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# A European reflection on the revision of the System of Radiological Protection

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**Abstract**—This paper provides HERCA’s reflections on the revision of the system of radiological protection. HERCA has identified four key areas of improvements of importance for HERCA members. These are simplification of the system of RP, justification and optimisation, use of reference levels, radon and communication. The paper elaborates the need for change identified in these four areas as well as in regard to a few other issues.

*Keywords:* HERCA; Revision of the system; Regulatory perspective

## 1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) has embarked on a review and revision of the System of Radiological Protection (referred to below as the RP System) HERCA (Heads of the European Radiological Protection Competent Authorities) welcomes the ICRP initiative to open and maintain transparent stakeholder engagement in the revision process. HERCA aims to be actively involved in providing a regulatory perspective. As a first step, HERCA has drafted a position paper (HERCA, 2022) providing the HERCA perspective on the revision of the RP System based on input received from HERCA members. In this position paper four key areas are identified where HERCA members have challenges applying the current system and therefore see a need for improvements. These four areas as well as other issues in need of attention are presented in this paper.

## 2. SIMPLIFICATION, CLARIFICATION AND OTHER GENERAL ISSUES

Regulators need a science-based, comprehensive and clear RP System that can be applied in regulatory frameworks in an efficient way. HERCA is of the view that dramatic changes to the RP System are not warranted at this time; fine-tuning is needed but rewriting should be resisted. It takes time to implement international standards and to align national regulations, and there is a need for continued stability. Furthermore, it is essential that any changes in the RP System, especially those likely to lead to a change in national regulatory frameworks, are justified as leading to a clear proportionate benefit, outweighing any drawbacks, in comparison with the current system. ICRP should therefore ensure that an impact assessment of any proposed change regarding implementation in regulatory frameworks is undertaken before recommendations are issued. For such impact assessments, HERCA will be of assistance to ICRP.

HERCA members recognise that the current system is complex and often difficult to explain. In some cases, the RP System is also difficult to transform into regulations that can be implemented and enforced in an effective way.

They also recognise that the system is robust and sophisticated, having evolved over a long period of time based on accumulated experience and knowledge. The RP System is, in general, effective and fit for purpose. However, several issues need to be clarified, and addressing these may lead to a level of simplification that could improve communication and enhance effective application. HERCA proposes that the focus of the revision should be to apply ethical concepts and new scientific knowledge to improve the system, seeking simplification where possible. Throughout this process, the possible negative impacts of any proposed simplifications on the RP System need to be considered and justified.

### **2.1. Exposure situations**

The move from a process-based to a situation-based RP System, recommended in ICRP *Publication 103*, should be maintained but there is a need for clear and unambiguous description of the underlying principles of protection for each exposure situation. There is also a need for greater clarity concerning the transitions between the three exposure situations, especially those involving existing exposure situations.

### **2.2. Interpretation of information on radiation-induced effects**

Some HERCA members highlighted the need to review and possibly reconsider the threshold for deterministic effects in light of recent scientific knowledge on cataract formation and diseases of the circulatory system. Other relevant issues include the definition of the dose and dose-rate effectiveness factor (DDREF) and the linear no-threshold (LNT) assumption related to the dose response relationship for stochastic effects. A consensus at international level is needed on these issues and their influence on ICRP recommendations and international standards needs to be clearly explained.

### **2.3. Dose and risk criteria**

The existence of various criteria and concepts for limiting exposure and/or optimising protection (dose limits, dose constraints, reference levels, diagnostic reference levels and operational limits) is perceived as one of the main sources of complexity. These criteria have solid scientific and conceptual bases justifying their existence, but they are also difficult to understand and to explain. There is a need for further guidance and clarification in the application of the concepts of limits, reference levels and constraints in different exposure situations.

### **2.4. Dosimetry and detriment**

The concept of detriment is a fundamental aspect of the RP System and new and proposed ICRP publications deal with the use of dose quantities, based on new insights on and more detailed calculation of detriment. There may be good scientific reasons for seeking better quantification of the effects of radiation. However, it is less clear whether there is sufficient justification for changing the dose quantities or risk models that are used in practical radiation protection and regulations. Again, there is a need to consider the consequences of making such fundamental changes to ensure that there is a real benefit.

There have been discussions regarding the application of detailed dosimetry modelling for individuals. The consideration of age- and sex-dependence of radiation sensitivity, and the differentiation of tissue weighting factors by sex and age groups, are positive developments. However, it is necessary to provide guidance on those situations where such approaches are of added value (e.g. for medical exposures). In many cases, such detailed modelling may add to



uncertainties in assessment and measurement in a way that would not lead to an improvement in radiation protection. There is also a need to address ethical and practical difficulties in the implementation of individual risk estimates in regulatory frameworks.

