INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION



ICNIRP STATEMENT PRINCIPLES FOR NON-IONIZING RADIATION PROTECTION

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Special Submission

PRINCIPLES FOR NON-IONIZING RADIATION PROTECTION

International Commission on Non-Ionizing Radiation Protection (ICNIRP)¹

Abstract—In this statement, the International Commission on Non-Ionizing Radiation Protection (ICNIRP) presents its principles for protection against adverse health effects from exposure to non-ionizing radiation. These are based upon the principles for protection against ionizing radiation of the International Commission for Radiological Protection (ICRP) in order to come to a comprehensive and consistent system of protection throughout the entire electromagnetic spectrum. The statement further contains information about ICNIRP and the processes it uses in setting exposure guidelines.

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INTRODUCTION

THE INTERNATIONAL Commission on Non-Ionizing Radiation Protection (ICNIRP) is an independent committee of scientific experts established to evaluate the state of knowledge about the effects of non-ionizing radiation (NIR) on human health, including well-being, and on the environment (see http://www.icnirp.org/en/about-icnirp/aim-statushistory/index.html). ICNIRP provides scientifically-based advice and guidance on protection against adverse effects of non-ionizing radiation, including the provision of guidelines on limiting exposure. ICNIRP is a non profit organization on

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non-ionizing radiation protection formally recognized by the World Health Organization (WHO), the International Labour Organization (ILO), and the European Union (EU). Further information about ICNIRP is provided in the Appendix.

This document describes the general principles used by ICNIRP to draft recommendations for exposure restrictions in order to provide protection against adverse health effects of exposure to non-ionizing radiation. In practice, the critical steps in applying these general principles may differ across the non-ionizing radiation spectrum. The procedures used by ICNIRP are described in the Appendix.

To establish a consistent framework of radiation protection over the entire spectrum of ionizing and non-ionizing radiation, the general principles for non-ionizing radiation protection are based, wherever appropriate, upon the wellestablished principles for protection against adverse health effects from ionizing radiation (ICRP 2007) and the underpinning ethical values, as published by the International Commission on Radiological Protection (ICRP).²

Definition of non-ionizing radiation. Non-ionizing radiation in this document refers to electromagnetic radiation and fields with a photon energy lower than 10 eV, corresponding to frequencies lower than 3 PHz (3×10^{15} Hz) and wavelengths longer than 100 nm. It is grouped into different frequency or wavelength bands, namely ultraviolet (UV) radiation (wavelengths 100–400 nm), visible light (wavelengths 400–780 nm),³ infrared radiation (wavelengths 780 nm–1 mm), radiofrequency electromagnetic fields (frequencies 100 kHz–300 GHz), low frequency (frequencies 1 Hz–100 kHz) and static electric and magnetic fields (0 Hz). Although not part of the electromagnetic radiation spectrum, mechanical waves in the form of infrasound (frequencies below 20 Hz) and ultrasound (frequencies above 20 kHz)

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²It is necessary to ensure that all persons are treated fairly and with dignity and respect (ICRP 2018).

³A precise border between UVR and visible radiation cannot be defined because visual sensation at wavelengths shorter than 400 nm is noted for very bright sources. Similarly, a precise border between visible and infrared radiation cannot be defined because visual sensation at wavelengths greater than 780 nm is noted for very bright sources (ICNIRP 2013).

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are also included in ICNIRP's remit, but audible acoustic waves (sound) are not.

For the purposes of radiation protection, different approaches are usually applied for adverse health effects that do and do not have thresholds to produce adverse effects. In addition, the exposure threshold required for an adverse health effect is of importance, as discussed below.

Principles for non-ionizing radiation protection. The key driver for both ionizing and non-ionizing radiation protection is to prevent harm to people and the environment. For humans the aim is to provide protection of all individuals, whereas for the environment it is to protect species, ecosystems and biota against adverse effects. The process of radiation protection includes making informed decisions even if full knowledge about the risks associated with exposure is not available.

Basic premise

ICNIRP aims to provide advice on protection against adverse health effects from both short- and long-term exposures to non-ionizing radiation and uses the WHO's definition of health: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."⁴ ICNIRP's advice is based on a detailed evaluation of the scientific evidence. Scientifically substantiated adverse health effects (see the Appendix) are identified and exposure limits are developed to prevent these. For the estimation of exposure limits, ICNIRP generally assumes worst-case situations and takes uncertainties in the scientific evidence into consideration.

ICNIRP has adapted relevant issues from the protection principles for ionizing radiation provided by ICRP (2007).

