INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION

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Participants in the Workshops on Ethics in Radiological Protection

IRPA Associate Societies

Special consultation on the draft report Ethical Foundations of the System of Radiological Protection

Dear Colleagues,

The system of radiological protection is based on three pillars: scientific knowledge that helps us understand how radiation effects people and the environment, ethical values that guide decisions about protection, and experience that teaches us what is practical in implementation.

Over the past three years the Commission has dedicated a significant effort to drawing out the ethical values underpinning the system of radiological protection. This is not the first time that this fundamental pillar has been examined, but it is the first concerted effort to develop an ICRP publication dedicated to it.

Engagement of the radiological protection community in the development of ICRP publications is essential to ensure the best possible system of protection for people and the environment. Normally this means involving a group of experts in the drafting, discussing progress and getting feedback in various forums, seeking comments through a process of open public consultation, and several steps of peer review prior to publication.

The nature of this publication demanded even more. We have engaged not only experts in radiological protection, but also experts in ethics, and individuals who are facing the everyday ethical dilemmas associated with revitalization of communities after the Fukushima Daiichi accident. This was accomplished through a series of six workshops organized in collaboration with ICRP. Four of the six workshops in the core series were organized by IRPA Associate Societies and the other two were hosted by prominent academic institutions: Harvard University in the USA, and Fukushima Medical University in Japan. ICRP also participated in several other similar events in which issues relating to the ethics of radiological protection were discussed.

In addition, we are now organizing an exceptional early consultation on this advanced draft. This targeted consultation seeks comments from the radiological protection community through IRPA, and the individuals involved in the workshops that have driven the development of this publication.

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Please send your comments on this draft to ethics@icrp.org by June 30, 2016. Your contribution will guide the preparation of a next draft that will undergo our usual public consultation.

Sincerely,

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Jacques Lochard, ICRP Vice-Chair

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Donald Cool, ICRP Committee 4 Chair

Kunwoo Cho, Chair of ICRP Task Group 94
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DRAFT

Ethical Foundations of the System of Radiological Protection

CONTENTS

PREFACE

Building on the results of several years of reflection on the ethics of radiological protection within ICRP Committee 4, during its meeting in Fukushima, Japan, in October 2012 the ICRP Main Commission established Task Group 94 of Committee 4 to develop an ICRP publication presenting the ethical foundations of the system of radiological protection.

As stated in the terms of reference for the Task Group, the purpose of this publication is to consolidate the recommendations, to improve the understanding of the system and to provide a basis for communication on radiation risk and its perception. In order to achieve these goals, the Commission asked the Task Group to review the publications of the Commission to identify the ethical and social values associated with the system of radiological protection for occupational, public and medical exposures, and for the protection of the environment.

Given the nature of the work the Commission also encouraged the Task Group to develop its work in close cooperation with specialists of ethics and radiological protection professionals from around the world. With this in mind, a series of workshops was organised by ICRP in collaboration with the International Radiation Protection Association (IRPA) and academic institutions to fully examine, discuss, and debate the ethical basis of the current system of radiological protection with radiation professionals and ethicists. These workshops were held in: Daejeon (Korea) and Milan (Italy) in 2013; Baltimore (USA) in 2014; and Madrid (Spain), Cambridge (USA) and Fukushima City (Japan) in 2015. Presentations were given to spur discussion in group sessions. Presenters were from a variety of backgrounds and fields of expertise. A list of participants is provided in Annex X.

The Task Group also benefited from discussion at an International Symposium on ethics of environmental health in Budweis, Czech Republic in 2014; the fourth Asian and Oceanic congress on radiation protection in Kuala Lumpur, Malaysia in 2014; UK workshop on the ethical dimensions of the radiological protection system in London, UK in 2014; and the third International Symposium on the system of radiological protection in Seoul, Korea in 2015.

The membership of the Task Group is as follows:

K.-W. Cho (Chair)	M.-C. Cantone	S. O. Hansson
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1. INTRODUCTION

1.1. Background

(1) In an address to the Ninth Annual Conference on Electrical Techniques in Medicine and Biology in 1956, Lauriston Taylor, then incumbent President of the National Council on Radiation Protection and Measurements (NCRP), and Chairman of the International Commission on Radiological Protection (ICRP), declared: “Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom.” (Taylor, 1957). By using the term ‘wisdom’, one of the fundamental virtues of the ethical tradition inherited from European classical antiquity, Confucianism, Hinduism, and Amerindian oral traditions, Taylor emphasized that beyond its undeniable and compelling scientific and ethical basis, radiological protection was also a question of insight, common sense, good judgment and experience. Through his formulation, he brought to light the three pillars of the system of radiological protection that had gradually built up for almost half a century, namely science, ethics and experience.

(2) Despite a long recognition that radiological protection is not only a matter of science, but also values, ICRP publications have rarely explicitly addressed the ethical foundations of the system of radiological protection. This does not mean that the Commission has been unaware of the importance of such considerations. Protection recommendations inevitably represent an ethical position, irrespective of whether that position is explicit or implied. As well, the discussion of ethical considerations is not entirely absent from ICRP publications.

(3) Regarding the ethical dimension, it should be pointed out at the outset that there are very few writings devoted to it compared to the vast literature related to the scientific, technical and practical aspects of radiological protection. The first contributions directly addressing the subject only appeared in the 1990s. Among them it is worthwhile mentioning the pioneering contribution of Giovanni Silini who reviewed the ethical foundation of the system during the Sievert Lecture he delivered in 1992 (Silini, 1992). He concluded his lecture emphasizing that the system has been developed rationally, but at the same time with the desire to act reasonably. Also interesting to note are the articles published subsequently by academics questioning the ethical theories underpinning the system (Oughton, 1996; Schrader-Frechette and Persson, 1997) which ultimately led to the recognition that the system of radiological protection can be seen as being based on the three major theories of philosophical ethics that combine the respect of individual rights (deontological ethics), the furthering of collective interest (utilitarian ethics) and the promotion of discernment and wisdom (virtue ethics) (Hansson 2007). In turn, inspired by these reflections, eminent professionals of radiological protection have seized the subject (Lindell, 2001; Clarke, 2003; Streffer et al., 2004; Gonzalez, 2011; Valentin, 2013). Most recently a number of authors explored a variety of western ethical theories along with cross-cultural approaches, covering a range of topics from humanistic considerations focusing on vulnerable populations to a wider view including ecosystems (Zölzer, 2013).

(4) This relatively recent interest in ethical aspects of radiological protection is certainly not unrelated to the difficulties encountered for decades by radiological protection professionals facing the questions and concerns of citizens. The traditional emphasis on the science of radiation has shown its limits and it is now recognized that human and ethical dimensions of exposure situations are important and sometimes decisive in the decision making process.

(5) The lessons learned from the management of the consequences from the Chernobyl accident have certainly played a key role in this awareness (Oughton and Howard, 2012; Lochard, 2013), as have challenges from radioactive waste management (NEA, 1995) and increasing use of medical applications (Malone, 2013). In this context ICRP initiated a reflection on the ethical foundations of the system of radiological protection in early 2010. After an initial phase during which ICRP Committee 4 reviewed the literature on the subject, a Task Group was created in autumn of 2013 on the ethics of radiological protection with the purpose of improving the understanding of the system, providing a basis for communication on radiation risk, and finally consolidating the Commission's recommendations. In order to involve in its reflection ethicists, philosophers, social scientists and radiation protection professionals from different regions of the world, the Commission initiated a series of regional workshops organised in collaboration with the International Radiation Protection Association (IRPA) and academic institutions.

1.2. Objective

(6) This report reviews the publications of the Commission to identify the ethical values associated with the ICRP system of radiological protection for occupational, public and medical exposures, and for protection of the environment. It identifies key components of the ethical theories and principles prevailing in the fields of safety, health, labour, environment, and sustainable development relevant to radiological protection.

(7) A clearer understanding of the core ethical values and related principles of radiological protection will help individuals and societies to address issues emerging from potential conflicts in decision-making. Ethics cannot provide conclusive solutions but it can help facilitate discussions among those seeking to promote the well-being of individuals, the sustainable development of society, and the protection of the environment.

(8) The work leading to this publication is the first concerted effort by the Commission to reflect upon and describe the ethical basis of the system of radiological protection in some detail. The Commission anticipates that this work will be followed with other publications that explore the issues in the context of specific situations and circumstances. Initiating a discussion of both the ethical values and their implementation should make ethical reasoning more accessible to those working in the field, and hopefully encourage them to apply it explicitly in decisions and practice.

1.3. Scope

(9) The scope of this publication is to elicit the core ethical values underlying the ICRP system of radiological protection based on a review of the publications of the Commission and relevant literature on radiological protection and ethics. It also discusses how these core ethical values form the basis of the principles of radiological protection, - namely justification, optimisation, and dose limitation - which are guiding the tools and procedures for practical implementation of the system of radiological protection. See Figure 1.