### **3. JUSTIFICATION AND OPTIMISATION: USE OF REFERENCE LEVELS**

#### **3.1. Optimisation**

According to ICRP *Publication 103*, optimisation is ‘the process of determining what level of protection and safety makes exposures, and the probability and magnitude of potential exposures, as low as reasonably achievable, economic and societal factors being taken into account’. Thus, optimisation of radiation protection is neither minimisation nor a standalone procedure. Ideally, a ‘holistic’ approach aimed at protecting health is needed; one that is integrated into a wider risk benefit approach which also takes account of societal and economic factors. Such approaches often lead to complex trade-offs between contributing factors and further guidance is needed on how to determine and to consider such factors. The risk-benefit analysis is especially complex in e.g. the case of NORM industries, like mining and milling, where a greater combination of radiation risks and other safety risks, as well as chemical and environmental risks and social and economic consequences need to be balanced.

There is a need for clarification and more guidance on the application of the optimisation of protection. The focus should not be limited to the application of reference levels but should also address optimisation in situations when the actual risk is known to be very low. The explanation of the underlying principles of both optimisation and justification could be improved. This would help to focus regulatory efforts on achieving the best possible level of radiation protection. HERCA encourages ICRP to elaborate further on the differences between the use of optimisation in medical exposures and optimisation in other exposure situations.

#### **3.2. Justification**

Holistic risk-benefit analysis is also relevant in the application of the justification principle not only in relation to planned exposure situations but also in the justification of countermeasures in emergency exposure situations and for remedial actions afterwards. Especially with regards to remediation strategies, as the work around Fukushima shows, simpler explanations and argumentative lines (even international good practices?) ought to be established.

The decommissioning of large nuclear and industrial facilities is either underway or set to begin in many countries. The determination of the end point is an important factor in the justification step in licensing decommissioning activities. Guidance and examples are needed to develop regulations that consider socioeconomic impacts when setting criteria for regulatory acceptance of the end point.

#### **3.3. Use of reference values**

The use of reference levels as a tool in optimisation is complex. A simplified system, combined with clear guidance on how to use and explain reference levels, would facilitate effective implementation and a more harmonised approach.

The use of different reference levels for different exposure situations, and their different meaning and use in practice, contributes to the complexity of the RP System. The difference between dose limits, dose constraints and reference levels are difficult to explain to stakeholders from both professional and public backgrounds. It is therefore important to

improve communication on the meaning and application of reference levels, stressing that they do not delineate what is ‘safe’ or ‘unsafe’. ICRP needs to provide more clarity and guidance on these aspects of the practical implementation and use of reference levels in regulatory frameworks.

## **4. RADON**

### **4.1. New dose conversion factors (DCFs)**

ICRP published new dose conversion factors (DCFs) for radon in ICRP *Publication 137*, which significantly changed the calculation of radon doses. The change in DCFs is strongly influencing the ongoing work of HERCA members and other regulators, particularly on developing national radon action plans and regulations related to the newly established requirements set out in ‘Radon in Workplaces’ (under EU legislation). Radon dose calculations are an essential input to decisions on whether further regulations are needed and the situation regarding adoption of the new DCFs is unclear. ICRP needs to provide guidance on how to evaluate and comprehensibly explain the difference between the epidemiological approach and the microdosimetry approach and how this translates into the actual radon detriment. The situation with new DCFs was particularly unfortunate because different international organisations supported different opinions.

### **4.2. Radon in workplaces and follow-up of people receiving high doses**

The newly introduced regulatory approach to radon exposure in workplaces is a significant regulatory challenge and practical implementation is leading to difficulties. ICRP should provide more guidance on how to deal with optimisation of radiation protection in workplaces where the doses to workers from radon are below reference levels.

There is a need for more recommendations and guidance for follow-up of individuals or groups of people including children who have been, or continue to be, exposed to very high radon levels over time, and the risks this involves. This is relevant for both the public, for instance people who have been living in homes with high radon levels for years, and workers exposed to high radon levels in their workplaces. It would be useful if ICRP could discuss and explore this issue further.

## **5. COMMUNICATION**

The broad scope of the RP System, which aims to cover all types of exposure situations, will always be complex and difficult to communicate to stakeholders. HERCA fully acknowledges the challenges ICRP faces in communicating these complex issues. HERCA members face this daily in their role as radiation protection authorities and welcome the fact that ICRP, in its ‘Fit for Purpose’ paper, targets improvement of communication as an important task for the future. The approach suggested in that paper, including its emphasis on the active engagement of stakeholders, transparency and inclusiveness, is welcomed.