ICRP aims to provide protection against adverse effects of ionizing radiation "without unduly limiting the benefits associated with their use." A core concept in ionizing radiation protection is *risk tolerability*, or the question of how much risk is acceptable. This means that, for the system of ionizing radiation protection, social and economic issues may be taken into account. ICNIRP recognizes that a complete system of protection against adverse effects of non-ionizing radiation also requires evaluations based on social and economic considerations. However, ICNIRP does not explicitly address social and economic issues, as these are deemed to be the remit of governments and relevant authorities.

Fundamental principles

The fundamental principles of ionizing radiation protection are Justification, Optimization, and Limitation:

• Justification: any decision that alters the radiation exposure situation should do more good than harm; May 2020, Volume 118, Number 5

- <u>Optimization:</u> all exposures should be kept as low as reasonably achievable, taking into account economic and societal factors, and with restrictions on individual exposure to limit inequities in dose distribution; and
- Limitation: the principle of application of dose limits where the total dose to any individual from regulated sources in exposure situations, other than medical exposure of patients, should not exceed the appropriate limits recommended.

These principles are applied and considered in different ways across the spectrum of non-ionizing radiation, since there are differences in the type of effects and their health consequences⁵ over the different frequency bands. An important issue is the concept of dose: this normally assumes an *accumulation* of damage and as such is the product of exposure intensity and exposure duration, whereby a similar effect or a similar risk for an effect may be obtained by a short exposure at high intensity and a long exposure at low intensity (reciprocity). For many effects (e.g., heating from exposure to high frequency electromagnetic fields and infrared radiation), both intensity and duration of exposure are important. However, for static or low frequency electric and magnetic fields, mainly the exposure intensity is relevant.

ICNIRP applies the principle of *limitation* throughout the non-ionizing radiation range. Exposure is limited to either below the level with an accepted risk for adverse effects, taking into account any beneficial effects (such as production of vitamin D in the skin with exposure to UV radiation), or below the threshold level for adverse health effects (where there is a known threshold), where it is feasible to reduce the exposure to below these thresholds. A general formulation of limitation for non-ionizing radiation is the exposure level or dose to any individual in situations other than exposures for medical purposes and exposures of volunteers, as described below, should not exceed the appropriate recommended restrictions.

ICNIRP also supports *justification* and *optimization* as useful and relevant concepts. Regarding optimization, for adverse effects with no threshold this would mean keeping exposure as low as reasonably achievable. When the exposure restrictions set by ICNIRP are well below threshold levels for adverse health effects, further reduction in the limit values does not result in additional health benefits, and therefore optimization is not necessary.

Categories of exposure

In non-ionizing radiation protection, a distinction is made between occupational exposure, exposure of the general public, and medical exposure of patients. One reason for the

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⁴Preamble to the Constitution of the World Health Organization (April 1948).

⁵Effects can for instance be life-threatening, such as cancer and excessive heating, or debilitating, such as eye damage.

distinction between restrictions for occupational and general public exposure is that occupationally-exposed individuals can be considered a more homogeneous group than the general population. Occupationally-exposed individuals are, in general, relatively healthy adults within a limited age range, while the general population contains diverse groups such as very young children and the elderly who might be more sensitive to adverse effects of non-ionizing radiation exposure, for instance because they have less efficient thermoregulatory capacity. Thus, it is assumed that there is greater variability in sensitivity among the general population than among occupationally-exposed individuals. Another reason is that occupationally-exposed individuals should be operating under controlled conditions and be informed about the risks associated with non-ionizing radiation exposure for their specific situation and how to reduce these risks. Members of the general public are, in most cases, unaware of their exposure to non-ionizing radiation and, without education, cannot reasonably be expected to take precautions to minimize or avoid any adverse effects of exposure. For types of radiation where there is an accumulation of damage in the long term, or where the risk depends on the total dose, another important distinction between occupationally-exposed individuals and the general population is the duration of exposure, which for occupational exposure is taken to be up to about 40 hours per week. In both ionizing and non-ionizing radiation protection, an individual is only considered to be occupationally exposed when performing their work duties under potentially controlled exposure and/or protection conditions. Outside work hours and when conditions are not appropriately controlled, they are considered to be a member of the general public.

Pregnant workers comprise a special category. The fetus has to be considered as belonging to the general population. If a female worker has declared that she is pregnant, she can only be exposed above the exposure restrictions for the general public provided that the exposure of the embryo or fetus remains below the general public restrictions.

