 6 GHz will not ensure compliance with the SC6 (2013) SAR basic restrictions. For a number of SAR studies involving child and adult human models under grounded and isolated conditions at certain frequencies, it has been demonstrated that measured field strengths in compliance with the SC6 (2013) reference levels can produce SAR values that are not in compliance with the basic restrictions. It is important to note that in these highlighted cases where a compliant reference level produces a non-compliant SAR basic restriction value, it is very unlikely that the SAR will be at a sufficient level to produce an adverse health effect in humans. This is because the deviations tend to be relatively minor and the proposed SAR basic restrictions include margins of safety. Also, the calculated deviations assume a "worst-case" body position that results in the highest SAR. An individual who moves about in the field would receive lower average exposures than the "worst case" calculations would indicate. The time-averaged SAR over the 6-minute reference period may well comply with the basic restrictions despite the fact that peak SAR values at any particular time may be above the limits.

However, for the reference level definition statement in SC6 (2013) "compliance with the reference levels will ensure compliance with the basic restrictions in this safety code" to be correct under all exposure scenarios, the reference levels in SC6 (2013) would need to be revised to address the deviations discussed above. The Panel recommends that Health Canada review the large number of dosimetry studies that have been produced since the last major revision of SC6 in 1999 and modify the proposed SC6 (2013) reference levels accordingly.

Currently available investigations continue to suggest that the SC6 (2013) electric, magnetic field strength and power density reference levels provide adequate protection against adverse health

effects in the 6 GHz to 300 GHz frequency range. However, similar to internal electric field dosimetry between 3 kHz and 10 MHz, dosimetry in this frequency range is still developing and further research is required to examine the effects of exposure to new and emerging technologies.

Should additional precautionary measures be introduced into the human exposure limits in SC6 (2013)? If so, what is recommended and why?

SC6 limits are science-based limits that are designed to avoid all known hazards of RF energy. The WHO has recommended that:

> "If regulatory authorities react to public pressure by introducing precautionary limits in addition to the already existing science-based limits, they should be aware that this undermines the credibility of the science and the exposure limits."

Based on this recommendation, this Panel does not believe that additional precautionary measures should be introduced directly into the exposure limits of SC6. However, other precautionary measures can and should be taken by Health Canada related to SC6. One example is to add statements to the SC6 documentation noting that it would be good practice to design systems that operate at the lowest power levels needed to achieve the operational goals of a project.

Health Canada has a fairly comprehensive website on RF energy and Cell Phones. However, public input indicates that more information (particularly, information that is seen as balanced) is desired about RF energy, the types of devices that use RF technologies and the levels emitted (see Section 8). This information could assist people in reducing exposure if they so choose. Health Canada does already recommend some practical measures that Canadians can take to reduce their risks around cell phone use (see Reduce your Risk http://healthycanadians.gc.ca/consumer-consommation/home-maison/cell-eng.php). Other strategies could be added to this list. Health Canada should aggressively pursue scientific research aimed at clarifying the RF-cancer issue, particularly with respect to exposure-response relationships, which would allow the government to develop protective measures if the risk were found to be substantiated.

During the public meeting and in other communications, this Panel heard from numerous individuals who felt that they are sensitive to low levels of RF energy in the environment from a variety of sources, a condition that is technically known as Idiopathic Environmental Intolerance Attributed to Electromagnetic Fields (IEI-EMF) or more popularly as Electrical Hypersensitivity. Many of the individuals who reached out to the Panel were clearly affected severely by the condition, in some cases being unable to lead normal lives. IEI-EMF is a medically unexplained condition in which an individual experiences a variety of nonspecific symptoms that he or she attributes to exposure to RF energy from commonplace technologies such as mobile telephones or Wi-Fi. However, extensive research has failed to link clearly a person's symptoms with actual

exposure to EMF and the etiology of the condition remains unknown and perhaps complex. (WHO 2005, fact sheet on IEI-EMF)

While this Panel feels strongly that these individuals need compassion and assistance in overcoming their symptoms, it also considers that such assistance should be provided by means other than a revision of SC6 because of the very unclear relation between the symptoms and actual exposure to RF energy. Currently there are only a limited number of clinics that treat people across the country (such as the Environmental Health Clinic in Women's College Hospital in Ontario). This Panel urges Health Canada to investigate the problems of IEI-EMF individuals with the aim of understanding the etiology of their condition, developing criteria for differential diagnosis of the condition, and finding ways to provide effective treatment for such individuals.

10.2. Summary of the Panel's Recommendations

Although not explicitly tasked with providing recommendations to Health Canada beyond the five questions above, the Panel has identified a number of gaps in our current knowledge about the impact of exposure to RF energy on human health, as well as the effectiveness of the proposed guidelines. To address these gaps, as well as concerns raised by the public, the Panel offers the following non-binding recommendations to Health Canada.

- Studies investigating the characterization of skin conductivity and the variability of the internal electric field strength in different human anatomical models, from exposure to external magnetic and electric fields, should be carried out in the near future to further test the suitability of the SC6 (2013) reference levels for the 3KHz to 10 MHz frequency range.
- The effectiveness of the SC6 (2013) reference levels should be examined against a larger number of new dosimetry studies than those specified in the SC6 (2013) Rationale. Additional data should be collected on child exposure, postured adult and postured child exposure, pregnant female and newborn exposure under grounded and isolated conditions.
- Dosimetry in the 6 GHz to 300 GHz frequency range is still developing and further research is required to examine the effects of exposure to new and emerging technologies
- Health Canada should aggressively pursue scientific research aimed at clarifying the RF-cancer issue, which would allow the government to develop protective measures if the risk were substantiated.
- Health Canada is urged to investigate the problems of IEI-EMF individuals with the aim of understanding the etiology of their condition, developing criteria for differential diagnosis of the condition, and finding ways to provide effective treatment for such individuals.
- Health Canada should develop a procedure for the public to report suspected disease clusters and a protocol for investigating them. This could be based on the US Centers for Disease Control protocol or on the 2011 Alberta protocol.

