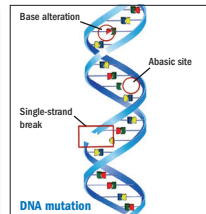


Radiological Protection Science and Application



Radiological Protection

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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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Foreword

Since the discovery of radiation at the end of the 19th century, the health effects of exposure to radiation have been studied more than almost any other factor having potential effects on overall health. While much more is known today about radiation exposure, a great deal remains to be discovered, and radiation effects at low doses continue to be an important area of scientific study.

The NEA has long been involved in discussions on the effects of radiation exposure, and more specifically on radiation protection. The NEA Committee on Radiation Protection and Public Health (CRPPH) has the broad mission of providing a timely analysis of new and emerging issues and making recommendations or taking action to further enhance radiological protection regulation and implementation.

In 1993, the CRPPH held a workshop on Radiation Protection on the Threshold of the 21st Century, following the development and issuing of the International Commission on Radiological Protection (ICRP) Publication 60. It was at the beginning of a period of adaptation, implementation and change. As such, the NEA felt that it would be a useful time to scan the horizon to see what types of issues could arise in the near future, so as to study their possible implications. The intention was to guide member country governments in better preparing their national policy and application through this period of flux. As a result of the 1993 workshop, the CRPPH published a summary report entitled *Radiation Protection Today and Tomorrow: A Collective Opinion of the CRPPH* (NEA, 1994). In addition to the value that this work brought to NEA member countries, it also served as a list of issues and areas for further study.

A key aspect of this report was its identification of the possible impacts of radiological protection science on radiological protection policy, regulation and implementation. As a result, the NEA agreed to develop a subsequent report to understand the scientific state-of-the-art and to review the scientific horizon for possible study results that could have significant implications for radiological protection. In 1998, the NEA published *Developments in Radiation Health Science and Their Impact on Radiation Protection* (NEA, 1998), a landmark publication that was used to guide the CRPPH programme of work for almost ten years.

With discussions beginning shortly thereafter on renewing the ICRP general recommendations, in 2004 the CRPPH held a topical session to identify areas that could have a significant influence on radiological protection policy, regulation and application, with a specific focus again on scientific developments. This discussion would result in the formation of the Expert Group on the Implications of Radiological Protection Science (EGIS), designed to address science at the service of mid- and long-term policy needs. In 2007, the EGIS published a report entitled *Scientific Issues and Emerging Challenges for Radiation Protection* (NEA, 2007).

Since 2007, radiological protection science has continued to advance on all fronts, and our understanding of radiation risks and effects, particularly at low doses, have improved. At the time of a policy debate during an NEA Steering Committee meeting in 2012, member countries indicated that it could be useful to obtain further input on the current scientific understanding of low-dose radiation effects and risks. The NEA Expert Group on Radiological Protection Science (EGRPS) was therefore created to produce the present report.

Acknowledgements

The NEA would like to acknowledge the significant contributions that were provided to the development of this report by Dr Augustin Janssens (retired Radiation Protection Unit Head, European Commission), Dr Ken Mossman (Professor of Health Physics, School of Life Sciences, Arizona State University), and Dr Bill Morgan (Professor and Director of Radiation Biology and Biophysics, Pacific Northwest National Laboratory). This report is dedicated to Ken Mossman and Bill Morgan, both of whom passed away before the report's release.

Table of contents

Public and policy overview	7
List of abbreviations and acronyms	9
Executive summary	11
General introduction and report structure	13
1. Biological and epidemiological research on effects of exposure	17
1.1. Cancer risk of low-dose and low dose-rate radiation exposure	17
1.2. Non-cancer effects.....	26
1.3. Individual sensitivity.....	34
2. Societal aspects of radiological protection	43
3. Implementation of the radiological protection system	53
3.1. Existing exposure situations	53
3.2. Planned exposure situations.....	60
3.3. Emergency exposure situations.....	67
3.4. Environmental radiological protection.....	79
4. International standards	89
5. Overall ways forward	93
Annex A. The system of radiological protection	103
Annex B. List of experts	113

Public and policy overview

The overarching objective of the radiological protection system is to contribute to an appropriate level of protection against the harmful effects of radiation exposure, without unjustifiably limiting the desired results from the human activity causing exposure. This is achieved by understanding as best possible the scientific characteristics of radiation exposure and related health effects, and by taking this knowledge into consideration when judging what protection decisions will ensure the best balance between social and economic aspects and risks.

In general, the existing radiological protection system works well and does not underestimate protection needs for either individuals or exposed populations as a whole. The latest International Commission on Radiological Protection (ICRP) recommendations were formed after a long and open dialogue with the public, where expert views were actively collected and discussed at national, regional and international levels.

Although the radiological protection system is still very effective, and there is no need for a prompt revision, it would seem an appropriate time to initiate a reflection on the latest scientific results and involve the entire radiological protection community in this reflection, benefiting from the input of other scientific disciplines and interested stakeholders.

Cancer is the second leading cause of death in OECD countries, accounting for approximately one-third of all deaths (OECD, 2015). Although many things can cause cancer (e.g. smoking, alcohol, exposure to certain chemicals, genetic predisposition), cancer development is a very complex process that is as not yet fully understood. Ionising radiation is classified as a weak carcinogen by the World Health Organisation, is known to cause cancer at higher doses and is regulated as though any dose, no matter how small, can cause cancer, despite scientific uncertainties in this regard.

Since the discovery of radiation at the end of the 19th century, the health effects of exposure to radiation have been studied more than almost any other factor having a potential effect on overall health. While much more is known today, there is an enormous amount to learn, and radiation effects at low doses continue to be an important area of scientific study.

We know that very high doses of radiation can cause serious damage to blood-forming organs, to the stomach, intestinal tract and to the central nervous system, which can lead to death. Doses at this level will normally only occur as a result of very serious accidents, and only to those physically very close to the source of radiation. Lower doses of ionising radiation can cause leukaemia and solid cancer, appearing a few to many years after exposure, and can potentially have effects on future generations. It has also been shown that high doses of radiation can cause health problems other than cancer, such as heart diseases, strokes and cataracts.

At lower doses, our scientific knowledge is much less complete, and it is not clear whether such low doses can cause health problems such as cancer and leukaemia. Low doses of radiation entail those doses that are less than approximately 50 times the dose that people receive each year from natural sources, the earth, the cosmos and their own body. It is nevertheless important to understand the nature of any health effects that these doses might cause because almost all man-made doses to humans are in this

low-dose range. Such doses may arise from accidents, from work and research activities involving radiation, from nuclear energy, or from hospital and industrial releases of radioactive substances to the environment. Low doses can also emanate from medical examinations, which are given for the benefit of patients, but can also carry some risk. Higher doses to individuals can originate from medical treatments, areas of high radon concentration or large-scale nuclear accidents.

While scientific evidence suggests that high doses of radiation can cause cancer, there is no clear scientific proof that this is true at low doses. However, to be conservative, regulatory authorities around the world assume that any dose, no matter how small, is a potential risk. Most scientists believe that this assumption – and it is an assumption and not a fact – does not under or overestimate radiation risks. Thus, it is important to prevent unnecessary exposure, and exposure caused by activities bringing little or no benefit. Regulations require that doses that are allowed are kept as low as reasonably achievable (ALARA).

Although the effects from low doses of radiation are scientifically uncertain, there are nonetheless many things that we do know. For example, some individuals can be more or less sensitive to radiation than others. Some people may be more sensitive because of their genetic background. Children are generally more sensitive to radiation than adults; women are more sensitive than men for certain health effects. However, much more research is needed to clearly understand these differences in sensitivity.

Radiation protection science can be complex, but needs to be understood by all those concerned so that protection choices and actions can at least attempt to meet everyone's needs. Such decisions can be made through dialogues with stakeholders, during which radiological protection professionals explain the complex science in simple language. Social scientists may also be of help when explaining such complex issues.

It is agreed that the environment must be protected from events or practices causing large-scale contamination of the environment. Although most scientists feel that nature is not at present threatened by man-made radiation, nature is very complex. As such, scientific approaches to radiological protection of the environment are still being refined, and further studies are needed in relation to the potential effects of radiation on the environment.

List of abbreviations and acronyms

ALARA	As low as reasonably achievable
COMET	Coordination and Implementation of a Pan-European Instrument for Radioecology
CRPPH	NEA Committee on Radiation Protection and Public Health
CRS	Chronic radiation syndrome
CT	Computed tomography
DCRL	Derived consideration reference level
DDREF	Dose and dose rate effectiveness factor
ERA	European Radioecology Alliance
IAEA	International Atomic Energy Agency
IBSS	International Basic Safety Standards
ICRP	International Commission on Radiological Protection
INEX	International Nuclear Emergency Exercise
LET	Linear energy transfer
LNT	Linear non-threshold
NEA	Nuclear Energy Agency
NORM	Naturally occurring radioactive material
OECD	Organisation for Economic Co-operation and Development
ORP	Occupational radiological protection
PNEDR	Predicted no effect dose rate
RAP	Reference animals and plants
STAR	Strategy for Allied Radioecology
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
WHO	World Health Organization

Executive summary

The NEA Expert Group on Radiological Protection Science (EGRPS) has taken stock of the knowledge basis and present consensus regarding radiological protection, and has identified ways in which research and the protection system might evolve to take into account all these factors. The following paragraphs summarise the findings in this report.

The radiological protection system and the risk of health effects

- The cancer risk from ionising radiation, at low dose (<100 mGy of absorbed dose) and low-dose rates (<5 mGy/hr of absorbed dose), can be described as having a linear relationship with doses down to 50-100 mSv (of an equivalent or effective dose), and that for children and *in utero* exposures this could be valid at even lower doses. The current radiological protection system, with its focus on optimisation and a linear extrapolation of the risk observed at high-to-medium doses to low doses with no threshold, does not underestimate protection needs.
- There is broad consensus that the current system of radiological protection neither under- nor overestimates radiological risks, but improvements in clarity and coherence are needed. Examples of areas where improvements are identified include existing or emerging situations in medical exposure, exposure to natural radiation sources and radiological protection during and after radiological accidents.
- Non-cancer effects are receiving more attention, but the occurrence and possible mechanisms at low levels of dose and dose rate remain uncertain. The International Commission on Radiological Protection (ICRP) has recommended a lower threshold for cataracts, but more research is needed for circulatory and other non-cancer effects. In this area, dialogue with other scientific fields is seen as fruitful.
- Development of possible biomarkers for radiation-induced diseases would greatly assist epidemiological studies. There is a need to integrate molecular, epidemiological and systems biological studies, for example using the Organisation for Economic Co-operation and Development (OECD) chemical risk approach.
- Although scientific knowledge has increased and resulted in new ICRP recommendations, including Publication 118 for new criteria for protection against cataracts and Publication 126 for radon (ICRP, 2014), the evolution of science has not changed the overall approach to radiological protection.
- Differences in individual sensitivity to ionising radiation (radiosensitivity) as a result of genetic, epi-genetic, age and gender variation does not merit changes in the radiological protection system. Screening tests for radiosensitivity, except for a few cancer types such as breast cancer, are not yet effective, and the ethical and moral issues that such tests present have not been resolved. The wise course of action is to keep the generic radiological protection framework and to rigorously implement measures to keep doses, and the risk of receiving doses, as low as reasonably achievable.

- Non-targeted effects, such as chemical communications between cells, have been confirmed experimentally at low doses, but their significance to radiological risk remains uncertain.
- Accurate dose assessment and recording, in particular for medical exposure, is needed to improve optimisation of protection.
- A policy challenge remains for the medical community to more explicitly consider the risks and benefits of procedures involving radiation (i.e. justification and optimisation).

Social and political factors, protection of the environment, communication and education

- Communication about radiological protection science issues, uncertainties, protection options and other subjects during stakeholder dialogues is important and requires training. Effective communication of complex issues to decision makers in general, and to members of the public in particular, is essential. To increase awareness of the system of radiological protection and how it takes account of societal aspects in decision making, professionals and scientists should establish an effective and wide-ranging dialogue. This requires understanding, co-operation, preparation and training.
- Societal and political demands, and protection of the environment, should be explicitly demonstrated in radiological protection decisions. The ICRP has recently developed a system, involving reference animals and plants, to protect the environment. Further research and development will assist in steering the development of an environmental radiological protection framework.
- Comprehensive education and training will continue to be an essential element of the overall radiological protection system.
- The complexity of scientific and social questions encountered in radiological protection strongly suggests that interdisciplinary dialogue is, and will continue to be, an important element that will contribute to acceptable and sustainable radiological protection solutions.

Research and development

- Fundamental research will continue to be an essential component of any low-dose risk programme, allowing for the testing of new ideas that might be on the fringe of the current state of knowledge. Such research will have a potential for high gain but with an uncertain outcome. Progress in the understanding of mechanisms of radiation carcinogenesis may well be improved alongside other progress enabling advancements in science and technologies, for example in systems biology or omics.

General introduction and report structure

Reports published by the NEA Committee on Radiation Protection and Public Health (CRPPH) in 1998 and 2007 provided an overview of the scientific knowledge available at that time, as well as the expected results from further research. They also discussed the policy implications that these results could have for the radiological protection system. The 2007 report highlighted challenges posed by developments in relation to medical exposure and by intentions to include the environment (i.e. non-human species), within the scope of the radiological protection system. It also addressed the need to be able to respond to a radiological terrorist attack.

This report picks up on where the 1998 and 2007 reports left off, and addresses the state of the art in radiological prevention science and application today.

It is divided into five chapters. Firstly, following broadly the structural topics from the 1998 and 2007 reports, the more purely scientific aspects of radiological protection are presented. These include cancer risk of low dose and dose rates, non-cancer effects and individual sensitivity. In view of the increasing importance of stakeholder involvement and individual and societal values in radiological protection decision making, Chapter 2 of this report addresses the societal aspects of radiological protection decision making. Chapter 3 addresses the application-related aspects of radiological protection. These include existing exposure situations, planned exposure situations, emergency exposure situations and environmental radiological protection. Chapter 4 of the report addresses international standards and Chapter 5 provides CRPPH views on overall ways forward.

Annex A provides a more detailed overview of the International Commission on Radiological Protection (ICRP) system of radiological protection, its interpretation in the International Basic Safety Standards (IBSS) and in the Euratom Basic Safety Standards (Euratom BSS). It demonstrates how the ICRP system may be influenced by both an evolving science and society, and in particular by the increasing focus on addressing protection in the context of prevailing circumstances.

Each chapter of this report was prepared by experts on the topic, and an attempt has been made to follow a common framework. Having a common framework for chapters addressing science and those addressing implementation proved to be particularly difficult. As a consequence, the report's structure is constructed in such a way so as to address the state of the art in each area, while attempting to present aspects under broadly common headlines.

Possible policy challenges from the 2007 report

Challenges from non-targeted and delayed effects

Development of a new radiation biology paradigm (combining targeted and non-targeted effects) may require changes to the current system of radiological protection, with possible implications for radiation risk assessment, the system of dose limitation and the management of radiological protection in all fields.

Individual sensitivity

- Development of the ability to link radiation exposure to susceptibility¹ at an individual level would pose questions in terms of how dose or risk controls are set and applied (e.g. different restrictions for different susceptibilities or restrictions based on the most susceptible group).
- Assessment of the wider social, ethical and legal implications of linking individual susceptibility to radiation through genetic testing (e.g. the right to require testing, or refuse testing, the risk of social discrimination or exclusion).
- New guidance or approaches to patient radiotherapy may be required.

Epidemiology

For a variety of reasons, epidemiology is currently the most informative approach for the estimation of health risks to humans from ionising radiation, although much remains to be learnt. Classical epidemiological studies are severely limited in statistical power because of the need for large study populations for the estimation of the effects of doses below 100 mSv. A key issue in “modern” radiation epidemiology today is the greater use of molecular epidemiology to better estimate risk, particularly at low doses and taking into account individual variations.

Challenges to the concept of dose as a surrogate² for risk

A consensus should be sought in situations where the use of the unified system may be inappropriate (i.e. when it is not sufficiently robust) or its application would incur costs that are grossly disproportionate to the actual reduction in risk. In such cases, alternative, more specific approaches will need to be developed and adopted.

Radiological protection in medical exposure

- Studies suggest that both patients and medical workers are being increasingly exposed to radiation, and thus it is important to ensure that exposures are justified and optimised through better and more meaningful dose information via equipment that measures and displays patient dose, as well as through the development of new optimisation approaches, new operational procedures and protocols.
- A sharing of knowledge in relation to medical and other types of exposure should be encouraged, so that all can benefit from different experiences.

Radiological protection of the environment

Ensuring that current tools and methodologies, as well as technical approaches developed to protect the environment from the adverse effects of ionising radiation are suitably compatible with other broader principles and conceptual approaches in areas related to environmental protection.

-
1. In the present document the term “susceptibility” is no longer used except in the context of for instance genetic susceptibility (or disposition).
 2. This term in the 2007 report is no longer used in the present document; dose, in particular effective dose, is a quantity that allows the expression of risk as a health detriment, in particular cancer risks, but it should not be regarded as a “surrogate” for the latter.

Health impacts of radiological terrorist attacks

- Development of a well-organised, effective medical response system, capable not only of handling direct medical effects but also of instilling confidence in, and supporting, the community.
- Development of a means to rapidly provide information to the public; and address the concerns of a considerable number of people with low or no exposure in order to maintain public confidence in government regulatory organisations in the event of an accident or attack, or in any post-incident rehabilitation strategy.

Current status of policy challenges from the 2007 report

Today, all the above challenges remain important issues. Further research has contributed tremendously to deepening our understanding of radiation effects, but not to an extent that a clear answer can be given to all the formulated challenges. Some issues are now believed to be of less importance for the estimation of radiation risks at low doses (e.g. the bystander effect). Other scientific developments, for instance on genetic factors affecting individual sensitivity, have shown that such factors are very complex and will not be fully understood anytime soon. A new challenge has arisen from scientific evidence that non-cancer effects may play a role at low doses, below the threshold that is assumed for non-stochastic effects. The ICRP has drastically lowered the organ dose limit to the lens-of-the-eye on the basis of such information (ICRP 118).

The year 2007 was also the year that new ICRP recommendations were published (Publication 103), which was advertised as an evolution rather than a revolution. The major change was the definition of exposure situations – rather than processes – for interpreting the principles of protection and optimisation, subject to constraints or reference levels depending on the type of situation. However, the transposition of ICRP recommendations into new international standards has led to a thorough analysis of the principles of protection. This analysis demonstrated that the new recommendations have more far-reaching implications than initially expected. This transposition and subsequent analysis has in particular led to the more prominent inclusion of natural radiation sources in the scope of regulations. In addition, epidemiological data on the association of lung cancer with indoor radon exposures – both among smokers and non-smokers – has led to more ambitious radon policies (prompted by the comprehensive handbook on indoor radon published by the World Health Organization [WHO, 2009]), and to a new consideration of the dose coefficient applicable to radon inhalation (or inhalation of radon decay products).

In 2011, the radiological protection philosophy was put to a demanding test by the accident in the Fukushima Daiichi nuclear power plant. Communication on the basis of the newly established radiological protection system proved rather difficult. The accident also highlighted changes in society, at least in industrialised countries with a high standard of living. On the one hand, information is now much more readily available through social media, and traditional media (press, television) are also driven by these sources of information. On the other hand, people increasingly want to understand what the exposure situation implies for themselves and for their families, and are not satisfied with an answer that is based on the average population.

The NEA has already undertaken some pioneering work on ways to involve stakeholders in complex radiological protection decisions. The Fukushima Daiichi nuclear power plant accident³ further emphasised the importance of societal factors in communication, perception and decision making.

Uncertainties in the scientific data will thus continue to be an important consideration in decisions for one or more decades, keeping in mind that certain factors will possibly never be understood, at least as long as we do not fully understand all aspects in the development of cancer and other radiation-related diseases. Today there is a strong societal demand for high environmental and health standards, with the implicit assumption that any disease has a cause that needs to be reduced if not eliminated. This presents enormous challenges for the management of exposure to ionising radiation in the absence of conclusive evidence that there is a threshold below which there is no risk.

Indeed, some prominent radiological protection experts and learned societies have advocated that there is such a threshold, and that even at low doses there is no health detriment, but rather a benefit (“hormesis”). The controversy between different schools of thought demonstrates how the prevailing uncertainties on radiation effects together with different societal perspectives and attitudes can lead to different conclusions.

This report addresses the current state of science in the assessment of the radiation detriment, and looks more explicitly at the societal and ethical context of radiological protection. It addresses the challenge of ensuring good radiological protection in all situations on the basis of international standards and communicating better and more convincingly on the performance of the radiological protection system. Finally, the report inquires whether this analysis may be a starting point for further reflection on the current radiological protection system.

References

- ICRP 103 (2007), “The 2007 recommendations of the International Commission on Radiological Protection”, *Annals of the ICRP*, Vol. 37 (2-4), Ottawa.
- ICRP 118 (2012), “ICRP statement on tissue reactions/early and late effects of radiation in normal tissues and organs – threshold doses for tissue reactions in a radiation protection context”, *Annals of the ICRP*, Vol. 41(1/2), Ottawa.
- WHO (2009), *WHO Handbook on Indoor Radon: A Public Health Perspective*, WHO, Geneva, www.ncbi.nlm.nih.gov/books/NBK143216/.

3. The term, “Fukushima accident” is used in this report to refer to the 2011 nuclear accident at the Fukushima Daiichi nuclear power plant in Japan.

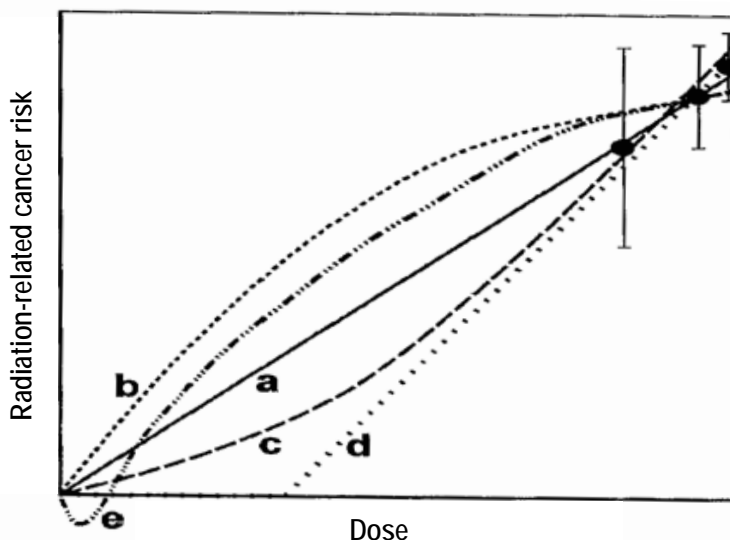
1. Biological and epidemiological research on effects of exposure

1.1. Cancer risk of low-dose and low dose-rate radiation exposure

What is the issue?

Although much is known about the quantitative effects of exposure to ionising radiation, considerable uncertainties and divergent views remain with regard to health risks at low doses. For largely pragmatic reasons (e.g. the regulatory precautionary principle), the linear non-threshold model (LNT) describing the relationship between dose and the appearance of radiation-induced cancer has been long used for radiological protection purposes. Similar pragmatism applies to concepts such as dose and dose rate effectiveness factor (DDREF), tissue weighting (W_T) factors and radiation weighting (W_R) factors that are all built on simplifying assumptions. There are still uncertainties in the mechanisms of radiation interaction with biological systems and radiation risk estimates at low doses, and consolidation of the scientific basis for the system of protection is needed. The risks associated with non-cancer diseases, such as cardiovascular disease, are also the subject of much discussion and uncertainty (see Section 1.2).

The shape of the dose-response curve below about 100 mSv – for which direct evidence of effects is limited – is a scientific question that has been strongly debated for some time with divergent views. At low doses and low-dose rates, the evidence for effects is poor and therefore the shape of the dose-response curve for radiation-induced cancer is a matter of critical judgement, with implications for radiological protection policy and risk assessment. In brief, five basic model options on low-dose response tend to be considered following exposure of the whole body or of individual tissues: a) linear; b) supra-linear; c) sub-linear; d) linear with threshold; and e) hormesis (Fairlie, 2012).



Many factors have been identified that can influence the shape or the steepness of the dose-response relationship. These include the type (quality) of ionising radiation and the way that it is delivered in time and space, the particular tissues of the body that are exposed and differences between individuals. While the main low-dose risk is currently cancer induction, and to a lesser extent hereditary effects, some non-cancer effects may also be of concern even at low doses (see Section 1.2).

Judgements on the validity of dose-response models are frequently questioned. The criticisms cover various sources of uncertainty such as over-interpretation of single epidemiological data sets, potential confounding factors and biases in epidemiological data, insufficient statistical power of some studies, generalisation of results from atypical or limited experimental models and insufficient understanding of low-dose radiobiology.

It is accepted that there is much uncertainty surrounding the shape of the dose-response for cancer derived from epidemiological studies below doses of about 100 mGy (or about 100 mSv of whole body low linear energy transfer [LET] radiation) and on the cellular/tissue mechanisms that determine the response, including the potential role of non-linear dose responses such as non-targeted effects. Nonetheless, there are a number of studies that provide evidence for a risk at doses below 100 mGy.

The International Commission on Radiological Protection (ICRP) combines the LNT hypothesis with a single value of 2 for the DDREF for cancer induction, with this value being chosen on the basis of judgement. The value is used to lower the dose-response slope, to allow for a presumed reduction of cancer risk at low dose and low-dose rate. In reality, there is no empirical evidence to support a single value. There is a wide range of values both for human and other mammalian species, dependent on parameters such as tissue or organ involvement and tumour type.

In essence, the DDREF is the ratio of the linear fit of data at high dose and high-dose rate to the linear, no-threshold fit to low dose (below 100 mGy) and dose rate data (below 0.1 mGy/min [UNSCEAR, 2010]). The ICRP recommends a DDREF of 2 to account for an assumed reduced risk of chronic and fractionated radiation doses at low dose rate. In 2006, the US Committee on the Biological Effects of Ionizing Radiation (BEIR) published *Health Risks from Exposure to Low Levels of Ionizing Radiation, Phase 2* (BEIR VII), using Bayesian analysis of pooled data from human and experimental animal data, derived a value of the DDREF of 1.5 with a confidence limit of 0.8-2.7 which the National Commission on Radiation Protection and Measurement (NCRP) subsequently decided to use. Data from several low-dose epidemiological studies (Mayak, Techa River, UK nuclear workers, the International Agency for Research on Cancer [IARC] 15-country study, etc.) indicates that the DDREF should be set to one (DDREF = 1). Other studies suggest that the DDREF should be greater than one (e.g. Akiba, 2013).

The low-dose response debate has often centred on external low-LET radiations where the dose response for many biological effects tends to have a greater-than-linear component at acute higher doses. On account of this shape, it is currently assumed for radiological protection purposes that the slope of the response at low doses and low-dose rates is reduced by a factor of two compared to high doses and dose rates. As LET increases, the dose response tends to linearity throughout the dose range (e.g. for alpha particles and fission neutrons). This feature has been associated in part with the induction by high-LET particles of more complex DNA lesions that are more prone to DNA misrepair and to the larger dose delivered to each individual cell traversed by a high-LET particle.

For internal exposure to radionuclides, particularly alpha emitters and other very short-ranged radiations, the localisation of the nuclide in tissues or tissue sub-regions can create difficulties in the interpretation of dose-response data. Such difficulties may be associated with nuclide bio-kinetics and/or target cell traversal probabilities and energy deposition in relatively small tissue volumes. For many tissues, the key features of cell biology (e.g. target cell identity and location) are not well understood. The possible

existence and the location of targets with characteristics of stem cells is a major factor in judgements on alpha-particle-induced tumours in some tissues.

It has been established that different tissues (or organs) of the body have different sensitivities for the induction of cancer by radiation. This is reflected in the use of tissue weighting factors in the current system of protection. The biological bases of these recognised differences are not well understood and current judgements are largely based upon empirical epidemiological observations after acute exposures to low-LET radiation. Epidemiological studies of sufficient power should be able to yield more information on these tissue sensitivities and the potential for modification by dose, dose rate, radiation type, gender and age (see Section 1.3).

Scientific evidence

Gaps in scientific knowledge in 2007 were such that research primarily focused on understanding the consequences of non-targeted effects and other low-dose biological phenomena. The 2007 NEA report stated that while the evidence was not conclusive, current and further radiation biological research, in areas such as non-targeted effects, adaptive response and dose response relationships, appeared likely to lead to the formulation of a modified radiobiological paradigm combining both the classical (targeted) and non-targeted radiation effects. There is now evidence to suggest that radiation effects are not limited to the exposed cells only, but that radiation may cause effects in non-exposed neighbouring cells (bystander effects) as well as delayed effects in descendants of irradiated cells (genomic instability). While it is clear now that non-targeted and other non-linear biological responses do exist, their significance is still not clear in terms of health detriment. Some of these effects are potentially harmful and some potentially beneficial. Other aspects of the current state of knowledge are discussed below.

What we do know

- The primary somatic effect of ionising radiation at low doses is the induction of cancer. At doses on the order of 500 mGy, deterministic effects (such as erythema, cataract and infertility) can also occur.
- There is evidence of radiation-induced cancer risk in humans following acute radiation exposures in excess of 100 mGy.¹
- No health-benefit, apart from medical applications and hormetic effects under certain circumstances, has been observed in humans exposed to high acute doses of ionising radiation.
- Various tissues and organs exhibit a wide range of sensitivities to radiation-induced cancers, and the same tissue can exhibit different responses at different levels of dose.
- Radiation-induced, solid cancers have a long latency period, generally greater than ten years. Leukaemia and thyroid cancer in children can appear as soon as a few years after exposure. Attribution is difficult because no biomarker for radiation-induced cancers is available.
- Various host factors (such as age at exposure, time after exposure, gender, or genetic predisposition) and environmental factors (such as cigarette smoking or infectious agents) influence cancer risk at exposure levels where radiation effects have been observed.

1. Earlier research, as documented in the 2007 NEA report, suggested that radiation-induced cancer risk in humans was seen in epidemiological studies at exposures in excess of 200 mGy.

- Cellular repair mechanisms are known to exist. These may be error-prone, leading to mutations or chromosomal rearrangements, or the repair system may fail to recognise/repair the damage, leading to persistent residual damage.
- The yield of primary molecular and cellular events sometimes depends linearly on absorbed energy. However, many multi-step biological processes are known to be non-linear.
- Epidemiological studies alone will not provide definitive evidence for the existence or non-existence of carcinogenic effects due to low dose or low-dose rate exposure.
- The developing embryo/foetus is more sensitive to exposure to ionising radiation than are children and adults. Children are generally considered more sensitive than adults.
- Epidemiological studies have not detected heritable effects of radiation in humans with a statistically significant degree of confidence. The frequency of congenital malformations did not show a significant difference between normal and high-level natural radiation areas.
- Heritable effects in humans due to recessive mutation have not been observed, but this is not proof that such effects do not exist.

What we do not know

- The shape of the dose-effect relationship at low doses and dose rates for radiation carcinogenesis in humans.
- In general, there is more uncertainty for health effects from internal exposure than for external exposure. The roles of host factors (such as age at exposure, time after exposure, gender and genetic predisposition) and environmental factors (such as cigarette smoking or infectious agents) as determinants of radiation risk are uncertain.
- For the same absorbed dose, different types of radiation (alpha, beta, gamma and neutron) show different efficiencies at inducing biological effects; the basis of biological effectiveness of different radiations at inducing late effects in humans at low doses and low-dose rates are not yet sufficiently understood.
- The mechanism of carcinogenesis, whether induced by radiation or by other agents, is believed to be a multi-step process that is not fully understood. The origin of cancer is hypothesised to be the result of mutational events to critical genetic loci, and of other factors such as hormone status, age and immune function. The effects of radiation on specific steps of carcinogenesis are not fully understood. Reliable biomarkers are not available.
- Although damage to DNA is assumed to be a key step in radiation carcinogenesis, DNA double-strand breaks appear to be critical lesions that are responsible for gene or point mutations and chromosomal aberrations or loss of heterozygosity associated with cancer. Cancer is a multifactorial disease and the cause of an individual cancer cannot be specifically tied to a given insult, such as radiation exposure.
- It is not known how many tumorigenic cells are necessary to produce a cancer in vivo.
- Dormant cancer cells have been identified, but their role in radiogenic cancer is not known.
- The influence of repair processes, including polymorphisms in DNA repair genes, on human radiogenic risk at low dose and low-dose rate is not fully understood;

however, biological and chemical repair processes of radiation damage are known to occur in cells. This contributes to the uncertainty in dose and dose rate correction factors used to estimate radiogenic risk.