Patients under medical care are another special category. They can be exposed to relatively high levels of nonionizing radiation for diagnostic or therapeutic purposes. If the applied non-ionizing radiation levels exceed the exposure restrictions for the general public, the intended benefits of the procedure should outweigh the possibility of adverse effects. This justification is the responsibility of physicians who are diagnosing or treating the patient, and who have been properly trained to make such judgements.

In general, people with medical conditions are included in the general public and the guidelines are protective for them. It should be noted, however, that the exposure guidelines are not meant to be protective for people with certain clinically substantiated diseases or conditions that may make them more susceptible to harm from non-ionizing radiation, e.g., patients with *Xeroderma pigmentosa*, or individuals taking photosensitizing medications.

Another special category includes allowable occupational exposure above the restrictions for emergency life-saving services to the public, e.g., electromagnetic pulse devices deployed for resuscitation.

Individuals who volunteer to participate in experimental procedures and product development studies or who voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing procedures for medical diagnosis or treatment involving non-ionizing radiation are a fourth special category. Exposure of volunteers for research requires an evaluation on a case-by-case basis that weighs the risks of non-ionizing radiation exposure against the benefits of the scientific or medical knowledge obtained, and such considerations are best made by an institutional review board or ethics committee. In the case of carers and comforters, such considerations are best made by the appropriate medical supervisors, who should also provide information about potential risks.

Exposure situations

The distinction that is made in ionizing radiation protection between planned, existing and emergency exposure situations is considered by ICNIRP to be less useful in general for non-ionizing radiation protection purposes. Instead, ICNIRP distinguishes between regulated and unregulated exposures. Exposure in occupational situations, both from natural and man-made sources, has to be regulated to prevent excessive exposure. It is also required that exposed workers be informed about the risks and measures they can take to prevent excessive exposure. Exposure of the general public can only be regulated when the source is man-made. In unregulated cases (such as with exposure to UV radiation from the sun) authorities can only inform the public about the risks and how to reduce them.

Another distinction that can be made is between intentional and unintentional exposures. Most non-ionizing radiation exposures are not intentional, even if they are regulated. For instance, the exposures to electromagnetic fields from power lines and mobile telecommunication systems are regulated and the applicable exposure restrictions should not be exceeded. However, the "intention" is to deliver power and provide communication respectively, rather than to expose a person. A special case of unintentional exposure is accidental over-exposure. If this results in exposure above the adverse health effect threshold, ICNIRP recommends medical examination and follow-up of the exposed individual and, in cases of occupational exposure, that the individual's symptoms be treated like other accidents at work according to national law and practices. Intentional exposures are mainly those during medical procedures and for cosmetic purposes. As stated above, for medical exposures the responsibility

for the justification rests with the treating physician. For cosmetic applications the primary responsibility rests with the relevant authorities, who have to determine whether they consider it acceptable to allow those subject to cosmetic procedures to be exposed above the ICNIRP guideline levels.

Biological and health effects

A biological effect is any biological, physical, or chemical change induced in a biological system. Living organisms have repair and feedback mechanisms that are designed to maintain homeostasis, the balanced situation in which a biological system can properly function. If the capacity of these compensatory mechanisms is overwhelmed or exhausted, this may result in adverse health effects. The ICNIRP guidelines are not intended to protect against biological effects as such, unless there is also an associated adverse health effect.

However, it is not always easy to draw a clear distinction between biological and adverse health effects, and indeed this can vary depending on individual susceptibility to specific situations. An example is sensory effects from nonionizing radiation exposures under certain circumstances, such as a tingling sensation resulting from peripheral nerve stimulation by electric or magnetic fields; magnetophosphenes (light flickering sensations in the periphery of the visual field) resulting from stimulation of the retina by electric fields induced by exposure to low-frequency magnetic fields; and microwave hearing resulting from thermoelastic waves due to expansion of soft tissues in the head which travel via bone conduction to the inner ear. Such perceptions may sometimes lead to discomfort and annovance. ICNIRP does not consider discomfort and annoyance to be adverse health effects by themselves, but, in some cases, annoyance may lead to adverse health effects by compromising well-being. The exposure circumstances under which discomfort and annoyance occur vary between individuals.