- Health Canada should expand their existing risk communication strategy to address consumer need for more information around RF energy, the types of devices that use RF technologies and the levels emitted. In addition, Health Canada should incorporate additional suggestions into their recommendations on practical measures that Canadians can take to reduce their exposure around cell phone use (for example, limiting use in areas with low signal strength, and using an earpiece).
- Health Canada should encourage inclusion of basic education on non-ionizing radiation in the curriculum of Canadian Medical Schools.
- Health Canada should pursue research to expand our current understanding of possible effects of exposure to RF energy at levels below SC6 (2013).
- Health Canada should evaluate the need for a document to encompass all aspects of MRI safety.

Appendix I: Health Canada's proposed Safety Code 6 (2013)

Limits of Human Exposure to Radiofrequency Fields in the Frequency Range from 3 kHz to 300 GHz

Consumer and Clinical Radiation Protection Bureau
Environmental Radiation and Health Sciences Directorate
Healthy Environments and Consumer Safety Branch
Health Canada

Safety Code 6 (2013)

Preface

This document is one of a series of safety codes prepared by the Consumer and Clinical Radiation Protection Bureau, Health Canada. These safety codes specify the requirements for the safe use of, or exposure to, radiation emitting devices. This revision replaces the previous version of Safety Code 6 (2009).

The purpose of this code is to establish safety limits for human exposure to radiofrequency (RF) fields in the frequency range from 3 kHz to 300 GHz. The safety limits in this code apply to all individuals working at, or visiting, federally regulated sites.

These guidelines may also be adopted by the provinces, industry or other interested parties. The Department of National Defence shall conform to the requirements of this safety code, except in such cases where it considers compliance to have a detrimental effect on its activities in support of training and operations of the Canadian Forces. This code has been adopted as the scientific basis for equipment certification and RF field exposure compliance specifications outlined in Industry Canada's regulatory documents (1-3), that govern the use of wireless devices in Canada, such as cell phones, cell towers (base stations) and broadcast antennae. Safety Code 6 does not apply to the deliberate exposure for treatment of patients by, or under the direction of, medical practitioners or to exposure of medical personnel operating RF-emitting medical equipment, such as magnetic resonance imaging equipment. Safety Code 6 is not intended for use as a product performance specification document, as the limits in this safety code are for controlling human exposure and are independent of the source of RF energy.

In a field where technology is advancing rapidly and where unexpected and unique exposure scenarios may occur, this code cannot cover all possible situations. Consequently, the specifications in this code may require interpretation under special circumstances. This interpretation should be done in consultation with scientific staff at the Consumer and Clinical Radiation Protection Bureau, Health Canada.

The safety limits in this code are based on an ongoing review of published scientific studies on the health impacts of RF energy and how they interact with the human body. This code is periodically revised to reflect new knowledge in the scientific literature and the exposure limits may be modified, if deemed necessary.

1. Introduction

Electromagnetic radiation is emitted by many natural and man-made sources and is a fundamental aspect of our lives. We are warmed by electromagnetic radiation emitted from the sun and our eyes can detect the visible light portion of the electromagnetic spectrum. Radiofrequency (RF) fields fall within a portion of the electromagnetic spectrum with frequencies ranging from 3 kHz to 300 GHz, below that of visible light and above that of extremely low frequency electromagnetic fields. RF fields are produced by many man-made sources including cellular (mobile) phones and base stations, television and radio broadcasting facilities, radar, medical equipment, microwave ovens, RF induction heaters as well as a diverse assortment of other electronic devices within our living and working environments.

It has long been recognized that sufficiently intense RF fields can cause heating of materials with finite conductivity, including biological tissues. A number of well-established biological effects and adverse health effects from acute exposure to intense RF fields have been documented (4-9). These effects relate to localized heating or stimulation of excitable tissue from intense RF field exposure. The specific biological responses to RF fields are generally related to the rate of energy absorbed or the strength of internal electric fields (voltage gradients) and currents. The rate and distribution of RF energy absorption depends strongly on the frequency, strength and orientation of the incident fields as well as the body size and its constitutive electrical properties (dielectric constant and conductivity). Absorption of RF energy is commonly described in terms of the specific absorption rate (SAR), which is a measure of the rate of energy deposition per unit mass of body tissue and is usually expressed in units of watts per kilogram (W/kg). Based on a large amount of scientific knowledge, national and international exposure limits have been established to protect the general public against adverse effects associated with acute RF field exposures (10-14).

The exposure limits specified in Safety Code 6 have been established based upon a thorough evaluation of the scientific literature related to the thermal and non-thermal health effects of RF fields. Health Canada scientists consider all peer-reviewed scientific studies, on an ongoing basis, and employ a weight-of-evidence approach when evaluating the possible health risks of RF fields. This approach takes into account both the quantity of studies on a particular endpoint (whether adverse or no effect), but more importantly, the quality of those studies. Poorly conducted studies (e.g. incomplete dosimetry or inadequate control samples) receive relatively little weight, while properly conducted studies (e.g. all controls included, appropriate statistics, complete dosimetry) receive more weight. The exposure limits in Safety Code 6 are based upon the lowest exposure level at which any scientifically-established human health hazard occurs. Safety margins have been incorporated into the exposure limits to ensure that worst-case exposures remain far below the threshold for harm. The scientific approach used to establish the exposure limits in Safety Code 6 is comparable to that employed by other science-based international standards bodies (15-16). As such, the basic restrictions in Safety Code 6 are similar

to those adopted by most other nations, since all science-based, standard-setting bodies use the same scientific data. It must be stressed that Safety Code 6 is based upon scientifically-established health hazards and should be distinguished from some municipal and/or national guidelines that are based on socio-political considerations.

In the following sections, the maximum exposure levels for persons in both controlled and uncontrolled environments are specified. These levels shall not be exceeded.

1.1. Purpose of the Code

The purpose of this code is to specify maximum levels of human exposure to RF fields at frequencies between 3 kHz and 300 GHz, to prevent adverse human health effects in both controlled and uncontrolled environments.

