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Aims and Scope

The International Commission on Radiological Protection (ICRP) is the primary body in protection against ionising radiation. ICRP is a registered charity and is thus an independent non-governmental organisation created at the 1928 International Congress of Radiology to advance for the public benefit the science of radiological protection. ICRP provides recommendations and guidance on protection against the risks associated with ionising radiation from artificial sources such as those widely used in medicine, general industry, and nuclear enterprises, and from naturally occurring sources. These are published approximately four times each year on behalf of ICRP as the journal *Annals of the ICRP*. Each issue provides in-depth coverage of a specific subject area.

Subscribers to the journal receive each new publication as soon as it appears so that they are kept up to date on the latest developments in this important field. While many subscribers prefer to acquire a complete set of ICRP publications, single issues of the journal are also available separately for those individuals and organisations needing a single publication covering their own field of interest. Please order through your bookseller, subscription agent, or direct from the publisher.

ICRP is an independent international network of specialists in various fields of radiological protection, typically numbering more than two hundred eminent scientists, policy makers, and practitioners from around the world. ICRP is composed of a Main Commission, a Scientific Secretariat, four standing Committees (on radiation effects, doses from radiation exposure, protection in medicine, and the application of ICRP recommendations), and generally about twenty Task Groups.

The Main Commission consists of a Chair and twelve other members. Committees typically comprise just over 15 members each. Task Groups are usually chaired by an ICRP Committee member and usually contain a number of specialists from beyond the Main Commission and Committees. They are assigned the responsibility for drafting reports on various subjects, which are reviewed and finally approved by the Main Commission. These reports are then published as *Annals of the ICRP*.

For further information please visit www.icrp.org, or contact *Annals of the ICRP* Editor-in-Chief and ICRP Scientific Secretary C.H. Clement at sci.sec@icrp.org.

Adelaide Convention Centre on the River Torrens / Karrawirra Parri

Annals of the ICRP

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Editorial

THE FIFTH INTERNATIONAL SYMPOSIUM ON THE SYSTEM OF RADIOLOGICAL PROTECTION

In November 2019, the International Commission on Radiological Protection (ICRP) held the Fifth International Symposium on the System of Radiological Protection in Adelaide, Australia. Each of these symposia, held once every 2 years, has been a milestone event for ICRP. They give us a platform to present our recent, ongoing, and upcoming work, and create a forum for a broad discussion about how ICRP can best fulfil our mission to advance radiological protection for the public benefit worldwide.

The symposia are also opportunities for ICRP members to come together. Although the vast majority of our work is done remotely, by telephone, e-mail, video calls, web meetings, and other means, occasional physical meetings continue to be important. This is especially true for an organisation like ICRP whose 300 or so members come from approximately 40 countries, most working on ICRP business part-time while employed by universities, research institutes, government agencies, hospitals, private companies, and the like. Physical meetings transform groups of individual experts into teams dedicated to achieving a common goal. They make it possible, for a few days, to focus together on this goal without the usual distractions. They create professional connections that enrich careers and benefit organisations, and personal connections that can last a lifetime.

Typically, each year, the Main Commission meets once or twice, each committee meets once, and many, but not all, task groups meet once each. Since long before I became ICRP Scientific Secretary in 2008, there has been a practice for the Main Commission and all committees to meet together in odd-numbered years, while organising separate meetings in even-numbered years. These joint meetings promote good collaboration between the committees, and strengthen the connection between the Main Commission and the committees.

The first ICRP meeting I organised was such a meeting. The Main Commission and Committees 1–5 met in Porto, Portugal, in November 2009. This was my second Main Commission meeting, although my first as Scientific Secretary, as I had joined the Main Commission meeting in Buenos Aires, Argentina the year before, 6 weeks

before I took on my current position. It was the first meeting with Claire Cousins as ICRP Chair. One of the more well-known outcomes of the meeting was the ICRP Statement on Radon, known to some as the 'Porto Statement', released online shortly thereafter and eventually published in *Publication 118* (ICRP, 2012).

The first ICRP symposium in the now-well-established series grew out of this tradition of joint meetings in odd-numbered years. My editorial in the proceedings of the fourth symposium (ICRP, 2018) recounts how this emerged. Each symposium has been a great success, with one being held every other year since the first. This fifth symposium in the series was no exception.

We have now held ICRP symposia in five major regions of the world: North America, the Middle East, Asia, Europe, and Oceania. Opportunities for experts in radiological protection from all over the world to join these symposia are crucial for an international organisation like ICRP, whose mission encompasses the globe and beyond.

Despite Australia being far from just about everywhere, the symposium attracted around 400 experts from 40 countries. The structure of the event was different from those in the past, with a focus on three main themes – Mines, Medicine, and Mars – with these and other topics also being covered in a poster session and in other oral sessions organised in conjunction with a symposium by the Australasian Radiation Protection Society (ARPS).

Highlights of the event included the three keynote talks linked to the three main themes: Paul Cuthbert, General Manager, Olympic Dam, Broken Hill Propriety Company (BHP) opened the Mines session; Professor Brendan Murphy, Chief Medical Officer of Australia, opened the Medicine session; and Dr Robert Thirsk, Canadian Space Agency, an astronaut who has spent more than 200 days in space, opened the Mars session. You can see videos of these presentations and most others from this and the previous symposia on the ICRP website or on ICRP's YouTube channel.

As always, organising an event of this magnitude is an enormous task, and many deserve sincere thanks. First, thanks go to ARPS and the Australian Radiation Protection and Nuclear Safety Authority (ARPANSA) for hosting the event. Both put in considerable effort, especially in terms of local arrangements and fundraising. Special thanks also go to the members of the Local Organising Committee:

Cameron Jeffries (Symposium Convenor), Brad Cassells, Christopher Clement, Kelsey Cloutier, Gillian Hirth, Jim Hondros, Tony Hooker, Lynn Lemaire, Uma Rajappa, and Brent Rogers.

In addition to being a host, ARPANSA was also one of the larger supporters. Other organisations whose financial support made the symposium possible were:

BHP (Platinum Sponsor), Tellus, Oregon State University, Rio Tinto, ANSTO, EPA South Australia, Government of South Australia Department of Energy and Mining, CamRad Radiation Services, Safe Radiation, Environmental Health Australia, and Australian Nuclear Association. Quantus was the airline partner.

Special thanks go to the German Federal Ministry of the Environment, Nature Conservation and Nuclear Safety, who provided support to make these proceedings freely available immediately after publication.

Ongoing contributions from organisations who regularly support ICRP also contributed significantly to the symposium:

Federal Ministry of the Environment, Nature Conservation and Nuclear Safety (Germany); Federal Authority for Nuclear Regulation (UAE); International Atomic Energy Agency; Environmental Protection Agency (USA); Japan NUS Co.; Canadian Nuclear Safety Commission; Health Canada; ANDRA (France); Australian Radiation Protection and Nuclear Safety Authority; China Society for Radiation Protection; IRSN (France); SSM (Sweden); Department of Energy (USA); Federal Office of Public Health (Switzerland); Swiss Federal Nuclear Safety Inspectorate; Japan Atomic Energy Agency; Radiation Effects Research Foundation (Japan); National Institutes for Quantum and Radiological Science and Technology (Japan); Korean Association for Radiation Protection; DSA (Norway); CSN (Spain); Nuclear Energy Institute (USA); Southern Urals Biophysical Institute (Russian Federation); Nuclear Energy Agency; International Radiation Protection Society; Reactor Institut Delft; GR (Iceland); STUK (Finland); SIS (Denmark); and Japan Radioisotope Association.

Most importantly, thanks to everyone who participated in the symposium. All of this is for you, and for the patients, workers, and members of the public who benefit from radiological protection.

Plans are well underway for ICRP 2021, the Sixth International Symposium on the System of Radiological Protection. It will be held in Vancouver, Canada on 1–4 November 2021. This is a particular pleasure for me as Canada is my home country. The flight from Ottawa, where my office is located, and Vancouver is only 5 h, and the time difference is only 3 h. It is not trivial, but is considerably closer than Adelaide! We are excited to be hosted by the Canadian Radiation Protection Association and the Canadian Nuclear Safety Commission, echoing arrangements for the symposium in Adelaide where we were also hosted by the national radiological protection association and the national regulatory authority.

Moreover, ICRP 2021, and the next few symposia after that, will play important roles in the review and refinement of the system of radiological protection. The current fundamental recommendations were published in 2007 after a decade of effort. Looking forward to the next fundamental recommendations, development of which will likely take a similar amount of time, it is clear that engagement of everyone involved in radiological protection is crucial to achieving the best outcome. ICRP 2021 will be an opportunity to explore which parts of the system need the most attention, shaping ICRP's programme of work and the global agenda in this area for years to come. Visit www.icrp2021.com for the latest details.

We have a very strong candidate for ICRP 2023 as well; stay tuned for more information. If you might be interested in hosting an international symposium on the system of radiological protection in your country in 2025 or beyond, do not hesitate to let me know.

CHRISTOPHER H. CLEMENT
ICRP SCIENTIFIC SECRETARY
EDITOR-IN-CHIEF

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The 2018 Bo Lindell Laureate Lecture: Finding common ground between science, ethics, and experience

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Abstract–The present system of radiological protection has evolved with the advancement of science; evolution of ethical and societal values; and the lessons of our individual, collective, and historical experience. In communicating with each other and members of the public, words are often not enough to completely relay thoughts, ideas, or experiences. Art is a shared experience, beyond the spoken language, where many can find common ground. This paper provides several examples of utilising the visual arts, cinema, and popular culture for communication in different contexts, with discussion of how each relates to the ethical values of the system of radiological protection. In this way, we find inter-relationships between science, ethics, and experience. Experience improves understanding; empathy, or the awareness and feeling of another's experience, can lead to similar understanding. Drawing on art and the broader human experience will help us improve our communication, promote transparency, and encourage empathy. Through this, we will be more likely to develop trust with stakeholders, which is an essential, yet challenging, aspect of radiological protection.

Keywords: Ethics; Art; System of radiological protection

1. INTRODUCTION

Lauriston S. Taylor (Fig. 1) was one of the founding members of the precursors to both the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements. One of many

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

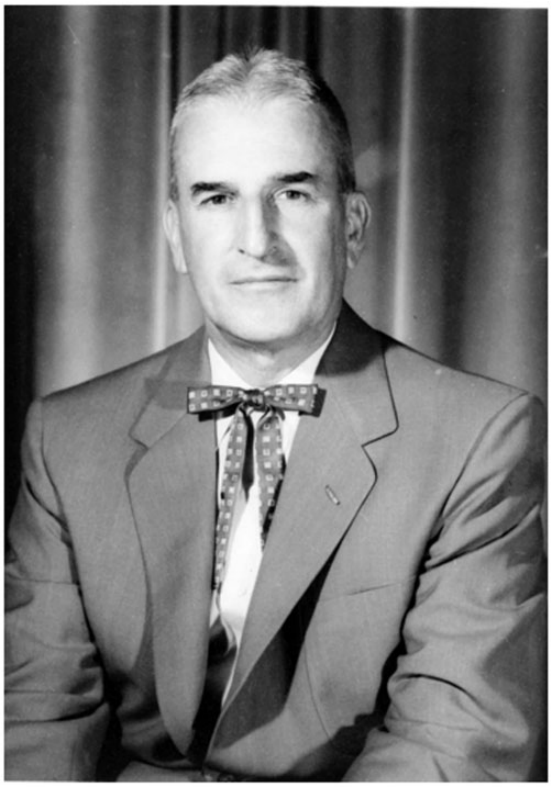

Fig. 1. Lauriston S. Taylor (1902–2004), at around age 55 years, was the first Chairman of the National Council on Radiation Protection and Measurements and a member of the International Commission on Radiological Protection by the time he was 26 years old. Courtesy of the Health Physics Society archives.

memorable speeches, he gave an address in 1956 which, to my knowledge, was the first explicit acknowledgement of the broad scope of radiation protection; he closed his speech with the words, 'Radiation protection is not only a matter for science. It is a problem of philosophy, and morality, and the utmost wisdom' (Taylor, 1957). Taylor periodically reiterated this idea, reminding the community that we should avoid setting standards that result in 'an imbalance in which personal risk is over-emphasized at the cost of overall social and economic gain' (Taylor, 1965), and that radiation protection considerations go 'well beyond science; into philosophical, sociological, political, economic, and moral areas wherever questions of the uses of radiation arise. It is through its relation to these fields that the problem of controlling radiation uses becomes today so complicated' (Taylor, 1980). Indeed, today we still find ourselves attempting to solve complex, multi-faceted problems in which science, although foundational and necessary, cannot alone provide adequate

answers, and thus must be informed by ethical considerations and practical experience. The system of protection has, in fact, evolved with the advancement of science and technology, the evolution of societal values, and lessons of our experience (ICRP, 2018). This experience is not just our individual, lived experience, but also our historical and collective experience that forms and moulds our value systems. As we practice within a technically minded profession, we, as radiation protectionists, tend to focus on the hard science of our field and have traditionally struggled with how to incorporate and apply the social sciences and humanities. Although certainly not comprehensive, this paper, adapted from the 2018 Bo Lindell Laureate Lecture,[1] reflects on several examples of utilising the visual arts, cinema, and popular culture for communication in different contexts, with discussion of how each relates to the ethical values of the system of protection as a way to help promote and understand the inter-relationships between science, ethics, and experience.

2. ETHICS

The central concerns of ethics, or moral philosophy, include identifying and distinguishing between 'right' and 'wrong'. It seeks to rationally and systematically discover valid principles for what ought to be, rather than what is. Ethics focuses on action and practice, and it is vital for understanding not only how we should practice our profession, but how we should live our lives (Pojman, 1995; NASEM, 2009).

2.1. Why ethics?

Science is built on trust, but 'this trust will endure only if the scientific community devotes itself to exemplifying and transmitting the values associated with ethical scientific conduct' (NASEM, 2009). Most scientists and engineers are familiar with a professional code of ethics, which may provide a succinct statement of ethical values, but more often focuses on obligations and duties of the profession. Such statements can serve as tools for addressing ethical problems, but often have limited usefulness due to lack of guidance on implementation, little explanation of the theoretical basis, and lack of interpretative statements (Wueste, 2005). Additionally, merely learning a concise list of bullet points is unlikely to provide the depth of understanding necessary for handling ethical dilemmas. Researchers receive responsible conduct of research training, but this training is not usually delivered in conjunction with education in the fundamentals of ethics, strategies for dealing with dilemmas, or how ethical conduct is relevant in our everyday interactions. Moreover, superficially following a formalism for professional practice is not an effective assurance of ethical conduct; incidents of misconduct in science and detrimental research practices continue to be reported worldwide, with issues ranging from

[1]Delivered on 17 October 2018 in Stockholm, Sweden (the home of Bo Lindell) on the occasion of the International Commission on Radiological Protection/International Commission on Radiation Units and Measurements 90th Anniversary Colloquium.

irreproducibility to fabrication and plagiarism to sexual harassment (NASEM, 2017, 2018). It is unlikely that the radiation protection community is immune to these issues.

Even in the medical community, where ethics training is a staple (Beauchamp and Childress, 2001), there is a persistent need for both practical implementation strategies and information on how to recognise an ethical dilemma when encountered (Myser et al., 1995; Roberts et al., 2005; NASEM, 2017; Malone et al., 2019). For example, in 2015, the American Association of Physicists in Medicine conducted a member survey related to ethical values and dilemmas. Drawing from 969 respondents, the results indicate that ethical dilemmas are frequently unnoticed and that there is an over-reliance on the individual 'moral compass', which is influenced by many factors and thus is inconsistent (Malone et al., 2019). Similar observations were made in a smaller study of US faculty from a variety of disciplines (Giorgini et al., 2015).

Familiarity with, and subsequent incorporation of, ethics in decision-making is important as a truly well-informed value judgement will involve both factual and normative information. Unfortunately, ethical theory is often perceived by non-philosophers (and particularly hard scientists) as irrelevant or impractical, outside of our expertise, and subjective (i.e. 'anything goes') (Martinez and Wueste, 2016). Emphasising the parallels between ethical and scientific theory (Fig. 2) may make ethics more approachable and less nebulous.

Science and ethics are both based in reason and our individual and collective experience; both seek the truth (i.e. 'the right answer') and adapt if previously unknown information is revealed. Both require rational and supported justification of claims (Pojman and Fieser, 2017). In proposing a new scientific theory, a scientist cannot simply say, 'Trust me! I know in my heart this is the answer!' without supporting evidence and be taken seriously. Feeling strongly about something is, in itself, insufficient in forming an argument concerning ethicality.

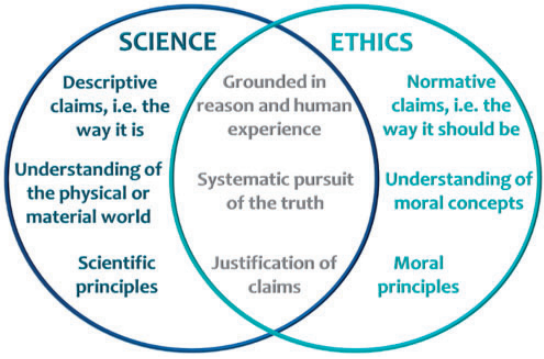

Fig. 2. Commonalities between science and ethics. Modified with permission from Martinez and Wueste (2016).

Moreover, without theoretical understanding of fundamental moral philosophy, we open ourselves up to logical fallacies when developing arguments for what is right and wrong. Examples of common flawed arguments include bandwagon, whataboutism, and strawman arguments. A bandwagon argument ('argumentum ad populum') assumes that widely held opinions must be true; however, it is direct, factual evidence, not popularity alone, that determines correctness. A strawman argument intentionally misrepresents a viewpoint such that it is easier to refute, but of course this misrepresentation is not the original argument. Whataboutism is particularly common in modern politics (Zimmer, 2017), and typically deflects away from the question at hand by making a reverse, often unconnected accusation. For example, in a case study (Manglass et al., 2020) considering the ethicality of purposeful mismanagement of samples from a site being remediated for radioactivity,[2] one might be tempted to ask 'well, what about the agency that set such an unrealistic clean-up level?' The clean-up level, whether unrealistic or not, has no bearing on whether or not the individuals involved exhibited ethical behaviour. Fig. 3 provides humorous examples of two of the above logical fallacies in a scientific context.

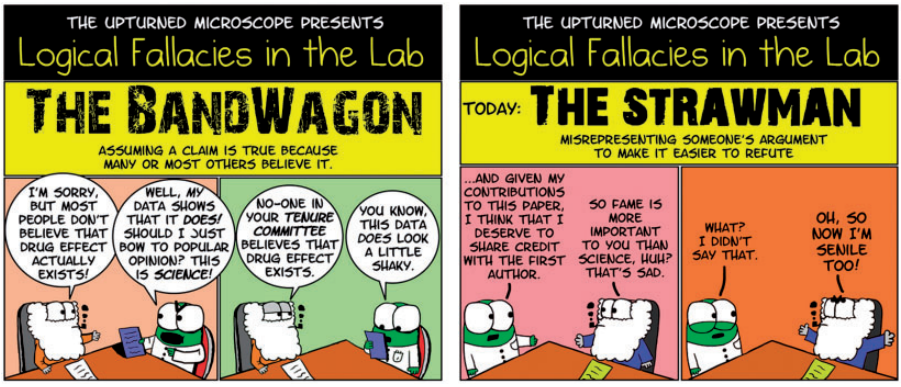

Fig. 3. Examples of logical fallacies. Copyright © Nik Papageorgiou of 'The Upturned Microscope'.[3]

2.2. Three major ethical theories and ethical decision-making

How, then, do we develop a supported normative argument without going back to school for a philosophy degree? Luckily, there are a variety of different strategies for incorporating ethics into decision-making. One of these involves the consideration of three major approaches in moral philosophy with a 'convergence begets confidence' methodology (Wueste, 2005; Martinez and Wueste, 2016). These three approaches are consequentialist ethics, deontological ethics, and virtue ethics, which focus,

[2]See https://www.nrc.gov/docs/ML1621/ML16210A216.pdf.
[3]With permission. For more of Dr. Papageorgiou's work, see https://theupturnedmicroscope.com/.

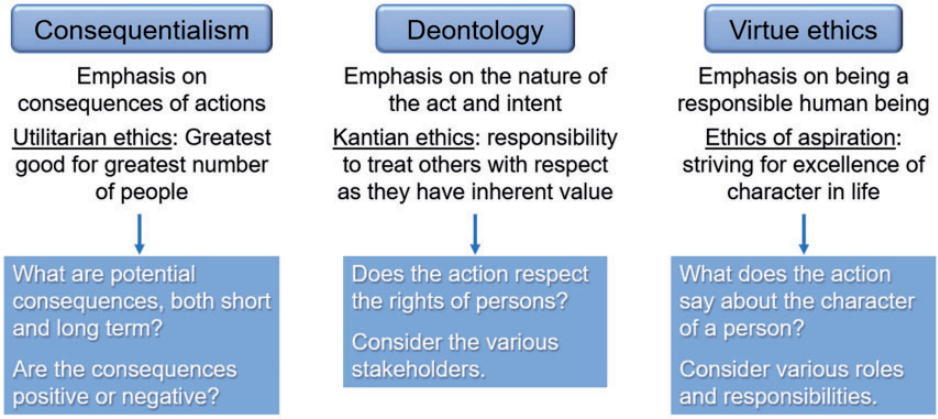

Fig. 4. Three major ethical theories that can be used together as a toolbox in ethical decision-making.

respectively, on the consequences of our actions, the alignment of actions with our moral duty, and the promotion of good character (Fig. 4).

For more specificity in terms of utility for the system of radiological protection, in terms of consequentialism, we can consider utilitarian ethics, which is the furthering of the collective interest, and Kantian ethics, which is the duty to respect others. These theories, along with virtue ethics, have different approaches to assessing ethicality. Thus, if we evaluate a situation in the context of each theory individually and we obtain the same result, we have greater assurance that our decision is the right one. As in science, the more lines of reasoning that support a conclusion, the greater confidence we have in it. If the outcome is inconsistent, we are provided with an opportunity to delve deeper into the situation and perhaps reveal something we missed in the first analysis; in other words, 'divergence stimulates discovery' (Barnett, 1990).

2.3. Ethical values of the system of radiological protection

After a series of international workshops, the ICRP released the first publication dedicated to the ethics underlying the system of radiological protection, *Publication 138* (ICRP, 2018). The three theories described in Fig. 4 have been found to form the ethical foundation of the system of radiological protection (Oughton, 1996; Shrader-Frechette and Persson, 1997; Hansson, 2007); *Publication 138* expands upon this theoretical basis to describe the fundamental ethical values of the system: beneficence/non-maleficence, prudence, justice, and dignity. It also highlights three additional ethical values associated with implementation of the system, namely, accountability, transparency, and inclusiveness.

Beneficence (doing good) and non-maleficence (the avoidance of causing harm) are grouped together in *Publication 138* (ICRP, 2018) as they are often applied

together. For example, a vaccine can protect against a potentially deadly illness, but is also associated with transient pain at the injection site. A key question, then, is are we doing more good than harm? For an environmental example, in the early 1990s, Par Pond (a reservoir at the Savannah River Site) was drawn down due to concerns about dam integrity. The risk to a hypothetical resident from exposure to radiocaesium in the newly exposed sediments would have necessitated a remediation anticipated to cost more than $4 billion. The US Department of Energy ultimately decided to repair the dam and refill the reservoir instead, which not only cost significantly less (~$12 million) but also preserved a large wetlands ecosystem (Whicker et al., 2004), wisely doing more good than harm.

Prudence refers to practical wisdom, or the ability to make informed decisions based on reason and rational discernment, even in the face of uncertainty. During the development of *Publication 138* (ICRP, 2018), 'prudence' proved to be difficult to translate from English, and we often struggled to distinguish it from 'overly precautious'. One way to make this distinction more clear is to consider allegories of prudence; as one of the four cardinal virtues adopted from Plato's 'Republic' into Christian theology, prudence is quite prevalent in classical Western art (Bejczy, 2011). For example, Fig. 5 (left panel) shows a common late 1500s representation of Prudence as a woman holding a mirror (representing self-reflection and insight), with a snake (representing wisdom) wrapped around her arm, and a face, usually older, on the back of her head (representing experience). From this, we can gather that prudence is a combination of insight, wisdom, and experience.

Later allegories of prudence (Fig. 5, right panel) exchanged the mirror for a book, with subtle alteration in the representation of the snake. Notice that the snake is winding around Prudence's arm in one allegory, whereas in the other, she has a firm

Fig. 5. (Left panel) *Prudentia*, Jacques de Gheyn II, c.1563. Copyright © The Trustees of the British Museum. (Right panel) Prudential Assurance Building, Nottingham, UK, 1880–1890. Copyright © Louise Jayne Munton.

Fig. 6. *An Allegory of Prudence*, Titian, c. 1550–1565. Copyright © The National Gallery.

hold on the snake. Edmund Burke (1730–1797), philosopher and politician, considered prudence to be the most important of the cardinal virtues, and discussed it in a variety of his writings. Of interest here is his observation that the 'same ways to safety do not present themselves to all men, nor to the same men in different tempers. There is a courageous wisdom: there is also a false reptile prudence, the result not of caution but of fear' (Burke et al., 1999). He goes on to say that there are often situations of such dire importance that 'the eye of the mind is dazzled and vanquished', and that although courage is necessary in such cases to make difficult decisions, we can become mistaken that difficulty arises from courage and thus choose inaction (Burke et al., 1999). We can then interpret the evolved allegory as maintaining wisdom (the book) with courage in the face of fear.

Another relevant painting from the 1500s is Titian's *An Allegory of Prudence* (Fig. 6), which across the top reads 'EX PRAETERITO/PRAESENS PRUDENTER AGIT/ NE FUTURA ACTIONE̅ DETURPET', or 'from the experience of the past, the present acts prudently, lest it spoil future actions'. Philip McCouat, an Australian art writer, observes that:

> *The Allegory is a perfect example of how a number of respected experts can come to quite different, but credible, interpretations of an artwork. As these interpretations cannot all be entirely correct, it may be seen as posing a problem – which do you believe? Perhaps, however, this is not really a problem. 'Certainty' is not necessarily a realistic goal in this type of enquiry. Where experts' interpretations differ (or even if they don't), the viewer*

must ultimately come to their own conclusions, tentative as they may be, based on their own critical judgment, degree of knowledge and preferences (McCouat, 2014).

This is an interesting and insightful observation, and is relevant to radiological protection as well, particularly with respect to interpreting data at low doses and dose rates. For example, McLean et al. (2017) review the current evidence associated with health effects at low-level exposure to radiation and observe that all six dose–response models considered are consistent with available data at sufficiently low doses. Deciding on the most appropriate model is then a value judgement. In the absence of additional data, we should focus on engaging with those affected, being transparent with information and unknowns, so that individuals can decide for themselves how to proceed. In other words, as we continue pursuing better science, there is a real and present need 'to find ways to help people understand what they are going through, help them find information that they can trust, and help them deal with uncertainty' (Beyea, 2018).

2.4. Cross-cultural considerations

The three major ethical theories mentioned above are a fundamental and important starting point for creating a dialogue and establishing useful vocabulary with respect to ethical values and decision-making. However, it is equally important to be aware of the cross-cultural applicability of such ethical values (Fig. 7), as cultural awareness and understanding are essential to the development of empathy and solidarity (Zölzer and Meskens, 2017).

Oral and written traditions reflect the values of a culture and, for many of us, how we were raised; it is part of our individual lived experience. There is frequently a

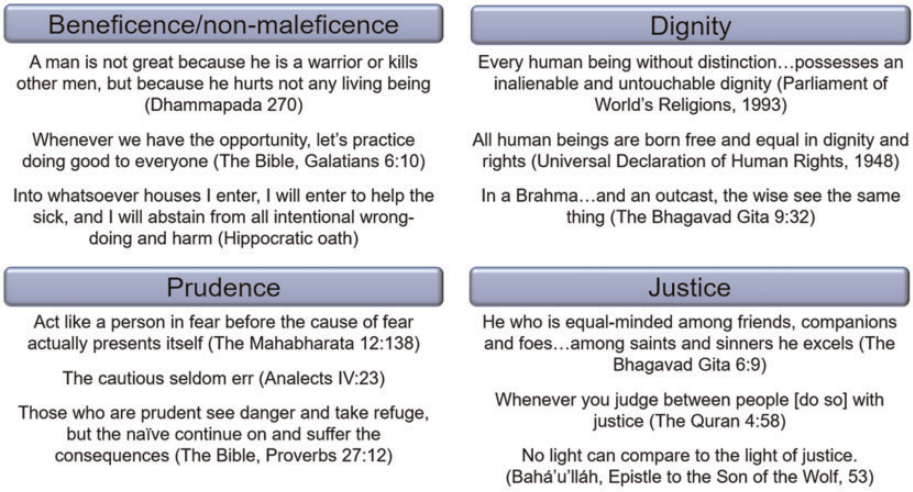

Fig. 7. Cross-cultural relevance of the core ethical values. See also Zölzer (2013, 2016).

familiarity with religion that can be used to help develop understanding of secular ethical ideas. Of course, in a professional context, it would be inappropriate to focus on a single religion or tradition, but identifying commonalities within a wide selection can help make the discussion of ethical values more accessible. We can also be more confident in our foundational ethical values knowing that they promote the respect of individual rights, the furthering of collective interest, and the development of discernment and wisdom. Various oral and written traditions contain threads of these ideas as well, in a sense finding a common morality. For example, a Humanist, a Christian, and a Buddhist could all agree as to the moral standing of the ethical values highlighted in Fig. 7. In other words, the ethical values of ICRP are compatible with, and supported by, three major theories of ethics and the broader human experience observed in oral and written traditions.

2.5. Value judgements

Scientists are generally results-driven, typically taking a utilitarian-style approach to solving problems. However, this approach often does not capture the whole picture. For example, in evaluating and managing risk from environmental contamination, consideration must be given to psychological, social, and economic factors, in addition to the quantitative estimate of potential harm (Smith and Beresford, 2005; Fjeld et al., 2007; Zölzer and Meskens, 2019). Philosophers are generally more process-driven with a focus on how results are achieved, with varying approaches used to solve ethical dilemmas. However, these approaches are not always realistic. Implicit in the strategies of both the scientist/engineer and philosopher is the balancing of competing values. Real-world application of the ethical foundations, then, requires at the outset a careful balance of theory and practical considerations.

One of my partner's favourite movies is 'Monty Python and the Holy Grail' (1975), and in this film, a local community has gone to the 'wisest' among them to discern whether a woman is, in fact, a witch. The logic followed to decide is as follows: a witch is a female who burns. Witches must burn because they are made of wood. Wood floats. What else floats on water? A duck; if something has the same weight as a duck it must float. A duck and 'scales' are fetched, and the woman and the duck appear to balance perfectly, as in Fig. 8. The community concludes that they must 'burn the witch!'

This silly example highlights two points about balancing values when making a judgement. The first is to avoid this type of situation, where there is only the 'appearance' of balance rather than a genuine balance. The second is to avoid jumping to the conclusion that something we disagree with has been inappropriately balanced. As scientists, we should be critically reflective, making space for the perspectives of others and challenging our own ideas such that we can, as a community, come to a robust, unbiased conclusion.

It should be noted here that the values highlighted in *Publication 138* (ICRP, 2018) are not the only values of importance; depending on the situation, there

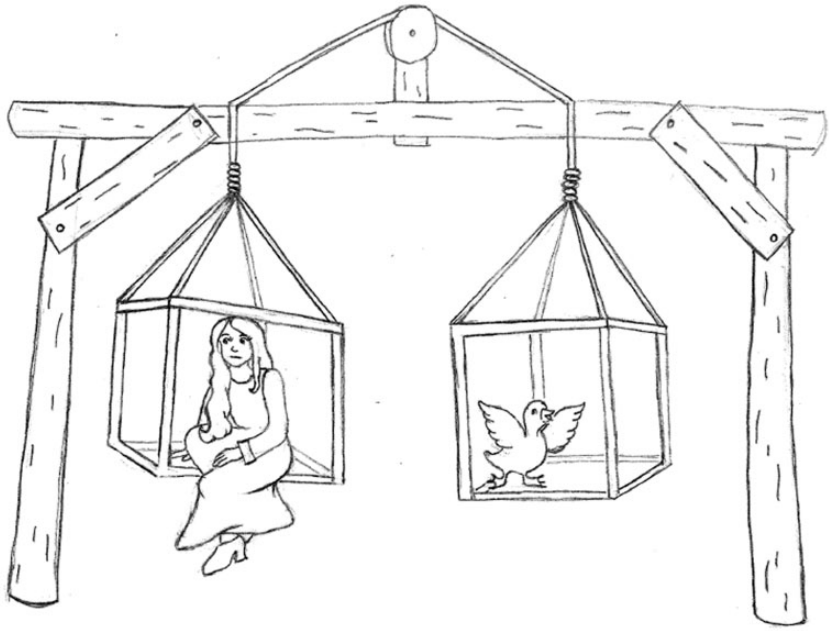

Fig. 8. Author's rendition of the 'Burn the Witch' scene, due to copyright restrictions on the original.

Stakeholder	Beneficence/ Non-maleficence	Prudence	Justice	Dignity	Others
Individual					
Regulator					
Community					
NGO					
Etc.					

+ +	Strongly supports the ethical value
+	Supports the ethical value
o	Not applicable
–	Opposes the ethical value
– –	Strongly opposes the ethical value

Fig. 9. Principle-based approach to ethical decision-making. NGO, non-governmental organisation.

may be many values to consider. For example, *Publication 91* (ICRP, 2003) discusses sustainable development, conservation, preservation, maintenance of biodiversity, environmental justice, and human dignity as ethical principles with respect to environmental protection. There is a need to balance these and other values depending on

the circumstance and stakeholders. There may be moral ties and indeterminacy, but this does not lead to relativism; there are still many wrong answers, even if there is not a uniquely right or 'perfect' answer.

Relatedly, another decision-making model, one commonly used in general ethics education, is the principles-based (i.e. value-based or value assessment) model (Kiely, 2014). In this model, as shown in Fig. 9, relevant values and stakeholders are selected, and then the values are evaluated for each stakeholder depending on the situation, proposed response, etc. This provides a structured way to begin to make value judgements, although the selection of values to consider is a value judgement in itself! Examples of this approach are presented for case studies related to radiation protection in medicine in Malone et al. (2019).

3. INCLUSIVITY, EMPATHY, AND SOLIDARITY

Inclusivity is a broad term, but here it effectively means to include those who might otherwise be excluded. Stakeholder involvement and public engagement in the radiological protection decision-making process are, of course, part of inclusivity, as are professional development, care, and respect for our colleagues.

3.1. Science communication

Experts often struggle with public communication, even though communication is widely recognised as an essential component of risk management (Fjeld et al., 2007; Smith and Martinez, 2017). This struggle is both in conveying technical information as well as in fully understanding and considering public concerns. However, we are used to communicating with each other, albeit in technical language. With every paper we write and presentation we give, there is the opportunity to develop art, as charts and figures, to explain our work more fully. Many journals now recommend, or even require, graphical abstracts to summarise a paper. For example, a pictorial summary of a method currently employed in my laboratory is shown in Fig. 10.

Although perhaps originally intended for our peers, graphical representation of our work can be more easily adapted to be accessible to the public, supporting both transparency and inclusivity. Many full journal articles are behind a pay wall, limiting availability; interested parties may only be able to view the abstract, so although technical language may be unavoidable in the text, a clear and easily understandable abstract is very important if we are interested in including both the general public and our peers in our scientific communication.

Related to communicating with our peers, one of my students developed and posted novel signage in and around open-source university laboratories in an effort to improve the radiation safety climate. These included internet memes, a scientist Barbie® with indication of what was and was not appropriate attire for the laboratory, and a safety newsletter (Root et al., 2020).

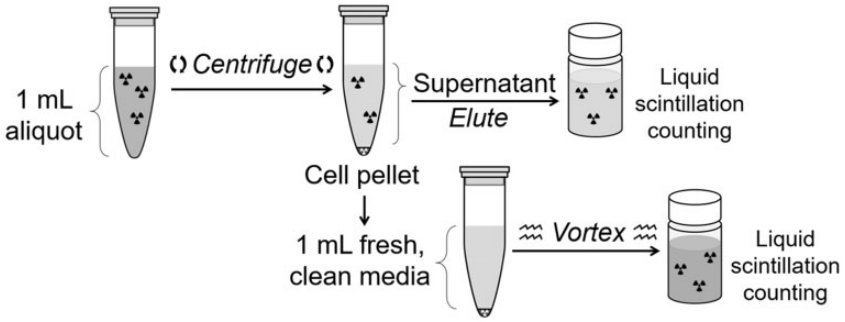

Fig. 10. Graphical depiction of the procedure for analysing radioisotope distribution in aqueous bacteria culture.

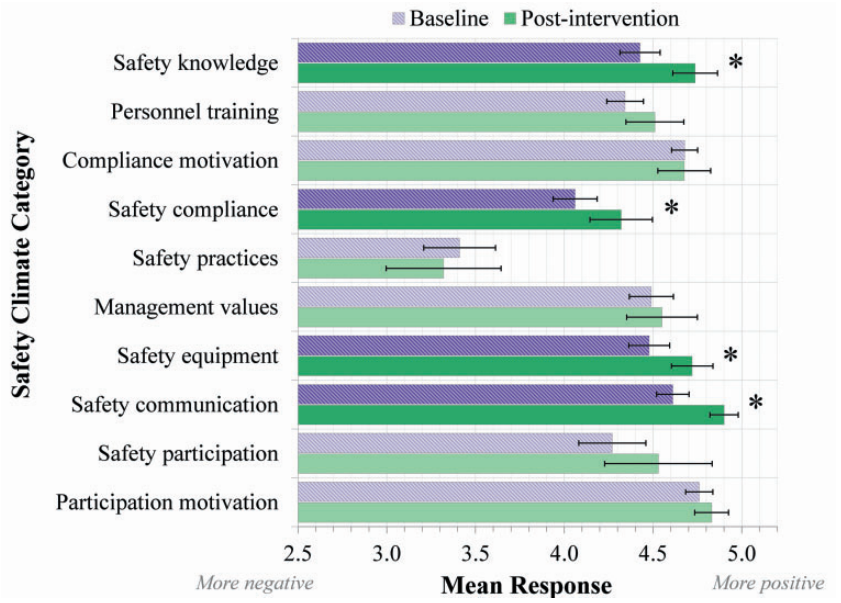

Fig. 11. Safety climate survey average responses with 95% confidence intervals before (top/purple bars) and after (bottom/green bars) intervention in Princeton University open-source laboratories. *Darker bars indicate significant differences. Data from Root et al. (2020).

I mention this study, along with the results, for two reasons. First, it demonstrates that novel communication strategies can be impactful, as several categories of safety climate improved after the intervention (Fig. 11). Second, if you are viewing this paper in colour, you will notice that Fig. 11 data are shown in purple and green. Although this colour combination is not terribly pleasing from an aesthetic

standpoint, it is accessible to most types of colour blindness (Manglass, 2019), something else we should ideally consider when developing graphics.

3.2. Why empathy?

Beyond clarity, effective communication with stakeholders requires mutual trust and understanding (Brandl and Tschurlovits, 2018), and development of this understanding requires empathy; simply sharing information does not build the trust necessary to develop a positive relationship with the public (Engdahl and Lidskog, 2014; Ando, 2018). Empathy is distinct from sympathy in that sympathy is 'feeling with' someone whereas empathy is 'feeling into' someone. An academic definition of empathy would be 'the capacity to feel and understand the emotional, affective but also motor, somatosensory, or intentional experience of others and their associated mental state, while adopting the others' visuo-spatial perspective and psychological viewpoint and consciously maintaining self-other distinction' (Thirioux et al., 2014, 2016). However, this definition may be a bit esoteric for many people. Again, a graphic (Fig. 12) is likely to be more effective in communicating the distinction between sympathy and empathy.

Ethical decision-making often requires an acknowledgement and balancing of multiple, possibly competing, values, as discussed above. In such difficult situations,

Fig. 12. Representation of sympathy vs empathy. Copyright © Angela Fernot.[4]

[4]With permission. For more of this artist's work, see https://angelafernot.wordpress.com/.

empathy can be an essential factor in recognising the impact our decisions can have outside our personal sphere. To truly work for the good of individuals and the community, experts must recognise the community's needs, challenges, and values in addition to possessing technical competency (Lavery et al., 2003; Amadei and Sandekian, 2010). Widening empathy is increasingly recognised as an essential component of successful community-based projects (Zölzer, 2014), and in fact, empathy has been suggested as the most fitting way to apply beneficence and solidarity (Zölzer, 2018).

3.3. Empathy and historical experience

In developing empathy, we also cannot forget the lessons of our past; 'our scars remind us that the past is real' (Harris, 1981; Shaddix and Esperance, 2005). For example, the legacy of harnessing radioactivity to develop nuclear energy, intended for the good of humanity, has left scars on the present.

Patrick Nagatani[5] (1945–2017) was an artist and professor with a fascinating body of work in photography and multi-media art (Roberts, 2017). Nagatani's family originated in Hiroshima, and both of his parents were held in Japanese internment camps during World War II. *Nuclear Enchantment* (see Nagatani and Parry, 1991) is a series of photocollages with a purposefully ironic name, harkening to New Mexico's nickname: the Land of Enchantment. Nagatani sought to highlight both the fascination and detriment associated with the Manhattan Project and Cold War legacies in New Mexico, frequently linking to Native American and Japanese culture, as he believed these two populations were those most severely and negatively impacted by these events. Two of my favourite pieces from the series are shown in Fig. 13. In both collages, Nagatani adopts symbology from the classic *One Hundred Famous Views of Edo* (名所江戸百景) (Fig. 14) by Japanese artist Hiroshige. These depictions of Edo (renamed 'Tokyo' in 1868) were originally woodblock prints, embellished with mica (Andō et al., 2010).

In the top panel of Fig. 13, Hiroshige's golden eagle soars over the site of the 1979 Church Rock, New Mexico spill, in which an earthen dam failure resulted in the release of mill tailings into the Rio Puerco, which was the largest release of radioactive material on US soil (Brugge et al., 2007). The seemingly small-scale exposure assessments and generally muted response to the spill and mining legacy in general has left the local community concerned for their long-term health and well-being. The eagle represents power but also recovery, and serves as a reminder that recovery is often long term and ongoing. Even something that happened a generation before is still with us, and we cannot forget lest we leave those impacted behind.

In the bottom panel of Fig. 13, carp banners overlay a series of graves with uranium mill tailings in the background. There are three banners, fading into the background to almost merge with telephone poles in the original photograph. Children's Day ('Kodomo no Hi, 子どもの日') is a national holiday in Japan celebrated

[5]For more of this artist's work, see https://www.patricknagatani.com/.

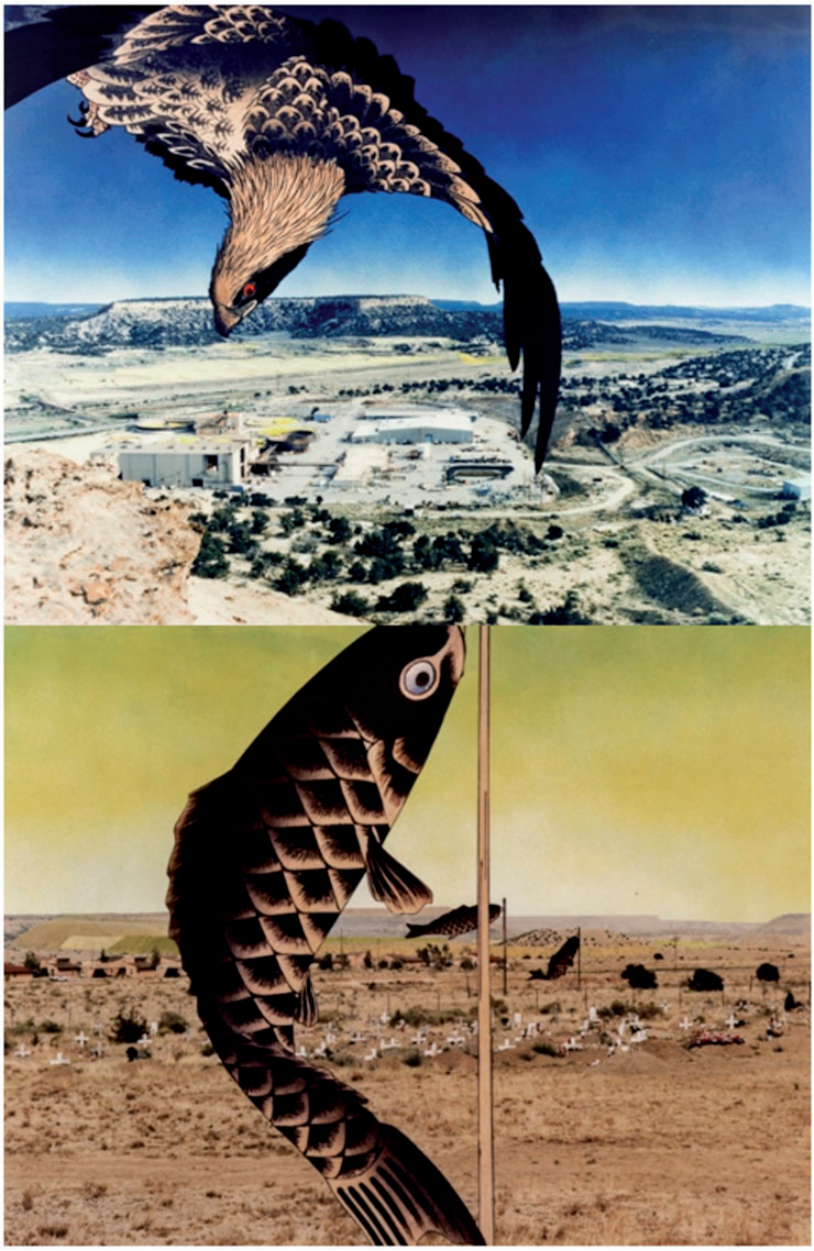

Fig. 13. (Top panel) *Golden Eagle, United Nuclear Corporation Uranium Mill and Tailings, Churchrock, New Mexico,* 1990. (Bottom panel) *Japanese Children's Day Carp Banners, Paguate Village, Jackpile Mine Uranium Tailings, Laguna Pueblo Reservation, New Mexico,* 1990. Copyright © 1989–1991 Patrick Nagatani, courtesy of Andrew Smith Gallery, Tucson, AZ, USA.

Fig. 14. (Left panel) *Fukagawa Susaki and Jumantsubo (Fukagawa Susaki Jumantsubo)*, 1857. Copyright © Los Angeles County Museum of Art, CA, USA/Bridgeman Images. (Right panel) *Suidō Bridge and the Surugadai Quarter (Suidobashi Surugadai)*, 1857. Copyright © Brooklyn Museum of Art, New York, USA/Gift of Anna Ferris/Bridgeman Images.

on the fifth day of the fifth month. Carp-shaped windsocks or streamers are raised to celebrate health, happiness, and success for children; carp represent strength, courage, and determination in overcoming life's difficulties due to their ability to swim against the current. The juxtaposition seems to ask: what is our children's future? What have we left for them? Here there is also a play on Trinity with the three carp banners, as in the Holy Trinity from the Christian tradition, with crosses on the graves, and the Trinity referring to the first nuclear device detonation, with tailings in the background.

Of course, it is not the only way, but art can help us move from an academic to an emotional understanding of the situation, in this way identifying with stakeholders and more fully grasping their concerns. A more holistic understanding of the circumstances puts us in a better position to work for the public benefit; in other words, the promotion of empathy can, in turn, help us develop solidary with the community.

3.4. Solidarity and building our community

In addition to stakeholder involvement, dignity and inclusiveness also apply to how we interact within our field. Although we may or may not have experienced it personally, harassment, bullying, and discrimination are still prevalent in many

workplaces (Nielsen et al., 2010; Gibney, 2016; NASEM, 2018), which not only can have a detrimental impact on someone's career but also on their overall health and well-being (Verkuil et al., 2015; Nielsen et al., 2016). This, in turn, can affect the health of the overall field or organisation, and even the progress of science.

There is a relatively new Japanese anime on Netflix, 'Aggretsuko', featuring a red panda who sings death metal karaoke to relieve her frustration with her job, including the workplace bullying she experiences. The popularity of the show suggests that people relate to the characters' experiences, with the charm of the show lying in the juxtaposition of the overall realistic theme in a 'kawaii' (cute) style (Russon, 2018). It is tempting to assume that our field is the exception, but it is important to be aware of and acknowledge the experience of others. Anecdotally (Gillenwalters and Martinez, 2017) and in an informal survey of members of the Health Physics Society (HPS) (Berry and Root, 2019), it is apparent we can do better as a community in supporting and caring for each other.

What are some things we can do to promote diversity and respect? It is one thing to observe a problem, but another to act. I do not have a unique answer, but we have been working in that direction. For example, at my home institution, we participate in Girl Scout Day and related outreach activities where young students come in to learn about science; encouraging girls and other under-represented populations in science can be impactful. Highlighting the contributions women have made to the field of radiation protection (e.g. Martinez, 2017) can also be encouraging to up-and-coming radiation protection professionals, and there has even been a special issue of *Health Physics* dedicated to woman-led articles (Martinez, 2018). There has been a Women and Minorities Reception at the annual HPS meetings since 2017. Everyone is welcome at the reception of course, but it provides an opportunity for explicit acknowledgement and appreciation of under-represented voices. There is also a new section in HPS called 'Women in Radiation Protection', open to all genders, whose mission is to 'build and maintain a supportive community that will advocate for the professional development of women and other underrepresented groups in health physics and related disciplines' (HPS, 2018). The 15th International Congress of the International Radiation Protection Association will have a special panel session on Women in Radiation. Note that although the percentage of health physics and nuclear engineering degrees awarded to women has increased over the past few decades (Fig. 15), there is still a very low percentage of these degrees awarded to racial minorities (Gillenwalters and Martinez, 2017), which we should actively address moving forward.

In terms of fostering respect, awareness and accountability go a long way, as will the renewed emphasis of ethical principles in radiation protection. In line with other scientific organisations (Favaro et al., 2016), HPS adopted a respectful behaviour policy (15 December 2017) to ensure, and provide a mechanism for enforcement of, a safe and inclusive environment for its members. Similarly, the Society for Radiological Protection recently updated its code of conduct which includes a more thorough outline of expectations for how members treat each other (SRP, 2019).

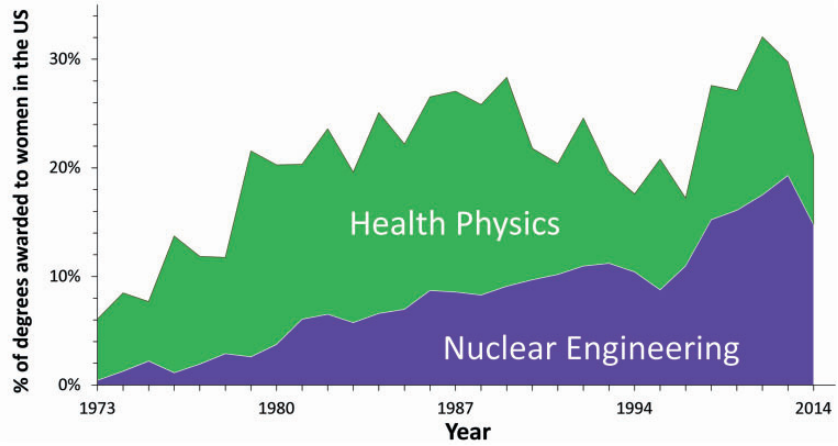

Fig. 15. Trends in health physics and nuclear engineering degrees (all levels) in the USA by sex. Modified with permission from Gillenwalters and Martinez (2017).

4. CONCLUSION

The common thread of this lecture is solidary; that is, the union arising from common interests and the ties that bind people together in society. Embracing unique, individual contributions enables our community to support its members more effectively, as well as work toward the benefit of society at large (Nhất Hạnh, 2012). Ultimately, finding common ground between science, ethics, and experience supports the development of trust both within the community and with other stakeholders to enable us to become more effective practitioners. A contemplative approach to science (e.g. Malone, 2013) incorporating the arts may help us to improve our communication ability as well as our understanding of others' perspectives while cultivating a greater appreciation for radiation's impact on the world.