CONCLUDING REMARKS

In this document, ICNIRP provides the fundamental principles that underlie its system of protection against adverse effects from exposure to non-ionizing radiation. These principles are based on those proposed by ICRP for ionizing radiation protection, in order to establish a comprehensive system of radiation protection over the entire electromagnetic spectrum and for infra- and ultrasound. Information on non-ionizing radiation, as well as all the guidelines and statements from ICNIRP, can be found at www.icnirp.org. Acknowledgments—Collaborators: Eric van Rongen (ICNIRP and Health Council, The Netherlands), Rodney Croft (ICNIRP and Australian Centre for Electromagnetic Bioeffects Research, Illawarra Health & Medical Research Institute, University of Wollongong, Australia), Maria Feychting (ICNIRP and Karolinska Institutet, Sweden), Adèle C Green (ICNIRP and QIMR Berghofer Medical Research Institute, Brisbane, Australia and CRUK Manchester Institute, University of Manchester, Manchester, UK), Akimasa Hirata (ICNIRP and Nagoya Institute of Technology, Japan), Guglielmo d'Inzeo (ICNIRP and La Sapienza University Rome, Italy), Carmela Marino (ICNIRP and ENEA, Italy), Sharon Miller (ICNIRP), Gunnhild Oftedal (ICNIRP and Norwegian University of Science and Technology), Tsutomu Okuno (ICNIRP), Martin Röösil (ICNIRP and Swiss Tropical and Public Health Institute, Basel, Switzerland), Zenon Sienkiewicz (ICNIRP), and Soichi Watanabe (ICNIRP and National Institute of Information and Communications Technology (NICT), Japan).

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APPENDIX

Further information about ICNIRP and its procedures for setting guidelines.

About ICNIRP

ICNIRP was chartered by the International Radiation Protection Association (IRPA) in 1992 as an independent commission to succeed the International Non-Ionizing Radiation Committee (INIRC) of IRPA (Repacholi 2017). The objective of ICNIRP as formulated in its charter is "The Commission is established for the purpose of advancing Non-Ionizing Radiation Protection for the benefit of people and the environment and in particular to provide guidance and recommendations on protection from NIR exposure" (see http://www.icnirp.org/en/about-icnirp/aimstatus-history/index.html). ICNIRP maintains a close but independent association with IRPA.

Membership in ICNIRP is limited to scientific experts who have no commercial or other vested interests. Candidates can be proposed by national and international radiation protection bodies and by current ICNIRP members. New members are elected by the Main Commission of ICNIRP from these candidates. The term of membership is four years and this term can be renewed twice.

ICNIRP has established the Scientific Expert Group (SEG), which consists of eminent scientists with different expertise deemed helpful in current and near-future activities of the Commission. SEG members, together with members of the Main Commission, form Project Groups that prepare the initial drafts of documents or guidelines. These are submitted to the Main Commission for further consideration and finalization. The term of membership of the SEG is four years.

In carrying out their voluntary work for the Commission or SEG, members do not represent either their country of origin or their organization. Commission and SEG members are required to declare any personal interests in relation to their activities for ICNIRP and update these annually; emeritus Commission members are required to submit a declaration of interests if they want to attend a meeting of the Commission. All declarations of interests are available on the website of ICNIRP (www.icnirp.org). The website also contains financial statements, which include ICNIRP's sources of funding.

Indirect effects

Most health effects considered in non-ionizing radiation protection are direct effects. However, health effects can also arise from indirect pathways. For instance they may occur from an electric discharge arising from metallic objects charged by exposure to some types of non-ionizing radiation; these types of indirect effects are considered by ICNIRP. Other types are not, for example, heating of metallic objects in the body, such as prostheses, or an influence on the operation of medical devices such as pacemakers. The latter electromagnetic interference effects are of a technical nature and do not fall within the remit of ICNIRP. Technical standards bodies normally set minimal requirements for the tolerance of equipment to external influences (while usually also setting limits for exposure of humans from the equipment).

Substantiated effects

ICNIRP sets its exposure guidelines only on the basis of scientifically substantiated effects. Depending on the type of study (epidemiological or experimental), different criteria are used to determine whether an effect is substantiated (or verified), but there are several criteria common to all types of study. In general, an effect needs to be observed in more than one study. An obvious requirement is that studies are performed according to accepted scientific practice and quality criteria. For experimental studies these include, but are not limited to, adequate dosimetry and inclusion of a sham-exposed group. For epidemiological studies an adequate description of the investigated population group, well-defined exposure contrasts and adequate identification and control of confounding factors and minimization of bias are essential. These are included in the criteria formulated by Bradford Hill (1965), and are important in determining the likelihood of causality. The analysis of data should be performed using appropriate statistical procedures. Further, the results should be explicable more generally within the context of the scientific literature. In the ICNIRP documents, "evidence" is used within this context, and "substantiated effect" is used to denote reported effects that satisfy this definition of evidence.