In this code, controlled environments are defined as those where all of the following conditions are satisfied:

> (a) the RF field intensities in the controlled area have been adequately characterized by means of measurements or calculation,
>
> (b) the exposure is incurred by persons who are aware of the potential for RF exposure and are cognizant of the intensity of the RF fields in their environment and,
>
> (c) the exposure is incurred by persons who are aware of the potential health risks associated with RF field exposures and can control their risk using mitigation strategies.

Situations that do not meet all the specifications above are considered to be uncontrolled environments. Uncontrolled environments are defined as areas where either insufficient assessment of RF fields has been conducted or where persons who are allowed access to these areas have not received proper RF field awareness/safety training and have no means to assess or, if required, to mitigate their exposure to RF fields.

2. Maximum Exposure Limits

The scientific literature with respect to possible biological effects of RF fields has been monitored by Health Canada scientists on an ongoing basis since the last version of Safety Code 6 was published in 2009. A significant number of new studies have evaluated the potential for acute and chronic RF field exposures to elicit possible effects on a wide range of biological endpoints including: human cancers (epidemiology); rodent lifetime mortality; tumor initiation, promotion and co-promotion; mutagenicity and DNA damage; EEG activity; memory, behaviour and cognitive functions; gene and protein expression; cardiovascular function; immune response; reproductive outcomes; and perceived electromagnetic hypersensitivity (EHS) among others. Numerous authoritative reviews have summarized the current literature (4-8, 17-36).

Despite the advent of numerous additional research studies on RF fields and health, the only established adverse health effects associated with RF field exposures in the frequency range from 3 kHz to 300 GHz relate to the occurrence of tissue heating and peripheral nerve stimulation (PNS) from short-term (acute) exposures. At present, there is no scientific basis for the occurrence of acute, chronic and/or cumulative adverse health risks from RF field exposure at levels below the limits outlined in Safety Code 6. The hypothesis of other proposed adverse health effects occurring at levels below the exposure limits outlined in Safety Code 6 suffer from a lack of evidence of causality, biological plausibility and reproducibility and do not provide a credible foundation for making science-based recommendations for limiting human exposures to low-intensity RF fields.

This safety code provides guidance for the avoidance of adverse human health effects resulting from exposure to RF fields, in terms of basic restrictions and/or reference levels. Basic restrictions are exposure indices within the body that should not be exceeded. These exposure indices are based upon physical quantities directly linked to established adverse health effects. The basic restrictions in this safety code are specified in terms of: a) internal electric field strength; and b) the rate of RF energy absorption (SAR). Since measurements of the SAR or internal electric field strength are often difficult to perform, reference levels for maximum human exposure to RF fields have also been specified in this safety code. The reference levels are specified in terms of unperturbed, externally applied electric- and magnetic-field strength, power density and in terms of electric currents in the body occurring from either induction or contact with energized metallic objects. They were established using dosimetric analyses that determined the levels of externally applied field strengths that would produce the basic restrictions within the body. Compliance with the reference levels will ensure compliance with the basic restrictions in this safety code, however non-compliance with the reference levels does not necessarily mean that the basic restrictions are not respected. In such cases, additional measurements or calculations may be required to assess compliance.

For frequencies from 3 kHz to 10 MHz, PNS from induced electric fields within the body must be avoided. Experimental studies have demonstrated that electric and magnetic field exposures can induce internal electric fields (voltage gradients) within biological tissue which, if sufficiently intense, can alter the "resting" membrane potential of peripheral nerves resulting in spontaneous depolarization of the nerve membrane and the generation of spurious action potentials (5, 10, 11, 13, 14, 35, 37). Basic restrictions for the avoidance of PNS are specified in this safety code in terms of maximum internal electric field strength within the body.

For frequencies from 100 kHz to 300 GHz, tissue heating can occur and must be avoided. Basic restrictions have been specified in this safety code for RF field exposures in the 100 kHz to 6 GHz frequency range, in terms of maximum whole-body SAR (averaged over the whole-body) and peak spatially-averaged SAR, (averaged over a small cubical volume). For frequencies above 6 GHz, RF energy absorption occurs predominantly in surface tissues (e.g. upper layers of skin) and the use of maximum SAR limits, either whole-body or averaged over a cubical volume, is

not appropriate. In lieu of basic restrictions, reference levels are specified for maximum unperturbed, externally applied electric- and magnetic-field strengths and in terms of power density, for the avoidance of thermal effects.

Studies in animals, including non-human primates, have consistently demonstrated a threshold effect for the occurrence of behavioural changes and alterations in core-body temperature of ~1.0 ^{O}C, at a whole-body average SAR of ~4 W/kg (5-8, 11, 12, 14, 36). Thermoregulatory studies in human volunteers exposed to RF fields under a variety of exposure scenarios have provided supporting information on RF field induced thermal responses in humans (38). This information forms the scientific basis for the basic restrictions on whole-body average SAR in Safety Code 6. To ensure that thermal effects are avoided, a safety factor of 10 has been incorporated for exposures in controlled environments, resulting in a whole-body-averaged SAR limit of 0.4 W/kg. A safety margin of 50 has been incorporated for exposures in uncontrolled environments to protect the general public, resulting in a whole-body average SAR limit of 0.08 W/kg.

Basic restrictions on peak spatially-averaged SAR have also been established in Safety Code 6 to avoid excessive thermal effects in localized human tissues (hot-spots). The peak spatially-averaged SAR limits reflect the highly non-homogenous nature of typical RF field exposures and the differing thermoregulatory properties of various body tissues. The peak spatially-averaged SAR limits pertain to discrete tissue volumes (1 or 10 g, in the shape of a cube), where thermoregulation can efficiently dissipate heat and avoid changes (>1^{o}C) in core body temperature. As such, the peak spatially-averaged SAR limits for exposures in controlled environments are 20 W/kg for the limbs and 8 W/kg for the head, neck and trunk. For exposures in uncontrolled environments, the peak spatially- averaged SAR limits are 4.0 W/kg for the limbs and 1.6 W/kg for the head, neck and trunk.