5. ACKNOWLEDGEMENTS

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I did not have the pleasure of meeting Bo Lindell, but hearing and learning more about him and what he accomplished and valued inspired me to choose the topic of this lecture. I am humbled beyond words to receive an honour that bears his name.

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The 2019 Bo Lindell Laureate Lecture:

On the use of interdisciplinary, stakeholder-driven, radiation protection research in support of medical uses of ionising radiation

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Abstract–Medical exposures form the largest manmade contributor to total ionising radiation exposure of the UK population. In recent years, new technologies have been developed to improve treatment and prognosis of individuals treated with radiation for diseases such as cancer. However, there is evidence of public, patient, and medical professional concern that radiation protection regulations and practices, as well as understanding of potential long-term adverse health effects of radiation exposure (in the context of other health risks), have not always 'kept pace' with technological developments in this field. This is a truly complex, multi-disciplinary problem for the modern world.

The 'Radiation Theme' of the Public Health England and Newcastle University Health Protection Research Unit on 'Chemical and Radiation Threats and Hazards' is addressing this need, with a key focus on a genuinely interdisciplinary approach bringing together world-leading epidemiologists, radiation biologists, clinicians, statisticians, and artists. In addition, the project has a strong grounding in public, patient, and medical professional involvement in research. Similarly, the EU-CONCERT-funded LDLensRad project seeks to understand the mechanisms of action of low-dose ionising radiation in the lens of the eye, and the potential

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contribution to the development of cataract – in contemporary research, such projects will only be considered successful when they make use of expertise from a variety of fields and when they are able to demonstrate that the outputs are not only of benefit to society, but that society understands and welcomes the benefits. Finally, successful engagement, training, and retention of early career scientists within this field is crucial for sustainability of the research. Herein, the contribution of embedded interdisciplinary working, stakeholder involvement, and training of early career scientists to recent advancements in the field of medical (and wider) radiation protection research is discussed and considered.

Keywords: Ionising radiation; Radiation protection; Multi-disciplinary research; Stakeholder involvement; Early career science; ICRP Bo Lindell Award

1. INTRODUCTION

Medical radiation protection is a topic of current interest worldwide. As new technologies are developed, it is hugely important that radiation protection legislation and guidance keeps pace, in order to derive the benefits of the new techniques while providing adequate protection and reassurance to the individuals occupationally exposed in medical settings and their patients (Journy et al., 2016).

As the international organisation that advances, for the public benefit, the science of radiological protection through provision of recommendations and guidance on all aspects of protection against ionising radiation, the International Commission on Radiological Protection (ICRP) is at the forefront of efforts in this area, with a number of key publications focused on medical radiation protection (ICRP, 2000, 2001, 2007, 2012, 2017). The new European Union (EU) Basic Safety Standards (BSS, 2014) reduced the dose limit for the lens of the eye, for example, on the basis of epidemiological evidence reviewed by ICRP (2012) for a lower threshold than previously thought. However, the ICRP recommendations concluded with a clear statement that the radiobiological, mechanistic evidence regarding the action of low-dose ionising radiation on the lens of the eye and other tissues is still lacking (ICRP, 2012).

In terms of medical protection, a number of recent authors have looked at whether tracking patient exposures and doses might further enhance patient safety (e.g. IAEA, 2019). At first glance, the use of complete historical information on prior exposure to underpin justification and optimisation would seem an obvious tactic; however, as the very recent review of Walsh et al. (2020) pointed out, this can also lead to problems if the users of the information do not have sufficient understanding of cumulative doses, not least due to the lack of evidence for a link between individual cumulative dose and individual long-term risk.

A key theme of contemporary research is the need for genuinely interdisciplinary working. This is nothing new; indeed, Stannard (1966) considered health physics and radiation protection as two of a collection of the ‘new biology’ interdisciplinary sciences. In 1993, Galas highlighted the need for interdisciplinary research in

elucidation of the mechanisms of radiation carcinogenesis (Galas, 1993). However, interdisciplinary working as standard is actually still a relatively novel approach that has not been widely adopted. In 2005, Moeller discussed the emerging interdisciplinary nature of environmental health physics in general (Moeller, 2005). By the early 2000s, following the recommendations of the High Level Expert Group on European Low Dose Risk Research (http://www.hleg.de/), the importance of research to reduce uncertainties in risk assessment of low and protracted ionising radiation exposures was of such high priority that the 'Multidisciplinary European LOw Dose Initiative' (MELODI) was initiated in Europe in 2010. The objective of MELODI was, and remains, integration of national and EC (Euratom) research with the key aim of promoting and supporting multi-disciplinary radiation protection research (Belli et al., 2011). Most recently, MELODI has been participating in the CONCERT European Joint Programme for the Integration of Radiation Protection Research, which seeks to contribute to sustainable integration of European and national research programmes in radiation protection (https://www.concert-h2020.eu/). Again, multi-disciplinary research is recognised as fundamental to the development of understanding to underpin effective radiation protection legislation and guidance. Such approaches have been demonstrated to lead to effective improvements in protection practice too; for example, in 2016, Moore reviewed interdisciplinary working in digital radiography protection, and concluded that interdisciplinary approaches to quality improvement, incorporating all relevant stakeholders, will lead to improvements in the associated radiation protection (Moore, 2016).

Further to this, it is now well understood that the engagement and involvement of stakeholders is a crucial part of interdisciplinary working, both in research and in policy development and implementation in the field of radiation protection and emergency preparedness (Alexander et al., 2005; Liutsko and Cardis, 2018). Genuine involvement of stakeholders, including the general public, comes with a number of challenges; however, the benefits are clear, and these include building mutual trust and understanding with all sectors of society, promoting adequate communication and reducing misinformation, and contributing to the development of robust and practical strategies for disaster recovery (e.g. Liutsko et al., 2020). However, a recent review undertaken as part of the EU CONCERT ENGAGE project identified that, while integration of industrial partners is relatively widespread, comprehensive involvement of wider sectors of society, particularly members of the public and patients, is still not standard practice in radiation protection research and development (Pölzl-Viol et al., 2018).

Finally, the training and career development of early career scientists is recognised as the foundation of an active, healthy, research community (Boice, 2017; Bradshaw et al., 2018; Ottolenghi et al., 2019a). Sustainability of research depends on maintenance of a skilled workforce, yet many areas of radiation protection research still struggle to address this need (Ottolenghi et al., 2019b).

This paper discusses how interdisciplinary working, stakeholder involvement, and training of early career scientists in a number of research projects involving the 2019

Bo Lindell Medal for the Promotion of Radiological Protection Awardee, have contributed directly to recent advancements in the field of medical (and wider) radiation protection research.

2. INTERDISCIPLINARY WORKING, STAKEHOLDER INVOLVEMENT, AND EARLY CAREER SCIENTISTS IN MEDICAL RADIATION PROTECTION RESEARCH

2.1. NIHR HPRU Radiation Theme

The Radiation Theme of the UK National Institutes for Health Research (NIHR) Health Protection Research Unit (HPRU) on Radiation and Chemical Threats and Hazards at Newcastle University, in partnership with Public Health England (PHE), was initiated with the aim of exploring how 'low-dose' medical radiation exposures (chiefly procedures involving x rays) affect population health, and how modifications in the utilisation of radiation might lead to improvements in population health outcomes. In the short term, the aims were to determine the risks for medically exposed populations in the context of other health risks, to use in-vitro approaches to identify novel biomarkers of exposure, and to determine the variability in clinical response in relation to biomarkers and measures of exposure in patients undergoing radiotherapeutic procedures. In the longer term, the objectives were to provide the evidence base for safe use of low-dose medical radiation exposures, and use a multi-disciplinary approach to further advance radiation protection in the medical context.

Since the start of the project in 2015, the Radiation Theme collaborators have investigated how the use of medical x rays could affect public health at various levels, with input from a variety of disciplines including radiobiological, dosimetric, and epidemiological. Work completed includes collection and, importantly, dissemination to the scientific and wider community of evidence to demonstrate that risks associated with having medical x rays as part of certain types of investigations are very small and are likely to be significantly outweighed by the benefits of carrying out the medical procedures. For example, epidemiologists at the University of Newcastle have increased the size of the UK CT scan study cohort to over 450,000 individuals (Bernier et al., 2019), which has provided a sufficiently large population for the Radiation Theme partners to investigate how computed tomography (CT) risks might be modified by underlying health conditions (Harbron, 2016) or other confounders (e.g. transplantation status) (Harbron et al., 2018a), together with improved dose assessment (Harbron et al., 2016) and overall risk of cancers (Journy et al., 2016, 2017; Harbron et al., 2017a, 2018a) for low-dose medically exposed populations. In the area of radiobiology, key recent outputs include development and validation of cytogenetic and genetic biomarkers of radiation exposure in medically exposed populations to underpin dose assessment (Cruz-Garcia et al., 2018; Einbeck et al., 2018; Moquet et al., 2018; O'Brien et al., 2018; Tichy et al., 2018), development of a new method of premature chromosome condensation to increase the speed of biological assessment of higher doses (Sun et al., 2019, 2020),

development of a new protocol for rapid gene-expression-based dose estimation (Polozov et al., 2019), and identification of further new genes suitable for biodosimetric purposes using rapid long-read DNA sequencing methods (Cruz-Garcia et al., 2020). Other major contributions include publication of peer-reviewed papers focused on the dose to the lens of the eye following CT scan exposures (Harbron et al., 2019), and the limited impact of iodinated contrast media on doses to haematopoietic stem cells (Harbron et al., 2017b, 2018b).

2.2. EU CONCERT LDLensRad Project

Human studies, for instance of the atomic bomb survivors, have led to the conclusion that the lens of the eye is more sensitive to ionising radiation exposure than previously thought (ICRP, 2012). New, substantially reduced dose limits came into force in Europe in early 2018 (BSS, 2014). However, it is still very unclear how low-dose ionising radiation might cause or be involved in the development of cataracts. This is an important current public health issue, particularly for medical radiation workers, many of whom will need to amend their working practices despite a clear lack of understanding of the effects of chronic, low-dose ionising radiation exposure of the lens of the eye.

The EU-CONCERT-funded LDLensRad project aimed to bring together experts from across Europe to answer a number of key research questions on this topic, including how does low-dose radiation cause cataracts, and how do genetic background and age influence cataract development after radiation exposure? Outcomes were anticipated to include information regarding the shape of the dose–response curve and thus the risk of radiation cataract at low doses (relevant for EU radiation workers), and thereby strengthen the evidence base for informed radiation protection.

The project results can be summarised as follows. Firstly, the partners have clearly demonstrated that both the dose and dose rate of ionising radiation are important in terms of how the lens of the eye responds to the radiation. Importantly, doses as low as a few mGy were found to cause quantifiable changes in the lens. Further, the long-term studies clearly demonstrated that genetic background, age, and sex are also important in the response and, further, these factors influence each other. Taken together, the data also advance our understanding of how ionising radiation is involved in radiation cataract formation, although unanswered questions concerning mechanisms, latency, and threshold remain. It is important to note that the project data were obtained using animal and cellular models, and human studies need to be carried out to better understand the mutual influence of these and other factors, and to understand whether the current radiation protection legislation and guidance might need to be reviewed (Ainsbury et al., 2020).

2.3. Interdisciplinary working, stakeholder involvement, and training of early career scientists in these projects

The recent results, publications, and outputs from the projects discussed in this article have involved contributions from scientists from a variety of backgrounds.

While some publications concern a single research topic, in most cases, the research would not even have been conceived were it not for interdisciplinary collaboration, for example between epidemiologists, dosimetrists, and lens biology specialists for the work on doses to the lens of the eye under the Radiation Theme, and between dosimetry specialists, radiation biologists, and pathologists for the findings of the LDLensRad project. There are further examples too numerous to mention from both projects and, indeed, examples of the projects working together too – the key point being that interdisciplinary working has been fully imbedded in both of these projects.

As outlined in the sections above, the research findings have resulted in many peer-reviewed publications, and the work has also been presented at numerous international scientific conferences. Here, the impact of such interdisciplinary working is also clear – not only in the volume of publications addressing a large number of different questions associated with use of low-dose ionising radiation in medical contexts, but also where medical radiation protection research has direct input from medical professionals; as discussed below, the outputs include suggestions on how medical practice can be altered to improve protection and limit doses.

Furthermore, members of the public have been actively involved in every stage of the projects – chiefly through membership of the Radiation Theme management board, attendance of biannual project-wide meetings for HPRU, and attendance of focused events for the LDLensRad project. Indeed, several of the publications contain ideas which originated during discussions with the 'lay' members of the team – the work on dose to the lens of the eye is an example of this. Project members from all disciplines have also been involved in a number of stakeholder dissemination activities, including workshops, to explain and elicit public response to the research. At a series of 'Public and Patient Involvement' workshops over the course of HPRU and LDLensRad projects, scientific stakeholders and members of the public have had the opportunity to talk directly to researchers about their work, to ask questions and explain their thoughts on the use of ionising radiation in society, and how the research contributes to radiation protection and safety. One such event – the PHE workshop on medical professional, public, and patient involvement in research into radiation cataract and radiation protection of the lens – took place in May 2018, with the following aims: to give the early career researchers involved the opportunity to outline current scientific understanding and need for scientific research on radiation cataracts to a non-research audience; to present the aims of the LDLensRad project and associated HPRU work; to highlight how the lens research programme fits in with PHE's wider health protection functions, and to answer any questions arising and collate comments and suggestions for the researchers from the attendees. The attendees included a cross-section of medical professionals, chiefly from hospital radiology departments, patients recently exposed to medical radiation, and interested members of the public. Presentations on the projects from the predominantly early career researchers, as a key element of their training, were followed by a detailed discussion with

the attendees of their impressions of the research and how it has been communicated, aided by the following questions:

- Question 1. What are your overall impressions of the project as a whole?
- Question 2. Can you see how the project contributes to PHE's core aim of protecting health and wellbeing?
- Question 3. Have we managed to convince you that this research is important and necessary, and a good use of public money?
- Question 4. Is there anything you think we could/should do differently?
- Question 5. What do you think are the best ways to involve key stakeholders (you!) in the project going forward?
- Question 6. How can we best disseminate our results to the public and medical professionals?

Regarding the projects themselves, the feedback received was excellent – all participants who answered these questions agreed that the project is legitimate and worthwhile in the face of new information on risk to the lens of the eye to inform setting dose limits, that the projects are a good use of taxpayers' money and a great example of multi-disciplinary working, and that stakeholder engagement of the type encouraged by the workshop is important too. Use of radiation in medical practice is increasing, and hospitals already have medical staff reaching the new dose limits so operational changes will be needed. Further, the culture in some hospitals/departments is still quite different to nuclear facilities; for example, where failing to wear personal protective equipment would mean immediate disciplinary action. Further dissemination and direct training will be hugely important going forward. Medical colleagues also welcomed the discussions around potential future studies, some of which could involve them or their departments, for instance, to focus on how practice can be modified to avoid lens exposures while not diminishing image quality or missing pathologies, whether this depends solely on technical capability or training. In a key example of direct impact for this type of activity, the medical professionals present left saying that they would check/amend practice in their own hospitals to ensure that doses to the lens of the eye are limited.

In terms of the format of the event, the participants thanked the speakers for giving clear presentations, making their research easy to understand. The attendees felt that they had received more information than expected, which had exceeded their expectations; that the mixed audience had worked well as it further facilitated genuine discussion; and this was a very good way to garner genuine stakeholder involvement and feedback. Many attendees praised the relaxed atmosphere fostered from the start, which meant that all participants felt comfortable contributing their thoughts and ideas despite the wide range of backgrounds and fields of expertise. The lay representatives also mentioned that they felt equally valued and trusted, and that while they had not all appreciated the risk to the lens of the eye (indeed, some were sceptical beforehand!), they could now see why it was important to

consider this as well as more commonly understood risks such as cancer, and were reassured that such research is taking place.

The fact that the LDLensRad and HPRU projects were presented in the context of PHE's wider programme of radiation and health protection was also appreciated, as it presented a united front, and it was clear to all participants who answered Question 2 that the projects fit PHE's core aims around health and wellbeing. However, some external participants were surprised when PHE representatives informally reported that this type of interdepartmental working was quite unusual, and suggested that such collaboration should take place more often; for instance, LDLensRad researchers could be more closely involved in development of practical guidance for medics to ensure a 'joined-up' PHE-wide approach.

In terms of how the projects or such events might be improved, it was suggested that the initial presentation of the LDLensRad project could have been more succinct, giving more detail (e.g. on plans and timescale), and some participants felt that more details on the 'bigger picture' of the project itself would have been useful, rather than just presenting some distinct aspects. The pre-meeting telephone briefing for lay attendees had been appreciated, but other attendees also felt that they would have benefited from this. It was also suggested that an additional presentation on how medical professionals use radiation, together with an explanation of the risk/benefit balance, could have been included to ensure that was clear to all the lay attendees. Wider dissemination of the strategy at an early stage was also encouraged. For future project involvement and dissemination events, it was suggested that such events should take place at an earlier stage – at the beginning or even before the research starts – to further facilitate genuine stakeholder input. The attendees also suggested some potential additional engagement activities, including joining wider events such as the Harwell Campus open day or New Scientist Live.

Going forward, participants agreed that another such meeting closer to the end of the project, when more results are available, also involving the European partners, would be useful. In addition, telephone discussions with the stakeholder group and for wider dissemination – leaflets, posters (e.g. in radiology department waiting rooms and staff rooms), contribution to relevant guidance, publication of reports or other project details on the PHE website, production of a newsletter, presentations at relevant conferences (e.g. PHE conference) and to relevant professional organisations (e.g. Society and College of Radiographers, British Institute of Radiology, Institute of Physics and Engineering in Medicine), public announcements and e-mails to interested parties, writing articles for other websites or magazines (e.g. Synergy News – magazine of the Society of Radiographers), making use of the stakeholder group established following this workshop to disseminate information amongst colleagues, and use of modern technologies including podcasts, blogs, and social media – were considered to be useful. The participants were also asked whether they would be willing to keep in contact in order to contribute to additional events. All participants answered positively and have therefore been added to the project stakeholder distribution list.

In conclusion, this event clearly demonstrated that the principles of good practice from experience in other projects developed in partnership with social scientists and radiation protection scientists (Liutsko et al., 2020), particularly early face-to-face meeting of project partners and stakeholders, and the importance of clear and concise messages, facilitated successful stakeholder contributions to these projects. Further, the early involvement of stakeholders enabled suggestions on engagement and dissemination within the projects to be incorporated into the project policies on this as they progressed. As a result of this activity and similar activities throughout the projects, early career scientists gained key experience in stakeholder involvement as a hugely important aspect of modern research, and public and industrial stakeholder support for the work and the outputs is also clearly documented. Key lessons learnt as a result of this activity include keeping in regular contact with all stakeholders willing to participate – they are a fantastic resource. In future activities, the recommendation of Liutsko (2020) around use of specific training courses for stakeholders who will use the project outputs will certainly also need to be considered.

3. DISCUSSION AND CONCLUSIONS

As noted in Section 1, the benefits of multi-disciplinary working, stakeholder engagement and involvement, and education and training of early career scientists have been addressed by many authors and are absolutely clear (Ottolenghi et al., 2019b; Liutsko et al., 2020). Indeed, in recent years, most, if not all, grant calls now ask for clear details of at least components of these to be addressed within the grant application. As such, it is within the interests of all members of our research community to fully engage with engagement.

Within the EU CONCERT project, a huge amount of work has been done to promote interdisciplinary working, stakeholder engagement and involvement, and education and training. As a result of this, researchers in the field of radiation protection research are now in an excellent position – many models and tools are available to support these activities. Further, it is the responsibility of all active scientists, project managers, and funding recipients to support sustainability within the fields of radiation protection research by recruiting, training, and supporting early career scientists. These key components are required for successful research projects which are genuinely able to contribute to scientific and policy developments in the field of radiation protection.

The projects discussed in this article give examples of how the use of interdisciplinary relationships, stakeholder involvement, and early career scientists can facilitate provision of clear evidence regarding the long-term safe use of ionising radiation in medicine. Such work underpins advice for medical staff regarding provision of informed consent, and reassurance for patients that procedures are safe and justified. Further, the direct impact of such activities is also clear – the lens dosimetry work, for example, has led to document changes in hospital practice around shielding of the lens of the eye during head and neck procedures.

However, there are still improvements to be made – for example, although the HPRU Research Theme had members of the public sitting on the project management board, the LDLensRad project rather relied on specific events focused chiefly on stakeholder dissemination and elucidation of comments/ideas, which is not necessarily the best way to facilitate regular genuine stakeholder involvement. For both projects, members of the public have been identified as the key stakeholders, and while the LDLensRad project has also involved industrial partners, wider stakeholders have not been as actively involved in the Radiation Theme as they could have been.

Ultimately, as with all projects, interdisciplinary working, the involvement and active training of early career scientists in both projects, and – to a certain extent – stakeholder involvement have relied on the need for these areas being specified in the grant calls, and also on them being facilitated by the funding models. It is very important to note that, as described here, mandating of these activities does not preclude them being of real benefit. As always, further work needs to be done to ensure that all research projects in this area recognise the importance of these activities in terms of generation of innovative answers to the open research questions, promoting communication on this important topic within society to build mutual trust and understanding and for long-term sustainability, and thus follow such models going forward. Furthermore, sustainability of research does not rely solely on funding, training, and retention of early career scientists; going forward, this also implies the additional consideration of environmental aspects of research – including (but certainly not limited to) the wider environmental and non-human implications of the use of ionising radiation in society and the research methods employed in this field (e.g. Vandenhove et al., 2018), and the use of video and other conferencing facilities to replace travel to limit the carbon footprint of research. Only by considering all of these aspects will radiation protection research be genuinely integrated into society, and be seen to be socially responsible and well oriented to address the needs of society.

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Olympic Dam: BHP thinking big about the future

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Abstract–Olympic Dam is one of the world's most significant polymetallic orebodies producing copper, uranium, gold, and silver in remote South Australia. The polymetallic deposit is located 520 km north-northwest of Adelaide, South Australia and has an inferred resource of 2660 Mt at 1.2% Cu, 1.4 kg t^{-1} U_3Os, and 0.5 g t^{-1} Au. Ore is mined from the underground operation at a rate of approximately 10 mt $year^{-1}$, and is processed on site through a concentrator and hydrometallurgical facility, smelter, and electrolytic refinery. Olympic Dam is one of the only sites in the world to claim the 'mine to market' title. Protection of the workforce and the environment has been a primary focus for the operations through its 30 + year life and will continue to be into the future. Broken Hill Propriety Company (BHP) believes that its most important asset is its people. With such a large orebody and a very long potential mine life, it is important to think strategically about the future to ensure the viability of the operation. This requires development of mine and surface processing facilities in a staged manner. Importantly, it also involves the development of people. This presentation provides an overview of BHP's work at Olympic Dam and outlines development plans for Olympic Dam into the future.

Protection of the environment

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Abstract–The International Commission on Radiological Protection's (ICRP) system to protect the living components of the environment is designed to provide a broad and practical framework across different exposure situations. The framework recognises the need to be able to demonstrate an adequate level of protection in relation to planned exposure situations, whilst also providing an ability to manage existing and emergency situations in an appropriate way. In all three exposure situations, the release of radionuclides into the natural environment leads to exposures of non-human biota (wildlife), as well as having the potential for exposures of the public. How the key principles of the ICRP system of radiological protection apply in each of these exposure situations will be discussed. Using examples, we will demonstrate how the overall approach provides a mechanism for industry to assess and demonstrate compliance with the environmental protection objectives of relevant (national) legislation, and to meet stakeholder expectations that radiological protection of the environment is taken into consideration in accordance with international best practice. However, several challenges remain, and these will be discussed in the context of the need for additional guidance on the protection of the environment.

Keywords: Environmental protection; Habitats; Non-human biota; Radiological protection; Exposure situations

1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) has stated that the primary aim of its 2007 Recommendations is to 'contribute to an appropriate

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level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure'. More specifically for the environment, the aim is 'preventing and reducing the frequency of deleterious radiation effects to a level where they would have negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats, communities and ecosystems' (ICRP, 2007).

In *Publication 108* (ICRP, 2008), ICRP set out its approach to the protection of both humans and the environment in relation to the three exposure situations (Fig. 1). ICRP describes how the system of radiological protection should be integrated to ensure human and environmental protection (ICRP, 2008). For example, while radiological protection for humans is subject to the application of dose limits, constraints, and reference levels according to the exposure situation, for the environment, there are 12 Reference Animals and Plants (RAPs) that have been used to define numeric criteria [derived consideration reference levels (DCRLs)]. DCRLs are defined as 'a band of dose rate within which there is likely to be some chance of deleterious effects of ionising radiation occurring to individuals of that type of Reference Animal or Plant, derived from a knowledge of defined expected biological effects for that type of organism that, when considered together with other relevant information, can be used as a point of reference to optimise the level of effort expended on environmental protection, dependent upon the overall management objectives and the exposure situation'. Fig. 2 shows the ICRP DCRLs for each RAP.

While dose criteria are expressed differently for humans and the environment, their use has the same purpose, namely to aid decision making on the appropriate level of protection to apply, while addressing the fundamental ethical principle of doing more good than harm (ICRP, 2014). That said, it is recognised that applying

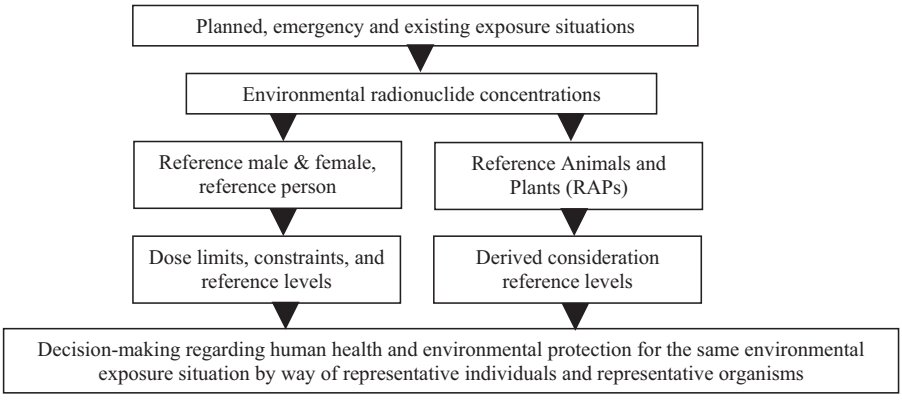

Fig. 1. Schematic approach to the protection of both humans and the environment in relation to any exposure situation (ICRP, 2008).

these dose criteria when carrying out dose assessments, and deciding on the implementation of a protection strategy, is highly dependent upon factors such as the exposure situation and its prevailing circumstances, relevant endpoints for the management processes, and non-radiological factors.

The RAPs have defined anatomical, physiological, and life-history information, and provide the basis to model the relationship from dosimetry to radiation effects for the set of 12 organism types (deer, rat, bee, earthworm, duck, frog, trout, marine flatfish, crab, pine tree, grass, and seaweed). It is important to remember that these are not necessarily the objects of the protection, but allow for consideration of the impacts on biological diversity, species' health, and natural habitats.

Given the different component parts, it is important to provide advice and guidance on how the radiological protection principles can be applied in the context of environmental protection under the three exposure situations recognised by ICRP (2008). The three exposure situations are as follows.

- Planned exposure situations – exposure situations resulting from the operation of deliberately introduced sources. Planned exposure situations may give rise to exposures that are anticipated to occur (normal exposures) and exposures that are not anticipated to occur (potential exposures).
- Emergency exposure situations – exposure situations resulting from a loss of control of a planned source, or from any unexpected situation (e.g. a malevolent event), that requires urgent action in order to avoid or reduce undesirable consequences.
- Existing exposure situations – exposure situations resulting from sources that already exist when a decision to control them is taken.

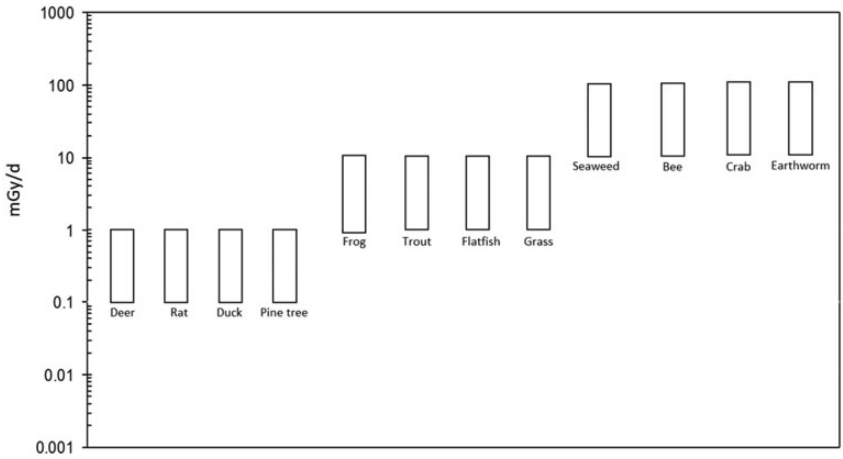

Fig. 2. Derived consideration reference levels for environmental protection for each Reference Animal and Plant (RAP) (ICRP, 2008, 2014).

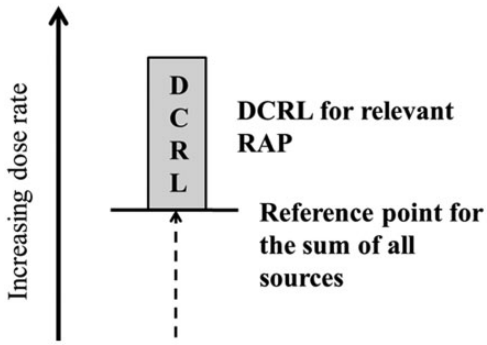

Fig. 3. Schematic approach to the protection of the environment under planned exposure situations (ICRP, 2014), showing that, ideally, discharges would not result in dose rates in, or above, the derived consideration reference level (DCRL) region. RAP, Reference Animal or Plant.

1.1. Applying the DCRLs in planned exposure situations

The concept for planned exposure situations, as outlined in *Publication 124* (ICRP, 2014), is that we should not 'plan' radiological protection that could potentially lead to harm to non-human biota in just the same way as we aim to prevent harm to humans, bearing in mind that the DCRL represents a 'band of dose rate' within which there is some chance of deleterious harm occurring (Fig. 3). The Commission has recommended that the lower boundary of the relevant DCRL band should be used as an appropriate reference point for the protection of the different types of non-human biota. It has been noted that cumulative impacts from multiple sources may need to be considered depending upon the prevailing circumstances being assessed.

1.2. Applying the DCRLs in emergency and existing exposure situations

For emergency exposure situations where control of the source has not been obtained, the estimated dose rates to non-human biota can be compared with the DCRL band (Fig. 4a) and used in communicating the likely risks to non-human biota that may be affected by exposure to radiation. It is unlikely that, during an incident, any specific activities will be taken to protect non-human biota present in an affected area. However, any initial decontamination/clean-up activities during the emergency phase that may reduce the dose rate for humans are likely to have the same consequential reduction in dose rate to non-human biota. Ideally, the choice of decontamination/clean-up methods should consider the non-radiological impacts (e.g. any chemicals used in the clean-up, physical removal of habitat including soil and flora) on non-human biota.

Using the DCRL bands, the consequences of dose rate reductions resulting from decontamination/clean-up activities can be assessed from a radiological perspective. The Commission stated in *Publication 124* (ICRP, 2014) that if the dose rates to non-

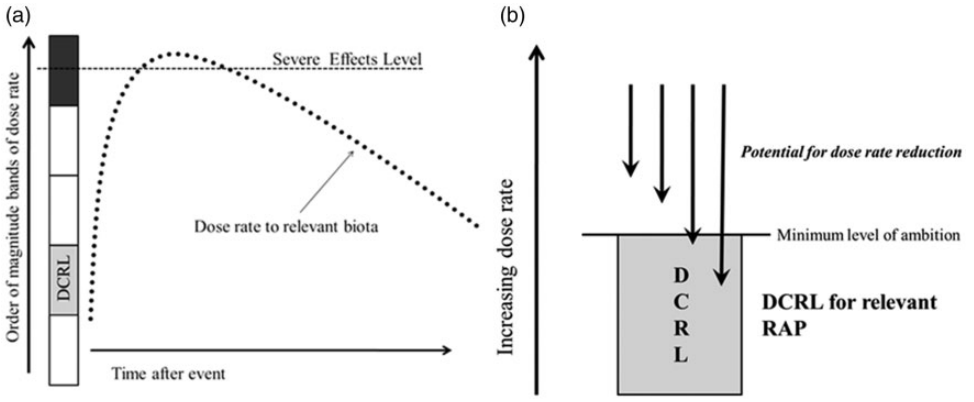

Fig. 4. Schematic approach to protection of the environment under (a) emergency and (b) existing exposure situations (ICRP, 2014). (a) The potential use of a severe effects level, in relation to the derived consideration reference level (DCRL), to relate exposure of non-human biota following an accidental or emergency release of radionuclides into the environment. Severe effect levels are often used in chemical risk assessment and have been considered by the International Commission on Radiological Protection to be approximately equivalent to a band of doses two orders of magnitude above the DCRL band. (b) The intent to move progressively towards (if above) and into the DCRL during the existing exposure situation.

human biota are above the relevant DCRL band, they recommend that the aim should be to reduce exposures to levels that are within the DCRL bands for the relevant populations (Fig. 4b). However, the Commission also recognises that it may be difficult, or impractical, to significantly reduce the concentrations or quantities of radioactive material that exist in the affected environment. Thus, in the case of existing exposure situations, the DCRLs are to be used as the criteria for mitigating environmental exposures, just as reference levels are used for mitigating individual exposures for human protection in such situations.

2. EXAMPLES OF APPLYING ICRP'S SYSTEM FOR RADIOLOGICAL PROTECTION OF THE ENVIRONMENT UNDER DIFFERENT EXPOSURE SITUATIONS

2.1. Applying the DCRLs in planned exposure situations

There are now a number of examples of radiological dose assessments for non-human biota for currently operating or planned sites. Some examples drawn from the UK are for:

- non-nuclear sites (e.g. hospitals, research facilities) (Allott et al., 2009; Environment Agency, 2019a);

- new-build nuclear power plants (e.g. Hinkley Point C, UK) (Environment Agency, 2012); and
- permit variations (e.g. the nuclear licensed site at Sellafield in Cumbria, UK) (Environment Agency, 2019b).

As an example, in their latest habitats assessment review using permit data from 2017 in England and Wales, the Environment Agency (2019a) showed that all 218 terrestrial sites assessed had a dose rate $<0.1\,\mathrm{mGy\,day^{-1}}$ (i.e. the lower boundary of the DCRL for the terrestrial RAPs). Similarly, all 129 assessed marine sites and 80 of 81 assessed freshwater sites were below $1\,\mathrm{mGy\,day^{-1}}$, which is the lower boundary of the DCRL for freshwater and marine RAPs. On further investigation, the one freshwater site had dose rates of 1.008, 0.8, and $0.5\,\mathrm{mGy\,day^{-1}}$ for insect larvae, vascular plants, and molluscs, respectively. These are all below the nearest appropriate RAP DCRL [e.g. while not aquatic, Reference Bee and Reference Earthworm ($10\,\mathrm{mGy\,day^{-1}}$) for insect larvae; Reference Grass ($1\,\mathrm{mGy\,day^{-1}}$) or Reference Seaweed ($10\,\mathrm{mGy\,d^{-1}}$) for vascular plants; and Reference Crab as the nearest RAP for molluscs ($10\,\mathrm{mGy\,day^{-1}}$)]. This also highlights some of the difficulties in applying the most appropriate RAP to the different wildlife species found in different environmental compartments.

More recently, non-human biota dose assessments are being conducted to explore 'what if scenarios' when considering decommissioning and radioactive waste disposal options. For example, in the petroleum industry, would more harm be done by removing radioactively contaminated pipelines from the seabed than by leaving them in situ based on the estimated radiological exposures to humans and non-human biota? In the UK, the environmental regulators have issued guidance on how nuclear licensed sites might be released from radioactive substances regulation (Environment Agency, Natural Resources Wales and Scottish Environment Protection Agency, 2018), and set out the requirements for waste management plans and site-wide environmental safety cases which include consideration of the options for disposal/decommissioning.

Generally speaking, radiological dose assessments for planned exposure situations provide reassurance that the dose rates to non-human biota are or will be low and below any threshold level that might be applied nationally (in the case of England and Wales, for example) or using the appropriate DCRL. This is perhaps not surprising given the controls on discharges that are applied for the public. In some cases (e.g. Allott et al., 2009; Environment Agency, 2019a), the dose assessments have been conducted for multiple sites (approximately 350 designated conservation sites). Often these assessments for planned exposure situations are conducted on a conservative basis by considering the dose rates arising from:

- discharges at the permitted limits;
- modelling approaches which do not take into account or limit dispersion in the environment; and

- use surrogate data where there are missing data, usually based on picking similar or conservative alternatives (e.g. where data are missing for radionuclide transfer), or picking transfer data from a similar organism type or similar radionuclide (e.g. from within the same group in the periodic table).

There are still knowledge gaps and improvements to the dose assessment methodology that can be applied. However, for the most part, as the conservatively estimated dose rates are well below any thresholds being used, these assessments can be accepted. However, for some site assessments, data are lacking because of gaps in our knowledge of radionuclide transfer (e.g. across all ecosystem types – temperate, arid, tropical, etc.). This was the case in Australia for assessments being conducted for the Ranger uranium mine in the Alligator River Region (ARR).

The ARR in Northern Australia is an area of past and present uranium mining activity. It is one of the most diverse biological regions in Australia with a wet–dry tropical climate, and around two-thirds of this area is the Kakadu National Park (a World Heritage site). Ranger uranium mine, which commenced operation in 1980, is located in the ARR. To support activities planning for the closure and rehabilitation of the Ranger uranium mine, concentration ratios (transfer parameters) for the wild plants and animals used by local Aboriginal people ('bush foods') and for non-human biota in their own right were required. Limited data from this type of ecosystem were available in the late 1970s, and the Environmental Research Institute of the Supervising Scientist (ERISS) of the Supervising Scientist Division of the Commonwealth Department of Agriculture, Water, and the Environment was established to undertake research and monitor the operation of Ranger uranium mine and other mining activities in the ARR.

ERISS has been undertaking research and monitoring to independently assess the environmental impacts of uranium mining in the region for around 40 years. ERISS has established a database for the storage and handling of data on natural series radionuclide and metal concentrations in Northern Australian bush foods and environmental media from the ARR (Doering and Bollhöfer, 2016). Colloquially referred to as 'BRUCE' (Bioaccumulation of Radioactive Uranium-series Constituents from the Environment), the database contains over 57,000 concentration values (Doering and Bollhöfer, 2016). Although not specifically designed for non-human biota, the scope of BRUCE now includes biota tissue samples of wildlife not usually eaten as bush foods (but could be of potential importance to estimate exposures to non-human biota). BRUCE can also be used to determine organism-to-media concentration ratios for some organism types for use in non-human biota dose assessment tools, and is an example of how new data can be collated. These transfer data have now been used to help prepare the mine closure plan by Energy Resources of Australia Ltd for the Ranger uranium mine (ERA, 2019).

Compilations of data for transfer parameters, such as BRUCE, compliment and extend international data collections such as the IAEA (2014a) and ICRP (2009) handbooks, which collate data on freshwater, marine, and terrestrial ecosystems to facilitate radiological dose assessments for non-human biota. Online databases for

transfer (http://www.wildlifetransferdatabase.org/; Copplestone et al., 2013) and effects (http://www.frederica-online.org/mainpage.asp; Copplestone et al., 2008) are available and underpin these handbooks for non-human biota.

2.2. Applying the DCRLs in emergency and existing exposure situations

Fortunately, large-scale radiological incidents occur infrequently, with Chernobyl and Fukushima being two of the best known incidents. Lessons can be learned from these events, and past accidents are currently the focus of a systematic review which is exploring the extent to which decisions regarding the clean-up considered the impact on the environment. Future integration of environmental considerations into protective action decisions may lead to early consideration of the environment. For example, planning where to place new facilities from the point of view of potential radiological impacts on non-human biota, or incorporating radiological considerations of the environment in emergency preparedness planning and in any potential longer-term recovery options that might be applied.

Existing exposure situations may occur following a nuclear or radiological emergency, or from the presence of historic contamination, past industrial practice (IAEA, 2014b), or as a result of naturally occurring radioactivity. The key point with existing exposure situations is the need to make a decision to bring the situation under improved radiological management based on the contamination levels and the associated radiation exposure to the public and the environment (ICRP, 2007; IAEA, 2014b). Two examples will be highlighted below where decisions of radiological management are either being considered or are required.

There are a number of sites where nuclear weapons tests were conducted, mainly during the 1950s and 1960s. For example, there were three nuclear detonations during the 1950s on the Montebello Islands, Western Australia, and radiological contamination is still present on the islands (Johansen et al., 2019) as there have been no major remediations of the area.

The Montebello Islands have mainly been assessed for human exposure alone, with the exposure criteria related to transient island visitors (Cooper et al., 1990). However, since the nuclear weapons tests, the Montebello Islands have been relatively undisturbed, and they now act as a refuge for endangered species such as flatback (*Natator depressus*) and hawksbill (*Eretmochelys imbricata*) sea turtles (Pendoley et al., 2016). Additionally, the Montebello Islands now serve as a refuge for critically endangered species of mammals (rufous hare-wallabies, *Lagorchestes hirsutus*) which have been translocated from the mainland (Langford and Burbidge, 2001). The conservation decisions have therefore brought species of high conservation value into areas contaminated with radioactivity, resulting in a need for both non-human biota and human dose assessments (tourists and researchers studying the species mentioned are spending increasing amounts of time on the Montebello Islands). Previous dose assessments have only considered humans.

When undertaking an integrated human and non-human biota assessment, consideration must be given to how people and the biota use the environment. For example, tourists tend to spend time in the intertidal area of the Montebello Islands and might only visit once; researchers may make repeated visits; and the turtles may visit the foredunes to lay eggs, which are then potentially exposed to radionuclides as they incubate in contaminated sands. Mammals might spend time in the more heavily contaminated areas where the weapons were detonated. Johansen et al. (2019) measured radionuclide levels in tissues from different biota, and showed that those coming into contact with the contaminated island soils typically had higher levels of radionuclide accumulation. The need to consider aspects such as these in the context of existing exposure situations was discussed further in Copplestone et al. (2017).

Integrated assessments will help inform any management decisions on the need for radiological protective measures on the Montebello Islands, and these should consider the potential damage to the islands' unique ecosystems. However, there are potential problems with this as the RAPs and DCRLs have few marine organisms and do not include a representative reptile, which potentially leaves gaps when defining appropriate risk assessment criteria.

In Australia, the past decade has seen significant advances in demonstrating radiation protection of non-human biota for planned and existing exposure situations. However, in the gas and petroleum industry, there is an emerging issue that highlights the need to connect environmental decision making with radiological risk assessment methods in an integrated manner. Decommissioning activities for offshore petroleum projects have been increasing, with operations expected to expand significantly in the next decade [estimated at US$210 bn (IHS Markit, 2016)]. The issue of removing or leaving seabed pipelines contaminated with radioactive scales remains a challenge for the industry and regulator to assess. For example, leaving contaminated pipelines in situ may have a radiological (and non-radiological) impact on wildlife, while removing the contaminated pipelines creates a human exposure pathway, land disposal challenge, the potential loss of marine life communities, and has a significant cost implication, although there may also be conflict with international agreements on dumping at sea to be considered. Balancing these factors requires an appropriate approach to an integrated human and non-human biota dose assessment, which needs to consider such things as: the species potentially impacted (are they transient or sessile, endangered or endemic?); the geographic and population scale of the impact on the biota; levels of radioactive (and non-radioactive) contaminants present in the pipe; whether the pipe remains intact or corrodes, with breakthrough occurring at some time in the future; potential transfer of radioactive contaminants through the marine food chain to the human consumer; and are the DCRLs and RAPs appropriate for assessing the benthic species found around the pipelines?

3. CONCLUSIONS AND FUTURE STEPS

Radiological assessments of non-human biota are increasing in number and scope, and the international framework for radiological protection of the

environment is enabling discussion, the writing of guidance, and standardisation of best practice. Assessments are being undertaken for a range of different planned and existing exposure situations including routine discharges, decommissioning scenarios, and contaminated environments. In the latter assessments, understanding the potential radiological consequences to non-human biota is helping to bring environmental considerations into decisions on remediation.

There remain challenges with our current assessment approaches, not least in terms of detailed guidance and recommendations for integrated human and non-human biota assessments under different exposure situations. There are also gaps and controversy in our scientific knowledge of radiation effects on non-human biota and, given the number of species that we need to consider, there are still gaps in our knowledge of radionuclide transfer (e.g. across all ecosystem types – temperate, arid, tropical, etc.). Activities are underway to address a number of these aspects. An integrated approach to radiological protection facilitates communication and dialogue over our continuing use of radioactive materials, and ensures that both human and environmental health is being considered when we make decisions regarding the management of, for example, radioactive wastes.

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Miner studies and radiological protection against radon

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Abstract–Fundamental estimates of radon-associated health risk have been provided by epidemiological studies of miners. In total, approximately 15 studies have been conducted worldwide since the 1960s. These results have contributed directly to radiological protection against radon. The present article summarises the main results, with a focus on analyses of miners exposed more recently, estimates of radon lifetime attributable risk, and interaction between radon and smoking. The potential for the upcoming Pooled Uranium Miner Analysis project to further improve our knowledge is discussed.

Keywords: Radon, Miner, Lung Cancer, Epidemiology

1. MINER STUDIES

Large-scale uranium mining began in the 1940s in Czechoslovakia during the Second World War (Tomasek et al., 1994) and in US mines in 1946 (NRC, 1999). The first epidemiological cohorts of miners began to be assembled in the 1960s. In total, more than 12 cohorts provided estimates of the exposure–risk relationship between radon and radon decay products and the risk of lung cancer among miners: in Australia (Radium Hill), Canada (Ontario, Newfoundland, and Eldorado, which combines the Beaverlodge and Port Radium cohorts), China (Yunnan), Czech Republic (Western Bohemia), France (CEA-COGEMA),

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Germany (Wismut), Sweden (Malmberget), and the USA (Colorado Plateau, New Mexico). Most cohorts included uranium miners, but some were based on tin (Yunnan), iron (Malmberget), or fluorspar (Newfoundland) mines. Most cohorts were composed essentially of males and considered mortality data alone.

Numerous reviews of miner cohorts have been published since the 1980s, especially by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 1982, 1988, 2000, 2009, 2019), the International Agency for Research on Cancer (IARC, 1988), and the International Commission on Radiological Protection (ICRP, 2010). Several combined analyses have also been performed (NRC, 1988, 1999; ICRP, 1993; Lubin et al., 1994; Tomasek et al., 2008a; Tirmarche et al., 2010; Leuraud et al., 2011; Hunter et al., 2013; Lane et al., 2019). The largest cohort, assembled at the end of the 1990s in Germany, is the Wismut cohort, including nearly 59,000 male workers (Kreuzer et al., 1999, 2018; Walsh et al., 2015). Notable combined analyses include *Publication 65* [including more than 31,000 miners from seven cohorts (ICRP, 1993)], the BEIR VI report [including more than 60,000 miners from 11 cohorts (NRC, 1999)], and the Alpha-Risk European project [including more than 50,000 miners from three cohorts (Tirmarche et al., 2010)].

These miner studies have had a significant influence on the understanding of radon risks. They consistently demonstrated a positive association between cumulative radon exposure and lung cancer death. On that basis, radon was classified as a recognised lung carcinogen in 1988 (IARC, 1988). In a recent review performed by UNSCEAR, the combined excess relative risk (ERR) estimated from these cohorts was 0.60 (95% confidence interval 0.34–0.87) per 100 working level month[1] (WLM) (UNSCEAR, 2019). In addition, these cohorts allowed quantification of the impact of factors that modify the exposure–risk relationship, such as attained age, age at exposure, time since exposure (TSE), and exposure rate. Several studies also considered the impact of other exposure factors present in the mines on the estimated risk of lung cancer, such as external gamma exposure and uranium ore dust (Marsh et al., 2012; Rage et al., 2012), arsenic, silica, or fine dust (Sogl et al., 2012; Walsh et al., 2015). The association between radon and lung cancer generally persisted after adjustment of these factors.

Outside of lung cancer, excesses have been reported in several miner cohorts for non-Hodgkin's lymphoma, multiple myeloma, larynx cancer, kidney cancer, liver cancer, and stomach cancer, and associations with cumulated radon exposure have been suggested for leukaemia, cancers of the extrathoracic airways, and cerebrovascular disease (Darby et al., 1995; Tomasek and Malatova, 2006; Kreuzer et al., 2014, 2017; Drubay et al., 2015). Nevertheless, all these observations are not consistent, and, at the present time, lung cancer is the only known health effect of radon exposure (ICRP, 2010).

[1]Working level is defined as any combination of the short-lived progeny of radon in 1 L of air that will result in the emission of 1.3×10^5 MeV of potential alpha energy. 1 working level $= 2.08 \times 10^{-5}$ J/m^3. Working level month is defined as the cumulative exposure from breathing an atmosphere at a concentration of 1 working level for a working month of 170 h.

2. ANALYSES OF MINERS EXPOSED IN RECENT PERIODS

Mining conditions have changed drastically over time, with improved working conditions, the introduction of forced ventilation, and the implementation of radiological protection measures from the late 1950s onwards. Fig. 1 shows the changes in mean radon exposure levels over time in the three cohorts of uranium miners (Czech, French, and German) involved in the Alpha-Risk European project (Tirmarche et al., 2010). Concentrations of radon progeny in the first underground mines were several orders of magnitude higher than what has been commonly encountered since the 1960s. It should be noted that these changes in mining conditions over time not only led to a reduction in WLM, but also to changes in the parameters involved in the exposure assessment (e.g. increase in ventilation, decrease in equilibrium factor, change in attached fraction, etc.) and an improvement in the air quality of the mining environment.

An inverse exposure–rate effect (or protraction enhancement effect) was observed in most analyses of miner studies (Lubin et al., 1994; NRC, 1999). Models have been developed to combine the modifying effects of TSE, age, and exposure rate. The first model was proposed in the BEIR VI report, in which exposure rate was an average calculated as the cumulated exposure divided by the number of years of exposure (NRC, 1999). An improved approach was later proposed in which radon exposure over time was distributed in different windows of annual exposure rate or different periods of exposure (Tomasek et al., 2008a; Tirmarche et al., 2010). This exposure rate effect is reflected by a lower ERR per 100 WLM estimated for high exposure rate categories (annual exposure of several WLM per year or higher) than for low

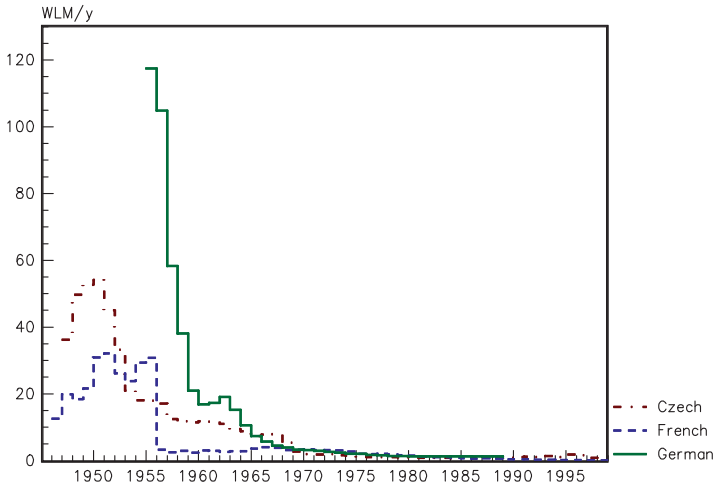

Fig. 1. Mean annual radon exposures [in working level months (WLM) per year] in the three European cohorts of uranium miners.

exposure rate categories (annual exposure of several WLM per year or lower). The inverse exposure rate effect was attenuated or no longer observed when restricting analyses to miners exposed to low levels of cumulative WLM exposure or hired in recent periods (Lubin et al., 1995; Tomasek et al., 2008a; Kreuzer et al., 2015, 2018), but estimated ERR per 100 WLM was generally higher than that estimated in the full cohort (ICRP, 2010; Tirmarche et al., 2012; Kreuzer et al., 2015). This was confirmed by a recent review performed by UNSCEAR; compared with the ERR of 0.6 per 100 WLM estimated from the full cohort, an ERR estimate approximately two-fold higher of 1.53 (95% confidence interval 1.11–1.94) per 100 WLM was obtained when restricting the analysis to more recent work periods and lower exposures or exposure rates (UNSCEAR, 2019). UNSCEAR indicated giving preference to the latter estimate due to improved radon exposure assessments in more recent periods, and to these radon exposures being more reflective of current mining conditions. However, it was noted that this estimate was less precise due to smaller sample sizes (UNSCEAR, 2019).