- It is unknown whether adaptation, observed in single cells under certain conditions, influences radiogenic risks in humans.
- It is unknown whether low doses of radiation, other than for medical purposes, have any direct benefit to health in humans.

Ongoing research and future directions

A number of potential candidate agents, including oxidative free radicals, are likely involved in the intercellular communication and bystander effects between irradiated and non-irradiated cells, and these communication processes are perturbed or stimulated by low-dose radiation. However, the relevance of these perturbations to health effects of radiation remains to be resolved. There is increasing evidence that oxidative damage induced in proteins and membranes (lipids) may modify cellular structures and functions including mitochondrial functions, enzymatic DNA repair and inherent defences against oxidative damage. Oxidation or free radical-induced changes of proteins and lipids can interfere with important regulatory and cellular signalling processes. Different sets of genes and proteins are expressed at high versus low doses, implying that mechanisms of radiation action may be different at high and low doses and dose rates.

In recent years, there has been considerable progress in science in many areas such as stem cell research, molecular biology (“omics”, epigenetics) and systems biology. Consequently, there have been advances in understanding the process of carcinogenesis. It is now assumed that the process of radiation-induced carcinogenesis involves persistent changes including, on the one hand, genetic (somatic mutations) and epigenetic alterations concomitant to genomic instability, and on the other hand, changes in the micro-environment of stem cells and differentiated cells and tissues. The cancer stem cell theory assumes that normal stem cells can be transformed into cancer stem cells. However, it is currently not known if low-dose ionising radiation can induce such change. At the population level, genome-wide association studies indicate that regulatory areas of genome rather than individual genes are associated with susceptibility to cancer. It is not known what this means in terms of radiation carcinogenesis or individual sensitivity (see Section 1.3).

Mathematical models currently used for risk assessment are primarily influenced by epidemiological data derived for medium or high doses (e.g. >100 or 200 mSv). The development of models to more reliably combine epidemiology data with experimental laboratory animal and cellular data can enhance the overall risk assessment approach by providing biologically refined data to strengthen the estimation of effects at low doses. There is hope that analysis of epidemiological data using biologically based models of carcinogenesis may shed further light on quantification of low-dose risk.

Another approach to link epidemiology and mechanisms of low-dose action is the use of biomarkers in molecular epidemiological studies of radiation-exposed populations. A variety of biomarkers describing radiation exposure, effects, susceptibility, risk or disease could potentially be applied. Advances in cellular and molecular biology are likely to yield potential biomarkers in the coming years, and their applicability needs to be investigated.

In general, there is a continuing need for studies on the mechanisms of biological response to radiation at low doses, including further development of experimental approaches to better understand the biological processes that underpin health effects.

This research should focus in particular on epidemiology, and combining mechanistic studies and epidemiology.

Epidemiology

High-quality epidemiological studies should continue to be pursued, and various means to reduce the uncertainties (such as improved dosimetry) could help improve the situation. According to the World Health Organization, radiation is only a weak carcinogen, with large, long-term epidemiological studies being key elements in the assessment of risks. Funding of such studies (e.g. the lifespan study of Japanese a-bomb survivors, the nuclear workers study, radon studies, studies of medically exposed cohorts, or studies of chronically exposed populations) should be provided over a sufficiently long time to ensure the correct and complete collection of relevant data. Due to limitations on statistical power and possible confounding factors, classical epidemiology alone is unlikely to be able to detect and measure risks of low-LET radiation at typical background levels. Molecular epidemiology may help to address this issue, as could the pooling of high-quality epidemiological studies to improve statistical power.

Studies on populations having a lower background incidence of cancer and higher sensitivity (such as children) could also be informative. Studies on high background areas of the world provide useful information on chronic low-dose/dose rate exposures, human populations being exposed throughout their lifetimes. The low-dose rate exposure in these areas gives a cumulative lifetime dose which can be >500 mGy, for which any health effect should be detectable.

The natural background radiation level in the Kerala coast due to terrestrial gamma rays emanating from the monazite sand containing thorium, varies from <1.0 mGy to 45 mGy/year with an average of approximately 4.0 mGy per year. A population size of about 70 000 was investigated in a sub-cohort aged 30-84 years in Karunaggappaly Taluk for cancer incidence. A total of 1 379 cancer cases were observed including 30 cases of leukaemia. These figures were no greater than expected, and therefore no excess risk for leukaemia or other cancers was observed from exposure to terrestrial gamma radiation.

The average annual effective dose in high background radiation areas (HBRA) of Yangjiang, China is 6.4 mSv (including internal exposure). A study was conducted to estimate cancer risk associated with the low-level radiation exposure in this area. The combined data for the period from 1979-1995, which included 125 079 subjects, had a total of 10 415 deaths, of which 1 003 were cancer deaths. The study did not reveal any increased cancer risk associated with the high levels of natural radiation. The mortality of all cancers in HBRA was generally lower than that in the control area, but not statistically significant.

Studies on medically exposed cohorts (e.g. computed tomography [CT] scans) have great potential in the clarification of low-dose risk. However, they suffer from possible reverse causation, i.e. the patients have been investigated because of some medical condition that may be associated with future cancer (e.g. brain tumours).

Leukaemia in children is considered to be one of the most important indicators for radiation effects. Recently, a number of studies have investigated the relationship between the risk of childhood leukaemia and the exposure to natural background radiation in areas that do not belong to high-level natural radiation regions. With respect to radon in homes, the results are contradictory. With respect to gamma radiation exposure to natural radiation, one large study suggests a possible effect, but the results are currently not conclusive.

Combining mechanistic studies and epidemiology

There is a need to continue epidemiological studies of low-dose responses in different tissues and to combine these with experimental studies. Mechanistic studies should be closely aligned, wherever possible, with computational approaches that specifically

incorporate biological processes in models of low-dose response. A systems biology approach is needed that involves integration of information across multiple scales of biological organisation, and combines quantitative experimental data and mathematical modelling of critical biological processes in the radiation response. Optimally, such an approach would involve experiments performed at low doses at different scales (cell, tissue, organ, organisms) and linking these to population studies. The long-term goal is for this strategy to deliver predictive models of the behaviour of the complex systems to radiation, allowing a better understanding of the risks to health from exposure at low doses and low-dose rates, and from different radiation qualities. A critical stage in the development of a systems approach is the co-operation between fundamental radiobiological research, mathematical-modelling communities and epidemiologists.

The methodology that is used to assess chemical effects – the adverse outcome pathway (AOP) methodology – could provide a framework for the assessment of radiation effects as well. In addition to systems biology, another approach for the integration of epidemiological and biological research would be molecular epidemiology, incorporating biomarkers and bioassays.

A methodology for relating diverse epidemiological and biological studies has recently been issued by the OECD (2013) for assessing risks from chemical exposures. This report provides a framework for consistent information gathering and organisation, including definitions for an AOP methodology-specific terminology. It also includes a template for developing AOPs to improve consistency across AOPs developed by different risk assessors and other stakeholders. The primary purpose of this guidance document is not to reproduce or replace the ever-expanding volume of journal articles, reports, documents and textbooks on AOPs, but to provide an introduction to the development and assessment of AOPs.

The historical paradigm for protecting humans and the environment from the adverse effects of chemicals has centred primarily on whole animal toxicity testing with single chemicals of concern. However, due to the costs and time involved, it is not practical or feasible to exhaustively test all chemicals that could adversely affect humans and ecosystems. These realities have long indicated the need for scientifically sound models and tools for predicting adverse effects of chemicals based on relatively little data. However, to date, our limited knowledge about biological systems has hindered efforts to use mechanistic information as a basis for effects extrapolation. Despite this, advances in toxicogenomics, bioinformatics, systems biology and computational toxicology are to be expected; noting that the performance of such test systems (e.g. their repeatability and reproducibility) and their toxicological relevance will need to be evaluated.

Possible policy challenges

Uncertainties in low-dose risk assessment have been recognised as problematic for regulatory policy and public communication. Despite scientific advances, low-dose risk will continue to be a matter for scientific debate.

Over the past decade, the increasing volume of epidemiology data and supporting radiobiology findings have aided in the reduction of uncertainty in the risk estimates derived. However, it is equally apparent that there remain significant uncertainties related to dose assessment, low dose and low-dose rate extrapolation approaches (e.g. the selection of an appropriate dose and dose-rate effectiveness factor), the biological effectiveness where considerations of the health effects of high-LET and lower-energy low-LET radiations are required and the transfer of risks from a population for which health effects data are available to one for which such data are not available.

It will take many years of further research, however, before the shape of the dose-response curve at low doses will be known with less uncertainty. There is no significant new evidence to support the use of a different model than the LNT model, which is the current basis of the radiological protection system. Hence the system, and the regulatory approaches based on it, will still be faced with the challenge of applying LNT, to allow for the uncertainties of risk estimates based on this hypothesis and for the possibility that different assumptions may become more plausible in future.

It should also be pointed out that the actual dose-response curve may be different for different types of cancer and different organs. Hence a deviation from the LNT hypothesis could also have implications for the concept of effective dose. Issues related to the radiosensitivity of particular individuals (e.g. due to age, gender, genetic make-up) are addressed in a subsequent section.

Recent publications

- Akiba, S. (2013), "Cancer risk associated with low dose and low dose rate ionizing radiation exposure", *Genes and Environment*, Vol. 35 No. 3, pp. 80-87, doi.org/10.3123/jemsge.2013.004.
- EC (2009), "Chapter 3: State of science and main research challenges", in *Report of High Level and Expert Group on European Low Dose Risk Research*, EC, Brussels, doi:10.2777/60680.
- Fairlie, I. (2012), "The linear no-threshold theory of radiation risks", www.ianfairlie.org/news/the-linear-no-threshold-theory-of-radiation-risks/.
- Kadhim, M. et al. (2013), "Non-targeted effects of ionising radiation-implications for low dose risk", *Mutation Research/Reviews in Mutation Research*, Vol. 752, No. 2, pp. 84-98, doi:10.1016/j.mrrev.2012.12.001.
- OECD (2013), "Guidance Document on Developing and Assessing Adverse Outcome Pathways", ENV/JM/MONO(2013)6, OECD, Paris.
- NCRP (2013), "Uncertainties in the Estimation of Radiation Risks and Probability of Disease Causation", NCRP Report No. 171, summary available in *J Radiol Prot.*, Vol. 33(3), pp. 573-88, doi:10.1088/0952-4746/33/3/573.
- UNSCEAR (2013), Vol. II. *Scientific Annex B: Effects of Radiation Exposure of Children*, United Nations, New York.
- UNSCEAR (2012), "Biological Mechanisms of Radiation Actions at Low Doses: A White Paper to Guide the Scientific Committee's Future Program of Work", United Nations, New York, www.unscear.org/docs/reports/Biological_mechanisms_WP_12-57831.pdf.
- UNSCEAR (2010), "Summary of low-dose radiation effects on health", in *Report of the United Nations Scientific Committee on the Effects of Atomic Radiation 2010*, United Nations, Vienna, www.unscear.org/docs/reports/2010/UNSCEAR_2010_Report_M.pdf.

Further reading

- Birschwilks, M. et al. (2011), "The European Radiobiological Archives: Online access to data from radiobiological experiments", *Radiat. Res.*, Vol. 175, No. 4, pp. 526-531.
- Boice, J.D. Jr. et al. (2010), "Low-dose-rate epidemiology of high background radiation areas", *Radiat. Res.*, Vol. 173(6), pp. 849-54, doi/abs/10.1667/RR2161.1.
- Kendall, G.M. et al. (2012), "A record-based case-control study of natural background radiation and the incidence of childhood leukaemia and other cancers in Great Britain during 1980-2006", *Leukaemia*, Vol. 27(1), pp. 3-9, doi:10.1038/leu.2012.151.

- Mullenders, L. et al. (2009), "Assessing cancer risks of low-dose radiation", *Nature Reviews Cancer*, Vol. 9(8), pp. 596-604, doi:10.1038/nrc2677.
- Nair, R.R. et al. (2009), "Background radiation and cancer incidence in Kerala, India-Karanagappally cohort study", *Health Phys.*, Vol. 96(1), pp. 55-66, doi:10.1097/01.HP.0000327646.54923.11.
- OECD (2015), *Health at a Glance 2015*, OECD, Paris, 2015, www.oecd-ilibrary.org/social-issues-migration-health/deaths-from-cancer/indicator/english_8ea65c4b-en?isPartOf=/content/indicatorgroup/bd12d298-en.
- Pearce, M.S. et al. (2012), "Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: A retrospective cohort study", *The Lancet*, Vol. 380, No. 9840, pp. 499-505, doi:10.1016/S0140-6736(12)60815.
- Tao, Z. et al. (2012), "Cancer and non-cancer mortality among inhabitants in the high background radiation area of Yangjiang, China (1979-1998)", *Health Phys.* Vol. 102, pp. 173-8, doi:10.1097/HP.0b013e31822c7f1e.
- Tao, Z. et al. (2000), "Cancer mortality in the high background radiation areas of Yangjiang, China during the period between 1979 and 1995", *Journal of Radiation Research*, Vol. 41, Suppl. 31-4, doi:10.1269/jrr.41.S31.
- Zablotska, L.B. et al. (2012), "Radiation and the risk of chronic lymphocytic and other leukaemias among Chernobyl clean-up workers", *Environmental Health Perspectives*, Vol. 121(1), pp. 59-65, doi.org/10.1289/ehp.1204996.

1.2. Non-cancer effects

What is the issue?

Non-cancer effects occurring after ionising radiation exposure are currently described as deterministic effects. That is, such effects appear beyond a threshold dose, depending on the adverse effect and on the tissue considered. The severity of the effect increases with increasing doses, leading possibly to a functional loss of the irradiated tissue or organ. Non-cancer effects such as disturbance of haematopoietic system (decreased lymphocyte counts), adverse skin effects, impairment of fertility, hypothyroidism, lens opacities up to cataract, neurological impairment, and/or cardiovascular diseases have been reported. Non-cancer effects include effects other than cancer, but also other stochastic effects, e.g. heritable effects. Heritable effects are not addressed in this report, nor are non-cancer effects from *in utero* exposure (still birth, malformations). However, it should be highlighted that a large-scale epidemiological study on over 140 000 newborns from normal and high-level natural radiation areas of Kerala coast (India, see Section 1.1) did not reveal significant differences in the frequencies of major and minor malformations, Down syndrome and still birth (average dose 4 mSv/a, maximum dose 45 mSv/a).

Thus far, numerous studies have been conducted which indicate that threshold values are not in the low-dose (<100 mSv) region. Nevertheless, some of the thresholds identified in the past (for cataract and cardiovascular diseases) are currently questioned, and lower threshold values are being considered on the grounds of new scientific data (including much longer follow-up times), and resulting from either acute or chronic exposure.

New scientific data suggest that effects described as cognitive, neurodevelopmental and circulatory effects are more complex than previously believed. Immune response and endocrine effects involving several organs are expected to occur after radiation exposure, but only limited data are available. Non-cancer respiratory and digestive diseases have also been described among atomic bomb survivors but have not been reported in other studies.

Often, psychological effects have been described after nuclear accidents, as in Chernobyl and Fukushima Daiichi, but these have also been observed after chemical accidents or natural disasters. In fact, it is very difficult and even impossible to identify whether psychological effects are attributable to radiation or to trauma resulting from the accident, but clearly these are the major health consequence of nuclear accidents involving low-dose radiation exposures.

Section 1.2 is concerned with non-cancer effects in humans at exposures on the order of 1 Gy and less, but such effects may also arise in non-human biota. The results of biological research on radiation effects in non-human biota are addressed in the section on protection of the environment (Section 3.4).

Scientific evidence

Lens opacities and cataracts

The process of opacification of the eye lens can result in a “cataract” at an advanced stage. There are three forms of cataract, depending on their anatomical location in the lens: cortical cataract (CC), involving the outer, more recently formed lens fibre cells, is the most common senile cataract; nuclear cataract (NC), beginning in the inner embryological and foetal lens fibre cells; and posterior subcapsular cataract (PSC), developing from abnormality in transitional zone epithelial cells resulting in an opacity at the posterior pole.

Some types of cataracts are induced by acute doses higher than 1 Gy of low linear energy transfer (LET) ionising radiation and 5 Gy of protracted radiation (e.g. PSC). Different studies relative to Japanese atomic bomb survivors, Chernobyl liquidators and US astronauts, suggest that CC could also be associated with ionising radiation. However, there is little evidence that NCs are radiogenic.

Data from atomic bomb survivors indicate that the possible threshold of cataract can vary from 0.5 to 0.8 Gy. Estimated thresholds for various cataract end points in a cohort of Chernobyl liquidators were in the range of 0.34 to 0.50 Gy. There are indications of radiation-associated cortical opacifications in a small group of US astronauts exposed to doses up to about 0.3 Gy.

Nevertheless, recent results suggest that the threshold dose for cataract may be lower than previously described. It has been reported that lens opacities may occur at doses of ~0.5 Gy although there is insufficient data to establish a pattern (ICRP Publication 118). From some results, cataractogenesis would appear to be better described as an effect appearing without threshold. ICRP (2012) has classified cataract disease as a tissue reaction (or deterministic) effect, with a threshold dose of 0.5 Gy.

Circulatory diseases

The “circulatory diseases” described here correspond to the diseases of the circulatory system classified according to the International Classification of Diseases (ICD) including: hypertensive diseases, angina pectoris, acute myocardial infarction, other ischaemic heart disease (IHD), pulmonary heart disease and diseases of pulmonary circulation, conduction disorders and cardiac arrhythmias, heart failure, cerebrovascular diseases, arteriosclerosis, varicose veins of lower extremities and “other diseases” of the circulatory system.

At radiation doses over about 1 Gy, exposure has been associated with circulatory diseases (e.g. heart diseases and strokes among Japanese atomic bomb survivors and radiotherapy patients). Several studies have highlighted a possible increased risk at radiation doses lower than 0.5 Gy for major subtypes of circulatory diseases. Such effects are still controversial. The ICRP has classified circulatory disease as a tissue reaction (or deterministic effect) with a possible threshold dose (e.g. organ equivalent dose) that may be as low as 0.5 Gy (see ICRP 118).

▪ Atomic bomb survivors

The Adult Health Study (AHS) was established in 1958 as a subset of the Life Span Study cohort, comprising 19 961 Hiroshima and Nagasaki subjects.

From the findings among Japanese atomic bomb survivors, non-cancer effects have been suggested to be compatible with dose thresholds of 0.6 Gy for cerebrovascular disease and 2.2 Gy for cardiovascular disease. The uncertainties of the model parameters inherent to this investigation method, however, do not support a consensus on the shape of the dose-response relationship.

In a recent follow-up of the AHS, a not-statistically significant increased incidence of hypertension and myocardial infarction associated with radiation was reported. In the same study, people exposed in early childhood (less than ten years old) showed a statistically significant increased incidence of non-fatal stroke or myocardial infarction, with an average heart dose of 0.13 Gy. For those exposed *in utero*, with a median dose of 1 mGy, no excess risk was observed.

From the atomic bomb survivors, a recent analysis suggests, but does not prove, an association between radiation dose and kidney disease mortality at doses under 3 Gy. Renal dysfunction could be a potential pathway resulting, to some extent, in increased cardiovascular disease mortality observed after a global irradiation. A review of more than 14 studies concerning patients also globally irradiated, but for a bone marrow

transplant (BMT), found the same result. Nevertheless, these two populations are difficult to compare (higher doses and often other therapies toxic to the kidneys for BMT population).

- **Occupationally exposed groups**

IARC 15-Country Study: Radiation worker information has been collected on diseases of the circulatory system, using the ICD. Results suggest that the circulatory diseases considered, including cerebrovascular diseases, could have a dose-related increasing trend. On the contrary, a decreasing trend for IHD, heart failure, deep vein thrombosis and pulmonary embolism was suggested. Overall, however, the results do not show that there is a statistically significant excess relative risk.

Chernobyl recovery workers: Among Chernobyl workers, an excess radiation-related incidence of IHD and cerebrovascular diseases morbidity was observed, but there was no indication of increased morbidity of hypertensive heart disease and other heart disease.

Mayak workers: The Mayak worker cohort is an important example of protracted radiation exposures: the workers were exposed to low and medium doses at low-dose rates. In this cohort the source of exposure was heterogeneous alpha-particle-emitting radioisotopes of plutonium, and external gamma rays from other radionuclides, resulting in average whole body doses of 0.83 Gy (with a range of 0 to 5.92 Gy). The morbidity and mortality among Mayak workers in studies on circulatory diseases have shown a statistically significant relationship with dose for IHD and cerebrovascular diseases; a statistically significant correlation of incidence with dose was found both for total external gamma-ray exposure and for internal exposure of the liver.

Uranium miners: Among various cohorts of uranium miners, there was no elevated risk for circulatory diseases observed. This includes the largest single cohort study, i.e. the German uranium miners study (Walsh, 2014). Only in the French cohort, results suggest an association between the mortality from cerebrovascular diseases and cumulative radon exposure. Due to a lack of data (e.g. on possible confounding factors) these findings should be interpreted with caution. Overall, results are more suggestive of no risk than they are of a risk related to radon exposure.

Environmentally exposed group: For the **Techa River** cohort (Southern Urals), a marginally statistically significant increase of all circulatory diseases and of IHD mortality was reported with latency periods higher than 15 years for an average heart dose of 0.035 Gy. These results are to be considered as preliminary in absence of consideration on lifestyle factors (such as cigarette smoking and alcohol consumption).

Nuclear weapons tests – Kazakhstan: Circulatory disease mortality was studied in a Semipalatinsk cohort of people from villages exposed and unexposed to fallout from nuclear weapons tests, and followed up between 1960 and 1999. When populations of exposed and unexposed villages were included in the analysis, the excess risks were statistically significant with a dose-response relationship. The risk among the exposed was about twice as high as the unexposed, independently of the dose category. The authors have therefore studied a potential relationship only among the cohort members from the exposed villages. However, no excess risk was reported for cardiovascular disease, heart disease or stroke.

It has been suggested that the significantly higher risk reported among people living near the test site than those living at distance could be partly explained by people in unexposed villages being more stable than those from exposed villages who had migrated from other locations. Increasing the lag time from a 10- to 20-year analysis of the restricted cohort to the exposed villages still resulted in a non-significant excess mortality risk from cardiovascular disease, heart disease or stroke. The results suggest that, at doses estimated with some uncertainty (between 0 and 0.63 Gy with a mean dose

of 0.09 Gy), there is no detectable excess mortality risk of radiation from cardiovascular diseases.

Cognitive and neurodevelopmental disorders

It is known that ionising radiation may impair the developing human brain as documented among children who were exposed *in utero* after the bombing of **Hiroshima and Nagasaki**. Small head sizes and severe mental retardation were observed, especially among survivors exposed *in utero*, from 8 to 25 weeks after ovulation.

Studies of childhood cancer survivors demonstrate cognitive impairment such as learning and memory disorders after high-dose cranial irradiation. But the effect of radiation is difficult to discriminate from that of the initial disease, surgery or chemotherapy.

Unexpectedly, cognitive impairment, such as damage in learning ability, logical reasoning and spatial recognition, was observed at doses greater than 100 mGy in a **Swedish group** (Hall, 2004) treated for cutaneous haemangioma in infancy (before the age of 18 months). The authors describe a 50% reduction in high school attendance and dose-related reductions in cognitive test performance.

The study of an **Israeli group** (Loganovsky et al., 2005) treated for ringworm of the scalp in childhood did not show any elevated risk of schizophrenia. In contrast, a **Danish study** (Ross, 2003) of childhood brain tumour survivors has shown an elevated excess risk of schizophrenia, the caveat being that this increase may not necessarily relate to the treatment received. In contrast to the Israeli study, doses are less well-known in the Danish study. A Japanese study has also suggested that prenatal exposure of atomic bomb survivors in Nagasaki could be associated with schizophrenia (Imamura, 1999).

Thus, the possible influence of dose and age with regard to radiation exposure to the brain, on cognitive function and brain diseases (such as schizophrenia) indicates that at present no firm conclusions can be drawn from these studies.

Endocrine effects and immune response

In situations of radiological contamination or accidents, important physiological functions, such as endocrine and immune reactions, could be impaired due to dysregulation of glands (e.g. the thyroid) or injury to the haematopoietic system (e.g. white blood cells made in the red bone marrow [RBM]) respectively. In some cases, disturbances of the immune system, or both gland and immune systems, could sometimes result in autoimmune diseases.

A chronic radiation syndrome (CRS) has been described among residents of the Techa Riverside villages, exposed to radiation from liquid radioactive waste released from Mayak for many years. People were exposed to external irradiation (the highest dose rate is estimated to be about 100 $\mu\text{Sv}/\text{hour}$) and to internal exposures due to strontium-90 and cesium-137. The severity of this syndrome varies depending upon the radiation dose and duration. Causing *functional* changes such as blood count modifications, vegetative dysfunction or asthenia, these symptoms transform into *organic* changes if the exposure continues, with bone marrow hypoplasia and *organic* damage to the nervous system. In the case of radiation exposure for several years, a proportion of Techa Riverside residents have suffered from insufficiency in the immune system and in haematopoiesis. Some ostealgic symptoms due to deposition of strontium-90 in bone have also been reported. It should be noted that confounding factors may influence these observations.

The symptoms observed in relation to the chronic radiation syndrome are non-specific, but their dynamics of occurrence seem to depend on dose and dose rates. From dosimetry studies, it was estimated that the maximum dose rate to the RBM had reached 1.26 Gy/year in 1951. However, average dose to RBM was reported to be 0.61 ± 0.02 Gy at

the time of diagnosis of CRS. The authors recognise that in a number of individual cases, the diagnosis for CRS has been over-estimated.

Few other studies have addressed the relationship between autoimmune thyroiditis and exposure to radiation. Twelve to fourteen years after the Chernobyl accident, the largest study, involving 12 240 residents in Ukraine, did not show any relationship between thyroid dose and autoimmune thyroid disease, confirming results observed among other exposed populations. The presence of thyroid autoantibodies was measured, but this is not considered as an indicator of clinically significant destruction of the thyroid. Longer observation periods are needed to exclude later effects.

The follow-up of the “Acute Radiation Sickness survivors” at the Ukrainian Research Center of Radiation Medicine (URCRM) up to the end of 2006 indicated an increased prevalence of endocrine diseases over time from 5-15 % in 1991 to 60-70% in 2006.

However, most often it will be difficult to identify the cause of diseases resulting from disturbance of the delicate balance of these systems.

Other non-cancer effects

There is significant excess risk for non-malignant respiratory and digestive diseases obtained from atomic bomb survivor data. However, this is not generally observed in other exposed groups.

Ongoing research and future directions

Precise dose thresholds for non-cancer effects remain uncertain, however, lower threshold values and even a possible stochastic nature of these effects will continue to be studied. The mechanisms and shape of the dose-response curve of the corresponding effects should be thoroughly investigated for *lens opacities, cataracts and circulatory diseases*.

Long-term circulatory diseases at low dose have been identified only recently, among the Japanese atomic bomb survivors and occupationally exposed cohorts. It has also been studied among the “environmentally exposed” cohorts in the Techa River and near the Semipalatinsk site. However, results have been heterogeneous, some significant and others not. The statistical power of the studies is another concern. Moreover, in most of the studies, no information on lifestyle factors has been provided. Dose and dose rate effects on circulatory diseases should be addressed both in animal studies and through human cohort analyses. Detailed mechanistic studies of the different types of cardiovascular effects need to be investigated, and specific biomarkers need to be identified. Further studies should discriminate between the roles of cell-killing effects on endothelial cells of blood vessels and the activation of inflammatory responses.

The comprehension of **cognitive effects** should benefit from investigations on animal models at different stages of brain development after radiation exposure. Irradiation may induce a decrease of the number of capillaries within the hippocampus – a region of the brain important for learning and memory. Consequently, it may contribute to radiation-induced cognitive decline. Research is required to better understand the influence of brain dose and age at exposure on cognitive function and brain diseases, such as schizophrenia.

Endocrine and immune diseases, which can appear rapidly after an adverse event but may also take several years to appear, are probably multifactorial. Consequently, the causes of these diseases are difficult to identify.

In general, *in vitro* studies are necessary to investigate the mechanisms of these different effects. *In vivo* animal studies will be necessary to generate data on biological parameters (blood pressure, blood count, hormone concentration, enzymatic activity, etc.), the influence of genetics, individual radiosensitivity and potential adverse health effects.

Future studies should target the following aspects:

- molecular mechanism of radiation-induced circulatory disease;
- dose and dose rate effects on circulatory diseases addressed both in animal studies and through human cohort analyses;
- a robust animal model for investigating non-cancer effects, particularly cardiovascular disease;
- interpretation of results from animal studies and their possible applicability for extrapolation to humans.

Cognitive, circulatory, endocrine effects and immune response would require further in depth studies to analyse their complexity and their possible thresholds. Studies have to be performed to investigate more precisely:

- the conditions of non-cancer effect occurrence;
- the potential relationships between these effects;
- their latency and potential reversibility;
- the influence of age at radiation exposure;
- the influence of dose rate;
- the influence of cumulative dose.

Dialogue with other scientific fields will be particularly fruitful in such areas. Biomarkers and modelling should be integrated with epidemiological studies to facilitate achieving useful results.

Possible policy challenges

Non-cancer effects are now receiving more attention, but the mechanisms and their induction at low doses and dose rates are still uncertain. How their contribution to radiological detriment should be accounted for is also still under discussion.

As a result of new scientific evidence, the ICRP has recommended a lower threshold for cataracts, and a decrease in the dose limit to the lens-of-the-eye to 20 mSv per year averaged over five consecutive years (100 mSv in five years) and a maximum of 50 mSv in any single year. For circulatory effects and other non-cancer effects, more work is needed before decisions on issuing practical protection recommendations for low doses and dose rates can be made. For both circulatory effects and cataracts, experimental studies are expected to evaluate more accurately the existence and value of possible thresholds, according to radiation dose and duration of exposure (acute or prolonged radiation exposure).

The severity of health detriment from non-cancer effects should be given due consideration. It should be pointed out that a cataract is relatively easy to treat medically. On the contrary, potential cognitive effects caused by irradiation can seriously impair an individual's life, and should thus be appropriately taken into account.

If further scientific results demonstrate the existence of lower or no thresholds for circulatory and cognitive effects, those who are of concern in view of their occupational or medical exposure should be informed of specific radiation risks. The justification of levels of use of radiation in medicine (health care) may need to be reconsidered, and the benefits and risks evaluated. For example, it should be underlined that the use of current imaging technologies, such as computed tomography, can deliver up to a few tens of mGy to the brain of an infant, and should be used very cautiously.