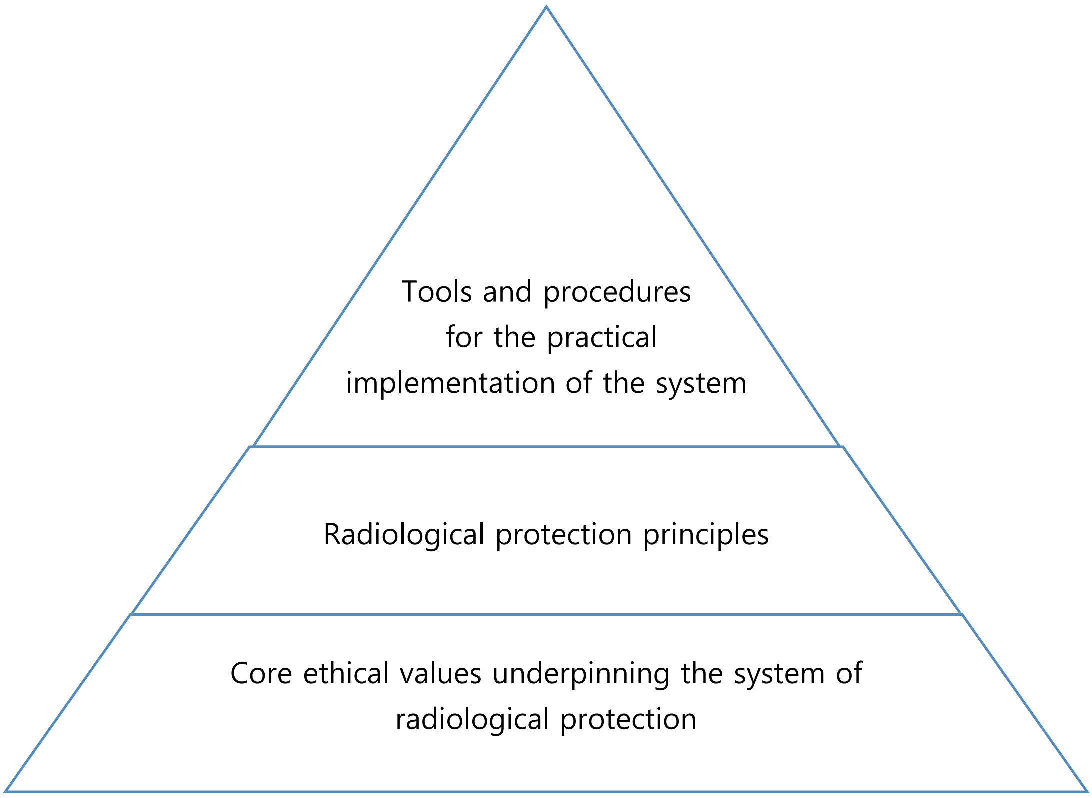

Fig. 1. The ethical dimension of the ICRP system of radiological protection

(10) The Commission recently adopted a Code of Ethics (ICRP, 2015b) setting out what is expected from its members in the development of its recommendations and guidance. In accordance with the Commission's objective this Code emphasizes the need for ICRP members to be committed to public benefit, and to act independently while being impartial, transparent and accountable. These behavioural requirements are beyond the scope of this report, and not discussed further here.

1.4. Structure of this report

(11) Chapter 2 presents the milestones, which marked the evolution of the system of radiological protection since the first ICRP publication in 1928 until today. Chapter 3 describes the core ethical values that shape the system. Chapter 4 addresses the two key concepts of tolerability and reasonableness that form the bridge between these core values and the basic principles of radiological protection. Chapter 5 discusses procedural ethical values for the implementation of the system. In the concluding Chapter 6, suggestions are made for the possible evolution of the system with respect to the ethical dimension.

2. EVOLUTION OF THE SYSTEM OF RADIOLOGICAL PROTECTION

(12) The present system of radiological protection is based on three pillars: the science of radiation combining knowledge from different disciplines, a set of core ethical values, and the experience accumulated from the day-to-day practice of radiological protection professionals. This basis has long been recognized, although explicit guidelines for balanced incorporation of all three pillars in decision-making are not often seen, seemingly because there is no direct, quantifiable way to do this: each pillar informs the others, yet has an individual nature that does not lend itself to a straightforward inter-comparison. Moreover, each exposure situation has unique characteristics or circumstances that need to be considered in making a decision. As such, instead of a fixed, universal response, value judgments are required to assess a particular situation and determine how the pillars should be combined and applied in that instance.

(13) The present system has evolved with this in mind and has matured to more clearly reflect the necessity of value judgments in interpreting risk and making appropriate decisions: "All of those concerned with radiological protection have to make value judgments about the relative importance of different kinds of risk and about the balancing of risks and benefits." (ICRP, 2007a). The guiding actions for radiological protection have been governed by the following questions, which necessitate value judgments in their response:

- Are the circumstances generating exposure justified?
- Are all exposures maintained as low as reasonably achievable under the prevailing circumstances?
- Are the radiation doses that individuals are exposed considered tolerable and/or acceptable?

(14) Of course, to make value judgments there must be corresponding knowledge about the circumstance and the possible implications of actions (information about what "is"), and ethical values on which to base decisions to act (a sense of what "should be"). As this publication is concerned with the ethical basis of the system of radiological protection, the focus here is on the pillar of core ethical values, with the intention of providing support for making value judgments. With the increasing complexity of the science of radiation, the increasing number of exposure situations incorporated into the system of radiological protection, and the growing involvement of stakeholders in the issues related to natural, technological and societal risks, maintaining the coherence of the system and particularly its ethical foundations is a challenge. The following sections describe how the system has progressively evolved during the twentieth century in relation to the historical events associated with the use of radiation and radioactivity. Through these considerations one can gain insight into the consistent set of core ethical values that have underpinned the present system since the beginning.

2.1. The early days: do no harm

(15) The system of radiological protection was born in 1928, with the first recommendations of the International X-Ray and Radium Protection Committee (IXRPC)

(IXRPC, 1928), although some advice had been published much earlier (Fuchs, 1896). Nearly three decades had passed since the discovery of X-rays (Roentgen, 1895), natural radioactivity (Becquerel, 1896) and radium (Curie, 1898), during which time the use of radiation in medicine had skyrocketed.

(16) The formation of the IXRPC (renamed ICRP in 1950) at the 2nd International Congress of Radiology, and their first recommendations, were prompted by a desire by the international medical community to address the sometimes serious skin reactions being observed in some medical practitioners and investigators. These 1928 recommendations focused squarely on protection of "X-ray and radium workers" in medical facilities, and provided advice meant to avoid harmful skin reactions: "the dangers of over-exposure ... can be avoided by the provision of adequate protection".

(17) This advice was based on the best scientific knowledge at the time about the effects of radiation exposure, the experience of nearly 30 years of practice, and the desire to avoid harm. The relatively simple, implicit ethical principle of "doing no harm", was sufficient, as it was thought that straightforward protection measures could keep exposures low enough to avoid injury entirely. The only type of effects known at that time were deterministic effects, which are considered to have a threshold below which no deleterious effects are seen, although they were not described in these terms until decades later.

(18) Over the next two decades the use of radiation continued to increase, not only in the medical field but also in the radium industry. To keep pace, the scope of the system expanded from protection of medical professionals to workers in other occupations. There was also an increasing understanding of the thresholds for various effects. In the 1934 recommendations (IXRPC, 1934) the concept of a "tolerance dose" of 0.2 roentgens per day was introduced. Scientific advancements resulted in refinements in the measures to be taken to avoid doing harm, but the basic ethical principle remained the same.

(19) The 1950 recommendations (ICRP, 1951) saw the first hints of the evolution of the ethical basis of the system beyond avoidance of doing harm, or at least that the practicalities of achieving this aim might be less straightforward than previously thought, recommending that "every effort be made to reduce exposures to all types of ionizing radiation to the lowest possible level".

2.2. A more complex problem: managing risk, a matter of balance

(20) The 1950's saw a growing concern about the effects of exposure to radiation, not only to workers but also to the public and patients. This was fuelled by the atomic bombings of Hiroshima and Nagasaki in 1945 and its aftermath, nuclear weapons testing after World War II causing global contamination, and highly publicized events such as the serious contamination of the Japanese tuna fishing boat The Lucky Dragon, exposed to fallout from a US atomic bomb test in 1954 (Lapp, 1958). The fate of the 23 fishermen aboard was followed closely by the media in Japan and around the world. Most experienced nausea, pain, and skin inflammation, all were hospitalized, and one died, although causality between radiation effects and his death remain controversial.

(21) This growing concern, along with the increasing use of radiation in many fields including the nuclear energy industry, potential hereditary effects suggested by animal experiments, and emerging evidence of increased leukaemia in radiologists and atomic bomb survivors, had a profound influence on the system. The 1954 recommendations (ICRP, 1955) stated that "no radiation level higher than the natural background can be regarded as

absolutely 'safe'" and recommended that "exposure to radiation be kept at the lowest practicable level in all cases". Furthermore, it was in these recommendations that the system first incorporated protection of the public.

(22) Cancer and hereditary effects (also referred to as stochastic effects), for which it was now assumed there is no absolutely safe level of exposure (no threshold), presented a much more ethically complex situation than before. It was no longer enough to avoid doing harm by keeping exposures low enough. The main problem shifted from avoiding harm to managing the probability of harm.

(23) It took many years to develop the framework to deal with this complex situation. In *Publication 9* (ICRP, 1966b), noting the absence of evidence as to the existence of a threshold for some effects, and in view of the uncertainty concerning the nature of the dose-effect relationship in the induction of malignancies, the Commission saw "…no practical alternative, for the purposes of radiological protection, to assuming a linear relationship between dose and effect, and that doses act cumulatively". By adopting this position the Commission was fully aware "that the assumptions of no threshold and of complete additivity of all doses may be incorrect" but it considered that there was no alternative given the information available at that time (ICRP, 1966b). Consequently, as any level of exposure to radiation was assumed to involve some degree of potential harm, in addition to the objective of preventing harm associated with deterministic effects, the Commission added the objective of limiting the probability of occurrence of damage associated with stochastic effects.

(24) This was further elaborated in *Publication 26* (ICRP, 1977), where the primary aim of the system was described as "protection of individuals, their progeny, and mankind as a whole while still allowing necessary activities from which radiation exposure might result". In a sense, protection was constrained to avoid interfering with "necessary activities". This publication also introduced the three basic principles of radiological protection (justification of practice, optimisation of protection, and dose limitation) and was the first attempt to introduce considerations about tolerability of risk to derive dose criteria. In *Publication 60* (ICRP, 1991) the primary aim of the system was reformulated to focus more on balancing the potentially competing priorities of the benefits of protection from radiation and the benefits of the use of radiation, rather than on constraining protection: "to provide an appropriate standard of protection for man without unduly limiting the beneficial practices giving rise to radiation exposure".