### **5.1. Risk perception and risk communication in the revision of the RP system**

It is likely that efforts to simplify the RP System will improve its communicability. However, simplification is limited by the need to maintain a system that is scientifically robust. Consequently, there is a need to make further efforts to improve clarity and communicability in addition to any simplification efforts. It is therefore important that communication aspects,

such as risk perception and risk communication, are included as an integral part of the review process and that risk assessments are explained clearly and based on a solid, fact-based approach. It is equally important to involve communication experts in the process.

### **5.2. Radiation risks in perspective**

When communicating about the potential adverse effects of radiation, it is necessary to be clear about the terminology used, particularly the term ‘risk’. It is often helpful to put such risks in context, for instance when formulating the advantages and disadvantages of a certain course of action, which may involve comparing with risks from other hazards. Another way of putting radiation risks in context is to compare them with the variability of natural background exposures or to compare the added detriment for an individual to a baseline detriment (like lifetime fatal cancer risk, not linked to a specific cause). HERCA welcomes further elaboration of these important aspects of communication of radiation risks.

### **5.3. Addressing certainties and uncertainties**

The RP System is based on robust scientific foundations. It is important to communicate this clearly and to distinguish between what we know, what we do not know and what we assume for protection or other purposes. Increasing the transparency of the use of certainties, uncertainties, assumptions and precautionary considerations would increase public trust. It would also be beneficial to explain the differences between science and relevant uncertainties on the one hand and value judgements (policymaking) on the other hand.

## **6. OTHER ISSUES**

A part from the four areas elaborated on above, other issues have been raised by HERCA members which should be considered by ICRP in the revision of the RP System. These are: i) medical exposures ii) radiation protection of the environment iii) education and training iv) responders in emergency exposure situations.

In addition to optimisation of medical exposures, which was addressed in section 3.1, other issues warranting discussion in international radiation protection fora were identified, particularly related to radiotherapy of children, and taking account of the increased risk of stochastic effects (secondary cancers), and emerging protection considerations resulting from the continuing development of new technologies using ionising radiation.

The ICRP revision process provides an opportunity to improve the way in which radiation protection of the environment is addressed and potentially integrated into the existing RP System without adding complexity to it. It would be beneficial if this process included consideration of approaches for other hazardous agents (e.g. chemicals) in the environment.

Education and training are essential to facilitate understanding of the ICRP RP System and its practical implementation. ICRP has developed recommendations on education and training specific to the medical field but further guidance for other fields would be helpful, especially for new practices that lead to elevated exposures of workers.

There is a need for ICRP to further develop the present guidance on informed consent for responders in the early and intermediate phases of an emergency. ICRP needs to address several aspects that are both philosophical and ethical, for instance: identification of the categories of personnel and volunteers who should be considered as responders (and when) and the circumstances under which responders have the right to refuse to work.

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## Communication of radiation protection issues

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**Abstract**—The International Commission on Radiological Protection (ICRP) has embarked on a review and revision of the system of radiological protection (RP System) that will lead to new General Recommendations refining and superseding ICRP *Publication 103*. The first major milestone in ICRP's work was the publication of the paper titled 'keeping the ICRP Recommendations Fit for Purpose', in 2021, aimed at encouraging discussions within the RP community. On this matter, the Spanish Nuclear Safety Council (CSN) has contributed to preparing the Heads of the European Radiological Protection Competent Authorities (HERCA) document titled 'Reflections on the Revision of the System of Radiological Protection' that were presented during the ICRP symposium named '6th International Symposium on the System of Radiological Protection'. In the latter, HERCA emphasised the need for simplification and clarification of the RP System, as well as other topics for future work: (i) to improve the fundamental principles of justification and optimisation; (ii) to broaden the guidance on radiation protection against radon exposure in workplaces; and (iii) to improve communication of RP. CSN is supportive of the HERCA reflections, and wants to elaborate more on Communication, an issue that is intimately related to the simplification and clarification of the RP System. In this paper, we propose that the revision and review of the RP System be conceived, since its very inception, on the grounds of communicability. We recognise that it is a huge challenge because the scientific robustness of the RP System is unnegotiable. The involvement of communication professionals in the process of the RP System revision may help clarify matters such as the reason why dose limits are established on one hand but reference levels are proposed, on the other, as well as why different dose limits are applicable depending on the exposure situations. The RP System is based on robust scientific foundations but there is a tendency to focus on 'uncertainties' rather than the many 'certainties' that are already well known. Undoubtedly, there will always be 'uncertainties', but it is the purpose of research and development (R&D) efforts and scientific discussions to turn them into certainties, which can be incorporated into regulations. However, the regulator's actions shall be based on certainties and presented whenever the public claims for information before incidents and accidents, admitting that uncertainties exist, when it may be needed.