For frequencies from 100 kHz to 10 MHz, since either PNS or thermal effects could occur, depending upon the exposure conditions (frequency, duty-cycle, orientation), basic restrictions for both internal electric field strength and SAR (whole-body and peak spatially-averaged) must be simultaneously respected. Safety Code 6 also specifies reference levels in the 3 kHz to 110 MHz frequency range, in terms of induced- or contact-currents (mA), for the avoidance of perception (nerve stimulation), shocks or burns (4, 6).

While the biological basis for the basic restrictions specified in this safety code has not changed since 2009, the reference levels have been modified to either account for dosimetric refinements in recent years (39-56) or where feasible, to harmonize with those of ICNIRP (10-11).

To determine whether the maximum exposure levels are exceeded, full consideration shall be given to such factors as:

(a) nature of the exposure environment (controlled or uncontrolled environment);

(b) temporal characteristics of the RF source (including ON/OFF times, duty factors, direction and sweep time of the beam, etc...);

(c) spatial characteristics between the exposure source and target (i.e. near-field exposures, whole body or parts thereof);

(d) uniformity of the exposure field (i.e. spatial averaging).

Where comparison is to be made to the SAR-based basic restrictions and/or reference levels at frequencies in the 100 kHz – 300 GHz range, higher exposure levels may be permitted for short durations of time under certain circumstances. For these situations, the field strengths, power densities and body currents averaged over any one tenth-hour reference period (6 minutes) shall not exceed the limits outlined in Sections 2.1 and 2.2.

SI units are used throughout this document unless specified otherwise.

2.1. Basic Restrictions

2.1.1 Internal Electric Field Strength Limits (3 kHz - 10 MHz)

Limits for internal electric field strength are intended to prevent the occurrence of PNS.

At frequencies between 3 kHz to 10 MHz, basic restrictions for internal electric field strength (Table 1) take precedence over field strength reference levels (Section 2.2) and shall not be exceeded. For conditions where the determination of internal electric field strength is not possible or practical (e.g. by measurement or modelling), external unperturbed field strength shall be carried out and reference levels outlined in Section 2.2 shall be respected.

Table 1. Internal Electric Field Strength Basic Restrictions (3 kHz – 10 MHz)

Condition	**Internal Electric Field Strength (V/m) (any part of the body)**
Controlled Environment	$\mathbf{2.7 \times 10^{-4} f}$
Uncontrolled Environment	$\mathbf{1.35 \times 10^{-4} f}$

1. Frequency, *f*, is in Hz.

2. Instantaneous, RMS values apply. In the case of pulsed RF fields, then RMS values during the pulse peak shall apply.

3. Values to be compared to the basic restriction are the 99th percentile of internal electric field strength, averaged over a 2 x 2 x 2 mm^3 volume in any tissue or organ.

2.1.2 Specific Absorption Rate (SAR) Limits (100 kHz – 6 GHz)

The specific absorption rate (SAR) is a measure of the rate at which electromagnetic energy is absorbed in the body. Basic restrictions for SAR are intended to prevent the occurrence of thermal effects from RF energy exposure on the body. At frequencies between 100 kHz and 6 GHz, the SAR limits (Table 2) take precedence over field strength and power density reference levels (Section 2.2) and shall not be exceeded.

The SAR should be determined for situations where exposures occur at a distance of 0.2 m or less from the source. In all cases, the values in Table 2 shall not be exceeded. For conditions where SAR determination is impractical, external unperturbed field strength or power density measurements shall be carried out and the limits outlined in Section 2.2 shall be respected.

Table 2. Specific Absorption Rate (SAR) Basic Restrictions (100 kHz – 6 GHz)

Condition	**SAR Basic Restriction (W/kg)****	
	Controlled Environment	**Uncontrolled Environment**
The SAR averaged over the whole body mass.	0.4	0.08
The peak spatially-averaged SAR for the head, neck and trunk, averaged over any 1 g of tissue*	8	1.6
The peak spatially-averaged SAR in the limbs, averaged over any 10 g of tissue*	20	4

*Defined as a tissue volume in the shape of a cube.
** Averaged over any 6 minute reference period.

2.1.3 Frequencies from 6 GHz – 300 GHz

For frequencies above 6 GHz, energy deposition occurs predominantly in the uppermost layers of superficial tissues (e.g. skin, cornea). In this case, power density is a more appropriate exposure limit metric. Therefore, for the frequency range from 6 GHz to 300 GHz, the incident unperturbed power density and its derived electric- and magnetic-field strengths (assuming a free-space impedance of 377 ohms) form the basic restriction in this safety code (Section 2.2.2) and shall not be exceeded.

2.2 Reference Levels

In practice, direct measurements of internal electric fields or SAR are often only feasible under laboratory conditions. Therefore, reference levels are specified in this safety code in terms of external unperturbed electric and magnetic field strength, power density, as well as induced and contact currents. In the far-field zone of an electromagnetic source, electric field strength, magnetic field strength and power density are interrelated by simple mathematical expressions, where any one of these parameters defines the remaining two. In the near-field zone, both the unperturbed electric- and magnetic-field strengths shall be measured, since there is no simple relationship between these two quantities. Instrumentation for the measurement of magnetic fields at certain frequencies may not be commercially available. In this case, the electric field strength shall be measured and used for assessing compliance with the reference levels in this code.

2.2.1. Electric and Magnetic Field Strength (3 kHz to 10 MHz)

To ensure compliance with the basic restrictions outlined in Section 2.1, at frequencies between 0.003 MHz and 10 MHz, both the PNS- and SAR-based reference levels for electric- and magnetic-field strength must be complied with simultaneously at frequencies where reference levels for both apply.

Table 3. Electric Field Strength Reference Levels

Frequency (MHz)	Reference Level Basis	Reference Level (ERL), (V/m, RMS)		Reference Period
		Uncontrolled Environment	Controlled Environment	
0.003 – 10	PNS	83	170	Instantaneous*
1.0 – 10	SAR	$87 / f^{0.5}$	$193 / f^{0.5}$	6 minutes**

- Frequency, *f*, is in MHz.
- PNS, peripheral nerve stimulation
- SAR, specific absorption rate
- The precise frequencies at which SAR-based electric field strength reference levels for Uncontrolled- and Controlled-Environments begin are 1.10 MHz and 1.29 MHz, respectively.

