INTERNATIONAL COMMISSION ON NON-IONIZING RADIATION PROTECTION

ICNIRP STATEMENT

GENERAL APPROACH TO PROTECTION AGAINST NON-IONIZING RADIATION PROTECTION

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International Commission on Non-Ionizing Radiation Protection*

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INTRODUCTION

This document explains the approach that ICNIRP uses in providing advice on protection against non-ionizing radiation (NIR) exposure to serve both as a guide for the understanding of ICNIRP's documents and for its future work. The activities of ICNIRP are delineated, and the relationships with other advisory and legislative bodies are described. Furthermore, ICNIRP's current general approach to the assessment of health risks as a basis for the development of guidelines on limiting exposure is explained.

Issues dealt with by ICNIRP relate to optical radiation (ultraviolet, visible and infrared) including lasers and electromagnetic fields (microwaves, other radiofrequency fields and fields of lower frequencies down to and including static electric and magnetic fields). Ultrasound and infrasound exposures may also be considered.

ICNIRP'S ROLE IN NON-IONIZING RADIATION PROTECTION

ICNIRP is an independent group of experts established to evaluate the state of knowledge about the effects of NIR on human health and well being, and, where appropriate, to provide scientifically based advice on non-ionizing radiation protection including the provision of guidelines on limiting exposure. For other approaches to protection against suspected harmful effects of NIR, the evaluation of literature by ICNIRP may serve as a valuable input. ICNIRP is the successor of the International Non-Ionizing Radiation Committee (INIRC) of the International Radiation Protection Association (IRPA) since 1992, and still retains a close association with the latter.

ICNIRP, as an international scientific advisory body, does not address social, economic, or political issues. Membership of ICNIRP is limited in time and also to experts who are not affiliated with commercial or industrial enterprises. Thus, ICNIRP is free of vested commercial interest.

ICNIRP is the formally recognized non-governmental organization in NIR protection for the World Health Organization (WHO), the International Labour Organization (ILO), and the European Union (EU). It maintains a close liaison and working relationship with other scientific and technical bodies. These include the International Electrotechnical Commission (IEC), the European Committee on Electrotechnical Standardisation (CENELEC), the European COST (Co-operation in the Field of Science and Technology) Actions in this field, the International Commission on Illumination (CIE), the American Conference of Governmental and Industrial Hygienists (ACGIH), the International Standards Organization (ISO), the International Commission on Occupational Health (ICOH), the Institute of Electrical and Electronic Engineers (IEEE), and the U.S. National Council for Radiation Protection and Measurement (NCRP). ICNIRP also enters into consultation with IRPA national radiation protection societies.

ICNIRP continuously monitors and periodically carries out critical reviews of the scientific literature concerned with the physical characteristics and sources of NIR and possible biological and adverse health effects. In doing so, ICNIRP limits its surveillance to published original scientific papers and reports that are generally available. ICNIRP performs such critical scientific analysis by evaluating the relevance and scientific quality of each report. To assist in this ongoing review process, ICNIRP has formed a number of scientific Standing Committees whose membership includes additional experts. In addition, the Commission may appoint further experts as consulting members. ICNIRP can be seen as a repository of information on the epidemiological, medical, biological, physical, and technological aspects of NIR.

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ICNIRP disseminates information on specific topics of importance to NIR protection and formulates its advice by means of scientific reviews, proceedings of scientific symposia, statements on specific topics, guidelines on limiting exposure, and practical occupational exposure guides (in collaboration with ILO). In accord with its collaboration with WHO, ICNIRP contributes scientific advice to that body.

ICNIRP recognizes that the acceptability and adoption of a complete system of protection also requires data and evaluations based on social, economic, and political considerations. It is ICNIRP's view that these matters are more appropriate to the functions of national governments and their designated authorities. ICNIRP and other scientific advisory bodies may, however, provide background information of relevance for such evaluations.

Whereas ICNIRP provides general practical information on measurable levels that are derived from basic restrictions on exposure, it recognizes the need for further technical advice on special exposure situations. This requires physics and engineering expertise to develop practical measures to assess and/or to enable assessment of compliance with ICNIRP exposure guidelines. This includes guidance on the principles and practice of measurements, design of equipment and/or shielding to reduce exposure, and, where appropriate, setting emission limits for specific types of devices. ICNIRP considers that these matters are more appropriate to the functions of international, regional, and national technical standards bodies.