*Keywords:* Communication; Stakeholder involvement; Building trust; Credibility, Regulatory body

### 1. BACKGROUND

The International Commission on Radiological Protection (ICRP) has undertaken a review and revision of the system of Radiological Protection (RP) that will lead to new General Recommendations refining and superseding ICRP *Publication 103*.

A major milestone in ICRP's work was the publication of the paper titled 'Keeping the ICRP Recommendations Fit for Purpose', in 2021, aimed at encouraging discussions within and asking for suggestions to the RP community (Clement et al., 2021).

On this matter, the Spanish Nuclear Safety Council (CSN) has contributed to preparing the Heads of the European Radiological Protection Competent Authorities (HERCA) document titled 'Reflections on the Revision of the System of Radiological Protection' that was presented at the ICRP symposium named '6th International Symposium on the System of Radiological

Protection' in Vancouver, in November 2022. In the latter, HERCA emphasised the need for simplification and clarification of the RP System, as well as other topics for future work: (i) to improve the fundamental principles of justification and optimisation; (ii) to broaden the guidance on how to implement radiation protection against radon exposure in workplaces; and (iii) to improve communication of RP (HERCA, 2022).

CSN is supportive of the HERCA reflections, and wants to elaborate more on Communication, an issue that is intimately related to the simplification and clarification of the RP System.

## **2. REFLECTIONS ON COMMUNICATION AND REGULATORY EFFECTIVENESS**

For a regulator, it is very difficult to access directly to the general public. On a regular basis, regulators post news, achievements, information related to incidents, etc., on their public websites and social media channels, in order to keep the public informed. However, these posts are generally consulted by professionals, either from the licensees or by specialised journalists after an incident or when an issue related to nuclear safety or radiation protection is hot.

These channels of communication need specialised human resources to provide them with content and to keep them permanently up to date so they can act as a reference for the society when they are looking for information. However, not only does this information need to be posted but most importantly, it should be formulated in a way that is attractive and understandable to people.

For example, when an emergency occurs, all media will have the urge to inform about it and, consequently, will start looking for experts who can act as speakers. They will also make enquiries about how severe the incident is, they will demand data and explanations, as well as they will look for guidance on what to do, how to prevent and protect the people and the environment, etc. In these situations, it can be a challenge for the regulators and authorities in charge to get their message across beyond the information overload produced by the non-specialised media and social networks.

In such circumstances, having properly trained experts on communication skills, approved protocols and, already prepared most frequently asked questions and their answers, may be vital to cope efficiently with the emergency from the communication perspective.

Generally, the authorities have their focus on technical and scientific issues, which are very important to manage the emergency (infrastructures, procedures, coordination with the licensee to follow the evolution of the accident, etc.). However, clear and easily shareable information about who the official source is and the advice that needs to be followed to protect people should not be considered less important. If the public do not follow the authorities' instructions during the emergency due to a lack of trust, miscommunications, etc., the emergency response may be compromised, or furthermore, the emergency consequences could be more severe.

Apart from emergencies, in daily life many circumstances require good communication skills from the regulator. A typical example could be having to answer to the enquiries coming from the non-specialist workers in hospitals who are worried about their potential exposure to the radioactive sources or equipment used in the medical facilities, or from people living or working in the surroundings of nuclear facilities.

Apart from communication skills, the regulator and authorities need to build and foster their credibility and trustworthiness. These attributes rely on many aspects, but from the CSN experience, one of the most important ones is having strong and fluent relationships with all relevant stakeholders, from agencies of the Administrations and local authorities, to professional societies, trade unions, etc.

As mentioned before, another aspect that is becoming increasingly more important is the clarity and simplicity of the message. Nonetheless, some channels only admit messages of a limited number of characters, and the public is becoming more used to and fond of shorter explanations.

The current system of RP is based on robust scientific foundations and ethical principles. However, it is admitted that the complexity of the system makes it difficult to implement, even for radiation protection experts that very often need guidance from the most experienced ones. Any effort to simplify the RP System without compromising the robustness of the science behind it will benefit its communicability, particularly to the public and in stressful situations.