References

- Agate, L. et al. (2008), "Thyroid autoantibodies and thyroid function in subjects exposed to Chernobyl fallout during childhood: Evidence for a transient radiation-induced elevation of serum thyroid antibodies without an increase in thyroid autoimmune disease", *J Clin Endocrinol Metab*, Vol. 93(7), pp. 2729-2736.
- Ainsbury, E.A. et al. (2009), "Radiation cataractogenesis: A review of recent studies", *Radiation Research*, Vol. 172, pp. 1-9.
- Akleyev, A.V. (2012), "Chronic radiation syndrome among residents of the Techa riverside villages", *Radiation Protection Dosimetry*, Vol. 151, No. 4, pp. 689-695.
- Azizova, T.V. et al. (2011), "Cerebrovascular diseases in nuclear workers first employed at the Mayak PA in 1948-1972", *Radiat Environ Biophys*, Vol. 50(4), pp. 539-52.
- Azizova, T.V. et al. (2010), "Cardiovascular diseases in the cohort of workers first employed at Mayak PA in 1948-1958", *Radiation Research*, Vol. 174(2), pp. 155-68.
- Grosche, B. et al. (2011), "Mortality from cardiovascular diseases in the semipalatinsk historical cohort, 1960-1999, and its relationship to radiation exposure", *Radiation Research*, Vol. 176, pp. 660-669.
- Hall, P. et al. (2004), "Effect of low doses of ionising radiation in infancy on cognitive function in adulthood: Swedish population based cohort study", *British Medical Journal*, Vol. 328, p. 19.
- Hamada, N. (2014), "What are the Intracellular targets and intratissue target cells for radiation effects?", *Radiation Research*, Vol. 181(1), pp. 9-20.
- Hammer, G.P. et al. (2013), "Occupational exposure to low doses of ionising radiation and cataract development: A systematic literature review and perspectives on future studies", *Radiat Environ Biophys*, Vol. 52, pp. 303-319.
- ICRP 118 (2012), "ICRP statement on tissue reactions and early and late effects of radiation in normal tissues and organs – threshold doses for tissue reactions in a radiation protection context", *Annals of the ICRP*, Vol. 41(1-2), pp. 1-322.
- Jaikrishan, G. et al. (2013), "Study of stillbirth and major congenital anomaly among newborns in the high-level natural radiation areas of Kerala, India", *J Community Genet.*, Vol. 4(1), pp. 21-31.
- Kempf, S.J., O. Azimzadeh, M.J. Atkinson and S. Tapio (2013). "Long-term effects of ionising radiation on the brain: cause for concern?", *Radiat Environ Biophys*, Vol. 52, pp. 5-16.
- Krestinina, L.Y. et al. (2013), "Chronic low-dose exposure in the Techa River Cohort: Risk of mortality from circulatory diseases", *Radiat Environ Biophys*, Vol. 52, pp. 47-57.
- Little, M.P. (2013), "A review of non-cancer effects, especially circulatory and ocular diseases", *Radiat Environ Biophys*, Vol. 52, pp. 435-449.
- Loganovsky, K.N. et al. (2005), "Whether ionizing radiation is a risk factor for schizophrenia spectrum disorders?", *The World Journal of Biological Psychiatry*, Vol. 6(4), pp. 212-230.
- Muirhead, C.R. et al. (2009), "Mortality and cancer incidence following occupational radiation exposure: Third analysis of the National Registry for Radiation Workers", *British Journal of Cancer*, Vol. 100, pp. 206-212.
- Neriishi, K. et al. (2012), "Radiation dose and cataract surgery incidence in atomic bomb survivors, 1986-2005", *Radiology*, Vol. 265, pp. 167-174.

- Ozasa, K. et al. (2012), "Studies of the mortality of atomic bomb survivors, 1950-2003: An overview of cancer and noncancer diseases", *Radiat Res.*, Vol. 177, pp. 229-243.
- Ramachandran, E.N. et al. (2013), "Cytogenetic studies on newborns from high and normal level natural radiation areas of Kerala in southwest coast of India", *Int J Radiat Biol.*, Vol. 89(4), pp. 259-67.
- Ross, L. et al. (2003), "Psychiatric hospitalisations among survivors of cancer in childhood or adolescence", *The New England Journal of Medicine*, Vol. 359(7), pp. 650-657.
- Sadetzki, S. et al. (2011), "Childhood exposure to ionising radiation to the head and risk of schizophrenia", *Radiat Res*, Vol. 176, pp. 670-677.
- Schöllnberger, H., J.C. Kaiser, P. Jacob and L. Wals (2012), "Dose-responses from multi-model inference for the non-cancer disease mortality of atomic bomb survivors", *Radiat Environ Biophys*, Vol. 51, pp. 165-178.
- Schultz-Hector, S. and K.R. Trott (2007), "Radiation-induced cardiovascular diseases: Is the epidemiologic evidence compatible with the radiobiologic data?", *Int J Radiat Oncol Biol Phys.*, Vol. 67(1), pp. 10-8.
- Shimizu, Y. et al. (2010), "Radiation exposure and circulatory disease risk: Hiroshima and Nagasaki atomic bomb survivor data, 1950-2003", *The BMJ*, 340: b5349.
- Tatsukawa, Y. et al. (2008), "Cardiovascular disease risk among atomic bomb survivors exposed in utero, 1978-2003", *Radiat Res*, Vol. 170(3), pp. 269-74.
- UNSCEAR (2008), "Annex D: Health effects due to radiation from the Chernobyl accident", in *Sources and Effects of Ionising Radiation*, Volume II, United Nations, New York.
- Walsh, L. et al. (2014), "A Review of the results from the German Wismut uranium miners cohort", *Radiat Prot Dosimetry*, Vol. 164(1-2), doi: 10.1093/rpd/ncu281.
- Worgul, B.V. et al. (2007), "Cataracts among Chernobyl clean-up workers: Implications regarding permissible eye exposures", *Radiation Research*, Vol. 167, pp. 233-243.
- Yamada, M. et al. (2004), "Non-cancer disease incidence in atomic bomb survivors, 1958-1998", *Radiation Research*, Vol. 161, pp. 622-632.

1.3. Individual sensitivity

What is the issue?

In general, enhanced radiosensitivity refers to an increased incidence of a potentially detrimental biological effect for a given radiation dose.

Differences in radiosensitivity may reflect genetic or epigenetic factors, ethnicity, differences in age- or gender-specific risk coefficients, or differences in lifestyle factors such as smoking or diet, which might enhance or protect against the effects of radiation. Individual radiosensitivity presents challenging problems in medicine and in radiological protection.

For radiological protection purposes the definition of radiosensitivity still lacks a proper quantitative criterion – i.e. how much must risk be increased over the population average before one would classify a person as radiosensitive?

Important information about radiosensitivity can be obtained from high-dose exposures, but the particular concern here is with the risks from low to moderate doses – especially radiogenic cancer risks.

Baseline cancer rates can vary widely from one population or subgroup to another, depending on organ, age, gender, genetic make-up, as well as on environmental and lifestyle factors. It is expected that many, if not most, of these factors will also produce variability in the risk of radiation-induced cancers. This association between baseline cancer rates and radiation risk has already been demonstrated in a number of cases, for example the general increase in cancer incidence with age at diagnosis, a higher risk among females and Ashkenazi Jews for thyroid cancer and a higher lung cancer risk from inhaled radon decay products² or plutonium among smokers.

Recent advances in medicine and radiobiology indicate that certain genetic mutations and diseases are related to increased sensitivity to ionising radiation exposure. Efforts are underway to correlate specific gene mutations with risk from complex diseases through genome-wide association studies. In particular, there is interest in the association of specific mutations with the incidence of certain types of cancers or with specific enhanced risks of radiogenic cancers. Identification of such mutations could then be used as a basis for screening individuals who are at risk, for instance in medical exposures.

Epidemiologic, clinical, and experimental data provide clear evidence that genetic factors can influence radiation cancer risk. Strongly expressed human mutations of this type are rare, but they are potentially important in the context of high-dose medical exposures. They are not expected to significantly influence estimates of population-based, low-dose risks. Hence, while evidence for the complex interaction of weakly expressing genetic factors in cancer risk is growing, current understanding is insufficient for a detailed consideration of the potential impact on population risk (NAS, 2006).

The percentage of the population with increased risk of radiogenic cancer associated with genetic susceptibility to cancer is not known but is estimated to be from 1 to 10%. This estimate is highly uncertain because the scientific data is limited.

Epidemiological studies have shown that children are generally at higher risk of radiogenic cancers than adults, and have also indicated that the excess absolute risk³ from a given dose of uniform, whole body radiation is about 50% higher for females than

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2. The relationship between radon and smoking is addressed in Section 3.1.
 3. The excess absolute risk is the difference in absolute risk between an exposed and unexposed control population.

males. In other words, the risk to females is estimated to be roughly 20-25% higher than the population average. These differences are presumably negligible compared with other differences in radiosensitivity across the population, but the gender and age differences can be significant for particular types of exposure (e.g. radionuclides) where the risk to females may be two or three times higher than that to males, or in large-scale exposures of mixed-age populations in, for example, emergency exposure situations.

Medical management of patients with known radio sensitivities is particularly challenging because patient doses from radiotherapy for cancer and certain interventional procedures (e.g. angiography, angioplasty) can be as high as 70 Gy to specified areas of the body. There is considerable interest in identifying sensitive individuals who are candidates for cancer therapy. Screening cancer patients for radiation (and chemotherapy) sensitivity could be useful in optimising treatments. If these differences can be identified, therapeutic doses could be adjusted downward for radiosensitive patients, but upward for radio-resistant patients. The treating physician needs to find the optimal therapy for the individual patient and his specific cancer, taking account of all available therapies (chemo, radio, hormone) and surgery.

There has been an explosive increase in the use of computed tomography (CT) scans as a diagnostic tool in medicine. Undoubtedly, great benefits have been gained from CT, but there is rising concern over the doses from these procedures, especially with respect to irradiation of children and young adults, who are generally more radiosensitive (UNSCEAR, 2008). When possible, it would be desirable to substitute an alternative imaging modality for such patients without compromising their medical care.

The framework for radiological protection has historically been based on the response of an average individual in an exposed population. There is now interest in adding information on individual responses to the existing set of radiological protection tools focusing on average response. It should be noted, however, that there are important ethical, legal and societal issues that could suffer from intense focus on an individualised approach.

For instance, there are issues involved in possibly choosing a gender-specific approach (equal job opportunity considerations), and in deciding to give priority to the protection of children in an emergency exposure situation or post-accidental existing exposure situation (strong focus on post-accident protection of children). The context of the exposure situation also determines whether the risk should be assessed on the basis of lifetime dose, or on considerations of the age at the time of exposure. Should differences in the age dependence of risk be factored in when dealing with episodic versus long-term exposures?

With regard to individual genetic sensitivity, there are important societal questions that need to be addressed, such as:

- Should worker and population dose limits be made more restrictive to account for more sensitive individuals?
- Should workers be treated differently because of increased radiation sensitivity?
- How should physicians manage patients with increased radio sensitivities?
- Should high-dose interventional procedures be modified to limit patient dose?
- When should a diagnostic or interventional procedure involving radiation be substituted by an alternative procedure?
- Should social and economic costs associated with identifying sensitive individuals and providing additional protective measures be an important factor in the analysis?

The analysis should also allow for the significance of the individual sensitivity. For workers, one should recognise that some health outcomes are more serious than others. Individuals at increased risk for non-melanoma skin cancers or cataracts are likely to require different risk management strategies than those at higher risk for colon cancer or leukaemia.

For short-term exposures, such as the potentially high doses that can be caused by a sudden nuclear accident, age at exposure is a significant risk factor. In general, it is important to take into account the enhanced contribution from childhood exposures in estimating the lifetime risk. For episodic exposures, it may be appropriate that radiological protection measures target the most sensitive age groups. For example, ICRP 101 (2006) recommends that optimisation of protection should take into account those most at risk.

Scientific evidence

Exposure to ionising radiation may result in the induction of various types of DNA damage in human cells. Efficient DNA damage response mechanisms, including recognition of damage and a range of DNA repair pathways, play an important role in restoring genome integrity. Any detrimental mutations in DNA repair genes may lead to genomic instability and an increased cancer risk. Genetic polymorphisms in DNA repair genes may also influence inter-individual variation in DNA repair capacity, thus increasing the susceptibility to cancer.

Clustered DNA lesions, often referred to as “locally multiply damaged sites”, are the most deleterious types of DNA damage induced by ionising radiation and likely play a fundamental role in cell killing and carcinogenesis following radiation exposure. While a deficiency in the repair of DNA double-strand breaks (DSBs) implies increased sensitivity to ionising radiation, there are several mechanisms by which this can occur including apoptotic failure and lack of cell cycle checkpoint control.

Importantly, defects in the repair of other types of DNA lesions or in the clearance of aberrant cells through processes such as apoptosis may also increase susceptibility to radiation-induced cancer.

DSB repair is one of the most studied DNA damage issues associated with radiation exposure. What we currently know about DSB repair is thus somewhat representative of our overall understanding of DNA damage, and will be described here in a generic sense.

Double-strand break repair

Induction of DSBs and other types of complex damage in DNA is known to play a fundamental role in radiation carcinogenesis. Therefore, it would not be surprising if mutations affecting such things as DSB repair or apoptosis are associated with a higher radiogenic cancer risk.

There are several mechanisms by which deficiency in the repair of DNA DSBs can occur. There can be deficiencies in either of the two primary pathways for repairing DSBs: homologous recombination repair (HRR) and non-homologous end joining (NHEJ). HRR uses the undamaged homologous chromosome as a template, which leads to “error-free” repair, assuming that the template contains a normal allele at the location of the DSB in the damaged copy. NHEJ, on the other hand, is “error-prone”. In addition to a deficiency in a gene associated with the HRR or NHEJ mechanism, DSB repair can be affected by mutations in genes involved in signalling of DNA breaks or in activating cell cycle checkpoints (HPA, 2013).

Evidence for genetic-based radiosensitivity comes mainly from high-dose medical exposures. A small number of human diseases such as ataxia telangiectasia (AT) and Nijmegen Breakage Syndrome (NBS) are associated with increased radiation sensitivity.

Patients with AT or NBS express severe normal tissue reactions not observed in the general population. Radiobiological studies indicate that cells from AT patients are more sensitive to the cytotoxic effects of radiation because of defects in DNA DSB repair capacity.

Epidemiological studies

There is limited evidence of enhanced radiosensitivity in humans following exposure to low doses of radiation. This is due, in part, to the difficulty of detecting small differences in risk in epidemiological studies of populations exposed to low doses. This difficulty is compounded if one is trying to test whether a particular gene mutation affecting a relatively small fraction of the population is associated with a higher risk from low-level radiation

A few autosomal dominant mutations confer a very high risk of cancer, but they are very rare in the population. Carriers of the recessive BRCA1/2 gene are at high risk for breast cancer through a somatic mutation in the normal gene copy. According to a 1998 review by the ICRP on genetic susceptibility (ICRP 79), it appears that the prevalence of highly penetrant cancer-predisposing mutations in typical human populations is about 1% or less. Moreover, there is no evidence for extreme increases in genetically linked radiation cancer risk. Consequently, these rare penetrant mutations are not expected to appreciably affect current estimates of radiation cancer risk in a population. Only a tiny fraction of radiogenic cancers in a population will be expected to occur in individuals inheriting familial cancer genes.

Apparently, for many of the recessive genes associated with a higher cancer risk (e.g. ataxia telangiectasia mutated [ATM]), the risk to heterozygotes is elevated only slightly (by less than 50%). It further appears that, while some individuals have a substantially higher genetic predisposition to cancer, this usually results from combined, relatively small effects of multiple gene mutations rather than a single high-risk mutation. The same situation probably holds for radiation-induced cancers, but the data are less conclusive. In some ways, the small contributions of individual genes is disappointing, making it more difficult to use the genetic information to screen for high risk individuals, or to substantially reduce risk by gene therapy targeting specific gene products.

Children and the foetus

Epidemiological studies of the Japanese A-bomb survivors and other irradiated cohorts have shown that a given radiation dose to children generally conveys a higher lifetime cancer risk than to adults. Based on BEIR VII or ICRP cancer risk models, for example, the lifetime risk from uniform, whole body radiation is typically two to three times higher for children (UNSCEAR, 2008: p. 5, para. 22; ICRP 103: Section 3.4, para. 97) than for the general population. The enhanced risk for children is clear for leukaemia and cancers of the thyroid, skin, breast, and brain (UNSCEAR, 2013). For some individual sites, however, the evidence is less compelling, in large part due to a paucity of data or, in some cases, the possible effects of other risk factors such as smoking.

Studies have indicated a relatively high risk of radiation-induced cancer in children irradiated *in utero*. The data are most convincing for exposures occurring in the last trimester. Irradiation of pregnant women in the first two trimesters has also been found to correlate with childhood cancers, but such circumstances have been infrequent, so the epidemiological studies lack statistical power. A recent study of irradiated mice indicated that prenatal irradiation can produce genomic instability persisting into adulthood, which can potentially be transmitted to subsequent generations.

The concern for the protection of children *in utero* also includes non-cancer effects. Damage to the developing brain by radiation has been observed. The central nervous system is particularly sensitive during the period 8-25 weeks post conception. Foetal doses in excess of 100 mGy may result in a verifiable decrease in IQ. A study of Swedish

infants (<18 months) for haemangioma was found to be associated with decreased cognitive function for brain doses only slightly higher than those delivered in a series of diagnostic head CT scans (Hall et al., 2004).

It is also possible that mutations or epigenetic changes occurring after conception might increase radiosensitivity. For example, it has been proposed that there may be an increased risk of acute lymphocytic leukaemia (ALL) – and possibly other types of leukaemia – in individuals due to a specific chromosomal translocation in a leukocyte occurring during gestation, which subsequently undergoes clonal expansion. Nakamura (2005) has suggested that a high proportion of radiogenic ALL cases may appear in this predisposed population, the radiation producing a second mutation in a cell already contained in a mutated cell population. Children found to have such pre-leukemic translocations would merit special follow-up after accidental or therapeutic radiation exposure.

Ongoing research and future directions

Improving understanding of variations in population sensitivity

There has been a rapid evolution in cancer genetics in recent years. The human genome has been sequenced, and data on individual genetic variation is emerging. These results will be important since much of human variation to external and internal agents and stimuli is thought to result from individual gene variations due to single nucleotide polymorphisms (SNPs), specific gene codon variations that result in a change of a single amino acid in the protein product of the gene. New biochemical approaches are helping to clarify our understanding of the impact of SNPs on gene products and how they affect cell and tissue function; research will continue to progress in this area and provide increased understanding of the genetic basis of individual radiosensitivity and radio-resistance, as well as overall cancer susceptibility.

Basic molecular biology has increased our understanding on the responses of cells to ionising radiation and mechanisms of radiation action. However, regardless how refined a picture emerges from human and animal experimental models, large-scale work in human populations is required to confirm effects in realistic settings and to quantitatively address public health implications. The feasibility of such studies is rapidly improving with the evolution of high throughput screening techniques such as DNA chips and “omics” technologies. Potential genes capable of modifying the radiation response include those involved in DNA repair and cell cycle control. Association of relevant gene variants with cancer, chromosomal aberrations and mutations should be carried out in exposed and control populations to evaluate their role in individual radiation sensitivity. Functional phenotype assays should be developed in parallel with the genotype analyses. Bio-sample banks of radiation-exposed populations are available and should be utilised in such studies.

The assessment of SNP variations in genes of particular relevance to radiation response will be valuable in assessing individual variations in radiation risk. Since the influence of some genes after high doses appears different from their influence after low doses, such understanding may have different implications for patient protection in a therapy setting than for radiological protection in a public, occupational or diagnostic radiology setting. It seems likely that (paralleling the case for many known, genetic diseases in humans) SNP variations will not be distributed normally across the entire human population, but will be biased on a regional or ethnic basis. It is possible, therefore, that ethnic or other differences in SNP distributions could reduce the efficacy of broadly based epidemiological studies unless those differences were accounted for in the study design. From studies of irradiated human lymphocytes, it appears that there are individuals who are hypersensitive to radiation-induced chromosome damage and are also predisposed to certain types of cancer. However, it has not yet been demonstrated that such individuals are predisposed to radiation-induced cancer. In

principle, studies of radiation-induced second cancers in therapeutically irradiated cancer patients can shed light on this question, but so far the data from such studies have been inconclusive.

Developing screening tests

Molecular epidemiology, whereby radiation exposure is linked to genetic susceptibility and effects, may help in assessing the variability in radiation sensitivity in the population. Several epidemiologic studies (e.g. Lloyd et al. [1980], Anderson et al. [2000] and Kasuba et al. [2008]) suggest that the rate of chromosomal aberrations in peripheral blood lymphocytes may be predictive of cancer risk. This association holds true not only for chromosomal aberrations induced by genotoxic agents such as ionising radiation, but also for unexposed persons, implying that part of the risk is explained by inherent (genetic) factors. Future research may investigate whether part of this individual variability can be explained by repair gene variants, other gene polymorphisms or dietary factors.

Possible policy challenges

Individuals may vary in their sensitivity to radiation because of genetic and epigenetic differences, but also because of age, gender and lifestyle. The implications of this variation will depend on the exposure situation and the category of exposure.

Protection of sensitive subgroups in the general population

The age dependency of risk after exposure raises a problem, since regulatory limits are commonly framed in terms of a maximum annual dose. The most conservative approach to this problem would be to ensure that even the most sensitive age-group does not exceed a perceived acceptable risk, but this may lead to a standard that is more protective than is warranted. Alternatively, if the purpose of a limit on releases from a source is to ensure that the additional lifetime risk for an individual living near that source is acceptable, then it makes sense to set exposure limits based on an estimated lifetime dose or risk from long-term exposure – or, equivalently, an age-averaged annual dose or risk.

The risk to some individuals may be significantly elevated over the risk to an average individual. Then, even if a regulatory standard reduces risk to an average individual to a level deemed acceptable, the risk to these radiosensitive people may still exceed that level. One factor to consider in addressing this issue is that such sub-populations are likely to already be at increased risk for cancer. Since radiogenic cancer risks often parallel baseline cancer rates, these sub-populations may have a higher incremental risk from a given radiation dose than the average individual but a similar percentage increase. It is also true that some lifestyle factors that raise radiogenic cancer risk are within the control of the individual.

The most salient example of this is the synergism between smoking and radon exposure in causing lung cancer. It has been suggested that radon reduction be specifically targeted towards smokers. Alternatively, in view of the greater risks from smoking, it has also been suggested that risk from radon among smokers be downplayed and instead a greater effort be made towards convincing individuals potentially exposed to elevated radon levels in homes or in the workplace to stop smoking.

Unfortunately, there are no solutions to the issue of potential inequity in radiological protection that will be satisfactory to everyone. Doses and risks from environmental releases are considerably lower than from occupational exposures and generally far lower than from natural background radiation. Indeed, it could be argued that radiosensitive individuals have been included in cohorts used to develop our current understanding of radiological risk, and are thus adequately protected by current public dose standards. For this reason, vigorous implementation of “as low as reasonably

achievable" (ALARA) measures to manage doses to the entire population around the site is reasonable.

Nevertheless, information on the distribution of radiosensitivity in the population could impact regulations and guidelines for exposure management. For example, some parts of the regulatory system could be tailored to take radiosensitivity into account, although using other quantities than effective dose to represent detriment.

Protection of sensitive subgroups among workers

Differences in radiogenic cancer risk among individuals working in radiological environments may be regarded as more realistic than among the general population. If workers with elevated risk can be identified, additional protective measures could be considered. This requires, however, a thorough reflection, on the one hand on the appropriate management strategy, and on the other hand, on the societal implications. The following paragraphs provide examples of where these issues could be raised should the identification of such groups become scientifically practical.

If it is decided that radiosensitive workers should have enhanced protection, this would require the adoption of an appropriate management strategy. One option would be that radiosensitive groups be stratified in accordance with the severity of their cancer predisposition. One might consider the establishment of separate, lower, dose limits for the radiosensitive groups. The current radiological protection framework already includes special considerations for pregnant workers, who are subject to more restrictive dose limitations during pregnancy.

Genetic testing, whether voluntary or involuntary, raises legal and ethical questions and also has implications for radiological protection policy. The rapid evolution in DNA technologies will most likely make it possible to obtain detailed genetic information on individuals. Some think that genetic information is like a Pandora's Box – do not open it or we will be in big trouble. At the individual level, one can argue between the right-to-know versus the right-not-to-know. Some people may not want to know if they carry genes that predispose them to a certain disease, whereas others may want to know so that they can do something about it (e.g. engage in risk avoidance behaviours like not smoking or eating a healthy diet). This reasoning also applies to genetic testing of members of the public and patients.

In general, genetic testing for radio sensitivity should be left up to the individual, but there may be certain employment situations where the employer legitimately requires such personal information.

Astronauts are in a special category in which an occupational exposure might foreseeably exceed established annual dose limits. In the US space programme, the National Aeronautics and Space Administration (NASA) has limited the estimated excess cancer mortality risk to astronauts in low earth orbit to 3%, specifically taking into account both age and sex. With further development of genetic screening, NASA may be faced with the decision as to whether data generated in this way should be used in selecting astronauts for long space missions involving high doses of radiation.

Genetic testing of employees is therefore a sensitive issue, which can be interpreted either as worker discrimination or as a prudent procedure in the best interests of the individual. Individuals with positive screening test results (either true or false) may be subject to employment, insurance and social discrimination. One should allow for false positive tests as well as false negative, both possibly giving rise to complaints and calling for compensation. It is therefore questionable whether radiosensitivity could be considered a legitimate pre-employment condition that requires testing. It would also raise the question of how radio sensitivity should be defined in terms of measurable criteria and standards.

It should be emphasised that the question of worker sensitivity extends beyond radiological protection. Individuals with enhanced radiosensitivity may also be sensitive to other carcinogens, particularly if cellular damage pathways are common to both. Accordingly, many of the issues raised here will need to be addressed in the context of occupational health more generally, and radiological protection policy will need to be developed in a broader framework.

Medical exposures

Individual radiosensitivity is an important issue in radiation therapy (in particular with regard to non-cancer effects at high doses, but also with regard to strategies for reducing the risk of secondary, radiation-induced cancers). In medical imaging, the justification and optimisation of individual procedures should allow for the age of the patient, in particular with regard to children undergoing CT. Changes in the use of diagnostic radiation procedures might also be warranted for other patients with enhanced radiosensitivity. With progress in individualised medicine and greater availability of genetic testing, patients may be anticipated to have access to information on their individual radiosensitivity. This information may then have implications if the patient also happens to be a radiation worker, or if the patient perceives the risk from exposure to environmental levels of radioactivity as very high.

Recent publications

- Anderson, R.M. et al. (2000), "Complex chromosome aberrations in peripheral blood lymphocytes as a potential biomarker of exposure to high-LET alpha-particles", *Int J Radiat Biol.*, Vol. 76(1), pp. 31-42.
- Barnett, G.C. et al. (2009), "Normal tissue reactions to radiotherapy: Towards tailoring treatment dose by genotype", *Nature Cancer Reviews*, Vol. 9, pp. 134-142.
- Hall, P. et al. (2004), Effect of low doses of ionising radiation in infancy on cognitive function in adulthood: Swedish population based cohort study, *BMJ*, Vol. 328, p. 19.
- HPA (2013), *Human Radiosensitivity*, HPA, London, www.gov.uk/government/uploads/system/uploads/attachment_data/file/333058/RCE-21_v2_for_website.pdf.
- ICRP 103 (2007), "The 2007 recommendations of the International Commission on Radiological Protection", *Annals of the ICRP*, Vol. 37 (2-4).
- ICRP 101 (2006), "Assessing dose of the representative person for the purpose of radiation protection of the public and the optimisation of radiological protection", *Annals of the ICRP*, Vol. 30.
- ICRP 79 (1998), "Genetic susceptibility to cancer", *Annals of the ICRP*, Vol. 28: pp. 1-157.
- Kasuba, V., R. Rozgaj and A. Jazbec (2008), "Chromosome aberrations in peripheral blood lymphocytes of Croatian hospital staff occupationally exposed to low levels of ionising radiation", *Archives of Industrial Hygiene and Toxicology*, Vol. 59(4), p. 251, DOI:10.2478/10004-1254-59-2008-1909.
- Lloyd, D.C., R.J. Purrott and E.J. Reeder (1980), "The incidence of unstable chromosome aberrations in peripheral blood lymphocytes from unirradiated and occupationally exposed people", *Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis*, Vol. 72, Issue 3, pp. 523-532.
- Nakamura, N. (2005), "A hypothesis: Radiation-related leukaemia is mainly attributable to the small number of people who carry pre-existing clonally expanded pre-leukemic cells", *Radiat. Res.*, Vol. 163, pp. 258-265.
- NAS (2006), *Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2*, US National Academy of Sciences, Washington.

NCRP (2010) *Potential Impact of Individual Genetic Susceptibility and Previous Radiation Exposure on Radiation Risk for Astronauts*, NCRP, Washington DC.

Pijpe, A. et al. (2012), "Exposure to diagnostic radiation and risk of breast cancer among carriers of BRCA1/2 mutations: retrospective cohort study", *BMJ*, Vol. 345.

Saunders, E.J. et al. (2014), "Fine-mapping the HOXB region detects common variants tagging a rare coding allele: Evidence for synthetic association in prostate cancer", *PLoS Genet.*, Vol. 10, doi:10.1371/journal.pgen.1004129.

Sigurdson, A.J. and D.O. Stram (2012), "Genetic predisposition to radiation-related cancer and potential implications for risk assessment", *Annals of the ICRP*, Vol. 41, pp. 108-116.

UNSCEAR (2013), Vol. II. *Scientific Annex B: Effects of Radiation Exposure of Children*, United Nations, New York, www.unscear.org/docs/reports/2013/UNSCEAR2013Report_Annex_B_Children_13-87320_Ebook_web.pdf.

UNSCEAR (2008), *UNSCEAR 2006 Report Vol. I: Effects of Ionizing Radiation*, United Nations, New York, www.unscear.org/docs/reports/2006/07-82087_Report_2006_Web.pdf.

2. Societal aspects of radiological protection

Radiological protection is not a purely technical endeavour. The science originally grew out of observation of the interaction between humans and radiation, and the deleterious effects that this interaction could have on human health (ICRP 109). The term “protection” emphasises that the integrity of humans (as well as of the environment) should be maintained. Radiological protection is a deeply social action, as well as a skilled technical activity. Radiological protection standards are established by humans, with their weaknesses, needs and limitations, as well as their intelligence and moral stances. Standards are for humans and the non-human biota, and therefore, necessarily encounters the beneficiaries’ own situation, expectations, desires, bias, disappointments and demands. Radiological protection is a complex science – a social science as well as a physical and medical one. It is appropriate then for radiological protection professionals to look explicitly into the social side of their profession.

It would be highly desirable that more research be conducted, in the social sciences and the humanities, on the ethical basis of the radiological protection system, the social and psychological factors affecting expert and stakeholder opinions, the factors affecting risk perception and acceptability of risks, media coverage, societal constraints affecting response to an emergency exposure situation, on all aspects of prevailing circumstances and on communicating in plain language. Such research is still scarce, however, and most information on the societal aspects of radiological protection arises from the experience of radiological protection experts in different situations. This chapter focuses on the latter experience more than on “social sciences in radiological protection” as such, in the hopes of inspiring reflection among practitioners as well as of identifying promising directions for formal research as well as training.

This chapter surveys some of the experience and information collected in this societal domain by the NEA Committee on Radiation Protection and Public Health (CRPPH). It highlights the focus by the CRPPH since its foundation on the interactions between radiological protection professionals and beneficiaries (patients, workers and citizens). Particular and early emphasis was given to a conception of beneficiaries as *stakeholders*. With this came the normative consideration that beneficiaries have rights and competences that together form part and parcel of radiological protection and render it better. The chapter recalls the attention given by the CRPPH to the direct involvement of stakeholders in decision making and decision aiding around radiological protection, through seminars, exercises and strategic reflections. Regarding both normative and practical dimensions of interactions between professionals and beneficiaries, it also briefly reviews knowledge on ethics, and best practice on communications with stakeholders. Overall, the chapter leads to considerations of how radiological protection professionals can be supported and trained in exercising their social skills, as they apply their physical and biological knowledge.

It should be noted that the success of any of the above-mentioned interactions between radiological protection professionals and stakeholders depends almost entirely on effective communication. This means dialogue, development of mutual understanding, and specifically addressing stakeholder questions and concerns, which may be radiological, social or economic. Having a successful interaction does not imply that the stakeholder will leave the discussion agreeing with the radiological protection

professional. Rather, the stakeholder will leave the discussion with sufficient understanding of the issues to make an informed decision.

What is the issue?

In 1992, the CRPPH held a workshop entitled “Radiological Protection on the Threshold of the 21st Century”, that for the first time within the context of the committee addressed the issue of stakeholder involvement in radiological protection decision processes. Initial discussions were focused on how best to transfer complex radiological information to stakeholders. Within two or three years, however, recognition grew that communication is a two-way process, and moreover, that radiological protection is just one process among many parallel processes taking place at any time in the community of beneficiaries. The subject turned to a relatively sophisticated reflection upon where radiological protection stood in the context of society. The first Villigen workshop, “The Societal Aspects of Decision Making in Complex Radiological Situations”, in 1998 asked the question: “Should we be integrating societal aspects into radiological protection decisions, or integrating radiological protection into societal decisions?”