APPROACH TO HEALTH RISK ASSESSMENT

Any single observation or study may indicate the possibility of a health risk related to a specific exposure. However, risk assessment requires information from studies that meet quality criteria as listed in the Appendix. Peer-reviewed literature usually provides information to judge the extent to which these criteria are met. Assessment of established risks normally requires consistent information from several such studies. ICNIRP, in carrying out its critical reviews, monitors the accumulation of new evidence, leading, as appropriate, to updating health risk assessments. These are based on the totality of the science, not just on the added information. In some cases, for example when a specific question or concern arises in public debate, or when a study appears that has or is perceived to have a major influence on the state of knowledge, a statement summarizing the scientific situation may be issued by ICNIRP. It is important to recognize that all assessments are based on current knowledge, and as such will be subject to revision in the light of new substantiated evidence.

The following sections deal with the nature of health effects and how they can be related to exposure. In subsequent sections, methods for categorizing and evaluating studies are presented, including how conclusions are drawn from the compiled and evaluated database.

Nature of health effects

Exposure to NIR may cause different biological effects, with a variety of consequences for a human being. Biological effects may be without any known adverse or beneficial consequences, other effects may result in pathological conditions (diseases), while still other biological effects have beneficial consequences for a person. Annoyance or discomfort may not be pathological per se but, if substantiated, can affect the physical and mental well being of a person and the resultant effect should be considered as a potential health hazard. ICNIRP seeks to define what is meant by adverse effects in its specific scientific reviews and guidelines. Examples are provided in Tables 1 and 2.

In determining whether an adverse effect is present in a person, it is useful to consider the different ways data have been obtained. Results of tests (e.g., chemical analysis of blood) may be read off an instrument. Signs are effects that may be observed by a physician or other examiner, e.g., a rash or swelling. Symptoms are effects that only the exposed subject experiences, e.g., pain, nausea, or fatigue. A diagnosis of disease is normally based on an agreed specific combination of such endpoints.

Biological effects without any identified adverse health consequences do not form a basis for limiting of exposure to NIR. However, ICNIRP recognizes that concern about other unsubstantiated health effects may in itself adversely affect the health of a person, and that this may be best addressed by providing appropriate information. The scientific evaluations performed by ICNIRP and other scientific advisory bodies could form a basis for such information.

If, in parallel to adverse effects, beneficial health effects or other benefits are involved, a balanced judgement will be required as to how the exposure limits are used in the process of societal policies on addressing risks. Benefits may be manifested both on an individual and at a societal level, one example being the information carried by electromagnetic fields for radio and television services. However, as such a balance will often involve social or economic considerations, this judgement is best performed by national authorities.

The question of whether a biological or physiological parameter (such as temperature or blood pressure) falls within the "normal range" is frequently posed. The implications of this in terms of adverse health effects will depend on the particular endpoint under consideration and may vary between populations and with the environment.

The exposure guidelines developed by ICNIRP are intended to protect against the adverse health effects of NIR exposure. Because adverse consequences of NIR exposure can vary across the entire range from trivial to life threatening, a balanced judgement is required before deciding on exposure guidance.

Exposure and dosimetry

A physical agent has to interact with the target tissue in order to induce a biological effect. The agent external

Table 1. Relevant mechanisms of interaction, adverse effects, biologically effective physical quantities and reference levels used in different parts of the optical spectrum.

Part of optical spectrum	Relevant mechanisms of interaction	Adverse effect	Biologically effective physical quantity	Exposure, reference level
Ultraviolet radiation UVA, UVB, UVC (180 to 400 nm).	Photochemical alterations of biologically active molecules such as DNA, lipids, and proteins.	Acute erythema, keratitis, conjunctivitis, cataracts, photoretinitis, accelerated skin aging, skin cancers.	Fluence and action spectrum weighted radiant exposure.	Radiant exposure at skin or cornea.
Visible radiation (380 to 600 nm).	Photochemical alterations of biological molecules in the retina.	Photoretinitis (“blue-light hazard”).	Retinal radiant exposure weighted by action spectrum.	Radiance and exposure duration.
Visible and near-infrared radiation (IRA) (400 to 1,400 nm).	Thermal activation or inactivation.	Thermal injury: skin burns and retinal burns.	Irradiance, radiant exposure and absorbing volume (spot size) at tissue site.	Radiance and exposure duration.
	Photocoagulation.	Thermal denaturation of proteins, tissue coagulation/necrosis.		
Middle (IRB) and far-infrared radiation (IRC) (3 μm to 1 mm).	Thermal activation or inactivation. Coagulation.	Thermal injury: skin and cornea1 burns, cataracts. Thermal denaturation of proteins. Tissue coagulation/necrosis.	Irradiance, radiant exposure and absorbing volume (spot size) at tissue site.	Radiant exposure and irradiance at skin or cornea.
Laser radiation (180 nm to 1 mm).	Photochemical, photothermal, photoacoustic, exposure duration $<$ 100 μs. Photoablative exposure duration $<$ 100 ns. Bubble or plasma formation (change of phase). Non-linear optical effects.	Tissue damage. Skin burns. Ocular burns. Tissue vaporization.	Radiant exposure and irradiance.	Radiant exposure and irradiance at skin or cornea; exposure duration.

