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PAPER

A coherent framework for non-ionising radiation protection

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Abstract

A coherent and overarching framework for health protection from non-ionising radiation (NIR) does not currently exist. Instead, many governments maintain different compliance needs targeting only some NIR exposure situations. An international framework developed by the World Health Organization would promote a globally consistent approach for the protection of people from NIR. Designed based on decades of practical experience the framework provides guidance on establishing clear national health and safety objectives and how they should be achieved. It supports multisectoral action and engagement by providing a common language and systematic approach for managing NIR. The framework should allow governments to respond to policy challenges on how to achieve effective protection of people, especially in a world that is rapidly deploying new NIR technologies. In this paper the concepts and key features are presented that underpin the framework for NIR protection, including examples of implementation.

1. Introduction

Non-ionising radiation (NIR) refers to the electromagnetic radiation part of the spectrum below ionising radiation (in terms of frequencies). At these lower frequencies, NIR has less energy than ionising radiation and, except for part of the ultraviolet (UV) band and very high irradiance laser beams and intense electric fields (where the air can be ionised), does not generally carry enough energy to cause ionisation. The electromagnetic field spectrum is usually defined from 0 Hz to 300 GHz and the optical spectrum from 300 GHz to 3 PHz (or from 100 nm to 1 mm in terms of wavelengths). NIR also includes mechanical (or acoustic) waves in the infrasound range (frequencies less than 20 Hz) and ultrasound range (frequencies greater than 20 kHz) (ICNIRP 1985) which, although not presenting the same physical phenomena as electromagnetic radiation, show similar physical behaviour.

Many different NIR sources exist all around us. Natural sources of NIR include lightning storms, light from the sun and the Earth's natural electric and magnetic fields. The primary natural source of NIR exposure of health concern for people is the sun, which is necessary for our survival, but solar radiation may be harmful at high levels without proper protection. A range of essential infrastructure services, from wireless communication to power lines, use artificial NIR sources. A number of consumer products utilise NIR, such as mobile phones and lasers, as well as many household appliances such as microwave ovens and Wi-Fi networks. Non-medical applications utilising NIR from lasers to artificial tanning devices are used extensively for cosmetic purposes and wellbeing reasons. In the occupational setting, workers deal with a

wide range of NIR sources from induction furnaces, welding, high-voltage power lines to operation of medical devices. Over the past decades, multiple diagnostic and therapeutic NIR techniques have been developed and are in use in daily clinical practice, such as MRI and ultrasound. Although the world's population is exposed to low levels of NIR every day, exposure to high levels of NIR may occur in some circumstances, potentially resulting in adverse health effects.

Many countries have multiple authorities and regulations in place for parts of the NIR spectrum that deal with only some public, occupational and medical exposures. This creates policy challenges for governments to ensure effective coordination of their functions to deliver the shared goal of ensuring protection and safety of people from NIR risks. Mandatory or voluntary product safety standards are relied upon by all stakeholders for the supply of safe NIR products to the community, but this approach struggles to keep pace with the health evaluation of new and emerging technologies and applications using NIR. Different national laws and regulatory approaches create further challenges. A consumer product which is banned or recalled in one country may still be sold in another. Approaches vary for the regulation of commercial service providers of cosmetic and wellbeing NIR applications, from self-regulation to mandatory oversight by health professionals. These contrasting approaches highlight a lack of coherence between health policy setting, regulation and safety standards on a global scale and give rise to public concern and even create barriers to trade and cooperation.

For decades basic safety standards for ionising radiation have been in place to help inform government regulation (IAEA 2014). In line with the core function of the World Health Organization (WHO) to develop ethical and evidence-based policy positions, the present framework for NIR protection (herein NIR Framework) is being developed. The NIR Framework reflects the importance of establishing globally consistent guidance for national governments.

This activity contributes to environmental health protection which needs to be scaled up to achieve the United Nations Sustainable Development Goals. The NIR Framework addresses the third 'one billion' goal in the WHO Thirteenth General Programme of Work targeting one billion more people with better health and well-being. This activity is supported by the WHO International Advisory Committee on Non-Ionizing Radiation Protection (WHO 2019).