2.3. A broader perspective: protecting the environment

(25) The system also expanded its view from human to non-human species. *Publication 26* (ICRP, 1977) was the first to mention of enlarging protection beyond humans, expanding the scope of the system to include protection of the environment. However, it did not go much beyond the assertion that "if man is adequately protected then other living things are also likely to be sufficiently protected". This statement, reworded, was repeated in *Publication 60* (ICRP, 1991) "the standards of environmental control needed to protect man to the degree currently thought desirable will ensure that other species are not put at risk".

(26) Over the next two decades there was a broad increase in environmental awareness, and a rise in societal expectations that protection of the environment must be assured rather than assumed. These ideas took hold globally following the 1992 Rio Declaration on Environment and Development (UNCED, 1992). Reflecting this shift, protection of the environment

was treated more substantially in *Publication 91* (ICRP, 2003) which introduced the ICRP framework for assessing the impact of ionizing radiation on non-human species.

(27) The elaboration of the framework included an explicit reflection on ethical values, touching on the different philosophical worldviews regarding how the environment is valued (i.e., anthropocentric, biocentric and ecocentric approaches) and presenting a selection of internationally agreed principles concerning environmental protection. These were sustainable development, conservation, preservation, maintenance of biological diversity, environmental justice, and human dignity. The publication also addressed procedural principles and operational strategies, including, amongst others, the precautionary principle, informed consent and stakeholder engagement.

2.4. Considering the diversity of exposure situations

(28) In recent decades, the system has been challenged by the widespread impact of the Chernobyl accident in 1986, the concern of malevolent acts following the September 11, 2001 attack on the World Trade Centre in New York City, as well as the increasing awareness of the legacy of areas contaminated by past activities and of the exposure associated with natural sources of radiation. Later, the Fukushima Daiichi accident in 2011 would challenge the system again in much the same way.

(29) No doubt, the core of the system remains the protection of the public, workers, and the environment from radiation sources introduced deliberately in the medical, industrial and nuclear domains. However, these circumstances well controlled, while the examples above highlight the need to also consider more carefully the circumstances where radiation sources are less controlled and the associated exposures raise complex societal issues. So, *Publication 103* (ICRP, 2007a) introduced the idea of "existing exposure situations" and "emergency exposure situations", as distinct from "planned exposure situations".

(30) This new framework better recognizes the distinct natures and associated challenges of the exposure situations resulting from loss of control of planned sources, unexpected events involving an uncontrolled source, and from natural and man-made sources that exist before the decisions to control them are taken (e.g. cosmic radiation or legacy sites). A critical aspect of these situations is that the public may be faced with significantly higher exposure levels compared to those prevailing with controlled sources and it is difficult to manage these situations without directly involving the affected people.

(31) This led the Commission to explicitly introduce “the need to account for the views and concerns of stakeholders when optimising protection” (ICRP, 2007a). This new general recommendation was illustrated shortly thereafter in *Publication 111* (ICRP, 2009b), which emphasizes the role of involving stakeholders in the management of post-accident situations in order for individuals to take informed actions to improve the radiological situation for themselves, their family, and their community. Such an approach implies a certain level of autonomy of individuals, relying on information, advice, and support from authorities and radiological protection experts.

2.5. The system of radiological protection today

(32) Today, the primary aim of the system remains "to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation

exposure without unduly limiting the desirable human actions that may be associated with such exposure" (ICRP, 2007a). For human health, the system aims to "manage and control exposures to ionising radiation so that deterministic effects are prevented, and the risks of stochastic effects are reduced to the extent reasonably achievable". Put another way, effects that can be prevented are prevented and effects where the risk cannot be prevented are managed through optimisation of protection, together with dose limitation. The aims for protection of the environment are to avoid having anything more than a "negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities and ecosystems".

(33) Serving these aims, the present radiological protection system consists of a set of interdependent elements interacting to achieve its objectives. The three fundamental principles of protection are central to the system and apply to the different types of exposure situations (planned, emergency and existing) and categories of exposure (occupational, public, medical exposure of patients and environmental):

- The principle of justification, which states that any decision that alters the exposure situation should do more good than harm. This means that, by introducing a new radiation source in planned exposure situations, or by reducing exposures in existing and emergency exposure situations, one should achieve sufficient benefit to offset any costs or negative consequences. The benefits are deemed to apply to society as a whole, and also to biota.
- The principle of optimisation, which stipulates that all exposures should be kept as low as reasonably achievable taking into account economic and societal factors. It is a source-related process, aimed at achieving the best level of protection under the prevailing circumstances through an ongoing, iterative process. This principle is central to the system of protection and applies to all types of exposure situations and all categories of exposure and thus includes environmental exposures. Furthermore, in order to avoid inequitable outcomes of the optimisation procedure the Commission recommends constraining doses to individuals from a particular source.
- The principle of limitation, which declares that individual exposures should not exceed the dose limits recommended by the Commission, and applies only to planned exposure situations other than medical exposure to patients. The purpose is to ensure an acceptable degree of equity of protection. For the protection of biota, the Commission does not recommend any general form of dose limitation as the need to ensure equity between individuals for human exposures does not apply to protection of the environment.

3. THE CORE ETHICAL VALUES UNDERPINNING THE SYSTEM OF RADIOLOGICAL PROTECTION

(34) As described in Chapter 2, although values were not explicitly referred to in ICRP publications during the development of the principles of justification, optimisation and dose limitation, they played a key role throughout. In retrospect, four core ethical values may be identified that underpin the current system of radiological protection: beneficence/non-maleficence, prudence, justice, and dignity. These are presented and discussed in the following sections.

3.1. Beneficence and non-maleficence

(35) Beneficence means promoting or doing good, and non-maleficence means avoiding causation of harm (Frankena, 1963). These two related ethical values have a long history in moral philosophy, dating back to the Hippocratic Oath, which demands that a physician do good and/or not harm (Moody, 2011). They were formalized in modern medical ethics in the late 1970s following the publication of the so-called Belmont report (DHEW, 1979) and the related seminal work of philosophers Tom Beauchamp and Jim Childress (Beauchamp and Childress, 1979).

(36) In its most general meaning beneficence can be seen to include non-maleficence, although it is sometimes argued that non-maleficence is given more weight than beneficence (Ross, 1930). While stated in this report as a single value, it is recognized that the two distinct components could also be viewed as two separate values. By developing recommendations seeking to protect people against the harmful effects of radiation, the Commission undoubtedly contributes to serving the best interest of individuals and indirectly the quality of social life. This is achieved in practice by ensuring that deterministic effects are avoided and stochastic effects are reduced as far as achievable given the prevailing circumstances. Non-maleficence is closely related to prevention, which aims to limit risk by eliminating or reducing the likelihood of hazards, and thus promote well-being.

(37) In a narrower sense, beneficence includes consideration of direct benefits, both for individuals and communities. The use of radiation, although coupled with certain risks, undoubtedly can have desirable consequences, such as the improvement of diagnostics or therapy in medicine, or the production of electricity. These have to be weighed against the harmful consequences.

(38) A key challenge for beneficence and non-maleficence is how to measure the benefits, harms and risks. In radiological protection this involves consideration of the direct health impacts of radiation exposure in addition to economic costs and benefits. From the viewpoint of evidence-based medicine and public health, a more complete analysis of medical factors that impact health is needed, including radiation and other exposures. In addition, a variety of social, psychological and cultural aspects need to be considered, and there may be agreement neither on what matters, nor on how to value or weight these factors. Nevertheless, it is recommended that such an assessment be transparent about what was included, recognise disagreements where they arise, and go beyond a simple balancing of direct health impacts against economic costs. In this respect it is worth recalling the WHO definition of health: “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” (WHO, 1948).

(39) An evaluation of beneficence and non-maleficence must also address the question of who or what counts in evaluation of potential harms and benefits, including, for example, non-humans and the environment. Protection of the environment was included in the primary aim of the system in *Publication 103* (ICRP, 2007a): "to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure". One could ask whether environmental harm is being avoided for the sake of people (an anthropocentric view), or whether the environment is being protected for its own sake (a non-anthropocentric approach) (ICRP, 2003). ICRP does not endorse any specific approach, and considers both to be compatible with the value of beneficence and non-maleficence.

3.2. Prudence

(40) Prudence is the ability to make informed and carefully considered choices without the full knowledge of the scope and consequences of actions. It is also the ability to choose and act on what is in our power to do and not to do. Prudence therefore has a direct relationship to action and practice. As such prudence is one of the core ethical values underpinning the system of radiological protection.

(41) Prudence has a long history in ethics. It is considered to be one of the main virtues rooted in the Western tradition developed by Plato and Aristotle, the teaching of Confucius, the Buddhist philosophy, and the ancient traditions of the peoples of Eurasia, Oceania and America. Originally prudence signifies “practical wisdom”, which is the meaning of the Greek word “phronesis”. It describes the wisdom of a person who has the reasonableness and morality to make practical decisions.

(42) The system of radiological protection is based on solid scientific evidence, however, there are remaining uncertainties. Value judgments are needed. Decision making requires prudence as a central value.

(43) It is worth noting that the term prudence only appeared in the most recent formulations of the Commission’s recommendations in relation with the linear no-threshold (LNT) model. Thus one can read: “The LNT model is not universally accepted as biological truth, but rather, because we do not actually know what level of risk is associated with very-low-dose exposure, it is considered to be a prudent judgement for public policy aimed at avoiding unnecessary risk from exposure.”(ICRP, 2007a).

(44) More specifically, the term prudence is explicitly used in connection with the different types of effects of radiation considered in the system:

- Deterministic effects - “It is prudent to take uncertainties in the current estimates of thresholds for deterministic effects into account… Consequently, annual doses rising towards 100 mSv will almost always justify the introduction of protective actions.” (ICRP, 2007a).
- Stochastic effects in general - “At radiation doses below around 100 mSv in a year, the increase in the incidence of stochastic effects is assumed by the Commission to occur with a small probability and in proportion to the increase in radiation dose… The Commission considers that the LNT model remains a prudent basis for radiological protection at low doses and low dose rate.” (ICRP, 2007a).