Table 2. Relevant mechanisms of interaction, adverse effects, biologically effective physical quantities and reference levels used in different parts of the electromagnetic field spectrum.

Part of NIR spectrum	Relevant mechanism of interaction	Adverse effect	Biologically effective physical quantity	Exposure, reference level
Static electric fields.	Surface electric charges.	Annoyance of surface effects, shock.	External electric field strength.	Electric field strength.
Static magnetic fields.	Induction of electric fields in moving fluids and tissues.	Effects on the cardiovascular and central nervous system.	External magnetic flux density.	Magnetic flux density.
Time-varying electric fields (up to 10 MHz).	Surface electric charges.	Annoyance of surface effects, electric shock and burn.	External electric field strength.	Electric field strength.
	Induction of electric fields and currents.	Stimulation of nerve and muscle cells; effects on nervous system functions.	Tissue electric field strength or current density.	Electric field strength.
Time-varying magnetic fields (up to 10 MHz).	Induction of electric fields and currents.	Stimulation of nerve and muscle cells; effects on nervous system functions.	Tissue electric field strength or current density.	Magnetic flux density.
Electromagnetic fields (100 kHz to 300 GHz).	Induction of electric fields and currents; absorption of energy within the body.	Excessive heating, electric shock and burn.	Specific energy absorption rate.[a]	Electric field strength; magnetic field strength; power density.
	$>$ 10 GHz: Surface absorption of energy.	Excessive surface heating.	Power density.	Power density.
	Pulses $<$ 30 μs, 300 MHz to 6 GHz, thermo-acoustic wave propagation.	Annoyance from microwave hearing effect.	Specific energy absorption.	Peak power density.

aged over an appropriate period of time and mass of tissue.

to the body and the biological endpoints are directly measurable, but the decisive interaction at the target is usually not. It is the nature (e.g., photochemical reactions or the induction of an electric current) and the efficacy of this interaction that determines the biological effect. Hence, the biologically effective quantity, which represents the efficacy by which a certain biological effect is induced, needs to be quantitatively linked with the associated external radiation or fields.

From this it follows that different types of effects may be related to different biologically effective quantities. This is clearly seen when comparing biological effects in different parts of the NIR spectrum. In addition, within a specific NIR spectral region, different effects may also be related to different biologically effective quantities (Tables 1 and 2).

A good understanding of the fundamental interaction and a correspondingly accurate definition of the biologically effective quantity are necessary when results from animal and in vitro experiments are used to evaluate possible responses in humans.

Relations between biologically effective quantities and effects

According to a simple but useful model, a biological effect can result from one of two processes: deterministic or stochastic. With the former, the magnitude of the effect is related to the level of exposure, and a threshold may be defined. A stochastic process, on the other hand, is one where the exposure determines the probability of the occurrence of an event (the biological effect) but not the magnitude of the effect. In principle, this distinction requires an understanding of the underlying mechanism. Thus, an important distinction is that some responses have a threshold (i.e., a minimum biologically effective quantity has to be applied for the effect to occur) and others do not. Additionally, different repair and protective processes may eliminate or substantially mitigate any effects of exposure. Such processes may occur at the molecular, cellular, organ, or whole organism level.

When characterizing the effects and their temporal relationships to exposure, it is important to clearly elucidate the meaning of the terms used to describe them.

The adverse effects that have been established most clearly in humans as consequences of NIR exposures are those developing immediately after a short term exposure. This is in contrast to effects that may appear only after a long term exposure and/or a long delay.