CRPPH contributions

In this context, the CRPPH began a sustained discussion focusing on stakeholder involvement in decision processes: its basis and rationale, its roles and facets, and the issues stirred up by this involvement. The discussion has included:

- Three Villigen workshops (1998, 2001 and 2003), broadly concluding that stakeholder involvement is essential to achieving sustainable, accepted decisions in complex radiological situations, such as emergency planning and management; post-accident recovery planning and management; siting of new nuclear installations or of waste disposal facilities.
- Three “Science and Values in the Evolution of the System of Radiological Protection” workshops (2008, 2009 and 2012), broadly concluding that decisions are informed by science but driven by social values; protection of children as a universal objective, and a focus on recovery activities; low-dose health effects are poorly understood by stakeholders; and stakeholder concerns need to be better addressed.
- Five international nuclear emergency exercises (INEX 1: 1993; INEX 2: 1996-1998; INEX 2000: 2001; INEX 3: 2006-2008; INEX 4: 2010-2012), broadly concluding that stakeholder involvement in emergency and recovery planning, preparedness and management is essential, is very case specific and is very difficult; mechanisms to integrate stakeholder bottom-up input into recovery traditional top-down management are needed; exchanges of experience with regard to organisational and administrative issues and processes for stakeholder involvement, particularly for such aspects as clean-up and return, are needed.
- Strategic assessment of emergency management (three reports in 2007 and 2010), broadly concluding that stakeholder involvement should be central to emergency and recovery management planning; and a multidisciplinary team of professionals is needed to deal with the spectrum of issues arising when stakeholder concerns are to be addressed.
- Lessons from recovery management in Chernobyl (NEA, 2006), broadly concluding that a top-down approach will need to evolve into a bottom-up approach; listening to and working with stakeholders can help to rebuild trust; and stakeholders are a resource to identify problems and practical solutions on the ground.

- A summary of the contribution of the CRPPH in bringing stakeholder involvement to the radiological protection profession (NEA, 2011), broadly concluding that radiological protection professionals should be at the service of society, and should address case-specific concerns as they arise.

Through this work and these discussions, the CRPPH has been a leader in the radiological protection community in terms of moving towards a better understanding of stakeholder involvement in decision making and decision aiding, and in developing procedural and process approaches and experience.

However, many policy and practical issues and questions remain, giving a significant and complex challenge to the radiological protection community. The multi-faceted nature of this challenge is exemplified by the need to more effectively take and support decisions that appropriately acknowledge and address stakeholder concerns. High-profile complex radiological protection situations in this area include: siting new nuclear installations; waste disposal installation siting – often because of the multi-generational implications of managing long-lived wastes – dealing with radon in a residential context; the management of operational discharges; and emergency and recovery management. Such situations bring together a broad range of stakeholders (e.g. ministry-level officials, other governmental and elected officials at various territorial levels, regulatory officials, citizens, non-governmental organisations), with different understandings, perceptions, viewpoints and objectives. In the case of long-lived radioactive waste management, beneficiaries are considered to include many as yet unborn generations whose concerns cannot be directly expressed. Within such a context, it can be difficult to achieve agreement on how to justify and optimise radiological protection; facilitating such decisions – or more modestly, simply delivering appropriate societal data to the optimisation equation – requires training that radiological protection experts often have not had, resource allocation that can be significant and at times long processes.

Social sciences

While experimental social science does exist, the “scientific evidence” referred to in our discussion of societal dimensions of radiological protection is obtained generally from case study analysis than from controlled experiments. There are unfortunately several outstanding example situations from which much experience can be gained, the two most obvious being the circumstances of human communities and environment following the Chernobyl and Fukushima nuclear reactor accidents. Other accidents, like Three Mile Island or Kyshtym, are also of interest from the social sciences point of view. The Villigen workshops (NEA, 2004a) analysed several additional types of cases, for example the siting of new nuclear installations (e.g. uranium mines) and the clean-up of existing situations (e.g. closed Wismut facilities in Germany). These case studies, whether anecdotal or systematically structured, have all contributed to the current level of understanding of approaches to communication and dialogue among stakeholders, which may result in accepted and sustainable radiological protection decisions.

The social science aspects of radiological protection have emerged around case-specific situations where radiological protection decisions need to be taken, either by government, by regulatory authorities, by local authorities, by affected citizens or by some combination of these. Given the uncertainties involved in the physical science of radiological protection, and given the normative nature of justification and optimisation, studies have suggested that such decisions are, in general, informed by radiological protection science, but driven by social values and judgements. Therefore, while the physical and medical scientific aspects of a particular radiological protection situation may be relatively well understood, and the uncertainty of the casual relationship between exposures and health detriments may be recognised or even quantified, this understanding generally does not provide the full basis for a decision. Instead, the basis for radiological protection decisions – and moreover, their actual application – tends to be dominated by the judgement of involved stakeholders, for instance with respect to equity

considerations, to the need to apply precaution and to risk acceptance. This observation is beginning to be accepted by the radiological protection community and will in fact become increasingly important in helping radiological protection professionals to more effectively interact with stakeholders. Indeed, effective interaction with stakeholders, like effective protection, may rely on making explicit – or at least embracing – the full host of criteria potentially applied when making decisions (which range from judgements on fully mastered or still uncertain scientific phenomena, through fully acknowledged or still obscure expectations, desires and fears).

Case studies

As noted above, the social scientific evidence brought to bear in radiological protection to date usually refers to case study experience. The CRPPH case study analyses point to societal interactions and decision approaches that may be more likely to result in radiological protection decisions that are accepted and sustainable.

Observation suggests that clarity and coherence of decision rationale are extremely important. A decision whose drivers are both articulated in a transparent fashion, and balanced in order to appropriately address stakeholders' concerns, is better implemented. An example of this is found in the Fukushima recovery situation, where a key driver for decontamination efforts was the broadly shared resolution to protect children. Among the first areas to be decontaminated in the springtime and summer of 2011 were schools and playgrounds, such that exposure of children could be reduced. Parents, teachers and municipal employees teamed together in several locations, often advised by private experts from Tokyo having local connections, in order to clean schools and school playgrounds significantly so that children could play outdoors in seasonal clothing and use swimming pools, instead of being covered in long clothing or confined indoors with the windows shut. The choice to address school decontamination as a priority arose naturally and gained quick support in several areas, clearly articulating the views of a broad range of stakeholders (NEA, 2004b).

Another situation, the decontamination of the Rocky Flats site in the United States, also demonstrates the importance of transparent articulation of decision drivers and their balanced adjustment to concerns. In this case, a site contaminated by a plutonium weapons production facility was to be cleaned up and released for public use. Local stakeholders initially refused to agree to the clean-up criteria announced by the US Department of Energy (DOE), which was in charge of the clean-up. Through a long stakeholder engagement process, members of the local population expressed their concerns (which often reflected their social role and activities as farmers, ranchers, mothers, children, etc.), and together with experts developed models of local lifestyles for which realistic dose estimates could be made. The level of clean-up required could then be determined as a function of lifestyles. This elaborative process addressed residents' desires to ensure that their personal characteristics were reflected in the assessment of risks, and enabled them subsequently to agree to adjusted clean-up criteria and post-clean-up utilisation of the site (NEA, 2004b).

In these two situations, not only were key drivers articulated, but also the very processes of interaction that led to decisions were open and transparent to all levels of stakeholders. By involving those concerned in such processes, a balance of decision drivers was achieved, and the decision rationale was clear to all and judged to be coherent with desired values. Thus, in terms of the science and the values influencing radiological protection decisions, the following aspects seem to be very important in achieving accepted and sustainable decisions:

- articulation of decision drivers of diverse types (physical, medical and social);
- transparency of the decision process, which includes a strong participative component;

- balance of decision drivers, i.e. coherence with both scientific knowledge and expressed social values;
- communication of knowledge and uncertainties;
- communication of decision rationale.

Several other case studies assessed by the CRPPH (NEA, 2004b) indicate the same type of results. Articulating drivers in a transparent, participative process, balancing drivers, and attending to the communication of final rationale do signify the need for authorities and radiological professionals to invest in a time- and resource-intensive activity, requiring special skills. However, decision outcomes of such processes have been shown to be accepted and sustainable, even in socially and scientifically complex situations (NEA, 2004b). In this way, the intensive communicative and participative approach is shown to be reasonable; choosing this option is an optimisation decision in the social realm, comparable perhaps to optimisation decisions at the health physics level for occupational radiological protection (ORP).

These cases also demonstrate the need for a very flexible approach to address the specific situation at hand and the involved range of stakeholders, noting that over the course of resolving a complex situation some individuals may leave and others may enter the scene. Moreover, as in all risk communication situations, all parties will need to seek language and expression that allow all counterparts to grasp their particular scientific or societal understandings and criteria. This dimension is further discussed below.

Finally, an area that the radiological protection community has now begun to discuss more thoroughly is the ethical basis of its system. More specifically, there have been suggestions that the pillars of the International System of Radiological Protection, as recommended by the ICRP, have identifiable analogues in ethical theory. Correspondence has been suggested (Ethics, 2013) between:

- Justification and teleology:
 - The teleological ethic focuses on consequences and states that the morality of protective action should be judged against its overall consequences.
- Optimisation and utility:
 - The utilitarian ethic focuses on utility and states that the morality of protective action should be judged against its contribution to the overall utility, namely to the best welfare among all people.
- Limitation and deontology:
 - The deontological ethic focuses on duty and states that the morality of protective action should be judged by its service to the duty to protect individual human beings, rather than by its overall consequences or welfare utility.
- Precaution/prudence and aretaicism:
 - The aretaic ethic focuses on virtue and states that the morality of protective action should be judged by its constant conformity to a definition of goodness or virtue, rather than by its consequences, utility or service to duty.

This discussion is being pursued within the ICRP and other relevant organisations through ethics workshops (Daejeon, August 2013; Milan, December 2013; Budweis, June 2014; Baltimore, July 2014; Madrid, February 2014; Cambridge, United States, March 2015; Fukushima, June 2015). The discussion is still at the philosophical level, trying simply to identify and clarify these concepts and relationships. The next step could be to test how a better understanding of the ethical underpinnings of the International System of

Radiological Protection will facilitate its application through case-specific decisions, and indeed add value. Examples of practical aspects that could be addressed include:

- What is the ethical basis of risk communication?
- What values drive interpersonal trust and confidence in systems and institutions?
- On what basis is the amount of precaution identified?
- How do ethics contribute to decisions in medicine, in industry, in education or in nuclear?
- What is the implication of differing ethical values/settings in different societies on radiation protection measures?

Practical ethical issues, such as how to handle radio sensitivity, whether protection should focus on the group that is most at risk (e.g. women, pregnant women, children) or if there is a need for individual risk assessment are also beginning to arise and may benefit from the ongoing discussion on the ethical underpinnings of radiological protection.

Risk communication

The approaches and processes that are inherent to achieving a balance in scientific and social value drivers in a clear and transparent process can be difficult to achieve, and several issues remain:

- What are the needs of society, how can radiological protection science contribute to resolving these needs?
- What are the cultural aspects of risk perception and precaution, and how do these influence decisions?
- How can scientific uncertainty best be communicated?

Insights gained from risk communication situations on how societies deal with risks are an important input to understanding societal aspects in the context of radiological protection decisions. The emergency and recovery management efforts following the Chernobyl and Fukushima accidents demonstrate that these approaches can be extremely resource intensive. It is not only in terms of the number of experts needed to discuss issues, but because radiological protection experts are not, in general, educated or experienced in plain-language communication. While it is safe to assume that the public is intelligent, they may be uninformed on radiological protection science, or have found unscientifically supported information on the internet. There is therefore a need to train radiological protection experts to more effectively participate in decision processes with stakeholder involvement.

A very simple model of communication is the sender-receiver model that assumes that communication involves a message being transmitted from a sender to a receiver. Transmission may suffer from interference of various kinds, emanating from the actors or from the surrounding field.

The potential pitfalls of communication are suitably described in a sentence attributed to the behaviourist Konrad Lorenz (1903-1989):

Thought does not always mean spoken out; spoken out does not always mean heard right; heard does not always mean understood; understood does not always mean agreed; agreed does not always mean applied; applied does not always mean maintained.

Models of communication that have been found useful by some radiological protection professionals include:

- The four-sides model (Schulz von Thun, 1981): It is obvious that communication, i.e. exchange of information, opinions and value judgements between a sender and a receiver, is subject to various interpretations. Each message has different facets that may or may not be intended to be transmitted by the sender or perceived by the receiver: the fact level, the relational level, the appeal level and the level of self-revelation. Successful communication strongly depends on the relational level. Only 20% of communication may be attributed to the factual level.
- Transactional analysis (Berne, n.d.): communication between humans involves different ego states – parent, adult and child. This approach aims at communicating between equals, in the best case between two adult ego states.

Successful communication requires that those involved share at least to some extent the same *code*. In the theory of communication, “code” is understood as not only verbalised (oral) language, but also non-verbal language, symbolism, etc. The NEA Forum on Stakeholder Confidence has published a report on the symbolic dimension of radioactive waste management that can be useful to stimulate reflection (NEA, 2010).

Practical training tends to emphasise that communication will fail when one partner places his or her own views and valuations above those of the communication partner. As a basic principle the conscious communicator should rather accept other positions as at least worthy of consideration.

In risk communication, it is essential to be aware of the differences in the formation of scientific risk assessment and societal risk perception. Aspects of scientific risk assessment make up only a small part of the formation of risk perception.

In some radiological protection contexts, the scientific professional may have the task of expressing complex scientific issues, known and remaining scientific uncertainties such that the concerned non-specialist stakeholder gains understanding sufficient to inform a decision (or sufficient to clarify the criteria retained for a decision). The professional may identify a need to provide both a comprehensive description of the processes of risk estimate and risk assessment, and a presentation of the central aspect of the risk or source of risk, such as the cause of a risk, probability of occurrence of risk, vulnerability, possible consequences of the risk and options for coping and protection.

The non-specialists’ interest in and understanding of the processes of scientific risk estimates and risk assessment may legitimately be limited. The professional is thus faced with the task of balancing the full delivery and the summarisation (or even transformation) of information in order to better facilitate the decision process – which remains the essential objective. The professional must be attentive to signs of understanding, skilled at seizing and responding to questions that are expressed in perhaps confused terms, and overall, empathetic to the underlying concerns of the stakeholders and respectful of their individuality. Successfully navigating this exercise appears to require great competence (both intellectual and emotional) and great experience, all the more so since radiological protection situations are often characterised by stress, distress and pluralistic ignorance. Communication is not commonly taught in the basic curriculum of radiological protection studies. With this in mind, the CRPPH organised a seminar in 2016 on stakeholder communication that is intended to transfer skills and experience from confirmed professionals to younger ones. To make the transfer accessible to the largest number of individuals, the meeting was organised as an Internet-based webinar. The box below gives seven cardinal rules of risk communication, which equally apply for emergency situations.

Box 2.1. Seven cardinal rules of risk communication

In 1988, the US Environmental Protection Agency published rules of thumb for communicating about risks with the general public or with involved stakeholders. These were developed on the basis of experience in public meetings where authorities met with citizens concerned by exposure to chemical risks. The rules are widely quoted and used in many risk communication settings.

Rule 1: Accept and involve the public as a legitimate partner.

Rule 2: Listen to the audience.

Rule 3: Be honest, frank and open.

Rule 4: Co-ordinate and collaborate with other credible sources.

Rule 5: Meet the needs of the media.

Rule 6: Speak clearly and with compassion.

Rule 7: Plan carefully and evaluate performance.

While these rules are developed for risk communication in normal situations, it has been pointed out that they also apply to crisis situations, like nuclear accidents (Carvello, 2011). It should be noted that these rules are important not only when talking with members of the concerned public, but also when talking with scientists from other scientific areas or with scientists whose own risk perceptions differ.

Good risk communication needs to be continuous, and promptly address emerging events in case of need. Vital aspects of risk communication are transparency of the processes currently underway, the results and findings, as well as the available information. It is also crucial to be clear on the goal of risk communication and make it transparent to the audience. Risk communication may be aimed at providing information, i.e. transferring knowledge, changing behaviour or resolving a dispute concerning the risk based on valuation differences.

When entering into communication, experts tend to think about whom they are speaking with. For instance, what are the respective roles (communication between scientific experts, between experts and authorities, with the press, with citizens, etc.); and how the relative position will affect the subjects addressed, the language used, the expectations by partners, the duties to be fulfilled. Also under consideration are the interlocutors' perceptions and opinions about the risk under discussion; noting that these will likely differ from expert valuations. Communication requires a two-way process of listening and adjusting one's understanding.

The interests and concerns of the public should be taken seriously. This requires thorough preparation. If there is no time to do so, it is necessary to show the required flexibility when dealing with interlocutors' opinions during communication. Respect must be given to interlocutors' viewpoints.

As for language, interlocutors will most likely not be experts in the field. Therefore, technical terms should be avoided wherever possible, or should be explained. Simple language should be used as if speaking to a 12-year-old student. Technical jargon and complex scientific wording is therefore avoided.

Keep in mind that conflicts in communication about risks may have various sources, and this source must be understood if the conflict is to be resolved. Sometimes, reasons for conflict are hidden from all the partners, so uncovering them requires diplomacy, a humble attitude, and possibly requests for insight from several quarters. Reaffirming wishes to help solve the radiological protection problem on participants' terms will help keep the focus on shared goals rather than on normal irritations and frustrations.

Source: Adapted from EPA, 2000; Carvello, 1988; Carvello, 2011.

Possible approaches to improving the situation

Radiological protection is recognised as both a technical and social endeavour, requiring a diverse range of skills. In particular, to improve service to society, the priority should be to enhance professionals' ability to establish effective dialogue among stakeholder groups in a given situation. A unified approach and set of participative techniques and communication skills may be useful for radiological protection professionals. However, the effective application of such resources will depend very strongly on the situation being considered. It will be necessary to not only involve to some degree concerned stakeholders but also to specifically co-operate with them so as to assess any situation, set accepted criteria, and arrive at applicable and sustainable protection decisions. As such, training, planning, preparation and means for continuous co-assessment of any complex situation need to be considered at policy, regulatory and implementation levels.

Recent publications

- Berne, E. (n.d.), Transactional Analysis (web page), www.ericberne.com/transactional-analysis/.
- Covello, V.T. and Allen F. (1988), "EPA's Seven Cardinal Rules of Risk Communication", www.wvdhhr.org/bphtraining/courses/cdcynergy/content/activeinformation/resources/EPA_Seven_Cardinal_Rules.pdf (accessed on 17 January 2014).
- Covello, V.T. (2011), "Risk communication, radiation, and radiological emergencies: strategies, tools, and techniques", *Health Phys.*, Vol. 101, pp. 511-30.
- EPA (2000), *Presenter's Manual for: "Superfund Risk Assessment and How You Can Help: A 40-Minute Videotape"*, EPA/540/R-99/013, EPA.
- Ethics (2013), "1st European Workshop on the Ethical Dimensions of the Radiological Protection System", 16-18 December 2013, Sala Napoleonica, Milan.
- Hansson, S.O. (2007), "Ethics and radiation protection", *Journal of Radiological Protection*, Vol. 27, No. 2, pp. 147-156, doi:10.1088/0952-4746/27/2/002.
- ICRP 109 (2009a), "Application of the commission's recommendations for the protection of people in emergency exposure situations", *Annals of the ICRP*, Vol. 39(1).
- ICRP 109 (2009b), "The history of ICRP and the evolution of its policies" (by R.H. Clarke and J. Valentin), *Annals of the ICRP*, Vol. 39, Issue 1, pp 75-110, Elsevier, Amsterdam.
- IRPA (2008), "Guiding Principles for Radiation Protection Professionals on Stakeholder Engagement", Ref: IRPA 08/08.
- Lochard, J. (2014), "An introduction to the ethical foundations of the radiological protection system", presentation at the First IRPA North American Workshop on the Ethics of Radiological Protection, Baltimore, Maryland, 17-18 July 2014, http://hps.org/documents/ethical_foundations_lochard.pdf.
- Mayo, D.G. and R.D. Hollander (eds) (1991), *Acceptable Evidence: Science and Values in Risk Management*, Environmental Ethics and Science Policy Series, Oxford University Press.
- NEA (2011), *Practices and Experience in Stakeholder Involvement for Post-nuclear Emergency Management*, Paris, OECD.
- NEA (2010), *More than Just Concrete Realities: The Symbolic Dimension of Radioactive Waste Management*, OECD, Paris, www.oecd-nea.org/rwm/reports/2010/nea6869-symbolic.pdf (also available in French).
- NEA (2006), *Stakeholders and Radiological Protection: Lessons from Chernobyl Twenty Years After*, Paris, OECD.

- NEA (2004a), *Stakeholder Participation in Radiological Decision Making: Processes and Implications – Summary Report of the 3rd Villigen Workshop (Switzerland), 21-23 October 2003*, OECD, Paris.
- NEA (2004b), *Stakeholder Participation in Radiological Decision Making: Processes and Implications – Case Studies for the 3rd Villigen Workshop, Switzerland, 21-23 October 2003*, OECD, Paris.
- Oughton, D. and S-O. Hansson (eds) (2013), *Social and Ethical Aspects of Radiation Risk Management, Radioactivity in the Environment, Vol. 19*, Elsevier Ltd.
- Schulz von Thun, F. (1981), *Miteinander reden 1 – Störungen und Klärungen, Allgemeine Psychologie der Kommunikation*, Rowohlt, Reinbek (in German).
- Shrader-Frechette, K. and L. Persson (2001), *Ethical Problems in Radiation Protection*, Swedish Radiation Protection Institute, Stockholm.
- Wikman-Svahn P. (2006), *Ethical Aspects of Radiation Protection*, US AB, Stockholm.

3. Implementation of the radiological protection system

3.1. Existing exposure situations

Introduction

The ICRP has defined existing exposure situations as those that already exist when a decision on protection needs to be taken. While international standards use a slightly more restrictive interpretation, this chapter discusses all situations that fit the broader ICRP definition. The source of existing exposure situations can be natural or anthropogenic. Existing exposure situations can result in both public and occupational exposures. Examples of existing exposure situations are:

- Exposure to radon in dwellings, public buildings and workplaces.
- Exposure to naturally occurring radioactive material (NORM).
- Exposure of aircrew and frequent air-travellers to cosmic rays (note that aircrew exposure can be considered as coming from an existing exposure situation – because the source cannot be affected – or from a planned exposure situation – because the work of aircrew can be planned and controlled).
- Exposure of people living in high radiation background areas.
- Exposure to residual radioactive material arising from past activities or practices.
- Exposure to residual radioactive material following an accident.

In existing exposure situations, radiation doses are generally well below the threshold for deterministic effects. Stochastic effects – mainly cancer – are the sole radiological health concern in existing exposure situations. Note that post-accident stress, which can be driven by concern over possible future cancers due to radiological exposures, is also a significant source of health detriment (see Chapter 2 on social effects).

This chapter touches upon traditional issues of radiological protection. Although neither the NEA 1998 or 2007 reports clearly addressed radiological protection in existing exposure situations, many issues relevant to existing exposure situations were dealt with indirectly, along with other issues or topics. This chapter will address such issues directly.

Scientific evidence

What do we know?

Exposure to indoor radon is identified as the second leading known cause of lung cancer after tobacco smoking (WHO [2009] suggests that 80% of lung cancer deaths can be accounted for by smoking, while only 10% by radon). Techniques are available to measure and reduce indoor radon concentrations effectively, at low or moderate costs. Radon-resistant new construction is a cost-effective way to reduce population exposure to

indoor radon. Thoron (radon-220) is likely to be a minor contributor to indoor radon exposure in many areas.

Exposure of workers in NORM industries (handling or processing naturally occurring radioactive materials) is a direct consequence of their work. Hence, according to international standards, these industries are required to be managed in the same way as practices involving artificial, man-made radiation sources within the overall framework of planned exposure situations. The new focus on radiological protection culture has increased awareness on the importance of NORM management. Exposure to NORM is now better managed, and relevant safety standards or guidelines have been developed. Such guidelines focus primarily on so-called technically enhanced NORM (TENORM), but the concept of existing exposure situations makes no distinction – regulatory or practical – between ores taken from the earth’s crust (e.g. granites) and TENORM (e.g. phosphor-gypsum).

It is recognised that outside of nuclear workplaces and uranium mines, exposure to elevated NORM can be a health concern. Studies have been conducted to characterise NORM exposure levels in situations commonly known to have NORM issues, such as mining industries other than uranium, fertiliser and phosphate industries and ceramics industries.

In addition to NORM industries, where occupational exposure is of concern, public exposures may result from the effluents of such industries, and from the release of residues in waste disposal sites such as landfills, or more importantly, recycled into building materials. The exposure to gamma radiation emitted from building materials, as well as radon or thoron exhalation from those materials, is regarded as an existing exposure situation. In some countries, and in the Euratom Basic Safety Standards Directive (Euratom, 2014), there are restrictions on the use of building materials based on a gamma radiation index.

Exposure to cosmic rays has been well studied internationally. Web-based dose assessment tools are available to frequent air-travellers and the public. Radiological protection measures for aircrews are implemented in many countries, especially in Europe where it is considered a planned exposure situation. However, a more globally consistent approach should be considered. Currently, it is not practically possible to regulate the occupational exposure of people frequently travelling by air for professional reasons (some of whom exceed the exposure of aircrew members). However, an assessment of the annual exposure of such professional air-travellers (e.g. air courier service, sky marshals) should be performed in order to better assess the need for further consideration.

Exposure of people living in high radiation background areas has been an important part of epidemiological studies on low-dose radiation effect. Significant progress has been made and summarised in a recent document by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 2010).

Similar to exposure in high radiation background areas, exposure to residual radioactive material arising from past activities or practices has also provided solid evidence on radiation health effects at low dose. However, as indicated in Section 1.1, epidemiological studies alone could not and will not provide definitive evidence of the existence or non-existence of carcinogenic effects due to low dose or low-dose rate exposure. The lack of epidemiological evidence for the existence of low dose and low-dose rate radiation-induced effects is however not proof that such effects do not exist.

Where are the gaps?

Although much is known about existing exposure situations, many gaps remain in the scientific knowledge, and application issues also need to be addressed. Most of these issues have been known to exist for decades, but new types of NORM industries have introduced new issues and challenges. These new challenges, as well as existing issues

not yet adequately addressed, will require more collaborative research activities and internationally harmonised policy development.

Indoor radon exposure

It has been acknowledged that radon (^{222}Rn) is the largest natural source of ionising exposure to humans, representing about 40 % of the exposure from all sources, including medical.

Although epidemiological studies demonstrate that lung cancers become statistically significant in populations living in concentrations as low as 100 Bq/m^3 , the calculation of lung dose as a result of living in such radon prone areas has been problematic. As such, the health risk (or lung cancer risk) from exposure to radon as a function of lung dose is inexact because of uncertainties in lung dosimetry. This uncertainty is not only related to the location of the target cells and to the physical properties of the decay products in indoor air, but also to the inadequacies of risk estimates based on effective dose. The use of effective dose for radon exposure introduces uncertainties in lung tissue weighting factors and in the radiation weighting factor for alpha radiation. However, using effective dose simplifies the risk estimate of a reference person because it represents an individual's total risk over all organs. It should be noted that individual's smoking habits are taken into account when estimating radon risk.

In ICRP Publication 65 (1993), the approach to management of radon exposures was based on the epidemiological study of uranium miners to estimate risks, using working level months (WLMs) as the prime quantity for risk estimation. In ICRP Publication 115 (2010) the commission concluded that radon and its progeny should be treated in the same way as any other radionuclide within the system of protection. In other words, doses from radon and its progeny should be calculated using ICRP bio kinetic and dosimetric models. This yields a higher dose conversion factor than that recommended in ICRP 65, but it has been argued that the results from ICRP 65 need to be corrected and allow for the lower cancer risk per unit dose put forward in ICRP Publication 103 (2007). The consistency of the results is, however, merely a coincidence in light of overall uncertainties. For the establishment of national policies on indoor radon exposure, many governments base criteria on airborne radon concentration, and as such, the possible shift to using the ICRP recommended dose conversion factor will most likely take some time. If national policies do not already consider smoking habits as part of their radon policy (or radon policy as part of national smoking policy) then consideration should be given to addressing both risks holistically. For workers in planned exposure situations and in existing exposure situations where the occupational dose limits have been applied by the regulator, the uncertainty of the dose conversion factor is an important issue.

In terms of assumptions made to estimate effective dose, the radon equilibrium factor, F , is important. The risk from radon exposure comes mostly from short-lived, alpha-emitting radionuclides in the decay chain. As nuclides are created through decay of radon gas in the air, some radionuclides are in a solid state rather than a gaseous one. These are in an ionised form, and thus may attach to airborne particulates before being inhaled. Inhaled radionuclides that are not attached to particles tend to deposit more often in the lungs, and thus will cause more significant lung-tissue irradiation than those attached to particles (which tend to deposit less in the lungs). Therefore the attached fraction has a significant environmental influence on lung dose. The commonly accepted F -factor is 0.4, but this is based on somewhat limited measurement data, in particular for public exposures in homes or public buildings. Clean indoor air generally has a low equilibrium factor, which is known to correlate with a high unattached fraction of radon progeny, resulting, on the one hand in a rapid plate-out on surfaces, and on the other hand, in higher dose to target lung cells. Hence, in the domestic environment and in non-industrial workplaces, the radon concentration in air has been traditionally used in risk assessment with the understanding that the relationship between radon concentration in

air and absorbed dose in lung tissue is complex. Research is thus needed to determine how representative this value is for various indoor environments. Research is also needed to better characterise radon exposure in workplaces other than uranium mines.

Even though radon-resistant new construction is known to be a cost-effective way to reduce population exposure to indoor radon, the experience is limited to some types of construction, and only a few nations have included specific features in their building codes. More actions are needed globally to broaden the experience.

Radon in water, such as well water or spas, could be an issue in some cases. Limited studies have shown that thoron is in general likely to be a minor contributor to indoor exposure in many areas. Elevated radon in public water supplies could enhance indoor air concentration. More studies are needed in this area.

While thoron may not always be a significant health concern, its effects on the measurement of radon-222 can have a significant impact on the results of risk assessment for radon-induced lung cancer. Some types of radon detectors used by epidemiological studies in the past were identified to be highly sensitive to environmental thoron. These findings have not yet been adequately considered by radon epidemiologists in their risk assessment.

Further research is needed to better understand the synergistic risk from radon and smoking, as well as the age-dependency of radon-induced lung cancer.

Exposure to naturally occurring radioactive materials (NORM)

While naturally occurring radioactive materials exist everywhere in varying concentrations, NORM exposure levels in some situations are not yet well characterised. Issues such as residence times, dust concentrations and factors affecting the equilibrium of decay products can affect exposures. Radiological protection in NORM industries is addressed by the International Basic Safety Standards (BSS) and by the European Basic Safety Standards Directive. However, the application of these safety standards in specific areas is not uniformly carried out around the world.

In addition to well-known NORM industries, new situations may also arise, for instance in ground water treatment plants or fish hatcheries, or in gas production by hydraulic fracturing.

Once exposure levels are well characterised, the question of how to apply radiological protection to NORM exposure in various situations also becomes a challenge, keeping in mind that exposure may have only a minor ranking in overall health and safety issues at work. If NORM industries are regulated, the management of occupational exposure would also be regulated through the application of dose limits for workers.

The disposal of NORM wastes, especially those with technologically enhanced radioactivity, should be included in NORM management. Research is needed to find good, practical solutions, for example, through the identification of situations where the mixing of higher and lower activity NORM residues may be justified.

Approaches to NORM management may also need to be harmonised internationally, especially as it applies to international trade and transportation of ores, building materials and finished products. Guidelines should be based on an assessment of doses to those buildings with or using NORM materials.

Although very low concentrations of artificial radionuclides in the environment may contribute to surprisingly high public concern, naturally occurring radioactive material in the environment – sometimes at harmful, concentrations – has often been ignored, with many members of the public believing that what is natural is normal. Therefore, a well-designed communication strategy needs to be developed for radiological protection in relation to exposures to NORM in order to raise awareness among concerned industries.