- For heritable effects in particular - “There continues to be no direct evidence that exposure of parents to radiation leads to excess heritable disease in offspring. However, the Commission judges that there is compelling evidence that radiation causes heritable effects in experimental animals. Therefore, the Commission prudently continues to include the risk of heritable effects in its system of radiological protection.” (ICRP, 2007a).

(45) Today, instead of speaking about prudence, policy makers have gradually become used to referring to the so-called precautionary principle, which was popularized by the Rio conference on environment and development (UNCED, 1992). This principle, originally developed in the German and US administration in the 1970s, was later formulated in juridical terms in international and European law, and has been much debated in connection with the ethics of decision making in recent years including in the domain of radiological protection (Streffer et al., 2004). Those who are in favour of the principle see it as a breakthrough in the management of uncertain risk. For detractors the principle is mostly a disincentive to innovation and entrepreneurship.

(46) In fact this debate, often obscured by academic and legal sophistications, does not add much to the experience of over half a century of radiological risk management based on practical wisdom inherited from ancient philosophers. In reality this management, which requires skills in gathering knowledge and making judgments about it can be considered a precursor to a reasoned and pragmatic application of the precautionary principle. Interestingly, the Commission does not elaborate on this point. It just mentions in its most recent recommendations that the use of the so-called LNT model remains a prudent basis for radiological protection at low doses and low dose rates considered “to be the best practical approach to managing risk from radiation exposure and commensurate with the ‘precautionary principle’ (UNESCO, 2005). (ICRP, 2007a).

(47) The implications of this prudent attitude have been significant for the subsequent structuring of the system of radiological protection. A careful study of the evolution of the Commission’s recommendations over the past decades shows that this central assumption led to gradually shaping the system as it stands now (Lochard and Schieber, 2000). This is clearly summarized by the Commission as follows: “The major policy implication of the LNT model is that some finite risk, however small, must be assumed and a level of protection established based on what is deemed acceptable. This leads to the Commission’s system of protection with its three fundamental principles of protection.” (ICRP, 2007a).

(48) In addition, the adoption of a prudent attitude induces a the duty of vigilance vis-à-vis the effects of radiation, resulting in an obligation to monitor and support exposed populations. Specifically, prudence implies the obligation to detect and if necessary treat possible pathologies (induced by radioactivity or otherwise) and to conduct relevant research (e.g. epidemiology, radiobiology, metrology, etc.) in an attempt to reduce existing uncertainties.

3.3. Justice

(49) Justice is usually defined as fairness in the distribution of advantages and disadvantages among groups of people (distributive justice), fairness in compensation for losses (restorative justice), and fairness in the rules and procedures in the processes of decision making (procedural justice).

(50) It must be emphasized that the Commission has not explicitly referred to justice in its previous recommendations. However, the idea of limiting individual exposures in order to correct possible disparities in the distribution of health risks due to radiation among exposed populations appeared as early as *Publication 26* (ICRP, 1977). In *Publication 60* the term inequity is used for the first time: “When the benefits and detriments do not have the same distribution through the population, there is bound to be some inequity. Serious inequity can be avoided by the attention paid to the protection of individuals.” (ICRP, 1991).

(51) Any exposure situation, whether natural or man-made, results in a more or less wide distribution of individual exposures. In addition, the implementation of protection measures can also induce potential distortions in this distribution that may aggravate inequities. In this context, the protection criteria of the system of radiological protection play a dual role.

(52) First, radiological protection criteria aim to reduce inequities in the distribution of individual exposures in situations where some individuals could be subject to much greater exposures than the average. This restriction of individual exposures is done through the use of dose constraints that apply to planned exposure situations and reference levels that apply to existing and emergency exposure situations. Dose constraints and reference levels are integral parts of the optimisation process and thus must be chosen depending on the prevailing circumstances by those responsible for protection.

(53) The second role of protection criteria is to ensure that exposures do not exceed the values beyond which the associated risk is considered as not tolerable given a particular context. This is ensured through the application of dose limits recommended by the Commission for occupational and public exposures for planned exposure situations. As with dose constraints and reference levels, dose limits are tools to restrict individual exposure in order to ensure fairness in the distribution of risks across the exposed group of individuals. However, given the predictable dimension of the planned exposure situations for which the radiation sources are deliberately introduced by human action, the numerical values of dose limits, unlike constraints and reference levels, are generally specified in legal instruments.

(54) Thus, through the protection criteria, the system of radiological protection aims to ensure that the distribution of exposures in the society meets the two principles of social justice. First, the principle of equity in the situations reflects the personal circumstances in which individuals are involved. It is the role of dose constraints and reference levels to reduce the range of exposure to individuals subject to the same exposure situation. Secondly, the principle of equal rights guarantees equal treatment for all with regards higher levels of exposure. It is the role of dose limits to ensure that all members of the public, and all occupationally exposed workers, do not exceed the level of risk deemed tolerable by society and recognized in law. (Hansson, 2007).

(55) Intergenerational justice has been addressed by the Commission for the management of radioactive waste with reference to “precautionary principle and sustainable development in order to preserve the health and environment of future generations” (ICRP, 2013, §14). In *Publication 81* the Commission recommends that ‘individuals and populations in the future should be afforded at least the same level of protection as the current generation’ (ICRP, 1998, §40). In *Publication 122*, the Commission introduces responsibilities towards future generations in terms of providing the means to deal with their protection: “… the obligations of the present generation towards the future generation are complex, involving, for instance, not only issues of safety and protection but also transfer of knowledge and resources.” (ICRP, 2013, §17).

3.4. Dignity

(56) Dignity is an attribute of the human condition: the idea that something is due to person because she/he is human. This means that every individual deserves unconditional respect, whatever age, sex, health, social condition, ethnic origin and religion. This idea has a prominent place in the Universal Declaration of Human Rights, which states that "All human beings are born free and equal in dignity and rights" (United Nations, 1948). Dignity has a long history as the central value in many ethical theories, including Kant's notion to treat individuals as subjects, not objects: "Act in such a way that you treat humanity, whether in your own person or in the person of any other, never merely as a means to an end, but always at the same time as an end." (Kant, 1785). Personal autonomy is a corollary of human dignity. This is the idea that individuals have the capacity to act freely i.e., to make uncoerced and informed decisions.

(57) Respect for human dignity was first specifically promoted in radiological protection with regard to the principle of "informed consent" in biomedical research, which is the idea that a person has "the right to accept the risk voluntarily" and "an equal right to refuse to accept" (ICRP, 1992). The concepts of "informed consent" and "right to know" were clearly established in *Publication 84* on pregnancy and medical radiation (ICRP, 2000). Beyond the medical field, human dignity was explicitly introduced as recognizing "the need for the respect of individual human rights and for the consequent range of human views" in the elaboration of the ICRP framework for the protection of the environment (ICRP, 2003). The Commission has also emphasized the promotion of autonomy through stakeholder involvement (e.g. ICRP, 2007a) and empowerment of individuals to make informed decisions, whether, for example, confronted with contaminated land (e.g. ICRP, 2009b), to radiation in airports (ICRP, 2014b) to radon in their homes (ICRP, 2014c) and to cosmic radiation in aviation (ICRP, 2016). The system of radiological protection thus actively respects dignity and promotion of the autonomy of people facing radioactivity in their daily lives. It is worth noting that the promotion of dignity is also related to a set of procedural ethical values (accountability, transparency, and stakeholder involvement), developed in Chapter 5, which are linked to the practical implementation of the system of radiological protection.

4. TOLERABILITY AND REASONABLENESS

(58) The four core ethical values discussed in Chapter 3 permeate the current system of radiological protection, but their relationship with the three principles of justification, optimisation and dose limitations is complex. This is not so much the case for justification, which can be understood as referring to beneficence/non-maleficence, or rather the balancing of “doing good” and “avoiding harm”. When it comes to optimisation and dose limitation, several of the core ethical values work together, and how they interact in the current system of radiological protection needs to be considered in greater detail. This brings into play two key concepts underlying optimisation and dose limitation, which are reasonableness and tolerability, respectively. Both can be traced back to more basic core ethical values such as prudence, justice, and dignity, and it is the purpose of this chapter to explore how this is done.

(59) In *Publication 1* (ICRP, 1959) the Commission stated that faced with ‘the existing uncertainty as to the dose-effect relationships for somatic effects’ and recommended ‘that all doses be kept as low as practicable’. Recognizing that man cannot completely avoid the use of ionising radiation, it is concluded that in practice it is necessary to limit doses so that the risk ‘is not unacceptable to the individual and to the population at large’. In 1966, the Commission went further: “As any exposure may involve some degree of risk, the Commission recommends that any unnecessary exposure be avoided, and that all doses be kept as low as readily achievable, economic and social considerations being taken into account” (ICRP, 1966b, §52).

(60) It took several decades for the Commission to clarify what was meant by ‘unnecessary exposure be avoided’ and ‘as low as readily achievable’ and on which criteria to ground the decisions about these intentions. However, these recommendations remain the core of the system of radiological protection today and lead to a continuous posing of the following guiding questions: What levels of exposure to radiation are considered by society to be tolerable? Are all tolerable exposures as low as reasonably achievable under the prevailing circumstances?

4.1. Tolerability

(61) The notion of tolerability is present from the early publications of the Commission. It can be found in the 1934 Recommendations under the name of tolerance dose (ICRP, 1934) and later in *Publication 1* (ICRP, 1959) in reference to the limit for the genetic dose (ICRP, 1960). In subsequent publications the notion of tolerability is only implicitly addressed through those of acceptability and unacceptability (ICRP, 1966a; ICRP, 1966b; ICRP, 1977). The notion reappears explicitly again in *Publication 60* with the introduction of the model of tolerability of risk.