Several explanations have been proposed to explain this effect:

- Measurement errors associated with exposure assessment in the early years. Before the 1960s, radon exposure was generally not recorded for each miner based on measurements, and the errors associated with exposure estimates were very large. Also, some type of systematic overestimation of the real exposure levels may have occurred (Allodji et al., 2012a). These errors may lead to underestimation of the estimated ERR per unit exposure associated with early-year exposures and high exposure rates. Similarly, epidemiological studies that correct for measurement errors have shown an increase in risk estimates (Stram et al., 2000; Allodji et al., 2012b; Heidenreich et al., 2012; Hoffmann et al., 2017). Overall, data quality was generally much better in recent periods, during which prospective monitoring of the workers was implemented in the mines, for both exposure and follow-up data. Studies of miners restricted to more recent work periods therefore allow analyses based on data of much better quality.
- Decreased risk of lung cancer at high radon levels. As illustrated in Fig. 1, before the implementation of ventilation and exposure control in the mines, some miners could receive several hundreds of WLM per year. If we apply the recent dose conversion coefficient of 10 mSv (effective dose) per WLM proposed by ICRP (ICRP, 2017), such levels of radon exposure correspond to effective doses of several hundreds or thousands of mSv per year. Estimated equivalent doses to the lung should be approximately eight times higher. At such dose levels, some health effects due to cell killing effects are expected. It is probable that elevated risks have been encountered by early miners for many different health effects, and the risk of lung cancer may be underestimated due to competing risks.
- Lower TSE effect due to shorter duration of follow-up. As stated above, a strong modifying effect of TSE has been observed in most analyses on miners. This TSE effect is reflected by a higher ERR per 100 WLM estimated 5–15 years after exposure than >25 years after exposure. Miners employed since the 1960s, but

not before, obviously have a shorter duration of follow-up than miners employed before the 1960s. Consequently, this shorter duration of follow-up could prevent the TSE effect from being fully expressed, and thus give rise to the impression of a higher coefficient in the cohort of miners hired in recent periods. Nevertheless, this hypothesis is unlikely as miners hired since 1960 had, in 2010, a possible follow-up duration of almost 50 years, with a potential attained age of approximately 70 years. Today, the characteristics of these cohorts of miners hired in recent periods make them perfectly capable of taking a possible TSE effect into account. Conversely, it is possible that the strong TSE effect observed in the complete cohorts may be due to underestimation of the risk among miners hired in earlier periods.

In conclusion, it appears that, for the purposes of radiological protection, the most relevant studies on miners are those with low cumulative exposure levels, long duration of follow-up, and good-quality data. Today, the cohorts restricted to miners hired in recent periods are capable of providing good estimates of the risk of lung cancer associated with cumulated radon exposure. Even if estimates of ERR per unit exposure of radon are associated with wider confidence intervals due to a restriction of population size, exclusion of miners employed in the early years appears to be the best way to reduce bias. Recent analyses of cohorts of miners hired in recent periods generally demonstrate a significant association between cumulated radon exposure and risk of lung cancer, with estimated ERR per 100 WLM approximately two-fold higher than the values that were estimated in the 1990s (ICRP, 2010; UNSCEAR, 2019). Furthermore, the heterogeneity between cohorts of ERR per 100 WLM estimated from analyses restricted to miners exposed to low levels of cumulative WLM exposure or hired in recent periods is much lower than from analyses of full cohorts (ICRP, 2010; Tirmarche et al., 2012).

3. ESTIMATED LIFETIME EXCESS RISK OF LUNG CANCER ATTRIBUTABLE TO RADON

Due to variations in the characteristics of the study populations (e.g. attained age, duration of follow-up), a direct comparison of estimates of ERR per unit exposure of radon obtained from different cohorts may be misleading. The calculation of the cumulated risk up to a given age (often called ‘lifetime excess risk’) in a specific exposure scenario can take such variations into account (Thomas et al., 1992) to reflect the risk attributable to radon exposure. Calculation of lifetime risk requires:

- a risk model derived from an epidemiological study, with modifying factors such as attained age, age at exposure, TSE, and exposure rate;
- a projection model, enabling extrapolation of risk outside the range considered by the epidemiological study and transport to other populations;

- baseline reference rates for all-cause and lung cancer mortality, and age distribution of the reference population – this allows calculation of the baseline lifetime risk of lung cancer in the absence of additional radon exposure; and
- a scenario of exposure.

Since the 1990s, several calculations of radon-induced lifetime excess risk have been performed (ICRP, 1993, 2010; NRC, 1999; EPA, 2003; Tomasek et al., 2008b; UNSCEAR, 2019). Most of these calculations used the same methodology and scenario of exposure as proposed in *Publication 65* (ICRP, 1993): a constant low-level exposure to 2 WLM per year during adulthood from 18 to 64 years of age, with the risk of lung cancer cumulated up to 90 or 94 years of age, and the same source of baseline rates [ICRP reference rates from *Publications 60* or *103* (ICRP, 1991, 2007)]. Therefore, these calculations can be compared.

Publication 65 (ICRP, 1993) estimated a lifetime excess risk of lung cancer of 2.8×10^{-4} per WLM for radon exposure. This result was based on a risk model taking account of modifying effects of age and TSE, but not exposure rate. New lifetime risk estimates were calculated in *Publication 115* (ICRP, 2010). Considering all available models derived from different single cohorts, estimated lifetime excess risks varied from approximately 3 to 7×10^{-4} per WLM, according to the model used. Priority was given to estimates based on models derived from combined analyses that were able to consider a modifying effect of exposure rate or hiring period; namely, the models from the BEIR VI report and the combined analysis of the Czech–French cohorts (NRC, 1999; Tomasek et al., 2008a). Results obtained from these two models were very similar, with estimated values between 4.5 and 5.5×10^{-4} per WLM. Based on these calculations, a rounded lifetime excess risk value of 5×10^{-4} per WLM was recommended by ICRP as the nominal risk coefficient for radon exposure for radiological protection purposes (ICRP, 2010).

Recent lifetime risk calculations performed by UNSCEAR gave similar results (UNSCEAR, 2019). Lifetime excess risk values were obtained by applying the BEIR VI exposure age–concentration model individually to the updated Czech Republic, Wismut, and Eldorado miner studies, and to the combined 11 miner studies used in the BEIR VI report. Values ranged from 2.4 to 7.5×10^{-4} per WLM for the Wismut and Eldorado studies, respectively. For the BEIR VI studies, the estimated lifetime excess risk was 5.5×10^{-4} per WLM (UNSCEAR, 2019).

In conclusion, miner cohorts provide a quantitative basis for estimating the excess risk of lung cancer attributable to radon exposure. Results appear to be very consistent, with variations within a factor of approximately 2. In the future, use of risk models derived from miners hired in recent periods may allow a reduction in this range of variation.

Calculations of lifetime excess risk of lung cancer attributable to radon exposure contribute directly to radiation protection. In 1993, ICRP adopted a nominal risk coefficient of 2.8×10^{-4} per WLM for radon exposure. Comparing this value with the total radiation detriment per Sv for adults given in *Publication 60* (ICRP, 1991),

a dose conversion convention of 4 mSv for 1 WLM was derived for workers (ICRP, 1993). In 2010, based on an updated review of epidemiological results, a nominal risk coefficient of 5×10^{-4} per WLM was recommended by ICRP for radiological protection purposes as a replacement for the previous value (ICRP, 2010). With this revised nominal risk coefficient and the detriment value of *Publication 103* for adults (ICRP, 2007), a dose conversion convention of 12 mSv per WLM was obtained (Marsh et al., 2010, 2017; ICRP, 2017). Taking account of both epidemiological and dosimetric approaches, *Publication 137* (ICRP, 2017) recommended the use of a single rounded value of 3 mSv per mJ h m^{-3} (approximately 10 mSv per WLM) in most circumstances for workers in buildings and underground mines.

4. INTERACTION BETWEEN RADON AND SMOKING

Although smoking is by far the strongest risk factor for lung cancer, most studies of miners did not take account of smoking habits. Nevertheless, available results indicate that the relationship between lung cancer mortality and radon exposure generally persists when smoking habits are taken into account, with only marginal changes in the risk of radon-associated lung cancer (Tirmarche et al., 2012). Application of an indirect adjustment method on the Colorado miner cohort suggested no confounding by smoking of the association between radon and lung cancer (Schubauer-Berigan et al., 2009; Richardson et al., 2014).

Most analyses are consistent with a submultiplicative or multiplicative interaction between radon exposure and smoking status (NRC, 1999; Leuraud et al., 2011; Kreuzer et al., 2018). When the smoking status is known, the estimated ERR per unit exposure of radon generally appears to be larger (even if not significantly) among non-smokers than among smokers (Lubin et al., 1994; Tomasek et al., 2002; Leuraud et al., 2011; Hunter et al., 2013). Nevertheless, an analysis of the Czech miner cohort concluded that an interaction close to additive between radon and smoking was observed (Tomasek, 2013). The explanation for this discrepancy is not known. It could be partly related to differences in the classification of smoking behaviour, or in the consideration of age and TSE in the modelling of the interaction between smoking and radon. Further analyses are needed to improve the characterisation of the joint effect of radon and smoking.

It is noticeable that almost all models derived from miner studies since the 1990s are ERR models (also referred to as 'multiplicative risk models'). Such models suppose that the excess risk of lung cancer associated with radon exposure is proportional to the baseline rate of lung cancer. As baseline rates are highly dependent on smoking habits, it is recommended that excess absolute risk (EAR) models (also referred to as 'additive risk models') should also be developed to better understand the interaction of radon and smoking on the risk of lung cancer. Assessment of the impact of changes in smoking prevalence on the baseline rate of lung cancer, and on the risk attributable to radon, is also worthwhile.

5. PERSPECTIVES

Most recently, the Pooled Uranium Miner Analysis (PUMA) study was launched. This assembles information on cohorts of uranium miners in North America (Canada and the USA) and Europe (Czech Republic, Germany, and France). Data include individual annual estimates of exposure to radon decay products, duration of employment of each worker, and information on vital status, date of death, and cause of death. The PUMA study constitutes the largest study of uranium miners conducted to date, encompassing 124,507 miners, 4.51 million person-years at risk, and 54,462 deaths, including 7825 deaths due to lung cancer (Rage et al., 2020).

The PUMA study provides opportunities to evaluate new research questions and to conduct analyses to assess potential health risks associated with uranium mining that have greater statistical power than can be achieved with any single cohort. Planned research topics include analyses of associations between radon exposure and mortality due to lung cancer, cancers other than lung cancer, and non-malignant disease. For the risk of lung cancer, analyses will consider both ERR and EAR models; specific analyses of the impact of uncertainties, exposure rate, and smoking on the estimated exposure–risk relationship; and quantification of overall mortality excesses and lifetime risks. This international study will improve our understanding of radon-related diseases and strengthen the basis for radon radiological protection.

6. CONCLUSION

Miner cohorts have made a major contribution to the understanding of radon-associated risks and the consolidation of radiation protection against radon exposure. Miner cohorts have provided consistent results on the existence of an increased risk of lung cancer associated with radon exposure, even at relatively low exposure rates. They have also provided results on the modifying effect of age and TSE on this association, and on the interaction with smoking. One recurrent criticism is on the uncertainties associated with these results. It now seems evident that a good way to reduce uncertainties is to focus analyses on cohorts of miners employed in more recent years, after implementation of ventilation and individual exposure control in mines. Analyses focused on such populations generally have data of much higher quality to provide risk estimates that are more consistent between cohorts, and consider exposure levels that are more pertinent for current radiation protection purposes.

In the near future, the PUMA study will provide consolidated information on quantification of the risk of lung cancer associated with radon, and on potential risks other than lung cancer. Important questions that cannot be answered by miner studies remain, especially regarding risks among females and risks associated with radon exposure during childhood. Results from miner cohorts need to be complemented by epidemiological studies of indoor radon, dose and risk modelling, and experimental research in order to further improve our knowledge in this area.

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ICRP recommendations on radon

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Abstract–The International Commission on Radiological Protection (ICRP) publishes guidance on protection from radon in homes and workplaces, and dose coefficients for use in assessments of exposure for protection purposes. ICRP *Publication 126* recommends an upper reference level for exposures in homes and workplaces of 300 Bq m^{-3}. In general, protection can be optimised using measurements of air concentrations directly, without considering radiation doses. However, dose estimates are required for workers when radon is considered as an occupational exposure (e.g. in mines), and for higher exposures in other workplaces (e.g. offices) when the reference level is exceeded persistently. ICRP *Publication 137* recommends a dose coefficient of 3 mSv per mJ h m^{-3} (approximately 10 mSv per working level month) for most circumstances of exposure in workplaces, equivalent to 6.7 nSv per Bq h m^{-3} using an equilibrium factor of 0.4. Using this dose coefficient, annual exposure of workers to 300 Bq m^{-3} corresponds to 4 mSv. For comparison, using the same coefficient for exposures in homes, 300 Bq m^{-3} corresponds to 14 mSv. If circumstances of occupational exposure warrant more detailed consideration and reliable alternative data are available, site-specific doses can be assessed using methodology provided in ICRP *Publication 137*.

Keywords: Radon; Thoron; Effective dose coefficients; Dose conversion convention; Reference levels

1. INTRODUCTION

For the first symposium of the International Commission on Radiological Protection (ICRP), Harrison and Marsh (2012) reviewed developments in the calculation of dose

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

coefficients for isotopes of radon. Since that time, ICRP has issued *Publication 126* (ICRP, 2014) giving guidance on protection, and *Publication 137* (ICRP, 2017) which includes dose coefficients for the inhalation of ^{222}Rn (radon), ^{220}Rn (thoron), and ^{219}Rn (actinon), together with their radioactive progeny. This article reviews the progression of ICRP recommendations from *Publication 65* (ICRP, 1993), through *Publications 103* and *115* (ICRP, 2007, 2010), to the most recent publications.

Radon, thoron, and actinon gases decay into a series of solid progeny that include alpha-particle-emitting radionuclides. It is these progeny that deliver the majority (>95%) of the dose received by the epithelial lining of the lung airways. For example, radon decays with a half-life of 3.8 days to progeny that include the alpha emitters ^{218}Po (half-life 3.1 days) and ^{214}Po (half-life 164 μs). As they are formed, progeny aggregate into clusters of approximately 1nm diameter, referred to as the 'unattached fraction', and also associate with existing aerosol particles in the air to form the 'attached fraction' with larger particle sizes of 10 nm to >1 μm (ICRP, 2017). In most circumstances, the concentration of progeny in inhaled air is less than that of the parent nuclide because of plate-out of particles on to surfaces and the effects of ventilation. This concentration difference between the gas and its solid progeny is quantified by the 'equilibrium factor' with typical values for radon and progeny in buildings of approximately 0.4. Air concentrations are measured in terms of the gas (Bq m^{-3}) or of the alpha particle energy emitted by progeny [mJ m^{-3} or working level (WL)], related by the equilibrium factor. Measurements of exposure introduce time, as Bq h m^{-3}, mJ h m^{-3}, and working level month (WLM; 1 WL for 1 working month).

The inhalation of radon and progeny has been unique among internal exposures in that there is strong quantitative evidence of the relationship between exposures and the induction of lung cancer from studies of underground miners and people in their homes (UNSCEAR, 2009, 2019; ICRP, 2010; Laurier et al., 2020). In general, control of radon exposures can be based directly on measurements of air concentrations and the setting of reference levels for homes and workplaces (ICRP, 2007, 2014). However, dose estimates and dose coefficients are required for circumstances where, from the outset, the exposure is considered to be occupational, and in circumstances where exposures in workplaces remain persistently above the reference level despite remediation. Dose estimates may also be required in assessing public exposures in some circumstances; for example, when considering doses resulting from past contamination of buildings with radium isotopes.

Exposures to thoron, and particularly actinon, are substantially less important in most cases but can be significant in particular circumstances (ICRP, 2017). This article focuses on radon but also mentions thoron; information on actinon can be found in *Publication 137* (ICRP, 2017).

2. ICRP PUBLICATIONS

2.1. *Publications 65* and *103*

Risks of lung cancer mortality from prolonged exposures to radon were estimated in *Publication 65* (ICRP, 1993) from studies of cohorts of underground miners.

The nominal 'fatality and detriment' coefficient obtained was 8×10^{-5} per mJ h m^{-3}, which corresponds to a rounded value of 3×10^{-4} per WLM. A dose conversion convention was used in which this risk coefficient was divided by the detriment coefficients for all stochastic effects from *Publication 60* (ICRP, 1991) of 5.6×10^{-5} per mSv for workers and 7.3×10^{-5} per mSv for members of the public. The conversion coefficients obtained were 1.4 mSv per mJ h m^{-3} for workers and 1.1 mSv per mJ h m^{-3} for members of the public (5 mSv per WLM and 4 mSv per WLM, respectively).

It was recommended that an action level for initiating intervention should be set nationally, corresponding to an effective dose of between 3 and 10 mSv year^{-1} for both homes and workplaces. The annual occupancy of homes is taken to be 7000 h and the working year as 2000 h; with the assumption of an equilibrium factor of 0.4, this range of action levels was calculated to correspond to radon concentrations of 200–600 Bq m^{-3} in homes and 500–1500 Bq m^{-3} in workplaces.

The 2007 Recommendations (*Publication 103*; ICRP, 2007) repeated the guidance provided in *Publication 65* (ICRP, 1993), and referred to upper values of reference levels of 600 Bq m^{-3} for domestic dwellings and 1500 Bq m^{-3} for workplaces, corresponding to an effective dose of 10 mSv year^{-1}. In addition, *Publication 103* (ICRP, 2007) noted that an action level of 1000 Bq m^{-3} had been established in the International Atomic Energy Agency's Basic Safety Standards (IAEA, 1996), and concurred that this could be used globally as the agreed entry point for occupational protection requirements. However, the existence of more recent epidemiological data was recognised, including results from cohort studies of miners and case–control studies of residential exposures. A task group started work in 2007 to review these data and provide the basis for updated recommendations.

2.2. *Publication 115*

The review of epidemiological studies of cohorts of underground miners provided in *Publication 65* (ICRP, 1993) was updated in *Publication 115* (ICRP, 2010), focusing on more recent studies with lower levels of radon exposure (see Laurier et al., 2020). Estimates of lifetime risks of lung cancer fatality based on the newer data were greater than those from earlier studies, and an increase in the lifetime risk coefficient was proposed from 8×10^{-5} per mJ h m^{-3} to 1.4×10^{-4} per mJ h m^{-3} (5×10^{-4} per WLM). Comparisons of studies of the risk of lung cancer in mines and in homes are not straightforward, mainly because of the different epidemiological designs of studies. However, comparisons were made with the results of a European pooling of studies of domestic exposures (Darby et al., 2005, 2006) and showed good consistency. The residential studies show a clear difference between smokers and non-smokers, with the risk of radon-induced lung cancer being increased substantially by smoking. The risk coefficient derived on the basis of the miner studies applies to a mixed population of smokers and non-smokers.

Publication 115 (ICRP, 2010) also included a statement on radon from ICRP, which adopted the revised risk coefficient proposed in the same publication, and

made changes to reference levels from those recommended in *Publication 103* (ICRP, 2007), confirming that an annual effective dose of approximately 10 mSv would almost certainly warrant action to reduce exposures. The upper reference level for radon exposures in homes was revised from 600 Bq m^{-3} to 300 Bq m^{-3}. For protection of workers, the statement referred only to the level of 1000 Bq m^{-3} to be set as the entry point for applying occupational protection requirements.

No revisions of dose conversion coefficients for radon were provided in *Publication 115* (ICRP, 2010), but instead the statement on radon signalled the intention that, in future, ICRP would provide dose coefficients for radon isotopes calculated using biokinetic and dosimetric models as for all other radionuclides.

2.3. *Publication 126*

Following the changes recommended in *Publication 115* (ICRP, 2010), *Publication 126* (ICRP, 2014) updated ICRP advice on protection of the public and workers against radon exposures. As in *Publication 103* (ICRP, 2007), the advice centres around the optimisation of protection to maintain or reduce exposures to levels that are as low as reasonably achievable, taking economic and social circumstances into account. The objective is to reduce both the overall risk of lung cancer in the general population and the individual risk to the most highly exposed individuals. Radon exposures are classified as an existing exposure situation, as defined in *Publication 103* (ICRP, 2007), and can only be controlled by actions on exposure pathways. Consequently, the appropriate reference level should correspond to an annual effective dose in the range of 1–20 mSv, and *Publication 126* (ICRP, 2014) reaffirmed previous advice that a dose of the order of 10 mSv should be regarded as a benchmark for setting a reference level.

For the practical implementation of protection of the public, the upper reference level of 300 Bq m^{-3} for homes, as recommended in *Publication 115* (ICRP, 2010), was confirmed in *Publication 126* (ICRP, 2014), with the advice that national authorities should set a reference level in the range of 100–300 Bq m^{-3} depending on their particular circumstances. This is consistent with advice given by the World Health Organization (WHO, 2009) that the reference level should be set at 100 Bq m^{-3} if possible, but otherwise at a level not exceeding 300 Bq m^{-3}.

For protection of workers, *Publication 126* (ICRP, 2014) goes further than *Publication 115* (ICRP, 2010), and recommends that the upper reference level of 300 Bq m^{-3} should apply generally to all buildings, and hence to workplaces, such as offices, as well as mixed-use settings, such as shops, restaurants, and schools. A graded approach is recommended in which protection is first optimised below the reference level. If remediation is unsuccessful in reducing exposures to below this level, a second step will be a realistic estimation of effective dose. If, despite all reasonable efforts to reduce radon exposures, the doses remain persistently above 10 mSv, the worker should be considered as occupationally exposed. It will only be in a relatively small number of occupations, such as underground mining, that the

radon exposure will be considered from the outset to be the responsibility of the operating management, and hence categorised as occupational exposure.

Fig. 1 summarises the *Publication 126* (ICRP, 2014) approach to protection from radon in buildings and other locations, applying to homes and workplaces. The intention is that an integrated approach will be taken to measures applied to buildings regardless of their use, and that the national authority will develop a radon protection strategy accordingly.

2.4. *Publication 137*

Publication 115 (ICRP, 2010) signalled the intention to provide dose coefficients for radon isotopes calculated using biokinetic and dosimetric models, and these are provided for occupational exposures in *Publication 137* (ICRP, 2017). A publication providing dose coefficients for members of the public is in preparation. *Publication 137* (ICRP, 2017) considers the inhalation of radon (^{222}Rn, half-life 3.8 days), thoron (^{220}Rn, half-life 56 s), actinon (^{219}Rn, half-life 4 s), and their progeny; the ingestion of

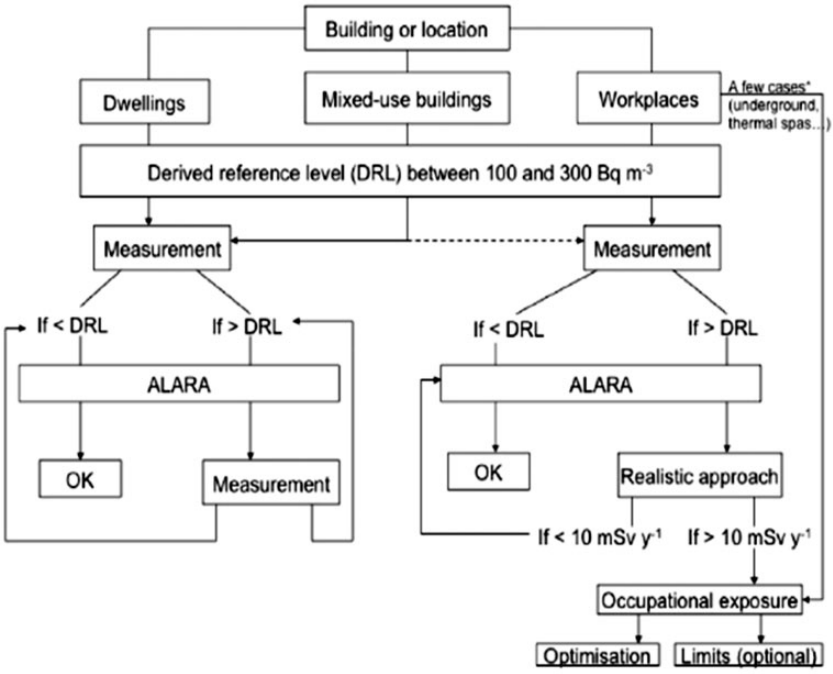

Fig. 1. General approach for the management of radon exposures. ALARA, as low as reasonably achievable, taking economic and societal circumstances into account. *Workplaces where radon exposures are considered by national authorities to be occupational from the outset.

radon gas is also considered because of its solubility in water. Effective dose coefficients are included in the publication; organ and tissue equivalent doses coefficients are available in an electronic annex (www.icrp.org).

Effective doses from the inhalation of radon isotopes are due largely to the equivalent doses received by the lungs, resulting very largely from the deposition of solid progeny aerosol particles in the airways. However, principally for radon because of its longer half-life, absorption of the gas to blood results in smaller doses to other body organs and tissues. The deposition of progeny aerosol particles in the airways is dependent on the particle size distribution, including the unattached fraction which deposits more efficiently than the larger particles of the attached fraction. Breathing rate also determines intake and hence dose.

Table 1 shows effective dose coefficients for inhalation of radon, thoron, and their progeny, as presented in *Publication 137* (ICRP, 2017). The dose coefficients for inhalation of radon and progeny, calculated using biokinetic and dosimetric models using the average breathing rate for the Reference Worker, are 3.3 mSv per mJ h m^{-3} (12 mSv WLM^{-1}) for mines, 5.7 mSv per mJ h m^{-3} (20 mSv WLM^{-1}) for indoor workplaces, and 6.7 mSv per mJ h m^{-3} (24 mSv WLM^{-1}) for the specific case of tourist caves. In these calculations, the Reference Worker is assumed to spend two-thirds of the time in exercise. Using a more realistic breathing rate for sedentary occupations, such as office work, gives a dose coefficient of 4.1 mSv per mJ h m^{-3} (14 mSv WLM^{-1}) (Harrison and Marsh, 2012). Using the same methodology, the dose coefficient for exposure in homes has been calculated as 3.7 mSv per mJ h m^{-3} (13 mSv WLM^{-1}) (Marsh and Bailey, 2013).

Table 1. Effective doses from inhalation of radon and thoron in workplaces by a Reference Worker with an average breathing rate of 1.2 m^3 h^{-1}.

			Effective dose per exposure*		
Exposure/place	Unattached fraction, f_p	F	mSv per WLM	mSv per mJ h m^{-3}	mSv per Bq h m^{-3}
Radon (^{222}Rn) gas + progeny					
Indoor workplace	0.08	0.4	20	5.7	1.3×10^{-5}
Mine	0.01	0.2	12	3.3	–
Tourist cave	0.15	0.4	24	6.7	1.5×10^{-5}
Thoron (^{220}Rn) progeny					
Indoor workplace	0.02	–	5.6	1.6	1.2×10^{-4}†
Mine	0.005	–	4.8	1.4	1.0×10^{-4}†

f_p, unattached fraction in terms of the potential alpha energy concentration; F, equilibrium factor; WLM, working level month.

*For radon, 1 WLM = $(6.37 \times 10^5/F)$ Bq h m^{-3}. For thoron, 1 WLM = 4.68×10^4 Bq h m^{-3} of equilibrium equivalent concentration of ^{220}Rn; 1 WLM = 3.54 mJ h m^{-3}.

†In terms of mSv per Bq h m^{-3} of equilibrium equivalent concentration of ^{220}Rn.

Publication 137 (ICRP, 2017) noted that inhalation of radon and progeny is a special case for which there is good epidemiology on the risk of lung cancer as well as good dosimetric models. Applying the dose conversion convention to the revised risk coefficient of 1.4×10^{-4} per mJ h m^{-3} (5×10^{-4} per WLM) derived in *Publication 115* (ICRP, 2010), and dividing by *Publication 103* (ICRP, 2007) stochastic detriment coefficients of 4.2×10^{-5} per mSv for workers and 5.7×10^{-5} per mSv for members of the public, the conversion coefficients are 3.3 mSv per mJ h m^{-3} (12 mSv per WLM) for workers and 2.5×10^{-4} per mJ h m^{-3} (9 mSv per WLM) for members of the public. *Publication 137* (ICRP, 2017) notes further that a more recent study of a large cohort of German uranium miners showed lower but broadly consistent results for the risk of lung cancer at lower levels of exposure (Kreuzer et al., 2015).

Taking account of all the available data, a single effective dose coefficient was recommended of 3 mSv per mJ h m^{-3} (approximately 10 mSv per WLM), applicable in the majority of circumstances of occupational exposure, with no adjustment for aerosol characteristics. In cases where aerosol characteristics are significantly different from typical conditions, sufficient, reliable aerosol data are available, and estimated doses warrant more detailed consideration, it is possible to calculate site-specific dose coefficients using the data provided in *Publication 137* (ICRP, 2017) and the electronic annex. A second higher value of 6 mSv per mJ h m^{-3} (approximately 20 mSv per WLM) was referred to in *Publication 137* (ICRP, 2017), but this may be seen as an example of requirements for more specific calculations when warranted.

Dose coefficients for the inhalation of thoron progeny are given for two situations of exposure: indoor workplaces and mines (Table 1). On the basis of these calculations, it is recommended that a single rounded value of 1.5 mSv per mJ h m^{-3} (5 mSv WLM^{-1}) should be used for all situations of occupational exposure. This dose coefficient is considered to be applicable to the majority of circumstances with no adjustment for aerosol characteristics. As in the case of inhalation of radon progeny, if sufficient, reliable aerosol data are available and estimated doses warrant more detailed consideration, calculation of site-specific dose coefficients can be carried out using the data provided in *Publication 137* (ICRP, 2017).

3. DISCUSSION

Work is in progress to provide updated dose coefficients for members of the public and to include radon isotopes. Effective dose coefficients and organ/tissue equivalent dose coefficients will be calculated for the standard ages considered by ICRP: the 3-month-old infant; 1-year-, 5-year-, 10-year-, and 15-year-old children; and adults. For radon, age at intake has little effect on the dose per exposure because competing effects tend to cancel out, including the opposite effects of lower breathing rates and smaller tissue masses. For example, Marsh et al. (2005) calculated effective dose for different age groups using the ICRP respiratory tract model and reported values of 9.6–12.9 mSv per WLM. ICRP has already indicated in its ICRPaedia notes on radon (www.icrp.org) that the same overall value of the dose coefficient of 3 mSv per mJ h m^{-3} (approximately 10 mSv per WLM) will apply to members of

the public as well as workers. Applying an equilibrium factor of 0.4, this corresponds to 6.7 nSv per Bq h m^{-3}.

The upper reference level of 300 Bq m^{-3} for radon exposures in homes, as recommended in *Publications 115* and *126* (ICRP, 2010, 2014), is established internationally and incorporated into the most recent Basic Safety Standards (IAEA, 2014). Taking the annual occupancy of homes as 7000 h, this corresponds to an effective dose of 14 mSv. The approach recommended in *Publication 126* (ICRP, 2014) of also applying this reference level to workers is less firmly established, with the Basic Safety Standards (IAEA, 2016) continuing to advise a reference level of 1000 Bq m^{-3}, although the European Council Directive (2012), for example, requires the use of 300 Bq m^{-3} (EU, 2014). For a working year of 2000 h, 300 Bq m^{-3} and 1000 Bq m^{-3} correspond to effective doses of 4 mSv and 13 mSv, respectively.

A United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) review of radon epidemiology and dosimetry should be published in 2020; a report to the United Nations General Assembly provides a summary of findings (UNSCEAR, 2019). UNSCEAR reviewed epidemiological studies of lung cancer in underground miners, and estimated lifetime risks using similar methodology to that applied in *Publication 115* (ICRP, 2010). New data from the large German Wismut cohort were analysed (Kreuzer et al., 2015, 2018), as well as updated studies for other cohorts. The estimates of lifetime excess absolute risk ranged from 2.4 to 7.5×10^{-4} per WLM. Applying the dose conversion convention using *Publication 103* (ICRP, 2007) detriment per Sv values, this range corresponds to ranges in dose conversion of 5.7–17.9 mSv per WLM for workers and 4.2–13.2 mSv per WLM for the whole population. The UNSCEAR review of published dosimetric assessments for exposures in homes, indoor workplaces, and mines showed a range of effective dose coefficients which, applying an equilibrium factor of 0.4, corresponds to 3–14 nSv per Bq h m^{-3}, with arithmetic/geometric means of 6–7 nSv per Bq h m^{-3}. UNSCEAR (2019) provides support for the ICRP effective dose coefficient of 3 mSv per mJ h m^{-3} (approximately 10 mSv per WLM), equivalent to 6.7 nSv per Bq h m^{-3} with an equilibrium factor of 0.4.

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Australian action to reduce health risks from radon

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Abstract–In Australia, worker exposure to radon in underground uranium mines has been a focus of policy makers and regulators, and has been well controlled in the industry sector. That cannot be said for public exposure to radon. Radon exposure studies in the late 1980s and early 1990s demonstrated that the levels of radon in Australian homes were some of the lowest in the world. The International Basic Safety Standards, published by the International Atomic Energy Agency, requires the government to establish and implement an action plan for controlling public exposure due to radon indoors. When considering different policy options, it is important to develop radon prevention and mitigation programmes reflecting elements that are unique to the region or country. The Australian Radon Action Plan is being considered at a national level, and presents a long-range strategy designed to reduce radon-induced lung cancer in Australia, as well as the individual risk for people living with high concentrations of radon. In Australia, workers who are not currently designated as occupationally exposed are also considered as members of the public. In the Australian context, there are only a limited set of scenarios that might give rise to sufficiently high radon concentrations that warrant mitigation. These include highly energy efficient buildings in areas of high radon potential, underground workplaces, workplaces with elevated radon concentrations (e.g. spas using natural spring waters), and enclosed workspaces with limited ventilation. The key elements for a successful plan will rely on collaboration between government sectors and other health promotion programmes, cooperative efforts involving technical and communication experts, and partnering with building professionals and other stakeholders involved in the implementation of radon prevention and mitigation.

Keywords: Radon; Action plan; Existing exposure

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

1. INTRODUCTION

It has been recognised that exposure to radon-222 (herein radon) and inhalation of its decay products increases the risk of developing lung cancer. In 1941, the US Advisory Committee on X-ray and Radium Protection (NBS, 1941) set 10^{-8} μCi cm^{-3} (370 Bq m^{-3}) as the value for the maximum permissible concentration for occupational exposure (40 h $week^{-1}$) to radon plus its decay products. Since 1953, the International Commission on Radiological Protection (ICRP) has been recommending maximum activity concentrations of radon in workplaces and homes to keep the risk as low as reasonably achievable.

In 2014, ICRP introduced the concept of a national radon protection strategy (ICRP, 2014) as radon is ubiquitous; it represents a significant source of radiation exposure; and, in most circumstances, it can be controlled. This recommendation is reflected in Requirement 50 of the International Basic Safety Standards (IAEA, 2014) which states that countries '... shall establish and implement an action plan for controlling public exposure due to radon indoors'. To assist countries, the World Health Organization provides options to reduce the health risk of radon, and sound policy options for prevention and mitigation of radon (WHO, 2009).

Australia is currently developing a radon action plan, which is intended to be a long-range strategy to reduce radon-induced lung cancer in Australia.

2. RADON IN AUSTRALIA

2.1. Levels of radon in Australia

Relative to most other countries, the levels of radon in Australia are very low. Fig. 1 indicates that mean indoor levels of radon in Australia are the lowest amongst member countries of the Organisation for Economic Co-operation and Development. On average, radon contributes less than one-third of the total dose due to all sources of radiation in the Australian environment. Fig. 2 shows that, based on an extensive survey of Australian homes (ARL, 1990), 99% of homes had indoor levels of radon below 45 Bq m^{-3}, and less than two in 10,000 homes had levels exceeding 100 Bq m^{-3}.

This means that the risk posed by radon is very low, except in circumstances where radon is allowed to accumulate to very high levels. In the Australian context, there are only a limited set of scenarios that might give rise to radon concentrations that exceed the reference level:

- highly energy efficient buildings in areas of high radon potential;
- underground workplaces;
- workplaces with elevated radon concentrations (e.g. spas using natural spring waters); and
- enclosed workspaces with limited ventilation.

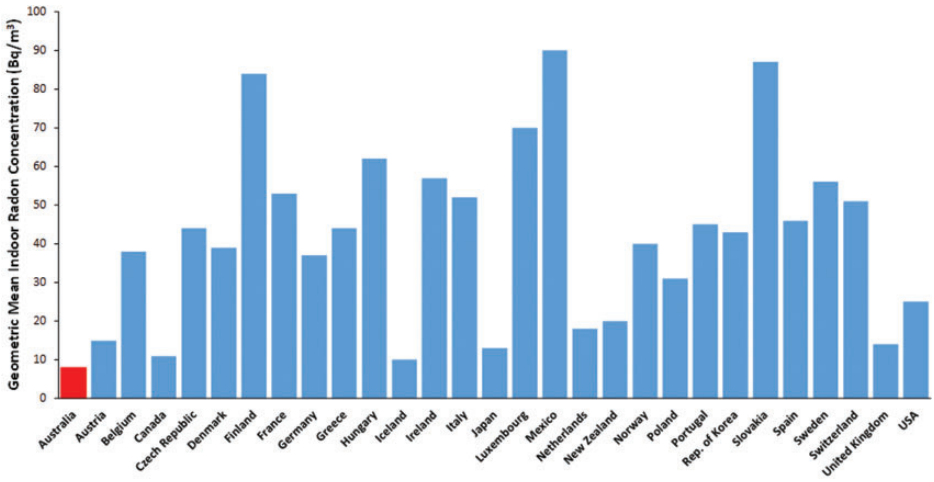

Fig. 1. Mean indoor radon concentrations in various member countries of the Organisation for Economic Co-operation and Development (WHO, 2009).

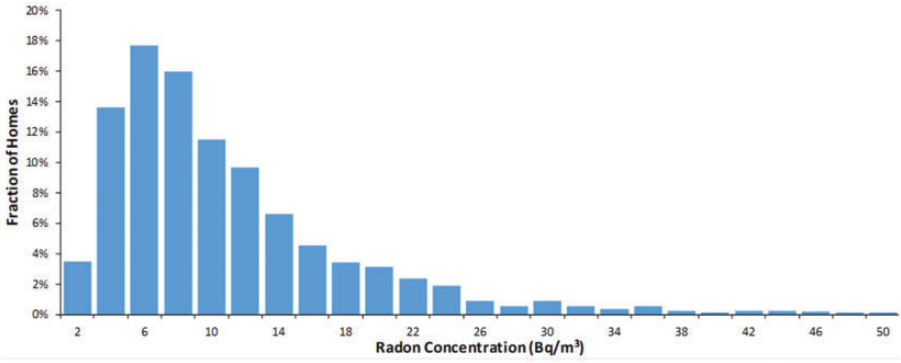

Fig. 2. Distribution of radon concentrations found in Australian homes.

2.2. Guidance for radon exposure in Australia

Within the system of radiological protection, radon exposure has the characteristics of an existing exposure situation, as the source is unmodified concentrations of ubiquitous primordial natural activity in the Earth's crust (ICRP, 2007). Human activities such as construction of buildings, operation of mines, or underground show caves (ARL, 1996) may create or modify pathways that increase exposure to radon and its progeny. These pathways can be controlled by preventative and mitigating actions.

The Guide for Radiation Protection in Existing Exposure Situations (ARPANSA, 2017) recommends a reference level of 10 mSv year^{-1} to provide an appropriate level of protection for the public and workers for exposure to radon in homes and workplaces in Australia. This guide recognises the challenges of measuring a dose from radon, and recommends derived reference levels that are consistent with a reference level of 10 mSv year^{-1}.

A derived reference level of 200 Bq m^{-3} for dwellings and mixed-use buildings (those used by both workers and members of the public) and a reference level of 1000 Bq m^{-3} for workplaces has been established for Australian conditions.

In most workplaces, radon exposures of workers that are not a result of their assigned or regular work activities are considered to be adventitious, and are not considered to be occupational exposures.

The Guide for Radiation Protection in Existing Exposure Situations recommends a specific graded approach in workplaces to control the level of radon. Attempts should be made to reduce the concentration of radon to a level to the same derived reference level established for dwellings and mixed-use buildings. If difficulties are met in reducing levels, optimising protection is recommended using the actual parameters of the exposure situation, such as occupancy and other site-specific factors, together with a derived reference level of 1000 Bq m^{-3}, averaged over 1 year.

For exposures in workplaces that persist above the derived reference level of 1000 Bq m^{-3}, averaged over 1 year, workers should be considered as occupationally exposed.

3. THE AUSTRALIAN RADON ACTION PLAN

The Australian Radon Action Plan proposes that the risk posed by radon in Australia will be minimised by taking action in four key areas:

- raising awareness;
- assessing workplaces and public buildings that may have elevated radon concentrations;
- providing advice and guidance to those workplaces and public areas that have radon concentrations exceeding the reference level; and
- minimising radon concentrations in new buildings in areas with high radon potential.

3.1. Raising awareness

The potential health impacts from exposure to radon in the mining and milling of uranium ores and mineral sands have been of concern since the 1950s. For this reason, authorities responsible for radiation protection have regulated radon exposure of workers in those industries. In Australia, legislation regulating exposure to radon does not extend to people exposed to naturally occurring levels of radiation in homes or mixed-use buildings.

Previous assessments of the risk to people exposed to naturally occurring levels of radiation have determined that the risk posed by radon in Australia was very low. Therefore, the range of regulatory authorities responsible for public and workplace health do not currently consider controlling exposure to radon. However, ICRP has re-evaluated its estimates of the risk of lung cancer for radon progeny and doubled its estimate of risk from exposure to radon (ICRP, 2010).

The regulatory authorities responsible for public and workplace health already have direct engagement with the broad spectrum of stakeholders that can manage public and workplace exposure to radon. It is these bodies that should be engaged, through the Australian Radon Action Plan, to promulgate public and workplace awareness of the potential risks of radon exposure.

In particular, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) will collaborate with Worksafe Australia, the Australian government statutory body established to develop national policy relating to workplace health and safety, to develop and publish a guide on radon exposure in the workplace.

3.2. Assessing workplaces and public buildings

In line with best practice in radiation protection and workplace health and safety, the strategy for dealing with radon in workplaces and public buildings should involve a graded approach to risk management and a careful targeting of resources.

In the first instance, radon should be recognised like any other potential hazard in workplaces and public buildings. Those responsible for the workplaces or public buildings should be encouraged to measure the concentration of radon to determine if it approaches the reference level.

In Australia, little is known about the level of radon in schools and preschools, presenting an opportunity for the education sector to conduct radon measurement surveys to better understand radon exposure and to introduce learning material into the classroom to raise awareness. In Australia, some underground show caves have been recognised as workplaces that have elevated levels of radon (ARL, 1996). In 2019, Solomon undertook a re-assessment of inhalation radon doses among Australian underground show cave workers. The re-assessment of historical data applied the new radon ICRP dose conversion factor, and identified that 15% of the workers exceeded 10 mSv $year^{-1}$ and 6% exceeded 20 mSv $year^{-1}$ from exposure to radon (Solomon, 2019). Although the total number of show cave workers in Australia is very small, the re-assessment indicates that radon exposure remains a significant radiation protection issue for show cave operators and workers.

ARPANSA has commenced work with show cave operators and workers to optimise protection against radon exposure for tour guides. This has involved site visits to educate workers, and collaboration with operators to develop protection strategies and monitoring programmes. ARPANSA will also explore cooperative arrangements with the mining industry to assess the levels of radon in underground mines.

3.3. Providing advice and guidance

Persons responsible for workplaces and public buildings found to have elevated levels of radon will require carefully considered advice and guidance on the potential health impact of past exposure and methods to minimise future exposure. Effective risk communication requires clear and coordinated messages aimed at target audiences. An assessment of perceptions and the level of knowledge regarding radon in the target audiences should be done both before and after a risk communication campaign.

In Australia, most control of elevated levels of radon will comprise of increasing ventilation in the building or workplace. However, there will be some cases where this may not be possible or cost-effective. In such cases, a radiation protection specialist will need to work with the management of the workplace or building to develop specific strategies to optimise protection against radon exposure. As community awareness increases and if there is a need to control radon exposure, regulatory authorities responsible for radiation protection will need to work with the radiation protection community to increase the number of services that can provide advice on radon exposure. By working with Worksafe Australia, ARPANSA can support the development of national uniform advice and industry-specific guidance on radon mitigation.

Through the development of a radon potential map, ARPANSA can map radon zones in Australia to identify areas of potential for elevated indoor levels of radon in homes and workplaces. The map is intended to help governments and other organisations to target risk reduction advice and guidance. Radon potential maps are developed using a combination of data on indoor radon measurements, geology, aerial radioactivity, and other geological information. A radon potential map builds on the post code maps generated as part of the 1990 survey of Australian homes (ARL, 1990).

3.4. Minimising levels of radon in new buildings

The 1990 survey of Australian homes (ARL, 1990) represents buildings that were constructed using building technology that did not focus on energy efficiency. This construction style resulted in well-ventilated houses that were typical for a majority of the Australian population, who live in temperate and subtropical climates. As Australia adopts new building technology to reduce total energy consumption and deliver more effectively heated and cooled dwellings, there is a need to understand and avoid negative impacts on indoor air quality. Modelling studies of home energy efficiency demonstrate that increasing the air tightness of dwellings can increase the mean indoor radon concentration (Milner et al., 2014). ARPANSA is committed to communicating with local governments in areas with high radon potential. This will alert local governments that new housing which aims to minimise air exchange to achieve energy efficiency may inadvertently elevate indoor levels of radon.

4. CONCLUSION

The Australian Radon Action Plan provides the overarching vision and direction for radon protection in Australia. It seeks to align priorities with national and international obligations, and presents a long-term strategy to optimise protection of people from exposures to radon and its progeny in homes and workplaces. The outcomes are designed to establish a strong foundation for future success.

It is recognised that indoor levels of radon in Australian homes are very low compared with most other countries. The shift from well-ventilated homes in subtropical and temperate climates to more energy efficient homes means that more Australians may be at risk from radon than ever before. When implemented, the goals of the Australian Radon Action Plan aim to reduce the risk of radon by increasing visibility and promoting broad attention for radon issues, research needs, and risk reduction practices for workplaces and public areas.

The success of the Australian Radon Action Plan will rely on stakeholder engagement and building partners who are affected by the actions or can influence implementation of the actions. As we build knowledge and monitor the performance of this plan, priority actions can be refined to better inform the steps we need to take to achieve the envisioned end result – reducing the risk of radon to the Australian population.

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ICRP approach for radiological protection from NORM in industrial processes

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Abstract–The International Commission on Radiological Protection (ICRP) recently issued ICRP *Publication 142* on radiological protection from naturally occurring radioactive material (NORM) in industrial processes. Industries involving NORM may give rise to multiple hazards, and the radiological hazard is not necessarily dominant. They are diverse and may involve exposure of people and the environment where protective actions need to be considered. In some cases, there is a potential for significant routine exposure of workers and members of the public. Releases of large volumes of NORM may also result in detrimental effects on the environment from radiological and non-radiological constituents. However, industries involving NORM present no real prospect of a radiological emergency leading to tissue reactions or immediate danger for life. Radiological protection in these industries can be appropriately addressed on the basis of the principles of justification of the actions taken and optimisation of protection using reference levels. An integrated and graded approach is recommended for the protection of workers, the public, and the environment, where consideration of non-radiological hazards is integrated with the radiological hazards, and the approach to protection is optimised (graded) so that the use of various radiological protection programme elements is consistent with the hazards while not imposing unnecessary burdens.

Keywords: NORM; Optimisation; Integrated approach; Graded approach

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) has recently engaged in a set of publications dedicated to applying the system of radiological protection to existing exposure situations. *Publication 126* (ICRP, 2014b) updated the recommendations for protection against exposure to radon. *Publication 132* (ICRP, 2016) is devoted to radiological protection from cosmic radiation in aviation. *Publications 109* and *111* (ICRP, 2009a,b) – on emergency exposure situations and living in long-term contaminated areas following a radiological emergency, respectively – are currently being updated. A publication is also in preparation dedicated to exposures resulting from contaminated sites from past industrial, military, and nuclear activities.

In the same line, in 2007, ICRP launched Task Group 76 (TG76) with the mandate to develop a report on the application of the Commission's recommendations on radiological protection of workers, the public, and the environment against exposures resulting from industrial processes using naturally occurring radioactive material (NORM). The aim of TG76 was to develop recommendations to cover the broad range of activities associated with the processing, production, use, and disposal of materials with enhanced levels of naturally occurring radionuclides. The report should also clarify the issues concerning the type of exposure situation, the categories of exposure, and the basic principles to be applied for the management of NORM. TG76 was relaunched in 2013 with a new membership.

The draft report by TG76 was available for public consultation on the ICRP website from 20 November 2018 to 22 February 2019. Twenty-five individuals and organisations provided comments, which were analysed and addressed by TG76. The report, modified accordingly, was approved by the Commission in July 2019, and issued in December 2019 as *Publication 142* (ICRP, 2019).

2. GENERALITIES ABOUT NORM

Radionuclides of natural origin are ubiquitous and are present in almost all materials on Earth. In general, they are not of radiological concern. Some human activities, however, have the potential to enhance radiation exposures from handling these materials.

Many organisations have produced comprehensive reviews of industries that may cause NORM-related radiation exposure of workers, the public, and the environment (UNSCEAR, 1982, 2008; EC, 1999; IAEA, 2006; EURATOM, 2013). Examples are given below. Further, previous industrial sites could have involved NORM, and these legacy sites may require attention.

- Extraction of rare earth elements.
- Production and use of metallic thorium and its compounds for their metallic properties and not for their fissile, fertile and radioactive properties.
- Mining and processing of ores (other than uranium or thorium for the nuclear fuel cycle).

- Oil and gas recovery process.
- Manufacture of titanium dioxide pigments.
- The phosphate mining and processing industry.
- The zircon and zirconia industries.
- Production of metal (tin, copper, iron, steel, aluminium, niobium/tantalum, bismuth, etc.).
- Combustion of fossil fuel (mainly coal).
- Water treatment.
- Geothermal energy production.
- Cement production and maintenance of clinker ovens.
- Building materials (including building materials manufactured from residues or by-products).

Typical industries involving NORM process a wide range of raw materials with different levels of activity concentrations, producing a variety of products, by-products, discharges, residues, and wastes. Although the radionuclides are not concentrated for their radioactive properties, these industries may or may not be of radiological concern depending on the activity concentrations in the raw materials handled, the processes adopted, the uses of final products, the reuse and recycling of residues, and the disposal of wastes.

Industries involving NORM are diverse, they do not correspond to a sector in itself, and they are often large industries of economic importance. These industries may give rise to multiple hazards, and the radiological hazard is not necessarily dominant. They may involve exposure of people and the environment where protective actions need to be considered. In some cases, there is a potential for significant routine exposure of workers and members of the public if suitable control measures are not considered. Releases of large volumes of NORM may also result in detrimental effects on the environment from radiological and non-radiological constituents. However, due to the activity concentration in NORM before and after processing, industries involving such materials present no real prospect of a radiological emergency leading to tissue reactions or immediate danger for life.

Industries involving NORM are generally subject to authorisation, although, in many cases, this is because of conventional hazards and not for radiological protection purposes, and these industries are familiar with risk management frameworks for the protection of workers, the public, and the environment. They should generally be able to apply the criteria and requisites set for radiological protection purposes. Most industries involving NORM have been ongoing for a long time, with concern about radiological protection being a relatively recent addition. While they have experience in risk management, these industries often have limited awareness of radiological protection; this can and should be developed.