The NIR Framework calls for multisectoral action, and is intended primarily for governmental bodies, including policy-makers and relevant authorities responsible for authorising products and services that use NIR. It is also geared to health and labour authorities, and to a broad range of stakeholders involved in the management of NIR applications and health protection, including professional bodies, service providers, and non-governmental organisations.

For many countries the NIR Framework will provide health and safety authorities the ability to increase consistency of administration, inspection and enforcement while reducing regulatory red-tape. The NIR Framework also fills a unique global gap and will allow countries and government bodies to benchmark their national NIR protection systems against a globally agreed framework. Some countries are also seeking to develop for the first-time health and safety legislation related to NIR protection. Often this is in response to growing public and political concern of potential health effects from new technologies. The NIR Framework will reduce their learning curve to develop their own systems. Enabling countries to harmonise approaches to NIR protection empowers both governments and those responsible for health and safety to implement protection strategies and approaches that promote provision of safe NIR services beyond country boundaries. This paper provides a description of the concepts and key features that underpin the NIR Framework, the implementation of which is intended to protect the people from adverse health effects of exposure to NIR.

2. Health effects of NIR

Health, as defined by WHO, is 'a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (WHO 2006a). Dependent on the energy and exposure time, NIR may cause different biological effects in the human body with a variety of consequences for human health ranging from adverse health effects, no impact on health (no adverse or beneficial consequences), beneficial health effects or a combination of both adverse and beneficial health effects. Annoyance or discomfort may not be a disease by itself but may affect the physical and mental well-being of a person.

Understanding the potential health effects from exposure to NIR is central to the development of standards for protection and safety. It enables an appropriate level of protection for people without unduly limiting the desirable human activities that may be associated with NIR. To make an informed conclusion from all the research studies, it is important to weigh the science in its totality. The NIR Framework relies on reviews of the evidence from international organisations (e.g. WHO Environmental Health Criteria and IARC monographs) and other high-quality national reviews regarding risks to human health.

Beneficial health effects of NIR include vitamin D production and likely lower blood pressure from exposure to portions of the UV radiation spectrum and the positive influence of light for vision and circadian rhythm entrainment.

Adverse health effects will depend on the ability of various types of NIR to interact with the human body and the absorption characteristics of different human tissue. Within the electromagnetic field spectrum, acute health effects from static electric fields are associated with the direct perception of fields through their interaction with body hair and discomfort from spark discharges. Strong static magnetic fields can cause observable effects on the heart and on blood circulation and can induce vertigo and nausea in fields in excess of about 2–4 T. Although transient, such effects may adversely affect the performance of workers executing delicate procedures (e.g. surgeons) with a concomitant impact on safety (WHO 2006b). At high intensity levels, low frequency fields can cause burns and stimulation of nerve and muscle functions (WHO 2007) and high frequency fields can produce excessive heating and burns, hence the need for restrictions near high power sources (e.g. radar and radio transmitters) (WHO 1993). Regarding long-term health effects based on IARC's evaluation of carcinogenicity, extremely low frequency magnetic fields have been classified as possibly carcinogenic to humans (IARC 2002) as have radiofrequency electromagnetic fields (IARC 2013). Static magnetic fields and static and extremely low frequency electric fields are not classifiable as to their carcinogenicity to humans.

In the optical region of the radiation spectrum, examples of acute health effects from infrared include thermal burns, thermal denaturation of proteins and tissue coagulation. Visible radiation (light) can cause photo retinitis, thermal denaturation of proteins and tissue coagulation while UV radiation can cause skin burns, keratitis and photo retinitis. Long-term health effects from UV radiation exposure can cause cataracts, accelerated skin aging and skin and eye cancers. Solar radiation, UV emitting tanning devices and UV radiation have been classified by IARC as carcinogenic to humans (IARC 2012).

In the non-audible acoustic spectrum, acute health effects from infrasound include annoyance and other symptoms resulting from body resonance effects. Depending on the type of application, ultrasound can cause acute erythema, burns and internal haemorrhage, fat atrophy, transient lip and/or brow paralysis and acute eye injury, mostly reported in the context of cosmetic medicine. To date, no long-term effects have been established.

3. NIR protection philosophy

The main aim of the NIR Framework is to provide a coherent set of criteria that are applicable for the wide variety of NIR applications and sources to protect human health.