(62) In *Publication 26*, which introduced the distinction between non-stochastic and stochastic effects, it is mentioned that: “The aim of radiation protection should be to prevent detrimental non-stochastic effects and to limit the probability of stochastic effects to levels deemed to be acceptable”. (ICRP, 1977, §9). For non-stochastic effects, the prevention consists in adopting an exposure limit below the threshold for occurrence of these effects: “The prevention of non-stochastic effects would be achieved by setting dose-equivalent limits

at sufficiently low values so that no threshold dose would be reached, even following exposure for the whole of the lifetime or for the total period of working life". (ICRP, 1977, §10).

(63) For the protection against stochastic effects, the Commission recommends values of dose limits for occupational and public exposures through comparison with other risks. In this approach, an annual dose criterion (expressed in mSv/y) is derived by dividing an annual level of risk considered as acceptable in other domains (expressed in individual risk of occurrence of fatal effect per year) by the radiation risk coefficient (expressed in risk of occurrence of radiation induced effects per mSv). In 1977, for occupational exposure, this level is considered to be in the range of 10^{-4} per year: "The Commission believes that for the foreseeable future a valid method for judging the acceptability of the level of risk in radiation work is by comparing this risk with that for other occupations recognized as having high standards of safety, which are generally considered to be those in which the average annual mortality due to occupational hazards does not exceed 10^{-4}." (ICRP, 1977, §96).

(64) In defining the annual dose criteria, the Commission introduced considerations on the distribution of individual occupational exposures: "When making comparisons with other safe occupations, it should be realised that the level of risk representative of a safe occupation relates to the average risk for all workers in that occupation, the risk for individual workers varying with their job and being distributed around this average". (ICRP, 1977, §99). This allows the Commission to assume that: "In many cases of occupational exposure where the Commission's system of dose limitation has been applied, the resultant annual average dose equivalent is no greater than one tenth of the annual limit. Therefore the application of a dose-equivalent limit provides much better protection for the average worker in the group than that corresponding to the limit". (ICRP, 1977, §99)

(65) These considerations led the Commission to adopt an annual dose limit of 50 mSv for occupational exposure, assumed to result in an average annual exposure of around 5 mSv and corresponding to a risk of approximately 5 x 10^{-5} per year for fatal cancers and 2 x 10^{-5} for hereditary effects, being in agreement with the average level of risk observed in other occupations.

(66) A similar approach was adopted for defining the annual dose limit for public exposure. In that case, the Commission referred to risks observed in everyday life, considered as acceptable: "From a review of available information related to risks regularly accepted in everyday life, it can be concluded that the level of acceptability for fatal risks to the general public is an order of magnitude lower than for occupational risks. On this basis, a risk in the range of 10^{-6} to 10^{-5} per year would be likely to be acceptable to any individual member of the public". (ICRP, 1977, §118).

(67) Based on the mortality risk factor for radiation induced cancers of 10^{-2} Sv^{-1} (ICRP, 1977, §60), the annual radiation dose corresponding to an annual risk of 0.01 % for the individual member of the public is about 1 mSv per year of life-long whole body exposure. As for occupational exposures, the Commission took into account the dose distribution and adopted an annual dose limit of 5 mSv for occupational exposure, considering that it "is likely to result in average equivalent dose of less than 0.5 mSv". (ICRP, 1977, §120).

(68) Referring to the work of the Royal Society (Royal Society, 1983) and the Health and Safety Executive (HSE, 1988) of Great Britain, in *Publication 60* the Commission introduced a conceptual framework for the tolerability of risk, allowing one to determine the degree of

tolerability of an exposure (or of the associated risk) and thus, depending on the exposure situation, to distinguish between unacceptable and tolerable levels of exposure. This led the Commission to define three levels in this framework (ICRP, 1991, §150):

- Unacceptable: corresponding to levels of exposure that would not be accepted on any reasonable basis in the normal operation of any practice of which the use is a matter of choice; individuals could be exposed to these levels only in exceptional circumstances;
- Tolerable: corresponding to levels of exposure that are not welcome but can reasonably be tolerated;
- Acceptable: corresponding to levels of exposure that can be accepted without further improvement i.e. resulting from the implementation of the optimisation principle.

(69) Figure 2 presents this model schematically, where the dose limit is the boundary between 'tolerable risk' and 'unacceptable risk' (but not the boundary between the ill-defined concepts of 'safe' and 'dangerous').

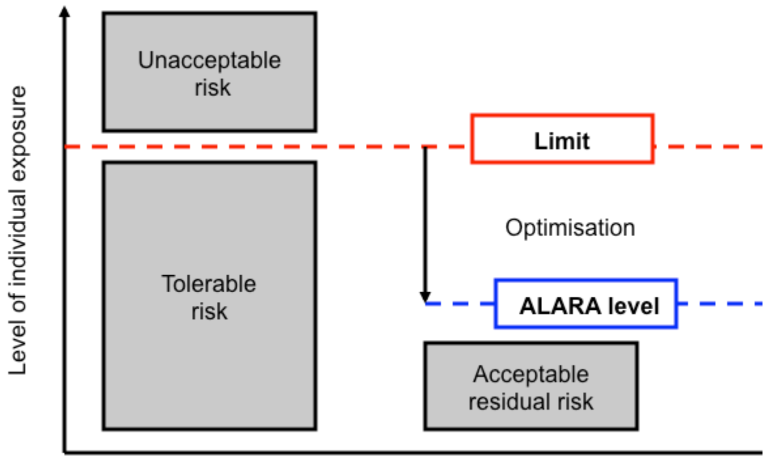

Fig. 2. The concept of the tolerability of risk in ICRP *Publication 60*

(70) With the introduction of the model of tolerability of risk, the Commission defines tolerable exposures as those that are 'not welcome but can be reasonably tolerated', thus linking reasonableness with tolerability. It is clearly stated that reaching the limit is not the ultimate aim of the system of protection. It is only considered as tolerable and exposure should be further reduced taking into account the application of the ALARA principle: "The dose limit forms only a part of the system of protection aimed at achieving levels of dose that are as low as reasonably achievable, economic and social factors being taken into account. It is not to be seen as a target. It represents, in the Commission's view, the point at which regular, extended, deliberate, occupational exposure can reasonably be regarded as only just tolerable." (ICRP, 1991, §169).

(71) The Commission acknowledges the introduction of value judgments for selecting the annual dose limit explaining that it allows taking into consideration a series of "inter-related factors", called "attributes". The following attributes are considered:

- The lifetime attributable probability of death;
- The time lost if the attributable death occurs;
- The reduction of life expectancy (a combination of the first two attributes);
- The annual distribution of the attributable probability of death;
- The increase in the age specific mortality rate, i.e. in the probability of dying in a year, at any age, conditional on reaching that age.

(72) Based on this approach, for occupational exposures, lifetime radiation induced detriments were calculated for exposures of 10, 20, 30 and 50 mSv/y and inter-compared. A dose limit of 20 mSv per year, averaged over 5 years (100 mSv in 5 years, with the provision that the dose should not exceed 50 mSv in one year), was chosen as it gives sufficient protection and offers some flexibility for the worker employment.

(73) For public exposures, a different approach was adopted based on the comparison of the variations in the doses occurring from natural sources: "The approach is to base the judgement on the variations in the existing level of dose from natural sources. This natural background may not be harmless, but it makes only a small contribution to the health detriment which society experiences. It may not be welcome, but the variations from place to place … can hardly be called unacceptable. " (ICRP, 1991, §190). As the annual effective dose from natural sources (excluding radon) is about 1 mSv/y, the Commission recommends 1 mSv/y as the dose limit for the public (with some flexibility under special circumstances).

(74) One of the major evolutions of the ICRP recommendations in *Publication 103* relies on the focus on the three exposure situations (i.e. existing, emergency and planned) for implementing the system of radiological protection. The reference to the tolerability is no longer based on quantitative values of risk but is now considered specifically in each exposure situation taking into account the various characteristics of the situation and not only the risk associated with the exposure.

(75) In terms of risk, the Commission gives general guidance to be applied in any exposure situation, and referring to avoidance of certain health risks: "At doses higher than 100 mSv, there is an increased likelihood of deterministic effects and a significant risk of cancer. For this reason the Commission considers that the maximum value for a reference level is 100 mSv incurred either acutely or in a year." (ICRP, 2007a, §236). Instead of adopting a generic level of tolerability, the Commission proposes a more pragmatic approach including various components for selecting dose constraints or reference levels according to the specific exposure situation: "For the selection of an appropriate value for the dose constraint or the reference level one should consider the relevant exposure situation in terms of the nature of the exposure, the benefits from the exposure situation to individuals and society, … and the practicability of reducing or preventing the exposures." (ICRP, 2007a, §242). For this purpose, the Commission proposes three bands of dose constraints and reference levels: greater than 20 mSv/y to 100 mSv (acute or in a year), greater than 1 to 20 mSv/y and 1 mSv/y or less (see ICRP, 2007a, Table 5).

(76) The reflection on tolerability has moved progressively from the quest for a level of risk considered as tolerable towards considerations of tolerability in the particular exposure situations. There is no universal value of risk considered to be tolerable in all circumstances. Thus, the definition of a dosimetric criterion (reference level or dose constraint) is intrinsically linked to the practical implementation of the system of protection and the optimisation principle. This criterion depends on the exposure situation and has to be defined with the involvement of the stakeholders. Nonetheless, the Commission maintains dose limits for protection of individuals from all regulated sources in planned exposure situations.