Several stages of production involving NORM can be identified: mineral extraction and processing, fabrication and use of products, reuse and recycling of residues, management of waste, and dismantling or rehabilitation of sites. Some industries may involve almost all of these stages, and others may involve only some of them.

When by-products and residues are used as feedstock by other industries involving NORM and/or in common practice (e.g. building materials), NORM enters a cycle which is possibly endless (i.e. NORM can be moved and/or reprocessed from place to place).

Industries involving NORM may need to be controlled, and the system of protection, including the principles of justification of the actions taken and optimisation of protection, as well as the corresponding dose criteria and requisites, can be applied.

3. THE NEED FOR A GRADED APPROACH

3.1. Taking account of the diversity of radiation exposures

The primary purpose of the ICRP recommendations is to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure. The ICRP system of radiological protection aims primarily to protect human health, with the objective of managing and controlling exposures to ionising radiation so that deterministic effects (tissue reactions) are prevented and the risks of stochastic effects (mainly cancer) are reduced to the extent reasonably achievable. The system applies to all radiation exposure to any natural or man-made controllable sources (ICRP, 2007).

The radiological protection system was developed gradually during the 20th century, integrating advances in knowledge about the effects of radiation, the evolution of ethical and societal values, and the feedback experience from its practical implementation. On these bases, ICRP issued several sets of fundamental recommendations describing its radiological protection system, particularly: *Publication 26* (ICRP, 1977), *Publication 60* (ICRP, 1991), and *Publication 103* (ICRP, 2007).

From a historical perspective, it should be noted that the scope and priorities of protection have changed. Until the Second World War, the Commission was almost dealing solely with the protection of medical staff. After the War, the focus was mainly on nuclear energy and radiological protection developed to protect workers inside nuclear installations and members of the public outside. This resulted in a coherent and effective regime of radiological protection based on solid concepts, principles, and norms issued in *Publication 60* (ICRP, 1991).

However,the reality of nuclear accidents, together with the threat of malevolent events and rising concerns on natural exposures and exposure situations inherited from the past, in the 1990s profoundly challenged the *Publication 60* (ICRP, 1991) system and resulted in the general principles presented in *Publication 103* (ICRP, 2007).

3.2. Through the structure of the ICRP system of protection

The main innovation of *Publication 103* (ICRP, 2007) was the end of the two-speed protection system (practices vs interventions) set in *Publication 60*

(ICRP, 1991). In one case, that of practices, the protection system included the setting of maximum dose criteria which should not be exceeded (individual-related dose limits and source-related dose constraints) framing the implementation of the optimisation principle. In the other case, that of interventions, the protection system used minimum dose criteria, such as action levels or intervention levels. Their numerical values were generally higher than the maximum dose criteria for practices, and action was only required when they were exceeded.

Publication 103 (ICRP, 2007) now recommends a unified approach modelled on that for practices, regardless of the exposure situation. This unified approach provides the use of maximum dose criteria (dose constraints or reference levels) selected in accordance with the characteristics of the exposure situation, and implementation of the optimisation process with the aim of reducing exposures to as low as reasonably achievable. The dose limit can still be used when the source is fully controllable (i.e. in planned exposure situations, excluding medical exposure).

The unified approach of *Publication 103* (ICRP, 2007) does not prevent the use of a graded approach according to the type of exposure situation. This publication introduced three types of exposure situation: existing exposure situations, where the source already exists when a decision on control has to be taken; planned exposure situations, involving the deliberate introduction and operation of sources; and emergency exposure situations, which may occur from any unexpected situation and require urgent action in order to avoid or reduce undesirable consequences.

Beyond the inevitable overlaps between the three types of exposure situation, the new situation-based system has not always been fully understood, especially the distinction between existing and planned exposure situations. Many people consider that a source is no longer 'existing' when it is included in a controlled process. While the keyword in the definition of a planned exposure situation is 'deliberate' (but ICRP could not call it a 'deliberate exposure situation'), many people consider that an exposure situation is planned as soon as its management can be planned (forgetting that plans also exist to manage emergency situations). Sometimes, it sounds like a return to the old system of practices vs interventions, with planned exposure situations grouping situations under regulatory control while the others can be called 'existing exposure situations'. From the point of view of ICRP, all exposure situations should be controlled appropriately, and the type of an exposure situation is determined by the status of the source.

Since the system of protection should be commensurate with the level of risk, the situation-based system recommended in *Publication 103* (ICRP, 2007) should be seen as a way to allow for a graded approach in protection. In this regard, several elements founding the gradation of radiological risk warrant the distinction between existing and planned exposure situations.

- Controllability of the source: when a source is introduced deliberately (essentially for its radioactive properties), it can be fully controlled from design to disposal. A decision on control of a source that already exists has to take the state of it into

account, even when the source is deliberately modified from its original state. This can affect the controllability of existing exposure situations.

- Level of risk: the level of risk is not only dependent on the level of exposures, but more globally on the distribution of the individual doses of all exposed people, including its evolution. It means that individual and collective exposures, as well as acute and chronic exposures, should be taken into account. Experience shows that exposures in existing exposure situations are generally chronic, and they can be higher than those in many planned exposure situations (well controlled). However, apart from some radon exposures, doses are rarely of a high level, regardless of the degree of control.
- Anticipation of exposures: when the source is introduced deliberately, the quantities of radioactive materials, their physicochemical forms, their concentrations, and flows are known precisely in advance. The facility is designed accordingly, including workstations. The level of corresponding exposures can be anticipated fairly precisely, facilitating control. When the source already exists, the above-mentioned parameters may be variable. Exposures can be anticipated but their levels cannot be fully assessed without characterisation of the exposure situation. This may be an impediment to control.
- Prospect to deterministic effects: in a planned exposure situation, without permanent vigilance in control, doses can reach a high or very high level, potentially inducing deterministic effects. On the contrary, whatever the degree of control, exposures arising from existing exposure situations are 'capped'. For example, no process involving NORM leads to a concentration of radionuclides such that the associated exposure can exceed a dose ceiling of the order of a few mSv per year – at worst, a few tens of mSv per year in a few cases – even without protective action. Exceptions would be very rare. For diverse reasons, other existing exposure situations present the same feature. Such levels of exposure cannot induce deterministic effects, even radon exposure. It is a key characteristic of existing exposure situations from a radiological protection point of view.
- Prospect of emergency: in the same line, while the loss of control of the source in a planned exposure situation may lead to an emergency exposure situation, it is quite never the case from an existing exposure situation.
- Multi-hazards situation: although it is grossly in line with the protection approach for conventional hazards, the system of radiological protection is generally more complex, more detailed, and more demanding, and it includes many specific features (e.g. specific expertise, specific procedures, specific controls). Practically, the focus is on the radiological hazard as soon as it is identified, even when it is not dominant. Controlling this hazard requires considerable attention and resources, potentially to the detriment of the control of other hazards. In the end, control of the different hazards may be unbalanced. Furthermore, in the case of limited resources, protection against hazards other than radiological hazards may be neglected. The problem can arise in both existing and planned exposure situations.
- When *Publication 103* (ICRP, 2007) explains how to select dose constraints and reference levels according to the characteristics of the exposure situation, some

key characteristics are mentioned: controllability of the source, benefit from the exposure situation (individual or societal, direct or indirect), and additional protection requirements for individuals who are more exposed (e.g. workers vs public). These characteristics can be used not only for the selection of dose criteria but also for a broader graded approach.

- Finally, economic and societal considerations may intervene in the establishment of a graded protection approach, whatever the type of exposure situation.

Whether industries involving NORM are existing or planned exposure situations is a controversial issue. It was the main point raised in comments during the public consultation. While both international (IAEA, 2014) and European (EURATOM, 2013) basic safety standards consider that these industries should be managed as planned exposure situations as far as exemption levels are exceeded, *Publication 103* (ICRP, 2007) indicates that NORM is a 'well-known example' of existing exposure situations. This opinion is repeated in *Publication 142* (ICRP, 2019). However, when NORM is processed for its radioactive, fissile, or fertile properties, ICRP considers it a planned exposure situation.

Indeed, although industries involving NORM are diverse, their main characteristics put them on the side of existing exposure situations rather than planned exposure situations: the source already exists and, even if it can be introduced deliberately in the industrial process, it is mainly incidentally; the source may be modified from its original state, but not for its radioactive properties (otherwise the exposure situation is considered as planned); exposures can be anticipated but, because the quantities, physicochemical form, concentrations, and flows of NORM are intrinsically variable, the level of exposures cannot be fully assessed without characterisation of the exposure situation; and exposures can be higher than those in nuclear industry, for example, but the exposure situation presents no real prospect of emergency leading to tissue reaction or immediate danger to life.

A graded approach is also appropriate for industries involving NORM due to the economic importance of these industries, large volumes of residues and wastes, limited options for management, and potentially high regulation costs in relation to reduced exposure. Industries involving NORM are generally situations where multiple hazards and pollutants can be present and where the radiological hazard is not dominant.

In such a context, the radiological protection system is not necessarily the only driving force in safety, and an integrated approach to all hazards should be employed. The graded approach to protection should first take account of the existing knowledge and experience of these industries in the management of industrial hazards, and then pragmatically integrate any additional measures necessary for the purposes of radiological protection (ICRP, 2019).

The ICRP system of radiological protection is also structured with categories of exposure. Processes involving NORM may lead to occupational exposure, public exposure, and environmental exposure. It should be noted that not all workers are intended to be considered as occupationally exposed. As explained in *Publication 103*

(ICRP, 2007), the Commission limits its use of 'occupational exposures' to radiation exposures incurred at work as a result of situations that can reasonably be regarded as being the responsibility of the operating management. A specific graded approach is recommended in *Publication 142* (ICRP, 2019) for the protection of workers (see below).

3.3. Through implementation of the radiological protection principles

Implementation of the three basic principles of radiological protection can also be the subject of a graded approach.

According to *Publication 103* (ICRP, 2007), the principle of justification requires that any decision that alters the radiation exposure situation should do more good than harm. It is also emphasised that for existing exposure situations, the justification principle is applied in making the decision regarding whether to take action to reduce exposure and avert further additional exposures. In industries involving NORM, as recommended in *Publication 142* (ICRP, 2019), it is primarily applied for both ongoing and new processes when making the decision regarding whether or not to implement a protection strategy for radiation exposures, after radiological characterisation of the exposure situation and taking into account health, economic, societal, environmental, and ethical considerations. As many industries involving NORM already exist, it has been suggested that a national list of industries involving NORM for which a radiological risk assessment should be undertaken in order to determine if a protection strategy is justified should be established. The level of control may then be determined through implementation of the optimisation principle.

The optimisation of protection is the central principle of the ICRP system. As far as human protection is concerned, it is defined as the process to keep the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures as low as reasonably achievable, guided by appropriate individual dose criteria, and taking into account economic and societal factors. The impact to the environment should also be kept as low as reasonably achievable (ICRP, 2007). In the case of industries involving NORM, the optimisation process is implemented in generally the same way as for other industries. However, because of the prevailing circumstances, and notably as the radiological protection should be integrated in a broader protection strategy in which the radiological hazard is not necessarily dominant, the options to reduce doses may be more limited and/or may require different resources. Such challenges suggest the need for flexibility in implementation of the optimisation process and application of regulatory structures. The involvement of relevant stakeholders early in the optimisation process will contribute to selecting the best option for protection, taking into account the characteristics of the actual exposure situation, and thus potentially to making protection more effective and efficient (ICRP, 2019).

The principle of application of dose limits is normally reserved for planned exposure situations (ICRP, 2007). However, it is recognised in *Publication 142*

(ICRP, 2019) that some authorities have specified dose limits for some industries involving NORM, in addition to industries where NORM is processed for its radioactive, fissile, or fertile properties. This may be particularly suitable in circumstances when the source is well characterised, there is an ongoing potential for significant levels of exposure, and it is necessary to properly demonstrate ongoing control of the radiological hazards.

The Commission recommends the use of reference levels as dose criteria in existing exposure situations. The reference level represents the value of dose used to guide and drive the optimisation process. Selection of the reference level should consider the actual individual dose distribution, with the objective of identifying those exposures that warrant specific attention. Reference levels are guides for selecting amongst protective options in the optimisation process in order to maintain individual doses as low as reasonably achievable, taking into account economic and societal factors, and thus to prevent and reduce inequities in dose distribution. Reference levels are also benchmarks against which the results of protective actions can be judged to determine if protection is reasonably optimised and effective.

As far as the protection of non-human species is concerned, the Commission recommends the use of derived consideration reference levels (DCRLs). DCRLs can be considered as a band of dose rates within which there is likely to be some chance of deleterious effects of ionising radiation occurring to individuals of that type of Reference Animal or Plant (derived from a knowledge of defined expected biological effects for that type of organism).

4. PROTECTION OF WORKERS, THE PUBLIC, AND THE ENVIRONMENT

4.1. Protection of workers

Workers in industries involving NORM are frequently exposed to radiation and other hazards. The radiological risk is often not the dominant hazard, and may historically not even have been a consideration. In such a context, there is often a lack of radiological protection awareness or a culture supporting such protection. However, such industries do have experience and expertise in the management of occupational health and safety, and there is an opportunity to build a radiological protection culture in an integrated fashion. In many cases, actions to reduce workplace hazards, such as airborne dust, will also restrict radiation exposures.

Experience shows that it is easier to develop an integrated multi-hazards approach to worker protection starting from conventional health and safety standards than from the system of radiological protection. In that context, the Commission recommends a realistic and pragmatic attitude, starting with characterisation of the exposure situation, and the integration, as necessary, of specific radiological protective actions to complement the protection strategy already in place or planned to manage other workplace hazards.

In practice, a graded approach can be realised through the selection of suitable dose reference levels, the selection of appropriate collective or individual protective

actions, and the integrated implementation of these actions. Exposure to radon is also treated using a graded approach, based first on application of typical radon prevention and mitigation techniques (see below), as described in *Publication 126* (ICRP, 2014a). The practical implementation of this approach will also help to determine whether or not the workers should be considered as occupationally exposed to radiation.

The appropriate reference level for the protection of workers can be selected based on the 1–20-mSv band recommended by ICRP for existing exposure situations (ICRP, 2007), taking into account the characteristics of the exposure situation, notably the actual and potential exposure pathways, the individual dose distributions, and the prospect for optimisation. The following values are recommended in *Publication 142* (ICRP, 2019):

- of the order of a few mSv $year^{-1}$, or below, for most cases; and
- above a few mSv, but very rarely exceeding 10 mSv $year^{-1}$, when necessary because of the circumstances involved.

As indicated above, these doses exclude exposures from radon or thoron.

For the selection of protective actions, the starting point should always be the existing industrial safety and hygiene controls, before the integration of additional radiological protection controls, as necessary. According to the graded approach, control of the workplace and the conditions of work to eliminate or minimise the risk should be considered first. Examples are characterisation of the situation, provision of radiological protection expertise, initial actions to prevent or reduce the hazard, delineation of areas, and engineering controls.

These protective actions, complemented by at least a general information programme for workers, may be sufficient for their protection in most industries involving NORM. However, they can be complemented, as necessary, by protective actions related to the individuals, such as: working procedures; instruction and training; personal protective equipment; dose assessment; dose recording; and health surveillance, as necessary. Moving from controls of the workplace to individual controls needs to be considered carefully as the individual controls may be costly.

Most of these collective and individual protective actions need to be implemented only to the extent necessary to achieve acceptable protection. According to the graded approach, the modalities for implementing these actions should also be adapted to the circumstances.

Workers are likely to be considered as occupationally exposed when, despite all reasonable efforts to reduce exposure, elevated individual doses persist, and when the application of special working procedures is necessary to perform the job.

This integrated and graded approach for the protection of workers can also serve as the basis for creating a common understanding between regulatory authorities and other stakeholders (e.g. operators; workers and their representatives; and health, safety, and environmental professionals) of the radiological aspects of the various

processes involved, and the ways in which these aspects can be addressed reasonably and effectively.

4.2. Protection of the public

A similar integrated and graded approach should be implemented for protection of the public. The general approach should start with characterisation of the exposure situation in order to determine who is exposed, when, where, and how. This characterisation includes the analysis of exposure pathways and dose assessments, and forms the basis for the justification of a protection strategy. Next, the optimisation process should be implemented, including the selection of a reference level, the selection and implementation of protective actions, the involvement of stakeholders in the decision-making process, and the provision of long-term monitoring of the situation, if necessary. Both radiological and non-radiological exposures should be considered and integrated in the optimisation process. This process should be implemented in a reasonable way, keeping in mind the ethical values of beneficence/non-maleficence, prudence, justice, and dignity (ICRP, 2018).

A reference level for protection of the public should be selected of the order of a few mSv per year, or below, to meaningfully guide the process of optimisation of protection. Protection of the public should be addressed as a whole (i.e. taking into account the different exposure pathways). In a given situation, the pathways need to be considered with respect to NORM discharge, waste, residue, and possible legacy sites. In practice, the most exposed individuals to each pathway belong to different groups, so the reference level can generally be applied to any given pathway. The reuse and recycling of NORM residues may be the starting point of a new NORM process.

Public exposure to radon or thoron arising from industries involving NORM is mainly due to the reuse of residues (e.g. in building materials), and should be dealt with according to the national action plan (see below) as recommended in *Publication 126* (ICRP, 2014b). The use of building materials should be considered as one of the exposure pathways, and addressed with the aim of promoting those that do not exceed the reference level (e.g. through information, labelling, and reasonable and feasible incentive or even mandatory provisions).

4.3. Protection of the environment

Large quantities of NORM may be present in the environment in the form of mixed material together with other contaminants. The application of an integrated and graded approach for protection of the environment, as for the protection of workers and the public, was mentioned in several comments during the public consultation.

Industries involving NORM have generally been following common standards to protect the environment from pollutants other than radioactivity. In *Publication 142*

(ICRP, 2019), the Commission recommends an integrated approach, which should encompass:

- all stressors or factors of concern (i.e. radiological and non-radiological); and
- human health effects due to environmental exposure of humans, and ecological effects due to environmental exposure of non-human species and their assemblage (i.e. from populations of species to communities and ecosystems).

Generally, this approach can be implemented in a graded way, as recommended in any environmental impact assessment (EIA), by starting with a very simple conservative assessment (screening stage making use of generic input data under the assumption of cautious exposure scenario) and then, if needed, by increasing the complexity and realism of the assessment as necessary (e.g. by using site-specific data and more detailed and realistic exposure scenarios) until a clear and defensible conclusion is reached (IAEA, 2018).

In the case of complex situations, the radiological characterisation of NORM released in the environment may be performed for the source and the environmental media of concern (e.g. air, water, sediment, soil). To be able to assess exposure of non-human species, it may be relevant to identify the mobility of radionuclides, their spatial and temporal variation, environmental pathways to plants and animals, and their bioavailability. An approach with Reference Animals and Plants and DCRLs has been developed in specific ICRP publications (ICRP, 2008, 2014a).

EIAs can be used as a basis for the justification of actions aimed at the protection of both human and non-human species, because decisions on restricting discharges will impact all types of exposure. The involvement of stakeholders is recommended. The long-term preservation of the environment is a global concern of the society, to which application of the ethical values of radiological protection can usefully contribute.

4.4. Protection against radon exposure

Radon may be a major source of exposure in facilities with NORM. The source of radon may be soil, processed NORM, or building materials. Some building materials may be made with NORM residues. *Publication 126* (ICRP, 2014b) addresses radon exposure in general and so is relevant for radon exposures in industries involving NORM. However, in accordance with comments received during the public consultation, explanation on how radon exposure associated with NORM processes should be dealt with is provided in *Publication 142* in sections related to the protection of workers and the public. This explanation is coherent with *Publication* 126.

An integrated approach for protection against radon exposure in all buildings is recommended, whatever their purpose and the status of their occupants. The strategy of protection in buildings, implemented through a national action plan, should include both prevention and mitigation of exposure on the basis of the optimisation principle, and use a reference level, expressed for practical reasons in concentrations

in air, to facilitate implementation. The Commission recommends that national authorities should set a reference level for radon in air that is as low as reasonably achievable in the range of 100–300 Bq m^{-3}, taking the prevailing economic and societal circumstances into account.

In workplaces, the Commission considers that radon, irrespective of the source, should be managed as a single source using the reference level set in the national action plan. When concentrations still exceed the reference level following application of radon prevention and mitigation measures, it may be necessary, within a graded approach, to undertake additional assessments of exposure in terms of dose. In such a case, a reference level of the order of 10 mSv $year^{-1}$ should be used.

Workers may be considered as occupationally exposed in some workplaces identified in a national list of activities or facilities in which workers are inevitably and substantially exposed to radon, and this exposure is more intimately and obviously related to their work activities. It may also be the case if the dose associated with radon exposure cannot be reduced to the reference level of the order of 10 mSv $year^{-1}$. In cases where radon exposure is concomitant with exposure from other radionuclides, the Commission recommends a pragmatic approach addressing radon exposure separately.

5. CONCLUSION

Any controllable source should be controlled as appropriate through implementation of the radiological protection system as recommended by ICRP. This system is now unified whatever the type of exposure situation. However, the basic principles of radiological protection should be applied using a graded approach, commensurate to the level of risk and other characteristics of the exposure situation. Regulatory control should be adapted accordingly.

Industries involving NORM may need to be controlled. The system of radiological protection, including the principles of justification and optimisation of protection, as well as the corresponding dose criteria and requisites, can be applied. In order to be adapted to the features of industries involving NORM, the Commission recommends, in *Publication 142* (ICRP, 2019), an approach considering the protection strategies already implemented by these industries to manage the hazards they are facing as a starting point, and then estimating, after characterisation, the need for further action for protection against radiation. Such an integrated approach can then be graded with proper balance between the different hazards, adopting a reasonable and prudent attitude, and taking economic and societal factors into account. Involvement of relevant stakeholders in the decision process is crucial.

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Trend of strengthening clearance regulation in Japan and concerns about its worldwide effects on regulations for natural and artificial radionuclides

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Abstract–The Nuclear Regulation Authority (NRA) of Japan invited comments from the public on a revised guide on measurement and evaluation for clearance in 2019, which included a strict decision on how to treat uncertainties in the measurement and the nuclide vector. To resolve the issue on the uncertainty in clearance, a probabilistic approach had been established previously in the Atomic Energy Society of Japan Standard and incorporated into International Atomic Energy Agency (IAEA) Safety Report No. 67. NRA's new decision on the uncertainty in clearance was up to 10 times stricter than the probabilistic approach. This issue has been discussed at an international level in the framework of the ongoing revision of IAEA Safety Guide RS-G-1.7. This discussion on the uncertainty in clearance has raised serious concerns about its effects on other radiological protection regulations worldwide. This is because if we need strict treatment for the uncertainty in clearance, the same or even stricter treatment for conformity assessment may have to be applied to other radiological protection criteria for doses exceeding 10 μSv year^{-1}. Radiological protection experts including regulators, professionals, and operators should be aware of the essential meaning of the radiological protection criteria by considering the background scientific basis on which they were established.

Keywords: Clearance level; Uncertainty; Conformity assessment; Regulation

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

1. INTRODUCTION

The term 'clearance' is defined as 'removal of regulatory control by the regulatory body from radioactive material or radioactive objects within notified or authorized facilities and activities' in the International Atomic Energy Agency (IAEA) Safety Glossary. The Nuclear Regulation Authority (NRA) of Japan drafted a revised guide on measurement and evaluation for clearance on 5 June 2019 which included a decision on how to treat the uncertainties in the measurement and the nuclide vector [ratio of difficult-to-measure nuclides, such as beta and alpha emitters (e.g. Sr-90 and Pu-239), to easy-to-measure nuclides, such as gamma emitters (e.g. Co-60 and Cs-137)]. This draft guide was open to public comments until 5 July 2019. More than 20 radiological protection experts submitted their individual comments objecting to NRA's strict decision on the uncertainties in the measurement and the nuclide vector in compliance with the clearance level. To resolve this issue on the uncertainty in clearance, a probabilistic approach had been established previously in the Atomic Energy Society of Japan (AESJ) Standard (AESJ, 2005) and incorporated into IAEA Safety Report No. 67 (IAEA, 2012). NRA's new decision on the uncertainty in clearance is up to 10 times stricter than the probabilistic approach.

In this paper, to address the issue on the uncertainty and facilitate constructive international discussion on radiological protection regulation among radiological protection experts including regulators, professionals, and operators, the clearance regulation for the treatment of uncertainty in Japan is historically overviewed, and international standards associated with uncertainty in measurements are reviewed. In addition, treatment of the uncertainty to be achieved in clearance is discussed from the viewpoints of the methodology used to derive clearance levels, the balance in a radiological protection system with a graded approach, the difference between product control and radiological protection, and understanding of the health risk of radiation on the order of $10\,\mu Sv\,year^{-1}$ by both the public and the regulators.

2. CLEARANCE REGULATION IN JAPAN

2.1. Approval of clearance application with probabilistic approach in 2006

In Japan, the Reactor Regulation Law was amended in May 2005, giving new clearance levels and the procedure for monitoring their compliance. The relevant regulations have been in force since December 2005.

The Standards Committee of AESJ started examining non-governmental standards for judging clearance in May 2003, and finally released the standard entitled 'Monitoring for compliance with clearance level' (AESJ, 2005) in August 2005. To resolve the issue of how to treat the uncertainties in the measurement and the nuclide vector used in clearance, a probabilistic approach was established in this AESJ standard and incorporated into IAEA Safety Report No. 67 (IAEA, 2012). If the nuclide vector is very high, exceeding a level sufficient to select the difficult-to-measure nuclide as a target nuclide for judging clearance (e.g. in the case of a nuclear

power plant with nuclear fuels damaged by an incident), this issue would be very serious. This probabilistic approach provides a method of judging whether the uncertainty of the nuclide vector is too large by giving a Monte Carlo calculation tool for free use that can be downloaded from the website of the Standards Committee of AESJ (http://criepi.denken.or.jp/en/nuclear/download/index.html). If it is too large, operators are required to set a safety factor for clearance judgement, which means a reduction in the clearance level for the easy-to-measure nuclides. If it is not too large, operators do not have to consider the uncertainty further in the clearance judgement.

In June 2006, the Japan Atomic Power Company (JAPC) submitted the first application regarding methods for the measurement and assessment of the radioactive concentration of waste from the decommissioning of the Tokai power station in accordance with the amended Reactor Regulation Law. The probabilistic approach in the AESJ standard was first used in the application for clearance from the Tokai power station. JAPC finally obtained approval from the Ministry of Economy, Trade and Industry/Nuclear and Industrial Safety Agency (METI/NISA) in September 2006.

2.2. New standard of examination for uncertainty in clearance in 2019

In September 2016, JAPC submitted an application for clearance regarding the decommissioning of Unit 1 of Tsuruga power station in Japan using the above-mentioned probabilistic approach. However, the regulatory organisation responsible for the approval of clearance was changed from METI/NISA to NRA in September 2012, and the probabilistic approach has not been approved as of September 2019. To justify not applying the probabilistic approach, NRA gave the reason that it was revising the guide for measurement and evaluation for clearance to give a clear requirement of the uncertainty, referring to ISO11929 (ISO, 2010). One of the clear requirements of the uncertainty was that when performing clearance measurements, the upper confidence level of the measurement and evaluation must be below the clearance level, taking relevant uncertainties into account.

NRA carried out a public consultation from 6 June to 5 July 2019 in accordance with the Administrative Procedure Act. Although more than 20 radiological protection experts submitted their individual comments objecting to NRA's strict decision on the uncertainties in the measurement and the nuclide vector in compliance with the clearance level, NRA discussed the results of the public consultation (e.g. considering the occurrence of an event exceeding the clearance level cannot be sufficiently restricted to low probability by the AESJ standard's approach), and finally decided to make the requirement of the uncertainty valid in the standard of examination established on 11 September 2019 (NRA, 2019), taking into consideration a precedent in Germany. The details of the precedent are described in the following section. NRA's new decision on the uncertainty in clearance is up to 10 times stricter than the probabilistic approach. Regarding the term 'stricter', one may argue that from the perspective of ensuring the quality of the clearance measurement, it is natural to require that the measurement uncertainty should be considered in the

conformity assessment, and it is not appropriate for this type of effort for ensuring the quality of clearance measurement to use the term 'stricter'. However, the author considers that such arguments are not applicable because it is an important fact that radiation measurement has been well managed with sufficiently high quality to date, restricting the uncertainty of the measurement within approximately 30% by satisfying a detection limit set below the required activity level without using NRA's approach. This is described in detail in Section 4.3.

It should be noted here that there are some aspects to be taken into account in NRA's new decision. Prior to the establishment of the new standard of examination, NRA had approved clearance applications on the basis of the approach similar to the standard of examination regarding the uncertainty of measurement. This indicates that the new standard of examination was established for clarification of such a requirement for uncertainty already used in the experiences obtained from the past clearance approvals. In addition, NRA also revised the standard of examination for clearance regarding requirements other than the uncertainty (e.g. deletion of requirement for 10 important radionuclides to be selected mandatorily, increase in maximum mass of decision unit for clearance, and expansion of type of solid materials for clearance) on the basis of their own knowledge accumulated in the experiences from prior clearance approval and the result of communication with operators in a transparent way. Nevertheless, regarding the requirement for the uncertainty, it is very unfortunate that the discussions with radiological protection experts who were associated with establishment of the AESJ standard were not carried out officially prior to the public consultation.

3. INTERNATIONAL STANDARDS FOR UNCERTAINTY IN MEASUREMENTS

ISO11929 is an international standard entitled 'Determination of the characteristic limits (decision threshold, detection limit and limits of the coverage interval) for measurements of ionizing radiation'. Although NRA referred to ISO11929 (ISO, 2010) for the requirement on uncertainty in the revised guide, neither ISO1129 in 2010 nor the newly revised ISO11929 (ISO, 2019a,b,c) include a description of conformity assessment using the upper confidence level of the measurement and evaluation data. ISO11929 simply provides a scientific foundation for the concepts of the decision threshold, the detection limit for measurements, and the coverage interval (called the 'confidence interval' in 2010).

JCGM106 (ISO/IEC Guide 98-4, 2012), entitled 'Evaluation of measurement data – the role of measurement uncertainty in conformity assessment' (JCGM, 2012), is an internationally used document providing standards or guidelines regarding conformity assessment considering the uncertainty of measurements. In this guide, the term 'conformity assessment' is defined as 'activity to determine whether specified requirements relating to a product, process, system, person or body are fulfilled'. This guide provides general guidance and procedures for assessing the conformity of an item (entity, object, or system) with specified requirements. Examples of

quantities intended to be measured for assessing the conformity are given in the scope of this guide (e.g. a gauge block, a grocery scale, or a blood sample). The scope of this guide seems to be mainly applied to the product control with a very severe requirement for accuracy (e.g. in the size or mass of the product). An example of the conformity assessment in this guide is shown in Fig. 1.

A measurement result can be summarised by giving a coverage interval with an associated coverage probability (e.g. 95%) for a measurand (conforming value) y. This guide shows as an example that if a coverage interval with a coverage probability of $\geq$95% lies within the tolerance interval, conformity can be decided.

This guide was adopted in a recommendation (SSK, 2016) by the German Commission on Radiological Protection (SSK) in September 2016 regarding the conformity assessment in radiation measurement. In addition, the same approach to the conformity assessment in clearance decisions using the upper limit of the 95% confidence interval can also be found in other documents [e.g. the German Institute for Standardization, Annex K.4 in DIN 25457-1 (DIN, 2014), Chapter 8 in SKB (Swedish Nuclear Fuel and Waste Management Company) Report R-17-05 (SKB,

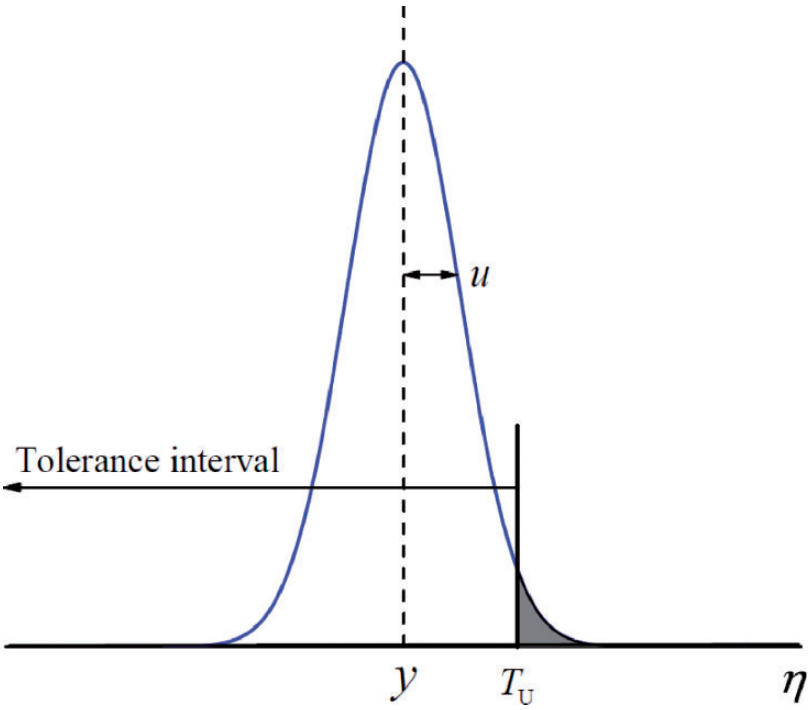

Fig. 1. Relationship between a single upper tolerance limit T_U and best estimate y of a conforming value, where u is associated standard uncertainty of normal probabilistic density function (blue curve). The conforming values lie in the interval $\eta \leq T_U$, where η is the variable describing possible values of a measurand (JCGM, 2012).

2017), and Appendix 7.1 in A Nuclear Industry Code of Practice (CEWG, 2005)]. NRA's approach to the uncertainty of measurement may be supported by these precedents in other countries, although a precedent in Germany, namely the SSK recommendation, was only cited in NRA's new standard examination as mentioned in Section 2.2.

4. DISCUSSION

As mentioned above, according to the international guide ISO/IEC Guide 98-4: 2012 (JCGM, 2012), it seems to be justified for NRA in Japan and the above-mentioned precedents in the other countries to require that the upper confidence level of the measurement results must be below the clearance level, taking relevant uncertainties into account. However, this requirement should be discussed carefully from the viewpoint of radiological protection. As this issue has also been discussed at an international level in the framework of the ongoing revision of IAEA Safety Guide RS-G-1.7 (IAEA, 2004), there is a possibility that this requirement might be shared worldwide in due course, leading to worldwide effects on clearance regulations among the IAEA member states.

Also, this requirement on the uncertainty in clearance raises serious concerns about its effects on various other radiological protection regulations for natural and artificial radionuclides. This is because if we need strict treatment for uncertainty, even in the case of compliance with a trivial dose criterion for clearance, the same or a stricter treatment for conformity assessment may have to be applied to other radiological protection criteria for doses exceeding 10 μSv year^{-1} (e.g. dose limits for workers and the public, national regulatory levels for radon concentration, surface contamination criteria for daily radiation control using survey meters, ambient dose equivalent rates on an external surface and at 2 m distance from the surface of transport packages, etc.), derived discharge limits for liquid and gaseous natural and artificial materials, and on- and off-site measurements in Fukushima. Actually, this requirement on uncertainty has been applied to an example of the conformity assessment in the radiological legal limit for Cs-137 in foodstuffs, which shows that the measurement result does not conform to the requirement because the upper confidence level (95th percentile value 101.1 Bq kg^{-1}) of the measurement exceeds the legal limit (100 Bq kg^{-1}) (Michel, 2017). This example is not assumed to be in the existing exposure situation after the Fukushima Dai-ichi nuclear power plant accident. However, this may be a case that will affect the off-site management in Fukushima (e.g. methodology for assessing the conformities of legal limits of activity concentrations in agricultural and marine products and other foodstuffs, and of legal screening levels for contaminated wastes after the Fukushima Dai-ichi nuclear power plant accident).

There is a need for the international radiological protection community to review whether the strict requirement using the upper confidence level is justified for compliance with clearance levels and other radiological protection criteria, taking into consideration all discussions from various viewpoints given in the following sections (e.g. the methodology used to derive clearance levels, the balance in a radiological

protection system with a graded approach, the difference between product control and radiological protection, and the understanding of the health risk of radiation on the order of 10 μSv year^{-1} by both the public and the regulators).

4.1. Methodology used to derive the clearance level

4.1.1. IAEA Safety Guide RS-G-1.7 and Safety Report Series No. 44

The exemption levels for bulk solid materials containing artificial radionuclides were provided in IAEA Safety Guide RS-G-1.7 (IAEA, 2004). This safety guide also provides the values of activity concentrations for radionuclides of natural origin, derived using the exclusion concept. These exemption and exclusion levels have been incorporated into the International Basic Safety Standards (BSS) as clearance levels (IAEA, 2014). Details of the assumptions used to derive clearance levels are provided by IAEA Safety Report No. 44 (IAEA, 2005).

In the derivation of clearance levels for artificial radionuclides, two dose criteria (10 μSv year^{-1} for realistic scenarios and 1 mSv year^{-1} for low-probability scenarios) were used in accordance with international agreements. This indicates that clearance levels have been determined while permitting the possibility of a dose exceeding 10 μSv year^{-1} in the case of low-probability situations. This permission can also be found in a procedure in which the clearance levels were selected as rounded values (e.g. 0.1, 1, 10, and 100 Bq g^{-1}) from calculation results of the radioactivity concentration that is equivalent to the dose criterion for each scenario. One more important point is that many conservative assumptions are included in the derivation of clearance levels.

Taking into account all of the above methodologies used to derive clearance levels, practical application of the methodology of the conformity assessment provided by international standards [e.g. ISO/IEC Guide 98-4: 2012 (JCGM, 2012)] to clearance regulations would lead to a serious imbalance between the concepts (or assumptions) adopted in the derivation of clearance levels, and strict requirements for the uncertainty of measurements in accordance with the regulation.

4.1.2. Publication 104

Publication 104 provides a definition of the scope of radiological protection control measures through regulations (ICRP, 2007b). Para. 95 contains an important phrase regarding uncertainties in the measurement and the nuclide vector:

> *In the case of a mixture of nuclides, it is generally only practical to measure easily measurable gamma emitters. To estimate the other alpha or beta emitters, most applicants of clearance use a previously assessed nuclide spectrum (namely, a nuclide vector) to ensure that the sum of the values obtained by dividing radioactivity concentrations by clearance levels is lower than 1 (IAEA, 2004). The Commission recognises that there may be uncertainty (or variation) in the radionuclide composition of a material. In such a case, there are some concerns that the public could be exposed to a dose above the dose criterion for exemption without further consideration (10 μSv/year), although this has quite a low probability of occurring. However, in the derivation of exemption levels in the BSS*

(IAEA, 1996) and in the safety guide on the application of the concepts of exclusion, exemption, and clearance (IAEA, 2004), which were agreed internationally, two dose criteria were used; 0.01 mSv/year for realistic scenarios and 1 mSv/year for low-probability scenarios. This indicates that the exemption levels agreed under the aegis of intergovernmental organisations allow the possibility of doses greater than 10 μSv/year in the case of low-probability situations. In this regard, the Commission considers that, in cases of uncertainty (or variation) in the radionuclide composition of a material, there is not usually a need to make clearance levels stricter. However, if the uncertainties in nuclide composition are very large, or if the presence of alpha- and beta-emitting nuclides cannot be adequately inferred through gamma measurements, the regulatory body may establish specific criteria for clearance, or may demand assessments involving radionuclide analysis in addition to, or in place of, gamma measurements' (ICRP, 2007b).

As seen in the above paragraph in *Publication 104* (ICRP, 2007b), ICRP considers that there is not usually a need for the activity concentration level for the measurable nuclide to be confirmed as lower and stricter, taking the uncertainties for radionuclide composition (or nuclide vector) into consideration. Instead, ICRP recommends the establishment of specific criteria for clearance if the uncertainty in the nuclide vector is too large. One of the specific criteria would be the probabilistic approach given in the AESJ standard (AESJ, 2005) and IAEA Safety Report No. 67 (IAEA, 2012). As ICRP recommended, if the uncertainty in the nuclide vector is judged to be smaller using specific criteria, there would be no need to apply a methodology of conformity assessment provided by international standards [e.g. ISO/IEC Guide 98-4: 2012 (JCGM, 2012)] to regulations for clearance.

4.2. Balance in radiological protection system with a graded approach

Regarding a graded approach, IAEA GSR Part 3 Requirement 6 states that:

The application of the requirements of these Standards in planned exposure situations shall be commensurate with the characteristics of the practice or the source within a practice, and with the likelihood and magnitude of exposures.

3.6. The application of the requirements of these Standards shall be in accordance with the graded approach and shall also conform to any requirements specified by the regulatory body (IAEA, 2014).

In addition, in a chapter defining the terminology in GSR Part 3, the graded approach is defined as:

For a system of control, such as a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is

commensurate, to the extent practicable, with the likelihood and possible consequences of, and the level of risk associated with, a loss of control (IAEA, 2014).

As clearance and exemption are also addressed in Requirement 8 in GSR Part 3, the above-mentioned requirements can be summarised specifically for clearance in an easy-to-understand manner: the requirements for clearance shall be applied using a method in which the stringency of the control measures is commensurate with the level of risk associated with 10 $\mu Sv\ year^{-1}$.

In the process of derivation of the clearance levels, the procedure in which the clearance levels were selected as rounded values (e.g. 0.1, 1, 10, and 100 $Bq\ g^{-1}$) may be a form of graded approach. One may argue that the margin which can be gained by the graded approach is already fully exhausted in derivation of the clearance levels, and any additional dose risks arising from remaining measurement uncertainty in the radioactive concentration measurement cannot be justified. Others may argue that the suggestion that serious measurements are not necessary is not an argument that comes out of the graded approach concept at all. However, the author considers that such arguments are not applicable because the stringencies between the derivation of clearance levels and conformity assessment for clearance levels should be well balanced. Moreover, the conformity assessment in compliance with such a rounded value to the nearest power of 10 using a near-logarithmic rounding approach does not require too much precision. For this reason, according to the graded approach, as the health risk of radiation on the order of 10 $\mu Sv\ year^{-1}$ is trivial, the use of a stringent method for clearance regulations [e.g. a methodology of conformity assessment provided by international standards (JCGM, 2012)] should obviously be avoided. IAEA has a peer review system – Integrated Regulatory Review Service (IRRS) – to review the regulatory framework for nuclear and radiation safety in the member states. The IRRS team carries out reviews in various areas in their regulatory frameworks, including clearance. To ensure the implementation of Requirement 6 in GSR Part 3 (IAEA, 2014), in the IRRS mission, it should be carefully reviewed whether the stringency of the control measures in the clearance process is commensurate with the level of risk associated with 10 $\mu Sv\ year^{-1}$.

4.3. Difference between product control and radiological protection

In the scope of ISO/IEC Guide 98-4: 2012, items used to demonstrate the assessment of conformity are, for example, 'a gauge block, a grocery scale or a blood sample' (JCGM, 2012). As shown in Section 3, the scope of this guide seems to be mainly applied to the product control with a very severe requirement for accuracy (e.g. in their size or mass control). On the other hand, radiological protection criteria were not originally established as the borderline between safety and danger. The effective dose criterion for clearance or exemption is a typical borderless case because it is not a single value of 10 $\mu Sv\ year^{-1}$, but is defined as a flexible value on the order

of 10 μSv year^{-1}. In addition, note that many conservative assumptions are included in the derivation of such radiological protection criteria.

When considering the meaning of conformity, we can easily find a significant difference between product control and radiological protection criteria including clearance levels. In the field of product control, there is no concept of the order of the dose criterion and radiation effects probabilistically occurring by gradation as a result of stochastic effects. Moreover, there is no similar rule in the accuracy control of products when applying a graded approach in the radiological protection system, as mentioned in the previous section.

In the field of radiological protection, the uncertainty in the measurement is always appropriately restricted provided that a measurement condition satisfies a detection limit defined in ISO11929. Section 5.1 of Safety Report No. 67 (IAEA, 2012) provides important knowledge about restriction of the uncertainty in the measurement while satisfying the concept of the detection limit:

> *The treatment of the uncertainty is strongly related to the detection limit. The uncertainty of measurement is generally expressed by a normal distribution. For example, in Japan, for a measurement to be considered as exceeding the detection limit, the net count must exceed by three times the net standard deviation of the measurement. In the case of the monitor checked on such a detection limit, the relative error of measurement results is always less than approximately 33.3%, since the measurement results are usually beyond the detection limit. This indicates that an uncertainty of less than approximately 30% is required in the measurement results.*
>
> *In the United States of America, the concept of detection limit is expressed by the minimum detectable concentration. In this case, the detection limit cannot simply be expressed by a factor of the standard deviation, but approximately regarded as 3.29σ, which is twice the value of 1.645σ. This implies that an uncertainty of less than approximately 30.4% is required in the measurement results, which is the same conclusion drawn in the Japanese concept of the detection limit.*
>
> *As described above, it can be ensured that the uncertainty of measurements is lower than approximately 30% by complying with the detection limit of measurement. On the other hand, there can be a large scattering of more than an order of magnitude of the radionuclide spectrum of target radionuclides, which can be expressed by a log normal distribution with two parameters, a geometric mean and a geometric standard deviation* (IAEA, 2012).

As the minimum detectable concentration is equivalent to the concept of the detection limit in ISO11929, if the measurement method complies with a detection limit of a required measurement, it can be ensured that the uncertainty in the measurement is restricted to within approximately 30%.

In addition, Paras 7.43 and 7.45 of General Safety Guide No. GSG-7 (IAEA, 2018) provide important recommendations on the uncertainty in the measurement by

personal dosimeters with reference to the relevant report (ICRU, 1992) and publication (ICRP, 1997), respectively:

> *7.43. For single measurements of the operational quantities, the ICRU [58] recommends that:*
>
> *in most cases, an overall uncertainty of one standard deviation of 30% should be acceptable. . . .The error of instruments may substantially exceed this limit at some radiation energies and for certain angles of incidence, but conform to it when they occur in a radiation field with a broad energy spectrum and broad angular distribution.*
>
> *7.45. Thus, the recommendations of the ICRP in Ref. [56] indicate acceptable levels of uncertainty at two dose levels:*
>
> (a) *In the region near the relevant dose limit, a factor of 1.5 in either direction is considered acceptable.*
> (b) *In the region of the recording level, an acceptable uncertainty of ±100% is implied.*

These recommendations indicate that the acceptable uncertainty for a dose of approximately 20 mSv year^{-1} up to 1.5 times the dose limit, and an uncertainty of up to twice the recording level is permissible for a dose of 1 (or 2) mSv year^{-1}. As the upper limit of the acceptable uncertainty increases with decreasing dose criterion for conformity assessment, if this concept is applied to a dose of 10 μSv year^{-1}, that is one-hundredth of 1 mSv year^{-1}, an acceptable uncertainty for clearance of nearly 10 times the dose criterion for clearance might be recommended.

Taking into account the different meanings of the criteria for product control and radiological protection, if the uncertainty in the nuclide vector is judged to be smaller using specific criteria, there would be no need to use a methodology of conformity assessment provided by international standards [e.g. ISO/IEC Guide 98-4: 2012 (JCGM, 2012)] as regulations for clearance and other radiological protection criteria. In the case of borderless radiological protection criteria, especially at doses <100 mSv, the requirement for the detection limit is generally sufficient for restriction of the uncertainty. However, if the uncertainty in the nuclide vector is too large, a safety factor might be needed for clearance judgement, as shown in Section 2.1, which leads to a similar result when the upper tolerance limit in the methodology of ISO/IEC Guide 98-4: 2012 (JCGM, 2012) is below 10 times the clearance level (equivalent to 100 μSv year^{-1}) rather than the clearance level (equivalent to 10 μSv year^{-1}).

4.4. Understanding of health risk of radiation of 10 μSv year^{-1}

Experiences in dialogue forums held in affected areas just after the Fukushima Dai-ichi nuclear accident found that an effective way to enhance public understanding of the radiation risk was to compare the radiation risk with the variation in

individual dose due to natural background radiation and the lifetime background cancer risk in the 47 Japanese prefectures.

It is important that such understanding of the radiation risk should be shared not only by the public but also by the regulators. The regulators may sometimes require the operators to apply an excessively conservative clearance process simply to gain public acceptance. The regulators should clearly understand that radiation exposure of the order of 10 μSv year^{-1}, which is a dose criterion for clearance or exemption, presents only a negligible health risk even if a precautional assumption of the linear non-threshold (LNT) model adopted for the purpose of radiological protection by ICRP (ICRP, 2007a) is used for risk prediction.

It should also be noted that clearance applicants and regulators should engage with interested parties in the public to discuss the various aspects of clearance, including the social, economic, and environmental benefits of clearance by increasing recycling, the derivation of clearance levels, application of the concepts of clearance, the national framework for clearance, and the approach to demonstrating compliance with clearance levels. To build confidence in the clearance process, this engagement should be carried out using clear terminology to avoid ambiguities, and should be carried out in a transparent manner.

The materials used in the dialogue forums are shown in the following two sections.

4.4.1. Map of natural background radiation

To increase public understanding of the radiation risk, a map of annual doses due to natural background radiation has been used frequently as a source of familiar knowledge on radiation (Abe, 1989). An example of the material used for public communication in the dialogue forum in Fukushima is shown in Fig. 2. This shows that the annual exposure from natural background radiation would be increased by 0.38 mSv year^{-1} for a person moving from Kanagawa Prefecture, with a natural radiation exposure of 0.81 mSv year^{-1}, to Gifu Prefecture, with a natural radiation exposure of 1.19 mSv year^{-1}.

4.4.2. Map of lifetime background cancer risk

Another example of materials used for public communication in the dialogue forum in Fukushima is given in Fig. 3. Using the LNT model and a risk coefficient of 5% Sv^{-1} (ICRP, 2007a), radiation exposures of 20 mSv and 1 mSv will lead to increases in risk of 0.1% and 0.005%, respectively. This means that the national average lifetime cancer risk will increase from 25.4% to 25.5% and 25.405%, respectively. On the other hand, the lifetime background cancer risk in daily life without additional exposure varies between 23.7% and 28.3% among the prefectures of Japan, with this variation being due to differences in lifestyle such as diet (Ogino and Hattori, 2014). Fig. 3 shows that in the case of radiation exposure of 10 μSv year^{-1}, the increase in the national average lifetime cancer risk is only 0.00005%, which is trivial compared with the variation in the lifetime background cancer risk among the 47 prefectures.

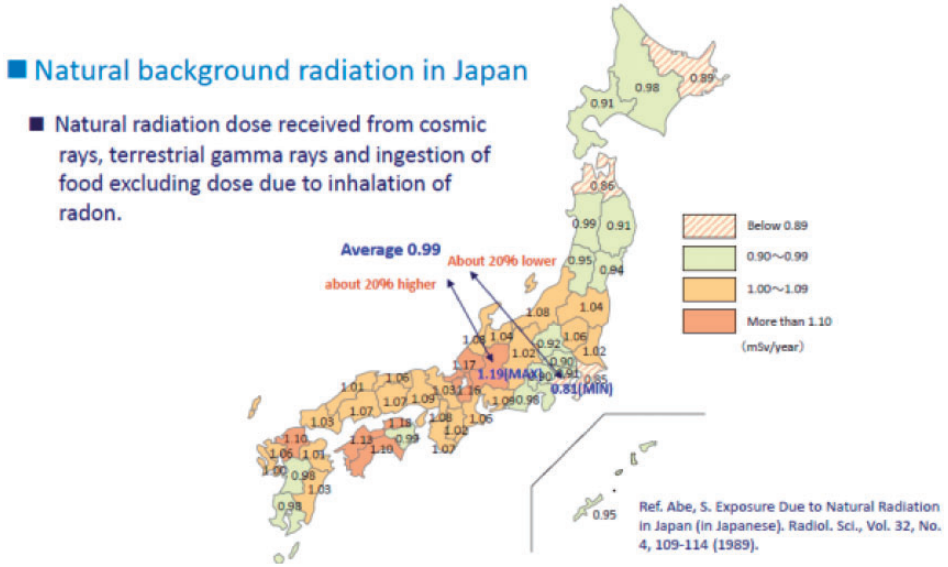

Fig. 2. Natural background radiation in Japan.