Table 4. Magnetic Field Strength Reference Level

Frequency (MHz)	Reference Level Basis	Reference Level (H_{RL}), (A/m, RMS)		Reference Period
		Uncontrolled Environment	Controlled Environment	
0.003 – 10	PNS	21	80	Instantaneous*
0.1 – 10	SAR	$0.73 / f^{0.5}$	$1.6 / f^{0.5}$	6 minutes**

- Frequency, f, is in MHz
- PNS, peripheral nerve stimulation
- SAR, specific absorption rate

Notes:

1. At no point in time, shall the RMS values for electric- and magnetic-fields exceed the reference levels with an instantaneous reference period in Tables 3 and 4. In the case of pulsed RF fields, the RMS value during the pulse ON time shall be compared to the reference level.
2. ** For exposures shorter than the reference period, field strengths may exceed the reference levels, provided that the time average of the squared value of the electric field strength and magnetic field strength over any time period equal to the reference period is smaller than E_{RL}^2 and H_{RL}^2, respectively. For exposures longer than the reference period, including indefinite exposures, the time average of the squared value of the electric field strength and magnetic field strength over any time period equal to the reference period shall not exceed E_{RL}^2 and H_{RL}^2, respectively.
3. Where external electric field strengths and magnetic field strengths (at frequencies at or above 100 kHz) are spatially non-uniform, comparison to the reference levels shall be made after spatially averaging the field strengths over the vertical extent of the human body. The spatial averaging procedure applied should conservatively estimate the equivalent uniform field strengths that would be incident upon all applicable body sizes. Where comparison is to be made to the reference levels based on PNS in Tables 3 and 4, spatial averaging is with respect to the sample values of the field strengths. Where comparison is to be made to the reference levels based on SAR in Tables 3 and 4, spatial averaging is with respect to the square of the sample values of the field strengths.
4. Where external magnetic field strengths are spatially non-uniform and are below 100 kHz, the maximum sample value for magnetic field strength over the vertical extent of the human body shall be compared to the reference levels in Table 4. (i.e. magnetic field strengths shall not be spatially-averaged at frequencies below 100 kHz)

5. For simultaneous exposure to multiple frequencies and where comparison is to be made to the reference level based on PNS, each of the field strength frequency component amplitudes shall be divided by the corresponding field strength reference level for that frequency, and the sum of all these ratios shall be less than unity. This may be expressed as $\Sigma (E_i/E_{RL}) \leq 1$ for electric field strength or $\Sigma (H_i/H_{RL}) \leq 1$ for magnetic field strength.
6. For simultaneous exposure to multiple frequencies and where comparison is to be made to the reference level based on SAR, each of the squares of the field strength frequency component amplitudes shall be divided by the square of the corresponding field strength reference level for that frequency, and the sum of all these ratios shall be less than unity. This may be expressed as $\Sigma (E_i/E_{RL})^2 \leq 1$ for electric field strength or $\Sigma (H_i/H_{RL})^2 \leq 1$ for magnetic field strength.

2.2.2. Electric Field Strength, Magnetic Field Strength and Power Density (10 MHz to 300 GHz)

To ensure compliance with the basic restrictions outlined in Section 2.1, at frequencies between 10 MHz and 300 GHz, the reference levels for electric- and magnetic-field strength and power density must be complied with.

Table 5. Reference Levels for Electric Field Strength, Magnetic Field Strength and Power Density in Uncontrolled Environments

Frequency (MHz)	Electric Field Strength (E_{RL}), (V/m, RMS)	Magnetic Field Strength (H_{RL}), (A/m, RMS)	Power Density (S_{RL}) (W/m^2)	Reference Period (minutes)
10 – 65	27.5	0.073	-	6
65 – 100	$221 / f^{0.5}$	$0.585 / f^{0.5}$	$129.1 / f$	6
100 – 6000	$6.97 f^{0.25}$	$0.0185 f^{0.25}$	$0.129 f^{0.5}$	6
6000 –15000	61.4	0.163	10	6
15000 – 150000	61.4	0.163	10	$616000 / f^{1.2}$
150000 – 300000	$0.158 f^{0.5}$	$4.21 \times 10^{-4} f^{0.5}$	$6.67 \times 10^{-5} f$	$616000 / f^{1.2}$

Frequency, *f*, is in MHz.

Table 6. Reference Levels for Electric Field Strength, Magnetic Field Strength and Power Density in Controlled Environments

Frequency (MHz)	Electric Field Strength (E_{RL}), (V/m, RMS)	Magnetic Field Strength (H_{RL}), (A/m, RMS)	Power Density, (S_{RL}) (W/m^2)	Reference Period (minutes)
10 – 65	61.4	0.163	-	6
65 – 100	$493 / f^{0.5}$	$1.309 / f^{0.5}$	$645.5 / f$	6
100 – 6000	$15.6 f^{0.25}$	$0.0414 f^{0.25}$	$0.6455 f^{0.5}$	6
6000 – 15000	137	0.364	50	6
15000 – 150000	137	0.364	50	$616000 / f^{1.2}$
150000 – 300000	$0.354 f^{0.5}$	$9.40 \times 10^{-4} f^{0.5}$	$3.33 \times 10^{-4} f$	$616000 / f^{1.2}$

Frequency, *f*, is in MHz.

Notes:

1. For exposures shorter than the reference period, field strength levels may exceed the reference levels provided that the time average of the squared value of the electric or magnetic field strengths over any time period equal to the reference period is smaller than E_{RL}^2 or H_{RL}^2, respectively. For exposures longer than the reference period, including indefinite exposures, the time average of the squared value of the electric or magnetic field strength over any time period equal to the reference period shall not exceed E_{RL}^2 or H_{RL}^2, respectively.
2. Where exposure is estimated in terms of power density and for exposures shorter than the reference period, power density levels may exceed the reference level provided that the time average of the power density over any time period equal to the reference period is smaller than S_{RL}. For exposures longer than the reference period, including indefinite exposures, the time average of the power density over any time period equal to the reference period shall not exceed S_{RL}.
3. Where external field strengths or power density are spatially non-uniform, comparison to the reference levels shall be made after spatially averaging over the vertical extent of the human body. The spatial averaging procedure applied should conservatively estimate the equivalent uniform plane-wave field strengths that would be incident upon all applicable body sizes. In the case of field strengths, spatial averaging is with respect to the squared values of the field strength samples while for power density, spatial averaging is with respect to the power density samples.