4.2. Reasonableness

(77) Reasonableness refers to reciprocity in the sense of a situation or a relationship in which two or more people or groups agree to do something similar for each other. It relies on the development of a reasoning accessible to others and the promotion of a fair cooperation. Reasonableness is linked to the core ethical values of justice and prudence. Reasonableness is considered an expression of wisdom, defined as “the quality of having experience, knowledge, and good judgement” (Oxford Advanced Learner’s dictionary). As a virtue, wisdom is the disposition to behave and act with the highest degree of adequacy under any given circumstances. In its popular sense, wisdom is attributed to a person who takes reasonable decisions and acts accordingly.

(78) In the 1950s, the Commission introduced the concept of reducing exposure as a cornerstone of its recommendations to deal with protection against stochastic effects: “Due to the uncertainty of the dose–effect relationship for stochastic effects, the use of a limit was no longer a guarantee of the absence of risk. This led the Commission to adopt a prudent attitude and to recommend ‘that every effort be made to reduce exposures to all types of ionising radiation to the lowest possible level’ (ICRP, 1955, §VI). This position facilitated the Commission’s introduction of the optimisation principle two decades later. (ICRP, 2006, §7).

(79) Table 1 summarizes the evolution of the optimisation principle, pointing out the introduction of economic and societal considerations and the place dedicated to reasonableness.

Table 1. Evolution of the wording of the optimisation principle

Formulation				Year
To **reduce** exposures	to the **lowest**	**possible** level		1955
To **keep** exposures	**as low as**	**practicable**		1959 (Pub. 1)
To keep exposures	as low as	**readily achievable**	**economic and social considerations** being taken into account	1966 (Pub. 9)
To keep exposures	as low as	**reasonably** achievable	economic and social considerations being taken into account	1973 (Pub. 22)
To keep exposures	as low as	reasonably achievable	economic and social **factors** being taken into account	1977 (Pub. 26)
To keep exposures	as low as	reasonably achievable	economic and **societal** factors being taken into account	2007 (Pub. 103)

(80) *Publication 22* was the first publication entirely devoted to the elucidation of the optimisation principle. It introduced the methodology of cost-benefit analysis as an approach to determine "the acceptability of levels of exposure to radiation proposed for a given activity…" This methodology played a leading role structuring practical implementation of the principle. The main objective of this methodology is to balance the risk associated with exposure (expressed in terms of radiation detriment) with the benefit provided by the activities or the situation for a given group of population: "It is then helpful to express the population dose not only in man-rems, but also in social and economic terms, for example, in terms of detriment or monetary units, so that the advantage of a reduction in collective dose can be compared directly with the detriment or cost of achieving this reduction." (ICRP, 1973, §18).

(81) In *Publication 37*, the Commission introduces further considerations on social aspects incorporated in monetary terms with the monetary value of a person-sievert: "…in some complex situations it may be desirable to add the costs associated with additional components of detriment to take account of non-objective features and of non-health detriments". (ICRP, 1983, §87).

(82) In the 1980s and 1990s, economic developments led to define the monetary value of the person-sievert as the probability of occurrence of a radiation-induced health effect associated with exposure to ionising radiation multiplied by the monetary value attributed to that health-effect, generally expressed as a number of years of life lost. Thus, the monetary value corresponds to what the decision-maker is willing to pay to avoid 1 unit of collective dose (Schneider et al., 1997).

(83) This approach has been largely implemented in decision-making processes for the selection of investments in radiation protection in the workplace for which it is generally possible to quantify all the components of the costs and the benefits. However, despite all efforts to anchor the optimisation of protection in the rationality of classical economics, the process to maintain levels of exposure as low as reasonably achievable remains essentially a matter of judgment mixing quantitative and qualitative values and field experience. This led

to the successive incorporation into the optimisation process of components developed in the field of management (ICRP, 1990) and approaches calling on the direct involvement of concerned parties in the implementation of protection (ICRP, 2006).

(84) In *Publication 55*, to incorporate the various components (referred as "attributes") in the decision-making process and to propose a structured approach for the implementation of the optimisation principle, the Commission describes the successive steps of the ALARA (As Low As Reasonably Achievable) procedure and proposed replacing cost-benefit analysis by a multi-attribute analysis for complex situations. The Commission also emphasised the usefulness of ensuring the traceability and transparency of the process: "A structured approach to optimization of protection is important to ensure that no important aspects are overlooked and to record the analysis for information and for assessment by others." (ICRP, 1990, §20).

(85) From the late 1990s, the search for reasonableness led to the development of stakeholder involvement approaches for the selection of protective actions to better cope with the specificities of each exposure situation. For this purpose, the key challenges are to develop evaluation procedures involving stakeholders and also to favour among them the development of radiological protection culture to aid deliberation on what are considered reasonable levels of exposures given the prevailing circumstances. Such procedures have been successfully implemented in the case of post-accident situations and exposure to radon. Such approaches need to foster the emergence of informed and advised stakeholders in order to engage them in dialogue to assess the benefits and drawbacks of various possible protection options for their own protection and well-being.

(86) Stakeholder involvement has been clearly introduced by the Commission in *Publication 101b*, aiming at broadening the process of optimisation of radiological protection: "The basic definition given in *Publication 60* (ICRP, 1991) remains valid, but the way in which it should be implemented is now viewed as a broader process reflecting the increasing role of individual equity, safety culture, and stakeholder involvement in our modern societies…" (ICRP, 2006, §4). Experience with the implementation of the ALARA principle clearly shows that decisions cannot be solely driven by theoretical knowledge and that it is inseparable from the establishment of a deliberative process to determine what to do for the protection of people, based on the specificities and characteristics of the situation.

4.3. Tolerability and reasonableness in practice

(87) For the implementation of the system of radiological protection, the Commission aims to avoid unacceptable risk and to reduce exposure as low as reasonably achievable. These objectives refer explicitly to the concepts of tolerability and reasonableness. Tolerability allows one to define boundaries for implementing the principles of radiological protection, while reasonableness contributes to decision about acceptable levels of protection, taking into account the prevailing circumstances.

(88) The problem of deciding what level of risk is considered tolerable and which actions are required to ensure that exposures are kept as low as reasonably achievable given the prevailing circumstances are central to the system of radiological protection. Both are consequences of the assumption that there is no threshold for stochastic effects. Tolerability

is intimately linked to the limitation principle, and reasonableness to the optimisation principle, which together reflect prudence and justice in protection.

(89) The quest for tolerability and reasonableness is an eminently ethical pursuit. Decades of effort to define these two concepts in a variety of recognized fields have shown that scientific rationality is not sufficient. It is also necessary to consider factors beyond simply the dose, the cost, and risks, to balance many societal and ethical considerations, including the experience accumulated over time, and common sense. As the philosopher Nicholas Rescher wrote a long time ago, the fundamental constituents of reasonableness (and we can add tolerability) are: "the willingness to use rational methods of inquiry, the regard for considerations of equity, the ability to view human actions and statements with perspective and judgments, the impartiality of approach to the means of adjudicating conflicting interests, the esteem for the judgment of others when based upon knowledge and experience, the respect for the agreed goods and goals of (competent) fellows." (Rescher, 1954).

(90) Tolerability and reasonableness are central to the complex relationship between science (in this case the science of radiation) and actions (the protection of exposed people). This is achieved by combining the core ethical values of beneficence, non-maleficence, prudence, justice and dignity, which are ingrained in the system of radiological protection. In practice, searching for tolerability and reasonableness is a permanent questioning which depends on the prevailing circumstances in order to act wisely based on accumulated knowledge and experience i.e. with the desire to do more good than harm, to avoid unnecessary risk, to seek a fair distribution of exposures and to treat people with respect.

5. ETHICS IN THE IMPLEMENTATION OF THE SYSTEM OF RADIOLOGICAL PROTECTION

(91) The implementation of the system of radiological protection is based the four core ethical values described in Chapter 3, and on the concept of tolerability and reasonableness which encapsulate key elements of these values as described in Chapter 4. Similarly, the process of this implementation carries with it procedural values which in turn serve as extensions of the core ethical values. The Commission does not go into minute detail, but provides broad recommendations concerning these values, leaving to other international organisations the task of fully developing them (IAEA, 2014). Three such procedural values are highlighted here because they are common to all exposure situations: accountability, transparency and stakeholder involvement.

5.1. Accountability and transparency

(92) Accountability can be defined as the procedural ethical value that people who are in charge of decision-making must answer for their actions to all those who are likely to be affected by these actions. In terms of governance this means the obligation of individuals or organisations to report on their activities, to accept responsibility, and to be ready to account for the consequences if necessary. According to the ISO transparency means “openness about decisions and activities that affect society, the economy and the environment, and willingness to communicate these in a clear, accurate, timely, honest and complete manner”. (ISO, 2010) Accountability and transparency can be mutually reinforcing. Together they allow citizens to be aware of up-to-date information required to make informed decisions and also to possibly participate in the decision making process. These two procedural ethical values tend to gradually be generalized in all fields and become a key part of a good governance policy in organisations.

(93) The concept of accountability explicitly appeared in *Publication 60* (ICRP, 1991) and then reaffirmed in much the same terms in *Publication 103* (ICRP, 2007a). Addressing the implementation of the recommendations and in considering organizational features: “In all organisations, the responsibilities and the associated authority are delegated to an extent depending on the complexity of the duties involved. (…). There should be a clear line of accountability running right to the top of each organization. (…) Advisory and regulatory authorities should be held accountable for the advice they give any requirements they impose”.

(94) The Commission also considered the accountability of the present generation to future generations, which is explicitly mentioned in *Publications 77* (ICRP, 1997b), *81* (ICRP, 1998), *91* (ICRP, 2003) and *122* (ICRP, 2013) related to waste management and the protection of the environment. As an example, *Publication 122* §17 states “… the obligations of the present generation towards the future generation are complex, involving, for instance, not only issues of safety and protection but also transfer of knowledge and resources. Due to the technical and scientific uncertainties, and the evolution of society in the long term, it is generally acknowledged that the present generation is not able to ensure that societal action will be taken in the future, but needs to provide the means for future generations to cope with these issues” (ICRP, 2013). Accountability in this context is the implementation of the value of intergenerational justice discussed in Chapter 3.