To assist governments in developing an effective system to meet health and safety objectives for different exposure scenarios, the NIR Framework divides NIR exposures into the following three categories:

- Occupational exposures are incurred by workers as a result of their working activities involving NIR sources.
- Medical exposures are incurred by patients as part of their medical treatment.
- Public exposures cover all exposures of people other than occupational and medical exposures of patients.

Implementation of radiation protection includes making decisions based on available scientific evidence, but also when full knowledge about the health risks associated with radiation exposure may not be available, all the while recognising that social and economic issues also need to be considered.

When there is potential for adverse health effects to occur in parallel to beneficial health effects, a balanced judgement is required as to how protection and safety are addressed and how exposure limitation is applied to ensure a net health benefit. For example, solar UV radiation is both the major cause of skin cancer and a natural source of vitamin D. A balanced judgement is therefore required to reduce the risk of skin cancer from too much sun exposure while maintaining adequate vitamin D levels. Many countries promote sun protection whenever possible, recommending vitamin D from diet or vitamin supplements rather than from exposure to solar UV radiation.

From a broader societal perspective, it is clear that NIR sources provide many benefits to society, e.g. reliable power supplies, the ability to connect renewable energy, improved quality of life, education, economy and safety from mobile communications and better health from NIR medical devices. However some countries have determined that there are some NIR sources and services that are unwarranted and do not benefit society or individuals e.g. keepsake ultrasound photographs, lasers in toys, cognitive enhancement devices and artificial UV tanning devices. Considering the overall balance of impacts of the exposures and the technologies that produce the impacts, it is important to strive for safe products and installations.

While the NIR Framework relies on scientific knowledge, it also considers practical experience. To date, a number of national governments have gained decades of practical experience in NIR protection for some

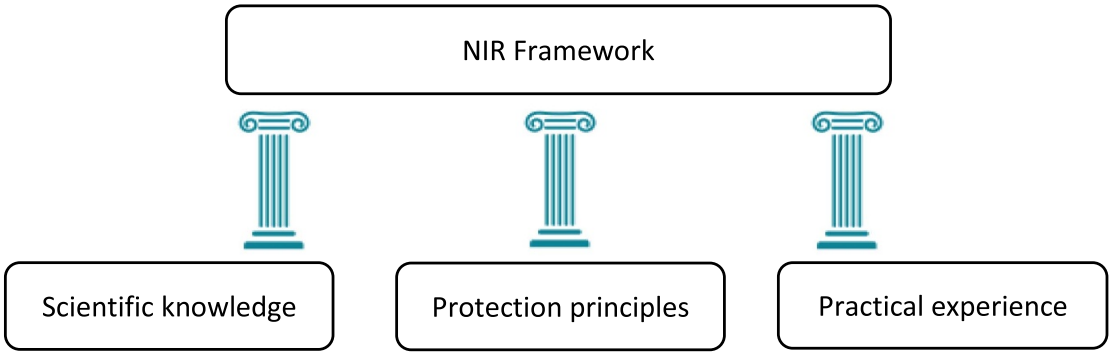

Figure 1. The three pillars of the NIR protection framework.

parts of the NIR spectrum. For example, countries in the European Union have implemented regulations regarding electromagnetic field exposure for the public since the late 90s and for workers for over a decade, but currently lack regulations protecting outdoor workers from solar radiation. Experience has also highlighted the challenges when a technology moves from one user community to another less controlled environment. From the first demonstration of the laser in 1960 until the widespread availability of handheld lasers to the public and particularly children, there were few injuries due to control measures required in the workplace. Since 2011 there have been many reports of children experiencing laser-induced eye injuries. A set of protection principles, that include ethical considerations, further underpins the development of the NIR Framework, which together with scientific evidence and practical experience from countries build a set of coherent criteria (figure 1).

3.1. Protection principles

The management of health risks from NIR exposure rests on a unified set of principles based on current understanding of the effects of NIR and possible associated risks for human health (ICNIRP 2020). The NIR protection principles are defined as:

- Limitation: exposure to any individual from NIR sources other than medical exposure of patients should not exceed the appropriate limits.
- Justification: any decision that alters the radiation exposure situation should do more good than harm.
- Optimisation: a process of balancing risks against benefits.