International standards should be developed to appropriately control and facilitate the trade of building materials.

The exposure of workers in NORM industries (handling or processing naturally occurring radioactive materials) is the direct consequence of their work. Hence, in principle, these industries should be managed in the same way as practices involving artificial, man-made, radiation sources. They should be managed within the overall framework of planned exposure situations.

A similar situation arises with the exposure of workers to radon in their place of work. For the International Basic Safety Standards (IBSS), in line with overall health and safety policies, all exposures incurred by workers in the course of their work can be considered as occupational exposure. This also means that occupational dose limits should apply to all regulated exposures, including to radon at work irrespective of the origin of radon ingress (in general from the earth's crust). The ICRP limits the use of the term "occupational exposure" to exposure "incurred as a result of situations that can reasonably be regarded as being the responsibility of the operating management". In a regulatory context, radon at work should be managed with occupational dose limits as a means of enforcement. This will help to ensure that optimisation leads to lower radon concentrations in the workplace, so that worker exposures are kept below the reference level, and if necessary, the presence of workers at specific premises is controlled so that the dose limit is not exceeded for individual workers.

Emerging issues of radiological protection in existing exposure situations

In addition to the traditional radiological protection issues concerning exposure to NORMs and TENORMs, the following two emerging issues are worth investigating: radiation food safety in non-emergency situations and environmental contamination from hydraulic fracturing.

Food safety in non-emergency situations

Guidelines to control radionuclides from emergency situations in commercial food have been established by many countries and international organisations. Most guidance documents provide guideline levels only for those radionuclides representative of a nuclear or radiological emergency. Generally these will focus on such radionuclides as cesium-137 and iodine-131. The international harmonisation of food guidelines, Codex Alimentarius, and standards with respect to international trade only applies to emergency situations.

In some countries, food guidelines or standards were established for non-emergency situations. Those guidelines or standards could provide maximum acceptable concentrations for different categories of food and for artificial as well as naturally occurring radionuclides. From the perspective of radiological protection, quality guidelines or safety standards should be considered more broadly for non-emergency situations.

Well-developed food guidelines for non-emergency situations do not exist in an internationally accepted sense, but could help to improve radiological protection culture in non-emergency situations. Such an improvement could make the risk communication in emergency situations easier and less confusing.

If radiological food safety is considered under normal conditions, naturally occurring radionuclides in food become the main concern. However it is broadly felt that currently, it is not justified to regulate the consumption of food products from this perspective.

Caution should be used here, because while food guidelines for non-emergency situations can be used as references for emergency situations, they could also be misused - for example they could be viewed as the level up to which releases of radioactive substances into the environment could be intentionally made, as determined

by the guidelines for non-emergency situations. Caution and clarity are thus essential should such new guidelines be developed.

Environmental impact from hydraulic fracturing

The technology of hydraulic fracturing has existed in oil and gas industries for decades. With the increased use of this technology, in recent years, there are also increased concerns, especially from the general public, in relation to elevated levels of radioactivity, metals and other contaminants in the environment resulting from the discharge of treated water during hydraulic fracturing activities.

In view of the increased use of hydraulic fracturing, further research is needed in order to more completely characterise the situation. This could include issues of radiological protection for the general public, but also for workers.

Possible policy challenges

Because of the health risks associated with radon, it is generally encouraged, and mandatory in some regions, to establish national radon reference levels for all indoor environments, for example in workplaces, homes and public buildings. The implementation and effectiveness of this globally protective policy needs to be monitored and evaluated for further development.

Since naturally occurring radionuclides are ubiquitous, the scope of regulatory control of industries involving NORMs – especially those not traditionally recognised as a NORM industry – is unclear in some cases. According to the IBSS, NORM industries are part of a broad family of natural radiation sources regarded as existing exposure situations, but where the activity concentrations exceed a threshold value, they are subject to requirements for planned exposure situations. Conversely, according to the Euratom BSS, *a priori* all NORM industries are viewed as planned exposure situations, but below a certain threshold, and with other conditions and criteria being satisfied, they are exempted from the corresponding requirements. While the two approaches are believed to be equivalent, it would appear that further demonstration in actual legal transposition and in application is needed.

Hydraulic fracturing is a growing method of gas and oil extraction in many regions, and therefore should be covered by radiological protection policy and basic safety standards.

Possible approaches to improve the situation

There are many application issues with regard to existing exposure situations. Some issues have been well addressed, but many still require continued research activities to better characterise radiation levels in the environment, and to improve the assessment of human health impact. For many exposure situations, international safety standards have been developed, reviewed and updated regularly. While developments in safety standards have never stopped addressing new challenges, there is a strong need for increased inter-government collaboration in order to reduce delay in the adoption and implementation of international safety standards already developed.

Most existing exposure situations involve low dose and low-dose rate exposures, such as exposure in areas with elevated radiation background or in areas contaminated as a result of past practices or accidents. Epidemiology is an important tool for research in this domain. However, epidemiological studies alone will not provide definitive evidence of health effects due to exposure at low dose and low-dose rate. To improve risk assessment, it has been proposed to combine epidemiology with information from studies of biological mechanisms.

Existing exposure situations deal with not only contaminants resulting from industrial releases or nuclear accidents, but also naturally occurring radionuclides in the environment. Radiological protection in these situations is designed to protect workers and the general public. In addition, all the issues we are facing should be addressed not only for emergency situations but also for non-emergency or normal situations. To improve radiological protection culture (IRPA Guiding Principles, July 2014) in such complicated situations, the scope and objectives of radiological protection activities need to be well defined so as to ensure consistent standards. Effective risk communication and stakeholder involvement needs to be included in all proposed efforts to address the radiological aspects of existing situations.

Recent publications

- Bartlett, D.T. et al. (1999), "The cosmic radiation exposure of aircraft crew", *Radiation Research*.
- Euratom (2014), "Council Directive 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom", *Official Journal of the European Union*, L 13/1.
- Feng, Y.J. et al. (2002), "Estimated cosmic radiation doses for flight personnel", *Space medicine & medical engineering*, Vol. 15(4), pp. 265-269.
- Grajewski, B. (2011), "Airline pilot cosmic radiation and circadian disruption exposure assessment from logbooks and company records", *The Annals of Occupational Hygiene*, Vol. 55, Issue 5, pp. 465-475.
- IAEA (2011), *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, No. GSR Part 3, IAEA, Vienna.
- ICRP 115 (2010), "Lung cancer risk from radon and progeny and statement on radon", *Annals of the ICRP*, Vol. 40(1), Ottawa.
- ICRP 103 (2007), "The 2007 recommendations of the International Commission on Radiological Protection", *Annals of the ICRP*, Vol. 37 (2-4), Ottawa.
- ICRP 65 (1993), "Protection against radon-222 at home and at work", *Annals of the ICRP*, Vol. 23(2), Ottawa.
- Schrewe, U.J. (1999), "Air Crew Radiation Exposure Monitoring: Results from the in-flight measurement programme of the PTB", Report PTB-6.31-99-1 (Physikalisch-Technische Bundesanstalt: Braunschweig).
- UNSCEAR (2010), *Fifty-seventh Session, Includes Scientific Report: Summary of Low-dose Radiation Effects on Health*, United Nations, New York.
- WHO (2009), *WHO Handbook on Indoor Radon: A Public Health Perspective*, WHO, Geneva, www.ncbi.nlm.nih.gov/books/NBK143216/.
- Yong, L.C. (2007), "Chromosome translocations and cosmic sources of ionising radiation: the NIOSH-NCI airline pilot biomarker study", *Proceedings of the 98th American Association for Cancer Research Annual Meeting*, April 14-18, 2007, Los Angeles, California. Philadelphia.

3.2. Planned exposure situations

Occupational radiological protection issues

Occupational radiological protection (ORP) has achieved high standards through a well-established, stable approach based on external and internal dosimetry, and on continuous efforts to apply the principle of optimisation. The application of the principle of optimisation is fostered by several professional networks – e.g. the Information System on Occupational Exposure (ISOE)¹ Network for nuclear power plants, and the European ALARA Network² for naturally occurring radioactive material (NORM), industrial and medical uses of radiation. Protocols for good dosimetry are based on the ICRP, International Commission on Radiation Units and Measurements (ICRU) and National Commission on Radiation Protection and Measurement (NCRP) recommendations. Professional networks such as the European Radiation Dosimetry Group (EURADOS)³ foster their improvement. The result of these efforts has been a steady, notable decrease of collective occupational dose, especially in the operation of nuclear power reactors (NEA, 2012). Average doses are now in most situations far below the dose limits for occupational exposure. Effective dose remains a proper expression of risk in this field of application, bearing in mind that it is gender and age averaged. Few workers approach the dose limits, and cases where they exceed these limits are very rare. Nevertheless, this does not apply equally to all types of situations. Occupational exposures can be high in non-destructive testing, in nuclear power plants pipe insulation, for certain categories of medical staff – in particular in interventional radiology – and in uranium mining. The application, following ICRP recommendations, of a much lower organ dose limit for the lens-of-the-eye may cause problems in specific occupational exposure situations. Current uncertainty with regard to the recommended dose conversion factor for inhalation of radon decay products may, for example, affect the compliance with dose limits for uranium miners.

In ICRP Publication 103 (2007), and in the new International Basic Safety Standards (IBSS) that implements Pub 103, more emphasis is placed on the use of dose constraints in the optimisation of ORP. The ICRP presents dose constraints as a prospective operational tool for the operator to plan and optimise protective actions. The ICRP recommends that the regulatory authority in charge of enforcement of legal provisions check the proper application of dose constraints and clearly distinguish these from dose limits. If the dose limits are exceeded, it would be considered a regulatory infringement. In some cases, it has been reported that dose constraints have in fact been taken by regulatory authorities to be criteria that, if exceeded, in practice, would result in a regulatory infraction. This approach is seen by operators as the imposition of new regulatory limits.

The dose limit applies to the sum of all occupational exposures received by an individual, and therefore remains very important for outside workers who may be exposed in several settings. The specific situation of outside workers underlines the need for a clear allocation of responsibilities between the employer and the operator managing the installation that leads to worker exposure. All those involved need to address the additional complexity caused when an outside worker is temporarily contracted by an undertaking in a foreign country where regulations, dose limits or dose limit periods (e.g. calendar year versus rolling 12 months) differ from those of the worker's employer in his or her home country.

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1. www.isoe-network.net.
 2. www.eu-alara.net.
 3. www.eurados.org.

The introduction of NORM industries in the regulatory framework for planned exposure situations, as recommended in the IBSS, when certain thresholds of activity concentrations in NORM material are exceeded, further emphasises the responsibility of the employer for overall health and safety at work, in settings which are quite different from nuclear industries. The consideration of occupational exposures in NORM industries and in some existing exposure situations has led to a definition of occupational exposures as all exposures incurred at work, regardless of their origin. The IBSS and the EU BSS Directive, however, restrict exposed workers to those exposed in certain practices and to specific sources, and those workers who are liable to exceed a dose limit for public exposure, respectively. This is the starting point of a graded approach to ORP and differentiation, for instance between the need for individual and workplace monitoring on this basis.

Finally, there is now more emphasis on the need for a transparent assessment of occupational exposures, and for easily accessible dose registries, which are of particular importance for outside workers.

Public radiological protection issues

Radiological protection in relation to public exposures has in general led to very small annual doses to the “representative person⁴” within exposed populations. Discharges of airborne and liquid effluents to the environment from nuclear installations have been driven by the use of *best available techniques*. Countries have different policies with regard to the establishment of discharge authorisations, but even where these are set on the basis of a constraint above say 0.1 mSv per year, actual doses are one or two orders of magnitude lower. The assessment of public exposures also varies between countries, ranging from a conservative, prospective approach to a realistic assessment on the basis of the characteristics of the environment and people’s habits. It is sometimes required that generic estimates are replaced with more realistic assessments when the releases exceed certain pre-set levels.

The inclusion of NORM industries in the control system for planned exposure situations will not change this picture much. Airborne effluent is in general of little importance, and while liquid effluent may be of concern for the quality of drinking water, resulting doses are well below the dose limit for public exposures. The new issue with NORM industries is the possible significance of a legacy of contaminated residues or tailings from mining, the accumulation of long-lived radionuclides in the environment – resulting from effluents or from the spreading of fertilisers – and the recycling of secondary products for different uses in the public domain, in particular for building materials.

Extrapolation to a distant future is difficult, particularly with regards to whether future exposures should be managed as planned exposure situations or as future existing exposure situations. This is especially relevant for the disposal of radioactive waste. The ICRP addresses this by recommending the application of its system in a flexible fashion, depending on the time frame (e.g. direct oversight, indirect oversight, no oversight [ICRP 122]).

The (effective) dose limit for public exposures is in most cases 20 times lower than that for occupational exposures. Regardless, constraints and actual exposures from any practice are much lower than the dose limit. It should be borne in mind that the dose limit applies to the sum of all exposures for any individual member of the public from all

4. Doses to the public cannot be measured directly and, in some cases, cannot be measured at all. Therefore, for the purpose of protection of the public, it is necessary to characterise an individual, either hypothetical or specific, whose dose can be used for determining compliance with the relevant dose constraint. This individual is defined as the “representative person”.

planned exposure situations (noting that dose limits do not apply to medical exposures). For situations involving artificial radionuclides, such summation was rarely relevant (except the situation of an individual working at several NPPs on the same reactor site). The consideration of NORM industries, and the very broad definition of “practices” in the new IBSS, made it important to emphasise that the dose limit relates only to exposures coming from regulated practices. In the IBSS, this has been translated into “practices subject to authorisation” (by licensing or registration). It is only the regulator who can assess overall public exposures, which can then be controlled by setting discharge authorisations.

Exposures resulting from radiological imaging for non-medical purposes could be regarded as a separate category (see below), but they are, in principle, regarded as public exposures.

Medical radiological protection issues

Medical exposures represent the largest man-made doses of radiation. Their frequency is increasing rapidly and will likely continue to do so.

The previous NEA report (NEA, 2007) addressed medical exposures among the “possible emerging challenges in the application of radiological protection”. The conclusions in that report on challenges and approaches to improve the situation are still broadly valid and will not be repeated here. It should be underlined, however, that the anticipated increase in computed tomography (CT) for medical imaging, together with fluoroscopy and nuclear medicine imaging exams has not only been confirmed but is occurring more quickly than anticipated in 2007, in particular with respect to the number of medical imaging units being used, the number and collective total of exposures and the speed with which technology is advancing. While some technological improvements have resulted in a reduction of doses for the same image quality, there is a notable increase in the population dose as a result of an increasing number of CT examinations and nuclear medicine (NM) imaging, and these high doses are of concern. This is particularly true with regard to exposure of the foetus and children, bearing in mind the sensitivity of the developing brain and the higher sensitivity of children than adults.

Managing the risks of radiation imaging procedures depends on an appropriate *justification* for performing each procedure (three levels of justification are introduced for medical exposure in ICRP 103), and careful *optimisation* of the procedure. When these exams are justified, the diagnostic procedure should subsequently be optimised so that the required image quality is achieved while unnecessary radiation dose to the patient is avoided. If precautions are not taken, patients may be exposed to radiation without clinical need or benefit.

Justification and optimisation of medical exposures are therefore still a major concern. The issue of justification was addressed in several fora, and countries have been making efforts to develop referral guidelines for radiological imaging. While the process of developing and endorsing such guidelines is very complex, it would seem worthwhile to join efforts, although it has proven to be difficult, for instance in European guidelines. It should also be underlined that the issue of justification is not only relevant to radiological protection but also to better, and less expensive, health care. As for optimisation, on the one hand, improved technology may result in lower doses for the same image quality. On the other hand, the proper use of equipment by radiologists should be fostered through the provision of adequate information on the irradiation parameters and corresponding doses.

An emerging issue is the occurrence of accidental or unintended medical exposures, particularly in radiotherapy. Such anomalies may result in patient deaths and secondary cancers, and it is now widely recognised that these occurrences need to be prevented

through clear protocols, and adequate software and training. The issue of accidental or unintended exposures is addressed in the IBSS.

In radiotherapy, the only planned exposure resulting in very high doses, the lessons learnt from serious accidental exposures should be implemented to prevent reoccurrence. Radiation therapy facilities are encouraged to share their experiences of actual and potential safety incidents through participation in database networks such as the Radiation Oncology Safety Information System (ROSIS).

While this retrospective approach is necessary, it is not considered to be completely sufficient. Since radiotherapy is always faced with new technologies (e.g. stereotactic and ion-beam radiotherapy), and with an increasing level of complexity, it is recognised that a proactive approach is needed. A safety culture should be developed that considers any potentially problematic events, gives attention to the occurrence and severity of such events and works to identify weaknesses in the system (failure mode and effects analysis [FMEA]). This is an essential component of safety assessment and of risk management.

Moreover, the decision to implement a new technology should be based on an evaluation of the expected benefit, rather than driven by technology itself. Justification criteria is a key component considered in the update of a quality assurance programme for the introduction of new technologies. The importance of introducing a level of responsibility for manufacturers, to deliver the correct equipment with the correct calibration files, and for providing the appropriate advice to the users should also be underlined.

Patients – as well as relatives, comforters and carers – increasingly ask for information about procedures to be undertaken, and medical doctors sometimes do not have sufficient knowledge to provide information about the procedures they are advised to undergo.

For an exhaustive overview of significant issues in medical exposures, the reader is invited to look into the proceedings of the recent conference on this subject in Bonn, which was a milestone in this respect. The resulting “Bonn call for action” will be instrumental in improving radiological protection in medical exposures (Bonn, 2013).

Non-medical imaging exposures

Non-medical imaging remains an important issue, in particular with regard to the justification of such exposures. These exposures are images taken for reasons other than clinical considerations, e.g. security scanners at airports, for the detection of concealed objects within the human body, for employment, immigration, insurance purposes. The ICRP no longer regards non-medical imaging as medical exposure (ICRP 125). Furthermore, the ICRP regards exposure for occupational, health insurance or legal purposes as unjustified if not being undertaken without reference to clinical indications. The caveat is formulated to indicate that medical expenses are not radiologically justified: “unless the examination is expected to provide useful information on the health of the individual examined or in support of important criminal investigations”. It is also stated that a clinical evaluation of the images is expected.

The increased use of security screening units with sources of ionising radiation has raised ethical questions. These units are found at ports, border crossings, bus and trucking terminals, entertainment events, prisons, etc. Human imaging without reference to clinical indication is normally not regarded as justified, but in exceptional circumstances the government or regulatory body can decide that such human imaging for specific practices can be considered as justified.

The issue is addressed in the new (IBSS) and EU BSS (Euratom BSS). Assuming that such imaging is considered neither as medical nor as occupational exposure, the International BSS indicates that the issue: “would normally be constrained by the public

dose limit and any other constraint” or “in general, the annual dose limits and corresponding constraints for public exposure should apply”, acknowledging that the doses could be higher than the public dose limit.

A better understanding of the categories of exposure is needed. Regarding non-medical imaging, a new ICRP publication (ICRP 125) on security screening has recently been issued. There is also a need however to pursue a more pragmatic classification of public/medical exposures, especially since in practice many of these examinations would have to be performed by medical staff. The WHO definition of health could be revisited to see if the present definition is too narrow. Notwithstanding such an analysis, the radiological protection community must demand that alternative measures are assessed before turning to the use of ionising radiation exposure.

Regulatory control and enforcement

Scope of regulatory control

The pillars of regulatory control are, on the one hand, the application of the principle of justification to each newly introduced type of exposure-causing situation, and on the other hand, the imposition of an authorisation regime on every such individual situation. Authorisation is based on the concept of notification (or reporting), registration and licensing, and appropriate inspections as different steps in an elaborate “graded approach”. The concept of “registration” is similar to the earlier concept of “authorisation in accordance with conditions laid down in national law” in the Euratom Standards, but its explicit introduction clarifies the distinction with licensing, a “licence” being an individual document for a specific undertaking.

An important element of this graded approach is that it makes provisions for exemptions both generically, on the basis of pre-established values, and for specific exemptions by the regulatory authority (or as defined in national legislation). Similarly, release from regulatory control (clearance) can be granted by the regulatory authority either on the basis of default clearance values or on the basis of any type of material and pathway of release, or on the basis of specific clearance levels. Such specific clearance levels have been defined in EC guidance for the recycling of scrap metal (RP 89, 1998) and for the reuse of buildings or the recycling of building rubble (RP 113, 2000). National studies have led to the establishment of specific exemption and clearance values for landfill disposal. Such specific clearance levels, which can be well above the default values, may be important in optimising strategies for the dismantling of nuclear installations or accelerators.

Dose criteria for exemption and clearance

The basis for exemption and clearance criteria for artificial radionuclides was described in IAEA SS89 (1989). This led to the incorporation in the IAEA Safety Guide RSG1.7, and the IBSS (IAEA, 1996), of a dose criterion of around 10 μ Sv per year as the basis for exemption, with radionuclide-specific activity concentration values derived on this basis. If, for specific situations or specific radionuclides, the exemption values are judged to be too low, then specific exemption may be granted by the regulatory authority. If the authority judges the radiation risks to be sufficiently low not to warrant regulatory control under the prevailing circumstances, and the practices and sources are inherently safe, exemption can always be authorised (even if the values are not judged to be too low). It is important to understand the above exemption practices to explain the approach followed for the exemption of naturally occurring radioactive materials.

Naturally occurring radioactive materials

In IAEA Safety Guide RSG1.7, the approach to define the scope of regulatory control was still based on the exclusion of levels on the order of the natural activity concentration found in the earth’s crust. On this basis, the International BSS threshold values for the

exemption of NORM industries, and for the clearance of their residues, are still 1 Bq/g for the uranium and thorium decay chains, and 10 Bq/g for K-40. In the Euratom BSS, the same values were taken for the application of the concept of exemption; hence the two approaches lead to an identical level of regulatory control, and both offer the same protection. Nevertheless, it should be pointed out that the approach based on exemption allows for situations where the exempt concentration can be higher for segments of the decay chain in case of non-equilibrium, and also for more restrictive values if pathways of exposure are identified that could lead to exposures above 1 mSv in a year (e.g. contamination of drinking water).

Exemption and clearance are important concepts for trade or emergency preparedness. Exemption levels and decisions which affect the public can only be set if they are accepted by the broader public. Such choices cannot be made by radiological protection experts alone, but need to account for a wide range of societal parameters affecting the tolerability of risk. Involving stakeholders in discussions that will lead to the regulatory establishment of criteria, and working to address their concerns with appropriate information and explanation, is of key importance to their final acceptance.

It should be noted that the exemption criterion of 1 mSv per year for NORM is two orders of magnitude higher than the criterion for man-made radionuclides, 10 μ Sv per year. This reflects a judgement on the appropriate basis for regulatory control, where, for example, significant reductions in individual or collective doses cannot be achieved by reasonable control procedures, rather than an unwarranted, different appreciation of the radiation risks.

Dose limits

Occupational and worker dose limits apply in planned exposure situations only, and not in the case of medical exposures to patients. The considered total occupational or public dose to an individual is the sum of public or occupational doses from regulated sources in planned exposure situations. The summation of doses provides a guarantee against unwarranted separate consideration of different sources. If sources and corresponding reference groups of affected populations were defined properly, however, it would be exceptional if public exposures from different planned situations would need to be considered together. For outside workers, of course, all occupational doses incurred in different undertakings need to be added, under the responsibility of their employer.

References

- Bonn (2013), "Bonn Call for Action: 10 Actions to Improve Radiation Protection in Medicine in the Next Decade – Joint Position Statement by the IAEA and WHO", www.who.int/ionizing_radiation/medical_exposure/bonncallforaction2014.pdf?ua=1.
- Broggi, S. et al. (2013), "Application of failure mode and effects analysis (FMEA) to pretreatment phases in tomotherapy", *J. Appl. Clin. Med Phys.*, Vol. 14, pp. 265-277.
- Cantone, M.C. et al. (2013), "Application of failure mode and effects analysis to treatment planning in scanned proton beam radiotherapy", *Radiation Oncology*, Vol. 8, p. 127, www.ro-journal.com/content/8/1/127.
- Ford, E.C. et al. (2014), "A streamlined failure mode and effects analysis", *Med. Phys.*, Vol. 41(6).
- IAEA (1996), *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources*, Safety Series No. 115, IAEA, Vienna.
- IAEA (2004), *Application of the Concepts of Exclusion, Exemption and Clearance*, Safety Guide No. RS-G-1.7, IAEA, Vienna.
- ICRP 125 (2014), "Radiological protection in security screening", *Annals of ICRP*, Vol. 43(2).

- ICRP 122 (2013) “Radiological protection in geological disposal of long-lived solid radioactive waste”, *Annals of ICRP*, Vol. 42(3).
- ICRP 112 (2009), “Preventing accidental exposures from new external beam radiation therapy technologies”, *Annals of ICRP*, Vol. 39.
- ICRP 103 (2007), “The 2007 recommendations of the International Commission on Radiological Protection”, *Annals of the ICRP*, Vol. 37 (2-4), Ottawa.
- NEA (2012), “Information System on Occupational Exposure: Twenty-second Annual Report of the ISOE Programme”, NEA/CRPPH/ISOE(2012)8.
- NEA (2007), *Scientific Issues and Emerging Challenges for Radiation Protection*, OECD, Paris.
- RP 113 (2000), “Radiation Protection 113: Recommended Radiological Protection Criteria for the Clearance of Buildings and Building Rubble from the Dismantling of Nuclear Installations”, <https://ec.europa.eu/energy/sites/ener/files/documents/113.pdf>.
- RP 89 (1998), *Radiation Protection 89: Recommended Radiological Protection Criteria for the Recycling of Metals from the Dismantling of Nuclear Installations*, Office for Official Publications on the European Communities, Luxembourg, <https://ec.europa.eu/energy/sites/ener/files/documents/89.pdf>.

3.3. Emergency exposure situations

Introduction

For some time, and particularly since the Fukushima Daiichi nuclear power plant accident, both the science and the values aspects of preparation and response to nuclear and radiological accidents, as well as malevolent acts, have been of significant interest both nationally and internationally. As a result of the 2001 terrorist acts, and the 2011 Fukushima Daiichi accident, national and international bodies with emergency management responsibilities have been studying responses to the accident in order to identify issues and lessons to be better prepared for an accident situation. This section will outline the most significant issues that have been identified, proposed changes, and areas in need of further research.

What are the issues?

Accidents and acts have highlighted several areas where possible improvements can be implemented. These aspects can broadly be divided into two groups: those emerging during the very early phase when information is scarce and uncertain; and those emerging during the later phase when there is less urgency but where more direct stakeholder participation is warranted.

Planning: Based on a national hazard assessment, governments should develop and stage an emergency plan such that each postulated nuclear installation accident can be addressed to avoid, or to minimise, public, worker and environmental exposures through the application of an optimised protection strategy. However, planning will most likely not fully reflect the prevailing circumstances that actually occur, such that plans and allocated resources will need to be flexible.

Early phase uncertainty: Early in an emergency situation, there is generally very little information available, and significant uncertainty, in particular with regard to the severity of the situation and to how the situation will evolve. As such, the course of action generally taken by decision makers is to follow pre-planned protection advice, adjusting as necessary to appropriately address the situation as it is understood at that time (which may be quite different than pre-accident planning). This may lead to many difficulties, which are all more-or-less related to the level of available information and of uncertainty.

Precaution: One of the key foundations of the International System of Radiological Protection is precaution. There are many applications of this concept, but with respect to emergency response, it is based on the idea that if radiological effects can be avoided or reduced by implementing an action, then that action should be considered for implementation even if the cause of the radiological effects is not certain to occur. As such, stakeholder engagement is crucial in the planning stage. The key challenge is appropriately balancing risks and benefits in a situation of significant uncertainty. As an example, the IAEA Glossary describes a precautionary action zone for the early phase of an emergency management situation as follows:

An area around a facility for which *arrangements* have been made to take *urgent protective actions* in the event of a nuclear or radiological emergency to reduce the risk of severe deterministic effects off the site. Protective actions within this area are to be taken before or shortly after a release of radioactive material or an exposure on the basis of the prevailing conditions at the facility.

The issue that has been highlighted by the Fukushima accident is that selecting the appropriate level of precaution for a given, very uncertain situation is challenging. This is illustrated by the evacuation caused by the accident. The Japanese government very

quickly fixed a 20 km evacuation zone around the Fukushima Daiichi plant, and a 20 to 30 km sheltering zone. Before the accident, however, the evacuation zone was fixed, in emergency plans, at 8 to 10 km, but this was expanded because of the government's assessment of the potential consequences, taking into account the very high level of uncertainty due to an extreme lack of reliable data. Other governments, performing independent assessments of the situation, and generally with even less information than the Japanese government, recommended that their own national citizens living in or visiting the Fukushima Prefecture to evacuate to even farther distances. While it is not the intention of this paper to suggest which evacuation distance was the most appropriate, it is nonetheless evident that precaution, as applied to several aspects of this quickly evolving situation, was judged in different fashions by governments around the world.

Uncertain conditions: A key reason for this diversity of assessment was the significant lack of information (on plant conditions, plant releases, etc.) available to those responsible for making decisions about urgent protective measures. The tsunami resulted in a relatively complete “blackout” of information about plant status and about eventual releases. This suggests that, in addition to the issue of diversity of precautionary protective approaches, there is also a significant issue with respect to developing more effective ways of collecting and disseminating information to decision makers.

Communication: Associated with these issues is the difficulty seen in terms of communication between an accident country and other countries. In the case of the Fukushima accident, this seems to have had two key causes: the overall lack of information, and the strain on national resources. The magnitude of the natural and the nuclear accident was well beyond the design basis used for emergency planning, and infrastructure damage not only challenged communications, but destroyed and cut power for many measurement instruments on-site and off-site. This severely limited the data that could be gathered, let alone shared. In addition, the magnitude of the accident put an extreme strain on Japanese expertise resources. This in turn resulted in the *de facto* prioritisation of work for Japanese experts to clearly focus on urgent issues within Japan. As a result, in spite of valiant efforts by Japanese experts to make information available in English, the need to focus limited resources on national concerns resulted in a relatively limited amount of information being made available internationally, and quickly enough to meet all the needs of regulatory authorities in other countries. The news stories, showing on-site explosions and scenes of evacuation, tended to enflame populations in Japan and around the world. This puts additional pressure on authorities to gather information and explain the situation, further exacerbating decisional and communication difficulties. Thus while the decision to focus on urgent Japanese issues was undoubtedly correct for the prevailing circumstances, the situation highlighted the international need for information, and the pressure that this put on Japanese resources. Such an issue should therefore be considered as part of emergency management resource planning in future.

The complexity of the radiological protection system also contributed to post-Fukushima public and governmental confusion. While this is not a new lesson, it was particularly the case with regard to quantities and units. A plain language approach is needed to communicate such quantities as ambient dose rate, organ dose, equivalent dose, and effective dose, in units such as Gy, mGy, Sv, mSv, Bq, TBq, rem or mrem.

Technical issues: Each accident has a tendency to be unique in its causes, in its development and in its results. As such, it is difficult to have detailed preparedness plans for consequence management. Lessons learnt from accidents and incidents have generally confirmed that detailed plans are of limited value. Rather, emergency management organisations around the world have focused on flexible processes, procedures and tools that can be adjusted to address whatever situation might arise. Such tools, in particular for modelling and measurement of releases, modelling and measurement of plumes and deposits, and dose estimations, have been developed and

continue to be improved. Yet in extremely uncertain situations, precaution will generally lead to the use of rather conservative, most-probable worst-case scenario assumptions in such models, giving bounding results that can span several orders of magnitude. The difficulty in quantifying uncertainty with regard to assumptions and model results makes it extremely difficult for deciders to understand the rational of the consequence boundaries that are developed. This complicates the decision-making process immensely, in particular because the standard urgent protective actions (e.g. evacuation, sheltering and stable iodine tablets) entail detriments (e.g. traffic accidents, patient care issues, food and water supply issues) that are difficult to balance in the face of large uncertainties. While this is a fundamental issue due to uncertainty, the technical tools that are used could better display the uncertainty that is inherent in any model predictions.