A fundamental aspect of any study investigating a potential adverse effect on health is the reliability of the exposure assessment. A lack of knowledge about the basic mechanism (consequentially no proper identification of the biologically effective quantity) constitutes a central problem with reliability. Even in circumstances where the biologically effective quantity has been identified, reliable dosimetry may be either difficult or impossible. For example, in an animal experiment, although the external exposure can be measured adequately, there are practical difficulties in relating this to the biologically effective quantity.

Another important aspect of the reliability of the exposure assessment is the accuracy of the exposure data. This becomes of critical importance in determining the quantitative relationships between exposure and effect. In this process, the determination of geometrical factors related to specific organ exposure (such as eye, skin, brain, or limbs) is important. In epidemiological studies, there is often a difficulty in establishing an individual's total exposure history, and surrogates for exposure are therefore often used.

Like the exposure, the biological effect needs to be adequately determined; i.e., it should be based on well-defined objective criteria. A biological effect may be quantified in several ways, and thus different relationships with exposure may be established. For example, one can measure the degree of an effect displayed by an individual, the percentage of individuals responding depending on the biologically effective quantity, or the relative risks comparing groups with different exposure levels. These measurements differ importantly in the way they contribute to the risk assessment. Dependent on the quality of the exposure assessment, they may also be of limited use for numerical assessment of the relationship between exposure and risk.

If the distribution of exposure can be determined for a population and the relationship between exposure and risk of adverse effect can be quantified, then, in principle, one can estimate the number of individuals who will develop the effect. It is this type of estimate (or, e.g., an estimate of a person's lifetime risk of adverse effects) that is the ultimate aim of a health risk assessment.

If several effects occur, it may be possible to rank them according to the exposure level at which each becomes relevant. The critical effect is the established adverse health effect that is relevant at the lowest level of exposure. In this ranking of effects and defining of the critical effects, additional judgements based on the severity of the effects may, at times, be needed.

Evaluation of data

Hierarchy of data. Because risk assessment is ultimately aimed at human health, ideally the data should be derived from human studies. The relationship between exposure and certain short-term biological effects can sometimes be evaluated from human laboratory studies, whereas data on long term human effects can only be derived from epidemiological studies. However, in spite of their direct relevance, the results of epidemiological studies may not, in themselves, provide sufficient evidence of causal relationships without biological plausibility or supportive data from experimental studies, especially when the suggested risks are small.

Animal experiments are valuable in the analysis of the biological effects and mechanisms, as they involve a complete organism, including all relevant in vivo reactions-at least for the animal. Long term animal experiments are useful when considering possible adverse health effects in humans. Such studies may also be useful in clarifying whether a causal relationship exists. In vitro

studies can provide detailed information on biophysical mechanisms at the level of molecular, cellular or intercellular interactions.

The results of animal and in vitro experiments need to be carefully interpreted in order to be meaningfully extrapolated to humans. Based on the premise that the mechanism at the target level is the same in the models and in the human body, the exposure-effect relationships found in the model may be adjusted for application to humans, using the biologically effective quantity. For example, damage inflicted by optical radiation depends on the transmission to the target, and this transmission (in the eye or skin) may vary significantly between an animal (e.g., a mouse) and a human. In general, supportive human data are important for a full evaluation of the relevance to human health of the results from animal studies.

Some clinical reports, although failing to fulfil the quality criteria given above for human health studies, may nevertheless provide complementary information. Anecdotal reports in themselves do not provide a basis for the assessment of risk, because of their inherent poor control and possible observational bias. They may, however, provide an indication of the need for further investigation or advice.

Selection of studies. The use of quality-oriented selection criteria for the literature to be evaluated and clear and transparent methods for its evaluation add confidence that the results and conclusions of the health risk assessment are valid and can be considered to assess possible health hazards from NIR exposure.

The evaluation is normally based on published peer-reviewed original scientific papers and reports. Technical reports may sometimes be acceptable as well, e.g., for details of exposure assessments. In this literature, descriptions of methods are normally given in sufficient detail to ascertain whether reasonable precautions were taken to meet requirements such as those given in the Appendix, and to assure that other researchers can reproduce the studies.

In principle, well-designed and well-conducted studies should be published regardless of the outcome, because negative results are as useful as positive studies when considering the overall literature. In practice, this is not always the case, and the possibility of such publication bias should be considered.

Evaluation process. The evaluation process used by ICNIRP consists of three steps. It is inevitable that parts of this process are a matter of scientific judgement, and that details of the process may vary depending on the question addressed. Hence, the description below provides overall guidelines, not strict rules.