These principles are applied in various ways across the different exposure categories (figure 2). Differences also occur across the spectrum of NIR, since there are differences in the type of effects and their relevance to health, both in terms of benefits and risks. These principles are similar to those implemented in ionising radiation protection but are applied differently as described recently by the International Commission on Non-Ionizing Radiation Protection (ICRP 103, ICNIRP 2020).

Ethical values play a key role in how the principles of limitation, justification and optimisation should be considered and applied. The NIR Framework relies on the following four core values to help clarify the inherent value judgements made in achieving the aim of protection:

- Beneficence and non-maleficence ('First do no harm') are directly related to the aim of preventing or reducing harmful effects.
- Prudence and precaution enable scientific evidence and its related uncertainties to be constantly considered to encourage value judgements.
- Justice enables social equity and fairness in decisions.
- Dignity and equity mean that every individual deserves unconditional respect, irrespective of personal attributes or circumstances.

The NIR Framework is aligned with the key ethical values in public health (WHO 2015) and the core and procedural values established for the system of ionising radiation protection (ICRP 2018). It recognises the role of ethics in NIR protection, for example the relationship between individual liberty and regulatory restrictions in the use of tanning services, or the deployment of new wireless technologies amidst societal concerns.

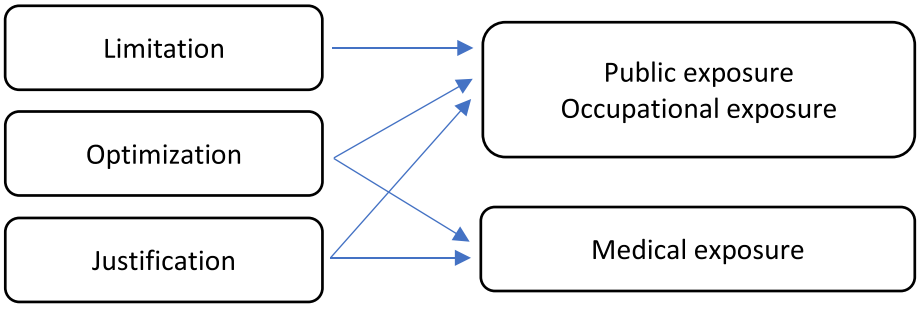

Figure 2. Relationship between the protection principles and the exposure categories.

4. Application of protection and safety

Natural and artificial NIR sources and exposures are ubiquitous. Governments are expected to ensure the protection of the public, workers and patients and the safety of NIR sources. NIR protection is primarily concerned with controlling exposure to radiation and its effects, whereas safety is primarily concerned with maintaining control over sources. Clearly the two are closely connected: NIR protection is very much simpler if the NIR source in question is under control, so safety necessarily contributes towards protection. In the context of NIR, this is most often the case, except for the sun which cannot be controlled at the source, but for which several other measures can be taken to lower health risks.

The NIR Framework calls for governments to consider national policies with clear health and safety objectives that address any exposure situation giving rise to NIR risks. When setting policy, the government needs to identify and address any specific national, regional, social and economic challenges to derive maximum impact of the policy, including regulatory burden and impact on business. In the broad field of NIR exposures, national policies for protection and safety should express a long-term commitment to safety and be promoted as a statement of the government's intent.

The NIR Framework establishes general criteria and criteria for specific categories of exposure to aid those responsible in the implementation of protection and safety.

4.1. General criteria

The NIR Framework describes the following general criteria that are applicable to all three categories of public, medical, and occupational exposure.

- Establishment of a framework of protection,
- Responsibilities for protection and safety,
- Management of protection and safety,
- Provision of information,
- Research and scientific update.

4.1.1. Establishment of a framework of protection and safety

Establishing and maintaining a coherent framework for protection and safety for all categories of NIR exposure would enable the provision of clear evidence-based standards and guidance, e.g. limits for public and occupational exposures and other policy measures for medical exposures.

To achieve this, governments often establish relevant authorities with specified responsibilities and functions, e.g. to set and apply mandatory or voluntary compliance requirements that include consumer product or medical device safety standards, and guidance and advice to achieve health and safety objectives. This includes responsibility for judging the justification of the overall benefit NIR exposure in the broadest sense to society and not necessarily to each individual. Given the wide variety of NIR sources and exposures, a challenge faced by governments is that there are often several authorities that have responsibilities for protection and safety related to exposure to NIR (e.g. ministry of health, ministry of environment, ministry of labour, ministry of energy, ministry of telecommunications). Through effective coordination of their functions, shared goals of protection and safety of people can be established reducing red-tape and strengthening protection.