(95) Similarly, transparency is the implementation of the value of procedural justice. It concerns the fairness of the process through which information is intentionally shared between individuals and/or organisations. Transparency does not simply mean communication or consultation. It relates to the accessibility of information about the activities, deliberations, and decisions at stake and also the honesty with which this information is transmitted. It is part of corporate social responsibility, ensuring that decision-makers act responsibly in the social, economic and environmental domains in the interest of individuals and groups concerned. Clearly, security or economic reasons can be put forward to justify the control or limitation of outgoing information from a business or an organisation. However, to allow good transparency, explicit procedures must be in place from the outset that exhibit accountability features. (Oughton, 2008).

(96) Regarding the system of radiological protection, transparency on exposures and protection actions for the workers has been integrated into ICRP recommendations since the 1960s. One can thus read: "Workers should be suitably informed of the radiation hazard entailed by their work and of the precautions to be taken." (ICRP, 1966b). This requisite has since been taken over and expanded in subsequent recommendations (ICRP, 1991; ICRP, 2007a). It was not, however, until the 2000s that transparency became a general principle applicable not only to information about exposures and protection actions but also on the decision-making processes concerning the choices of protective actions by policy makers. Moreover it was generalized to all categories of exposure: occupational, patients and members of the public. This was introduced for the first time in *Publication 101b* dedicated to the optimisation of protection and bearing the evocative subtitle 'Broadening the process': "Due to its judgmental nature, there is a strong need for transparency of the optimisation process. All the data, parameters, assumptions, and values that enter into the process must be presented and defined very clearly. This transparency assumes that all relevant information is provided to the involved parties, and that the traceability of the decision-making process is documented properly, aiming for an informed decision." (ICRP, 2006).

(97) In practice, transparency depends on the category of exposure and the type of exposure situation. In the medical field it is implemented according to different modalities and procedures based on categories e.g. through training for workers (ICRP, 1997a) and informed consent in the medical field (ICRP, 1992; ICRP, 2007b). It also appears as the right to know principle for the public in the case of security screening for example (ICRP, 2014b). In its latest recommendations the Commission emphasized that "… scientific estimations and value judgments should be made clear whenever possible, so as to increase the transparency, and thus the understanding, of how decisions have been reached." (ICRP, 2007a). This shows that the requisite of transparency should apply wherever value judgments are involved in the system of radiological protection.

(98) Informed consent has been well-developed in the context of medical ethics, but also has important applications in other areas. Prerequisite elements of informed consent include information (which should be appropriate and sufficient), comprehension, and voluntariness (avoiding undue influence), which is associated with the right of refusal and withdrawal (without any detriment) Almost all of these elements were described in *Publication 62*: "The subject has the right to accept the risk voluntarily, and has an equal right to refuse to accept."; "By free and informed consent is meant genuine consent, freely given, with a proper understanding of the nature and consequence of what is proposed,..", also mentioning that "consent can be withdrawn at any time by the subjects." In *Publication 84* on pregnancy and medical radiation, informed consent is regarded as 'doctrine' and 'five basic elements' were

described as "competent to act, receives a through disclosure, comprehends the disclosure, act voluntarily, and consents to the intervention." For vulnerable people with diminished competency; under undue influence; or pregnant, additional protection both in terms of consent and strict risk benefit assessment is required. These three types of protection for vulnerabilities in terms of consent are described in *Publications 62 and 84*: "

- For "children or those who are mentally ill of defective", "those responsible for such individuals might be able to agree to their participation." (ICRP, 1992)
- "If the subject is in a position of obligation towards the investigators, for example as an employee, a student or even a patient, or can expect some non-health benefit such as promotion, special privileges or payment,…It is particularly important in such circumstances that consent should not be influenced unduly and should be given as freely as possible." (ICRP, 1992)
- "…full and informed consent of the pregnant patient must be obtained and it would usually be appropriate to seek the same from the father" (ICRP, 1992); additionally, "the mother has a role-related responsibility to care for her unborn child as well as to make decisions about herself." (ICRP, 2000)

(99) The right to know is another important concept related to transparency. It emerged in the US in the 1970s in connection with the efforts of the Federal Occupational Safety and Health Administration (OSHA) to ensure that workers benefit from safe and healthy working environments. It has evolved to be defined as a requirement to disclose full information on hazardous materials disposed, emitted, produced, stored, used or simply present in working places or the environment of communities (e.g. radon, NORM, …). It can be found in a number of ICRP publications:

- Protection in medicine - "the pregnant patient or worker has a right to know the magnitude and type of potential radiation effects that may result from in-utero exposure" (ICRP, 2007b)
- Protection in security screening - "The role of radiological protection is to provide information on the risks of using radiation, and thus contribute to a well-informed discussion during the justification of use. (…) The latter takes the form of ensuring that there is sufficient information and opportunity to address an individual's right to know as part of the screening process." (ICRP, 2014b)
- Protection in aviation - "…, for the sake of transparency and applying the right to know principle, the Commission recommends that general information about cosmic radiation be made available for all passengers, and the Commission encourages national authorities, airline companies, consumer unions and travel agencies to disseminate general information about cosmic radiation associated with aviation." (ICRP, 2016)

(100) In publications on environmental protection (ICRP, 2003; ICRP, 2014a) transparency, which enables social control and vigilance of public, is also emphasized. "The principle of informed consent, which emphasizes the need for communication and public involvement, starting at the planning stage and well before decisions are taken from which there is no return. Such transparency of decision-making should enable analysis and understanding of all stakeholders' arguments, although decisions against certain stakeholders may not be avoided. Transparency is usually secured by way of an environmental impact assessment."

5.2. Stakeholder involvement

(101) Stakeholder involvement, also referred to as stakeholder engagement, means “involving all relevant parties in the decision-making processes related to radiological protection” (IRPA, 2008). In recent decades, stakeholder involvement has become an essential part of the ethical framework in private and public sector organisations; inclusiveness is one of the essential procedural values, along with transparency and accountability, needed to make ethical decisions in organisations. Most likely it was Lauriston Taylor who first suggested engaging with stakeholders in radiological protection. In the Sievert Lecture he gave in 1980 one can read: “Aside from our experienced scientists, trained in radiation protection, where do we look further for our supply of wisdom? Personally, I feel strongly that we must turn to the much larger group of citizens generally, most of whom have to be regarded as well-meaning and sincere, but rarely well-informed about the radiation problems that they have to deal with. Nevertheless, collectively or as individuals, they can be of great value … in developing our total radiation protection philosophy.” (Taylor, 1980).

(102) Concretely, engaging stakeholders in radiological protection emerged in the late 1980s and early 1990s in the context of the management of exposures in area contaminated by the Chernobyl accident and sited contaminated by past nuclear activities in United States (IAEA, 2000). Citizens found themselves directly confronted with radioactivity in everyday life, and these situations posed new questions that the system in place at the time had difficulty in answering. This in turn led the Commission to replace the process-based approach of using practices and interventions with to a situation-based approach. (ICRP, 2007a).

(103) Stakeholder involvement was first introduced by ICRP in *Publication 82* - “Many situations of prolonged exposure are integrated into the human habitat and the Commission anticipates that the decision-making process will include the participation of relevant stakeholders rather than radiological protection specialists alone.” (ICRP, 1999) - and became a requisite in *Publication 103* in relation to the principle of optimisation of protection - “It should also be noted that the Commission mentions, for the first time, the need to account for the views and concerns of stakeholders when optimising protection.” (ICRP, 2007a).

(104) Engaging stakeholders in the decision-making process related to optimisation is an effective way to take into account their concerns and expectations as well as the prevailing circumstances of the exposure situation. This in turn enables adoption of more effective and fair protection actions as well as empowerment and autonomy of stakeholders especially in situations where they are directly confronted with radiation. Experience from the management of the consequences of the Chernobyl accident, and more recently the Fukushima accident demonstrated that empowerment of affected people helps them to regain confidence, to understand the situation they are confronted with, and finally to make informed decisions to act accordingly. In other words, engaging stakeholders is a way to respect those affected, and in the case of post-accident situations, to help restore their dignity (Lochard, 2004).

(105) In most existing exposure situations it is the responsibility of experts and authorities to ensure fair support of all groups of exposed people. Fairness in this respect refers to the fundamental values of equity and transparency. The requirement to be treated fairly is a key condition for those desiring to enter into a dialogue with the authorities with the objective to promote well-being. This dialogue with experts allows citizens to better understand their individual situations and helps empower them to make informed decisions. This

empowerment process relies on the development of ‘practical radiation protection culture’ among individuals and communities. This last notion was introduced in *Publication 111*, which is devoted to the protection of people living in long-term contaminated areas after a nuclear accident (ICRP, 2009b). Practical radiation protection culture can be defined as the knowledge and skills enabling each citizen to make well-informed choices and behave wisely when directly confronted with radiation. It is a duty of radiological protection professionals to highlight these choices with the resources of science and experience along with the core ethical values that underlie the system of radiological protection (ICRP, 2009b).

(106) A recent ICRP publication gives explicit procedural recommendations for effectively involving stakeholders: “Guidelines should be established at the beginning to ensure that the process is effective and meaningful for all parties” and that “Some of these guidelines include, but are not limited to the following: clear definition of the role of stakeholders at the beginning of the process; agreement on a plan for involvement; provision of a mechanism for documenting and responding to stakeholder involvement; and recognition, by operators and regulators, that stakeholder involvement can be complex and can require additional resources to implement.” (ICRP, 2014a).

6. CONCLUSION

(107) The system of radiological protection is based on three pillars: science, ethics, and experience. As far as ethics is concerned, the system is rooted in the three major theories of moral philosophy: deontological ethics, utilitarian and virtue ethics and relies on four core ethical values: beneficence/non-maleficence, prudence, justice and dignity. Beneficence and non-maleficence are directly related to the aim to prevent deterministic effects and to reduce the risk of stochastic effects. Prudence allows taking into account uncertainties concerning both the deterministic and stochastic effects of radiation on health. Justice is the way to ensure social equity and fairness in decisions related to protection. Dignity is to take into account the respect that one must have for people.