The search for and analysis of relevant studies should to the extent possible be carried out according to systematic procedures following a priori defined protocols. ICNIRP may use comprehensive and systematic reviews performed by competent non-commercial national and international organizations, such as WHO, as the basis for its health risk evaluation.

ICNIRP values and takes into account the opinions of other scientific experts, both members of the SEG and others, in assessing whether an effect is scientifically substantiated. However, the final determination is made by the Main Commission of ICNIRP.

Health effect threshold

When a reported effect is considered by ICNIRP to be substantiated, the next step is to determine whether it is adverse to humans or the environment, and if so, whether there is an adverse health effect threshold. An adverse health effect threshold is the lowest exposure level known to cause Health Physics

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the health effect. If no such threshold can be explicitly obtained, ICNIRP sets an "operational threshold" that is based on knowledge of the relation between exposure and adverse health effect. The adverse health effect threshold (or the operational threshold) then forms the basis for setting exposure limits.

Reduction Factors

Studies of biological and adverse health effects invariably carry uncertainties. There is biological variability in responses, both between individuals from the same species as well as between species. In addition, there is uncertainty in the dosimetry, i.e., the assessment of the exact exposure level or dose received by the biological entity. This applies to both measurements (where inherent uncertainties of measuring equipment are important) and to calculations (where most uncertainties arise from the models used and the electromagnetic parameters assigned to tissues). In setting exposure guidelines, ICNIRP takes all these uncertainties into consideration, as well as the degree of importance to health of the effect, by applying a range of conservative steps, including the application of reduction factors to the adverse health effect threshold. Reduction factors may vary depending on the severity of the impact on health, and on the degree of certainty with which the health effect level has been obtained. Under certain circumstances there may be no need to apply a reduction factor because the effect threshold is known with high precision. This part of the exposure guideline setting process is largely dependent on expert judgement.

Basic restrictions and reference levels

For electromagnetic fields with frequencies below 300 GHz, the actual exposure limits in the guidelines are called basic restrictions. Several of these are provided as internal physical quantities that are impractical to measure, such as the electric field inside an organism for low frequencies, or the absorbed energy for radiofrequencies. Therefore, reference levels utilize quantities that are more practical to measure: the external electric and magnetic fields that an individual would be exposed to. They are provided as alternative means of showing compliance with the mandatory basic restrictions. The reference levels are calculated so as to be highly conservative under typical exposure scenarios. As a result, it can be assumed that under most exposure scenarios, if the reference levels are not exceeded, the basic restrictions also would not be exceeded. Further, because of the conservative nature of the calculation of the reference levels, exceeding them does not necessarily imply that the basic restrictions are exceeded. If the reference levels are exceeded, it has to be determined by other means whether there is compliance with the basic restrictions.

As a result of the application of reduction factors, the basic restrictions would need to be exceeded by a substantial margin in order to result in harm, and small violations are unlikely to result in an adverse health effect.

The guidelines for optical radiation do not use the concept of basic restrictions and reference levels, but instead use exposure limits. In the few cases where internal metrics are dose-limiting, these are linearly correlated with external metrics that are then used to assess compliance.

Revision of limits

Estimates of thresholds and their associated exposure limits may not be precise. ICNIRP acknowledges this and accordingly incorporates a conservative approach within a number of stages of the guideline setting process. Also after release of any guidelines, ICNIRP continues to monitor the relevant scientific developments and updates the limits when deemed necessary. Where potential changes to existing ICNIRP limits are considered, the magnitude of the change relative to the uncertainty in the threshold for adverse health effects is considered in determining whether a change is required.

Transparency

Descriptions of procedures and deliberations specific to various frequency or wavelength regions and sources of information are disseminated by ICNIRP in its scientific reviews, exposure guidelines, statements, and practical guidance, as well as during public presentations and forums.

ICNIRP considers it important for all steps in the guideline setting process to be transparent about why and how decisions are made. This means that detailed rationales are provided in the guidelines and sufficient references to the basic scientific material are given.

Draft guidelines are made available for public consultation via the ICNIRP website. All comments received are duly considered by ICNIRP and may be reported on the website. However, it is not a general policy to report back to all individuals or organizations regarding ICNIRP's response to their comments.

Concluding remarks

ICNIRP uses standard procedures to arrive at its guidelines for limiting exposure. These guidelines are established using a conservative approach, which means that compliance with the recommended exposure limits will provide a very high level of protection from substantiated adverse health effects due to the exposure.