Governments may also engage other relevant stakeholders (such as industry sectors and civil society) to inform national policy decisions, enabling information exchange, and promoting consensus building and transparency in decision making.

4.1.2. Responsibilities for protection and safety

The person or organisation responsible for services and activities that give rise to NIR risks has primary responsibility for protection and safety needs. Those responsible need to establish and implement a protection and safety programme that is commensurate with the NIR risks associated with the exposure situation and that is adequate to ensure compliance with relevant standards, rules and regulations.

Parties responsible for protection and safety include manufacturers of products and suppliers of services and activities giving rise to public exposure to NIR, employers in relation to occupational exposure to NIR, and health professionals and health care institutions that offer NIR medical applications.

4.1.3. Management of protection and safety

Those responsible for services and activities that give rise to NIR risks should ensure that protection and safety are effectively integrated into their overall management system and that they promote and maintain a safety culture at all levels of the organisation both in the design and use of the service or product.

A management system is a tool designed to assist those responsible to enhance protection and safety by describing the planned and systematic actions necessary to provide adequate confidence in meeting protection and safety objectives. By using a management system and following unified processes regardless of the hazard, those responsible can ensure that NIR protection and safety are not compromised by other requirements.

Those responsible should ensure that personnel engaged in services and activities relevant to protection and safety have appropriate education, training and qualifications so that they understand their responsibilities and can perform their duties competently, with appropriate judgement and in accordance with procedures. This is particularly important in this field as NIR-based technologies are constantly evolving and launched on the market very rapidly.

Review and evaluation of the management system through the life cycle of a NIR service or activity allows identification of good practices and need for corrective actions in relation to equipment, human behaviour and the management system for safety, as well as changes to regulatory requirements and modifications to regulatory practices.

4.1.4. Provision of information

Those responsible for any service or activity that gives rise to NIR risk should communicate to the relevant audience (public, workers or patients) the risks and benefits and, if necessary, inform them about the level of exposure, possible adverse health effects and any measures needed to manage exposures. Messages should be tailored to consider the different audiences that are likely to have different interests, values, education and understanding.

For example, parties responsible for occupational exposure should make suitable arrangements to provide workers with the information, instruction and training necessary to restrict potential exposures. Education may also be necessary for providers of cosmetic services using NIR, for example staff in the sunbed service industry should be taught about the health risks from UV exposure and the need for protective measures (e.g. goggles and limiting exposure duration). Health professionals should be educated about NIR to be able to provide relevant and clear information about treatment options, including the potential benefits, risks, trade-offs and uncertainties of each option, to ensure patients can be actively involved in decisions about their health care.

Awareness programs can also play an important role in promoting positive behavioural change in the public. National sun-awareness and prevention programs delivered through mass media campaigns have proven effective in some countries to reduce the burden of skin cancer.

4.1.5. Research and scientific update

National and international research should be encouraged and supported to enable early detection of emerging risks, fill essential knowledge gaps and inform sound health policy objectives. When considering health effects from exposure to NIR, an interdisciplinary approach is needed. Experts from various disciplines of science, including biology, epidemiology and medicine, as well as physics, engineering, social sciences and public health, need to be involved as all these disciplines play important roles in identifying possible adverse health effects and in providing information on the need for, and approaches to, protection.

Research also builds national competency and provides a platform for educating the next generation of scientific experts. Given that many of the NIR applications and services are used globally, national experts can collaborate at the international level, providing a global research approach to assess current and new evidence and scientific data on health risks, as well on the success of applied protection measures.

4.2. Criteria for specific exposure categories

The NIR Framework describes specific criteria to address the differences between the three categories of public, occupational and medical exposures.