(108) The principle of justification requires that any decision that alters a radiation exposure situation should do more good than harm. This means that, by reducing existing exposure or introducing a new radiation sources (planned exposure situation) the achieved benefit to individuals and the society should be greater than the associated disadvantages in terms of radiation risk but also of any other nature. Thus, the justification principle combines the ethical values of beneficence and non-maleficence but also prudence since part of the estimated detriment may be associated with hypothetical stochastic effects given the no threshold assumption.

(109) The principle of optimisation of protection, in turn, requires that all exposures should be kept as low as reasonably achievable taking into account economic and societal factors using restrictions on individual exposures to reduce inequities in the distribution of exposures among exposed groups. This is the cornerstone of the system. On the one hand it is a principle of action, which allows the practical implementation of prudence. On the other hand it also allows the introduction of fairness in the distribution of exposures among people exposed. This dimension of fairness, or equity as designated by the Commission, refers directly to the ethic of justice.

(110) Finally, the principle of limitation of individual exposures requires that all individual exposures do not exceed the protection criteria recommended by the Commission. Like the principle of optimisation it refers directly to the ethical values of prudence but more so to justice by restricting the risk in an equal manner for a given exposure situation and category of exposure.

(111) Note that the application of the three principles will depend on the exposure situations and the category of exposure, particularly in medical exposure. Dose limits do not apply to medical exposures of patients. Here the vast majority of the risk and benefit accrue to the individual patient, so inequity is not relevant and any such restriction might interfere with providing the best "margin of benefit over harm" for the individual patient. In reality, the ethical considerations are more complex, as there is also potential for benefit and harm to others, most notably to the medical staff who also receive some dose, and others such as family and friends who may receive some dose depending on the type of procedure and who might also gain an indirect benefit derived from the medical benefit to the patient.

(112) Integrated into the three structuring principles of justification, optimisation and limitation, the core ethical values allow one to act virtuously while taking into account the uncertainties associated with the effects of low dose and to evaluate the criteria for judging the adequacy of these actions. In practice, the search for reasonable levels of protection (the principle of optimisation) and tolerable exposure levels (the principle of limitation) is a permanent questioning which depends on the prevailing circumstances in order to act wisely

i.e. with the desire to do more good than harm (beneficence/non maleficence), to avoid unnecessary exposure (prudence), to seek for fair distribution of exposures (justice) and to treat people with respect (dignity).

(113) Over the past decade the system has also integrated procedural values such as accountability, transparency and stakeholder involvement, reflecting the importance of allocating responsibilities to those involved in the radiological protection process, properly inform and also preserve the autonomy and dignity of the individuals potentially or actually exposed to radiation.

(114) Until now the basic aim of the system of radiological protection for humans was to prevent deterministic effects and reduce stochastic ones to reasonably achievable levels taking into account of economic and societal considerations. Recent developments have suggested enlarging this aim to the individual and collective well-being of exposed people to also include mental and social aspects. This is particularly the case for the management of post-accidental situation as stated in *Publication 111* (§ 23) with the objective to improve the daily life of exposed individuals.

(115) The inclusion of natural or man-made radiation in existing exposure situations in the latest recommendations of the Commission have also highlighted the need to foster the development of an appropriate radiological protection culture within society in the stakeholder engagement process, enabling each citizen to make well-informed choices and behave wisely when directly confronted with radiation.

(116) The primary goal and responsibility of the Commission should rest on developing the science of radiological protection for the public benefit. Nevertheless the Commission thinks that by eliciting and diffusing the ethical values and related principles that underpin the radiological protection system both experts and the public will undoubtedly gain a clearer view of the societal implications of its recommendations. Just as science, ethics alone is unable to provide a definitive solution to the questions and dilemmas generated by the use or presence of radiation. However, ethics certainly can provide useful insights on the principles and philosophy of radiological protection and thus help the dialogue between experts and citizens.

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ANNEX X

Participants at the Workshops on the Ethics of the System of Radiological Protection Organised in Cooperation with ICRP and Supporting the Development of this Publication

1st Asian Workshop on the Ethical Dimensions of the Radiological Protection System

August 27-28, 2013

Daejeon, Korea

Organized by the Korean Association for Radiation Protection (KARP)
Hosted by the Korea Institute of Nuclear Safety (KINS)

Min Baek
Marie Claire Cantone
Kun-Woo Cho
Hosin Choi
Mi-Sun Chung
Christopher Clement
Moon-Hee Han
Sungook Hong
Seoung-Young Jeong
Kyu-Hwan Jung
Keon Kang
Chan Hyeong Kim
Il-Han Kim
Jong Kyung Kim
Kyo-Youn Kim
Sung Hwan Kim
Chieko Kurihara-Saio
Dong-Myung Lee
Hee-Seock Lee
JaiKi Lee
Senlin Liu
Jacques Lochard
Seong-Ho Na
Viet Phuong Nguyen
Enkhbat Norov
Hiroko Yoshida Ohuchi
Woo-Yoon Park
Ronald Piquero
Sang-Duk Sa
Sohail Sabir
John Takala
Man-Sung Yim
Song-Jae Yoo

1st European Workshop on Ethical Dimensions of the Radiological Protection System

December 16-18, 2013

Milan, Italy

Organised by the Italian Radiation Protection Association (AIRP) and the French Society for Radiological Protection (SFRP)

Marie Barnes
François Bochud
Giovanni Boniolo
Marie-Charlotte Bouesseau
Marie Claire Cantone
Kunwoo Cho
Christopher Clement
Roger Coates
Renate Czarwinski
Daniela De Bartolo
Biagio Di Dino
Marie-Helene El Jammal
Eduardo Gallego
Alfred Hefner
Dariusz Kluszczynski`
Chieko Kurihara
Ted Lazo
Jean-François Lecomte
Bernard Le Guen
Jacques Lochard
Jim Malone
Gaston Meskens
Celso Osimani
Deborah Oughton

Guido Pedroli
Francois Rollinger
Thierry Schneider
Michael Siemann
John Takala
Richard Toohey
Emilie van Deventer
Sidika Wambani
Dorota Wroblewska
Margherita Zito
Friedo Zölzer

1st North American Workshop on Ethical Dimensions of the Radiological Protection System

July 17-18, 2014

Baltimore, USA

Organised by the US Health Physics Society (HPS), Canadian Radiation Protection Association (CRPA), and the Mexican Society for Radiological Protection (SMSR)

Ralph Anderson
Edgar Bailey
Mike Boyd
Dan Burnfield
Donald Cool
Renate Czarwinski
Yuki Fujimichi
Nobuyuki Hamada
Raymond Johnson
Ken Kase
Toshiso Kusako
Cheiko Kurihawa
Ted Lazo
Jacques Lochard
Yasuhito Sasaki
Glenn Sturchio
Dick Toohey
Brant Ulsh
Richard Vetter
Harry Winsor

2nd European Workshop on Ethical Dimensions of the Radiological Protection System

February 4-6, 2015

Madrid, Spain

Organised by the Spanish Society for Radiological Protection (SEPR), Italian Society for Radiological Protection (AIRP), French Society for Radiological Protection (SFRP), and UK Society for Radiological Protection (SRP)

Antonio Almicar
Marie Barnes
François Bochud
Francesco Bonacci
Marie-Charlotte Bouesseau
Marie Claire Cantone
Pedro Carboneras
Kunwoo Cho
Christopher Clement
Roger Coates
Marie-Helène El Jammal
Sebastien Farin
Eduardo Gallego
Cesare Gori
Klazien Huitema
Dariusz Kluszczynski
Chieko Kurihara
Jean François Lecomte
Bernard Le-Guen
Jacques Lochard
Jim Malone
Gaston Meskens
Mohamed Omar
Deborah Oughton
María Pérez
Volha Piotukh
Thierry Schneider
Patrick Smeesters
Behnam Taebi
John Takala
Jim Thurston
Richard Toohey
Eliseo Vañó
Dorota Wroblewska
Friedo Zolzer

2nd North American Workshop on Ethical Dimensions of the System of Radiological Protection

March 10-12, 2015

Cambridge, USA

Organised by the Harvard Kennedy School, Belfer Center, Harvard University, and ICRP

Kunwoo Cho
Christopher Clement
Andrew Einstein
Stephen Gardiner
Nobuyuki Hamada
Bjørn Morten Hofmann
Sheila Jasanoff
Cheiko Kurihara-Saio
Jacques Lochard
Nicole Martinez
Gina Palmer
Laura Reed
Behnam Taebi
John Takala
Friedo Zölzer

2nd Asian Workshop on the Ethical Dimensions of the System of Radiological Protection

June 2-3, 2015

Fukushima, Japan

Organised by Fukushima Medical University, and ICRP

Tazuko Arai
Kathleen Araujo
Ryoko Ando
Cécile Asanuma-Brice
Marie-Claire Cantone
Chris Clement
Aya Goto
Nobuyuki Hamada
Toshimitsu Homma
Audrie Ismail
Wataru Iwata
Michiaki Kai
Mushakoji Kinhide
Mariko Komatsu
Atsuchi Kumagai
Chieko Kurihara
Edward Lazo
Jean-François Lecomte
Jacques Lochard
Nicole Martinez
Hideyuki Matsui
Gaston Meskens
Michio Miyasaka
Makoto Miyazaki
Toshitaka Nakamura
Ohtsura Niwa
Sae Ochi
Deborah Oughton
François Rollinger
Kiriko Sakata
Hisako Sakiyama
Yasuhito Sasaki
Thierry Schneider
Lavrans Skuterud
Megumi Sugimoto
John Takala
Toshihide Tsuda
Fumie Yamaguchi