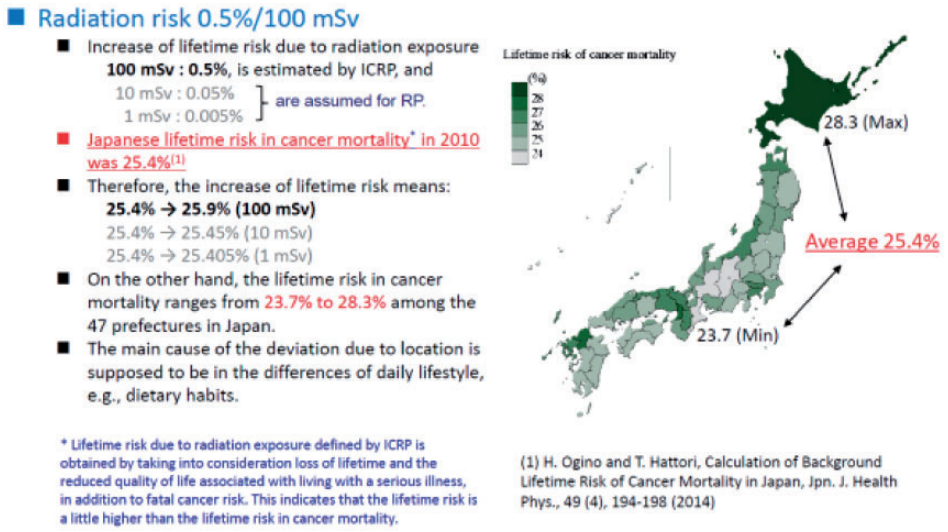

Fig. 3. Variation in lifetime background cancer risk in Japan as of 2010. RP, radiological protection. Source: http://www.aesj.or.jp/en/about_us/ps/AESJ-PS004e_r2.pdf.

5. CONCLUSION

NRA proposed a new decision on the uncertainty in clearance using the upper confidence level, which is up to 10 times stricter than the probabilistic approach provided by IAEA Safety Report No. 67 (IAEA, 2012). A similar approach to NRA's decision was found in an international guide for conformity assessment [ISO/IEC Guide 98-4: 2012 (JCGM, 2012)] and in some documents related to clearance in other countries. However, as a result of discussions from various viewpoints (e.g. the methodology used to derive clearance levels, the balance in a radiological protection system with a graded approach, the difference between product control and radiological protection, and understanding of the health risk of radiation on the order of $10\,\mu Sv\,year^{-1}$ by both the public and the regulators), it has been recommended that there is no need to apply a methodology of conformity assessment provided by international standards [e.g. ISO/IEC Guide 98-4: 2012 (JCGM, 2012)] to regulations for clearance and other radiological protection criteria.

There is a need for the international radiological protection community to review whether the strict requirement using the upper confidence level is justified for compliance with clearance levels and other radiological protection criteria. In the review process, radiological protection experts including regulators, professionals, and operators should be aware of the essential meaning of the radiological protection criteria by considering the background scientific basis on which they were established. Moreover, consideration should also be given to the extensive national resources that must be supplied by both private and governmental organisations with nuclear reactors and facilities handling radioactive isotopes or accelerators, including hospitals and universities, when strict regulations with excessive conservatism are imposed.

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Use of artificial intelligence in computed tomography dose optimisation

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Abstract–The field of artificial intelligence (AI) is transforming almost every aspect of modern society, including medical imaging. In computed tomography (CT), AI holds the promise of enabling further reductions in patient radiation dose through automation and optimisation of data acquisition processes, including patient positioning and acquisition parameter settings. Subsequent to data collection, optimisation of image reconstruction parameters, advanced reconstruction algorithms, and image denoising methods improve several aspects of image quality, especially in reducing image noise and enabling the use of lower radiation doses for data acquisition. Finally, AI-based methods to automatically segment organs or detect and characterise pathology have been translated out of the research environment and into clinical practice to bring automation, increased sensitivity, and new clinical applications to patient care, ultimately increasing the benefit to the patient from medically justified CT examinations. In summary, since the introduction of CT, a large number of technical advances have enabled increased clinical benefit and decreased patient risk, not only by reducing radiation dose, but also by reducing the likelihood of errors in the performance and interpretation of medically justified CT examinations.

Keywords: Artificial intelligence; Deep learning; X-ray computed tomography; Dose optimisation; Patient dose

1. INTRODUCTION

Artificial intelligence (AI) was recognised as an academic discipline in the middle of the 20th century, followed by cycles of optimism and disappointment as the field

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

progressed to its prominence today, where various elements of AI impact almost every aspect of modern technology. Much of the success of the field in recent decades can be attributed to advances in computation power, vast digital datasets, and the rise of cloud computing infrastructures, in combination with improved understanding of theoretical aspects of AI and implementable algorithms. By the early 21st century, AI was being developed in earnest by technology leaders such as IBM, Google, Microsoft, Apple, and Facebook. Today, we can use speech to direct electronic devices to perform tasks for us. Software can recognise features in images to identify individual people within photographs or, in medicine, specific pathological features in computed tomography (CT) or other images of the human body.

1.1. Introductory concepts in AI

AI is a broad discipline that contains a number of subfields, each of which approaches the overall tasks using different strategies, wherein the overall task is to develop hardware and software approaches by which a machine can perform cognitively complex tasks, including decision making. In machine learning, algorithms are trained to perform specific tasks by learning patterns from large datasets. Deep learning is a subset of machine learning whereby artificial neural networks, inspired by the design of the human brain, are used in conjunction with very large amounts of data to solve highly complex problems (Chartrand et al., 2017; Erickson et al., 2017).

1.1.1. Machine learning

In classical computer programming, the developer has a specific set of mathematical or logic rules to follow to turn input data into output answers. That is, the developer knows the rules to be applied to the data to yield the desired answers.

In machine learning, these rules are not known *a priori*. For example, in supervised learning, the developer has access to large amounts of input data paired with output answers. The relationship between the input and output information is highly complex, and difficult or impossible to define *a priori*. Machine learning is ideally suited for this task, in which the known input data/output answer pairs are fed into a machine learning framework to train the algorithm in such a way that it learns the rules to move from input data to output answers. Once trained (i.e. once the rules have been learned), inputting any future datasets into the same algorithm is expected to yield correct output answers.

1.1.2. Neural networks and deep learning

Artificial neural networks are a series of cascaded mathematical prophecies intended to loosely model the complex decision trees of the human brain. The network is composed of a number of layers, each performing one task in a long series of cascaded tasks. The phrase ‘deep learning’ is used to describe a neural network with a large number of hidden layers, in addition to the input and output layers. In CT, most deep learning applications use a type of artificial neural network known as a

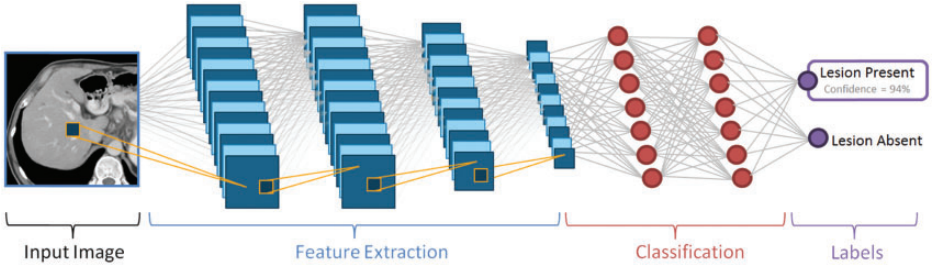

Fig. 1. Subsequent to training with large amounts of data where both the input images and output labels are known with confidence, a new input image (in this case, a computed tomography image of the liver) can be fed through the network, where important features are extracted and passed to classification layers. Finally, the decision, or label, is presented to inform the user whether a lesion is present or absent at any given location.

'convolutional neural network'. During the training process, input data are fed into the cascaded networks, each composed of a set of neural nodes that are connected to downstream nodes that perform various simple mathematical functions, such as convolution. Throughout the process, some nodes and node connections are cut and others are reinforced, and the weightings linking one node to another are adjusted so that at the end of the training, the weights, or parameters, of the neural network have been adjusted so that the difference between the network's output and the output data ('truth') used for training for a given input are minimised. Subsequently, new data on which the network has not been trained previously can be input into the network to yield output information that is deemed to reflect anticipated truth. The overall number of weightings on a network can be in the millions, and although convolution operation is fundamentally linear, the overall process becomes highly non-linear due to the existence of non-linear activation functions. An example is provided in Fig. 1.

1.1.3. AI applications in medical imaging

At the current time, AI, whether in the form of traditional machine learning, or the more recent deep learning, other types of learning, has been demonstrated to successfully detect and characterise areas of pathology, accurately segment areas of pathology or organs, synthesise presented information to make a diagnosis, label types and locations of pathology and anatomy, reduce quantum noise in images, and even reconstruct cross-sectional images from multiple views (or projections) around the patient. This article describes currently available AI approaches that facilitate optimisation of patient radiation dose from CT imaging. The word 'optimise' is used, as opposed to the word 'reduce', because the goal of medical imaging is to arrive at an accurate diagnosis using the lowest dose of radiation that is reasonable to achieve. That is, the benefit (i.e. achieving an accurate diagnosis) is maximised and the potential risk (i.e. the dose of radiation or iodinated contrast media to the patient) is minimised. As will be emphasised in the concluding section of this article, reducing

the dose of radiation or iodinated media to a level where an accurate diagnosis is difficult to achieve or cannot be achieved is inappropriate, because it compromises the overall care of the patient.

2. APPLICATIONS OF AI IN CT

Fig. 2 illustrates the processes involved in a CT examination, from setting up the patient on the scanner table through to reconstruction of the final images.

AI techniques can be incorporated into each of these steps.

2.1. Patient positioning

The geometry of the CT system is such that the x-ray tube–detector pair rotates around a fixed centre, referred to as the 'machine isocentre'. A physical object, referred to as a 'bow-tie filter', is used to decrease the number of x-ray photons hitting the patient periphery, because the patient's thickness is smaller there and fewer photons are needed. As patients are thickest at the isocentre, the filter has the lowest amount of attenuation there. The bow-tie filter is an important tool for patient dose optimisation. However, if the patient is not centred around the isocentre, there is a mismatch between the assumption used in developing the bow-tie filter and the actual patient set-up. This causes dose to be misapplied in some body locations, and image noise is increased relative to when the patient is positioned at the isocentre.

Since approximately 2000, CT systems have incorporated a feature, referred to as 'automatic exposure control' (AEC), which increases the tube current (i.e. increases the number of x-ray photons) for thicker body regions and decreases the tube current (i.e. decreases the number of x-ray photons) for thinner body regions. For the system

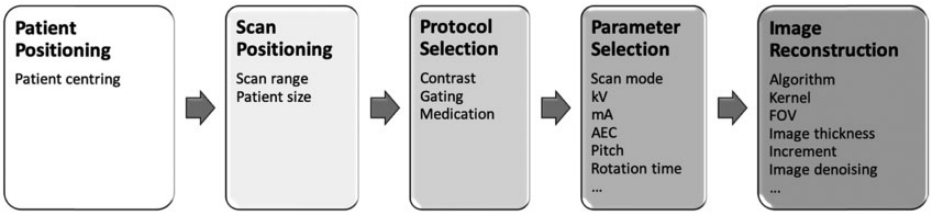

Fig. 2. Illustration of the performance of a computed tomography (CT) examination. The patient is placed on the scanner table, and the anatomy of interest is positioned around the centre of the CT gantry. A CT localiser radiograph is acquired, and the operator marks the start and end locations over which the scan is to be acquired. The correct scan protocol is selected, based on the clinical indication for the examination, and then the specific scan parameters are selected to produce images of the quality required for that diagnostic task. Finally, images are reconstructed using a range of parameters that determine the characteristics of the image, such as image sharpness and FOV, field of view.

to estimate the attenuation of a body region, it relies on the information provided by the CT localiser radiograph, which is essentially a digital x ray acquired on the CT scanner with the x-ray tube in a fixed position. As shown in Fig. 3 with the x-ray tube beneath the patient table, if the patient is positioned too high or too low with respect to the isocentre, the system perceives the patient as being too thin or too thick, respectively. This is because the spatial calibration of a CT system is performed at the isocentre (McCollough et al., 2006).

While manufacturers have implemented AEC systems somewhat differently in their commercial products, the fundamental principles remain the same, and the result is that the system automatically determines the required number of photons at every projection through the patient. For very large patients, this means that the system needs to further increase the number of photons in order to achieve the specified examination quality to accomplish the specified clinical task. As patients are not homogeneous cylinders, the end result is typically that the tube current oscillates up and down within a single rotation of the gantry, and increases, on average, through thick body regions (e.g. the shoulders and hips), and decreases, on average, through thinner body regions (e.g. the chest). For these algorithms to operate properly, it is essential that the patient is centred about the system's isocentre. However, as patient anatomy is quite variable, this can be difficult to achieve in practice.

Recently, a CT manufacturer has integrated a three-dimensional infra-red camera into their system (Fig. 4). The camera is located on the ceiling above the patient table and produces a three-dimensional image of the patient's surface with depth information. Using an AI algorithm, which was trained on over 1000 patients from three different hospitals, it detects specific landmarks on the patient's surface; based on the

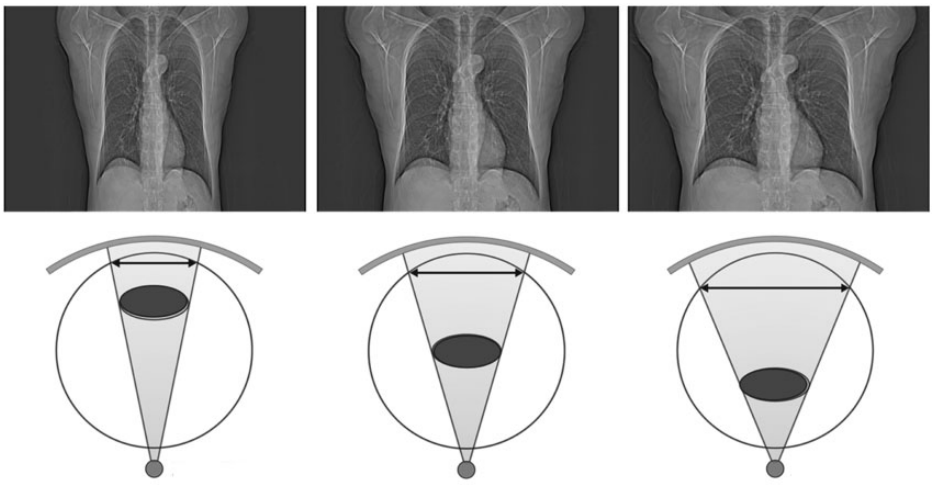

Fig. 3. Illustration of the performance of automatic exposure control on a computed tomography scanner.

Fig. 4. The three-dimensional camera and its location above the patient table (left). Optical image and three-dimensional depth map of the patient acquired using the overhead camera (right).

portion of the body to be scanned and the current height of the table, the system automatically moves the table vertically to position the patient such that the majority of the scanned anatomy is located at the isocentre (Saltybaeva et al., 2018; Booij et al., 2019). Table 1 summarises the results of a study by Saltybaeva et al. (2018), demonstrating that the average and maximal errors are decreased substantially using this AI algorithm to centre the patient automatically. Considering an error >20 mm to be clinically unacceptable, the AI approach reduces serious errors from 40–50% to 0.

2.2. Scan positioning

Once the patient is centred appropriately on the scanner table, the operator must prescribe the specific anatomy over which data are to be acquired. This process also uses the localiser radiograph (Fig. 5). Typically, the operator must move a line manually to the start and end positions of the desired scan. Operator-to-operator variations result in either too much or too little anatomy being covered. Operators have the tendency to be somewhat cautious; therefore, they often extend the scan range further than necessary to avoid the potential of excluding any anatomy from the scan. AI algorithms have been trained to accurately identify specific human anatomy from medical images. Based on the examination indication (and hence, the instructions selected by the operator for the examination), the system can automatically choose the scan range that is optimally centred around the required anatomical coverage.

Table 1. Summary of errors from manual and automated positioning.

Anatomic region and centring method	Average absolute error ± standard deviation (mm)	Maximum absolute error (mm)	Percentage of patients with error >20 mm
Chest			
Manual	19 ± 9	39	50%
Automatic	7 ± 4	15	0%
Abdomen			
Manual	18 ± 11	43	40%
Automatic	4 ± 2	9	0%

Source: Saltybaeva et al. (2018).

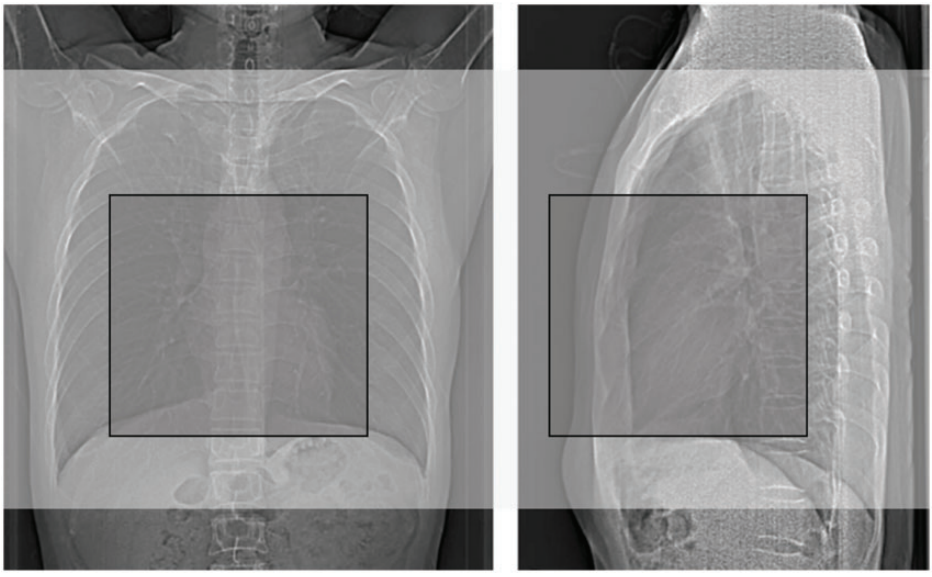

Fig. 5. A computed tomography localiser radiograph acquired in the anterior–posterior orientation (left) and in the lateral orientation (right). The artificial intelligence algorithm can position the scan range automatically to cover all of the lung anatomy (transparent grey box) or cardiac anatomy alone (dark grey box).

2.3. Protocol selection

Currently, selection of the scan protocol is a process that begins with the referring physician, who requests a scan to diagnose a specific condition. The radiologist then helps decide what type of medical images are most appropriate to diagnose that

condition. Finally, the CT operator, who knows the specific variations of protocols programmed into the scanner for a given condition, chooses the correct protocol for the specific modality. Algorithms are under development that could lead any of these stages via a decision matrix to select the optimal protocol. However, at this time, such a system, which takes required contrast material, medication, or gating schemes into account, is not available.

2.4. Parameter selection

For a given type of scan protocol and clinical indication, many parameters need to be properly selected in order to optimise the CT examination. For data acquisition, these parameters are related to how the radiation is applied to the patient, how the patient table and x-ray tube move, and whether or not other special techniques (e.g. cardiac gating) are used. Currently, some AEC systems use simple machine learning techniques to select the optimal tube potential and tube current. One of the more complicated decisions involves setting up the contrast injection and scan acquisition time, such that the iodine enhancement is greatest over the anatomy of interest during data acquisition. To accomplish this, data at multiple time points were acquired on a large number of patients as the contrast was injected and travelled through the patient's cardiovascular system. Based on these data, an algorithm is able to predict the ultimate height and width of the resulting contrast enhancement curve in the aorta. In subsequent patients beyond the training data, the system can predict the whole contrast enhancement curve using only a few data points on the rising edge of the curve, based upon which the optimal timing of the scan to be performed can be set as the contrast is flowing through the patient (Hinzpeter et al., 2019). Clinical studies have demonstrated better uniformity of contrast enhancement over the scan range in parallel to a reduction in the required dose of iodinated contrast media. The reduction in iodine can be accomplished by decreasing the rate of injection, which decreases the risk of damage to the vein into which the material is injected (Gutjahr et al., 2019).

2.5. Image reconstruction

The process of reconstructing a series of images from the acquired projection data requires the operator to carefully choose parameters that will impact the final characteristics of the image, including, but not limited to, the spatial resolution in the image, amount of overlap between consecutive images, thickness of anatomy represented in the image, image noise level, and magnification of the anatomy within the reconstructed image. An exciting application of AI in CT is the use of a convolutional neural network (CNN)-based deep learning approach to reduce image noise (also referred to as 'denoising') (Chen et al., 2017; Yang et al., 2018; Yi and Babyn, 2018). Missert et al. (2020) developed a CT image denoising technique that is trained to identify noise and not specific anatomical structures (Fig. 6), which is

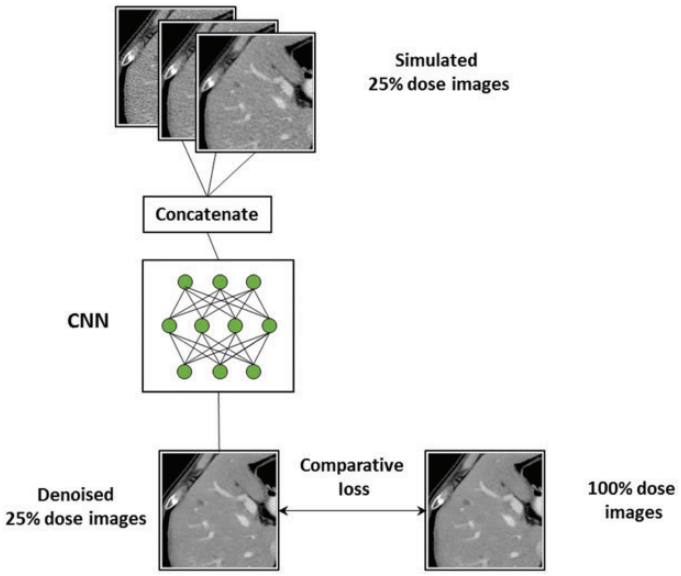

Fig. 6. A convolutional neural network (CNN)-based image denoising technique implemented using a residual network can identify image noise, which is consequently removed from the low-dose (high-noise) images to generate low-noise images.

subsequently subtracted from the original images to improve image quality and reduce radiation dose.

The algorithm was trained with millions of small patches from clinical patient data through the abdomen. For those patient cases, reduced dose images were simulated using a validated noise insertion technique (Yu et al., 2012; Chen et al., 2015). Thus, the training set contained simulated low-dose images (at 25% of the clinical dose level) and images acquired at the clinical dose level. From these data, the algorithm was trained to find image noise (Fig. 7). The reduction in noise is dramatic, without any loss of spatial resolution (Missert et al., 2020).

AI, particularly CNN-based deep learning, requires the use of training datasets to establish the correct weightings of the connections between various neural nodes and network layers. The network illustrated in Fig. 6, which produced the results shown in Fig. 7, was trained with low-dose (25% of full dose) and full-dose images. To assess the generalisability of the network to images from the same system having different input noise levels, we reconstructed the full-dose data, which decreased the noise of the full-dose images substantially. The network performed extremely well for that case, presumably because the datasets were so similar, and the CT image noise for that particular system was able to be modelled accurately by the network, independent of the specific noise levels. It is this ability to reduce image noise, after the data have been acquired, that allows an operator to reduce the dose during data acquisition and yet still achieve a high-quality image with an acceptable noise level.

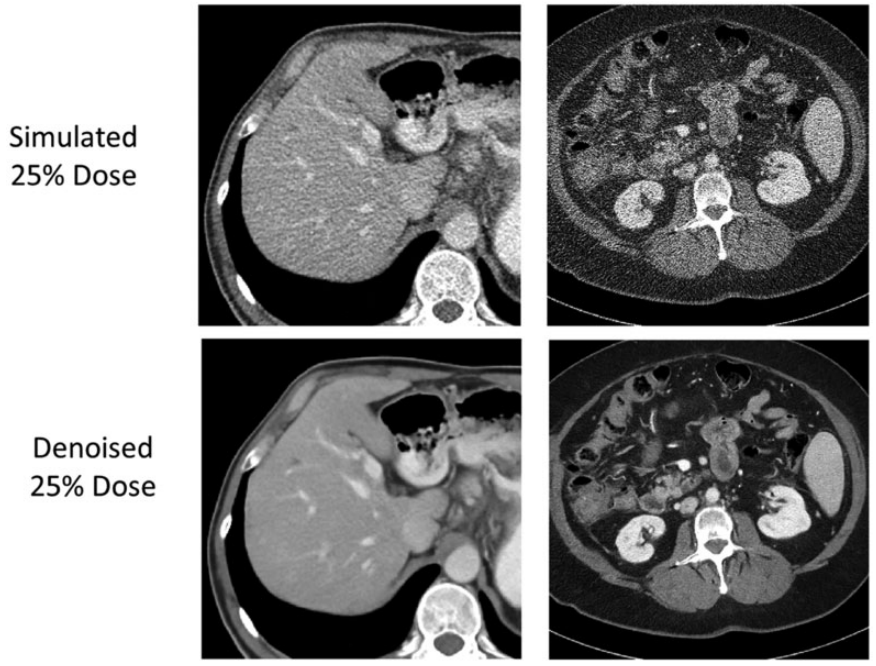

Fig. 7. Dramatic noise reduction is achieved using a convolutional-neural-network-based denoising algorithm, evidenced by the comparison of images from simulated and denoised 25% dose.

However, AI networks are trained using specific datasets, which represent specific image characteristics; data acquired on different CT scanner models or with different acquisition or reconstruction parameters typically do not work well with networks that have been trained under different conditions. This lack of generalisability is one of the most fundamental barriers to widespread deployment of deep-learning-based image denoising.

3. LIMITATIONS

Since the widespread introduction of CT of the torso in the mid-1980s, the routine dose for an average-sized patient has decreased by approximately a factor of 4. As expressed in terms of the volume CT dose index, the routine output for a body CT examination has decreased from approximately 46 mGy in the early 1980s to approximately 11 mGy in recent years (Kanal et al., 2017). Use of AI to denoise reconstructed images, or even to perform the image reconstruction itself, will further reduce the required dose for body CT images of diagnostic quality. There is, however, a fundamental limitation regarding how low a dose can actually be achieved. The panel of images relating the number of photons needed to form the image to the

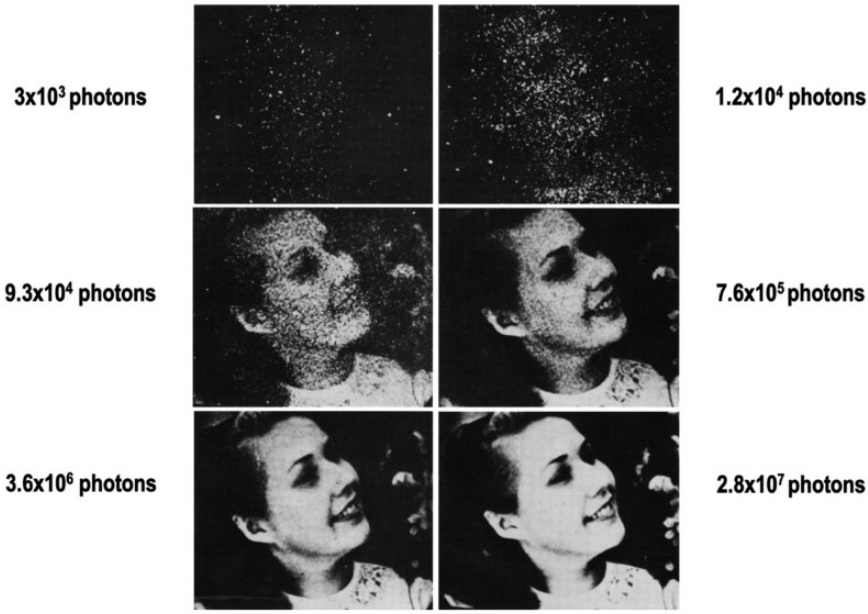

Fig. 8. The panel of images relating the number of photons needed to form the image to the ability of the observer to recognise the object contained in the image. Reprinted with permission from Rose (1973).

ability of the observer to recognise the object contained in the image (Fig. 8), made famous by Rose (1973), demonstrates that there is a number of photons below which the statistical information needed to form a meaningful representation of the object being imaged is not present.

This principle has been demonstrated in recent years with the use of iterative reconstruction techniques to reduce image noise. These non-linear processes have been shown to degrade spatial resolution for objects that have low levels of signal contrast relative to background material. Favazza et al. (2017) demonstrated that although image noise is maintained, when the dose is decreased too much, subtle signals are lost. This is because the algorithm can no longer distinguish subtle features from the background, and in its effort to reduce high noise levels associated with reduced dose levels, the edges of subtle anatomy are blurred out. That is, there is a dose level at which the signal is not statistically strong enough to be maintained. For small nodules, this means that they can no longer be observed (Fig. 9).

4. SUMMARY

In summary, AI techniques can be used at every stage of a CT examination to benefit the quality of the resulting images, make the work flow more efficient for the operator and radiologist, and reduce image noise such that the radiation dose

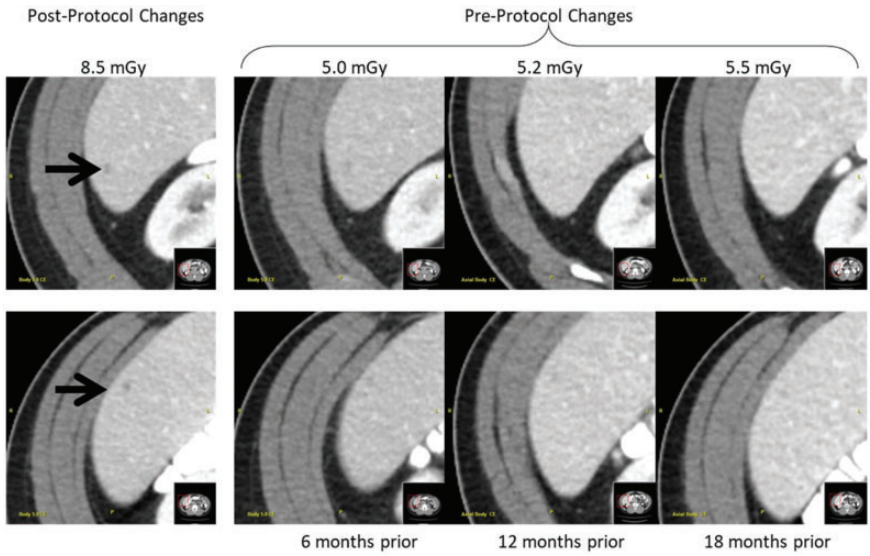

Fig. 9. Low contrast lesions seen in routine dose scans (post-protocol changes) are not clearly visible in low-dose previous scans (pre-protocol changes), although image noise is generally comparable among all scans. Reprinted with permission from Favazza et al. (2017).

applied to the patient can be reduced during data acquisition. Currently, the use of a three-dimensional infra-red camera allows for automated positioning of the patient at the isocentre as well as automated prescription of the start and end rotations of the scan. Continued work in the field of optimising the scan acquisition and reconstruction parameters, as well as selecting optimal scan protocols, will enhance the reproducibility of CT images, improve the diagnostic value of the CT images, and reduce the dose to the patient. AI methods to reduce image artefacts, such as those caused by metal within the scan volume, are also anticipated. However, as exciting as new technology can be when first introduced, there will be limitations with how and when AI approaches are applied when first applied to practical problems. Generalisability will be one of the most challenging limitations to overcome. Thus, while it is clear that AI will be a part of medical imaging going forward, both manufacturers and users must proceed with caution, lest we repeat the mistake made with the introduction of iterative reconstruction and, as a consequence, miss important diagnosis. Further, it is not yet clear how these algorithms can be evaluated in the clinical setting, particularly for AI techniques that continuously 'learn' from the clinical information flowing through the network. What tests can be performed, and what datasets should be used, to confirm that a system performs as claimed by the manufacturer, and what tests and data should be used to confirm that the algorithm performs consistently at that level over time? These important questions remain to be answered.

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Effective dose in medicine

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Abstract–The International Commission on Radiological Protection (ICRP) developed effective dose as a quantity related to risk for occupational and public exposure. There was a need for a similar dose quantity linked to risk for making everyday decisions relating to medical procedures. Coefficients were developed to enable the calculation of doses to organs and tissues, and effective doses for procedures in nuclear medicine and radiology during the 1980s and 1990s. Effective dose has provided a valuable tool that is now used in the establishment of guidelines for patient referral and justification of procedures, choice of appropriate imaging techniques, and providing dose data on potential exposure of volunteers for research studies, all of which require the benefits from the procedure to be weighed against the risks. However, the approximations made in the derivation of effective dose are often forgotten, and the uncertainties in calculations of risks are discussed. An ICRP report on protection dose quantities has been prepared that provides more information on the application of effective dose, and concludes that effective dose can be used as an approximate measure of possible risk. A discussion of the way in which it should be used is given here, with applications for which it is considered suitable. Approaches to the evaluation of risk and methods for conveying information on risk are also discussed.

Keywords: Effective dose; Risk calculation; Patient dose

1. INTRODUCTION

The dose quantities for medical procedures using ionising radiations that are measured cannot readily be used to compare exposures in relation to risk.

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

Radiation exposures are seldom uniform over the whole body and usually involve irradiation of several organs and tissues; this has a significant effect on the relative risks. However, the radiations used for diagnostic and interventional procedures are always x rays, gamma rays, beta particles, or positrons. Therefore, the differences in biological effectiveness of the radiations in damaging tissue are relatively small and have less influence on the risk. The concept of combining doses to individual organs weighted according to their sensitivity to induction of stochastic effects in order to derive an effective dose linked to risk was first proposed in 1975 (Jacobi, 1975). The International Commission on Radiological Protection (ICRP) developed this principle further, and recommended derivation of a dose-equivalent limit based on the total risk to all tissues irradiated, linked to stochastic effects derived from results of epidemiological studies. The approach stems from the principle that the risk associated with the dose quantity should be equal to that from a similar uniform dose to the whole body. This was achieved by summing doses to individual tissues, each modified by a tissue weighting factor based on an assessment of the risk from stochastic effects, namely cancer and genetic effects (ICRP, 1977). A remainder was included consisting of an average dose for other tissues that were potentially at risk from cancer induction. The initial dose quantity was called the 'effective dose equivalent' and was applied in the evaluation of doses received by radiation workers and the public. The primary organs at risk that were included were the gonads for genetic effects, and the breast, lung, and bone marrow for cancer, with lower weighting for the thyroid and bone surfaces relating to malignancy. It was used to provide a method for judging the acceptability of the level of risk in radiation work by allowing comparisons of the risk from radiation exposure with the risks for other occupations, as well as planning of operations and optimisation of procedures to keep dose levels to radiation workers and the public at acceptable levels. The cancer risk data used in derivation of the tissue weighting factors are largely from the Life Span Study of the Japanese survivors from the atomic bombs detonated in 1945. The lifetime risks of developing cancer from exposure of different organs compared with dose data, which appear linear between doses of <100 mGy to several Gy, are extrapolated down to low doses (ICRP, 2005; Shore et al., 2018). This linear no-threshold (LNT) model is used to calculate the probability of radiation-induced cancer for organs and tissues for which there are sufficient data (ICRP, 2007).

ICRP renamed the quantity 'effective dose' when the fundamental recommendations on radiological protection were updated (ICRP, 1991). Changes were made in the organs/tissues included in the effective dose and the tissue weighting factors because of growing evidence of links between cancers in other tissues and radiation exposure identified through the Life Span Study. Further modifications in the formulation were made in the last set of fundamental recommendations based on changes in analyses of the epidemiological data and the calculation of radiation detriment (ICRP, 2007). The weighting factors are rounded to facilitate calculation in order to provide a radiation protection dose quantity that is easy to apply in practice. Thus, effective dose is a protection quantity designed for easy application,

rather than a scientific quantity that can be measured, and is acknowledged to be an approximation with inherent uncertainties (Martin, 2007; McCollough et al., 2010).

2. DOSE QUANTITIES USED IN MEDICAL APPLICATIONS

2.1. Measurable dose quantities

Radiation is used in a wide range of applications in medical diagnosis and therapy. For diagnostic and interventional x-ray applications, radiation doses received by patients are recorded in terms of quantities that can be measured and are generally displayed on equipment consoles. For radiography and fluoroscopy, they take the form of entrance surface air kerma, that relates to dose to the skin surface, and kerma-area product (KAP; P_{KA}), that gives a measure of all radiation incident on the patient. For computed tomography (CT), they take the form of the CT dose index that is associated with doses to the tissues within the section of the body being imaged, and the dose length product (DLP) that gives a measure of dose from a whole procedure. These measured quantities can be recorded and applied readily for assessment of dose levels, and are used for collection of data in patient dose surveys, comparisons of doses for examinations at different healthcare facilities, optimising procedures, and setting diagnostic reference levels (Martin, 2011a; ICRP, 2017). In fact, they are useful for most applications where a measure of dose is required, such as for recording patient dose information in medical reports, as required by European member states (EU, 2014) and for joint common accreditation in the USA, and for tracking doses to individual patients accumulated over time (Rehani et al., 2014). The activities of radionuclides, together with the type of radiopharmaceutical administered to each patient, fulfil the same roles in nuclear medicine.

2.2. The need for and evolution of effective dose in medicine

In medicine, imaging examinations using ionising radiations are performed on different parts of the body to aid diagnosis and treatment of a wide range of diseases. Judgements have to be made about examinations relating to the level of risk, but radiation quantities that can be measured often give little indication of potential risk. Comparison of KAP values for the chest and abdomen do not have much relevance, nor do comparisons of KAP and DLP for the same body region, or the measured dose for an x-ray procedure with the amount of radioactivity administered for a nuclear medicine examination. In all these cases, the distributions of radiation doses to organs and tissues within the body will be very different. There is a need for a dose quantity that supplies some information on risk to inform decisions about the appropriateness of radiation exposures used for diagnosis and management of treatments for large numbers of patients.

Effective dose was designed as a protection quantity to enable decisions to be made about potential exposures of workers and the public, and to set dose limits, constraints, and reference levels. However, ICRP acknowledged that it could provide a useful measure of doses to nuclear medicine patients in whom radionuclides

accumulated in various organs around the body, and that its use could facilitate comparisons between different types of medical radiological investigation (ICRP, 1987). Since that time, ICRP Committees 2 and 3 have collaborated to derive coefficients to enable absorbed doses to organs and tissues, and assessments of effective doses received by nuclear medicine patients to be quantified in order to fill this gap. The reports use biokinetic models developed from available data within a generic framework to evaluate the activities of different radionuclides that are likely to accumulate in different organs (e.g. ICRP, 1988, 2015). Radionuclide distributions and transit times through different organs are evaluated and activity–time curves generated. These are used, together with mathematical models of the anatomy for a reference person, to obtain absorbed doses for all the organs and tissues within the body from the accumulated activity in the 'source' organs. Coefficients have since been published to enable calculation of organ and effective doses for diagnostic x-ray procedures by a number of organisations, and these can be applied to the entrance surface air kerma or KAP for radiography and fluoroscopy (Hart et al., 1994; Ranniko et al., 1997; Kramer et al., 2004), or the DLP for CT (Ding et al., 2015; Shrimpton et al., 2016). Values of effective dose calculated with these coefficients can be used to compare doses from a wide range of medical procedures that expose different regions of the body, and these have been instrumental in raising awareness of dose levels from diagnostic imaging procedures among medical physicists, clinicians, and radiographers.

2.3. The application of effective dose to medical patients

Effective dose is now used in training medical professionals in radiological protection, and can provide a broad understanding of possible risks associated with radiation exposures. It has provided a universal dose quantity that can be used as a reference against which improvement in radiological protection in medical practice can be judged, and gives an indication of radiation dose relating to possible risks to health that can be understood by clinicians and non-specialists in radiological protection. The details of how, and for what purposes, effective dose is applied vary across the world, but include decisions made as part of the process for justifying imaging exposures for individual patients and optimising protection through selection of the most appropriate technique. Generic values of effective dose calculated for common procedures provide a straightforward tool that can be used for making these everyday decisions.

However, the application of effective dose to medical procedures is rather different from occupational and public applications, in which the requirement is for a measure relating to risk that can be used in the optimisation of protection below constraints or reference levels. With medical x rays, the exposure is planned, limits on the region of the body exposed are defined, and simulations are used to evaluate doses to individual organs, although these are in reference anatomical phantoms rather than the patient. Thus, more is known about the dose distributions from medical exposures than those to workers. This creates the impression that the doses to

patients are known with much greater certainty than they actually are, and has led to users losing sight of the many approximations employed in the derivation of effective dose (Martin, 2007; McCollough et al., 2010). In the use of effective dose for evaluation of occupational and public doses, there had been little need to consider these uncertainties.

3. UNCERTAINTIES IN CALCULATIONS OF EFFECTIVE DOSE AND RISK

3.1. Approximations made in the derivation of effective dose and its use in medicine

As effective dose can express dose in terms related to relative risk from exposures of different parts of the body, it is admirably suited for application to medical exposures. However, approximations involved in the derivation and uncertainties in the calculation need to be taken into account in its application to assessment of doses to patients.

3.1.1. Age and sex

The risk estimates to which effective dose relate have been derived for populations of all ages, so while medical exposures may relate to individuals, effective dose applies to a sex-averaged reference person exposed in the same way (ICRP, 2007).

3.1.2. Tissue weighting factors

As effective dose is a practical operational tool, the most important requirement is for it to be simple to calculate and use. Tissue weighting factors are rounded approximations related to the risks that stem from epidemiological data that are judged to be acceptable for deriving a radiation protection dose quantity. Differences from the risks calculated from epidemiological data are an approximation that give another source of inaccuracy.

3.1.3. Dose measurements

Values for effective dose are computed from the results of practical measurements of dose quantities in which there are uncertainties. For example, for x-ray exposures, there will be uncertainties not only in the tissue dose measurement itself, but also in the extent of the region of the body exposed that relates to the size of the x-ray field.

3.1.4. Computations

The derivation of effective dose requires values for doses to all of the organs exposed to be computed, and this is done via Monte Carlo simulations. There are significant uncertainties in these calculations that combine with those in the boundaries of the radiation fields in radiology (Martin, 2007). For nuclear medicine examinations, uncertainties in the radionuclide dose transit time curves include factors such as the time that radioactivity remains in the bladder, which is dependent on the

patient's actions. They also depend on patient anatomy, which determines the proximity of organs for which absorbed dose is being assessed to those in which radioactivity accumulates (Martin, 2011b).

The net result is that there may be an uncertainty of ±40% in values derived for effective dose as a relative indicator of risk to a reference person when applied to medical imaging procedures in general (Martin, 2007). For some diagnostic nuclear medicine investigations where the dose to the target organ, or to the bladder and colon irradiated during the excretion process, represents a significant proportion of the total dose, the uncertainty may be ±50% (Martin, 2011b). When this is considered in terms of radiation exposure and risk in general, the magnitude of the uncertainty is not unreasonable, and effective dose provides a useful comparator for making overall judgements about the relative risks from different types of medical procedure and making comparisons with doses from other sources. However, because of the uncertainties, effective dose should only be quoted to one significant figure for values less than 1 mSv, and two significant figures for values above 1 mSv.

Effective dose is the only relatively simple way in which a dose with some link to risk can be expressed, but users must acknowledge its approximate nature, use it as a guide in making decisions and steering practice, and recognise that it has large uncertainty and applies to a reference person rather than an individual. Comparisons of effective doses for medical procedures with everyday exposures from natural background radiation and from cosmic rays during a plane flight, to which people can relate, is sometimes helpful. These comparisons can be particularly useful in discussions with patients who have little or no knowledge about radiation, and may have an unrealistic fear of the potential harm from an exposure.

When using effective dose, it should be borne in mind that the potential risk for patients from medical exposures is generally lower than that for a reference population due to their higher average age and the reduced life expectancy due to disease (Loose et al., 2009). However, risks for paediatric patients are generally higher and this potential increased sensitivity should be recognised (ICRP, 2013).

In medical examinations where only one organ is exposed, estimates of the dose to that organ or tissue should be used instead of effective dose. Examples are radiological imaging of anatomic areas outside the trunk, such as the breast in mammography or the brain in head CT. This also applies to radioiodine uptake by the thyroid, quoted in terms of absorbed dose to the thyroid, and gonad dose where this makes up the majority of the dose received.

3.2. Use of effective dose in conveying radiation risk

Risks of cancer incidence relating to effective dose are quoted in the fundamental recommendations of ICRP (ICRP, 2007). These are helpful in providing a calibration of effective dose in terms of risk. In a forthcoming ICRP publication on use of the protection quantities, it is concluded that effective dose can be used as an approximate measure of possible risk. This wording was chosen to emphasise the uncertainties inherent in the estimation of risk, and to acknowledge that the doses

under consideration are, in many cases, below the levels at which direct epidemiological observations of excess cases of cancer are available.

3.2.1. LNT model

Effective dose employs the LNT model, as this is considered to be the best approach to quantifying the risk–dose relationship on the basis of current knowledge (ICRP, 2005; NCRP, 2018; Shore et al., 2018). By assuming that the lifetime risk of cancer is directly proportional to the dose, doses from all radiation exposures can be summed. This means that small radiation doses well below the level at which any effect can be demonstrated are taken into account and considered to be potentially harmful. It is not possible to prove a definitive form for the link between exposure and cancer at these dose levels, as this would require study of populations of tens of millions of individuals whose exposures were known, together with matched control groups. The uncertainty in the LNT model applies to any calculation of risk at low doses, whether calculated from effective dose or doses to individual organs.

3.2.2. Adjustments for exposed populations

Risks of cancer originate from epidemiological studies, predominantly of the Japanese survivors of the atomic bombs detonated over Hiroshima and Nagasaki. Recent cancer risk vs dose models have been constructed from mortality data for leukaemia and cancer incidence data for solid tumours (BEIR, 2006; ICRP, 2007; Berrington de González et al., 2012). Two approaches are used to obtain projections of lifetime risk. The first, called the 'excess absolute risk' (EAR) or 'additive risk model', assumes that the excess absolute risk is proportional to the dose to the tissue. The second, called the 'excess relative risk' (ERR) or 'multiplicative model', includes an adjustment linked to the relative rates of cancer incidence in the target population and the unexposed study population (ICRP, 2007). The target population used by ICRP aims to provide global average values, and bases its assessments on a composite population comprising four Asian populations, two European populations, and a US population. Risks for the breast are based on the EAR model, risks for the thyroid and skin are based on the ERR model, risks for the lung are based on an ERR:EAR weighting of 0.3:0.7, and risks for other organs are based on a 0.5:0.5 ratio. Decisions about the weighting stem from the expert opinion of members of the committee formulating the values. Risks per unit organ dose published in BEIR (2006) and Berrington de González et al. (2012) differ from those in ICRP (2007) as they use a US population with slightly different factors (Martin, 2019).

3.2.3. Dose and dose rate effectiveness factor

Radiobiological experimental investigations have tended to show that risks are reduced for fractionated or protracted exposures, suggesting that high-dose, acute exposures may overestimate the risk of cancer induction. Therefore, in ICRP (2007), the risk estimate is divided by 2.0, but this is again an approximation that stems from earlier methods and views of Commission members. The value used in BEIR (2006) and Berrington de González et al. (2012) for risk calculations is 1.5.

3.2.4. Other uncertainties

There are other sources of uncertainty in any risk estimates. For example, there will be interactions between radiation exposure and other cancer risk factors, notably smoking history in the case of lung cancer, and reproductive history in the case of female breast cancer. Another example is the assumption inherent in the application of a single radiation weighting factor of 1 to describe the relative biological effectiveness for all photon radiations in the 30–200-keV range (Heyes et al., 2009) and beta-particle radiations.

There has been a desire to quote risks from radiation exposure in numerical terms in many countries, and effective dose has been used to calculate a figure for the excess lifetime risk of cancer. However, even for the ICRP reference person, actual risks might be three times higher or lower than the estimate, but the uncertainty could be much greater given the lack of definitive proof for the LNT model at low doses. The use of medical radiation has been increasing rapidly over the last 20 years, and there is a need to try to reduce numbers of unnecessary exposures. In promotion of this message, claims have been made quoting large numbers of additional cancers that could result from this increase (Brenner and Hall, 2007; Berrington de González et al., 2009). These numbers are derived using the BEIR (2006) model, but with little account taken of the uncertainties in epidemiological data, the extrapolation to low doses, or the reduced life expectancy of patients because of their illnesses. Such numerical assessments can give a false impression of accuracy, and should be appropriately caveated with consideration of uncertainties and background rates. The use of general terms linked to possible levels of cancer risk, as shown in Table 1, avoids the impression of precision in risk estimates. These terms are considered to be reasonable indications of the risk from cancer induction for those aged between approximately 20 years and 60 years. When using these terms in discussions about patients, the influence of their disease, condition, and age on life expectancy should be taken into account.

3.3. Application of risks to individual patients

The risk estimates used in the derivation of effective dose have been age- and sex-averaged. Some of the differences between risks for an individual and those for the ICRP reference person can be taken into account if required. The differences are listed below.

3.3.1. Age

Overall lifetime risks of cancer from radiation exposure decline with age, with risks for exposure of children aged 0–10 years being approximately double those for exposure in middle-aged adults (30–50 years), and those for the over 60 s being approximately half. The greater radiosensitivity of tissues in children contribute to their higher risk, but variations with age at exposure primarily reflect differences in the remaining lifetime after exposure. There are substantial differences between cancer types, with risks of lung cancer induction increasing in middle age, and

Table 1. Dose ranges and terminology for describing the excess lifetime risks of cancer incidence from different medical diagnostic procedures for adult patients of average age (30–39 years).

Effective doses (mSv)	Risk of cancer inferred from LNT model*	Proposed term for dose level	Examples of medical radiation procedures within different dose categories
<0.1	$<10^{-5}$	Negligible	Radiographs of chest, femur, shoulder limbs, neck, and teeth
0.1–1	10^{-5}–10^{-4}	Minimal or extremely low	Radiographs of spine and trunk, and ^{99m}Tc lung ventilation and renal imaging
1–10	10^{-4}–10^{-3}	Very low	CT scans of head and body, cardiac angiography, and a variety of nuclear medicine examinations
10–100	10^{-3}–10^{-2}	Low	Multiple CT scans of trunk with contrast and higher dose interventional procedures
100 s	$>10^{-2}$ based on epidemiology	Moderate	Multiple procedures and follow-up studies

LNT, linear no-threshold; CT, computed tomography.
*Risk bands are lifetime detriment adjusted incidence to nearest order of magnitude.

risks of thyroid and female breast being high for the young and falling to a low level by 30–40 years (ICRP, 2007).

3.3.2. Sex

Lifetime cancer risks differ for the two sexes, with the significant risks of breast cancer applying virtually exclusively to females. In addition, risks of thyroid cancer are four to five times greater in females, and risks of lung cancer are almost double. For cancers such as colon and leukaemia, the risk in males is 40–50% higher.

3.3.3. Health status

Patients undergo examinations to investigate disease, and in many cases, the medical risk from their condition is likely to reduce their life expectancy and therefore the risk of radiation-induced cancer (Loose et al., 2009).

3.3.4. Genetic factors

There are known to be differences in genetic susceptibility to cancer, with certain sections of the population likely to be more susceptible to cancer induction by radiation.

Epidemiological data have been used to determine risks from exposure of individual organs and tissues within the body (BEIR, 2006; ICRP, 2007), so if a more accurate

assessment of risk is deemed necessary, this can be calculated using the risk coefficients for each organ and tissue separately, based on the age and sex of the exposed individual. Brenner (2008, 2012) proposed the use of the term 'effective risk' to describe an approach to the summation of risks estimated in this way. However, while this approach uses the available data on age- and sex-specificity of the different cancer types, it does not take account of the large uncertainties described in Section 3.2.

4. APPLICATIONS OF EFFECTIVE DOSE IN MEDICINE

In its forthcoming publication on protection dose quantities, ICRP has set out the purposes for which use of effective dose is recommended in medicine, and these are given below.

4.1. Referral guidelines and justification of procedures

Effective dose provides information on relative magnitudes of doses from different types of examination that can be used in referral guidelines and in justification of techniques at national level. In addition, it can be used by clinicians in making decisions as part of the justification of procedures for individual patients. Effective dose provides sufficient information to allow clinicians to weigh the benefit from the diagnostic information needed for management of the patient's disease against the potential risk from radiation exposure, taking account of the sex, age, medical risk from their condition, and life expectancy (Loose et al., 2009).