4.2.1. Public exposure

For public exposure, the NIR Framework establishes specific criteria that assign responsibilities to the government, manufacturers and suppliers using NIR. The government is responsible for setting regulatory and compliance expectations, while manufacturers of consumer products and suppliers of services using NIR need to ensure safety. In particular, suppliers of services using large-scale installations (e.g. power grids, wireless networks) should restrict the public from areas where exposure limits may be exceeded. Suppliers of commercial services of cosmetic and other elective applications should be responsible for the safety of clients.

There are important gaps in regulation of some NIR consumer products, for which only the quality of manufacture is addressed, but not the health risks associated with their use. For example, consumer laser products may fully comply with the requirements of the international standard but may not be safe for use by consumers who often have little or no awareness of the risks. Every year there are incidents of eye damage, especially to children. For this reason, several countries are now restricting consumer laser products to certain laser classes but are facing difficulties in controlling personal imports of such products.

A number of medical devices using NIR are being used off-label. An example is UV light, originally used for dermatological conditions such as psoriasis, and now used in artificial tanning devices for cosmetic or wellbeing purposes. These are designed to provide a very high UV dose within minutes and their use has been associated with increased incidence of skin cancers. Momentum has been building among policy-makers to regulate the use of artificial tanning devices, with governments around the world implementing restrictions or even outright bans (WHO 2017). More recently, medical devices used for therapy and treatment of brain function have become available for the public as cognitive enhancement devices. When used outside the clinical setting, these devices are unregulated and do not have to undergo pre-market assessment and only need to meet basic product safety standards, without any information requirements regarding risks and side effects.

4.2.2. Occupational exposure

The NIR Framework aligns with most national governments' approach for employers to provide and maintain safe working environments. It establishes specific criteria that assign responsibilities to different stakeholders. First, the government needs to set exposure limits for workers to prevent occupational diseases or other adverse health effects. Second, employers are assigned responsibility for the protection and safety of workers and need to ensure that protection and safety is optimised and that occupational exposure limit values are not exceeded. Finally, workers have a duty to take care of their own health and safety and must cooperate with employers' efforts to improve health and safety in the workplace.

Skin cancer and eye disease can result from repeated and long-term exposure to solar UV radiation in the workplace. Solar UV radiation is, therefore, a workplace hazard where the risk of overexposure must be reduced as much as reasonably practicable. Employers, by providing a safe working environment should take the proper steps to reduce overexposure to solar UV radiation for workers who spend all or part of their time working outdoors and to carry out workers' health surveillance to ensure the effective protection of workers. To work safely in the sun, workers should follow workplace sun protection policies and procedures (e.g. use personal protective equipment as instructed) and attend instruction and training.

4.2.3. Medical exposure

Over the past decades, multiple diagnostic and therapeutic NIR techniques have been developed resulting in general health care improvement of patients. It is important to ensure that their use does not carry unwarranted risks to health. The NIR Framework sets justification and optimisation as the two cornerstones of NIR protection of patients. For medical exposures of patients, the NIR Framework establishes specific criteria that assign responsibilities to the government to develop and maintain a system for protection and safety from medical exposures to NIR. Health professionals and health care institutions should ensure that responsibility has been assumed for ensuring protection and safety, that no person incurs a NIR medical exposure unless there has been an appropriate referral and that each NIR medical exposure is justified and optimised.

While NIR medical devices are often deemed safe compared to IR devices, they may emit hazardous NIR. Ultrasound diagnostic imaging is an example of a valuable NIR tool for the diagnosis of infectious diseases as well as non-communicable diseases (e.g. breast cancer, cardiovascular disease). In many countries, women are examined with ultrasound at least once and often multiple times during pregnancy. Whether in the context of diagnostic or therapeutic procedures, operator's knowledge of the mechanical or thermal

bioeffects of the technology and of the specifications of ultrasound devices is important for the safety of the patients and users.

Protection strategies, as appropriate, should be established for NIR exposures of carers and comforters. Volunteers participating in a programme of biomedical research involving NIR exposure should be clearly informed of the potential health risks.

5. Conclusion

In this paper, the protection philosophy along with an overarching set of basic safety criteria for health protection from NIR exposures are proposed. General criteria that are applicable to all three categories of public, medical, and occupational exposures are described along with specific criteria to address the particularities of these categories. Such a protection framework is expected to fill existing safety gaps (e.g. in unregulated applications of NIR), assist national governments in the elaboration of their national regulation and promote consistent approaches across the world.

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