The three steps are as follows:

- Evaluating single studies in terms of their relevance to the health effects being considered and of the quality of methods used. The criteria described in the Appendix can be used as guidance in this evaluation, and may result in the exclusion of some studies from further use, or assigning different weights to studies, depending on their methodological quality. Such judgements should be made in light of the hypothesis to be evaluated, as the ability of a study to contribute to this evaluation may vary depending on the hypothesis.
- For each health effect evaluated, a review of all relevant information is required. At first, this review is normally done separately for epidemiological studies, for human laboratory, for animal studies and for in vitro studies, with further separations as appropriate for the hypothesis.
- Finally, the outcomes of these steps need to be combined into an overall evaluation including an evaluation of consistency of human data, animal data and in vitro data.

ICNIRP's Standing Committees, with support from consulting members as appropriate, normally perform the first two steps of this process, while the full Commission in collaboration with the Standing Committees performs the last step.

Overall evaluation. A decision must first be made whether the data considered allow the identification of an exposure hazard, i.e., an adverse health effect that is caused by an NIR exposure. By this identification, the effect becomes "established" in the sense used in the next chapter. In spite of the evaluation process described above, uncertainties and inconsistencies may still be encountered in comparative evaluations of the literature. Thus, it is recognized that this evaluation is at least partly based on scientific judgements. Various schemes and "criteria" exist in order to facilitate this judgement process (Hill 1965; IARC 1995).

For an actual estimate of risk in the general population or in a specific group, the selected studies should provide additional information, including

- the definition of the biologically effective quantity, which may vary with organ;
- exposure-effect relationship, and identification of a threshold, if any;
- exposure distribution and identification of sub populations with high exposure; and
- differences in susceptibilities within a population.

This information in whole or in part also in principle forms the necessary background for the development of advice including guidance on limiting exposure.

PRINCIPLES OF DEVELOPMENT OF GUIDANCE ON LIMITING EXPOSURE

Following the evaluation of the literature (as described above), it may be possible to identify adverse effects on human health related to NIR exposures that are judged to be well established. The existence of such established NIR effects forms the rationale for the ICNIRP exposure guidelines.

The following sections deal with the nature of the exposure, the effects, their relationships, the individuals being protected, and the use of reduction factors in determining the precise form of the guidelines.

The nature of exposure- effect relationships

Ideally, advice on limiting exposure to NIR can be developed based upon a quantitative relationship between the exposure and the adverse effect. In many cases, such a quantitative relationship could take the form of a threshold. It may then be possible to state a level of exposure below which the adverse effect can be avoided.

If available data permit the identification of an adverse effect, but not the detection of a threshold, other risk reducing strategies may be employed. The role of ICNIRP as a scientific advisory body would be to analyze the risk in terms of levels of consequences that could be quantified. The acceptability of such risks would, however, be based also on social and economic considerations, and, as such, fall outside the remit of ICNIRP. National authorities responsible for risk management may provide further advice on strategies to avoid the effect or limit the risk.

The nature of the effect

The identification of an immediate effect is generally straightforward because the cause and effect relationship can be easily established. Furthermore, the quantitative relationships are more easily determined and validated. If an adverse effect follows the exposure with considerable delay, the identification of an adverse effect requires a more difficult scientific judgement, especially in the absence of a known biophysical interaction mechanism. In addition, even in the case of an identified (delayed) adverse effect, the quantitative relationships between exposure and effect may be difficult to ascertain, because it may be difficult to determine the exposure pattern retrospectively, and the applicable exposure metric may not be known.

In principle, ICNIRP guidelines are set to protect against critical effects of exposure. Accordingly, protection is also offered against all effects occurring at higher exposure levels. However, as the critical effect is related to a specific definition of the biologically effective quantity, other effects may be critical under other exposure definitions. Examples are the formulation of exposure limitations in terms of Specific Energy Absorption (SA), Specific Energy Absorption Rate (SAR), blue light exposure, and exposure rate to the retina.

Exposure characterization

As described above, the biologically effective quantity reflects the efficacy by which the external exposure causes a certain biological effect. This quantitative relationship between external measurable exposures and the target tissue biologically effective parameter is unique to a single exposure condition. Therefore, for a given level of external exposure, any change in the exposure condition may affect the efficacy of the interaction by which a certain biological effect is induced.