4.2. Choice of imaging technique

Effective dose enables doses from procedures in which the dose distributions are different to be compared (e.g. x ray and nuclear medicine). Decisions about which technique to use will be based primarily on the type of information each will provide for the potential benefit to the patient, but the relative effective dose is a secondary factor that can be taken into account when appropriate.

4.3. Optimisation of technique

In general, effective dose is not the best quantity for making comparisons between doses for similar techniques for which there are measurable quantities such as KAP or DLP. However, if the dose distribution within the body changes, because of radiographic projection, tube potential, or addition of a filter, effective dose may be useful for evaluating changes in exposure of the different organs and tissues.

4.4. Doses to research volunteers

Before a research proposal is approved, the possible detriment for the individuals involved should be evaluated and recorded (ICRP, 1992). Effective doses from the

various radiation procedures that are to be performed can be summed to give an indication of the possible overall radiation-related health detriments that may accrue to the volunteers. Effective dose is particularly useful because the procedures performed may involve different dose distributions within the body, but it should be recognised that it is estimated for a reference person, so when considering the potential radiation-related risks, the age, sex, and health status of the volunteers should be taken into account.

4.5. Reporting of unintended exposures

Effective dose can provide enough information for assessments of unintended exposures and overexposures of patients in diagnostic procedures due to procedural errors or equipment faults. It can be assessed during incident investigations and included in reports (Martin et al., 2017). For more substantial exposures that may approach or exceed 100 mSv, estimates of risk using the best scientific data will be appropriate.

4.6. Efficacy of imaging for health screening or non-medical applications

Effective dose can be used in the evaluation of health screening procedures that involve exposure of many organs within the trunk.

4.7. Doses to carers

Medical exposures are considered to include exposures incurred knowingly and willingly by individuals helping in the support and comfort of patients undergoing diagnosis or treatment. This application is more akin to that in occupational exposure, and methods for the prediction of values for effective dose are similar. A typical example where this might be required is the exposure of family members from a patient discharged after thyroid treatment with unsealed ^{131}I. The effective doses that might be received by the individuals involved and the acceptability will be determined by the individual circumstances (ICRP, 2007).

4.8. Education and training of clinicians and other healthcare professionals

It is often difficult for clinicians who refer patients and perform medical procedures involving radiation to take potential risks into account when requesting or justifying patient diagnostic or interventional exposures (ICRP, 2009; Loose et al., 2009; Zanzonica and Stabin, 2014). Effective dose provides a single value which can be used to compare different exposure scenarios, and a knowledge of typical effective doses from common procedures should be included in the education and training of medical practitioners. Effective dose is an appropriate quantity for straightforward

communication when explaining possible risks to patients, and allows comparisons of the possible health risks of an exposure with risks from other exposure scenarios.

4.9. Use of collective effective dose for medical exposures

Effective dose has been used in evaluating the level of exposure in different countries (UNSCEAR, 2008). The use of collective effective dose in this way has been used for deriving average population dose per caput from medical exposures. It has contributed to the raising of awareness of doses from medical procedures in the USA (NCRP, 2009, 2019) and UK (Wall et al., 2011), and optimisation efforts following on from these surveys have led to significant reductions in doses from medical procedures. However, extending the use of collective effective dose to predict health effects should be treated with caution.

5. CONCLUSIONS

Effective dose in medicine provides a tool that can aid judgements that have to be made about diagnostic examinations and patient management relating to the level of risk. Values of effective dose can be derived from measurable quantities and comparisons made between medical procedures using different imaging modalities or exposing different regions of the body. Effective dose has proved to be a valuable tool in medicine, providing a single dose quantity for communication with clinicians and patients. Doctors who refer patients or perform medical procedures involving radiation may have little understanding of the potential health detriment from radiation exposure, and a knowledge of typical effective dose values for common medical procedures is used in training medical professionals and informing judgements on relative radiation dose levels. Such information is then used in making everyday decisions; for example, as part of the referral and justification process for imaging exposures for individual patients, and in the selection of appropriate imaging techniques.

A forthcoming ICRP publication discusses the use of protection quantities, and concludes that effective dose can be used as an approximate indicator of possible risk. There are substantial uncertainties in the estimation of risk at low doses, recognising that the doses under consideration are likely to be below the levels at which direct epidemiological observations of excess cases of cancer are available. However, the most straightforward interpretation of the available scientific evidence for the purposes of radiological protection is that a nominal lifetime fatal cancer risk estimate of approximately 10^{-4}–10^{-5} per Sv applies at low doses or low dose rates. The evidence also shows differences in risk between males and females, and particularly with age at irradiation. Such differences can be taken into account when considering risks to individuals. It is emphasised that situations that require best estimates of risk should be evaluated using the best scientific data – including organ/tissue absorbed doses; relative biological effectiveness estimates; and age-, sex- and population-specific risk estimates – with consideration of uncertainties.

The use of effective dose has helped to raise awareness of dose levels from diagnostic imaging procedures among healthcare staff. However, users often forget the approximations made in the derivation of effective dose, and overstate its accuracy. Effective dose is only accurate to perhaps ±40% as a relative indicator for a reference person; as such, it should not be stated to more than two significant figures. Use of effective dose to predict the risk of cancer induction from a low-dose radiation imaging procedure introduces much greater uncertainties, so descriptive terms are recommended for conveying risk which reflect uncertainties in risk predictions. These terms are sufficient in many cases because the risks from most medical diagnostic exposures are small. If it is considered necessary to calculate a more accurate assessment of risk, this should be based on doses to all of the exposed organs and risk coefficients used for a person of the same age and sex, with appropriate consideration of uncertainties.

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What is the point of innovation in patient dose monitoring?

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Abstract–*The Medical Futurist* says that radiology is one of the fastest growing and developing areas of medicine, and therefore this might be the speciality in which we can expect to see the largest steps in development. So why do they think that, and does it apply to dose monitoring? The move from retrospective dose evaluation to a proactive dose management approach represents a serious area of research. Indeed, artificial intelligence and machine learning are consistently being integrated into best-in-class dose management software solutions. The development of clinical analytics and dashboards are already supporting operators in their decision-making, and these optimisations – if taken beyond a single machine, a single department, or a single health network – have the potential to drive real and lasting change. The question is for whom exactly are these innovations being developed? How can the patient know that their scan has been performed to the absolute best that the technology can deliver? Do they know or even care how much their lifetime risk for developing cancer has changed post examination? Do they want a personalised size-specific dose estimate or perhaps an individual organ dose assessment to share on Instagram? Let's get real about the clinical utility and regulatory application of dose monitoring, and shine a light on the shared responsibility in applying the technology and the associated innovations.

Keywords: CT; Dose; Innovation; Applications

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

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Ethical aspects in the use of radiation in medicine: update from ICRP Task Group 109

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Abstract–Whereas scientific evidence is the basis for recommendations and guidance on radiological protection, professional ethics is critically important and should always guide professional behaviour. The International Commission on Radiological Protection (ICRP) established Task Group 109 to advise medical professionals, patients, families, carers, the public, and authorities about the ethical aspects of radiological protection of patients in the diagnostic and therapeutic use of radiation in medicine. Occupational exposures and research-related exposures are not within the scope of this task group. Task Group 109 will produce a report that will be available to the different interested parties for consultation before publication. Presently, the report is at the stage of a working document that has benefitted from an

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international workshop organised on the topic by the World Health Organization. It presents the history of ethics in medicine in ICRP, and explains why this subject is important, and the benefits it can bring to the standard biomedical ethics. As risk is an essential part in decision-making and communication, a summary is included on what is known about the dose–effect relationship, with emphasis on the associated uncertainties. Once this theoretical framework has been presented, the report becomes resolutely more practical. First, it proposes an evaluation method to analyse specific situations from an ethical point of view. This method allows stakeholders to review a set of six ethical values and provides hints on how they could be balanced. Next, various situations (e.g. pregnancy, elderly, paediatric, end of life) are considered in two steps: first within a realistic, ethically challenging scenario on which the evaluation method is applied; and second within a more general context. Scenarios are presented and discussed with attention to specific patient circumstances, and on how and which reflections on ethical values can be of help in the decision-making process. Finally, two important related aspects are considered: how should we communicate with patients, family, and other stakeholders; and how should we incorporate ethics into the education and training of medical professionals?

Keywords: Ethics; Radiological protection; Medicine; ICRP publication

1. INTRODUCTION

In many developed countries, medicine has become one of the greatest areas of government expenditure. This level of investment can only occur when the community regards it as important and in line with ethical expectations (Malone et al., 2018). Fuelled by an increased aversion of medical paternalistic attitudes, healthcare providers are pressured to provide more openness, accountability, transparency, and honesty. Likewise, there is now a high level of consensus in most political, social, and legal systems to respect the dignity of individuals, their autonomy, and their rights in general. All this, and other obligations including prudence, imposes new burdens on healthcare professions and practices, including radiological protection, which have not been accustomed to this type of expectation and related oversight (Malone and Zolzer, 2016; Parsa-Parsi, 2017).

1.1. Ethical values in radiological protection

The International Commission on Radiological Protection (ICRP) was founded at the second International Congress of Radiology held in 1928, in response to increasing concerns about the need for guidance to address health effects from ionising radiation in the medical community. For more than 90 years, ICRP has continued to provide recommendations and guidance to protect patients, workers, and the public. In this context, ICRP recently published *Publication 138* which defines the ethical foundations of the system of radiological protection (ICRP, 2018). It proposes a set of values that are similar, but not identical, to the principles of biomedical ethics established by Beauchamp and Childress (1979). *Publication 138* (ICRP, 2018)

presents four core values: beneficence/non-maleficence, prudence, justice, and dignity. In addition, three procedural values that play a role in the practical implementation of the core values are also discussed: accountability, transparency, and inclusivity (i.e. stakeholder participation). For readers unfamiliar with these values, a definition of the main ethical values is given below (ICRP, 2018).

'Beneficence' means promoting or doing good, and 'non-maleficence' means avoiding causation of harm. Beneficence includes consideration of direct benefits, both for individuals and communities. The planned use of radiation, although coupled with known and unknown risks, can undoubtedly have desirable outcomes. These potential benefits have to be weighed against the potential harms. This is achieved in practice by: (i) ensuring that the use is justified; and (ii) ensuring that acute tissue effects are avoided or minimised, and stochastic effects are reduced as far as reasonably achievable while still providing the desired outcome given the prevailing circumstances (i.e. optimisation). From the viewpoint of evidence-based medicine and public health, the application of beneficence and non-maleficence requires an evaluation of the benefits, harms, and risks. This is neither straightforward nor sufficient. A variety of social, psychological, and cultural aspects also need to be considered. Furthermore, there may be disagreement on what matters most or on how to value or weigh these factors. In this respect, it is worth recalling the World Health Organization's (WHO) definition of health: 'Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity' (WHO, 1948).

Prudence is the ability to make informed and carefully considered choices without full knowledge of the scope and consequences of actions. It is also the ability to choose and act on what is in our power to do and not do. The system of radiological protection is based on solid scientific evidence, but the remaining uncertainties at low levels of exposure necessitate value judgements. Decision-making requires prudence as a central value, but policy makers generally refer to the precautionary principle instead. This principle, which states that lack of full scientific certainty shall not be used to justify postponing appropriate preventive measures 'where there are threats of serious or irreversible damage', has been much debated in connection with the ethics of decision-making in recent years. This is also at stake in the domain of radiological protection (Streffer et al., 2004). Neither prudence nor the precautionary principle should be interpreted as demanding zero risk, choosing the least risky option, or requiring action just for the sake of action. Instead, potential risk should always be considered in the context of benefit, either directly to the exposed individual or to the community at large. The experience of over half a century of applying the optimisation radiation protection principle can be considered as a reasoned and pragmatic application of prudence and/or the precautionary principle.

Justice is usually defined as fairness in the distribution of advantages and disadvantages among groups of people (distributive justice), fairness in compensation for losses (restorative justice), and fairness in the rules and procedures in the processes of decision-making (procedural justice). The system of radiological protection aims to ensure that the distribution of individual exposures meets two principles of

distributive justice. First, the principle of equity reflects the personal circumstances in which individuals are involved. It is the role of dose constraints and reference levels to reduce the range of exposures to individuals subject to the same exposure situation. Second, the principle of equal rights guarantees equal treatment for all individuals belonging to the same exposure category in planned exposure situations. It is the role of dose limits to ensure that all members of the public, and all occupationally exposed workers, do not exceed the level of risk deemed tolerable by society and recognised in law (Hansson, 2007). Note that dose limits do not apply for patients because the method of choice for diagnosis or treatment may result in higher exposures, and therefore such limits would do more harm than good (ICRP, 2007). Equality is therefore not deemed a prime consideration. Reference levels are intended to at least reduce the variations between patients with similar size and conditions.

Dignity is an attribute of the human condition; the idea that something is due to a person because she/he is human. This means that every individual deserves unconditional respect, irrespective of personal attributes or circumstances such as age, sex, health, disability, social condition, ethnic origin and/or religion, etc. This idea has a prominent place in the Universal Declaration of Human Rights which states that 'All human beings are born free and equal in dignity and rights' (United Nations, 1948). Personal autonomy is a corollary of human dignity. This is the idea that individuals have the capacity to act freely (i.e. to make uncoerced and informed decisions). Respect for human dignity was first promoted in radiological protection as 'informed consent' in biomedical research, which means that a person has 'the right to accept the risk voluntarily' and 'an equal right to refuse to accept' such risks (ICRP, 1992). In a number of different ways, the system of radiological protection actively respects dignity and promotion of the autonomy of people facing ionising radiation in their daily lives.

In addition to the core ethical values, *Publication 138* (ICRP, 2018) sets out a number of requirements relating to the procedural values and organisational aspects of radiological protection: accountability, transparency, and inclusivity. All are inter-related and have strong ethical aspects.

Accountability can be defined as the procedural ethical value that people who are in charge of decision-making must answer for their actions to all those who are likely to be affected by these actions. Transparency is also part of implementing the value of procedural justice. It concerns the fairness of the process through which information is intentionally shared between individuals and/or organisations. Transparency does not simply mean communication or consultation. It relates to the accessibility of information about the activities, deliberations, and decisions at stake, and also to the clarity, practicality, and honesty with which this information is transmitted.

The value of inclusivity is usually presented with the phrase 'stakeholder participation', which is the way the value is applied in practice. Stakeholder participation, also noted as stakeholder involvement or engagement, means 'involving all relevant parties in the decision-making processes related to radiological protection' (IRPA, 2008). Empathy was not proposed explicitly as a procedural value in *Publication 138* (ICRP, 2018), but it deserves to be introduced here because it is linked to the concept

of inclusivity. Empathy can be defined as the capacity to understand what another person is experiencing from within the other person's frame of reference, or, more prosaically, the capacity to place oneself in another's shoes. So far, empathy has not been widely accepted as an ethical value, yet it plays an essential role in situations where perceived and factual risks often diverge.

1.2. Application of ethics in radiation medicine

Once the ethical framework of radiological protection had been established, ICRP mandated Task Group 109 (TG109) to advise medical professionals, patients, families, carers, the public, and authorities about the ethical aspects of radiological protection of patients in the diagnostic and therapeutic use of radiation in medicine. Occupational exposures and research-related exposures are not within the scope of this task group.

TG109 is composed of a group of medical professionals and academics, a patient advocate, and an ethicist. It has held two face-to-face meetings and benefitted from an international stakeholders' workshop organised on the topic by WHO in Geneva in September 2019.

The goal of this article is to report on the approach proposed by TG109. Although this is a work in progress, TG109 has already identified that the presence of guidelines is not in itself sufficient to ensure that practice will be ethically acceptable. Ethical values together with critical thinking need to be deeply rooted in health professionals in order to be effective. Thus, the task of TG109 includes not just identifying the guidelines, but also suggesting related supportive actions, including education, ongoing training, and audit to ensure that an ethics curriculum becomes a widely accepted part of practice and professional culture. The outline of the current version of the working document is presented in Fig. 1.

2. STATUS OF THE WORKING DOCUMENT

2.1. Ethical aspects of the dose–effect relationship

If radiological imaging and therapy involving ionising radiation had no negative biological effects, their use in medicine would require much less ethical consideration, as is the case with ultrasound imaging for example. Of course, there would still be cost and justification considerations which apply to all medical resources. The type of effects (e.g. erythaema, organ breakdown, cancer, etc.), together with their potential for harm (i.e. severity or likelihood), are directly related to acceptance of the benefit that can be expected from a medical exposure. Appropriate information of the possible unwanted health effects arising from the use of ionising radiation is an essential step in the acceptance of a medical procedure by the patient. This must be complemented with information about the expected benefits of the radiological procedure, as well as the potential consequences of not performing that examination or initiating the proposed treatment. This follows directly from the value of dignity.

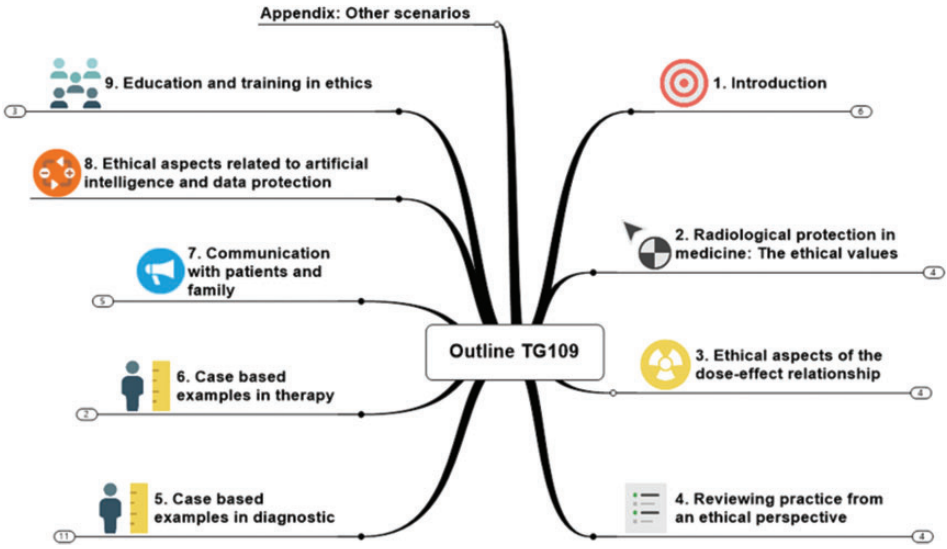

Fig. 1. Present outline of the working document of the International Commission on Radiological Protections's Task Group 109.

Another ethical issue related to the dose–effect relationship comes from the fact that the risk tends to decrease with age, with some exceptions (e.g. pregnancy, breast feeding). This justifies why specific precautions should be applied to children. However, the same reasoning could also have implications for the elderly, where the non-maleficence of an exposure tends to increase with age.

Finally, and despite the fact that scientific knowledge on the effects of ionising radiation is better compared with knowledge on other sources of hazards, there are two large sources of uncertainty. The first concerns the dose–effect relationship at low dose at the population level; it cannot be asserted with certainty that a dose below 50 mSv delivered to each individual of a population will result in a measurable increase in the number of induced cancers. The ethical value of prudence is usually used to justify that any level of dose could be harmful. The second large source of uncertainty concerns the variation of radiosensitivity among individuals. Except for a few specific cases (e.g. patients with ataxia-telangiectasia), it is very difficult to know if a patient is more or less sensitive to ionising radiation than the average population. Here again, one should resort to the value of prudence.

Estimates of radiation-induced harms, including deaths and future cancers, hide notable uncertainty about their origins, significance, and how they might be presented to patients and other health professionals. For example, the importance of a risk of death of a few percent 10 years into the future may be seen very differently by a young mother and an octogenarian man with multiple health conditions. Likewise, there are great differences between the way in which risks are calculated and benefits are estimated; frequently, it is very challenging to make benefit/risk estimates with

sound evidence or that gain consensus amongst colleagues. Similar considerations may apply to comparisons with benefits and risks from other treatments/procedures and/or medications.

2.2. Evaluation method

In general, when evidence is lacking from a guideline or the scientific literature, providers often turn to talking with their colleagues and relying on their clinical experience and ethical training. There is very little literature to identify when ethical evaluation is needed for medical applications of radiation. Self-assessment of compliance with the key ethical values would have great benefits in improving sensitivity to ethical issues. A thorough assessment of ethical compliance supported by the advice of an ethical committee would not be practicable nor useful in every single scenario where radiological protection principles have to be applied for the medical use of radiation, and would not be justified. In unusual scenarios, medical providers may consult with ethics committees for help in resolving complex patient care difficulties. More practical, however, is the incorporation into daily practice of an approach to identify the specific situations where ethical dilemmas may arise in order to perform a more comprehensive ethical evaluation.

As such, a relatively simple tabulated evaluation method is proposed to perform a quick self-assessment of the compliance/non-compliance of a given scenario with six key ethical values (Malone and Zölzer, 2016). It is intended to be applied by healthcare providers prescribing and/or performing radiological medical procedures. Based on this initial assessment, further actions can be considered, including evaluation of the particular case by the relevant ethics committee or radiation protection committee.

The method asks the stakeholder to score a given scenario on a six-point scale as compliant (or non-compliant) with the values identified. Compliance with a value is indicated as being strong (☺☺), weak (☺), or neutral (−). Likewise, non-compliance is indicated as strong (☹☹), weak (☹), or neutral (−). Some aspects of scenarios can demonstrate compliance with a value when considered from one perspective, and non-compliance when considered from another. Thus, it is possible to score both ☺☺/☺ and ☹☹/☹ for the same value. The method is open to development in terms of incorporating additional values, or being used serially to assess how situations appear when assessed from different perspectives. It can also be used as a teaching tool; for instance, to illustrate balancing values. It should be noted that there may be no correct answers to this method. Different observers may come to different conclusions for a variety of reasons that are all considered valid.

2.3. Specific situations

2.3.1. General approach

In order to be useful for the day-to-day stakeholders, the report proposes to consider specific situations in radiological diagnostic imaging and therapy involving

ionising radiation. Although it is planned to include therapeutic procedures at a later stage, at the time of writing of this article, only the imaging and interventional procedures have been established for 10 situations:

- Adult population
- Pregnant patient
- Breast feeding
- Paediatric exposure
- Elderly exposure
- End-of-life medical radiation imaging
- Chronic disease
- Asymptomatic individual health assessment
- Organised population screening
- Carers' and comforters' exposures

For didactic reasons and in order to show how ethics can be addressed in practice, each situation will be discussed in three steps. First, a realistic scenario that contains interesting ethical issues will be presented. Second, a table containing a possible ethical grading of the scenario will be proposed and discussed. Finally, a more general discussion about each situation will be presented.

In this article, a scenario regarding the exposure of an elderly patient is presented as an example. It is important for the reader to realise that this evaluation necessarily contains aspects which are not fully determined. This highlights a level of uncertainty encountered in practice, and the value of having different points of view when ethical issues are complex.

2.3.2. Example of elderly exposure scenario

During his annual health check, Mr Michael, 66 years of age, is given an abdominal ultrasound scan for liver and gallbladder analysis. His doctor prescribes him a computed tomography (CT) scan with contrast agent due to the suspicion of a potential kidney problem. The patient is not given any specific information about the risk and benefit of the CT examination, which is considered as a routine examination to verify the status of his kidney. The CT scan clearly confirms the presence of an early-stage tumour in the right kidney. This is followed, within 3 days, by an interview with the urologic surgeon, who carefully and completely explains the tumour context and suggests that tumour removal surgery should be performed as soon as possible. Thanks to his private insurance, Mr Michael can skip the typical 2-month waiting list, and his operation is performed within 1 week of the meeting with the surgeon. After surgery, the patient is informed that the tumour was small and well located. It is therefore decided not to carry out radiotherapy or other radiological treatments. However, in order to follow the local guidelines, a follow-up CT scan is prescribed every 4 months for 2 years.

After his release from hospital, Mr Michael wants to understand more about his health situation and starts to surf the web. He cannot find any information about his

Table 1. Grading of the elderly exposure scenario.

	Beneficence/ non-maleficence	Prudence/ precaution	Justice	Dignity/ autonomy	Transparency/ accountability	Inclusivity/ empathy
Compliance	☺☺	☺☺	☺☺	☺	–	–
Non-compliance	☹	–	☹	☹☹	☹	☹☹

follow-up CT scans on the hospital website. However, after consulting the website of the national society of radiology of his country, he is particularly concerned about the follow-up CT scans because they are carried out with ionising radiation and that, in general, ionising radiation is associated with possible risk to his health, such as the induction of tumours. At this point, Mr Michael becomes anxious, realising that he had just been successfully treated for a tumour and that, in the recommendations that are indicated for the next 2 years, he will be exposed to radiation that could potentially cause another cancer.

2.3.2.1. Beneficence/non-maleficence

The benefit of performing the first CT scan can be considered as fully justified because the ultrasound examination could not provide adequate information. Furthermore, the skills and high level of professionalism of the medical team cannot be questioned. There is therefore strong compliance with beneficence/non-maleficence (☺☺).

However, some non-compliance with this ethical value can be identified. Mr Michael received no warning about the risk of ionising radiation, and he was not informed about the postoperative CT checks. That made him feel like a passive recipient of health care and may have contributed to induce a persistent state of anxiety. We therefore propose to score non-compliance with beneficence/non-maleficence as weak (☹).

2.3.2.2. Prudence/precaution

At older ages, patients tend to become less sensitive to the effects of ionising radiation. Taking into consideration that the CT scan is recognised to be a highly effective tool for Mr Michael's health situation, we consider that there was adequate and sufficient prudence to keep any foreseeable possible developments under control. We therefore propose to score compliance with prudence/precaution as strong (☺☺), with a neutral score for non-compliance (–).

2.3.2.3. Justice

From a pure radiological protection point of view, Mr Michael's examinations were performed in due time, followed the recognised guidelines, and did not differ from what would have been done for other patients in his country. We therefore propose to score compliance with (distributive) justice as strong (☺☺).

The fact that Mr Michael was not considered as a full partner of the decision process shows some non-compliance in terms of procedural justice. Furthermore, the fact that he could skip the waiting list thanks to his private insurance draws some ethical issues regarding distributive justice. However, this latter point is out of the scope of radiological protection, and we propose to score non-compliance with justice as weak (☹).

2.3.2.4. Dignity/autonomy

The fact that Mr Michael was treated quickly and efficiently shows that he was respected as a person by the medical staff. We therefore propose to score compliance with dignity as weak (☺).

On the other hand, there was some serious non-compliance with autonomy. Mr Michael was barely involved in the available therapeutic and follow-up choices, and no spontaneous information about the risk associated with ionising radiation was given to him. This is unfortunate because the patient felt that he was just a receiver of health care and not an actor of his life. This led to notable concern on his part that he might have been exposed to undue risk without his consent. If this had been different, this could have increased his self-esteem, improved his quality of life, and therefore had a good influence on the treatment and his health in general. This is why we propose to score non-compliance with dignity and autonomy as strong (☹☹).

2.3.2.5. Transparency/accountability

Mr Michael was not given a spontaneous, complete, and comprehensible picture of his situation. Presently, many hospitals invite their patients to look at their website or provide printed leaflets to inform them about common procedures and radiation risk. This lack of transparency and accountability towards Mr Michael led us to score non-compliance with transparency and accountability as weak (☹).

2.3.2.6. Inclusivity/empathy

Mr Michael's strong need for information and desire to be involved could have been anticipated by applying the value of empathy. Indeed, it is reasonable to think that the health professionals considered in their soul and conscience that the proposed treatment was the best and only reasonable decision. However, visibly, Mr Michael had concerns that were not imagined by the professionals. For this reason, we propose to score non-compliance with inclusivity and empathy as strong (☹☹).

3. CONCLUSION

A set of specific ethical values for radiological protection were proposed in *Publication 138* (ICRP, 2018). This article presents the state of work of TG109, which aims to advise medical professionals, patients, families, carers, the public, and authorities about the ethical aspects of radiological protection of patients in the diagnostic and therapeutic use of radiation in medicine. It is proposed to use a relatively simple tabulated evaluation method to perform a series of self-assessments

of the compliance/non-compliance of a given patient scenario with six key ethical values. The case of an elderly exposure is presented as an example. In the final report, it is planned to treat a wide range of practical situations typically encountered in medicine using radiological imaging and therapy. Each situation will be initiated by a realistic scenario, where the evaluation method will help the reader to identify the relevant ethical issues. This will serve as an introduction to a more general discussion about each situation. The final report also plans to address other key topics, such as communication with patients and family, artificial intelligence, and education and training of health professionals.

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Patients' perspectives on radiation in health care

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Abstract–As radiation therapy is needed by approximately 50% of patients with cancer there needs to be ongoing research to ensure that radiation therapy targets the tumour effectively and minimises potential side effects. Major advances in radiation therapy, due to improvements in engineering and computing, have made it more precise, reducing side effects and improving cancer control. Patients need to be informed of its risks, both short and long term, to enable them to be active participants in their cancer treatment path.

Keywords: Long-term toxicities; second malignancies; cardio toxicities; radiation-induced fibrosis; patient-centred care; computed tomography; linear accelerator advances; artificial intelligence; real-time tumour targeting; treatment system design; oligometastic settings

1. INTRODUCTION

In 2005, Lee was diagnosed with a Her2-positive, grade 3 breast tumour. Her treatment consisted of AC chemotherapy (a combination of adriamycin and cyclophosphamide), a 30-cycle course of radiation therapy, and 17 cycles of a new targeted drug, Herceptin. At the multi-disciplinary team clinic, she was warned that her lungs could be burnt by the radiation, her hair would fall out, and she would need a cocktail of additional drugs to combat the nausea of chemotherapy. She knew a little about chemotherapy, but had no knowledge regarding radiation therapy. She did not receive any written information about the three treatments, nor specifics regarding therapy-induced side effects.

A few years after treatment, she started to experience late-onset side effects. One was an excruciating pain that travelled from the base of her oesophagus upwards towards the back of her throat. An endoscopic examination by a gastroenterologist

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

revealed that her oesophagus was rigid in sections. It is believed that the stiffness was caused by the radiation therapy. Another symptom that emerged was fainting. It is believed that her heart muscle was affected by the AC chemotherapy. Adriamycin is most commonly linked to changes in the heart muscle. She undertook vascular surgery to improve blood flow to her heart. As further side effects develop, she has learnt to treat them or modify her life.

Like all cancer treatments, radiation therapy often causes side effects. These are different for each person and depend on the type of cancer, its location, the radiation dose, and the patient's general health. Most people will have some mild side effects during and just after treatment. Three long-term side effects are: radiation-induced second malignancies; cardiotoxicity, and problems in the heart and vascular system; and radiation-induced fibrosis.

- Radiation-induced second malignancies. As children and young adults are likely to survive for a longer duration after anticancer therapy, they are at a greater risk than older adults. There is a need for integrated research involving clinical studies, radiobiology, and physics to estimate and reduce the risk of treatment-related second cancers.
- Cardiotoxicity, and problems in the heart and vascular system. Cardiotoxicity is a risk when a large volume of heart muscle is exposed to a high dose of radiation. Patients who develop radiation-related cardiotoxicity should be under the care of a cardiologist who understands the relationship between cancer treatment and heart problems.
- Radiation-induced fibrosis. Fibrosis may cause the bladder to hold less urine, the breasts to feel firmer, the arms or legs to swell, breathlessness due to the lungs being less stretchy, and narrowing of the oesophagus, making it difficult to swallow. There is a real need for ongoing research to find therapies that can prevent formation of fibrosis or to treat the disease. Prevention has focused on improvements in radiation therapy technique.

The main goal of cancer treatment is to extend life, but the quality of that extended life is also important for the patient. Some patients do not care much how a treatment affects quality of life. They want to fight to get to a particular milestone, even if their quality of extra life is poor. For others, quality of life is as important as length of life, or maybe even more so.

The risks and side effects of radiation therapy need to be communicated effectively to the patient. Frequently in the culture of 'doctor knows best', the patient with cancer trusts their doctor to do what is appropriate and does not discuss the attendant risks. To support understanding by patients, the creation of patient-centred resources regarding radiation treatment and possible side effects is necessary. Written information allows the patient to reflect on what will be involved during the therapy, enables accurate understanding for discussion with family and friends, and becomes an excellent reference for managing both short-term and late-onset therapy-induced side effects.

2. WHAT ADVANCES HAVE OCCURRED IN RADIATION THERAPY?

Radiation therapy techniques have changed significantly over the past few decades, thanks to improvements in engineering and computing. Major advances in radiation therapy have made it more precise, reducing side effects and improving cancer control.

- Computed tomography (CT), magnetic resonance imaging, and functional imaging such as positron emission tomography provide definitive imaging before treatment, allowing a more accurate assessment of disease spread and more effective treatment planning. Four-dimensional CT is becoming available in the clinical setting. There is integration of imaging information in every phase of treatment, from simulation to planning to delivery. Treatment imaging allows the clinician to correct for patient movement, internal organ movement, and change in tumour size, enabling personalised treatment. In addition, advancements in the treatment couch can correct for pitch, roll, and yaw, resulting in a more accurate and reliable treatment set-up.
- Advances in the capability of linear accelerators enable the delivery of high-dose treatment to tumour cells whilst sparing tissue that is healthy. At one time, radiation therapy was delivered in large fields with a static dose, but now intensity-modulated radiation therapy allows the radiation dose to conform more precisely to the three-dimensional shape of the tumour by modulating the radiation beams into multiple smaller beams.

3. WHAT WILL RADIATION THERAPY LOOK LIKE IN THE FUTURE?

- Artificial intelligence in health care will complement doctors, offering several advantages by assisting doctors to make better data-driven decisions. Artificial intelligence can help to improve the efficiency of diagnosis, management, administration, and treatment. It will improve imaging and delivery to ensure consistent treatment for all patients with cancer.
- Magnetic resonance linear accelerators will help to visualise and target the tumour during treatment, allowing greater precision in cancer treatment, maximising the chance of the best-possible outcome for the patient.
- As the human body is a dynamic system, tumours move during radiation treatment. Several solutions for real-time tumour targeting are in development. Kilovoltage intrafraction monitoring is one of the technologies being clinically pioneered in Australia to turn today's standard linear accelerator into tomorrow's real-time cancer targeting system. It is purely a software solution.
- Rethinking cancer treatment system designs with the patient experience, safety, and costs in mind may improve global access to radiation therapy. Three designs

are in development at the Australian Cancer Research Foundation Image X Institute which are smaller, and cheaper to manufacture and house.
- Radiation therapy will be used increasingly in the oligometastatic setting, given the positive results of several clinical trials. A phase II trial found that radiation therapy can generate an immune system response that was not previously believed possible in oligometastatic prostate cancer.

As radiation therapy is needed by approximately 50% of patients with cancer at some stage in their treatment journey, there needs to be ongoing research to ensure that radiation therapy targets the tumour effectively and minimises potential side effects. It is important that patients with cancer are informed of its risks, both short and long term, along with those of other cancer therapies, to enable them to be active participants in their cancer treatment path.

Radiation protection challenges in applications of ionising radiation on animals in veterinary practice

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Abstract–As we work towards a holistic approach to radiation protection, we begin to consider and integrate protection beyond humans to include, among other things, non-human biota. Non-human biota not only includes environmental flora and fauna, but also livestock, companion animals, working animals, etc. Although under consideration, there is currently little guidance in terms of protection strategies for types of non-human biota beyond wildlife. For example, in recent years, veterinary procedures that make use of ionising radiation have increased in number and have diversified considerably, which has made radiation protection in veterinary applications of ionising radiation more challenging, both for humans and the animal patients. In fact, the common belief that doses to professionals and members of the public from these applications will be very low to negligible, and doses to the animals will not be acutely harmful nor even affect their lifetime probability of developing cancer, needs to be revisited in the light of higher dose diagnostic and interventional techniques, and certainly in the case of therapeutic applications. This paper provides a brief overview of the initiatives of the International Commission on Radiological Protection concerning radiation protection aspects of veterinary practice, and poses a variety of perspectives for consideration and further discussion.

Keywords: Veterinary radiological protection; Non-human biota; ICRP

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1. INTRODUCTION

After Roentgen's discovery of x rays, veterinarians were among the first to perceive the potential benefits of radiology for animal health care (Schnelle, 1968; Kealy, 2002). Starting with the increase in small animal practice in the 1930s, plain film radiography was the only veterinary application of ionising radiation for many decades. Moreover, the number of procedures was limited and the doses to human bystanders were low to trivial, provided that some simple rules were followed. Consequently, veterinary use of ionising radiation was not a high priority for radiation protection, although there were some relevant publications (e.g. NCRP, 1970; NHMRC, 1982, 1984). Even 15 years ago, the prevalence of veterinary radiology was acknowledged to be low (NCRP, 2004). However, since then, veterinary procedures making use of ionising radiation have increased substantially, with available modalities now as diverse as in human health care. Veterinary diagnostic radiology has become more popular worldwide for various reasons, including digitalisation and the wider availability of higher dose applications such as computed tomography (CT) and cone beam computed tomography (CBCT) scanning. Interventional radiology procedures have entered the practice field, and so have nuclear medicine applications, both diagnostic and therapeutic. Lastly, external beam radiotherapy has become available in several centres around the world.

Radiation-related risks have also increased and diversified because of these important practice changes. For example, in addition to the external exposure associated with nuclear medicine procedures, relevant veterinary clinics also need to consider the risk of contamination by radioactive substances to staff, owners, handlers, and the environment. Lessons learned from human medicine inform us that radiation exposure of veterinary staff involved in interventional procedures needs to be monitored closely as doses could be far from negligible (e.g. Klein et al., 2009; Durán et al., 2013; Ko et al., 2018), as could the doses to the animal patients themselves (e.g. Wagner, 2007; Balter and Miller, 2014; Arkans et al., 2017). Moreover, unique issues associated with animal patients may result in higher occupational doses associated with certain procedures (Martinez et al., 2012).

Societal changes also play a role in the increasing number and diversity of procedures performed on animals. Many companion animals are considered by their owners to be 'part of the family', and therefore entitled to the best care available. The same may hold true for working animals, exotic animals, and sports animals, simply because of their monetary value. More and more animals have health insurance, which may not only imply radiological examinations as part of insurability checks, but also removes financial barriers that would otherwise restrict the use of these more expensive imaging or treatment options. The imaging of animals also has a prominent place in a wide variety of suitability checks, such as suitability for breeding or for a career in sports. These procedures, which are not primarily performed for the benefit of the animal exposed, may become a radiation protection challenge in terms of the high number of exposures, and the fact that a limited number of staff and laypersons may be involved in many procedures.

The impact of these changes in veterinary practice on radiation protection needs and challenges has not gone unnoticed, and some authorities and organisations have produced guidance accordingly. For example, the National Council on Radiation Protection and Measurements revised the relevant 1970 report in 2004, and succinctly summarised the goal of radiation protection in veterinary medicine (NCRP, 2004):

> *The reasons for using radiation in veterinary medicine are to either obtain optimum diagnostic information or to achieve a specific therapeutic effect while maintaining the radiation dose to the radiological personnel and the general public as low as reasonably achievable (the ALARA principle). Similarly, it is also important to avoid all unnecessary irradiation of the animal patient.*

Additionally, the Australian Radiation Protection and Nuclear Safety Agency was one of the first to publish relevant guidance in its 2009 'Code of Practice and Safety Guide for Radiation Protection in Veterinary Medicine', updating similar reports from the 1980s (ARPANSA, 2009). More recently, the International Atomic Energy Agency has prepared a draft safety guide related to radiation protection and safety in veterinary medicine (the publication of which is imminent), and numerous activities have been developed by a dedicated working group within the Heads of the European Radiological Protection Competent Authorities, a voluntary organisation of Europe's radiation protection regulatory authorities.

The International Commission on Radiological Protection (ICRP), now recognising that the complexities of veterinary practice warrant dedicated clarification within the system of radiological protection, has decided that there is a need to strengthen the application of its protection principles in this area. The objective of the associated work is to provide an initial set of relevant recommendations; its primary focus will be the protection of humans involved in or affected by the procedures, both professionals and members of the public. Protection of the animal patient and the environment from nuclear medicine applications are also considered.

2. VETERINARY MEDICINE WITHIN THE SYSTEM OF RADIOLOGICAL PROTECTION

The primary aim of the system of radiological protection is 'to contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure' (ICRP, 2007a). For people, radiation exposures are managed with the goal of reducing stochastic effects to the extent reasonable, and preventing tissue reactions that are unnecessary (e.g. in radiotherapy, a tissue reaction may be unavoidable in order to obtain effective treatment). Different exposure situations and categories are defined within the system of radiological protection to take into consideration the specific circumstance under which an

exposure occurs. The exposure situations include planned (situations in which protection can be planned ahead of time), emergency (unexpected situations that may necessitate urgent intervention), and existing (situations that already exist and may need a decision on management or control).

Exposure categories include public (exposure received apart from occupational, medical, and natural background), occupational (exposure received at work due to the nature of the work), and medical (exposure received as a patient or from a patient as a volunteer comforter/carer). As the recommendations are currently written (ICRP, 2007a,b), the medical exposure category appears to apply solely to human medicine. As veterinary medicine appears to fall somewhere in between, or at the intersection of, the above exposure categories, local governments and regulatory agencies manage veterinary exposures in different ways. Although not specified as such, environmental exposure (exposure to the living environment) is a fourth category. Thus far, ICRP has focused on the natural environment, with the goal of maintaining biological diversity, conserving species, and maintaining the health status of associated habitats, communities, and ecosystems. Task Groups 107 (Advice on Radiological Protection of the Patient in Veterinary Medicine) and 110 (Radiological Protection in Veterinary Practice) are the first initiatives within ICRP to consider non-human biota in the managed environment, namely, companion animals and livestock.

The core of the system of radiological protection consists of three fundamental principles: justification, optimisation, and application of dose limits. The principle of justification specifies that any activity or intervention that changes the exposure scenario should be overall beneficial to individuals and/or society. The principle of optimisation specifies that doses should be as low as reasonably achievable, considering economic and societal factors. The principle of limitation applies to planned exposure situations (other than medical and environmental), and indicates that doses should not exceed appropriately established limits. Limitation does not apply to medical exposures in order not to interfere with necessary, medically indicated diagnostic or therapeutic procedures. In these cases, justification and optimisation are strongly emphasised. Additionally, diagnostic procedures use diagnostic reference levels, which are not seen as limits but instead indicate if a dose received from an imaging procedure is unusually high or low, to guide the optimisation process and thus help manage patient exposures (ICRP, 2007b). Neither do limits apply to environmental radiation protection, but derived consideration reference levels are used to inform the appropriate level of management or control of an exposure. Derived consideration reference levels are bands of absorbed dose rates, usually an order of magnitude, likely to affect key biological parameters of a reference species (ICRP, 2014). Finally, emergency and existing exposure situations utilise reference levels rather than limits, because what defines a reasonable or tolerable exposure will be strongly dependent on the prevailing circumstances of the exposure in these situations. The current work on radiation protection in veterinary practice focuses on planned exposure situations, although there will potentially be veterinary concerns in the other exposure situations as well.

The three main ethical theories underpinning the system of radiological protection (utilitarianism, deontology, and virtue ethics) are also frequently taught in veterinary ethics (Fawcett et al., 2018). The core ethical values of the system are beneficence/non-maleficence, prudence, justice, and dignity (ICRP, 2018), which are consistent with, but not the only ethical values or principles important in, veterinary practice. For example, the 'One Welfare' framework (Garcia Pinillos et al., 2016; Fawcett et al., 2018) recognises and emphasises the inter-relationships between human health and well-being, animal welfare, socio-economic development, biodiversity, and environmental conservation, and highlights additional ethical principles consistent with a holistic approach to sustainable development, similar to, but broader than, those presented in *Publication 91* (ICRP, 2003). At this early stage, we have not prioritised or chosen specific values to highlight within radiation protection in veterinary medicine, but anticipate a more thorough discussion in the full report and/or an accompanying paper.

3. CURRENT STATUS OF THE USE OF IONISING RADIATION IN VETERINARY MEDICINE

As many applications have come about without the active involvement of persons knowledgeable in radiation protection, and often also in the absence of an appropriate radiation protection framework, several issues have arisen. These need to be identified and rectified, preferably with close collaboration between the relevant stakeholders (e.g. the practising veterinarians and the radiation protection competent authorities). The issues listed should be seen as illustrative and by no means have the pretention of being exhaustive.

3.1. Unique aspects

Compared with human medicine applications, challenges for radiation protection could be greater in veterinary practice. Many radiological procedures on large animals are performed outside of a regulated environment, or new equipment may have been retrofitted in an existing building without due consideration of shielding requirements. Justification is not supported by a veterinary equivalent of the 'referral guidance' or 'appropriateness criteria' we know from human medicine, there are no diagnostic reference levels, there is little to no agreement on activities of radiopharmaceuticals to be administered for therapeutic purposes, there is no involvement of a medical physicist, and, last but not least, not all practitioners performing higher dose diagnostic or even radiotherapy procedures have undergone specific or specialist education and training.

Conventional radiology is available in many small veterinary practices. CT scanners, CBCT, C-arms, and O-arms can be found in an ever-growing number of veterinary clinics, where shielding strategies may require particular attention because of retrofitted devices. The use of mobile radiographic equipment is standard in dealing with large animals as it is performed on farms, in stables, at auctions, or in the

open field. The delimitation of a safe working area and proper use of mobile equipment may require extra attention. Nuclear medicine diagnostics and treatments are not so common, but may have been introduced without sufficient consideration of contamination problems, such as in dealing with radioactive waste, particularly urine. Some therapeutic interventions may be performed outside of veterinary clinics, such as when radioactive substances are administered into a horse's joints at a riding stable, resulting in potential contamination concerns. In nuclear medicine in general, the animal as an ambulatory radiation and possible contamination source deserves specific consideration, particularly when outside the clinic. Other radiotherapy treatments, either teletherapy or brachytherapy, are still fairly rare and restricted to veterinary clinics, but the potential radiological risks – both to the animals and to people involved in the procedures – should not be neglected.

Although more and more dedicated veterinary equipment is becoming available, second-hand equipment coming from human medicine is still very prevalent in veterinary practice. Safety and performance of the equipment should be verified before first use and then on a regular basis afterwards by means of a quality control programme. Mobile equipment may need more frequent checks than fixed installations. Quality checks need to include all pieces of equipment throughout the imaging or treatment chain, and should not be restricted to radiation-emitting equipment or sources. This means the inclusion of software, cameras in nuclear medicine, image monitors, etc. There is a growing influx of specialty veterinary equipment (e.g. FIDEX CT) that falls under industrial rather than medical standards. Additionally, mobile equipment is being marketed as 'lighter' because shielding has been reduced from, say, 6 kg to 4 kg. Although dedicated, fit-for-purpose equipment is certainly welcome in principle, it must still meet appropriate radiation safety standards. Similarly, clinics may not have given due consideration to shielding needs. For example, a room may have been designed to have adequate shielding for conventional x-ray applications on a fixed table with the primary beam directed from the ceiling to the floor, but that room may not be adequately shielded for interventional procedures using a C-arm.

For historic reasons, most veterinarians learn how to use standard radiologic equipment (fixed, mobile, or both) in their basic curriculum. This should comprise at least the basic notions of radiation protection. More risk-baring applications, such as the use of scanners, interventional radiology, nuclear medicine, and radiotherapy, certainly call for additional education and training, including the corresponding radiation protection. Such programmes are on offer, for instance, through the American College of Veterinary Radiology and European College of Veterinary Diagnostic Imaging, but they are not systematically formally required by the relevant authorities. One could ask whether practising these more complex and risk-baring techniques should not be restricted to veterinarians who have successfully completed such 'specialist' programmes. In general, there are striking differences in the basic and specific education and training requirements related to applying different imaging and therapy modalities in veterinary applications of ionising radiation.

These differences can also be observed for the connected radiation protection requirements, where some harmonisation of training requirements seems necessary (Gregorich et al., 2018). This includes continuous efforts to refresh, update, and, where needed, extend theoretical knowledge and practical skills, as well as adapt competences and attitudes. It should be obvious that if other professional groups, such as radiographers, radiotherapy technologists, and the like, actively intervene or even autonomously perform radiologic or radiotherapeutic procedures of any type, they should have had, and continue to have throughout their professional life, corresponding education and training. This should necessarily include radiation protection. It is up to the licensee, or otherwise authorised person or entity responsible for the installation, to clearly establish the roles and responsibilities of all those involved in the procedures, within the bounds of the appropriate regulatory framework, and ensure that they have, and continue to have, corresponding education and training.

3.2. Justification

Compared with human medical applications, the absence of an equivalent to 'referral guidelines' or 'clinical imaging guidelines' is striking. This may lead to the impression that ionising radiation is used intuitively rather than based on scientific evidence. This absence of formal consensus on what type of imaging is (most) indicated to diagnose or exclude a given health condition may be partly responsible for the impressive number of radiologic/nuclear medical examinations to which some racehorses and showjumpers are submitted (e.g. Judy, 2013); series are often repeated when another potential purchaser shows up.

In terms of balancing risk and benefit within justification, little concern has been demonstrated for the possible detrimental effects on the animals exposed, apart from radiotherapeutic applications. The scarcity of scientific data on the possible effects of low-dose radiation exposures on typical companion animals, horses, etc. is not helpful in this respect. Human exposure related to diagnostic procedures has also rarely been regarded as a risk worth considering, although this attitude certainly needs to be revisited in view of higher potential exposures in CT, nuclear medicine, interventional radiology, and radiotherapy. Anecdotally, there is also a common misconception that an animal with a short life span compared with a human will not experience radiogenic cancer. In fact, cancer patterns in mammals are similar and, in general, are relative to life span (e.g. Albert et al., 1994), and animal models are frequently used to extrapolate health risk, carcinogenic or otherwise, to humans (Fjeld et al., 2007). Although not specific to the practice of veterinary medicine, and predominantly high doses or dose rates, there is a good amount of data on the effects of animal exposure to a variety of radiation types (e.g. Haley et al., 2011; Tang et al., 2017).

The three levels of justification for a radiological practice in medicine, described in *Publication 105* (ICRP, 2007b), can also be applied to veterinary medicine. Level 1 justification requires that the proper use of radiation in veterinary medicine does

more good than harm to society. As radiological procedures are now integral to veterinary practice worldwide, level 1 justification is taken as a given and is not further discussed in this article. At the second level, a specified procedure would be considered generically justified for a specified clinical objective if it will improve diagnosis or treatment of a defined group of veterinary patients, or if it will provide necessary information about exposed animals. Level 3 justification requires that the application of a radiological procedure is judged to do more good than harm in the management of the individual veterinary patient.

Lately, there has been increasing concern about the overuse of radiological procedures in medicine, with a substantial proportion of medical imaging procedures deemed unjustified. While similar surveys have not been carried out in veterinary medicine, the problem of unjustified use of ionising radiation likely exists here as well, as many of the drivers of overuse are also present in veterinary medicine. These include, among others, lack of awareness of doses and associated risks, self-referral, 'self'-presentation, defensive medicine, lack of access to previously performed examinations at other veterinary practices, and lack of confidence in the clinical diagnosis.

Self-referral is the norm rather than the exception in veterinary medicine. Radiographic equipment is widespread, both in general veterinary practice and in larger veterinary hospitals. Frequently, the veterinary practitioner ordering a radiological procedure will also be the person performing the procedure and interpreting its results. This person may also be the owner of the radiographic equipment or may be employed by a veterinary practice which explicitly or implicitly expects their staff to ensure return on their investment in radiographic equipment. Hence, strong financial incentives for the use of radiological equipment are often present in veterinary medicine. Of particular concern recently is the wide adoption of CT, and the corresponding use (i.e. repeated studies from a young age, generally employing a full-body CT) and impact of teleradiology. Additionally, there is a growing impact of commercial firms providing easy access to sophisticated equipment, and then pressuring the facility or veterinarian to generate a certain amount of financial gain from that equipment's use.

'Self'-presentation, in which the owner or handler of an animal requests a diagnostic imaging or therapeutic procedure without previous clinical examination of the animal and hence without a radiology referral from a veterinary practitioner, or where the owner/handler demands a diagnostic or therapeutic procedure not considered to be indicated by their veterinary practitioner, is also a pertinent issue in veterinary medicine. As the veterinary field is service-oriented and is comprised mainly of private practitioners, some veterinarians may feel compelled to comply with such consumer demands to avoid losing business to veterinary practices that oblige such requests.