4. For simultaneous exposure to multiple frequencies and where exposure is estimated in terms of power density, each of the power density frequency component amplitudes shall be divided by the corresponding reference level for that frequency, and the sum of all these ratios shall be less than unity. This may be expressed as: $\Sigma (S_i/S_{RL}) \leq 1$.
5. For simultaneous exposure to multiple frequencies and where exposure is estimated in terms of field strength, each of the squares of the field strength frequency component amplitudes shall be divided by the square of the corresponding field strength reference level for that frequency, and the sum of all these ratios shall be less than unity. This may be expressed as $\Sigma (E_i/E_{RL})^2 \leq 1$ for electric field strength or $\Sigma (H_i/H_{RL})2 \leq 1$ for magnetic field strength.
6. For pulsed RF field exposures estimated in terms of power density, the time-averaged power density shall respect the reference levels listed in Tables 5 and 6 and the peak power density, as averaged over the pulse width, shall not exceed 1000 times the reference level S_{RL}.
7. For pulsed RF field exposures estimated in terms of field strength, the time-averaged field strengths shall respect the reference levels listed in Tables 5 and 6 and the peak RMS field strength, as averaged over the pulse width, shall not exceed 32 times the reference level E_{RL} or H_{RL}.

2.2.3. Induced and Contact Current (3 kHz – 110 MHz)

Induced current is defined as the current flowing through a single foot to ground in a free-standing body (no contact with conductive objects) in the presence of an electric field. Where assessment is made of the current flowing through both feet, the result shall be compared to twice the reference level for a single foot.

Contact current is defined as the total current flowing through the body to ground resulting from finger-touch contact with an insulated conductive object that has been energized in an electric field. Conversely, it can be defined as the total current flowing in an insulated body that has been energized in an electric field and is in finger-touch contact with a grounded conductive object. The current path in the body is from point of touch to ground through the feet. The total current can be assessed anywhere along the path of flow.

Table 7. Induced Current Reference Levels

Frequency (MHz)	Reference Level Basis	Reference Level (I_{RL}), through a single foot (mA, RMS)		Reference Period
		Uncontrolled Environment	Controlled Environment	
0.003 – 0.4	PNS	100 *f*	225 *f*	Instantaneous*
0.4 – 110	SAR	40	90	6 minutes**

- Frequency, *f*, is in MHz.
- PNS, peripheral nerve stimulation
- SAR, specific absorption rate

Table 8. Contact Current Reference Levels

Frequency (MHz)	Reference Level Basis	Reference Level (I_{RL}), (mA, RMS)		Reference Period
		Uncontrolled Environment	Controlled Environment	
0.003 – 0.10	PNS	200 *f*	400 *f*	Instantaneous*
0.10 – 10	SAR	20	40	Instantaneous*
10 – 110	SAR	20	40	6 minutes**

- Frequency, *f*, is in MHz.
- PNS, peripheral nerve stimulation
- SAR, specific absorption rate

Notes:

1. At no point in time, shall the RMS values for induced and contact currents exceed the reference levels with an instantaneous reference period in Tables 7 and 8. In the case of pulsed currents, the RMS value during the pulse ON time shall be compared to the reference level.
2. ** For exposures shorter than the reference period, currents may exceed the reference levels, provided that the time average of the squared value of the current over any time period equal to the reference period is smaller than I_{RL}^2. For exposures longer than the reference period, including indefinite exposures, the time average of the squared value of the current over any time period equal to the reference period shall not exceed I_{RL}^2.
3. For simultaneous exposure to multiple frequencies and where comparison is to be made to the reference level based on PNS, each of the induced- or contact-current frequency component amplitudes shall be divided by the corresponding reference level for that

frequency, and the sum of all these ratios shall be less than unity. This may be expressed as $\Sigma (I_i/I_{RL}) \leq 1$.

4. For simultaneous exposure to multiple frequencies and where comparison is to be made to the reference level based on SAR, each of the squares of the induced- or contact-current frequency component amplitudes shall be divided by the square of the corresponding field strength reference level for that frequency, and the sum of all these ratios shall be less than unity. This may be expressed as $\Sigma (I_i/I_{RL})^2 \leq 1$.
5. For pulsed induced- or contact-currents where a 6 minute reference period applies, the time-averaged induced- or contact-currents shall respect the reference levels listed in Tables 7 and 8 and the peak RMS induced- or contact-current, as averaged over the pulse width, shall not exceed 32 times the reference level I_{RL}.

Acronyms

A – ampere

EEG – electroencephalogram

EHS – electromagnetic hypersensitivity

E_i – electric field strength frequency component amplitude (RMS)

E_{RL} – electric field strength reference level

g – gram

GHz – gigahertz

h – hour

H_i – magnetic field strength frequency component amplitude (RMS)

H_{RL} – magnetic field strength reference level

Hz – hertz

ICNIRP – International Commission on Non-Ionizing Radiation Protection

I_i – current frequency component amplitude (RMS)

I_{RL} – current reference level

kg – kilogram

kHz – kilohertz

m – meter

mA – milliampere

MHz – megahertz

mm – millimeter

RMS – root mean square

PNS – peripheral nerve stimulation

RF – radiofrequency

SAR – specific absorption rate

SI – Système international d'unités (International System of Units).

S_i – power density frequency component amplitude (RMS)

S_{RL} – power density reference level

V – volt

W – watt

Definitions

Antenna – an electrical device that converts electric currents into propagating electric and magnetic fields in the form of waves (e.g. radio waves) and vice versa.