In some NIR exposure situations (such as when surface effects are considered), the biologically effective quantity can be conveniently and directly evaluated by measuring external exposures. This is generally the case for all optical radiation and for microwave radiation at frequencies greater than about 10 GHz, as well as for electric fields of low frequencies. For low frequency magnetic field exposures or for electromagnetic fields of higher frequencies, however, this is not the case. In such cases a conservative estimate is made of parameters reflecting the relationship between the identified biologically effective quantity and the external, more easily measured exposure level. This can be achieved by mathematical modeling and extrapolation from the results of laboratory investigations at specific frequencies, using worst case assumptions.

The general strategy of ICNIRP is to define a basic restriction in terms of the biologically effective quantity, and then, if necessary, to relate this to reference levels expressed in terms of a directly measurable external exposure (e.g., ii-radiance, power density, and field strength). In this way, a level (reference level) can be expressed in terms of an external exposure metric. This allows the development of strategies of exposure restrictions based on internal basic restrictions but implemented through reference levels. The use of reference levels ensures compliance with basic restrictions on exposure, since the relationships between them have been developed for situations of maximum absorption or coupling conditions between the external radiation or field and the exposed person (worst case). If the reference level is exceeded, the basic restriction is not necessarily exceeded. Whether this is so must be ascertained through a more detailed investigation. The procedure enables the professional investigator to make measurements as appropriate and interpret the results using his or her professional judgement.

The use of this procedure has several advantages:

- The basic restrictions (in terms of the biologically effective quantities) are closely related to the biological mechanisms, while
- the reference levels are easier to evaluate, and, through further technical evaluations, more easily related to emission levels from sources.

In addition, complicated dosimetric relationships are often avoided in practical occupational hygiene.

In expressing the reference levels, ICNIRP strives to avoid using either overly complex variations with time and frequency (or wavelength) or overly simplified, excessively restrictive expressions. With changing technology, refinements in the reference levels may be made to aid in the ease of applications, provided that the basic restrictions are still met. For the success of this strategy, it is important that the exposure metric has been demonstrated to be the effective one and that the biological mechanism is accepted as relevant for the adverse effects in question.

Reference levels are therefore provided strictly as an aid for practical exposure assessments to determine

whether the basic restrictions are likely to be exceeded. ICNIRP recommends the use of reference levels as a general guidance for limiting exposures of workers and of the general public.

The basic restriction-reference level strategy depends on an understanding of the interaction mechanism and the appropriate development of dosimetric relationships. In some circumstances, an adverse effect may be identified, but the exposure limitation can only be described in terms of the external exposure. In such cases, reference levels may be used to control the exposure directly.

Depending on the specific biophysical mechanism involved in the interaction process, the exposure condition relevant for the biological effect of the non-ionizing radiation can be quantified either in terms of the instantaneous level (or time-dependent function thereof) of the biologically effective parameter or as its time integrated value. Examples of the use of the former include interaction processes involving the heating of tissue (for example infrared absorption rate) and of the latter photochemical processes (for example blue-light effects and ultraviolet radiation induced erythema).

Tables 1 and 2 summarize currently established mechanisms of interaction, adverse effects, biologically effective quantities, and corresponding external exposure parameters across different parts of the NIR spectrum.

People being protected

Different groups in a population may have differences in their ability to tolerate a particular NIR exposure. For example, children, the elderly, and some chronically ill people might have a lower tolerance for one or more forms of NIR exposure than the rest of the population. Under such circumstances, it may be useful or necessary to develop separate guideline levels for different groups within the general population, but it may be more effective to adjust the guidelines for the general population to include such groups.

Some guidelines may still not provide adequate protection for certain sensitive individuals nor for normal individuals exposed concomitantly to other agents, which may exacerbate the effect of the NIR exposure, an example being individuals with photosensitivity. Where such situations have been identified, appropriate specific advice should be developed-within the context of scientific knowledge.

In some circumstances, it may be advisable to distinguish between members of the general public and individuals exposed because of or while performing their work tasks (occupational exposure). In its exposure guidelines, ICNIRP distinguishes occupational and public exposures in general terms. When applying the guidelines to specific situations, it is ICNIRP's opinion that the relevant authorities in each country should decide on whether occupational or general public guideline levels are to be applied, according to existing (national) rules or policies. Environmental conditions may also influence the effect of whole-body exposure to optical or RF radiation.

Many forms of NIR find application in medical practice, often at exposure levels that are much greater than those to which the general population might be exposed. In the case of patients receiving NIR exposures as a part of their medical treatment, ICNIRP considers that the provision of advice on such exposures lies outside the scope of its exposure guidelines. Seriously ill patients might be considered as more vulnerable when exposed to NIR, but ICNIRP guidelines do not consider these potential vulnerabilities because such patients are under active medical management.