Diagnostic techniques are also quite commonly used for economic purposes rather than the health of the examined animal, such as in the case of pre-sales examinations on racehorses or showjumpers, as mentioned previously. Screening programmes for canine hip and elbow dysplasia are also in place in many countries,

and large numbers of animals are thus imaged as part of the breeding selection process. For such non-medical procedures on asymptomatic animals, there should be a scientific basis for the imaging procedures, a demonstrable relationship between the outcome and goal of the screening, and stricter requirements for evidence bases than for individual medical procedures.

3.3. Optimisation

Veterinarians face many occupational challenges and hazards, one of which is exposure to ionising radiation. Optimisation in veterinary care is a process to ensure that the likelihood and magnitude of exposures and the number of individuals exposed are as low as reasonably achievable, with consideration given to practical, animal welfare, economic, societal, and environmental factors.

From the point of view of procedure optimisation, considerable differences in approach can be observed. In some countries, the presence of non-professionals, such as the owners or handlers, during x-ray procedures on small animals is prohibited, whereas in many other countries, it is common practice for them to be present and restrain the animal.

The presence of members of the public is very common in radiographic procedures performed with mobile equipment outside of veterinary practices or clinics. Some persons, such as stable boys, may be repeatedly involved in assisting with these procedures, which might not be performed in an optimised fashion from a radiation protection point of view. The question then is whether some of these people should be considered as professionally exposed, whereas, in general, they are considered as members of the public. Data on the exposure of human bystanders, both professionally exposed persons and members of the general public, are scarce in veterinary practice settings. If data are available, they most often relate to actual practices, rather than what would result from best practice.

Activities of the same radioactive substance, administered to examine or even treat animals of the same species and characteristics in similar clinical settings (e.g. administration of ^{131}I to cats weighing approximately 4 kg, presenting with hyperthyroidism) may differ considerably from one centre to another, indicating important room for evidence-based optimisation.

Data on doses to the animals themselves are even more rare. A practical difficulty with second-hand equipment such as CT scanners coming from human medicine is that their standard protocols have been designed to offer high-quality images for reasonably optimised exposure settings, but with the human patient as a reference. Dose estimates presented by these machines suffer the same restriction, and should not be applied as such on animals that have different anatomical features and dimensions. In veterinary medicine, the lack of supporting professionals such as medical physicists (Arkans et al., 2017) could potentially allow the continued use of non-optimised protocols. Animals may therefore be exposed to doses in excess of what is required, which consequently leads to excessive doses to humans as well.

4. RELEVANT ICRP INITIATIVES AND SCOPE OF ONGOING WORK

There is a real need to strengthen the radiation protection framework and its application in practice about where exposure of animals to ionising radiation takes place, in part because of the connected exposure of humans. As such, ICRP initiated work to clarify and elaborate upon its recommendations with respect to veterinary medicine, resulting in the establishment of two related task groups, as mentioned above.

The mandate of Task Group 107 was to advise the ICRP Main Commission on the possibility and desirability of it becoming involved in protection of the patient with respect to the application of ionising radiation in diagnostic, interventional, and therapeutic veterinary medicine. With the final report delivered to the Main Commission in October 2018, the work of this task group is complete, concluding that ICRP should consider the animal patient in its recommendations.

The current mandate of Task Group 110 is to advise the ICRP Main Commission on radiological protection aspects involved in the applications of ionising radiation in veterinary medicine. As such, this includes treatment of occupational and public exposure of humans as it relates to delivery of veterinary care, and radiological protection considerations for the animals receiving such care. In addition, Task Group 110 is to consider the risks resulting from contamination of the environment from the applications of nuclear medicine in veterinary medicine. Task Group 110 will include the ethical considerations underlying various types of veterinary practice, and the ethics applied to protection of animals and plants in the environment. This publication will provide initial guidance and set the stage for additional considerations that may be appropriate.

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Radiological protection of the patient in veterinary medicine and the role of ICRP

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Abstract–At the request of the Main Commission of the International Commission on Radiological Protection (ICRP), Task Group 107 (TG107) was set up to consider the issue of radiological protection of the patient in veterinary medicine. TG107, who authored this article, brought together information relating to the use of diagnostic imaging and radiation oncology in veterinary medicine. A number of specific areas were identified that appeared to be appropriate for attention by ICRP. These included the use of dose quantities and units, the need for re-evaluation of stochastic and deterministic risks from ionising radiation in animals, and the growing use of imaging and therapeutic equipment for animals that is little different from that available to humans. TG107 unanimously recommended that it was both appropriate and timely for ICRP to consider and advise on these issues, and the Main Commission agreed. This paper summarises the findings of TG107.

Keywords: Radiation protection of animal patients; Dose quantities and units in veterinary medicine; Scope of radiological protection

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

1. INTRODUCTION

Concerns about radiological protection of the animal as the patient in veterinary medicine were first raised by Pentreath (2016), and the International Commission on Radiological Protection (ICRP) quickly responded by announcing the establishment of Task Group 107 (TG107) to advise the Main Commission on the subject (Clement, 2018). The issues to be addressed by TG107 were: the extent to which ionising radiation is used in veterinary medicine; the international setting in which any specific advice on the radiological protection of the animal as the patient is already being provided; the areas that it would be most useful for ICRP, together with the veterinary profession, to pursue in order to provide further advice; and the broader implications for ICRP and, indeed, for the radiological protection community as a whole, should it become involved in this subject. TG107, chaired by Jan Pentreath, completed its task and presented its findings to ICRP in October 2018. This article is a brief summary of the findings.

2. USE OF RADIATION IN VETERINARY MEDICINE

Radiation is now widely used in veterinary medicine, and its rapid growth parallels that in human medicine. Most clinics in Europe and North America have access to x-ray machines, and increasing use, at specialist centres, is made of computed tomography (CT), fluoroscopy, gamma camera imaging, positron emission tomography (PET), and combined single-photon emission computed tomography (SPECT)/CT and PET/CT scanners. Radiotherapy may include superficial or orthovoltage (keV) units; cobalt-60 units; intensity-modulated radiation therapy; brachytherapy; the use of radioiodine, technetium, or linear accelerators; and multi-leaf collimators. The basic equipment used is essentially the same as that for humans, but procedures can take place in a variety of non-dedicated facilities that may pose unique problems and necessitate specific education and training for veterinary practitioners. The handling of animals in many situations may involve the presence of specialised personnel (animal handlers), which may also result in the need to take specific protective measures.

Not all radiographic examinations are undertaken because the animals are unwell. One of the most frequent uses of radiography seems to be the examination of horses prior to their purchase, or for breeding, as a result of which they may be examined many times throughout their lives. Dogs are also radiographed as part of selective breeding programmes. Sheep, pigs, and other animals may be CT scanned simply to assess their fat and meat content.

By and large, the majority of animals examined, and treated, are essentially ‘valuable’ in one sense or another, but the list of those known to be examined or treated includes small and large animal pets (also referred to as ‘companion animals’), exotic pets such as reptiles, and those in zoological gardens and wildlife parks. Radiation therapy primarily relates to cats, dogs, and horses, and may involve brachytherapy and the application of radionuclides.

It is presumed that the use of these techniques around the world will increase as facilities become more available, the costs of examination and treatment reduce, and the demand from animal owners increases (Baker, 2017). There are already tele-imaging, for-profit, veterinary companies that provide certified veterinary radiologists, but the lack of published literature to demonstrate standardisation, guidelines, and protocols suggests that there are opportunities for ICRP to collaborate in this area of radiological protection. There is also a growing awareness within the veterinary profession that there is a greater need for guidance and the establishment of best practice, although this need has been primarily in the context of the radiological protection of veterinarians, their staff, and the owners of the animals, rather than of the animals themselves. The number of facilities used for diagnostic or therapeutic veterinary medicine worldwide is not known, but there are over 100 radiation oncology treatment sites registered in the USA alone. There are more than 20 centres across Europe that provide megavoltage, brachytherapy, and orthovoltage therapies, and there are probably many more centres that provide radioiodine treatment (predominantly for hyperthyroid cats) and a few centres that provide other radionuclide therapies. There are currently eight small veterinary teaching hospitals and three private referral hospitals using megavoltage facilities in Japan. There are even more diagnostic radiology facilities within the USA, Europe, and Japan. Many private practices and most veterinary colleges now have CT scanners. Some of these scanners may be 'second hand'.

3. CURRENT RADIOLOGICAL PROTECTION ADVICE FOR VETERINARIANS

Specific advice on the subject of radiation protection in veterinary medicine has been produced in some countries, aimed at the veterinary practitioners and, to a limited extent, the owners of the animals, but not the animals themselves. Such examples are those issued by the Radiological Protection Institute of Ireland (RPII, 2002), the National Council on Radiation Protection and Measurements (NCRP, 2004), and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA, 2009), and in a leaflet by the Heads of the European Radiological Protection Competent Authorities (HERCA, 2020). In the USA, the American College of Veterinary Radiology and the American Veterinary Medical Association provide their members with advice on radiation safety and treatment protocols. In addition, the American Hospital Association provides accreditation and some radiation safety training, and the Veterinary Interventional Radiology and Interventional Endoscopy Society aims to advance the art and science of veterinary interventional radiology, interventional endoscopy, and other image-guided procedures. Also of relevance is the Veterinary Cancer Society, which has members beyond the USA. Elsewhere, there are national organisations, such as the Australasian Association of Veterinary Diagnostic Imaging which covers both Australia and New Zealand, the Japanese Veterinary Medical Association which provides information concerning radiation safety and the handling of animals, and

the Japanese Society of Veterinary Science which has an advisory board for providing radiation safety and related guidelines. Within Europe, there is the European College of Veterinary Diagnostic Imaging which consists of specialists in both diagnostic imaging and radiotherapy, and the European Association of Veterinary Diagnostic Imaging. There is also the International Veterinary Radiology Association. There are no formal connections between any of these bodies and ICRP, and no known connections between these bodies and the International Commission on Radiation Units and Measurements (ICRU), the International Radiation Protection Association (IRPA), the International Atomic Energy Agency (IAEA), and any other international body with radiological protection responsibilities or interests.

Notwithstanding the above professional bodies, it seems that there is still considerable opportunity for radiation protection guidance and collaboration within the veterinary profession. A recent survey of veterinary specialists in the USA (Gregorich et al., 2018) concluded that: 'Radiation safety training, although more common in academia, was not universally available and may not meet radiography equipment license requirements for some institutions. Most radiologists, internal medicine clinicians, and EEC clinicians had a poor understanding of the amount of ionising radiation associated with medical imaging procedures and the potential hazards to their patients'. Apparently, 34% of those asked did not know what 'ALARA' (as low as reasonably achievable) stood for.

It is therefore of interest that IAEA, under the umbrella of its Fundamental Safety Principles, has drafted a safety report on 'Radiation Protection and Safety in Veterinary Medicine' to provide guidance with respect to veterinary uses of ionising radiation. This report, because of the limitations of the Basic Safety Standards to human radiation protection, does not mention any issues or guidance in relation to the protection of the animal as the patient.

4. SPECIFIC ISSUES

4.1. Dose quantities and units

Radiotherapy doses in veterinary medicine always appear to be expressed in Gy, but doses received by animals undergoing CT examination are usually expressed in terms of mSv (it is not always clear whether it is the equivalent dose or the effective dose that is implied in its use, although the latter is often specified). However, CT scanners estimate 'dose' based on the scan factors selected and on measurements made in the factory on cylindrical phantoms for human use. The quantities that the machines produce are volume CT dose index (CTDI volume), in mGy, and dose length product, which is the CTDI volume multiplied by the scan length, in mGy cm. This is the case for all CT scanners with respect to DICOM (Digital Imaging and Communications in Medicine) which is the international standard for transmitting, storing, retrieving, printing, processing, and displaying medical imaging information. These measured quantities may be converted to effective dose or organ dose estimates by third parties in order to arrive at 'risk' estimates depending on the organ

irradiated. The results are then expressed as mSv. Scanners also produce a 'patient protocol' after a CT examination is completed, giving a breakdown of doses for each scan phase performed during the examination, and the cumulative dose. The ICRP guidance for medical imaging dose tracking is to use measured quantities rather than effective dose (ICRP, 2007a). It therefore appears that no CT scanner interpretation in veterinary medicine is based on any animal (non-human) data, but this fundamental point does not seem to be made explicit in the relevant veterinary publications. There also seems to be no acknowledgement that the quantities of equivalent and effective dose are related specifically to human beings, and that they are not, strictly speaking, scientific quantities but practical quantities created by ICRP for use in the calculation of reference doses for the purposes of human radiological protection. Neither is measurable, although both can be calculated.

4.2. Diagnostic procedures

A wide range of imaging modalities is now used in veterinary medicine for animals of all shapes and sizes (Fig. 1), including PET scans (Fig. 2). Such techniques are of value, but optimisation and an understanding of risks relating to all of these diagnostic procedures are not well documented. There are also concerns about the number of radiographs and, particularly, CT scans taken of the same animal; for example, by different potential buyers of a horse. Concerns have also been raised

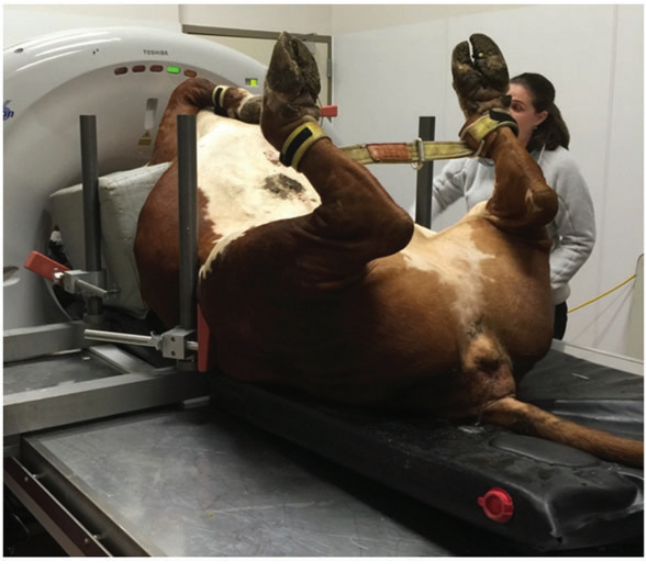

Fig. 1. A computer tomography scan of a 12-year-old cow (source: J. Gambino, Mississippi State University, USA).

Fig. 2. A portable positron emission tomography scanner being used for diagnosis of the left hind leg of a horse (source: Dr Spriet, UC Davis Veterinary Medicine, USA).

about the failure to determine, or even to consider, whether or not the animal is pregnant, and the failure to screen gonads in such procedures regardless of the reproductive state or age of the animal. Specific concerns have been raised about the lack of draped shielding in the radiography of dogs (Nemanic et al., 2015), and it is recommended that protective shielding should be used on all veterinary patients, drawing particular attention to the risks related to breeding animals, those receiving multiple radiographs over their lifetimes, and in breeds known to have increased susceptibility to cancer. In general, therefore, there appears to be nothing that is equivalent to the human medical imaging guidelines set out in *Publication 121* (ICRP, 2013), and no equivalent approach to that of the use of diagnostic reference levels as advocated for human medical imaging in *Publication 135* (ICRP, 2017).

There is clearly scope to increase awareness of the basic principles of radiation protection in this field with respect to justification, optimisation, and dose limits. The overall problem with respect to diagnostic procedures is perhaps exemplified by a recent survey in the USA (Gregorich et al., 2018), which found that over 60% of veterinary radiologists and associated staff did not believe that the doses of ionising radiation used in veterinary CT scanning carried any increased risk of potentially fatal cancer to their patients. Indeed, the majority (74%) of those surveyed, even if they were aware of the risks, did not warn veterinary clinicians or animal owners that the use of ionising radiation in imaging procedures may carry an increased risk of cancer to the patient. The same study also concluded that there was probably a general belief that dogs and cats do not live long enough to develop cancer as a result of exposure to ionising radiation. This appears to be a common belief, notwithstanding the experiments with thousands of dogs, in particular, relating to

cancer induction, from both internal and external sources, including exposures during the fetal and neonatal periods (Benjamin et al., 1975, 1978; Gillette, 1990). Analogous to human diagnostic imaging systems, there is therefore an opportunity to develop reporting databases, especially for CT imaging, and practice learning and improvement programmes for such situations.

4.3. Therapeutic procedures

Veterinary radiation oncology is relatively new compared with that for humans (McEntee, 2006). However, linear accelerators are now used routinely to provide therapeutic treatment, although some use is still made of brachytherapy (Fig. 3), proton therapy, and carbon ion therapy in some centres. Doses delivered can be up to 70 Gy (to dogs) (Coomer et al., 2009), and there is already some concern about the knowledge upon which such treatment is based. There are not many published scientific reviews of the damage incurred to healthy tissues, and very few of the consequences of errors in therapeutic treatment, although examples are not difficult to find (Fig. 4a,b). In one example, Arkans et al. (2015) reported a specific case of

Fig. 3. Brachytherapy of a horse being treated for sarcoid (source: J. Benoit).

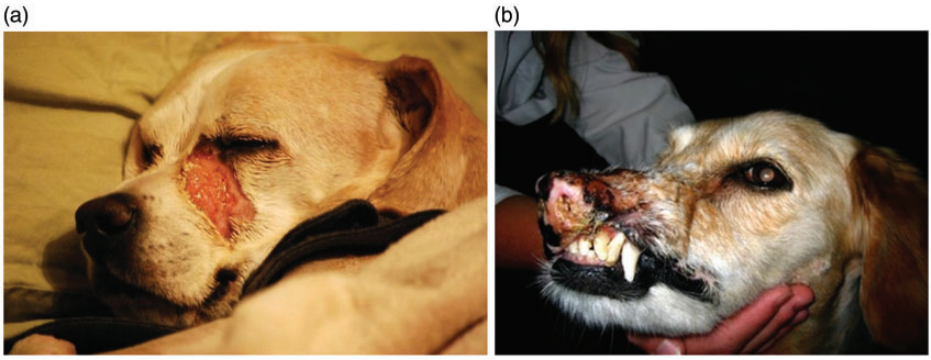

Fig. 4. (a) Radiation treatment burns 1 week after tomotherapy for nasal carcinoma (source: T. Loughlin). (b) Fibrosis in a dog 3 years after hypofractionated radiotherapy for mast cell tumour of the lip (source: J. Benoit).

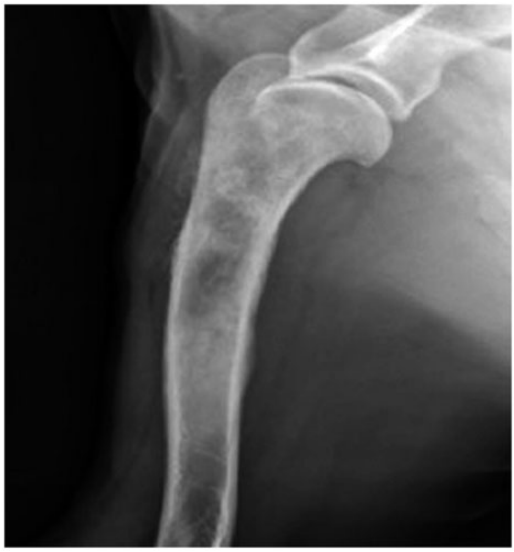

Fig. 5. Osteosarcoma in a dog 5 years after treatment for mast cell tumour (source: J. Benoit).

misadministration of radiation therapy to a dog, where mistakes led to application of the wrong treatment plan, notwithstanding the use of a 'record and verify' system. Late effects (Fig. 5) are also known but not well recorded, although a review of acute and chronic effects published over 20 years ago stated that severe reactions occurred in less than 5% of treated animals (Harris et al., 1997).

Considering the subject as a whole, in another review of practices in the USA, Keyerleber et al. (2012) looked at the completeness of reporting (in published studies) of treatment planning, radiation dose, treatment delivery, quality assurance,

and adjunctive therapies. They found that in the vast majority of published manuscripts, the information provided was lacking or insufficient to allow complete interpretation of the results, or the reproduction of how treatments were planned or delivered. None of the studies provided a level of completeness consistent with the ICRU guidelines (ICRU, 2010), and only 24% reported more than 50% of the items evaluated. (ICRU emphasises the importance of standardisation in reporting for optimal interpretation of clinical results and for repeatability of treatments.) It was therefore concluded that there was a clear need for the adoption of standards for the reporting of clinical studies, as well as for the reporting of details of radiotherapy planning and delivery, and that such developments were essential for the progress of this area of veterinary practice.

A serious concern was that of inconsistencies in the definition of target volumes during the treatment planning process. This is particularly true for 'conformal' radiotherapy, where the expected therapeutic benefit, as well as the increased risk of missing part of the cancer cell population, is heavily dependent on tumour delineation. The accurate reporting of margins around a target is obviously necessary for any useful exchange of information between centres, and to ensure repeatability of results. Thus, Christensen et al. (2016) have shown that, even within a single institution, the routine evaluation of contouring nasal tumours, which should be reasonably straightforward, resulted in variabilities of gross tumour volume, clinical target volume, and planning target volume that constituted a significant barrier to the accurate reporting of the results of radiation therapy.

As in human radiotherapy, fractionation has been a mainstay in veterinary practice, but protocols differ considerably, even for the curative intent of the same condition; for example, two, three, or four fractionation protocols for osteosarcoma in dogs (Coomer et al., 2009). However, with the advent of intensity-modulated radiation therapy and stereotactic techniques, there has been a shift towards hypofractionation, although it is considered that more clinical experience is needed, and that biological models to test different fractionation schemes for both tumour control probability and normal tissue complication probabilities are necessary to determine, at least theoretically, the feasibility of such protocols. Thus, for example, Rohrer Bley et al. (2017) modelled two protocols using different fractionation schemes for brain tumours in dogs, and determined that they could safely increase the dose per fraction and decrease the number of fractions without incurring a large risk of late complications for selected brain tumours. In general, therefore, there are many areas of interest, such as the uncertainties over the reconstruction of dose and how this relates to the risks of late effects in different types of animals, which are essentially similar to those arising from the treatment of human patients (Vu Bezin et al., 2017).

Clinical trials are also imperative to progress veterinary radiation oncology, but there appears to be an over-reliance on retrospective studies (considered to be a poor basis for evidence) to assess clinical outcomes. One important limitation is the issue of incomplete or missing data. A recent review (Kent et al., 2018) referred to various studies relating to intracranial tumours in dogs, and concluded that prospective

clinical trials are needed to answer lingering questions about efficacy outcomes, such as survival. Case selection to identify patients best suited for different procedures is also seen as an area requiring more attention with regard to the adoption of newer approaches (Kubicek et al., 2016).

Arkans et al. (2015) discussed the common issue of the risk of potential sources of error arising, and thus of potential harm to the patient, simply because of the increasing complexity of the treatments that may now be used. Useful comparisons were drawn between the roles of medical personnel in human and veterinarian radiation oncology (at least in the USA) and of quality assurance issues, even in the presence of 'record and verify' systems. Other matters arising were those relating to the certification of radiation therapists with respect to veterinary medicine, licensing, error reporting (or the lack of error reporting), the need for more guidelines to be drawn up, and so on. There has also been an increase in the use of radiation for palliative care, particularly for cats and dogs, but there appears to be a lack of agreed protocols with respect to such use, such as for nasal tumours in dogs (Tan-Coleman et al., 2013), in order to do so.

5. PROVISION OF RADIOLOGICAL PROTECTION ADVICE IN VETERINARY MEDICINE AND ITS IMPLICATIONS FOR THE DISCIPLINE OF RADIOLOGICAL PROTECTION AS A WHOLE

It is evident from these and other reviews that, as well as scope, there is a clear necessity for the provision of guidance specifically relating to the protection of the individual animal as the patient in veterinary medicine. This applies across all of the modalities being used and, although many of them are only currently available in a limited number of treatment centres, their availability is expected to increase rapidly in the near future. The necessary guidance needs to cover all of the issues identified above, including diagnostic and therapeutic imaging protocols, treatment planning and delivery, education and ongoing training [e.g. by drawing upon *Publication 113* (ICRP, 2009)], and quality assurance. There is also scope for mutually beneficial biomedical research opportunities that include biological models, animal dose, and the dose quantities used, and all against a deeper understanding of the ethics of radiological protection in a veterinary context, which has yet to be developed.

Given time, there is also much more that could be done by the radiological community to improve the current situation. There are large databases relating to dogs, in particular (NCRP, 2004), that have been obtained in order to inform radiological protection of humans, and these could now be used to provide better guidance in veterinary medicine for thousands of dogs themselves, although it might take a determined effort to consider such databases in this way. Although guidance specifically for protection of the animal as the patient is needed, it would appear opportune that the radiological protection community and the veterinary imaging

communities in particular are ready to collaborate and learn from each other. Adding specific advice on the protection of the patient to that of advice with regard to the veterinarians and their assistants would provide a more valuable holistic approach to the profession as a whole. As NCRP Report 148 (NCRP, 2004) noted: 'To the extent that the animal patient exposure is reduced, there is usually a proportionate decrease in the exposure to personnel'. This argument also applies to human medical radiation protection, and is often cited (ICRP, 2013, 2017).

6. CONCLUSIONS, OUTCOME, AND NEXT STEPS

The Main Commission of ICRP accepted the findings of TG107, and has now created a new task group (TG110) to take these matters forward. In doing so, it is important to recognise that the provision of advice by ICRP has evolved continually over its 90-year history. Initially, it was aimed at the use of radiation in medicine, but it then expanded to include protection of those who were occupationally exposed, and protection of the general public who were exposed to man-made sources including the testing of nuclear weapons, discharges from the nuclear industries, accidental releases, and from natural (but variable) radiation sources. It then evolved from the aim of protecting people and their environment to one that is now designed to: 'contribute to an appropriate level of protection for people and the environment against the detrimental effects of radiation exposure without unduly limiting the desirable human actions that may be associated with such exposure' (ICRP, 2007a). In support of this specific aim, ICRP has published several reports to help achieve it, including *Publications 108* and *124* (ICRP, 2008, 2014). However, IAEA, in its latest Safety Glossary (IAEA, 2019), states that: 'The accepted understanding of the term radiation protection is restricted to protection of people. Suggestions to extend the definition to include the protection of non-human species or the protection of the environment are controversial'. The current IRPA evaluations of radiation protection are similar (Coates and Czarwinski, 2018), and only refer to protection of humans.

Many of the principles and guidelines needed for protection of the animal as the patient are, however, not dissimilar from those set out in *Publication 121* (ICRP, 2013), which provides guidance in paediatric diagnostic and interventional radiology. Consideration of the lack of patient cooperation, wide ranges in size and disease conditions, and the need to provide guidance for patient comforters and holders are all similar to paediatric medical care. A more suitable starting point would be the production of an over-arching document as a parallel to that of *Publication 105* (ICRP, 2007b), which considers all of the issues with respect to radiological protection in medicine for humans. In accepting the contents of the report by TG107, TG110 will provide such a document that will consider veterinary medicine as a whole, veterinarians, staff, their patients, and the public, whilst acknowledging that additional work will be needed in the future.

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Health care for deep space explorers

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Abstract–There is a growing desire amongst space-faring nations to venture beyond the Van Allen radiation belts to a variety of intriguing locations in our inner solar system. Mars is the ultimate destination. In two decades, we hope to vicariously share in the adventure of an intrepid crew of international astronauts on the first voyage to the red planet.

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

This will be a daunting mission with an operational profile unlike anything astronauts have flown before. A flight to Mars will be a 50-million-kilometre journey. Interplanetary distances are so great that voice and data communications between mission control on Earth and a base on Mars will feature latencies up to 20 min. Consequently, the ground support team will not have real-time control of the systems aboard the transit spacecraft nor the surface habitat. As cargo resupply from Earth will be impossible, the onboard inventory of equipment and supplies must be planned strategically in advance. Furthermore, the size, amount, and function of onboard equipment will be constrained by limited volume, mass, and power allowances.

With less oversight from the ground, all vehicle systems will need to be reliable and robust. They must function autonomously. Astronauts will rely on their own abilities and onboard resources to deal with urgent situations that will inevitably arise.

The deep space environment is hazardous. Zero- and reduced-gravity effects will trigger deconditioning of the cardiovascular, musculoskeletal, and other physiological systems. While living for 2.5 years in extreme isolation, Mars crews will experience psychological stressors such as loss of privacy, reduced comforts of living, and distant relationships with family members and friends.

Beyond Earth's protective magnetosphere, the fluence of ionising radiation will be higher. Longer exposure of astronauts to galactic cosmic radiation could result in the formation of cataracts, impaired wound healing, and degenerative tissue diseases. Genetic mutations and the onset of cancer later in life are also possible. Acute radiation sickness and even death could ensue from a large and unpredictable solar particle event.

There are many technological barriers that prevent us from carrying out a mission to Mars today. Before launching the first crew, we will need to develop processes for in-situ resource utilisation. Rather than bringing along large quantities of oxygen, water, and propellant from Earth, future astronauts will need to produce some of these consumables from local space-based resources.

Ion propulsion systems will be needed to reduce travel times to interplanetary destinations, and we will need systems to land larger payloads (up to 40 tonnes of equipment and supplies for a human mission) on planetary surfaces. These and other innovations will be needed before humans venture into deep space.

However, it is the delivery of health care that is regarded as one of the most important obstacles to be overcome. Physicians, biomedical engineers, human factors specialists, and radiation experts are re-thinking operational concepts of health care, crew performance, and life support. Traditional oversight of astronaut health by ground-based medical teams will no longer be possible, particularly in urgent

situations. Aborting a deep space mission to medically evacuate an ill or injured crew member to Earth will not be an option. Future crews must have all of the capability and responsibility to monitor and manage their own health. Onboard medical resources must include imaging, surgery, and emergency care, as well as laboratory analysis of blood, urine, and other biospecimens.

At least one member of the crew should be a broadly trained physician with experience in remote medicine. She/he will be supported by an onboard health informatics network that is artificial intelligence enabled to assist with monitoring, diagnosis, and treatment. In other words, health care in deep space will become more autonomous, intelligent, and point of care.

The International Commission on Radiological Protection (ICRP) has dedicated a day of its 5th International Symposium in Adelaide to the theme of Mars exploration. ICRP has brought global experts together today to consider the pressing issues of radiation protection. There are many issues to be addressed:

- Can the radiation countermeasures currently used in low Earth orbit be adapted for deep space?
- Can materials of low atomic weight be integrated into the structure of deep space vehicles to shield the crew?
- In the event of a major solar particle event, could a safe haven shelter the crew adequately from high doses of radiation?
- Could Martian regolith be used as shielding material for subterranean habitats?
- Will shielding alone be sufficient to minimise exposure, or will biological and pharmacological countermeasures also be needed?

Beyond this symposium, I will value the continued involvement of ICRP in space exploration. ICRP has recently established Task Group 115 to examine radiation effects on the health of astronaut crew and to recommend exposure limits. This work will be vital. Biological effects of radiation could not only impact the health, well-being, and performance of future explorers, but also the length and quality of their lives.

While humanity has dreamed of travel to the red planet for decades, an actual mission is finally starting to feel like a possibility. How exciting! I thank ICRP for its ongoing work to protect radiation workers on Earth. In the future, we will depend on counsel from ICRP to protect extraterrestrial workers and to enable the exploration of deep space.

SAGE ICRP

Recent progress in space weather research for cosmic radiation dosimetry

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Abstract–The radiation environment in space is a complex mixture of particles of solar and galactic origin with a broad range of energies. In astronaut dose estimation, three sources must be considered: galactic cosmic radiation, trapped particles, and solar energetic particles (SEPs). The astronaut dose due to SEP exposure during a space mission is more difficult to estimate than the other components because the occurrence of a large solar particle event cannot be predicted by the current space weather research. Thus, several models have been proposed to estimate the worst-case scenario and/or the probability of the integral SEP fluence during a particular space mission, considering the confidence level, solar activity, and duration of the mission. In addition, recent investigations of the cosmogenic nuclide concentrations in tree rings and ice cores have revealed that the sun can cause solar particle events much larger than the largest event recorded in the modern solar observations. If such an extreme event occurs during a mission to deep space, astronauts may suffer from radiation doses in excess of the threshold value for some tissue reactions (0.5 Gy) and their career limit (0.6–1.2 Sv). This article reviews the recent progress made in space weather research that is useful for cosmic radiation dosimetry.

Keywords: Space dosimetry; Solar particle event; Ground-level enhancement; Worst-case scenario

1. INTRODUCTION

The estimation of cosmic radiation doses is indispensable in the design of manned space missions, such as long-term stays at the International Space Station (ISS) and

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future expeditions to the moon and Mars (Durante and Cucinotta, 2011). Three radiation sources must be considered in the estimation: galactic cosmic radiation (GCR), trapped particles (TPs), and solar energetic particles (SEPs). GCR enters the heliosphere continuously from all directions and is modulated by the interplanetary magnetic field produced by the charged particles emitted by the sun, the so-called 'solar wind'. Thus, its flux near the Earth is anticorrelated with the solar activity. SEPs are emitted from the surface of the sun by coronal mass ejections over the course of hours or days. TPs are trapped in the Earth's magnetic field as a result of the interaction of GCR and SEPs with the Earth's magnetic field and the atmosphere. In addition to these sources, solar wind and solar storm protons, as well as auroral and trapped electrons, exist in space; these make a very minor contribution to the total astronaut dose because their energies are too low to penetrate the spacecraft shielding. A synoptic view of the integral particle fluence rate of each cosmic radiation source is shown in Fig. 1, and their features are summarised in *Publication 123* (ICRP, 2013).

The fluxes of GCR and TPs are relatively stable and predictable compared with those of SEPs, and the procedures for calculating GCR (Nymmik et al., 1995; Matthiä et al., 2013; O'Neill et al., 2014; Slaba and Blattnig, 2014) and TP (Ginet et al., 2013) fluxes are fairly well established. Therefore, the radiation doses due to GCR and TP exposure for various scenarios, such as inside the ISS and on the surfaces of the moon and Mars, can be evaluated with a certain degree of precision (e.g. Matthiä et al., 2016; Sato et al., 2018b).

In contrast, SEP fluence during a space mission is unpredictable because it may increase suddenly if a large solar particle event (SPE) occurs. Therefore, space weather research plays a very important role in ensuring astronaut radiation safety,

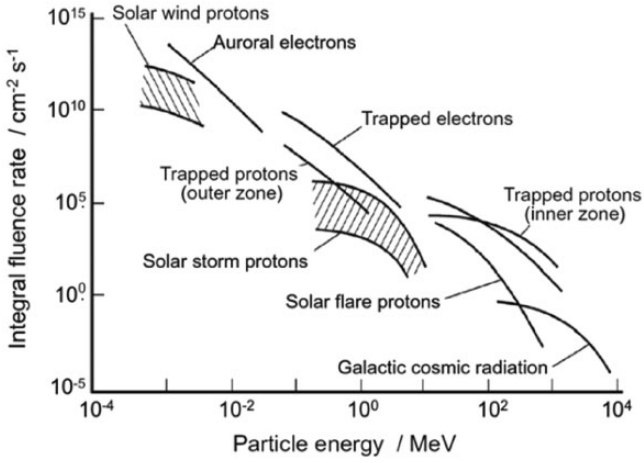

Fig. 1. Synoptic view of integral particle fluence rate of each cosmic radiation source (Wilson, 1978).

particularly when it comes to issuing alerts and estimating the worst-case SEP exposures. The occurrence of a large SPE is also regarded as a serious hazard to air crews and flight passengers. Thus, the International Civil Aviation Organization (ICAO) has recently decided to use the radiation dose as mandatory information to operate their centre. This article summarises the recent progress made in space weather research that is useful for cosmic radiation dosimetry.

2. RECENT PROGRESS IN SPACE WEATHER RESEARCH

2.1. SPE detection and alerts

The occurrence of an SPE is related to various physical processes yet to be fully understood, such as solar flares, coronal mass ejections, coronal and interplanetary shock waves, and particle acceleration and transport mechanisms. Therefore, it is very difficult to predict SPEs based on solar observation, and differentiate them from other space weather hazards, such as magnetospheric substorms. Consequently, it is important to detect the arrival of SEPs around the Earth and issue an alert immediately. The detection of relativistic electrons at satellites can be utilised as a pre-alert of an SPE because they can arrive at the Earth prior to SEPs (Posner, 2007).

There are two main methods for issuing an SPE alert: one is based on the high-energy proton detectors mounted on geostationary operational environmental satellites (GOESs), and the other is based on the neutron monitors on the surface of the Earth. These datasets are publicly available from the Space Weather Prediction Center of the US National Oceanic and Atmospheric Administration (ftp://ftp.swpc.noaa.gov/pub/lists/particle/) and the Neutron Monitor Database (http://www.nmdb.eu/), respectively. The former can detect SPEs directly by measuring proton fluxes >1 MeV, while the latter detects SPEs indirectly by measuring the secondary neutrons generated through the nuclear interactions induced by SEPs in the atmosphere. SPEs with a significant increase in neutron monitor count rates are rarely observed in comparison with those with an increase in the GOES proton fluxes, because most SPEs do not emit high-energy protons ($E > 450$ MeV) that can create neutrons reaching the surface of the Earth. These events are called 'ground-level enhancements' (GLEs), and only 72 GLEs have been recorded over eight decades of observation. The profiles of each GLE are summarised in Asvestari et al. (2017).

Fig. 2 shows the GOES proton and x-ray fluxes, and the count rates of the Oulu neutron monitor for 6–11 September 2017. It is evident from Fig. 2A that several solar flares occurred that week, but only the last flare was associated with a large SPE, indicating that the SEP fluxes cannot be estimated solely from the solar flare class, as discussed by Takahashi et al. (2016). The large SPE observed on 10 September 2017 resulted in GLE72, as shown in Fig. 2B, but the neutron monitor count rates only increased by a few percent above the background level. This is because the SEP spectrum during this event was so soft that most protons and their secondary neutrons could not penetrate deep into the atmosphere. In addition, a decrease in the neutron monitor count rates, the so-called 'Forbush decrease', was

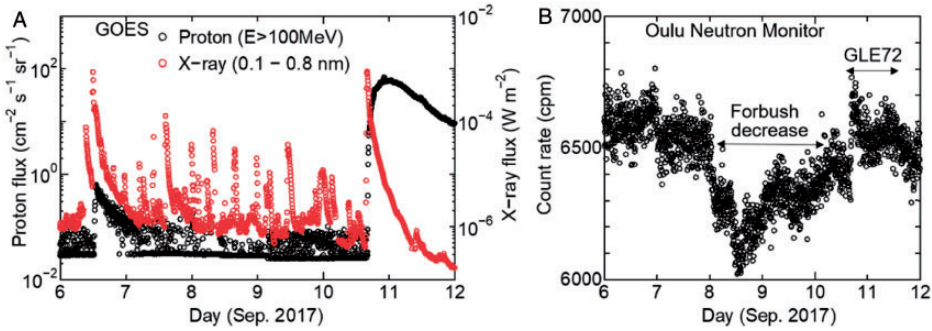

Fig. 2. (A) Geostationary operational environmental satellite proton and x-ray fluxes, and (B) count rates of the Oulu neutron monitor for 6–11 September 2017.

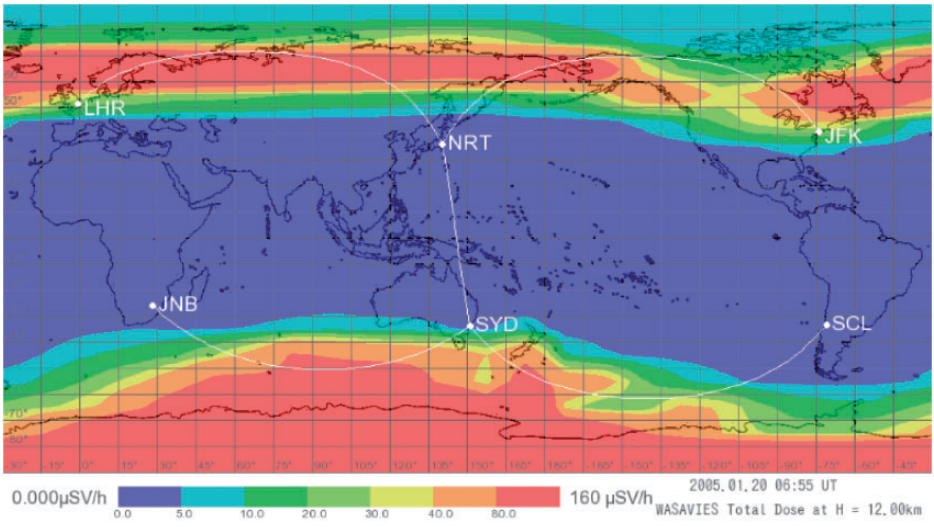

Fig. 3. Worldwide dose rate map at 12-km altitude during the GLE69 peak (6:55 UT, 20 January 2005) drawn by WASAVIES (https://wasavies.nict.go.jp/).

observed on 8–9 September 2017, which occurred due to the magnetic field of the strong solar wind that could sweep GCR away from the Earth. Thus, the occurrence of a large solar flare does not always result in an increase in radiation dose on the Earth.

Using real-time data of the GOES proton fluxes and/or neutron monitor count rates, several systems have been developed to issue an SEP exposure alert at flight altitudes, such as AVIDOS (Latocha et al., 2009), NAIRAS (Mertens et al., 2010), SiGLE (Lantos et al., 2003), and WASAVIES (Kataoka et al., 2018; Sato et al., 2018a). As an example, Fig. 3 shows the worldwide dose rate map at 12-km altitude

during the GLE69 peak (6:55 UT, 20 January 2005) drawn by WASAVIES. When a GLE occurs, the radiation dose data calculated by these systems are provided to ICAO and used as the mandatory information to operate their centre.

2.2. Worst-case scenario estimation

The worst-case scenario of SEP exposure is generally considered in the design of a space mission. Several models have been proposed to reconstruct the SEP fluence during a historically large SPE. Their results are summarised in web-based tools, such as the On-Line Tool for the Assessment of Radiation in Space developed by the National Aeronautics and Space Administration (Singleterry et al., 2010) and the Space Environment Information System developed by the European Space Agency (Heynderickx et al., 2004). These tools also have functions for considering the influences of magnetosphere and spacecraft shielding on SEP fluence; therefore, they are widely used in the design of space missions to estimate the worst-case scenario of SEP exposure. In addition, Tylka and Dietrich (2009) recently proposed a new model for representing SEP fluence with a double power law function of rigidity, the so-called 'Band function' (Band et al., 1993), and evaluated the parameters used in the function for many GLEs. Fig. 4 shows some examples of SEP fluences for historically large GLEs calculated by the Band function (Durante and Cucinotta, 2011). It is known that GLE5, which occurred in February 1956, is the largest event observed since the neutron monitors went live in the 1940s, and its spectrum was much harder in comparison with those of the other events.

In addition, several probabilistic models were proposed to predict the integral SEP fluence accumulated during a mission at a certain level of confidence. For example, Feynman et al. (2002) developed the Jet Propulsion Laboratory Model based on Monte Carlo simulation, and Kim et al. (2009) proposed the use of the

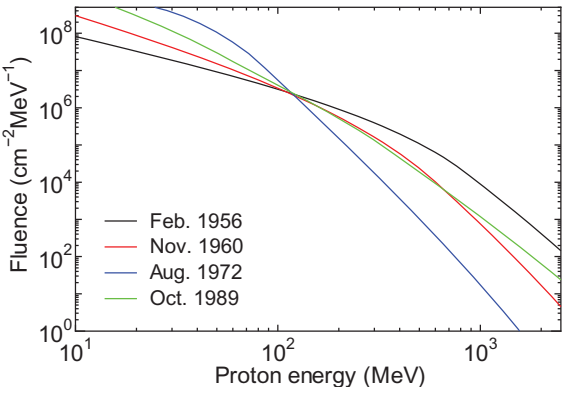

Fig. 4. Examples of solar energetic particle fluences for historically large ground-level enhancements calculated by the Band function.

integral fluence of SEPs >100 MeV to estimate the percentiles of dose to blood-forming organs during a particular mission. Jiggens et al. (2012) developed SEP environment modelling, which is based on 'virtual timelines' rather than traditional Monte Carlo approaches; and Raukunen et al. (2018) systematically investigated the distributions and relationships of the spectral fit parameters of the Band function for GLEs occurring in solar cycles 19–24. These probabilistic models enable a more sophisticated mission design, considering the confidence level, solar activity, and duration of the mission, rather than simply assuming the worst-case scenario.

Note that most models for estimating the worst-case scenario and/or the probability of the integral SEP fluence during a mission were developed based on the modern solar observation data obtained using neutron monitors and/or satellites. However, the sun can cause solar flares much larger than the largest flare recorded in the modern solar observations, such as the Carrington event, which occurred in 1859. Fortunately, the SEP spectrum generated by the Carrington event is estimated to have been softer than those for historically large GLEs (Townsend et al., 2006). Instead, recent investigations on the cosmogenic nuclide concentrations in tree rings and ice cores have revealed that extremely large SPEs with hard SEP spectra occurred in AD 774/5 and 993/4 (Miyake et al., 2012, 2013, 2015). The total SEP fluences during these events were estimated to be 119–141 and 51–68 times higher than those during GLE69, which is the largest event to have occurred to date in the 21st century (Mekhaldi et al., 2015). If a male astronaut had stayed in an ISS-type spacecraft in deep space during GLE69, his red bone marrow dose and dose equivalent would have been approximately 5 mGy and 8 mSv, respectively, as estimated by the WASAVIES simulation (Sato et al., 2019). Therefore, astronauts may suffer from radiation doses in excess of the threshold value for some tissue reactions (i.e. >0.5 Gy) (ICRP, 2012), as well as their career limit (i.e. >0.6–1.2 Sv) (McKenna-Lawlor, 2014), if a once-in-a-millennium-class SPE occurs during their mission to deep space. Consequently, real-time monitoring of radiation doses is indispensable during missions to deep space to take adequate actions during an SPE, such as sheltering astronauts in well-shielded locations in their spacecraft (Mertens et al., 2018; Townsend et al., 2018).

3. CONCLUSIONS

Recent progress in space weather research has enabled more sophisticated design of space missions with respect to SEP exposure, taking the confidence level, solar activity, and duration of the mission into account. It has also been revealed that the sun can cause much larger SPEs than the largest event recorded in the modern solar observations. If such an extreme event occurs during a mission to deep space, the dose and dose equivalent for astronauts may exceed the threshold values for some tissue reactions and their career limit, respectively. The strategy of radiological protection against such low-probability and high-risk events must be discussed in the future.

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Operational radiation protection for human space flight: the flight surgeon's perspective

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Abstract–Yuri Gagarin was the first human in space in 1961 almost 60 years ago. Eight years later Neil Armstrong left his footprints on the Moon – the first human on the surface of a celestial body other than Earth. By now long-duration missions of up to 1 year have become a reality for humans in space. Nearly 19 years of continuous human presence at the International Space Station (ISS) have provided a unique insight into human life in space. Humans are reaching out for more – targeting missions to take us outside the protective hull of low earth orbit into deep space. The challenges to human health and well-being remain significant and increase with distance and time from Earth. The lack of gravity, the ubiquitous ionising radiation, remoteness, and confinement are just some examples of the hostile environment of space. More hurdles have to be overcome prior to the human endeavour of reaching out into deep space and radiation is one such primary and inevitable factor that is key to crew health, safety and overall mission success. This presentation will provide an introduction into operational space medicine and radiation protection for humans in space as executed on ISS, in low earth orbit and in preparation for the scenarios 'beyond'.

This abstract does not necessarily reflect the views of the International Commission on Radiological Protection.

Practicalities of dose management for Japanese astronauts staying at the International Space Station

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Abstract–Japanese astronauts started staying at the International Space Station (ISS) in 2009, with each stay lasting for approximately 6 months. In total, seven Japanese astronauts have stayed at the ISS eight times. As there is no law for protection against space radiation exposure of astronauts in Japan, the Japan Aerospace Exploration Agency (JAXA) created its own rules and has applied them successfully to radiation exposure management for Japanese ISS astronauts, collaborating with ISS international partners. Regarding dose management, JAXA has implemented several dose limits to protect against both the stochastic effects of radiation and dose-dependent tissue reactions. The scope of the rules includes limiting exposure during spaceflight, exposure during several types of training, and exposure from astronaut-specific medical examinations. We, therefore, are tasked with calculating the dose from all exposure types applied to the dose limits annually for each astronaut. Whenever a Japanese astronaut is at the ISS, we monitor readings of an instrument in real-time to confirm that the exposed dose is below the set limits, as the space radiation environment can fluctuate in relation to solar activity.

Keywords: ISS; Dose management

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1. EXPOSURE MANAGEMENT OVERVIEW FOR JAPANESE ISS ASTRONAUTS

1.1. History

In 1992, the first Japanese astronaut went into space in a space shuttle. At the time, there were no rules or guidelines regarding astronaut radiation protection in Japan, although the National Council on Radiation Protection and Measurement (NCRP) had released Report 98 entitled 'Guidance on radiation received in space activities' in 1989 (NCRP, 1989). Once Japanese participation in the International Space Station (ISS) programme was decided, meaning that astronauts would stay in space for longer periods than when in the space shuttle, guidelines were needed for radiation protection of Japanese ISS astronauts. The National Space Development Agency, the former name of the Japan Aerospace Exploration Agency (JAXA), established an advisory committee to formulate these guidelines. The committee created rules using the risk assessment method shown in Annex C of *Publication 60* (ICRP, 1991). JAXA developed its own rules to manage radiation exposure of Japanese ISS astronauts based on these guidelines, and has continued to manage radiation exposure of Japanese ISS astronauts since then. In 2013, the committee revised the career effective dose limits according to the risk assessment method shown in Annex A of *Publication 103* (ICRP, 2007).

1.2. Overview

Fig. 1 shows an overview of the exposure management for Japanese ISS astronauts. Exposure management starts during the astronaut selection phase and continues until the astronaut retires. Management of astronaut exposures consists of four categories: dose management, explanation of risk, monitoring and measurement, and medical countermeasures. Operations of each category link to other categories. As such, in this article, operations of dose management are introduced in the next section.

2. DOSE MANAGEMENT FOR JAPANESE ISS ASTRONAUTS

2.1. Dose limits

JAXA has its own dose limits for radiation protection of Japanese ISS astronauts, as do other ISS international partners (Cucinotta, 2010). These are fundamental tools for dose management for Japanese ISS astronauts. The JAXA dose limits consist of two types: one is related to the stochastic effects of radiation, and the other is for protection against tissue reactions (JAXA Space Radiation Health WG, Manned Mission Support Committee, 2001).

Table 1 shows the JAXA dose limits for stochastic effects. These are career effective dose limits, which vary according to gender and age at the first spaceflight. The objective of these limits is to keep excess cancer mortality lower than an unacceptance level of risk. To calculate excess cancer mortality, it was assumed that Japanese ISS astronauts stay at the ISS three times every 3 years. This is a stricter scenario for spaceflight than typical astronaut assignments. We calculated the excess cancer

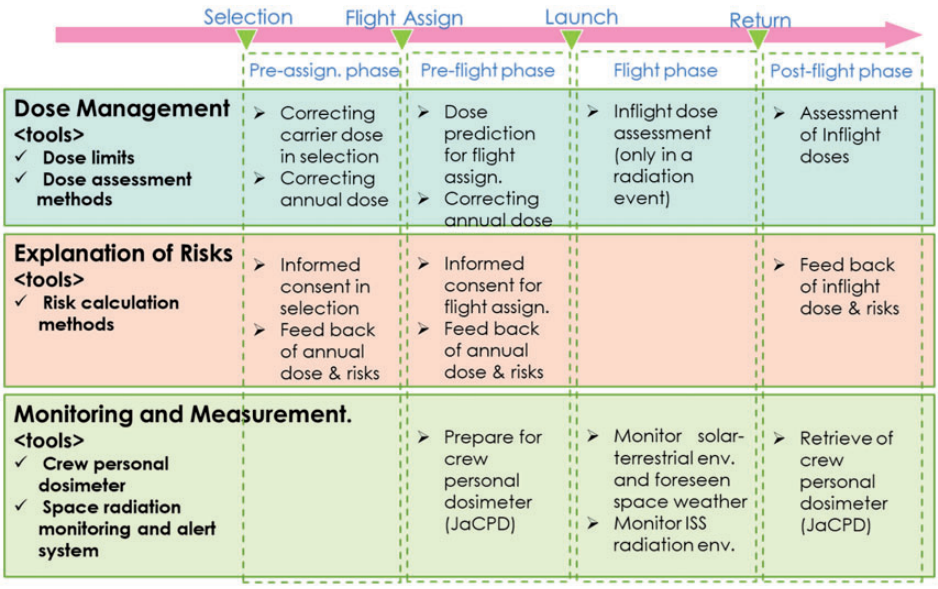

Fig. 1. Overview of exposure management of Japanese International Space Station (ISS) astronauts.