Worker protection: One of the consequences of the large magnitude of the Fukushima accident was that the protection of on-site workers became more of a challenge. The reliance of many nuclear power plants on electronic dosimetry suggests that planning will need to address the possibility of the long-term loss of on-site power. The physical isolation of the Fukushima site caused by the earthquake and tsunami resulted in challenges in terms of the availability of protective equipment. Early work on-site in buildings with no light or electricity was also challenging. While the TEPCO teams on-site worked diligently to address the issues they encountered, the situation illustrates that further planning would be of value. The NEA/IAEA jointly sponsored Information System on Occupational Exposure (ISOE) recently published a report on this topic: *Occupational Radiation Protection in Severe Accident Management* (NEA, 2014; MHLW, 2014).

Early issues

In general, the early phase of an emergency situation is characterised by uncertainty. The following bullet list summarises the types of issues that typically present challenges:

- Precaution is inherently judgemental, but has not been sufficiently discussed internationally so as to bring views closer together.
- Mechanisms in support of urgent information exchange are in need of further improvement in the early phase.
- Infrastructure for emergency workers is necessary.
- Expert and instrumental resources can be severely strained if insufficiently sized.
- Instrumentation and procedures to measure releases and deposition need to be robust.
- Radiological support for those responsible for bringing the source under control is important.
- Information provided to deciders in uncertain circumstances should better present uncertainty and bounds.
- Instrumentation, procedures and resources are needed to develop early and realistic individual dose estimates, in particular thyroid dose from radioactive iodine.
- All aspects of protective actions should be discussed with stakeholders during the planning stage.

In the later phase of an accident, control of the installation causing the release of radiological substances will be regained, much more information about releases and depositions will be available, and characterisation of contamination and estimation of doses will improve. Affected populations move towards a transition to “life-after-the-

accident”, with larger or smaller changes in lifestyle being necessary for “sustainable and accepted” circumstances to develop. However, as control of a post-accident situation develops, the need to address stakeholder concerns increases. Local projects, often in need of infrastructural and technical support, increasingly arise; and detailed local knowledge (e.g. contamination distribution, habits, business and agricultural processes) becomes more central to sustainably addressing the complex situation. It thus becomes necessary to move from a top-down management approach, where governmental decisions and resources are implemented to ensure urgent protective actions, to a bottom-up management approach, where progressively more individually driven concerns generate increasingly individually-driven information and support needs.

Public involvement in planning: The populations living near nuclear and radiological installations are the ones who should be most actively informed and involved in planning and preparations for incidents. It is, however, generally quite difficult to get such stakeholders to spend valuable free time providing input to plans for a response to an accident that they are told is extremely unlikely to happen. As such, while stakeholder groups generally exist in all countries with such installations, informative materials are generally made available to all members of the population in order to solicit feedback and to ensure understanding of accident response procedures. The issues raised here relate both to the need to identify approaches that will solicit stakeholder input to emergency response planning and preparedness, as well as the need to identify approaches to improve the provision of understandable and practical information to relevant populations regarding emergency response situations so that these populations will be more effectively prepared to react.

In order to involve populations living near installations that could have large radiological releases, the entire population in the country should also have some level of understanding of post-accident risks and responses. This can be at least partially addressed through plain-language presentations of radiological risks and effects, for example on the website of a well-trusted organisation. However, accidents generally degrade significantly trust in organisations that are involved in the industry causing the accident, or in governmental regulatory bodies tasked with the oversight of nuclear activities, making an additional issue to be addressed.

In addition, experience has shown that medical practitioners play a major role in the response to major nuclear accidents, mainly because they are trusted. Without appropriate involvement in planning, they will not have the knowledge needed to provide the necessary input. Their participation in planning is thus extremely important.

Public involvement in recovery: Once an accident has occurred, and control of the situation has been mostly reclaimed, both those directly and indirectly affected by the situation will tend to express concerns, and would like to have these concerns be reflected in any decisions that are taken. As the situation progresses, and characterisation of all radiological aspects (e.g. contamination maps, understanding of individual doses) becomes more detailed, those stakeholders who are directly involved will begin identifying their own specific needs, and expect or at least hope for support, both in the form of expertise and financing.

As noted above, management of the situation will become more bottom-up, involving such things as:

- establishing and maintaining radiological infrastructures by government, universities, research laboratories or non-governmental organisations (e.g. distributing and measuring personal dosimetry);
- offering whole body counting; providing detector equipment for local monitoring home-grown or forest-collected food and training local operators; organising medical follow-up studies);

- expertise and financial support from government (providing technical expertise and advice to local group, municipal and regional projects as identified by stakeholders; and providing financial support to such projects);
- ensuring that radiological protection education is appropriately included in school curricula;
- drawing issues and lessons from activities such that national and local emergency planning and preparation is better equipped.

Criteria for food: A key issue following a nuclear or radiological accident is the management of food, both home-grown food and products for the open market. In general, the consumption and marketing of food products coming from areas affected by or potentially affected by an accident are banned, as one of the early protective actions taken by governmental decision makers. As the accident source is brought under control, and the radiological situation becomes more characterised, there will be a need for the accident country to develop criteria for the national consumption of food and for the export of food. Such criteria will be used to decide whether commercial crops may be marketed, and whether “back-yard garden” items (fruits, vegetables, and perhaps such things as chickens, eggs, etc.) may be consumed. Countries receiving food from the accident country will need to develop national criteria for accepting importation of food.

International criteria exist for managing post-accident international trade in food. The *Codex Alimentarius* provides internationally agreed concentrations (in Bq/kg or Bq/L) of a long list of radionuclides below which international trade should not be hindered. These numbers are based on a series of assumptions:

- the “food basket” of the importing country is assumed to be 10% contaminated;
- the consumption of food containing radionuclides at or below the Codex limit should not cause an individual’s exposure to exceed 1 mSv in a year.

However, exposures from the consumption of food in the country where the accident occurred requires different assumptions than those used by Codex for international trade (different quantities of food eaten, different percentage of the “food basket” contaminated, different contaminated products eaten, etc.). As such, it is likely that the criteria an accident country would use for protection of its own population (in the accident-affected and non-affected national territories) would not necessarily be in alignment with the criteria used by Codex for importation of food from an affected area (this was the case for the Japanese criteria used after the Fukushima accident).

In developing criteria for the management of food from the affected areas, there are several considerations to be taken into account. In general, it should be recognised that accidents are rare, that an accident will most likely affect only a discrete area, and that any affected area will likely produce only a limited variety of export food products. Importantly, public protection and export criteria are a matter of national choice and will evolve with the post-accident situation circumstances. Given these considerations, and the need to focus on prevailing circumstances, an approach to having a coherent national/ international framework for the management of post-accident food would include the following elements:

- Food should be restricted during the emergency phase, and permission to eat and trade will be granted only after measurement/certification processes have been established. While the situation is being brought under control, characterisation of the situation is being accomplished and measurement processes are being implemented, national food-management criteria will be adapted from pre-planned criteria to address the specific circumstances at hand.
- National criteria should focus on protection of the most exposed group – those living in the affected area. National criteria will be based on pre-accident risk

assessments and pre-established food criteria. However, once an accident occurs there will most likely be a need to reassess predefined criteria in a situation-specific fashion. The focus of food management will be to protect the most affected group, those living in the affected territories. If reasonable given the prevailing circumstances, a level of 1 mSv/a, or moving towards 1 mSv/a, will be used to calculate food-specific criteria.

- It will be socially and politically difficult for an affected country to use different criteria for its own population and for exports.
- National criteria should be situation-specific and may evolve as the situation evolves. The CODEX criteria, which apply to importation, could be considered as the upper-bound for national criteria.

Criteria for goods: Another key issue following a nuclear or radiological accident is the management of goods (products made, assembled, or transported through the affected area) and transportation (airplanes, ships, trains, trucks, cars) leaving areas affected by a nuclear or radiological accident. No pre-established international radiological criteria exist for acceptable levels of contamination on surfaces (e.g. from fallout or from having passed through a radioactive plume) or for acceptable volumetric contamination (e.g. from contamination incorporated in such materials as metal, plastic, glass, wood). For example, what criteria should be used to judge whether:

- The surface contamination on an airplane having flown from an affected area or through a contamination plume is sufficiently low to allow regular handling (e.g. maintenance, refuelling)?
- The surface contamination on containers or exposed products (e.g. new cars) having passed through or coming from a contaminated area is sufficiently low to allow regular handling (e.g. unloading from ship or train, removal of contents for subsequent transportation)?
- The volumetric contamination in products (electronics produced in contaminated areas, metal from foundries in affected areas, plastics fabricated in affected areas) is sufficiently low to allow their sale?

As with the management of food from an affected area, the management of goods, including internal use, export and import, will be a matter of national choice. However, there is great value in encouraging an international understanding of a framework for the development of such criteria. Indeed, there is a need to reach international consensus on a framework for the development of national criteria for the management of goods from affected areas.

Protection of the environment: The ICRP has recently issued its recommendations with regard to its framework for the radiological protection of the environment in planned, emergency and existing exposure situations. For emergency exposure situations, and for existing exposure situations arising post-accident, the practical implication of the ICRP recommendations will need to be assessed and, as appropriate, implemented. In support of addressing radiological protection, it should be noted that a large amount of environmental radiological assessment data is routinely collected around nuclear installations, and such data has also been collected by radiological research projects in the areas affected by Chernobyl, Fukushima and other large-scale contamination events. In order to better understand the practical implications of the ICRP's recommendations, national experience and current approaches to radiological characterisation and protection of the environment in emergency and existing exposure situations should be shared, and should be viewed in the context of the new ICRP recommendations.

Late issues

Later in an emergency situation, the focus of protection actions will shift to recovery issues and the re-establishment of “normal life”, where the new radiological circumstances are now “normal”. A normal life is one where affected populations do all that is reasonable for “well-being”, in the broad sense advocated by the WHO. In such a state, those affected are satisfied that they are doing enough to protect themselves and their families, and are not overly stressed by their new reality. Those not able to achieve such a state of well-being should probably leave the affected areas to avoid stress-related health issues.

Several issues need to be addressed, in planning and in implementation, to help affected populations achieve such a state of well-being. The following bullet list summarises the types of issues that typically present challenges:

- Public involvement in planning (both before and during an accident):
 - Approaches to solicit stakeholder input to emergency response planning and preparedness should be discussed/shared.
 - Approaches to provide understandable and practical information to relevant populations regarding emergency response situations should be discussed/shared to enable affected populations to make informed decisions.
 - Approaches to involving/informing those indirectly affected should be discussed/shared among responsible governmental organisations.
 - Approaches to build/rebuild trust following an accident should be discussed/shared.
- Public involvement in recovery:
 - Experience in moving from “top-down” to “bottom-up” situation management should be discussed/shared.
 - Experience with radiological protection education and “radiological protection culture” should be discussed/shared.
 - Processes and procedures to ensure governmental support and advise to local protection initiatives should be discussed/shared.
 - Instrumentation, procedures and resources need to be ready to perform very detailed contamination and dose rate maps to support prioritisation of decontamination work, and to support self-help recovery projects.
- Criteria for food:
 - The bases for accident-affected countries to establish food-consumption criteria for its citizens should be shared/discussed for:
 - areas directly affected by the accident;
 - areas indirectly affected by the accident.
 - The basis for accident-affected countries to establish criteria for the exportation of food should be shared/discussed.
 - Whether criteria should remain constant or should be changed as the radiological situation evolves should be discussed/shared.
 - The basis for countries not directly affected by the accident to establish import criteria for food should be discussed/shared.

- Criteria for goods:
 - The basis for criteria for trade in goods and transportation, and the criteria themselves, should be discussed/shared.
- Protection of the environment:
 - Existing national environmental measurement and protection approaches should be assessed in the context of new ICRP recommendations.

What do we know?

As with Section 4.4, the “scientific evidence” referred to here, from an emergency and recovery management viewpoint, addresses more the analyses of case study examples than “scientific experiments”. In terms of impacts from accidents and malevolent acts, what we know and what we do not know have less to do with scientific evidence than with approaches and judgements. As such, and based on the issues identified above, this section will discuss the generic status of emergency planning, preparedness, response and impacts, and areas where further work needs to be done.

The generic situation

Since the accident at Three Mile Island in 1979, and more so since the Chernobyl accident in 1986, national governments and relevant international organisations have been studying and improving emergency planning, preparedness and response capabilities. As a result, significant improvement has been made in these areas. Further, since the Chernobyl accident, significant effort has been put into better integrating radiological protection into the societal aspects of emergency planning, preparation and response. Such work has in particular been undertaken by the NEA Committee on Radiation Protection and Public Health (CRPPH)⁵: many lessons have been learnt, and improvements in response preparations have been substantial.

Current knowledge

We know that radiological emergency situations involving radionuclide contamination can be extremely complex and are generally of a nature at least somewhat different than the situation for which plans have been made. As such, planning and preparedness has been made as flexible as possible, to be able to quickly adjust to the actual conditions and circumstances that a situation presents.

It is known that the resources needed to properly manage consequences include such essential elements as:

- expertise and equipment to collect and organise radiological pre-release, release and deposition data;
- expertise and assets to assess the situation and recommend protection approaches to appropriately address the situation;
- expertise and assets to communicate among all relevant national organisations, to governmental organisations from other countries and to relevant international organisations, in particular the IAEA.

5. Villigen workshops (1998, 2001, 2003); Chernobyl-related work (*Chernobyl: Assessment of Radiological and Health Impact*, 2002; *Stakeholders and Radiological Protection: Lessons from Chernobyl 20 Years After*, 2010); workshops on science and values in radiological protection decision making (2006, 2009, 2012, 2015); workshop on stakeholders in emergency response (*Practices and Experiences in Stakeholder Involvement for Post Nuclear Emergency Management*, 2010).

The nature of the accident can challenge planned preparedness resources, such that supplemental resources should also be available.

What remains to be done?

Although plans and preparations are made to be flexible and responsive, the Fukushima accident showed that events that could lead to a station blackout may well also lead to significant damage to broad areas around the accident site, which can then degrade measurement and response capabilities. Again, although a future accident will likely present different circumstances, a key lesson from the Fukushima accident suggests that it is important to build capabilities that are flexible, independent and that foster communication and information sharing.

- For the early phase:
 - Mutual understanding, among all governmental organisations and all other potentially affected stakeholders, of national post-accident precautionary approaches and assumptions should be further developed.
 - Monitoring equipment (e.g. instrument stations to measure releases, and on-site and off-site deposition) that functions independently from site power for significant periods should be standard emergency management equipment.
 - Quickly dispatchable, trained radiological technicians to perform monitoring should be available.
 - Processes, procedures and equipment to facilitate urgent inter-governmental discussion and information exchange need to be improved.
 - Qualified human resources to handle international communications and information exchange (in English) need to be flexibly sized to meet demands.
 - Processes and trained personnel to develop plain language recommendations for deciders, including plain language expressions of uncertainties and assumptions, need to be available.
 - Early response requires having a source of funding available to move skilled individuals and the necessary equipment to the disaster site(s).
 - Informed contact points, with sufficient resources for response, are necessary to inform national and international media (newspapers, radio, television) of whom to contact should such an event occur. This would enable a coherent and consistent message to be delivered in a crisis situation.
- For the late phase, actively involving stakeholders:
 - Effectively involving stakeholders in planning and response activities.
 - Criteria for consumption of and trade in food from countries affected by an accident or malevolent event need to be developed.
 - Criteria for trade in goods from countries affected by an accident or malevolent event need to be developed.
 - A radiological protection scenario for the environment (non-human biota) in the event of an accident or malevolent event need to be developed.

Possible policy challenges

The study of emergency and recovery management has for some time focused on the assessment of actual accident case studies (such as the Chernobyl and Fukushima accidents), and on emergency exercises (such as the NEA International Nuclear Emergency Exercise [INEX], the IAEA Convention Exercises [ConvEx], the EC European

Community Urgent Radiological Information Exchange [ECURIE], and numerous national exercises). The results of such studies tend to drive the evolution of national response and recovery programmes (policies, regulations, procedures), and of international standards and recommendations. The early and late phase issues mentioned above are all currently under examination, and studies will hopefully develop coherent approaches to better address these issues.

Of the issues mentioned above, some are more challenging to current national policies than others.

Protection of sensitive individuals (e.g. children, pregnant women)

The International System of Radiological Protection, as recommended by the ICRP, currently suggests that protection should be broadly population-based. Risk assessment quantities, like effective dose, are measured in Sv and Gy, and are based on an age and gender averaged approach to risk assessment. The rationale behind this approach derives from the desire to be forward-looking with radiological protection, and thus to be somewhat generic in nature. But it also derives from the known level of scientific detail, with knowledge of age and organ specific risks growing, but still fairly incomplete. But as was illustrated by the Chernobyl and Fukushima accidents, there is a strong social drive to focus post-accident radiological protection efforts on the protection of children. This has manifested itself in the focus of protection plans to specifically address protection of children, and has raised the question of whether or not the quantities used (e.g. those measured in Sv and Gy) are sufficiently descriptive of children's risks. While effective dose is age and gender averaged, it is known that risks to children are somewhat higher than are adult risks to the same exposures, and this raises the question of whether the use of such quantities is sufficient to appropriately allow protective actions to be developed. While post-accident situations generally do not focus on "numbers", but rather on improving the situation, having an accurate representation of the risk to children is certainly something that would be of use in stakeholder relations. However it presents a challenge to the current, average-based system used around the world. Section 1.3 discusses this issue in general terms.

Co-ordination of criteria for food and goods

The current international guidance on the management of food in a post-accident situation consists of:

- the Codex Alimentarius agreement, which provides radiological criteria for imported food, and is based on a dose of 1 mSv/a;
- the European Union Council Regulation (3954/87/EURATOM), which provides maximum permitted levels of contaminated food and feed which are also based on a dose of 1 mSv/a;
- the IAEA Safety Requirements Level documents, which establish criteria for the consumption of food in contaminated areas, and are based on a dose of 1 mSv/a for the longer term:
 - *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards.*
 - *Preparedness and Response for a Nuclear or Radiological Emergency.*

The Codex agreement is the only internationally agreed criteria for post-accident situations, but it only provides criteria for the importing of post-accident foods. The EC Directives and IAEA Standards refer to the protection of individuals in accident-affected territories. None of these instruments were appropriate during the Fukushima accident (NEA, 2015b), and thus there is a need to review current approaches. In doing so, an overall approach that covers protection of those living in affected territories, those living in the accident country(ies) but outside of the affected territories and those receiving food from affected territories would be useful.

Protection of the environment

International recommendations for the radiological protection of the environment have been evolving over the past ten years, but the options for protection in emergency and recovery planning are rather limited. Further study of these situations, from a practical standpoint, would be useful, keeping in mind that protection of the environment cannot be regarded separately from emergency and recovery actions. The involvement of stakeholders in decisional processes is central to the development of accepted and sustainable protection options.

Precaution

The application of precaution is a key aspect of post-accident emergency and recovery management. The level of precaution should be a function of radiological protection objectives, and should be applied in a graded fashion. Questions such as when to start a protective action, when to end a protective action, and what level of decontamination should be the objective will all directly or indirectly depend on what level of precaution is being sought. While precaution will not be characterised in a strictly numerical fashion (although a dose objective may characterise the desired result), the stakeholder judgement of when it is appropriate to start or stop a protective or recovery action may have significant impacts on post-accident activities. As such, a clear articulation of a starting point for discussions of the desired level of precaution could be of great use, but remains a policy challenge.

Possible approaches to improving the situation

Several possible aspects of planned or possible activities could address these issues. The ICRP is currently developing a new recommendation document on the nature and use of effective dose, which could well facilitate better understanding of an individual's risks. However, the most appropriate approach to a better understanding of these issues is through international discussions among radiological protection experts, and including input from relevant stakeholders. The above-mentioned challenges could be good topics for international workshops addressing:

- food and goods criteria;
- application of precaution in emergency exposure situations.

References

- EU (1987), "Council Regulation No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs following a nuclear accident or any other case of radiological emergency", (OJ L-371 of 30/12/87, page 11).
- MHLW (2014), "Response and Action Taken by the Ministry of Health, Labour and Welfare of Japan on Radiation Protection at Works Relating to TEPCO's Fukushima Daiichi Nuclear Power Plant Accident", 2nd Edition (Fiscal Year of 2014), MHLW.
- NEA (2015a), "Occupational Radiation Protection in Severe Accident Management", NEA/CRPPH/R(2014)5, OECD, Paris.
- NEA (2015b), "An Evidence-based Approach to Post-Accident Food Safety Policy and Insights for Protection Optimization", NEA/CRPPH/R(2015)1, OECD, Paris.
- NEA (2014), "Occupational Radiation Protection in Severe Accident Management", NEA/CRPPH/R(2014)5, www.nea.fr/documents/2014/san/crp-ph-r2014-5.pdf, OECD, Paris.

- NEA (2013), "Third Workshop on Science and Values in Radiological Protection Decision Making: Summary Report of the Workshop and of the 6th Asian Regional Conference on the Evolution of the System on Radiological Protection, Tokyo, Japan, 6-8 November 2012", OECD, Paris.
- NEA (2011a), *Practices and Experiences in Stakeholder Involvement for Post-Nuclear Emergency Management Workshop*, OECD, Paris.
- NEA (2011b), *Science and Values in Radiological Protection – Summary of the CRPPH Workshops held in Helsinki (2008) and Vaux-de-Cernay (2009)*, OECD, Paris.
- NEA (2011c), *Practices and Experiences in Stakeholder Involvement for Post-Nuclear Emergency Management*, OECD, Paris.
- NEA (2006), *Stakeholders and Radiological Protection: Lessons from Chernobyl 20 Years After*, OECD, Paris.
- NEA (2004a), *Stakeholder Participation in Radiological Decision Making: Processes and Implications – Summary Report of the 3rd Villigen Workshop (Switzerland), 21-23 October 2003*, OECD, Paris.
- NEA (2004b), *Stakeholder Participation in Radiological Decision Making: Processes and Implications – Case Studies for the 3rd Villigen Workshop, Switzerland, 21-23 October 2003*, OECD, Paris.
- NEA (2002), *Better Integration of Radiation Protection in Modern Society: Workshop Proceedings – Villigen, Switzerland, 23-25 January 2001*, OECD, Paris.
- NEA (1998), *The Societal Aspects of Decision Making in Complex Radiological Situations – Workshop Proceedings, Villigen, Switzerland, 13-15 January 1998*, OECD, Paris.

3.4. Environmental radiological protection

Introduction

As modern societies have developed and human activities expanded, environmental problems that may be linked to a range of human activities have increased society's concerns about the resultant environmental risks. Such concerns are driven by a desire to maintain a suitable environment in which humans can exist not only now, but also in the future – a “sustainable ecosystem”. Associated with this is a view that humans should be cautious in interfering with the ecosystem on which they depend, since the ecosystem is very complex and far from fully understood. Protection of the environment (from a range of human activities) is an issue that has evolved significantly over the past 30-50 years. In the case of ionising radiation, it was assumed that if people were adequately protected then the environment would also be adequately protected. However, in the late 1990s, the ICRP felt that a framework was needed so that the protection of the environment could be explicitly demonstrated, addressing political and societal demands for better scientific understanding of possible radiological harm to non-human species and their related ecosystems, in particular from chronic exposures.

Until the publication of ICRP 103 (2007) the recommended radiological protection framework was designed for the purpose of protecting humans from exposures to ionising radiation. As noted above, society has demanded that the level of protection should not just be assumed, but rather demonstrated, and that any protection strategies should specifically and explicitly include protection of the environment to satisfy the desire to intentionally protect the environment from harm. Work to address approaches to demonstrate possible environmental impacts of radiation, and to support the initial questioning of the ICRP's assumption and of its change of approach in ICRP 103, began earlier. This section will outline the most significant issues that have been identified since the recommendations for protection of the environment from ionising radiation were published, any proposed changes and the areas in need of further research and development.

What is the issue?

When the NEA discussed this topic in its 2007 report (NEA, 2007) the key issue and policy challenges lay in *developing an understanding – meaning an approach as well as experimental data – that will allow regulators and others to demonstrate the level of environmental protection achieved*. The framework that has subsequently been developed is “based upon a reference organism approach that was analogous to the system for human protection”. From a scientific point of view, in the early stages of development, it was understood that no significant harmful effects in animals and plants that could put whole species at risk or promote irreversible imbalances between species had been observed below $40 \mu\text{Gy}\cdot\text{h}^{-1}$ of radiation exposure. However, this was based mainly on external and acute exposure to gamma irradiation, with observations made at the level of individuals (UNSCEAR, 1996). Later research demonstrated that significant effects had been observed at lower dose rates, leading to a predicted no effect dose rate (PNEDR) for all ecosystems in chronic exposure situations of $10 \mu\text{Gy}\cdot\text{h}^{-1}$ above the natural background radiation (Garnier-Laplace et al., 2008; Andersson et al., 2009).

The assessment methodology that has been developed by the ICRP for protection of the environment has relied on various extrapolations, the robustness of which has needed to be demonstrated. Ongoing research to address gaps in this scientific knowledge has focused on understanding the biological effects of:

- long-term chronic exposures to low doses of radiation;
- long-term internal exposures to bio-accumulated alpha (α) and beta (β) emitting radionuclides;

- radiation stress combined with other toxicants or stressors;
- the indirect effects driven by inter-species ecological interactions;
- consequences at higher levels of biological organisation such as population, community and ecosystem.

While the framework that has been developed has made significant progress towards better demonstration of “protection of the environment”, some consider that the reference organism approach may have difficulties in actually demonstrating that environment protection objectives are being met, especially those at population and ecosystem level. This has led to ongoing discussion about what is actually meant by “protecting the environment” and further development of an “ecosystem approach” which, in the context of environmental impact assessment, is conceived as a holistic strategy that integrates toxicological knowledge with ecological understanding.

What do we know?

A recommended framework for protection of the environment

ICRP Publication 103 (2007) included, for the first time, protection of the environment as an issue to be addressed explicitly. The ICRP’s stated aim is that of: “...preventing or reducing the frequency of such radiation effects to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities and ecosystems”. The objectives of environmental protection were explored and the basis for the proposed reference animal and plant (RAP) approach was explained. This now forms the basis of a structured approach to assessment of exposures to and effects of ionising radiation. ICRP 103 was followed by the publication of ICRP 108 (2008) which dealt with the concept and use of the RAPs and described in detail the framework for protection of the environment. ICRP 114 (2009) provided environmental transfer information for the set of RAPs. Within this framework, the ICRP recommended derived consideration reference levels (DCRLs) that can be used to identify where there is likely to be some chance of deleterious effects of exposure to ionising radiation on individual RAPs, and similar organism types. The DCRLs are presented as ranges of dose rates with lower and upper bounds. The ICRP RAPs range from 4 to 4 000 $\mu\text{Gy}\cdot\text{h}^{-1}$ (ICRP 108, 2008). The ICRP more recently published ICRP 124 (2014), which consolidates ICRP recommendations on environmental protection and provides further guidance on how its framework for protection of the environment should be applied under different exposure situations.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) has also reported that chronic dose rates of less than 100 $\mu\text{Gy}\cdot\text{h}^{-1}$ to the most highly exposed biota individuals would be unlikely to have any significant effects on most terrestrial communities, and that maximum dose rates of 400 $\mu\text{Gy}\cdot\text{h}^{-1}$ to any individual aquatic organisms would be unlikely to have any detrimental effects at the population level (UNSCEAR, 2010). While the values reported by UNSCEAR are not as low, they are within the range of ICRP DCRLs. Work has also been undertaken (for example, the Environmental Risk from Ionising Contaminants: Assessment and Management [ERICA] and Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium [PROTECT] projects) to determine a PNEDR. The PNEDR of 10 $\mu\text{Gy}/\text{h}$ above natural background radiation levels is recommended for use as a screening level, that is, a level that should be appropriate in most circumstances (see ICRP Publications 91 and 92) to effectively distinguish situations that are below concern from those which may require a more considered evaluation. The PNEDR has been derived from statistical analysis of radiation effects data using an accepted methodology for the derivation of benchmark values for other chemical stressors on the environment. It represents the dose rate at which 95% of the species in an ecosystem are expected to be protected,

acknowledging that this will over protect some species and may under protect others (Garnier-Laplace et al., 2008; Andersson et al., 2009).

During the past decade, assessment tools largely compatible with the RAP approach have also been developed. (ERICA tool, RESRAD-BIOTA [latest 2009], EA R&D 128 [2001-2003], radon dose calculator [Vives I batlle 2008, 2012], SADA [US NRC], Marine dynamic model). The International Atomic Energy Agency (IAEA) has now also included the requirement to explicitly demonstrate protection of the environment in their latest basic safety standards (IAEA, 2011). Through a number of IAEA and European Commission co-operative research programmes (ERICA; Environmental Modelling for Radiation Safety [EMRAS] I; EMRAS-II; Modelling and Data for Radiological Impact Assessments [MODARIA]; Strategy for Allied Radioecology [STAR]; Coordination and Implementation of a Pan-European Instrument for Radioecology [COMET]) work has been undertaken to improve capabilities in the field of environmental radiation dose assessment for non-human species. This has been based on the RAP approach and has seen the establishment of international databases of radiation effects (Copplesstone et al., 2008) and environmental transfer parameters (Copplesstone et al., 2013), to support the framework, testing and comparison of a range of models to assist with reaching a consensus on modelling philosophies, approaches and parameter values, and to develop improved methods of assessment.

As a result of these advances, a number of national institutions are now developing systems for the radiological protection of the environment based on a RAP approach. These regulatory systems are designed with the aims of providing conceptual approaches and methods for undertaking environmental risk assessments that demonstrate protection of the environment and support regulatory decision making, especially with respect to situations of existing or possible future environmental contamination. These approaches generally focus on equilibrium situations and/or prolonged exposure to sources of ionising radiation.

Ongoing research and international collaboration

The implementation of the framework for protection of the environment from ionising radiation and recommendations from other groups such as the NEA and the International Union of Radioecology (IUR) have also resulted in other advances, particularly in the European community, to strengthen the supporting research network in the field of radioecology. The establishment of the European Radioecology Alliance (ERA) and the research programmes STAR and COMET have worked towards addressing gaps in scientific knowledge that were discussed in the 2007 NEA report (NEA, 2007). While progress has been made in this regard, ongoing work to address these gaps is still required. The research community is continuing to focus on improving the robustness of environmental risk assessment methodologies that were developed and addressing shortfalls or weaknesses when they are identified.

More recently, research results have identified potential discrepancies between laboratory or controlled radio-toxicity tests and field data on wildlife chronically exposed to ionising radiation. The overall sensitivity of end points observed in terrestrial species from the Chernobyl Exclusion Zone (CEZ) appears to be higher than the sensitivity end points tested under laboratory or controlled field conditions (Garnier-Laplace et al., 2013). The results of this study suggested that organisms in their natural environment were more sensitive to radiation. This has implications for the adopted or recommended benchmark screening values (i.e. DCRLs) that are largely based upon laboratory studies from a few species thought to be representative of biodiversity. These discrepancies must be resolved as environmental managers and regulators are being questioned about the accuracy of the data they use in their assessments, and some groups perceive the current benchmark dose and dose rates as not being low enough, despite being close to typical natural background dose rates (excluding that from inhalation of Rn and its daughters) (Deryabina et al., 2015).

Future work that is currently planned in ongoing research programmes (MODARIA; STAR; COMET) is moving towards:

- developing a more profound understanding of the environmental processes within major ecosystems that significantly influence the transfer of radionuclides so as to be able to more accurately predict exposures to both humans and wildlife;
- developing and proposing an integrated approach for assessing the radiological risk for humans and for the environment;
- examining the relevance of taking into account the context of multi-pollution circumstances, which could modify the risk estimated for pollutants taken in isolation due to interactions between contaminants;
- determining the relevant ecological consequences for situations that represent realistic exposure conditions and proposals for associated environmental protection criteria.

Possible policy challenges

An approach (based on experimental data) has now been developed that allows regulators, as they move towards implementation of an approach, to better demonstrate a level of environmental protection. While this is an achievement in itself, there are ongoing policy challenges that will need to be addressed as the reference organism approach is implemented and tested internationally across a range of exposure situations. Some questions that could be posed are:

- Does the framework provide adequate guidance to enable clear demonstration of protection of the environment?
- What are the implications of ongoing scientific research?
- Is the framework being implemented by national institutions in a consistent manner?
- Is there room for protection of the environment during or following emergency situations?