The distribution of levels of exposure and the fraction of the population that may be exposed at each level are important factors in relation to exposure guidelines for NIR. Often there are few data on such distributions, but where they exist, they can provide an important insight as to the social and economic impact of implementation of recommended guidelines for NIR exposure.

The use of reduction factors

The identification and quantification of various adverse effects of NIR exposure on health and wellbeing are difficult at best, and such judgements require extensive experience and expertise. Uncertainties in the knowledge are compensated for by reduction factors, and the guidelines will accordingly be set below the thresholds of critical effects. Some of the immediate effects can be quantified with reasonable precision, and derivation of guidelines will not require a substantial reduction below the observed threshold levels. When the precision and certainty of the relationship between exposure and adverse outcome is lower, a larger reduction may be warranted. There is no definite basis for determining the precise magnitude of the reduction factors, and the choice of the reduction is a matter of scientific judgement. As with all the procedures, setting reduction factors should be free of vested commercial interest.

Some examples of sources of uncertainty about exposure-effect threshold levels include the extrapolation of animal data to effects on humans, differences in the physiological reserves of different people with corresponding differences in tolerance, and statistical uncertainties (confidence limits) in the dose-response function. In ICNIRP's view, uncertainty in measurements used to implement the guidelines is a problem more appropriate to the functions of organizations responsible for the development of compliance methods. It is not considered in the setting of reduction factors by ICNIRP.

It should be noted that the use of reference levels may, in many cases, result in additional reductions as they correspond to basic restrictions only under maximum absorption or coupling.

Approaches to risk management

The ICNIRP approach to providing advice on limiting exposure to NIR necessarily requires well-based scientific data related to established health effects. When, in the absence of sufficient scientific evidence for the existence of a suspected adverse health effect, there are

calls for protective measures, a number of approaches to risk management have been applied. These approaches generally center on reducing needless exposure to the suspected agent. However, ICNIRP emphasizes the need to ensure that the practical manner in which such approaches are applied should not undermine or be to the detriment of science based exposure guidelines.

ICNIRP notes the clarification afforded by the European Commission (CEC 2000; Foster et al. 2000) on the practical application of one such approach, the Precautionary Principle. For example, this includes the degree to which the Principle is based on the science (requiring an evaluation of risk research), and the provisional nature of measures pending further acquisition of scientific data.

CONCLUDING REMARKS

This document describes the philosophy and general methodology by which ICNIRP evaluates the scientific literature on possible health risks of non-ionizing radiation, and the procedures by which ICNIRP uses such data in formulating its advice on non-ionizing radiation exposure. In practice, the critical steps in applying these general procedures may differ across the non-ionizing radiation spectrum. Several steps in these procedures require scientific judgement, e.g., on reviewing the scientific literature and determining appropriate reduction factors.

This document provides a transparent general framework for these procedures. Descriptions of procedures and deliberations specific to various frequency or wavelength regions and sources of information are disseminated by ICNIRP in its scientific reviews, guidelines, statements, and practical guides. Through its independence and structure as described in this document, ICNIRP is also well placed to consult widely on these issues.

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APPENDIX

Criteria for the design and evaluation of single studies

The following criteria are primarily intended for use when designing, conducting, and reporting a single study. By their nature, these criteria can also be used as a guide in evaluating studies. It should be kept in mind, however, that useful complementary data might be obtained also from studies that do not fulfil these criteria.

Epidemiological studies

Investigations of associations in people between exposure levels and adverse health effects can utilize both human laboratory and epidemiological studies (for laboratory studies, see below). Epidemiological studies require the fulfillment of a number of criteria that effectively take into account and reduce the possible impact of bias, confounding, and chance variation in the interpretation of results. Guidelines on the conduct of high-quality epidemiology have been given, e.g., by Rothman and Greenland (1998). A summary is given below:

- The study design should attempt to gain maximum efficiency, both in reaching study objectives and in utilizing resources. Depending on the nature of suspected relationships between exposure and adverse health effects, as well as the specific study aim, various designs, such as case-control or cohort, may be appropriate.
- Ascertainment of an adequate population sample size and statistical power should be based on prior statistical evaluation.
- In cohort studies, the study populations should be well defined from the outset. Hypotheses to be investigated must be explicitly and clearly stated. The manner by which cases of adverse health are ascertained must also be clearly stated, and case identification must be independent of exposure.
- In case-control studies, controls should be appropriately chosen, taking into account the specific study aim. This enables the study to minimize the impact of factors other than those under study.
- Regardless of study design, the minimization of non-response, non-participation, and incomplete follow-up

is important, both to achieve the required study sample size, and to minimize the possibility of selective non-response (e.g., related to both disease and exposure status). If response rates are low, the results should be accompanied by an appropriate analysis of non-respondents.