Basic restriction – maximum allowable internal electrical quantities in the body, arising from exposure to incident external fields, that prevent the occurrence of all established adverse health effects.

Contact current – the total current flowing through the body to ground resulting from finger-touch contact with an insulated conductive object that has been energized in an electric field, or from an insulated body that has been energized in an electric field and is in finger-touch contact with a grounded conductive object.

Controlled environment – an area where the RF field intensities have been adequately characterized by means of measurement or calculation and exposure is incurred by persons who are: aware of the potential for RF field exposure, cognizant of the intensity of the RF fields in their environment, aware of the potential health risks associated with RF field exposure and can control their risk using mitigation strategies.

Electric field – the region surrounding an electric charge, in which the magnitude and direction of the force on a hypothetical test charge is defined at any point.

Electromagnetic radiation – a form of energy emitted by accelerating electric charges, that exhibits wave-like behavior as it travels through space.

Far-field zone – the space beyond an imaginary boundary around an antenna, which marks the beginning of where the angular field distribution is essentially independent of the distance from the antenna. In this zone, the field has a predominantly plane-wave character.

Field strength – the magnitude of the electric or magnetic field, normally a root-mean-square (RMS) value.

Frequency – The number of cycles in the variation of the amplitude of an electromagnetic wave within one second, expressed in units of hertz (Hz).

General public – individuals of all ages, body sizes and varying health status, some of whom may qualify for the conditions defined for the controlled environment in certain situations.

Induced current – current flowing downwards in the lower limbs, through the feet, to ground in a human body exposed to an electric field.

Limbs – extremities distal from the shoulder and hip joints, which do not include the gonads.

Magnetic field – a region of space surrounding a moving charge (e.g. in a conductor) being defined at any point by the force that would be experienced by another hypothetical moving charge. A magnetic field exerts a force on charged particles only if they are in motion, and charged particles produce magnetic fields only when they are in motion.

Near-field zone – a volume of space generally close to an antenna or other radiating structure, in which the electric and magnetic fields do not have a substantially plane-wave character, but vary considerably from point to point at the same distance.

Non-thermal effects – biological effects resulting from exposure to RF fields, that are not due to tissue heating.

Power density – the rate of flow of electromagnetic energy per unit surface area usually expressed in W/m^2 or mW/cm^2 or $\mu W/cm^2$.

Radiofrequency (RF) – is a rate of oscillation in the range of about 3 kHz to 300 GHz, which corresponds to the frequency of radio waves typically used in radio communications.

Reference level – an easily measured or calculated quantity (i.e. externally applied electric field strength, magnetic field strength and power density or resulting body current), that when respected, ensures compliance with the underlying basic restrictions in Safety Code 6.

Reference period – a time period used for averaging temporally non-uniform RF field exposures, for comparison with the exposure limits in Safety Code 6. The reference periods specified in Safety Code 6 are based upon the relevant adverse health effect to be avoided and the time for those responses to occur.

RMS (root mean square) – a statistical measure of the magnitude of a varying quantity. Mathematically, it is the square root of the average of the squares of the instantaneous field strength or current taken over a sufficient period of time to achieve a stable mean.

Safety – The absence of adverse health effects caused by RF field exposures.

Specific absorption rate (SAR) – is a measure of the rate at which energy is absorbed by the body (or a discrete tissue volume) when exposed to a radiofrequency (RF) field. *SAR* is expressed in units of watts per kilogram (W/kg), and can be calculated from the product of the tissue conductivity (S/m) and the square of the RMS electric field strength induced in the tissue (V/m), divided by the mass density (kg/m^3) of the tissue.

Thermal effects – biological effects resulting from heating of the whole body or a localized region resulting from exposure to RF fields, where a sufficient temperature increase has occurred that results in a physiologically significant effect.

Uncontrolled environment – an area where any of the criteria defining the controlled environment are not met.

Wavelength – the distance travelled by a propagating wave in one cycle of oscillation.