Table 1. The Japan Aerospace Exploration Agency's career effective dose limits.

Age at first spaceflight (years)	Male (mSv)	Female (mSv)
27–30	600	500
31–35	700	600
36–40	800	650
41–45	950	750
>46	1000	800

mortalities to several ages for males and females using excess relative risk and excess absolute risk models with coefficients from *Publication 103* (ICRP, 2007), and set the dose limits so that the mean values of the excess cancer mortalities from both models do not exceed around 3% over the course of an astronaut's career (JAXA Space Radiation Health WG, Manned Mission Support Committee, 2013).

Table 2 shows the JAXA dose limits related to tissue reactions. These are tissue equivalent dose limits which were set to prevent irreversible tissue reactions. We used threshold values from *Publication 60* (ICRP, 1991) on potential tissue reactions in organ systems, including disturbance of haematopoiesis in blood-forming organs (BFO), lens cataract, early erythema of the skin, and permanent infertility of testis. It was confirmed that infertility of ovaries can be protected in other set dose limits.

Table 2. The Japan Aerospace Exploration Agency's tissue equivalent dose limits.

	Blood-forming organ (Sv)	Lens (Sv)	Skin (Sv)	Testis (Sv)
1 week	–	0.5	2	–
1 year	0.5	2	7	1
Career	–	5	20	–

These dose limits are applied to occupational exposures of Japanese astronauts, which can occur as a result of spaceflight, exposure from training, and exposure from astronaut-specific medical examinations. Radiation exposure is unavoidable for some aspects of astronaut training. For example, flight operation training with aeroplanes at high altitude, during which an astronaut is exposed to space radiation; and behaviour training in a cave, during which an astronaut is exposed to radiation from radon. An astronaut should be annually certified as healthy by a medical professional, and even these evaluations lead to exposures that are considered among the types of occupational exposure for an astronaut. However, doses from these exposures are quite small compared with the doses experienced during spaceflight.

2.2. Operations

Practical operations of dose management can be divided into two types: regular activities for both non-mission-assigned and mission-assigned astronauts; and specific activities for mission-assigned astronauts alone.

2.2.1. Regular activities

All astronauts undergo medical examinations and receive an annual medical certification from a flight surgeon (i.e. a medical doctor who conducts astronauts' medical operations, and gathers all information about radiation exposure for the astronaut to date). The information includes times of aeroplane flight operation training, radon concentration, duration of cave training, number of x-ray examinations, etc. A radiation exposure management specialist, certified by JAXA, calculates doses related to the dose limits and records the doses in a radiation exposure history file for the astronaut. The flight surgeon confirms that the cumulative doses are less than the dose limits. The radiation exposure management specialist uses this information to formulate a risk explanation report for the astronaut himself/herself.

2.2.2. Spaceflight-specific activities

When an astronaut is assigned a specific increment of time to spend at the ISS, the radiation exposure management specialist predicts doses, using the space environment model and radiation transportation code, to determine the effective dose and organ doses related to dose limits. She/he also makes a report for risk explanation and explains it to the astronaut to obtain informed consent.

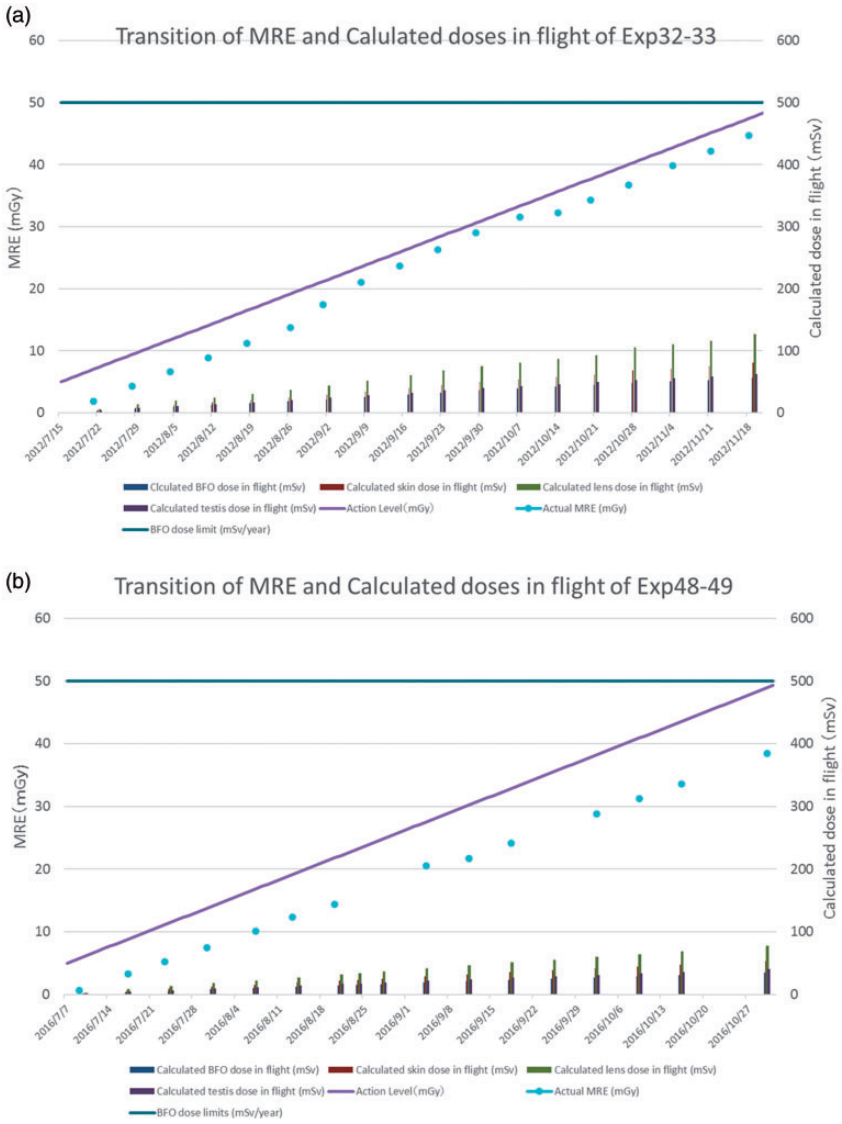

Fig. 2. (a) Relationship between mission reference exposure (MRE) and actual calculated cumulative doses related to dose limits during Exp. 32–33 in a solar maximum. (b) Relationship between MRE and actual calculated cumulative doses related to dose limits during Exp. 48–49 in a solar minimum.

Whenever a Japanese astronaut is at the ISS, we monitor readings of an instrument in real-time to confirm that the exposed dose is below the set limits, as the space radiation environment can fluctuate in relation to solar activity. As it is difficult to calculate doses related to dose limits in real-time, readings from on-board dose

measurement instruments are used. JAXA uses absorbed dose values from the ISS tissue equivalent proportional counter provided by the National Aeronautics and Space Administration (NASA) as values to be monitored in real-time. In the ISS programme, the value is called the 'mission reference exposure' (MRE). An 'action level' has been set for MRE by consensus of all international partners of ISS, which is a value provided by NASA predictions. If MRE exceeds the action level, certain 'positive' actions would be required. These can include evacuation to a well-shielded area in the ISS, restriction of extravehicular activity etc., which would be required to reduce radiation exposure. Fig. 2 shows the relationship between MRE and JAXA-calculated doses related to dose limits during a specific increment of an ISS stay. Fig. 2(a) is an actual result during a solar maximum in 2012 and Fig. 2(b) is an actual result during a solar minimum in 2016. In both cases, cumulative doses remained much less than the dose limits, as MRE was kept under the action level.

After the astronaut returns to earth, a JAXA passive individual dosimeter is retrieved and analysed to obtain the absorbed dose and linear energy transfer spectrum accumulated during the astronaut's stay at the ISS. JAXA radiation exposure management specialists use the values to calculate doses relative to dose limits, known as the 'effective dose' and the 'organ equivalent doses'. The doses are recorded and used to make a risk report for the astronaut.

3. SUMMARY

JAXA created its own rules for radiation exposure management for Japanese ISS astronauts, and has conducted radiation management operations while cooperating with all international partners of the ISS programme for almost 10 years.

JAXA will contribute to developing new guidelines for radiation exposure management in future manned space missions with these experiences.

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Lifetime radiation risk of stochastic effects – prospective evaluation for space flight or medicine

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Abstract–The concept of lifetime radiation risk of stochastic detrimental health outcomes is important in contemporary radiation protection, being used either to calculate detriment-weighted effective dose or to express risks following radiation accidents or medical uses of radiation. The conventionally applied time-integrated risks of radiation exposure are computed using average values of current population and health statistical data that need to be projected far into the future. By definition, the lifetime attributable risk (AR) is an approximation to more general lifetime risk quantities and is only valid for exposures under 1 Gy. The more general quantities, such as excess lifetime risk (ELR) and risk of exposure-induced cancer, are free of dose range constraints, but rely on assumptions concerning the unknown total radiation effect on demographic and health statistical data, and are more computationally complex than AR. Consideration of highly uncertain competing risks for other radiation-attributed outcomes are required in appropriate assessments of time-integrated risks of specific outcomes following high-dose (>1 Gy) exposures, causing non-linear dose responses in the resulting ELR estimate.

Being based on the current population and health statistical data, the conventionally applied time-integrated risks of radiation exposure are: (i) not well suited for projections many years into the future because of the large uncertainties in future secular trends in the population-specific disease rates; and (ii) not optimal for application to atypical groups of exposed persons not well represented by the general population. Specifically, medical patients are atypical in this respect because their prospective risks depend strongly on the original

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diagnosis, the treatment modality, general cure rates, individual radiation sensitivity, and genetic predisposition. Another situation challenging the application of conventional risk quantities is a projection of occupational radiation risks associated with space flight, both due to higher radiation doses and astronauts' generally excellent health condition due to pre-selection, training, and intensive medical screening.

An alternative quantity, named 'radiation-attributed decrease of survival' (RADS), known in past general statistical literature as 'cumulative risk', is recommended here for applications in space and medicine to represent the cumulative radiation risk conditional on survival until a certain age. RADS is only based on the radiation-attributed hazard rendering an insensitivity to competing risks or projections of current population statistics far into the future. Therefore, RADS is highly suitable for assessing semi-personalised radiation risks after radiation exposures from space missions or medical applications of radiation.

Keywords: Radiation exposure; Detrimental effects; Time-integrated risk; Medical radiation exposure; Radiation exposure in space

1. CONVENTIONAL RISK METRICS

The current system of radiation protection (ICRP, 2007) is set to reduce detrimental stochastic effects due to radiation exposure to a practically achievable minimum. Correspondingly, risks associated with the harmful effects need to be quantified and used prospectively for assessment of radiation detriment due to stochastic effects, of which malignant neoplasms represent the major health concern.

For the purposes of expressing cumulative risk of detrimental effects of radiation exposure, the concept of time-integrated risk based on representation of cumulative failures (disease occurrences) within a certain period or lifetime has been in use for decades (e.g. Vaeth and Pierce, 1990; Kellerer et al., 2001). This concept is generally based on survival statistics methodology and requires, for the risk assessment, models of radiation risk per se and detailed statistical information on the population of interest, including demographic data (life tables) and health statistics (incidence rates of various diseases).

The goal of the present work is to briefly review metrics used to express prospective risks of radiation exposure for radiation protection of populations and of special or atypical groups, such as medical patients and space crew members, not well represented by the general population data.

1.1. Time-integrated or lifetime attributable risk

A risk metric widely and commonly applied to express future detrimental effects of radiation exposure (e.g. risk of stochastic effects outcomes such as malignant neoplasms) stems from survival statistics methodology (e.g. Selvin, 1996; Kalbfleisch and Prentice, 2002; Kleinbaum and Klein, 2012) and is termed the

'time-integrated or lifetime attributable risk' (AR) (Vaeth and Pierce, 1990; Thomas et al., 1992; Kellerer et al., 2001):

$$\mathrm{AR}(a|e,D) = \frac{1}{S(e)}\left(\int_e^a \lambda_c^*(t|e,D)S(t)\mathrm{d}t - \int_e^a \lambda_c(t)S(t)\mathrm{d}t\right) \quad (1)$$

where e and a denote age at exposure and age of interest, respectively; $S(t)$ is the disease-free survival function for the target population, dimensionless; $\lambda_c^*(t|e,D)$ is the outcome-specific incidence rate following radiation exposure at age e with organ dose relevant to the considered outcome D; and $\lambda_c(t)$ is the outcome-specific incidence rate in the matching non-exposed population. If the upper integration limit in Eq. (1) is set to infinity, the resulting quantity is conventionally termed the 'lifetime attributable risk' (LAR) and is widely used in radiation-protection-related areas [e.g. to calculate nominal detriment values for definition of the tissue weighting factors used to calculate effective dose (ICRP, 2007)]. AR and LAR represent the fraction of the population alive and disease-free at age e, which will be affected by additional radiation-attributed incidence of the outcome considered, and indicates risk for a 'typical' member of the population to get the outcome considered before a certain age (AR) or during their lifetime (LAR).

1.2. Risk of exposure-induced cancer

Eq. (1) assumes that radiation exposure does not affect the population's survival chances and, therefore, the survival function for the general population can be used to express radiation risk for the exposed population. Generally, this assumption has some weaknesses, and exposure to higher doses of radiation (>1 Gy) may result in detrimental effects which can reduce the population survival chances. To account for the effect of reduced survival, the concept of risk of exposure-induced cancer (REIC) was introduced (UNSCEAR, 1994, 2000), replacing the survival function for the general population, $S(t)$, with the survival function for the exposed population, $S^*(t)$:

$$\mathrm{REIC}(a|e,D) = \frac{1}{S(e)}\left(\int_e^a \lambda_c^*(t|e,D)S^*(t)\mathrm{d}t - \int_e^a \lambda_c(t)S^*(t)\mathrm{d}t\right) \quad (2)$$

REIC assumes that the baseline incidence rates of the outcome of interest are the same in the exposed and the non-exposed populations. This assumption is valid only at low-dose exposures, where the radiation-attributed excess rate is small in comparison with the baseline rate and other competing hazards. Radiation exposure creates additional hazards and, correspondingly, reduces the number of competing outcomes in the population. Qualitatively, this effect is illustrated in Fig. 1, which shows that an attributed hazard results in attributed disease cases in the population, thus reducing the number of disease cases due to spontaneous cancer or other competing causes.

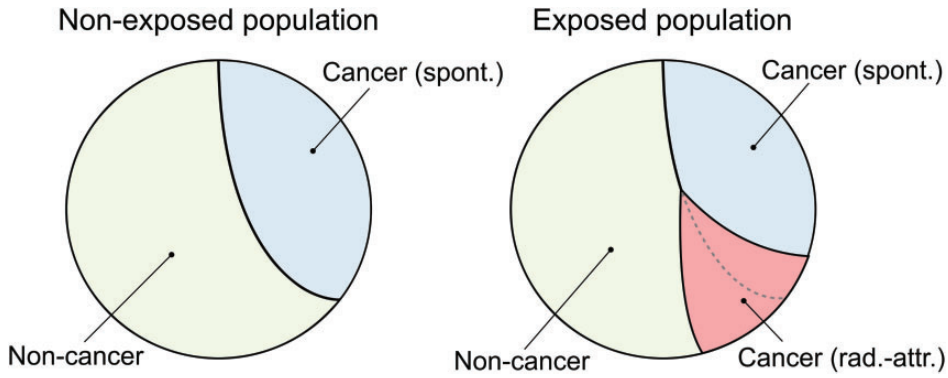

Fig. 1. An illustration of cumulative risks in non-exposed (left) and exposed (right) populations. Additional hazard due to the radiation exposure reduces the cumulative risks of spontaneous cancers and of other – non-cancer-related – competing diseases or mortality causes.

1.3. Excess time-integrated or lifetime risk

Another quantity for time-integrated risk, excess risk (ER), is robust against effects of competing risks and can better model the observations by expressing risk as the difference between the time-integrated risks of the disease in matching exposed and non-exposed populations:

$$\mathrm{ER}(a|e,D) = \frac{1}{S(e)}\left(\int_e^a \lambda_c^*(t|e,D)S^*(t)\mathrm{d}t - \int_e^a \lambda_c(t)S(t)\mathrm{d}t\right) \tag{3}$$

With the upper integration limit in Eq. (3) set to infinity, this quantity is conventionally termed the 'excess lifetime risk' (ELR).

ER can be regarded as a general quantity which correctly addresses integral risks of radiation exposure when comparing two identical exposed and non-exposed populations. However, even this definition, as discussed by Thomas et al. (1992), is not free from conceptual difficulties connected with radiation exposures at high doses (>1 Gy), because the total survival in the exposed population becomes significantly reduced in comparison with that in the non-exposed population, and the resulting ER [Eq. (3)] is decremented during integration to the full lifetime of the non-exposed population.

1.4. Limitations of the conventional risk metrics

AR is a low-dose approximation which works well for rare diseases, such as cancer, if the effect of radiation on the disease rate and, consequently, survival chances, can be neglected. When radiation-attributed risk is increased (by an exposure to higher dose) or the outcome of interest is a more prevalent cause, such as

cardiovascular disease, the effects of attributed competing risks become essential and the simple approximation is no longer valid. Due to this, AR is not well suited for medical and occupational exposures related to doses >1 Gy, and may lead to significant overestimations of AR or paradoxes. For example, a radiation treatment plan which maximises survival chances of a patient (i.e. the 'best' treatment plan) will always be associated with the highest AR of the second primary cancer or other late effects.

Both REIC and ER consider survival in the exposed population; however, while the former expresses the radiation effect via excess rate in the exposed population alone, the latter derives the radiation effect as the difference of the outcome incidence rates in the non-exposed and exposed populations. REIC assumes the incidence rates of spontaneous disease (baselines) to be the same in the exposed and non-exposed populations. This assumption is not necessarily always valid, especially at high-dose exposures. ER is methodologically straightforward and appropriately represents a fraction of the exposed population which will develop the additional outcomes of interest in comparison with the identical non-exposed population. On the other hand, ER decrements when it is integrated to times exceeding the lifetime of the exposed population; REIC is free from this feature.

These risk metrics have common properties which lead to certain difficulties for prospective risk estimations. Computation of the risks [Eqs (1–3)] involves survival functions and disease incidence rates which are generally taken from demographic and health statistical data registered in the target population for a given year. These data are neither representative for generations nor are they properly suited for long-term risk projections and integrations during decades into the future.

Another shortcoming associated with Eqs (1–3) is due to use of the general population statistics for their computation. Estimations of radiation risks become less credible for persons whose survival chances are not represented by those of the general population (e.g. medical patients having a disease and undergoing radiation therapy, or occupationally exposed people who are pre-selected and undergo periodic medical checks or screening, such as astronauts or nuclear workers).

2. ATTRIBUTABLE FRACTIONS AND RADIATION-ATTRIBUTED DECREASE OF SURVIVAL

2.1. Survival chances and excess risk

The survival function can be factorised using incidence rates for specific outcomes, including diseases of interest:

$$S(t) = \prod_i e^{-\Lambda_i(t)} \tag{4}$$

where $\Lambda_i(t) = \int_o^t \lambda_i(x)dx$ is the cumulative incidence for the disease or death due to cause i; and $\lambda_i(t)$ is the incidence rate, PY^{-1} (PY = person-year). Correspondingly,

ER [Eq. (3)] can be expressed for a single radiation-attributed outcome, as follows (see Ulanowski et al., 2019 for details):

$$\mathrm{ER}_c(a|e,D) = \frac{1}{S(e)}\int_e^a \lambda_c(x)S(x)\left[e^{-H_c(x|e,D)}\left(1+\frac{h_c(x|e,D)}{\lambda_c(x)}\right)-1\right]\mathrm{d}x \qquad (5)$$

where λ_c and h are the baseline and excess incidence rates for the outcome of interest c, PY^{-1} ; and $H_c(x|e,D) = \int_e^x h_c(u|e,D)\mathrm{d}u$ is the cumulative excess incidence.

An analogue of Eq. (5) was presented previously in the UNSCEAR 2006 Report (UNSCEAR, 2006, Annex A, Appendix B), where it was noticed that this equation explicitly shows that the time-integrated radiation risk is inherently non-linear function of dose, even for the radiation risk models with linear dose-response effects. Apparently, for low-dose exposures, which result in small excess incidence rates, Eq. (5) converges to the conventional definition of AR (Eq. 1), which can therefore be regarded as a linear low-dose approximation.

2.2. Attributable and baseline survival fractions

The general formula for ER (Eq. 5) is computationally complex and is not free from the inherent reduction of ER at ages close to the lifetime of the general population. Alternatively, detrimental effects of radiation exposure can be expressed via reduction of survival chances due to radiation-attributed or spontaneous diseases. For this purpose, the baseline and attributable survival reduction fractions are recommended for application (see details in Ulanowski et al., 2019):

$$BF_c(a|e) = \frac{S(a)}{S(e)}\left(e^{\Lambda_c(a)}-1\right) \qquad (6)$$

$$AF_c(a|e) = \frac{S(a)}{S(e)}\left(1-\mathrm{e}^{-H_c(a|e,D)}\right) \qquad (7)$$

These quantities [Eqs (6, 7)] represent fractions of the population being alive and exposed at age e who will either not survive or not survive outcome-free beyond age a for a specific cause, either spontaneous, $BF_c(a|e)$, or radiation-attributed, $AF_c(a|e)$; therefore, they are termed 'fractions' here, despite the latter quantity being described as a 'crude radiation risk' by Groer (1980). These fractions are defined via the general population's survival function; thus, their age dependence follows that of the general survival function and, correspondingly, they are influenced by competing risks.

Both ER [Eqs (3, 5)] and the survival fractions [Eqs (6, 7)] represent the detrimental effect of spontaneous or attributed disease as a fraction of the population alive at age e. However, ER [Eqs (3, 5] provides the cumulative losses in the population during the period from e to a, while the fractions (Eqs 6, 7) characterise a fraction of the population not surviving beyond age a because of the specified cause, either spontaneous or attributed to radiation.

2.3. Radiation-attributed decrease of survival

The attributable survival fraction [Eq. (7)] is computationally simpler than the formula for ER [Eq. (5)]; however, calculation of the former metric still requires the values of the survival function which can be influenced by many competing causes, especially at ages above 50 years. The additional radiation-attributed hazard reduces the survival curve, so the ratio of the attributable fraction (AF) [Eq. (7)] and the general survival function at age a would show the relative effect of the attributed hazard conditional to survival to age a. The radiation-attributed decrease in survival (RADS) is defined as follows:

$$\mathrm{RADS}_c(a|e,D) = 1 - \mathrm{e}^{-H_c(a|e,D)} \tag{8}$$

This represents the net effect of radiation-attributed hazard and was known in statistical literature as 'cumulative risk' (Esteve et al., 1994).

An illustration of the differences between the conventional risk metrics, AF, and RADS is given in Fig. 2, where the time-integrated estimates are shown for outcomes of all solid cancers for males and females after whole-body exposure at 20 years of age with a colon dose of 1 Gy. The details of the risk model and data used are given in the next section. For AF and RADS, the model uncertainty bands for the 95% confidence level are shown as shaded areas.

As seen from Fig. 2, all risk metrics are close to each other during ages below 50 years. At 50 years, when the other competing risks begin to reduce the general population's survival curve, the risk estimates diverge. AR significantly overestimates in comparison with ER; this demonstrates an effect of radiation-attributed incidence on the survival function. AF follows the behaviour of the survival function and reduces at older ages exceeding 80 years. RADS demonstrates insensitivity to the

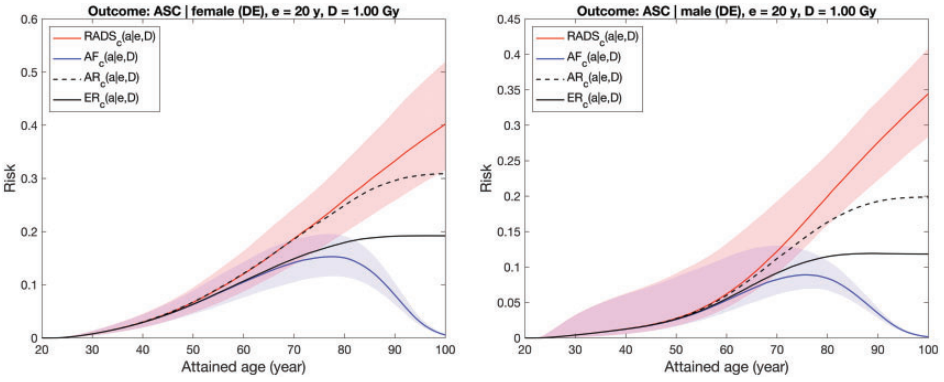

Fig. 2. Comparison of various risk metrics for the incidence of all solid cancers following whole-body exposure at 20 years of age with a colon dose of 1 Gy for females (left) and males (right).

competing outcomes and reduction of survival; the age dependence of RADS is defined by that of the applied models for excess incidence rate, so RADS reflects model-extrapolated expectations.

2.4. Effect of competing radiation-attributed risks

In the preceding subsections, Eqs (5–8) present situations when the only outcome of interest is radiation-attributed, and the other competing failure causes are due to spontaneous diseases or other mortality causes not attributed to radiation. This assumption seems reasonable at low-dose exposures when competing attributable excess rates are small, and only the outcome of interest affects the survival curve. For exposure to high doses, such an assumption loses plausibility as, besides the outcome considered, other competing radiation-attributed outcomes affect the survival and incidence of the considered outcome. Accounting for the effect of the competing radiation-attributed outcomes results in the following:

$$\mathrm{ER}_c(a|e,D) = \frac{1}{S(e)}\int_e^a \lambda_c(x)S(x)\left[e^{-H_d(x|e,D)-H_c(x|e,D)}\left(1+\frac{h_c(x|e,D)}{\lambda_c(x)}\right)-1\right]\mathrm{d}x \qquad (9)$$

where $H_d(t|e,D) = \int_e^a h_d(x|e,D)\mathrm{d}x$ is the cumulated incidence of all competing radiation-attributed causes.

Correspondingly, RADS is also affected by the competing radiation-attributed risks and can be written as follows:

$$\mathrm{RADS}_c(a|e,D) = e^{-H_d(a|e,D)}\left(1-\mathrm{e}^{-H_c(a|e,D)}\right) \qquad (10)$$

It follows from Eq. (10) that the competing radiation-attributed risks reduce RADS for the considered outcome of interest. That is, forecasting radiation risks for persons exposed to high doses (e.g. medical patients, astronauts) requires a coherent consideration of all possible radiation-attributed risks.

3. EXAMPLES AND DISCUSSION

The sample calculations below were performed for several outcomes, ranging from the combined all solid cancer incidence to rare thyroid cancer incidence, and different radiation organ doses from 0.1 to 3 Gy, for both sexes. For the selected outcomes, all the risk metrics described above were used and their values are shown together for different times following radiation exposure.

Risk computation and uncertainty modelling methodology, used to produce the tables below, is described in Walsh et al. (2019) and Ulanowski et al. (2020). The risk model for all solid cancers is as given by Grant et al. (2017), without adjustment for smoking status. The risk model for thyroid cancer was taken from Jacob et al. (2014a,b). The female breast cancer risk model was based on the pooled study of

Table 1. Time-integrated point estimates for different risk metrics for all solid cancer incidence following radiation exposure with dose of 3 Gy (colon) of a 10-year-old female.

Age in years (*a*)	AR (%)	REIC (%)	ER (%)	AF (%)	RADS (%)
10	0	0	0	0	0
20	1.25	1.24	1.24	1.24	1.25
30	5.6	5.5	5.4	5.4	5.5
40	14.2	13.2	13.1	13.1	13.4
50	28.9	24.9	24.1	24.1	25.6
60	49.6	38.6	35.9	35.5	40.8
70	74.5	51.1	44.7	42.6	56.3
85	109.2	62.9	48.1	32.1	74.7

AR, attributable risk; REIC, risk of exposure-induced cancer; ER, excess risk; AF, attributable fraction; RADS, radiation-attributed decrease in survival.

Preston et al. (2002) and was applied as described in Ulanowski et al. (2020). The calculations were performed using the German-specific population statistics for 2013–2015 (Statistisches Bundesamt, 2016) and cancer incidence data for 2013–2014 from the German national cancer register (RKI-GEKID, 2017).

An example of radiation risk estimates for a high-dose whole-body exposure is given in Table 1, where risk estimates are given for a female with colon dose of 3 Gy. Again, as indicated above, the different risk metrics provide very similar answers for young ages, when the survival chances are not significantly affected by any cause. The difference between the risk metrics manifests for older ages when survival becomes significantly reduced. It is remarkable that AR and REIC significantly overestimate radiation risks for older ages compared with ER. AR even exceeds 100% (see Table 1).

Another example related to low-dose exposure is given in Table 2. This shows the risk estimates for female breast cancer after exposure to breast dose of 0.1 Gy at 20 years of age. It is seen now that different risk metrics provide almost the same results, and the degree of risk overestimation by AR and REIC becomes small.

Risk estimates for a cancer with a low spontaneous incidence rate (e.g. thyroid cancer) after exposure to a low dose (e.g. 0.1 Gy of thyroid dose) are provided in Table 3. This shows that the attributed excess rates for the outcome of interest (i.e. thyroid cancer) do not affect survival, and the low-dose exposure does not result in significant excess rates for other competing outcomes. As a result, all three conventional risk metrics – AR, REIC, and ER – are consistent in the full range of ages considered. The RADS results are also essentially close to conventional estimates.

The results of sample calculations indicate that, of the conventional risk metrics, only ER accounts for the effect of survival reduction due to attributed excess rates or competing outcomes. AR, being a linear approximation, is prone to strong overestimation of radiation risk which, in the case of high-dose exposure, may result in implausible values. Both REIC and ER account for the effect of radiation exposure

Table 2. Time-integrated point estimates for different risk metrics for female breast cancer incidence following radiation exposure with breast dose of 0.1 Gy (colon) of a 20-year-old female.

Age in years (a)	AR (%)	REIC (%)	ER (%)	AF (%)	RADS (%)
20	0	0	0	0	0
30	0.01	0.01	0.01	0.01	0.01
40	0.05	0.05	0.05	0.05	0.05
50	0.13	0.13	0.13	0.13	0.13
60	0.26	0.26	0.26	0.25	0.27
70	0.41	0.41	0.39	0.36	0.44
85	0.61	0.61	0.57	0.36	0.73

AR, attributable risk; REIC, risk of exposure-induced cancer; ER, excess risk; AF, attributable fraction; RADS, radiation-attributed decrease in survival.

Table 3. Time-integrated point estimates for different risk metrics for thyroid cancer incidence following radiation exposure with a thyroid dose of 0.1 Gy of a 10-year-old female.

Age in years (a)	AR (%)	REIC (%)	ER (%)	AF (%)	RADS (%)
10	0	0	0	0	0
20	0.01	0.01	0.01	0.01	0.01
30	0.02	0.02	0.02	0.02	0.02
40	0.05	0.05	0.05	0.05	0.05
50	0.09	0.09	0.09	0.09	0.09
60	0.13	0.13	0.13	0.12	0.13
70	0.16	0.16	0.16	0.15	0.17
85	0.20	0.20	0.20	0.12	0.22

AR, attributable risk; REIC, risk of exposure-induced cancer; ER, excess risk; AF, attributable fraction; RADS, radiation-attributed decrease in survival.

on survival function, but they define the excess cases differently (the former metric implicitly assumes baseline incidence in the exposed population to be the same as in the non-exposed population, while the latter metric considers the radiation effect between the exposed and non-exposed matching populations). RADS, in this sense, is the most robust quantity as it, by definition, does not depend on survival changes, thus being better suited for risk projections for exposures at high doses or for populations or groups different from the general population.

4. CONCLUSIONS

Exposure to ionising radiation is known to increase risks of harmful health effects, of which malignant neoplasms are the main stochastic detrimental effects. In many

situations of unavoidable radiation exposure, either occupational or medical, risks of additional future health effects are estimated and compared with spontaneous incidence observed in the contemporary population. Correspondingly, the conventional techniques of radiation risk assessment are based on the application of contemporary demographic and health data, and are representative for an average member of the current general population. However, medical patients treated with radiation are unlikely to be similar to the average, mostly healthy, member of the general population; people exposed occupationally, such as astronauts, are often selected based on their health status, they undergo periodical medical checks and screenings, and as such they are not well represented by the average member of the general population. Use of current, cross-sectional, population statistics for projection of lifetime radiation risks also brings significant uncertainties to the risk estimates due to unknown future changes of health and vital statistics. This paper reviews the conventional metrics used to express future radiation risks, demonstrates their limitations and difficulties with their use, and suggests an alternative quantity to express the risk, which is insensitive to competing risks and robust against unknown future changes in the population's health and demographic data.

For risk projections, where future survival and health statistics are unknown, RADS is suggested and is complementary to conventional lifetime risk quantities. RADS represents the risk of radiation detriment alone and has the following advantages:

- independence from current and unknown future temporal trends in population survival functions known at the time of estimation – only the estimated radiation-attributed incidence rate (hazard) is required for this quantity;
- aids in avoiding paradoxical situations in radiation therapy, because the same radiation dose applied for patients with cancer diagnosed at different stages will result in the same radiation risk of the second primary cancer, regardless of the differences in relative survival; and
- a higher degree of suitability for application in risk assessments for exposed but highly atypical populations (e.g. astronauts), where baseline rates and survival functions pertaining to the general population would be poor approximations (due to distinctly different levels of lifestyle factors such as smoking and fitness, pre-selection, and different levels of medical surveillance or cancer screening).

The suggested quantity, RADS, is better than conventional risk metrics suited for projections of personalised risks; however, individual variability or predisposition may bring significant uncertainty to such projections. RADS is conditional on an adopted radiation risk model, which is typically derived from an epidemiological cohort with a certain applicability domain; therefore, plausible risk projections using RADS are anticipated either within the applicability domain or by using radiation risk models with well-justified highly significant parameters.

RADS is not suggested as a replacement for conventional quantities used to communicate radiation risks for the purposes of radiation protection of populations

exposed to low doses, such as AR or ER. RADS has its own niche – communicating radiation-attributable risks for atypical groups or individuals and application for radiation doses >1 Gy (e.g. interventional and therapeutic radiation exposures).

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Recent progress on the Chinese space programme and radiation research

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Abstract–Manned space exploration was initiated in China in 1992, and substantial progress has been made. The next step is to build the Chinese Space Station (CSS), which is planned to be launched in 2020. The CSS will provide an on-orbit laboratory for experimental studies including space radiation research. The health risk of space radiation, especially carcinogenesis, is a major concern for long-term space exploration. Establishing a risk assessment system suitable for Chinese astronauts and developing effective countermeasures are major tasks for Chinese space radiobiologists. The Institute of Space Life Science of Soochow University has focused on these topics for years. We established cancer models with low-dose-rate exposure of alpha particles, and elucidated a microRNA-TGFβ network regulating bystander effects and a lncRNA-cytoskeleton network regulating genomic instability induced by ionising radiation. We also confirmed the radioresistance of quiescent cells, which inspires a potential strategy to improve individual radioresistance during long-term space travel. However, we believe that a multi-disciplinary strategy must be developed to protect astronauts from highly energised space radiation.

Keywords: Space radiation; Chinese Space Station; LncRNA; RAC2; Bystander effect

This paper does not necessarily reflect the views of the International Commission on Radiological Protection.

1. RECENT PROGRESS ON BUILDING THE CHINESE SPACE STATION

The Chinese Space Station (CSS) will be launched in 2020 and will serve as a research laboratory in outer space for at least one decade. There will be three experiment racks in the CSS available for radiobiological studies. The life ecological experiment rack is well equipped with a life support system and radiation monitoring system, and is suitable for studies with various experimental models. The biotechnology experiment rack is for tissue culture, protein crystallisation, biomechanical studies, *etc*. The third rack is for space radiation exposure outside the experimental modules. In addition, sample storage and observation stations will be included.

Two large-scale programmes with relevance to space radiobiological study will be funded and performed in China in the future. One is the construction of a manned moon base and the other is exploratory missions to Mars. As space radiation is one of the main threats to Chinese astronauts and her international partners in manned explorations to the moon and Mars, fundamental radiobiological studies to address these concerns have been initiated in China.

The CSS will not only provide platforms for Chinese scientists to perform experimental studies in outer space, but will also provide opportunities for open international co-operations. At the Global Space Exploration Conference (GLEX 2017), it was announced that the CSS will open to international collaboration. In 2018, the Chinese Space Agency officially announced 70 projects as the first series of scientific studies on the CSS; these were proposed by experts from more than 20 countries.

2. RECENT PROGRESS ON CHINESE SPACE RADIATION RESEARCH

2.1. Biological effects of low-dose radiation

To support the booming field of life sciences in space, several research centres that are dedicated to space radiobiological studies have been set up, including the Institute of Space Life Sciences, Soochow University in 2016. Multi-disciplinary studies have been performed, and some progress has been made at the institute, especially in radiation risk assessment and the development of countermeasures against space radiation.

Due to the low dose rate of space radiation, bystander effects, or abscopal effects *in vivo*, are dominant; these increase concerns about the health risk of space radiation to astronauts. Several signalling factors mediating bystander effects, including TGFβ, CPR-4, *etc*., have been identified. We elucidated a feedback loop of a miR-663-TGFβ network which suppresses out-of-field cells to secret bystander signals; this suggested that bystander effects mediated by TGFβ are not enhanced unlimitedly.

Risk of cancer is one of the major health issues faced by astronauts. However, the contribution of bystander effects to radiation-induced carcinogenesis remains vague. We exposed human lung epithelial cells to 20 mGy of alpha particles every 3 days to

simulate space radiation, and found that long-term low-dose-rate exposure induced lung carcinoma in a dose-dependent manner, and the malignancy was higher than the same dose received as a single exposure. These results confirmed the high cancer risk of low-dose space radiation.

Detailed studies on the biological effects of space radiation are essential to provide considerable data to reduce the uncertainty of risk assessment of space radiation. The skin dose limits of Chinese astronauts for short-term low-earth-orbit missions are 0.15 Sv for 3 days, 0.20 Sv for 7 days, and 0.40 Sv for 30 days. In the coming CSS era, Chinese astronauts will spend much longer in space; dose limits for long-term space missions will be released shortly. A risk assessment model including recently published data, particularly data on Chinese cancer incidence and death rates, is still under development.

2.2. Mechanism underlying space radiobiological effects

The generally accepted dogma is that DNA is the main target of ionising radiation. However, we believe that the cellular cytoskeleton is another of the major targets of ionising radiation because it is a ubiquitous subcellular organelle maintaining cell morphology, mediating material transportation, and sensing mechanical alterations inside a cell. We identified a radiation-inducible long non-coding RNA, namely LNC CRYBG3, that regulated cytokinesis, migration, and metabolism by interacting directly with the actin cytoskeleton. LNC CRYBG3 binds to the ^{14}Ser of G-actin and inhibits the assembly of F-actin, which results in an incomplete cytoplastic division and consequent genomic instability. Obviously, the cytoskeleton-lncRNA network plays a very important role in regulating carcinogenesis associated with space radiation.

We further confirmed the functions of LNC CRYBG3 in regulating the carcinogenic effects of space radiation. LNC CRYBG3 was found to bind with LDHA to promote glucolysis, and LNC CRYBG3 was found to bind with Bub3 to interfere with the spindle assembly and separation of sister chromatids, resulting in aneuploidy and genomic instability. Therefore, a piece of radiation-induced long non-coding RNA leads to carcinogenesis by interacting with multiple targets.

2.3. Countermeasures against space radiation

Shielding cannot completely block highly energised space radiation. Anti-radiation medicine is not the first option, either. Novel strategies against space radiation have to be developed for long-term space exploration. Very possibly, a multi-disciplinary strategy will be taken in the future. It is generally believed that cells which are more proliferative are also more radiosensitive. Our previous work confirmed that quiescent cells are relatively resistant to ionising radiation, including high z and high-energy particles, due to the relatively low expression of RAC2, a main subunit of NADPH oxidase, and consequent low yields of intrinsic reactive oxygen species. These findings imply that risk assessment of space radiation based on

results obtained with routine exponentially growing cells might be overestimated. These findings also highlight the potential application of cellular metabolism for modulating individual radiosensitivity.

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Abstracts from the 44th Conference of the Australasian Radiation Protection Society, Held in Conjunction with the 5th International Symposium of the International Commission on Radiological Protection

This section is dedicated to presentations given in sessions at the 44th Conference of the Australasian Radiation Protection Society. This includes the Boyce Worthley Oration given in the opening session; oral presentations in sessions on future challenges, naturally occurring radioactive material (NORM) and natural radiation, radiation biology and protection, aviation and beyond: radiation biology and protection, nuclear facilities and training, and radiation protection in medicine; and poster presentations.

1. Boyce Worthley Oration

A controversy that needs to be resolved

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The atomic bombing of Japan that ended World War II was the first public demonstration of nuclear power, and the Life Span Study of the Japanese bomb survivors has provided most of the data on the risks of long-term health effects of radiation exposure, viz: doses >500 mSv certainly caused significantly increased risk of cancer, and doses <100 mSv did not cause any discernible risk but this may be because the risks (if they exist) are too small to be statistically significant. However, it has been

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claimed that there is evidence of reduced incidences of cancer at low doses (sometimes called 'radiation hormesis'). Data from other sources, particularly animal experiments but also human exposures, show that there are beneficial health effects (reduction of cancer mortality) from doses up to at least 100 mSv, and that protracted exposures up to at least 100 mSv $year^{-1}$ have either no discernible physical health effect or beneficial effects.

This situation has led to controversy regarding whether the risk from high levels of exposure should be extrapolated to low levels of exposure, in accordance with the 'linear no-threshold' (LNT) assumption. Unfortunately, well-informed opinions are strongly divided on the matter, which causes unwanted confusion and undermines public confidence in the radiation protection profession.

This controversy needs to be resolved and there are four essential questions to be answered:

- How can a commitment to LNT be reconciled with scientific evidence of benefits to health from low levels of exposure to radiation ('radiation hormesis')?
- Why should radiation that causes no perceptible harm be feared?
- Should protection be afforded against radiation at levels that cause no perceptible harm and is more likely to be beneficial than harmful?
- Should the use of the LNT calculation model be curtailed in the best interests of society?

2. Future challenges

Low dose radiation – science, policy, and public opinion

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The truth, the whole truth, and nothing but the truth

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Achieving harmonisation of radiation protection legislation across Australian jurisdictions

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All solid cancer incidence and mortality dose–response in the Life Span Study of atomic bomb survivors

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Cancer risks following low-dose radiation: what do we know about the dose–response curve?

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3. NORM and natural radiation

Radon distribution and appraisal of its radiation dose in the groundwater of a small tropical river basin, Kerala, India

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Validation of an effective dosimeter for radon decay products

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Design and development of a radon calibration chamber for Canada

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Review of uranium oxide transport in South Australia

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Cave radon exposure, dose, dynamics and mitigation

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Radon progeny and uranium ore dust personal alpha dosimetry in uranium mines – the Canadian experience

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A new diffusion battery for the assessment of aerosol characteristics

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A discussion on the potential impact of residential radon exposure on radon risk assessment for uranium miners

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A small animal radon chamber for environmentally relevant exposures

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Finding a solution for managing our low-level radioactive waste and bringing stakeholders along on the journey

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Radiation monitoring of uranium mining sites in the Alligator Rivers Region, Northern Territory, Australia

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Implementing environmental radiation protection guidance: a case study in Australia that includes terrestrial and marine pathways as well as assessment of noble gas radionuclides

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Developing international radiological risk assessment tools and approaches for Australian arid environments

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The IAEA forum for regulators of uranium and NORM activities

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NORM: a planned or existing exposure situation?

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Use of case studies in progressing guidance on the application of recommendations on radiological protection in the existing exposure situations

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4. Radiation biology and protection

Are clinical nuclear medicine settings compliant with proposed new ICRP lens of eye dose limits?

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Analytic estimation of the anatomical data for Malaysian radiation adult phantom

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Radiosensitivity changes in HPV + and HPV- head and neck cancers following fractionated irradiation

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Is particle therapy the answer for pancreatic cancer?

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DMAPT is an effective radioprotector of normal tissues from short- and long-term radiation-induced damage while radiosensitising prostate tumour tissue

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Experimental microdosimetry for radiation risk assessment of particle therapy patients and astronauts using a novel passive microdosimeter

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5. Aviation and beyond: radiation biology and protection

Space radiation effects, space health and human radiosensitivity

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How can we manage the cosmic radiation exposures of frequent flyers?

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Development of a new radiation safety standard in Victoria – CT based units for security or quality control purposes

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A solid-state microdosimeter for radiation protection for astronauts in space

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6. Nuclear facilities and training

Simple contamination, comprehensive solution – a case study

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Radiation protection performance and challenges at U.S. nuclear power plants

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Rethinking the challenge of radioactive contamination at the OPAL multipurpose reactor

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2019 challenges facing the waste isolation pilot plant

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The safety control system at a nuclear fusion experimental facility

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Successfully working together: nuclear power and radiation safety

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7. Radiation effects

Exploring the effects of ionizing radiation beyond Earth's orbit and deep underground in a novel yeast model system

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A multi-target dietary intervention protects from radiation-induced cognitive impairment and normal tissue injury

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Radiation effects on the lens of the eye: assessing the risk level for cataractogenesis

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The REPAIR project: a deep underground experiment investigating the biological significance of terrestrial and galactic cosmic natural background radiation

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Scientific insights into the current ICRP judgments for radiation effects on the lens of the eye

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8. Radiation protection in medicine

Are lightweight lead garments the emperor's new clothes of the angiography suite?

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Evaluation of basic performance of real-time wireless dosimetry system for interventional radiology

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Unshackling vascular surgery from ionising radiation: a review of innovative no-radiation and low-radiation ('No-Lo') imaging techniques

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Improvement of the use rate of the personal dosimeter and protector by interventional radiologists with radiological technologist leadership

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Analysis of mammography doses in Western Australia

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Radiation safety culture

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CT scan exposure before age 20 and cancer risk: using propensity scores to account for confounding by indication

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Patient-specific organ dose estimation in paediatric chest CT: the MEDIRAD project

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ARPANSA's national diagnostic reference level service – providing guidance on typical doses in medical imaging

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Calibration of an internal exposure measurement device using computational human phantoms

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Age dependent dynamic absorbed dose calculations to the urinary bladder wall for ICRP compartmental models of radiopharmaceuticals

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Conservatism in linear accelerator bunker shielding

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Potential for nuclear medicine source tracking and licensing on a blockchain – lessons from pilot studies in nuclear safeguards

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Advantages for a primary standards dosimetry laboratory in having a medical linear accelerator

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Learning from the Australian Radiation Incident Register

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9. Poster presentations

Advancing a radiotherapy predictive model to incorporate nanoparticle radiosensitisation in head and neck cancers

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RPS8 assessments: a 19-year review. Time for change?

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Gallium-67 waste management for incontinent patients

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Quantification of lead equivalence using radiographic imaging

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Comparison of dose to organs at risk in radiotherapy for stomach MALT lymphoma: three-dimensional vs. intensity-modulation vs. MR guidance

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Calculation of effective dose for intraoral dental radiography using Monte Carlo simulation in Korea

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Operator lens exposure assessment and dose reduction in ERCP: analysis of dose reduction effect by multiple stages of protective measures

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Estimated organ absorbed doses from almost 1 million CT scans in young Australians

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ARPANSA's educational materials for radiation protection in medicine

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Absorption dose in boron neutron capture therapy using optical fiber

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Sensitivity analysis of the NASA space cancer risk model

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Activity estimation during accelerator-based BNCT treatment

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An assessment of 30 years of personal dose records at Peter MacCallum Cancer Centre

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A bird's-eye view of ALARA in vascular surgery – ruffling feathers in the angiography suite

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Monte Carlo investigation of gold nanoparticle enhanced proton therapy and the enhancement mechanisms

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Estimating doses to aircrew using a web application programming interface (API) to a validated model of cosmic radiation in the atmosphere

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Novel applications of a 235 MeV proton therapy medical cyclotron in space radiation research

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Optimizing radiation protection for patients in cerebral angiography: the possibility of establishing diagnostic reference levels by imaging objectives/disease groups

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An on-going review of space exploration cancer and non-cancer risk models

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The development of an advanced airborne gamma-ray spectrometry system

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Solid-state microdosimeter for personal radon dosimetry in mines and caves

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The status of NORM regulation in Republic of Korea

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Impact of new ICRP dose coefficients on tourist caves

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Investigation of ^{210}Po activity concentration in Chinese typical seafood and dose assessment

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Trace of radiocesium-bearing particles in masks worn by members of the public in Fukushima

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Cosmic radiation exposure to the Australian public

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Effect of new ICRP dose coefficients on workplace exposures

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Safety issues of radon from the processed products containing natural radionuclides

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Radon/thoron scoping study in selected historic buildings in Brisbane

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A review of major exposure factors for assessment of radiation dose due to indoor radon

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Assessment of radioactivity levels and radiological hazards in building materials

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Efforts to deliver accurate information on radon in Republic of Korea

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Radon, thoron and progeny distribution in a low air mixing environment

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Review of guidance on radiological quality of Australian drinking water: alignment of the Australian drinking water guidelines with international guidance

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Elimination of self-activity signals using peak-to-charge discrimination method for $LaBr_3$:Ce scintillator

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The future of computer simulation in radiation protection

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Development of a function for estimating intakes of radionuclides using the models and data based on ICRP 2007 Recommendations

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Improving operational efficiency, compliance and community perception with real-time radiation and radon data

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Murapeptide protects mice and cells against ionizing radiaiton through Nod2 and ATR activation

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Australian National Radiation Dose Register

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Effect of doping and codoping on thermoluminescence properties of $NaMgF_3$

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Estimation on lifetime attributable risks for thyroid cancer incidence of Korean population due to a hypothetical nuclear accident in China

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Synthesis and thermoluminescence studies of $CaSiO_3$:Yb phosphor

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Analysis of dose rate effects on lifetime attributable risks for thyroid cancer incidence

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Fibre optic based sensing of alpha and beta particles in liquids

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Radiation protection in case of TENORM operations

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Personal alpha dosimetry service – quality assurance matters

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Calculation of the decommissioning radiation field of nuclear power plants based on the coupling of MC and point kernel integration – study on the method and its application

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Online monitoring technology for Pu-239 aerosol based on ICP-MS

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Managing existing exposure situations in the Australian context

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Radionuclide uptake mechanisms by native flora in the vicinity of uranium mines in arid South Australia

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The economics of radiation protection in medical settings: time for a new paradigm

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International survey on status of medical examinations for radiation workers – assisting comprehensive discussion

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The EURADOS intercomparison action on internal dose assessment for occupational exposures: ICIDOSE 2017

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The optimisation of ANSTO Tc-99m generator assembly process

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Optimisation of a Tc-99m generator assembly process

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Study about decontamination of an effective radioactive material

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Quantitative assessment of provability of radiation-related cancers considering unavoidable existence of unadjusted risk factors

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Effect of sieving size and sealing time of soil samples on radionuclide activity concentrations by gamma-ray spectrometer

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Classifying CT scans as causal exposures vs. reverse causation exposures: a finite mixture model approach

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Modulatory effect of the translocator protein (TSPO) on gamma radiation-induced neurogenic, neuroinflammatory and systemic immune responses

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Effects of radiofrequency radiation from GSM base station on reproductive performance and sperm head abnormalities on (F_1-F_3) of albino mice, mus musculus

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The latest activity of network for low dose radiation research in Japan: PLANET

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Stochastic models for cancer: implications for low-dose radiation and time since exposure effects

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Consideration of low-dose radiation risk in the presence of measurement error, from a statistical perspective

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Design of a wide energy range neutron REM counter

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Monitoring and evaluation of environmental dose equivalent levels around HFETR

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The IAEA-coordinated research on characteristics, environmental behaviour and biological impact of radioactive particles

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Comprehensive baseline environmental monitoring of an interim legacy waste store in arid zone Australia

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