- Both in study design and analysis, researchers should take into account the possibility of confounding factors. Data on potential confounders should be collected and appropriate statistical analysis should be used to minimize the effect of confounding on conclusions.
- Investigators should characterize the exposure as precisely as possible. Data on different levels of exposure, its duration, and temporal location should be collected, and the dosimetric measure utilized should be identified. Preferably, exposure assessment should be on an individual basis. The exposure should be assessed independently of the adverse health status.
- In light of the complexity of the topic, studies should be designed and implemented using expertise from all appropriate scientific disciplines.
- The methods used for statistical analysis should be appropriate for the purpose of the study, and they should be clearly described. The authors should report the basic data on which conclusions are founded.
- To allow combined analysis of several studies in the future, appropriate means to enable this, such as the use of standardized questionnaires, methods, and reporting data, should be considered.

Laboratory studies

Detailed guidelines on the conduct of high quality laboratory research can be found in the good laboratory practice of the US Food and Drug Administration (FDA 1993) and in the specifications of the US National Toxicology Program (NTP 1992). Here, we consider laboratory studies on the effects of NIR on humans, animals and on in vitro systems.

Essential points for the conduct of high quality research are:

- Experimental techniques, methods, and conditions should be as completely objective as possible and based on biological systems appropriate to the endpoints studied. Safeguard from bias, such as double-blind techniques, blind scoring or codes, should be used where appropriate. The sensitivity of the experiment should be adequate to ensure a reasonable probability that an effect would be detected, if one exists.
- Environmental conditions should be measured and recorded periodically (i.e., temperature, humidity, vibration, sound as well as the background levels of appropriate parts of the NIR spectrum). The NIR exposure under study should be fully characterized and re-measured periodically. Where appropriate, detailed descriptions of the dosimetry should be made.
- All data analysis should be completely objective, with no relevant data deleted from consideration and with uniform use of analytical methods. When results are reported as ratios, the underlying data should also be reported or be available for in-depth analysis.
- Studies should be designed with sufficient statistical power so that results demonstrating an effect of the relevant variable at a high level of statistical significance using appropriate tests are obtainable. If studies are non-positive, this should also be demonstrated with some assurance.
- Results should be quantifiable and susceptible to confirmation by independent researchers. Preferably, the experiments should be repeated and the data confirmed independently, or the claimed effects should be consistent with results of similar experiments, for which the biological systems involved are comparable. Theories (e.g., for mechanisms of interaction) should make sufficiently concrete predictions that they can be tested experimentally.
- Results should be viewed with respect to previously accepted scientific principles before ascribing them to new ones. Research findings pointing to previously unidentified relationships should be carefully evaluated and appropriate additional studies should be conducted before the findings are further accepted.
- An indication of the relevance of the model and the endpoint to human health would increase the usability of the results.
- In human experimental studies, such as clinical trials or provocation studies, good practice should include appropriate and well described criteria for inclusion and exclusion of volunteers, and adherence to relevant ethical rules and restraints.

Additionally, some general information can be found in:

- International Commission on Non-Ionizing Radiation Protection. Guidelines on Limiting Exposure to Non-Ionizing Radiation. A reference book based on guidelines on limiting exposure to non-ionizing radiation and statements on special applications. Matthes, R.; Bernhardt, J. H.; McKinlay, A. F. (eds.). International Commission on Non-Ionizing Radiation Protection. ISBN 3-9804789-6-3; 1999.
- International Commission on Non-Ionizing Radiation Protection. Measurement of optical radiation hazards. A reference book based on presentations given by health and safety experts on optical radiation hazards. Gaithersburg, Maryland, USA September l-3: 1998. Matthes, R.; Sliney, D.; DiDomenico, S.; Murray, P.; Wengraitis, S.; Phillips, R. (eds.). International Commission on Non-Ionizing Radiation Protection. International Commission on Illumination. ISBN 3-9804789-5-5; 1998.

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