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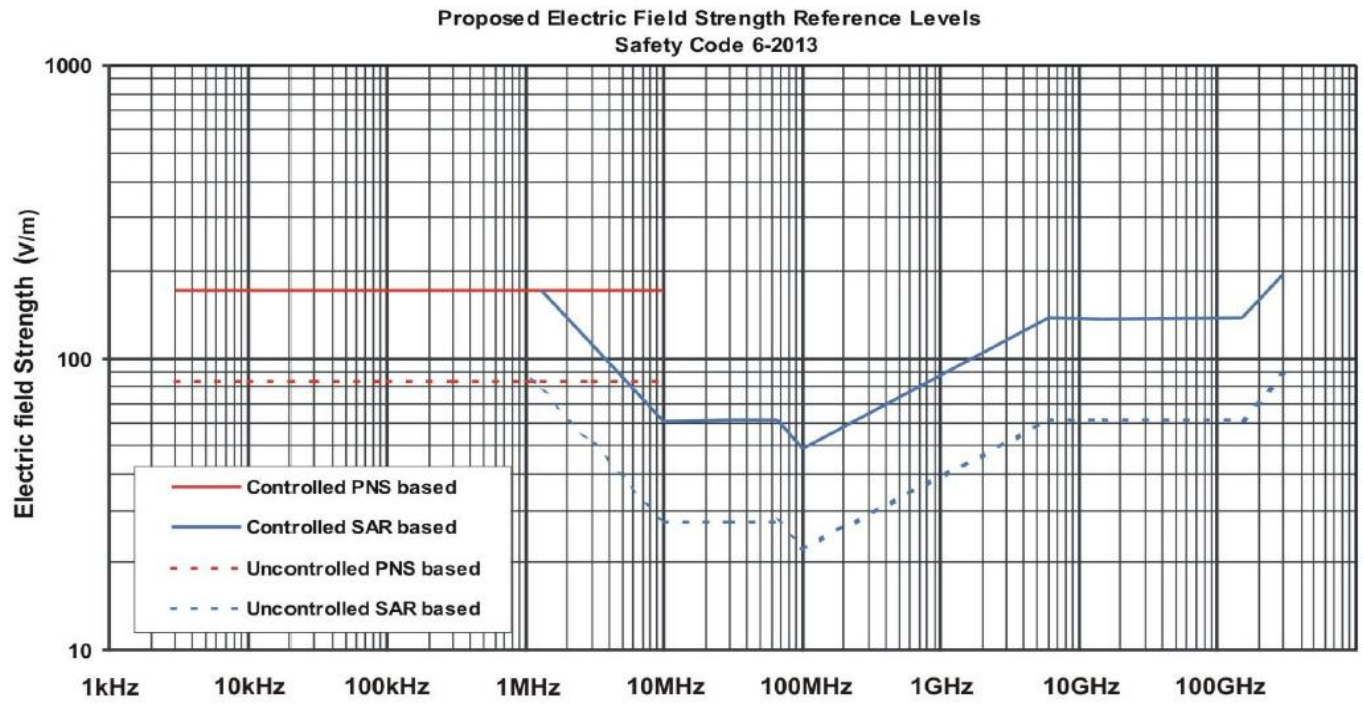
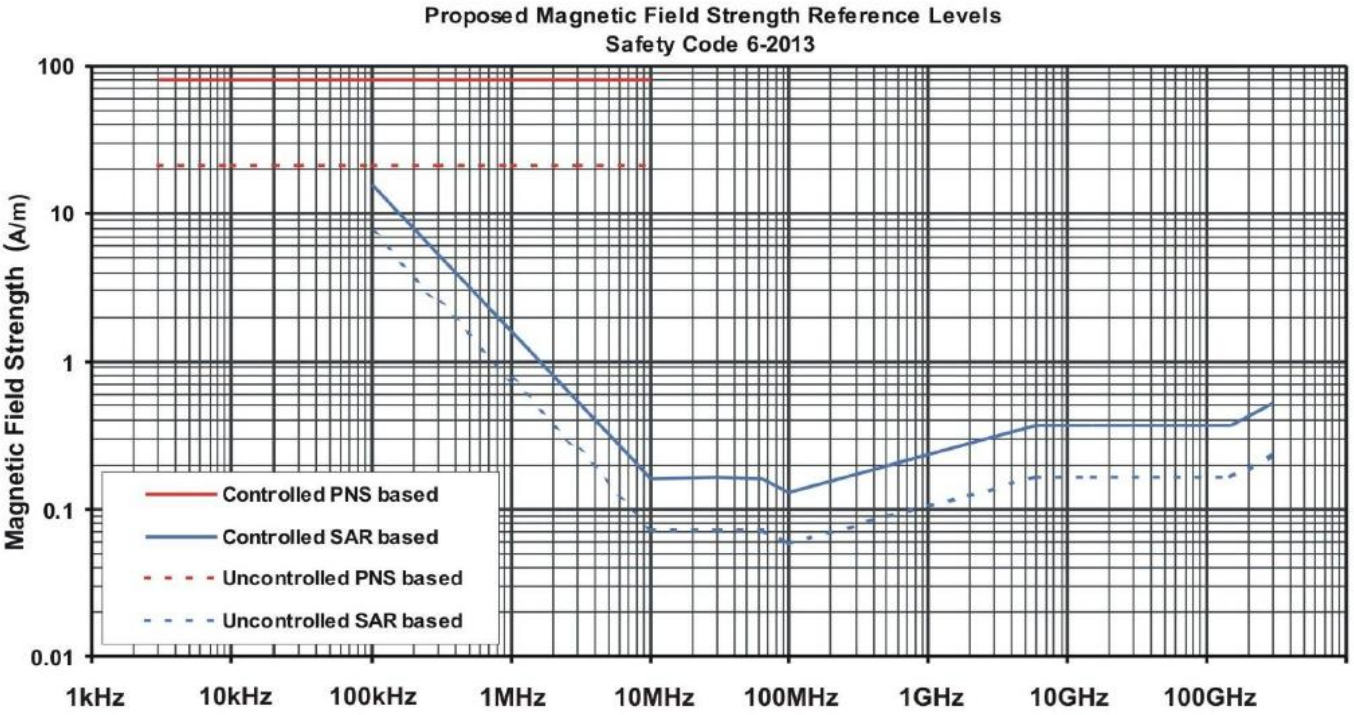
Appendix 1


Proposed Electric Field Strength Reference Levels
Safety Code 6-2013
Electric field Strength (V/m)
1000
100
10
Controlled PNS based
Controlled SAR based
Uncontrolled PNS based
Uncontrolled SAR based
1kHz
10kHz
100kHz
1MHz
10MHz
100MHz
1GHz
10GHz
100GHz


Proposed Magnetic Field Strength Reference Levels
Safety Code 6-2013
Magnetic Field Strength (A/m)
100
10
1
0.1
0.01
Controlled PNS based
Controlled SAR based
Uncontrolled PNS based
Uncontrolled SAR based
1kHz
10kHz
100kHz
1MHz
10MHz
100MHz
1GHz
10GHz
100GHz

Appendix II: Selected human anatomical models used for non-ionising calculations since 1999

Model	References
Adult models	Christ et al., 2010; Dimbylow, 2002, 2005a, 2005b; Findlay, 2013; A.-K. Lee et al., 2006; C. Lee et al., 2006; Mason et al., 2000; Nagaoka et al., 2004; Sandrini et al., 2004; T. Wu et al., 2011
Child models	Bakker et al., 2012; Christ et al., 2010; Dimbylow, 2002; Dimbylow and Bolch, 2007; Keshvari and Lang, 2005; Nagaoka et al., 2008
Postured models	Allen et al., 2003, 2005; Findlay and Dimbylow, 2005, 2006; Findlay et al., 2009; Nagaoka et al., 2008; Uusitupa et al., 2010
Pregnant models	Dimbylow, 2006; Dimbylow and Bolch, 2007; Nagaoka et al., 2007; X. Xu et al., 2007
Foetal models	Dimbylow, 2006; Dimbylow and Bolch, 2007; Kawai et al., 2006; Nagaoka et al., 2007; X. Xu et al., 2007
Newborn models	Dimbylow et al., 2010; Lee et al., 2007

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