Does the framework provide adequate guidance to enable clear demonstration of protection of the environment?

The ICRP's stated aim is that of: "...preventing or reducing the frequency of such radiation effects to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities and ecosystems". Integration of the RAP approach into regulatory frameworks in order to demonstrate protection of the environment is still in the early phases and there has been reluctance from some countries to upgrade or change their current system of radiological protection to include protection of the environment. The reasons for this reluctance have not been elaborated. However, it may be related to a need for additional guidance to support implementation. In many instances, implementation of the proposed system should not result in additional burden, and may in fact increase the acceptability of radiological applications, as the society may view the implementation of a system that demonstrates protection of the environment from ionising radiation as an improvement on a system that relies on the assumption that if humans are protected then the environment is also protected.

Discussions within the radioecology research community about the development of an "ecosystem approach" are also ongoing. The ecosystem approach was discussed in the NEA 2007 report, and reconciliation between the RAP approach and the ecosystem approach will continue to be a policy challenge. One of the major justifications for

continuing to explore the “ecosystem approach” stems from the mismatch between current methodologies, which are largely based upon toxicological data gathered for individual organisms, and the recognition that the most widely accepted goal of biota-protection generally sits at the population and ecosystem levels of organisation (IUR, 2012). The ecosystem approach provides a range of population and community level end points that can be monitored (for example, population growth rate, density, size and reproduction rates; biodiversity, taxonomic composition, food web structure). Variation in these end points would prompt examination of the reasons for the change, which may or may not be a consequence of ionising radiation when multiple stressors are present. This approach has been adopted in other situations, and it is believed appropriate for radiological protection to move in the direction of an ecosystem-based approach in order to improve the relevance and coherence of information being provided to decision makers. This does not mean, however, that the RAP approach should be abandoned, but rather harmonised with ecosystem-scale approaches and end points. This harmonisation could lead to consistency in management approaches across stressors and will enable radioecologists to take advantage of scientific advances being made in other related fields (Bradshaw et al., 2014).

What are the implications of ongoing scientific research?

While the framework was developed on the basis of as much experimental data and scientific knowledge as possible, there are still a number of assumptions and extrapolations required to underpin the assessment approaches and methodologies developed. Continuing scientific research to support the RAP approach has been essential to demonstrate the robustness of the methodology. However, the scientific research that has been undertaken is, in some cases, creating some policy challenges. This is already being demonstrated, as outlined above, in relation to the discrepancies between the adopted or recommended DCRLs that are largely based upon laboratory studies, and the observed effects data from field studies on wildlife chronically exposed to ionising radiation. It highlights the importance of properly considering confounding factors when undertaking any field studies.

Another issue is that some DCRLs have been set on a precautionary basis where no data are available, and this may lead to discrepancies when data becomes available. Once the scientific evidence is available, these discrepancies must be resolved as quickly as possible and the approach adapted, if required. This will assist regulators who are ultimately required to provide the assurance to society and politicians, to maintain credibility and public confidence that the assessments are appropriate and robust.

Is the framework being implemented in a consistent manner by national institutions?

A number of countries are already establishing their own guidance and recommendations for demonstrating protection of the environment in a regulatory context. In Australia, where the RAP approach is already being applied (primarily to uranium mining situations), issues have arisen that stem from different levels of understanding of the approach in general. These have included:

- establishing appropriate scenarios that reflect an understanding of the exposure pathways that are being assessed;
- selecting the most appropriate representative organisms for assessments and the subsequent extrapolation from RAPs;
- understanding different models and their underlying data as well as assumptions and how these may impact the estimated dose rates;
- understanding the meaning of a reference level, how this is different from a screening level and how the two levels may be applied by a regulator when considering an assessment;

- understanding detriment of dose, interactions and roles of co-contaminants that may be present in the environment and how these apply in a practical sense;
- understanding what data may be required to support an assessment, and collecting the right data in an appropriate manner.

In order to address these issues in Australia, national guidance has recently been developed to support operators and regulators (both environmental and radiation) to reach a common understanding of what is required from an assessment.

To ensure consistency in implementation, it is important that guidance at the international level continues to be developed and refined so that adequate information and guidance for all relevant stakeholders (regulators/environmental assessors, facility operators, contaminated site managers, environmental consultants) can be provided. Dialogue among such stakeholders and among national institutions as they progress in the implementation of their frameworks to demonstrate protection of the environment should also be encouraged and promoted.

Protection of the environment in emergency situations

Protection of the environment in emergency situations also has some possible policy challenges. In an emergency exposure situation the focus is on immediate measures to protect the human population. The impact of countermeasures to protect humans and, if possible, to protect non-human species from exposure to ionising radiation are themselves liable to cause environmental damage.

In view of this focus on human-protective actions during emergency exposure situations, and of the difficulty and environmental damage that could be caused by actions to protect the environment, considerations of post-accident environmental protection are perhaps best taken in the planning stage. Such considerations could influence the siting of new installations, and be considered as a factor when considering safety modifications. For such a role, assessment methodologies and models will be needed.

The assessment methodologies and models that have been developed to date to demonstrate or predict protection of the environment are largely based on equilibrium situations. While this is appropriate for estimating or predicting the consequences of an accident once it has entered the recovery phase and has reasonably become an equilibrium situation, the dynamic nature of an accident in the early phases makes many of the models less appropriate for the prediction of exposure and the potential effects during the early phases of an accident.

The assessment of the radiation exposures and effects on non-human biota as a result of the Fukushima Daiichi nuclear accident after the 2011 Great East-Japan earthquake and tsunami (UNSCEAR, 2014b) has been able to apply assessment methodologies that were developed over the last decade to demonstrate protection of the environment. This included estimating doses to biota and potential effects during the late phases of the accident. However, in order to estimate the doses and potential effects during the early phases of the accident and for releases to the marine environment, the methodologies required modification and combination with dynamic models. The UNSCEAR (2014a) assessment applied dynamic models in order to characterise the environment in terms of compartments that represent distinct features, for example, soil layers and body organs. Rate constants were used to express the exchange between compartments and simulations performed using a mathematical representation of the system, with the net result being a description of the evolution of radionuclide concentration over time. Once this radionuclide concentration was determined, taking into account the dynamics of the situation, the potential effects could then be estimated using the more standard methods. This highlighted that more work is needed in order to adequately apply predictive assessment tools to dynamic situations. The importance of

understanding confounding factors and dosimetry aspects when undertaking field studies were also noted in the UNSCEAR assessment, and support the conclusions made by Garnier-Laplace et al. (2013).

Finally, in emergency (or dynamic) situations, dose rates may increase rapidly after an accident or release, and accumulation may occur over a longer period of time. Direct dose, redistribution of dose and accumulation of radioactivity may all have varying effects on an organism and/or ecosystem. A better understanding of the long-term effects in these situations, taking into account the life cycle/species variation and impacts on the ecosystem as a whole, may have a significant impact on one species which has follow-on effects for other species.

Possible approaches to improve the situation

Significant progress has been made in the past decade in developing a framework to demonstrate protection of the environment, and initiatives that have been implemented (ERA, STAR, COMET) to promote radioecology and maintain expertise in this area have been crucial. A strong foundation has been established across the European community and the efforts employed here should be expanded, and strengthened in this field of expertise at the international level.

Combined research across a range of disciplines should continue to be explored, and analogies of biological mechanisms in human and non-human cells should be exploited where possible in ongoing research. Future research should continue to work on addressing data gaps and refining existing models, as well as a strategy to build on the reference organism approach and move towards an “ecosystem approach” that demonstrates protection of the environment.

The priority should be to examine the discrepancies between laboratory outcomes versus field studies in order to reconcile or refine the recommended DCRLs, as well as how they are applied. The DCRLs should be tested in light of any new data that is obtained. It would also be beneficial to examine additional data related directly to chronic, low-level irradiation conditions of relevance for animals and plants in the wild (exposures of 0.1 to 1 mGy/d) over the life span of an organism, and considered variations in the radiosensitivity of organisms (not covering all taxa) both within and between taxonomic groups, as well as how this extends to different stages of the life cycle for any given organism.

Further development of international and national guidance on how to effectively demonstrate protection of the environment for a range of exposure situations, which can be used by operators, environmental managers and regulators alike, is still required. This advice needs to consider the analysis of ecosystems as a whole and whether the most effected species (most highly exposed) is actually the critical group to be considered. Assessments should be considered in combination with societal considerations and the different values that may be placed on an ecosystem. These efforts should be commensurate with the expected benefit, and justification of regulatory control is an issue that still needs to be resolved at the international level to ensure a consistency in approach to the protection of the environment.

Overall, more work is needed in order to adequately apply predictive assessment tools to dynamic situations. The importance of understanding confounding factors, and dosimetry aspects when undertaking field studies, should be more fully addressed.

In reconciling the differences between the reference organism and ecosystem approaches, the recommendations made by the IUR in its report (IUR, 2012) should be recalled:

- Promote dialogue between environmental assessors and environmental managers (facilities operators, contaminated site managers, and other regulators) to increase the chances of improving the value of information flow (two-way dialogue).
- More integrated and functional end points to expand beyond the organism level. This could also include consideration of additional indices that embed the existing and new end points (decomposition, primary productivity, etc.).
- Reference organism approach – improve to incorporate ecological functionalities, other ecological criteria and reference species versus reference organisms to facilitate an ecosystem approach. Better consideration of taxonomy such as insects, bacteria and fungi to cover ecological functionality, and to make it more accessible to people within different geographical areas and biomes.

References

- Andersson, P. et al. (2009), “Protection of the environment from ionising radiation in a regulatory context (protect): proposed numerical benchmark values”, *Journal of Environmental Radioactivity*, Vol. 100(12), pp. 1100-1108, Elsevier, Amsterdam.
- Bradshaw, C. et al. (2014), “Using an ecosystem approach to complement protection schemes based on organism-level endpoints”, *Journal of Environmental Radioactivity*, Vol. 136, pp. 98-104, Elsevier, Amsterdam.
- Copplestone, D., N.A. Beresford, J. Brown and T. Yankovich (2013), “An international database of radionuclide Concentration Ratios for wildlife: development and uses”, *Journal of Environmental Radioactivity*, Vol. 126, pp. 288-298, <http://dx.doi.org/10.1016/j.jenvrad.2013.05.007>, Elsevier, Amsterdam.
- Copplestone, D., J.L. Hingston and A. Real (2008), “The development and purpose of the FREDERICA radiation effects database”, *Journal of Environmental Radioactivity*, Vol. 99(9), pp. 1456-1463, Elsevier, Amsterdam.
- Deryabina, T.G. et al (2015), “Long-term census data reveal abundant wildlife populations at Chernobyl”, *Current Biology*, Vol. 25, Issue 19, Elsevier, Amsterdam.
- Garnier-Laplace, J. et al. (2013), “Are radiosensitivity data derived from natural field conditions consistent with data from controlled exposures? A case study of Chernobyl wildlife chronically exposed to low dose rates”, *Journal of Environmental Radioactivity*, Vol. 121, pp. 12-21, Elsevier, Amsterdam.
- Garnier-Laplace, J. et al. (2008), “Issues and practices in the use of effects data from FREDERICA in the ERICA integrated approach”, *Journal of Environmental Radioactivity*, Vol. 99(9), pp. 1474-1483, Elsevier, Amsterdam.
- ICRP 124 (2014), “Protection of the environment under different exposure situations”, *Annals of the ICRP*, Vol. 43(1), London.
- ICRP 114 (2009), “Environmental protection: Transfer parameters for reference animals and plants”, *Annals of the ICRP*, Vol. 39(6), London.
- ICRP 108 (2008), “Environmental protection: The concept and use of reference animals and plants”, *Annals of the ICRP*, Vol. 38(4-6), London.
- ICRP 103 (2007), “The 2007 recommendations of the International Commission on Radiological Protection”, *Annals of the ICRP*, Vol. 37 (2-4), London.

- IUR (2012), 2nd Edition: *Towards an Ecosystem Approach for Environment Protection with Emphasis on Radiological Hazards*, International Union of Radioecology, Saint-Paul-lez-Durance.
- NEA (2007), *Scientific Issues and Emerging Challenges for Radiation Protection: Report of the Expert Group on the Implications of Radiation Protection Science*, OECD, Paris.
- UNSCEAR (2014a), “Annex A: Levels and effects of radiation exposure due to the nuclear accident after the 2011 Great East-Japan earthquake and tsunami Effects of Ionising Radiation”, in *United Nations Scientific Committee on the Effects of Atomic Radiation 2013 Report to the General Assembly*, United Nations, New York.
- UNSCEAR (2014b), *The Fukushima-Daiichi Nuclear Power Plant Accident*, report to the General Assembly with Scientific Annexes. United Nations, New York.
- UNSCEAR (2010), *Sources and Effects of Ionizing Radiation: United Nations Scientific Committee on the Effects of Atomic Radiation 2008 Report to the General Assembly with Scientific Annexes*, United Nations, New York.
- UNSCEAR (1996), “Effects of radiation on the environment”, in *Sources and Effects of Ionizing Radiation: UNSCEAR 1996 Report to the General Assembly*, United Nations, New York.

4. International standards

Regulatory framework

To be effective, the ICRP recommendations need to be transposed in a legal framework or applied in the regulation of radiological protection. While, overall, the ICRP recommendations have contributed tremendously to the drafting of international standards addressing all exposure situations and all categories of exposure, both the International Basic Safety Standards (IBSS) and the EU BSS slightly depart from the exact wording of ICRP 103. This resulted, on the one hand, from further reflection on the general intent of the new recommendations, and on the other hand, and unavoidably, from the conversion of the recommendations into precise, legally enforceable requirements. Where there are differences, they need to be explained; otherwise, they may lead to different interpretations, confusion and a loss of credibility.

Discussions about the deviations from ICRP recommendations in the International and EC BSS documents were included in the earlier section on implementation, and these will not be repeated here. Quite often they were introduced without a clear basis in the recommendations of the ICRP, and this may be cause for confusion. It applies in particular to the definition of exposure situations, as discussed below.

The new approach to exposure situations introduced by the ICRP (Publication 103) affected the formulation of the principles of radiological protection and led to a thorough review of the regulatory framework laid down in international standards. The sections below analyse how the international standards have shed new light on some radiological protection principles that are relevant to regulatory control.

The IBSS have been structured along the three exposure situations, within which the different categories of exposure are considered (e.g. medical exposures only within planned exposure situations). The Euratom BSS focuses its structure to offer more clarity on legal requirements for each category of exposure.

It should be emphasised that the ICRP's definitions of the three classes of exposure situations are essentially descriptive; they are merely intended to convey the key messages on the management approaches appropriate to different situations. The ICRP definitions offer no clear delineation, and they are not intended to address the legal responsibilities for managing a situation from an operational or a regulatory point of view. From the regulatory perspective, the regime of regulatory control should be quite different for each type of exposure situation. Legal responsibilities for the operation of the facility or for the conduct of the activities can be defined in a planned situation, whereas for the regime applying to the existing situations in general this is not the case. In an emergency exposure situation, there has been a loss of operational/regulatory control, and in this case, the aim will be to restore an adequate level of operational/regulatory control to end the emergency and move towards managing an existing exposure situation.

Eventually, a broader definition of planned exposure situations was introduced in the International BSS: "... a situation of exposure that arises from the planned operation of a source or from a planned activity that results in an exposure from a source". Semantically, this definition links "planned" to "situation" (of exposure) rather than to

“exposure” as such. Similarly, the term *practice* was reintroduced to facilitate the drafting of the requirements, but in a broader sense than before: “any human activity that introduces additional sources of exposure or additional exposure pathways (from existing sources), or modifies the network of exposure pathways from existing sources so as to increase the exposure or the likelihood of exposure of people or the number of people exposed”.

In this way, for the ICRP, all exposures to natural radiation sources can be, *a priori*, managed as existing exposure situations. In the International BSS, this depends on whether the exposures are the result of, or are affected by, an activity. For instance, while cosmic radiation obviously exists before a regulatory decision on the protection of space crew is being considered, it is considered as a planned exposure situation. The same can apply to aircrew, but the International BSS and the Euratom BSS choose different exposure situations for this situation.

Another important feature of the International BSS is that the definition of “occupational exposures” includes all exposures at work, whether caused by the practice conducted in the workplace or not. The employer is responsible for health and safety at work, irrespective of the origin of the health concern. Where this responsibility is clear, and requires a corresponding management of relevant exposures, the International BSS requires these exposures to be managed in the same way as planned exposure situations, even for the exposure to high radon concentrations in ordinary workplaces, which by definition are an existing exposure situation. Hence, dose limits for occupational exposure can also apply.

Protection of the environment

The ICRP has chosen a proactive approach regarding the protection of the environment and, starting with the latest main recommendations in ICRP Publication 103, subscribes to a philosophy to maintain biological diversity, the conservation of species and natural habitats, communities and ecosystems.

The ICRP previously concerned itself with humankind’s environment as a pathway for the transfer of radionuclides to humans, primarily in relation to planned exposure situations (e.g. practices). Standards for protecting the general public were considered sufficient to ensure that other species are not put at risk. The ICRP continues to believe that this is likely to be the case. The ICRP has, however developed a system of reference animals and plants to provide a framework in which radiological protection decisions could be directly related to the demonstration of environmental protection. By establishing a framework and data on which decisions may be considered, the ICRP now offers more practical advice than in the past.

The IBSS has introduced general requirements on the protection of the environment, along the same lines as the principle already included in the Safety Fundamentals, but has not specified how an environmental protection scheme should be developed. In the Euratom BSS Directive, the European Commission had proposed a more elaborate scheme. However, in the Directive adopted by the Council, a recital was kept to the effect that the protection of the environment should be incorporated within the framework of “long-term health protection”. The protection of the environment is part of the procedure for discharge authorisations, where appropriate.

The ICRP recognises that the proposed system for environmental radiological protection is less mature than the existing system of radiological protection for humans, and that the proposed system should complement controls to protect the public and not unnecessarily add to their complexity.

There is, in society, often broad, general public support for protection of the environment and actions to reduce man-made pollution, radioactive or not. Application

of the suggested ICRP system for protection of the environment will, however, still be controversial if the suggested approach does not address when and how the environment needs to be protected. The relevant end points, and a methodology to define and evaluate detriment, needs to be internationally agreed. It has been argued by many that radioactive and other substances (synergetic or antagonistic effects of multiple stressors) must be studied together, and that priority should be given to end points like ecosystems, or biodiversity, rather than to individual plants or animals. A challenge will therefore be to show that the system proposed by the ICRP is simple and robust, and that the resources and efforts that are spent are appropriate to reach protection objectives.

Reference

ICRP 103 (2007), "The 2007 recommendations of the International Commission on Radiological Protection", *Annals of the ICRP*, Vol. 37 (2-4), London.

5. Overall ways forward

A focus on radiological protection where it matters

The implementation of the radiological protection system has been very successful for the protection of workers and of members of the public in most exposure situations, in particular in the normal operation of regulated practices. Application of the system should however be strengthened in cases where doses are high, or there is a significant frequency of accidental exposures, particularly where the impact of regulations or of protection efforts is currently low.

Progress in the justification and optimisation of medical exposures must be pursued, on the one hand through more strict regulatory supervision, and on the other hand through better motivation, education and training of the medical profession.

Exposures to natural radiation sources are relatively high, and there is room for reducing such exposures, in particular for indoor radon and for the exposure of workers in naturally occurring radioactive material (NORM) industries. The integration of all exposure situations in the radiological protection system is an opportunity to make progress in these areas. For example, achieving a long-term reduction in the incidence of lung cancer attributable to radon and a standard of protection for workers in NORM industries such as the nuclear industry would entail a considerable advance.

The regulation of NORM industries will have an impact on their operational cost and on the options for the management of secondary products, residues and waste products. The level of safety achieved through regulation should be addressed coherently, taking into account prevailing circumstances. The NORM industries would benefit from a coherent level of regulation across the world. A harmonised implementation of regulations, as required in the International Basic Safety Standards (IBSS), could help to achieve this goal.

Members of the public may receive high doses in the case of a nuclear or radiological accident, or in the case of a malicious act.¹ Experience thus far, in particular after the Fukushima accident, has shown that national arrangements for emergency preparedness and response are often poor, not sufficiently tested or not flexible and robust enough in a wide range of anticipated and unanticipated emergency situations. Political decision makers are often not well prepared to deal with such an event, and communicators are frequently not able to explain in simple language either the health consequences of, or the rationale behind, decisions on countermeasures. The interaction between bodies dealing with nuclear safety and security and radiological protection authorities and experts should be improved for a better safety assessment and for better emergency preparedness.

In the overall management of the health consequences of an emergency, radiological protection may in fact be of relatively minor relevance. The direct and indirect consequences of countermeasures may be more important, for instance road accidents

1. Terrorist attacks are dealt with in the 2007 report, and while not developed further in the present document, remain an important issue. See also ICRP Publication 96 (2005).

during massive evacuation, or providing the appropriate care during the evacuation of hospitalised patients. Hence, decisions on countermeasures to reduce the exposure of the population are not a matter of radiological protection alone.

Many countries also lack preparedness for a long-term post-accidental situation, which requires specific management with a thorough involvement of stakeholders. The Fukushima accident revealed a need to develop an internationally agreed approach to the management of contamination in food. It should be understood that for the accident country it may be appropriate to have different domestic levels in food (lower or higher depending on the circumstances) than the current, internationally agreed post-accident radiological standards for the importation of food. For other types of commodities, apart from the transport regulations applicable to normal, regulated shipments, there are currently no international criteria. It is very important therefore to agree internationally on certain levels for the free trade and circulation of merchandise and people.

The focus on situations where radiological protection really matters does not imply that good radiation practice in other, well-established situations deserves less attention and appraisal. Nevertheless, it should be recognised that the emerging issues given as examples here, while often complex and with no prospect of immediate resolution, need to be tackled vigorously and without delay.

Clarity in the ethical basis of radiological protection

The ICRP has already put much effort into examining the principles of radiological protection in the light of different ethical doctrines. The need to understand the ethics of the radiological protection of human and non-human biota is now widely recognised among professional bodies. Ongoing reflections should result in reports that are written in a clear language so that they can be fully understood by all stakeholders. The three pillars of the radiological protection system, the principles of justification, optimisation of protection, and of application of dose limits could be explained directly in terms of actual ethical principles (precaution, equity, fairness or justice). Hence, communications may be more effective when referring to ethical principles rather than to the principles of radiological protection.

The deepening understanding of the ethics of radiological protection should benefit from the involvement of professionals in social sciences, ethics and philosophy attempting to bridge the gap between technical and scientific matters. The involvement of social science experts would also help the radiological protection community to better interact with stakeholders.

The risks that people are willing to take are connected with the circumstances in which they find themselves and with their personal value judgements. Value judgements vary among individuals in a society, but also among societies. Following the Fukushima accident, for example, a large portion of the Japanese population had little trust in radiological protection authorities and experts, particularly the post-accident situation. Radiation risk perception is affected by history and by the resulting bias. The occurrence of bias among experts and scientists should also be recognised however. Social sciences reveal that there are factors affecting people's minds that are not specific to radiation risks alone.

Public perception is important in relation to how the public should be involved in decision making on radiation and waste safety issues, and how it will react to decisions. Radiological protection is not decided by experts, but rather emerges from a societal dialogue that encompasses social, economic, moral, ethical and legal issues, as well as science. There is clearly room for improvement when it comes to public involvement in the regulatory process.

A graded approach to protection of the environment

The development of an approach to environmental protection also needs a clear ethical and societal basis. It is important to understand which objectives are pursued and how they meet societal needs. A clear distinction needs to be made between objectives set on the basis of a scientific agenda and objectives set to meet societal needs. Quite elaborate means are now available for the assessment of a possible environmental detriment and for criteria to be applied in different exposure situations.

While further research on the effects of radiation on non-human species should be pursued, and while more elaborate approaches may be developed for the assessment of detriment to ecosystems, it is appropriate today for regulators to decide which practical, graded approach needs to be applied for the demonstration of compliance with environmental protection standards in planned and existing exposure situations. Such a demonstration should start with an adequate screening methodology, with a more elaborate assessment being required only if it is warranted. The regulatory effort should be commensurate with the possible environmental benefit.

Strengthening the scientific basis of radiological protection

Latest scientific knowledge

The radiological protection system must be robust and simple to use. This would inevitably lead to simplifications and averaging. For broad planning purposes, generic responses are preferred over accounting for actual ranges of different individuals and allowing for individual factors. Regulations cannot always reflect the most advanced status of scientific knowledge, nor need doses or risks be assessed with the highest possible accuracy. There are considerations and limitations to consider in terms of cost, the need to keep things simple, and the importance of ethical factors that must be accounted for in rule making. This does not mean, however, that as new information becomes available, and research advances and experience accumulate, old issues should not be revisited.

Low dose and dose rate cancer risk, and the linear non-threshold model

Information on the effects of exposure to external radiation indicates that the risk of mortality and morbidity in adults from all solid cancers combined is not inconsistent with a linear relationship with doses down to 50-100 mSv, and that for children and *in utero* exposures this could be valid at even lower doses. The extrapolation of risk estimates to low doses, based on observations at moderate-to-high doses, continues to be the primary basis for estimation of radiogenic risk at the low doses and dose rates that are of interest to the radiological protection community. However, many studies using low dose and dose rates of low linear energy transfer (LET) suggest that the biological processes occurring in cells and tissues in response to low dose and dose rates or to fractionate doses could be fundamentally different from those that result at moderate-to-high doses. More work is needed to combine radiation biology with epidemiology so as to guide the regulatory process in the low-dose domain.

The ICRP system of radiological protection (ICRP 103) continues to be based on the assumption that, at doses below 100-200 mSv, a given increment in dose will produce a proportional increment in the probability of incurring cancer or heritable effects attributable to radiation. The ICRP considers that the adoption of the “linear-non-threshold” (LNT) model combined with a judged value of a dose and dose rate effectiveness factor (DDREF) provides a prudent basis for practical purposes in radiological protection. The ICRP however judges that it is inappropriate to calculate hypothetical numbers of cancers or heritable diseases associated with small radiation doses received by large numbers of people over long periods.

The LNT model is supported by many organisations such as the US National Academy of Sciences (2005), the US Environmental Protection Agency (2011), the National Council on Radiation Protection and Measurements (2012) and the UN Scientific Committee on the Effects of Atomic Radiation (2012). Nevertheless, there are opponents to this model, including the French Academy of Sciences (Académie des Sciences) and the French National Academy of Medicine (Académie Nationale de Médecine), who declared their opposition to the LNT model in 2005.

The Swiss Commission for Radiation Protection and Surveillance of Radioactivity recently updated this information and issued a statement supporting the use of the LNT model: *Position der KSR/CPR zum LNT-Modell* (KSR/CPR, 2013). In their report, they present proponents and opponents of the LNT model and give references to recent publications.

Despite inherent limitations, the LNT model is, in regulation and practice, the most widely used and recommended approach for prospectively managing radiation risks.

Non-cancer effects at low doses

The present ICRP system of radiological protection, when addressing late effects, mainly considers cancer and heritable effects. Non-cancer effects other than heritable effects are not considered as part of any detriment at low doses. Regardless, in April 2011, the ICRP addressed cataracts and lowered the dose limit to the lens of the eye.

Some studies now call into question whether circulatory diseases and effects on cognitive function following radiation exposure in infancy should be excluded from the ICRP concept of detriment. The mechanisms behind non-cancer effects are however not well understood. Information from epidemiological studies remains incoherent and thus more research is necessary for doses below 0.5 Gy.

It should be emphasised that the possible inclusion of non-cancer effects at low doses would require a judgement on their relative severity and reversibility.

At present, there is no pressing reason to change the risk estimates per unit dose since, for example, cardiovascular effects are not confirmed at doses below 0.5 Gy for exposure in adulthood. The application of dose limits and optimisation would appear to be sufficient at present. This view, however, does not in any way diminish the need for research so as to obtain a better understanding, especially with regard to exposure in childhood.

Individual sensitivity

The relationship between individual genetic sensitivity and risk of cancer is complex and may never be fully understood. The disappointingly small contribution of single, identifiable genes to an individual's sensitivity offers little prospect for individual sensitivity screening. Hence, the pursuit of individual screening may be of little use at this time. Further reflection since the previous NEA report (NEA, 2007) has also made it clear that even if such screening was technically and economically feasible, very important ethical objections may be raised, for example with regard to equal opportunities in work that involves occupational exposure, and in terms of privacy. Individual health consequences should not be considered prospectively for all members in a particular population. Hence, the current rationale to set dose limits that are applicable to "average" individuals remains valid.

The age dependency of radiation doses and risks can in general be ignored for chronic low dose-rate exposure situations, where the protection objectives concern an entire population that is chronically exposed. Nevertheless, age-dependent exposure pathways may need to be taken into account in optimisation, possibly through specific constraints. In a radiological emergency, radiological protection should focus on the most sensitive groups, and thus age dependence should be considered in decisions on countermeasures. It must be borne in mind however that for many countermeasures (e.g. evacuation and sheltering), families need to stay together so that a more global

optimisation is warranted. In some cases (e.g. in schools), specific countermeasures may be indicated.

Defining the scope of “effective dose”

Effective dose is still a powerful construction that allows the expression of radiation exposure and resulting physical energy deposition directly as a stochastic radiation detriment. Without this concept, radiological protection standards are prone to becoming very complex. At the same time, it must be kept in mind that effective dose implies a significant simplification of the scientific knowledge. Is it a fair assumption for example that total risk can be expressed as the sum of weighted doses to different organs? Irrespective of whether the LNT hypothesis is valid or not, the actual relationship may be different for different organs and different types of radiation, having different biological mechanisms for the development of radiogenic cancer.

Hence, the use of effective dose may enhance the possible error in relation to an individual’s actual radiation risk. This does not pose a problem as long as doses are low, and protection objectives and approaches are defined in a conservative fashion so that individuals are not under-protected.

Given the scope for the use of effective dose, there would seem to be no merit in incorporating individual sensitivities or non-cancer effects in the definition of effective dose. At the same time, effective dose does not allow for these effects, and in some cases they may need to be taken into account in optimisation and in setting specific constraints on organ or tissue doses.

The use of effective dose should be avoided in situations where it induces uncertainties and controversy. An example is the association of lung cancer with indoor radon exposure. In the context of indoor radon as a public health issue, national policies should not dismiss the specific information on smoking habits relevant to their country. A global risk factor yields odd results in countries with a relatively high radon concentration and low smoking prevalence. Hence, within the current radiological protection system, and as long as further research does not reduce the uncertainty on the dosimetric approach, radon policies should continue to be based on radon gas concentration in occupational exposure situations (i.e. time-integrated radon concentration or working level months) rather than on effective dose. While absolute risk remains important to provide a perspective for radon mitigation policies, communication on individual radon risks might better be based on relative risk rather than on absolute risk.

Tolerability of risk and dose limits

It is important that risks are put into perspective and that the reasons behind radiological protection decisions are clear to all concerned. In many cases, decisions on release limits, waste streams or allowable levels of direct exposure from installations are best made from a source-related perspective. Suitable source-related dose constraints, together with optimisation, are of key importance and in general provide a sufficient level individual protection for the circumstances being addressed. It could then be argued that the dose limit for public exposure is of little use and could be abandoned.

The ICRP suggested abandoning public and worker dose limits in the early days of the development of Publication 103, but decided against it because of a strong request from both regulators and operators concerned that national guidance on dose limits would develop in different ways. Dose limits are set for the protection of individuals and should best reflect risk estimates and international knowledge. The ICRP advocates that the dose limit should be set somewhere between a tolerable and an acceptable dose. However, dose limits apply only to public and worker exposures in planned exposure situations.

Thus, as a general ICRP principle, the “application of dose limits” does not apply universally, as the ICRP principles of justification and optimisation do.

The limitation of dose is intended to protect individuals from receiving exposures that could be judged as being intolerable under the prevailing circumstances, and this is achieved using either dose limits or reference levels. Hence, the ICRP principle of “application of dose limits”, applicable only to exposure management in planned situations, could perhaps be better expressed as “limitation of dose” or “restriction of dose”, which would be universally applicable as are justification and optimisation. The applicability of “restriction of dose” could then be explained more easily, without referring to exposure situations: a dose restriction is selected to appropriately manage individual exposures, such that any exposures that may occur will not be judged to be intolerable under the prevailing circumstances. The ICRP should continue to recommend numeric values for such restrictions (e.g. worker and public dose limits for planned exposure situations, and reference level bands for emergency and existing exposure situations), but such values could be viewed as tools to apply the general principle in order that any exposures that may occur are tolerable. A thorough reflection on the role of the “application of dose limits” principle in the radiological protection system and in international standards is therefore warranted.

Improving communication in the radiological protection system

It is important for authorities and radiological protection experts to take part in public discussions to ensure that communication is not left to different interest groups and opinion makers. Regulators and scientists should give relevant information about regulatory decisions regarding radiological protection matters. It is indeed their duty to communicate present knowledge, and to outline possible solutions, the rationale for, and consequences of, possible decisions. In many situations, however, risk communication will have little impact without the proper involvement of stakeholders in decisions.

Good communication also requires training for communicators. Where scientists or regulators are required to communicate, they will need training to improve their communication skills. In addition, professional communicators will need to acquire a good understanding of radiological protection.

More reflection is needed on whether the current radiological protection system is well suited for the purpose of public communication. The current radiological protection system is an efficient but complex construction, and its technical details – such as radiation quantities and units – are often poorly understood. Risks are hard to grasp when the implied probabilities of occurrence of an event or detriment are very low. This may explain why the concept of effective dose and its associated risk is not successful in communication. On the other hand, such a concept has the merit of simplicity in a radiological protection system that is already too complex.

Further reflection and research is needed to explore whether communication on risks should be based on absolute or on relative risks. Where the use of relative risk is appropriate, exposures may be better expressed as organ and tissue doses rather than as effective dose. Organ doses also allow communication on health detriments other than cancer.

The current radiological protection system is essentially focused on protection of the individual. In some situations (e.g. to assess the consequences of a nuclear accident), it could be necessary to explore whether communication on the collective detriment is not equally relevant should be explored. The concept of collective dose has been misused to calculate a theoretical, highly uncertain number of deaths. New concepts are needed to express collective detriment, in particular in terms of the discernibility of the health consequences. This concept could be based on the excess relative risk for specific

cancers, the size of the affected population and the statistical threshold for meaningful epidemiological studies.

Preparing the future radiological protection system

In general, the present radiological protection system works well and does not underestimate protection needs for either individuals or exposed populations as a whole. The latest ICRP recommendations were formed after a long and open dialogue, and public and expert views were actively collected and discussed, at the national, regional and international levels.

The role of the ICRP in clarifying the radiological protection system and in making recommendations on the tolerability of risks is not disputed. On the other hand, the transposition of the recommendations into international standards is a very demanding task. The situation is prone to inducing apparent inconsistencies between standards and recommendations that should be elucidated or at least well explained.

The schematic presentation of the different exposure situations and of the system of protection by the ICRP should not be regarded as written in stone. The onus is on the international standards to translate ideas into clear-cut binding requirements. The realisation of the ICRP recommendations into standards necessitates a pragmatic use of the different exposure situations as described by the ICRP. The recommendations from the ICRP should offer clarity on how a system of protection can be arranged, while staying short of actually drafting regulations.

It is important that any subtle differences between international standards and ICRP recommendations be explained so as not to confuse the radiological protection community, deciders or the public. Now that standards are in the process of being adopted, applied and evaluated, the time seems right to explore whether the doctrine should be adjusted or given a flexible interpretation. This analysis should extend beyond exposure situations to yield a better visibility of the ethical principles underlying the radiological protection system, which may mean revisiting the three pillars of justification, optimisation and in particular application of dose limits.

Reflection is needed on the relationship between the ICRP and international bodies to avoid future inconsistencies. One option would be for the ICRP to refrain from addressing regulatory issues. The other option would be to ensure close co-operation between the ICRP and international organisations ensuring the regulatory implementation of the radiological protection system.

It should be underlined that the radiological protection system remains very effective, and there is no need for a prompt revision. The time scale for implementing any changes should allow the incorporation of the latest scientific results. Nonetheless, it would seem appropriate to start reflection now, and involve the entire radiological protection community, while benefiting from the input of other scientific disciplines and broader stakeholders.

International collaborative research

Mechanisms of radiation action at low doses and dose rates

Current understanding and quantification of risk at low doses is limited by the uncertainties inherent to available scientific methods and by a lack of understanding of basic biological mechanisms. This situation can only be improved by a long-term commitment on the part of all scientific disciplines involved, a shared view on the roles of these disciplines within a research strategy and a common vision in the research community.

Much of the research will be of an applied nature and clearly targeted towards resolving key policy issues. More basic research will be an essential component of any low-dose risk programme, given the nature of the challenges and the timescales required for the resolution of some issues. In other areas, reinforcing of understanding could be an appropriate way to proceed at present. Such research is necessary to test new ideas that might be at the fringe of the current state of knowledge, and will have a potential for high gain, although with uncertain success. Progress in the understanding of mechanisms of radiation carcinogenesis may well be improved alongside progress in enabling science and technologies (systems biology or omics).

Further research is needed to integrate knowledge from radiation biology with epidemiology to guide the regulatory process in the low-dose domain. Several important related research areas are mentioned in other parts of this report. It is important to be able to finance and continue epidemiological studies such as the Life Span Study LSS or the Mayak worker dosimetry study to allow for long-term follow-up of the exposed persons in order to reduce uncertainties and improve statistics. The follow-up of health effects from the Fukushima accident will be equally important.

Joint research strategies, agendas and studies, and co-ordination of resources

Since the previous NEA report (NEA, 2007), uncertainties in low-dose risk assessment have been thoroughly discussed in the European region. The European High-Level Expert Group (HLEG) was formed to consider strategic issues related to low-dose risk research in Europe and the HLEG published its report in 2009. Subsequently, the Multidisciplinary European Low Dose Risk Initiative (MELODI) was established in 2010 as an association of organisations that share commitments and duties related to radiological protection research and funding of research. MELODI developed and regularly updates the Strategic Research Agenda (SRA) for low-dose risk research specifically addressing risks from low doses and dose rates, and also co-ordinating the development and accessibility of infrastructures and training activities (www.melodi-online.eu).

Research infrastructures

Overall, it is of major importance to ascertain long-term sustainability of the research infrastructure to avoid unnecessary duplication of costly installations and facilitate access to infrastructure resources, to increase visibility of work and results, and to foster harmonisation of approaches so as to facilitate inter-comparison.

Infrastructures include so-called large infrastructures such as exposure facilities, the collection and storage of data from cohort studies and animal experiments, as well as biobanks and analytical platforms. The importance of research infrastructures is highlighted within the MELODI SRA.

The number of **exposure facilities** is limited, and efforts have to be made to increase their visibility in order to make them available for researchers from other laboratories, both nationally and internationally, and to provide information on the kind of exposures that can be studied (e.g. external, internal).

The collection and collation of **cohort data and data from animal experiments** is a key to future risk analyses because a large number of these studies cannot be repeated for reasons of ethics, finance or exposure. In addition to data, it is not only important to establish **biobanks** but also to allow **access to biomaterial** from new and past studies so as to conduct analyses with new questions and new technologies. Since new technologies are getting more and more sophisticated, it is also advisable to set up analytical platforms that can be used by researchers from different areas.

Attempts have been made or are underway in the United States, in Europe and in Japan to obtain **data and biomaterial** from past studies. In the United States, the JANUS database allows access to data from past animal studies and to some extent to biomaterial from these experiments. Another resource regarding human studies is the US Transuranium and Uranium Registries (USTUR) archive. In Europe, the European Radiobiological Archives (ERA) (BfS, n.d.) have been set up to allow free access to data from almost all animal studies that have been conducted in Europe from 1960 to 1998. Since comparable archiving activities were initiated in the United States (establishing the National Radiobiology Archives [NRA] – now the Janus Tissue Archives [Janus, n.d.] – and the USTUR [n.d.]) and in Japan (establishing the Japanese Radiobiology Archives [JRA]), the three archives have been able to include data from almost all radiobiological animal experiments carried out in the above-mentioned time frame in Europe, the United States and Japan. All information is available in the ERA database that includes 151 studies from 21 laboratories. Further in Japan, the J-SHARE initiative has been established and is attempting, as a first step, to make data available from animal studies that are relevant to the assessment of the health effects from the Fukushima accident.

In addition to archiving information from past studies, it is important to establish a platform that allows storage of data, and a repository for material from newly conducted research so as to facilitate the sharing of such precious information. To that end, the European STORE platform was established (STORE, n.d.). Existing or newly established biobanks should be made more visible, as does the extent to which biological material is available. Support of activities to identify valuable materials and archives that could be included in the database and the tissue bank, as well as to maintain relevant biobanks and rescue material from endangered biobanks. STORE is aimed at sharing data from epidemiological studies, making data directly available through STORE or through pointers to places where one can have access to data.

The maturation of the so-called “omics” technologies and systems biology may offer novel opportunities for radiological protection research. To use this information to its full extent, **analytical platforms** are needed. Ideally, these platforms should include quality control and assurance, harmonisation of practices among multiple facilities, and well defined accessibility (service, or collaboration), flexibility (tools and available equipment) and bioinformatics and statistics support. In the case of a major nuclear accident or attack, biodosimetric analytical platforms have to be accessible for the rapid and reliable assessment of radiation exposure. Such platforms can also contribute to research, for example in molecular epidemiological studies or long-term follow-up when large numbers of bioprobes need to be analysed.

Training and education

As highlighted by the 2009 HLEG report, there is an urgent need to maintain the range of expertise that is essential to continue with an effective research programme in relation to the risks to humans from low-dose radiation. One major topic is knowledge management across generations, particularly as radiation-related courses at universities worldwide have been cut back as well as research programmes related to low-dose radiation. It is therefore necessary to design other educational paths in order to achieve sustainable continuity and development. One step in this direction could be to include engineering and technology (E&T)-related activities in research funding structures. A further important role of E&T within any specialised research area is the dissemination of new technologies, skills and knowledge. To that end, more emphasis should be placed on interdisciplinary workshops, seminars, summer schools and specific training courses, but on the integration of knowledge from outside the radiation area. This is especially important with respect to molecular epidemiology and to emergency preparedness, as the latter has to consider lessons learnt from non-nuclear accidents like Seveso or Bhopal and has to recognise information from social sciences on societal and psycho-social impacts.

References

- BfS (n.d.), European Radiobiological Archives (web page), www.bfs.de/EN/bfs/science-research/projects/era/era_node.html.
- HLEG (2009), "Report of High Level and Expert Group on European Low Dose Risk Research", www.hleg.de/fr.pdf.
- Grahn, D. et al (1995), "Studies of acute and chronic radiation injury at the Biological and Medical Research Division, Argonne National Laboratory, 1970-1992: The JANUS Program Survival and Pathology Data", doi:10.2172/10124634.
- ICRP 103 (2007), "The 2007 recommendations of the International Commission on Radiological Protection", *Annals of the ICRP*, Vol. 37 (2-4), Ottawa.
- J-Share (2015), "Radiobiological archive of large-scale animal experiment in NIRS", J-Share, <http://jairo.nii.ac.jp/0409/00021529/en>.
- KSR/CPR (2013), "Position of the KSR/CPR Concerning the Linear Non-threshold Model (14.11.2013)", www.ksr-cpr.ch.
- Janus (n.d.), Janus Tissue Archives (web page), <http://janus.northwestern.edu>.
- NEA (2007), *Scientific Issues and Emerging Challenges for Radiation Protection*, OECD, Paris.
- STORE (n.d.), STORE Database (web page), <http://rbstore.eu>.
- USTUR (n.d.), US Transuranium & Uranium Registries (web page), www.ustur.wsu.edu.

Annex A. The system of radiological protection

The overarching objective of the system of radiological protection is to contribute to an appropriate level of protection against the harmful effects of radiation exposure, without unjustifiably limiting the desired results from the human activity causing the exposure. This is achieved by understanding as best possible the scientific characteristics of radiation exposure and related health effects, and by considering this knowledge when judging what protection decision will best balance social and economic aspects and risks.

Since 1928, the International Commission on Radiological Protection (ICRP) has issued recommendations providing guidance on the central principles on which proper radiological protection can be based. ICRP has developed, maintained, and elaborated the system of radiological protection: on the basis of the evolving understanding of the science of radiation exposures and effects; on value judgements taking into account societal expectations and ethics; and considering experience gained in application of the system.

The commission's latest general recommendations, ICRP Publication 103: *The 2007 Recommendations on the International Commission on Radiological Protection* formally replaced the commission's 1990 recommendations (ICRP Publication 60). As before, ICRP considered two types of radiation effects: tissue reactions (previously labelled deterministic effects) and stochastic effects, e.g. cancer and heritable effects. The commission judged that non-cancer effects should not, at this stage of knowledge, be included in the estimation of the detriment following low radiation doses, less than about 100 mSv, agreeing with the conclusion of UNSCEAR in 2008 (UNSCEAR, 2008). No simple or single definition of the protection of the environment is given, but more attention is given to this emerging issue through the definition of reference animals and plants (RAPs) which the commission proposes to use to demonstrate that the environment is protected.

An ICRP statement on tissue effects (ICRP 118) was issued in April 2012. The ICRP declares that for some tissue reactions, threshold doses are or might be lower than previously considered. The threshold in absorbed dose for the lens of the eye was lowered to 0.5 Gy, and for occupational exposure situations an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of five years, with no single year exceeding 50 mSv is now recommended. Furthermore, although uncertainty remains, ICRP states that the absorbed dose threshold for circulatory disease may be as low as 0.5 Gy to the heart or the brain. Optimisation of protection should be applied in all situations and the commission emphasises that protection should be optimised also for exposure of specific tissues, particularly the lens of the eye, the heart and the cerebrovascular system.

Additional ICRP publications cover different exposure situations or specific topics, such as emergency exposure situations, post-accident recovery, cardiology, radiotherapy, paediatrics, geological disposal of long-lived wastes or protection of the environment. These are, in general, updates amending earlier guidance in the light of the latest general recommendations, and in light of experience (e.g. ongoing review of ICRP Publications 109 and 111 on emergency and post-accidental situations).

The evolution of scientific knowledge and of societal values on the protection system becomes obvious looking at the ICRP recommendations from a historical perspective. For example, following the creation of the ICRP (the first decades after 1928) deterministic risks to individuals were the only effects known and were the focus of recommendations. Later, during the 1950-1960s, heritable effects were better understood scientifically and were much discussed. In the 1970s, 1980s and 1990s, society focused on the effects of fallout from nuclear weapons testing and gave increasing attention to optimising protection of groups of workers. The concept of collective dose was also developed and refined. In the last decade, societal concern for protection of the environment has to a certain extent intensified work in this area and prompted a series of ICRP recommendations. Today, the emerging trends are driven by such things as the social impact of post-accident recovery, our increasing but still incomplete understanding of low-dose health effects, increasing medical exposures, the management of exposures from naturally occurring radioactive materials (NORM), and the variability of individual sensitivity to radiation. These issues and changes mirror developments in scientific knowledge, in public debate and in prevailing societal views.

Exposure situations

One of the main features of the recommendations in ICRP 103 is the application of the principles of justification and optimisation to all classes of exposure situations, now characterised as planned, existing or emergency exposure situations. This approach, based on a focus on the situation, evolved from the previous (ICRP 60) process-based approach based on practices and interventions. In the new system, an existing exposure situation is one that already exists when a decision on control has to be taken. An emergency exposure situation is an unexpected situation requiring urgent action, which most likely arises from a planned situation (but may also be caused by a malicious act). A planned exposure situation is just that, a situation where protective actions can be put in place before exposure-causing activities have occurred.

Sources

The commission uses the term “source” for any physical entity or procedure that results in a potentially quantifiable radiation dose to a person or a group of persons. Sources will often be part of a planned exposure situation (natural radiation sources are also considered as part of an existing exposure situation), as well as the releases of radioactive substance to the environment due to an accident or a malevolent act (emergency exposure) situation.

The broad use of the term source is important for the radiological protection system in the sense that an individual may be exposed to several sources. The ICRP emphasises the primary importance of source-related assessments, in particular the practical focus of optimisation on protection from a specific source. This has led to the introduction of dose constraints in ICRP 60, and an emphasis on these in ICRP 103, as prospective source-related restrictions on an individual’s dose from a source in planned exposure situations. The concept of reference levels is very similar to that of constraints, and applies to a specific source (taken in the broad sense, e.g. indoor radon exposure, exposures caused by a radiological accident) in existing and emergency exposure situations. In general, the source is linked to the protection strategy, and once the agreed arrangements by the regulatory body and the relevant parties (e.g. users) in defining a source are made, further aggregation or sub-division of the source is not helpful since this can distort the protection strategy. It should be noted that the ICRP recommends that diagnostic reference levels be used in the management of medical exposures as a type of benchmarking tool for procedure exposure trends.

Categories of exposure

A distinction between public, occupational and medical exposures was introduced at an early stage of the development of the radiological protection system, broadly because protection against each of these exposures is independent, and thus protection criteria (e.g. limits, constraints) can be established for each type of exposure. In effect, the system of radiological protection was created in the 1950s primarily to address what are now called planned exposure situations. With the recognition of the level and significance of other exposure circumstances, the radiological protection system is now based on three types of exposure. Occupational exposures are those incurred by workers in the course of their work. Medical exposures are those delivered to patients for diagnostic or treatment purposes. Public exposures are any exposures other than occupational or medical.

It should be noted that the application of the protection framework to medical exposures of patients is a bit more complex than for other exposures. In particular, the justification of medical exposures is a three-stage process: i) the use of radiation in medicine (this has been accomplished); ii) justification of a particular type of procedure; and iii) justification for applying the procedure to an individual patient. Protection of medical staff is, however, similar to protection against occupational exposure in other planned exposure situations.

The recognition of other exposure situations has led to a less straightforward delineation of occupational exposures (emergency workers, exposure as a result of radon in the workplace other than in uranium mines, etc.).

The protection quantities – effective dose and weighting factor

The ICRP uses absorbed dose, D , (gray [J/kg]) – the energy deposited in organs and tissues as the basic protection quantity. In Publication 60, the ICRP introduced equivalent dose, H_T , (sievert [J/kg]) and effective dose, E , (sievert [J/kg]) to replace earlier protection quantities.

The equivalent dose H_T in a tissue or organ T is the weighted sum of the absorbed dose caused by different types R of radiation: $H_T = \sum w_R \cdot D_{T,R}$. The selected radiation weighting factors, updated in ICRP 103, represent several simplifications and are only to be used for “dose limitation and assessment and control of doses in the low-dose range” for radiological protection purposes.

The effective dose, E , is likewise the weighted sum of tissue equivalent doses as: $E = \sum w_T \cdot H_T$ where w_T is the tissue weighting factor for tissue T and $\sum w_T = 1$. The sum is performed over all tissues, organs considered to be sensitive for the late, stochastic effects. The tissue weighting factors, as given in ICRP 103, are based on relative radiation detriment and represent mean values for humans averaged over both sexes and all ages and do not relate to particular individuals.

Principles of protection – justification, optimisation and application of dose limits

The principle of *justification* and the principle of *optimisation of protection* apply equally to all controllable exposure situations, and the principle of application of *dose limits* applies to public and occupational exposures in planned situations.

Justification

Despite the primary importance of optimisation, the principle of justification is usually listed first because optimisation only applies to situations that first have been judged to be *justified*. Both optimisation and justification involve consideration of the radiation

detriment in relation to the benefit, to the exposed individual and to society. Both optimisation and justification allow for economic and societal factors, but justification decisions on the grounds of the benefit to society often require a judgement far beyond the scope of radiological protection. *Justification* merely requires the net benefit to be positive, “do more good than harm”, while *optimisation* aims at maximising the net benefit, allowing for the cost of protection measures.

The ICRP distinguishes between two approaches to justification. The first approach is used in the introduction of new activities where radiological protection is planned in advance and “the necessary actions can be taken on the source”. No planned exposure situation should be introduced unless it is judged to produce a sufficient net benefit to the exposed individual or to society so as to offset the radiation detriment it would cause. The second approach, judging whether a proposed remedial action is likely to be beneficial overall, is used where exposures can be controlled mainly by action to modify the pathways of exposure and not by acting directly on the source. Broadly speaking, the first approach applies to planned exposure situations and the second to existing and emergency exposure situations. However, in all situations justification is applied broadly in the same fashion, requiring that the overall social benefit be positive.

Optimisation

The principle of optimisation remains the cornerstone of the protection system. It has received new emphasis through the new weight put on *dose constraints* and the introduction of *reference levels*, and through recognition that the application of the principle in any exposure situation is basically the same. In all cases it should lead to the selection of the best option for protection under the prevailing circumstances. Irrespective of the class of exposure situation, the doses to be compared with a dose constraint or reference level are usually prospective, i.e. doses that may be received in the future, and can be influenced by decisions on protective actions (ICRP 101). Although there is no *a priori* point below which optimisation is not necessary, optimisation should not be confused with minimisation.

Application of dose limits

Dose limits, as defined by the ICRP, apply only in planned exposure situations, but not to medical exposures. The ICRP concluded that the existing dose limits recommended in ICRP 60 continue to apply and provide an appropriate level of protection. The dose limits for occupational and public exposures are the values of the effective dose or equivalent dose that should not be exceeded. The limits on effective dose apply to the sum of doses due to external exposures, and the committed doses from internal exposures due to intakes of radionuclides. The considered total dose to an individual is the sum of doses from regulated sources in planned exposure situations. The ICRP indeed recognises that not all controllable exposures and sources, and not all human actions, can or need be equally considered when establishing the legal and regulatory framework for the application of the system of protection.

Implementation issues

The International System of Radiological Protection, as recommended in ICRP 103, is now, several years after it was issued, increasingly appearing in international documents and national regulations. This transposition is broadly working well, but it is also highlighting a few difficulties. The most important of these are the designation of worker protection in existing and emergency exposure situations, and the nature and use of dose limitations.

A key focus of the ICRP system in ICRP 103, although not directly expressed, is the need to focus protection decisions clearly through the optic of prevailing circumstances. This is to say that in planning and implementing protective decisions, it is essential to begin with as clear an understanding as feasible of the radiological and non-radiological conditions that cause the need for protection decisions. In fact, prevailing circumstances, and the ability to control the source of exposure and to manage exposure pathways, given the prevailing circumstances, provide a central rationale for the selection of the type of exposure situation, and for the tolerability of exposures, i.e. the selection of the appropriate band for dose limitation criteria.

The ICRP radiological protection system provides a framework in which protection decisions should be taken. A way to approach the difficulties that have been encountered, and to give the system more flexibility, is to consider the relationships among the three ICRP principles, the three ICRP exposure situations and the three ICRP types of exposure. The following interpretation, and slight refocusing of ICRP 103, provides a somewhat new picture, asserting that the prevailing circumstances drive the choice of management tools.

Type of situation

The characterisation of the type of situation is based broadly on the ability to control the source of exposures and exposure pathways under the prevailing circumstances. The prevailing circumstances thus have a central role in defining the type of exposure situation. A key aspect of the prevailing circumstances is the controllability of exposures and exposure pathways, and this aspect is central to the concept of tolerability of exposure. Thus, selection of the “band” within which exposures would be expected to fall, and above which exposures would not be planned to occur, will be very strongly influenced by prevailing circumstances.

Planned exposure situation

A new exposure-causing situation is one that is planned but has not yet occurred, for which virtually any type of protection can be planned, implemented and updated as necessary to appropriately address the prevailing circumstances in order to achieve the pre-planned level of radiological protection. In this interpretation, “new” does not exclude that the source already exists, for example, a nuclear power plant, but rather that the work to be performed can be planned and has not yet taken place. The source, pathways to exposure, and the exposure of individuals can all be planned and radiologically managed. This would broadly include the construction and operation of new facilities.

Broadly, in planned exposure situations, the prevailing circumstances are such that:

- the source(s) can be created or not, and are all regulated;
- exposure pathways and sources are under control;
- there is little uncertainty in terms of sources or pathways;
- exposures are generally low to moderate;
- worker exposures are generally short term (part of the working day), but may be received over a working lifetime;
- public exposures are generally chronic;
- medical exposures are all planned, and can be very high and repeated.

Existing exposure situation

This is an exposure-causing situation that already exists, and has generally existed for some time, such that it is not possible to “control” the source, but for which the pathways to exposure, and the exposure of individuals can be controlled. In these situations, the types of protection are inherently somewhat limited in that the source itself is virtually impossible to control. This would include situations causing exposures to “naturally existing” sources and long-term post-accident situations.

Broadly, in existing exposure situations the prevailing circumstances are such that:

- The source(s) exist(s), and removal is very difficult or impossible.
- Exposure pathways and sources are fairly well characterised, but generally not in a specific, detailed fashion, i.e. there is some uncertainty in terms of sources and pathways.
- Exposures are generally low to moderate, but may also be relatively high.
- Worker exposures are generally short term (part of the working day), but may be received over a working lifetime. Their level will vary with the prevailing work circumstances, but within a particular circumstance will most likely be relatively constant over time.
- Public exposures are generally chronic, and will be relatively constant over time.

Emergency exposure situation

This is an exposure-causing situation that is the result of the loss of control of an existing, radiologically managed source, or is the result of a malevolent act, for which it is important to implement urgent protective actions to appropriately protect the public, workers and the environment. In these situations, it is not possible to “control” the source. However, the pathways to exposure and the exposure of individuals can be somewhat controlled, as best as possible under extremely uncertain circumstances.

Broadly, in emergency exposure situations the prevailing circumstances are such that:

- The source is accidental, and as such is surrounded by uncertainty.
- Exposure pathways are rapidly evolving and urgent actions are needed to manage exposures.
- There is significant uncertainty in terms of sources and pathways.
- Exposures can be moderate to high, and may be very high.
- Worker exposures are generally short term (part of the working day), will only be received during the time of the emergency exposure situation, and may vary in level significantly over the course of the emergency exposure situation.
- Public exposures are generally received during the time of the emergency exposure situation, and may vary in level significantly over the course of the emergency exposure situation.

Type of exposure

The characterisation of the type of exposure is based broadly on the rationale behind why the individual is being exposed under the prevailing circumstances. All exposures should be managed in a graded fashion to appropriately consider both radiological and non-radiological aspects of the prevailing circumstances.

Occupational exposure

An individual's exposure may be characterised as being occupational because of the following prevailing circumstances:

- The exposure occurs at work.
- The exposure is reasonably well under the control of the employer and can be managed.
- The exposure situation is known, and radiological hazards can be or are already characterised.
- The exposure circumstances are not exempt or excluded.
- Regulatory authorities have decided to manage individual exposures in the prevailing circumstances as occupational.

Medical exposure

An individual's exposure may be characterised as medical because of the following prevailing circumstances:

- The exposure is being deliberately given to an individual in the context of medical treatment or diagnosis deemed to be medically important/relevant for that individual in the prevailing circumstances.
- The exposure is being delivered under medical supervision.

Public exposure

An individual's exposure may be characterised as public because of the following prevailing circumstances:

- The exposure does not occur at work, or if it does occur at work is deemed to not be under the control of the employer.
- The individual being exposed can generally not affect the source of the exposure, but may be able to affect, under the prevailing circumstances, the pathways to exposure (internal and external) and the situation that they are in which results in their exposure through individual behaviour choices.

Radiological protection principles

The radiological protection principles that can be selected to address protection under the prevailing circumstances are part of a radiological "tool box" that are used in order to achieve the desired level of protection for any exposed individuals.

Justification

In order for a protective action to most effectively protect exposed or potentially exposed individuals, the situation must be assessed in the context of the prevailing circumstances and shown to do more good than harm. Assessment should include both radiological and non-radiological aspects.

Optimisation of protection

For those protective actions that have been assessed and are deemed to be justified, their protection should be optimised to result in as much good as is reasonably achievable under the prevailing circumstances.

Restriction of individual dose (limitation of dose)

It is important that any residual exposures resulting from the prevailing circumstances are agreed by all relevant stakeholders, in particular those receiving the exposure, to be tolerable. Because the three types of exposure and the three exposure situations are in general managed in very independent fashions, it may be appropriate to establish separate criteria for each prevailing circumstance being addressed. Restrictions can be established to be legally binding, or as guidance for optimisation.

As presented in ICRP 103, the third principle is “The principle of application of dose limits”, and it is stated that “One principle is individual-related and applies in planned exposure situations” (ICRP 103: paragraph 203). As such, the application of dose limits was a key distinction between planned exposure situations, and existing and emergency exposure situations. It is suggested here that the selection of the type of exposure situation is based broadly on the prevailing circumstances, and that the ICRP principle of restrictions of individual dose may be applied to any exposure situation. Dose limitation in medical planned exposures is inappropriate, nevertheless the use of diagnostic reference level is recommended (ICRP 103: Chapter 7).

In ICRP 103 (paragraph 203), the concepts of dose constraints and reference levels are associated with the principle of optimisation of protection. However, it is suggested here that dose constraints and reference levels, like dose limits, are used as dose restrictions to assure that doses that may be received are both tolerable (dose limits) and fairly distributed (dose constraints and reference levels).

Framework for the system of radiological protection

The framework for protection, as described above, consists of three ICRP principles (justification, optimisation of protection, limitation of doses), three ICRP exposure situations (planned, existing, emergency), and the three ICRP types of exposure (occupational, medical, public). Depending on the prevailing circumstances, the relevant aspect of each of the three parts of the framework can be selected, and the appropriate radiological protection tools can be implemented to achieve desired protection objectives. The selection of each of these three aspects can be made in a broadly independent fashion.

The radiological protection framework is intended to facilitate the selection of protection options. It should be borne in mind that the distinctions among these framework elements relate essentially to such things as: the differences in the exposure circumstances; the balance of detriment and benefit; the extent to which an individual can manage their own exposure; and who has legal responsibility for the exposure.

The implication of the distinction between different framework elements is that exposures to an individual incurred in different circumstances should be considered and managed separately. For example, radiological protection choices for an individual’s occupational exposure in a planned exposure situation should be justified, optimised and subject to dose limitation. However, these principles should be implemented independently from protection choices being made for the same individual subject to exposure from other circumstances (e.g. occupational exposures in emergency or existing exposure situations, public exposures in any exposure situation, or medical exposures).

References

ICRP 118 (2012), “ICRP statement on tissue reactions/early and late effects of radiation in normal tissues and organs – threshold doses for tissue reactions in a radiation protection context”, *Ann. ICRP*, Vol. 41 (1-2).

- ICRP 109 (2009a), "Application of the commission's recommendations for the protection of people in emergency exposure situations", *Annals of the ICRP*, Vol. 39(1).
- ICRP 111 (2009b), Application of the commission's recommendations to the protection of people living in long-term contaminated areas after a nuclear accident or a radiation emergency, *Annals of the ICRP*, Vol. 39 (3).
- ICRP 101 (2007a), "Assessing dose of the representative person for the purpose of radiation protection of the public and the optimisation of radiological protection", *Annals of the ICRP*, Vol. 36.
- ICRP 103 (2007b), "The 2007 recommendations of the International Commission on Radiological Protection", *Annals of the ICRP*, Vol. 37 (2-4), Ottawa.
- ICRP 60 (1991), "1990 recommendations of the International Commission on Radiological Protection", *Annals of the ICRP*, Vol. 21(1-3).
- UNSCEAR (2008), "Annex D. Health effects due to radiation from the Chernobyl accident", *Sources and Effects of Ionising Radiation*, Volume II, United Nations, New York.

Annex B. List of experts

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Radiological Protection Science and Application

Since the discovery of radiation at the end of the 19th century, the health effects of exposure to radiation have been studied more than almost any other factor with potential effects on human health. The NEA has long been involved in discussions on the effects of radiation exposure, releasing two reports in 1994 and 2007 on radiological protection science.

This report is the third in this state-of-the-art series, examining recent advances in the understanding of radiation risks and effects, particularly at low doses. It focuses on radiobiology and epidemiology, and also addresses the social science aspects of stakeholder involvement in radiological protection decision making. The report summarises the status of, and issues arising from, the application of the International System of Radiological Protection to different types of prevailing circumstances.