With that being said, we think that the efficiency of the system of RP depends very much on its:

- understandability;
- readiness to be used by a wide range of professionals; and
- capability to send messages whose rationality is easy to understand and follow by the professionals and the public.

Consequently, we think that the ICRP has the challenge to review the system of RP system to keep its scientific robustness while making it more communication friendly.

### **3. A RADIATION PROTECTION SYSTEM CONCEIVED ON COMMUNICATION GROUNDS**

The ICRP has already addressed the issue of communication and stakeholder involvement as one of the overarching considerations in the document titled ‘Keeping the ICRP recommendations fit for purpose’ (Clement et al., 2021).

Even more, in its *Publication 146*, ICRP has introduced the very interesting concept of the ‘co-expertise process’ based on the involvement and empowerment of stakeholders (ICRP, 2020).

CSN recognises and praises the ICRP initiatives to improve communication and stakeholder involvement and believes that the on-going efforts for simplification and clarification of the RP System will improve its communicability.

As stated before, the current system of RP is based on robust scientific foundations. However, the focus looks occasionally biased towards ‘uncertainties’ rather than ‘certainties’. This is understandable from a scientific standpoint, but non-professionals in radiation protection tend to identify this approach as a weakness of the system that eventually may discredit it for that.

We believe that the system of RP should emphasise the many certainties that provide its robustness, be very cautious about the uncertainties in the formulation of the system and leave them within the scientific research field as much as possible.

Besides, several issues need a communication approach in its very formulation, such as the rationality of establishing dose limits on one hand and proposing reference levels on the other one, or why different dose limits are applicable depending on the exposure situations, not to mention the Linear-non-threshold model. Ethical principles have a huge influence on the system of RP and ICRP has issued specific publications on the matter. However, these principles are not always obvious and it is easy to get confused when someone tries to understand the system only on scientific grounds.

For all these reasons, we think that the involvement of communication professionals in the revision process of the system of RP, from the very beginning, may help to formulate it in such

a way that the public questions can be properly addressed and consequently, the system will result more understandable.

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## Example of the misleading results caused by LQ model in calculating the fractionation effect in radiation therapy

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**Abstract**—The linear quadratic model (LQM) has been commonly used for calculating radiotherapy and/or radioprotection. It is a mechanistic, biologically-based model with few parameters and is used to do quantitative predictions of dose fractionation dependences for cases such as radiation protection, and radiotherapy. Here we demonstrate that LQM does encounter serious pitfalls both from a theoretical and phenomenological point of view. LQM is traced back to the famous *Drosophila* experiments (Muller, 1927). Scientists had believed that mutation was cumulative and irreversible until the dose-rate effects were found by Russell mega-mouse project (Russell). Unfortunately, this message was not taken correctly except for the difference between low and high dose-rate cases and people were content with such notions as dose and dose rate effectiveness factor (DDREF), dose rate effectiveness factor (DREF), and low dose effectiveness factor (LDEF). However, the concept should have been seriously taken into account the important evidence existing in the biological organism, namely the mutation frequency can be reduced by repairing and cell exclusion mechanisms. Especially an apparent inconsistency of the notion of ‘fractionation effect’, which was thought to be related somehow to the so called Elkind-type Recovery, and is utilised in the treatment of cancer in radiation therapy. Here we take a simple thought experiment to show such fractionation calculus leads complete inconsistent result. Why does it happen? The answer is simple: LQM predicts that the risk stays constant so far as D does not change. In actual cases, however, the risk function changes over time due to preventing mechanism. To this end, we have constructed the ‘Whack-A-Mole’ (WAM) Model to take account of input and output processes. Indeed, calculations of clinical circumstances are getting important. Due to this the mutated cells decreases over time after the irradiation stops, while LQM predicts no change since the accumulated total dose, D remains constant. The details will be seen in a separate ICRP publication.

**Keywords:** LNT; LQM; Fractionation; Whack-A-Mole; Dose-rate effect

### 1. LQM WITH THE NOTION OF DDREF

Let us start with a rough sketch of the essence of linear quadratic model (LQM) (Muller, 1927, 1932; Timoféeff-Ressovsky, et al., 1935; Spencer et al., 1948), which is based on the standard Lea’s theory (Lea, 1946). BEIR VII summarised the historical results and referred the well-established formulae. By taking the mutation frequency as an example, we make quick review of the notations used in radioprotection reports. From the mutation frequency  $F(D)$  let us define the excess mutation frequency  $E(D)$ , by subtracting the background (or control) mutation frequency  $F(D=0)$ ,

$$\begin{aligned} E(D) &= F(D) - F_s \\ F_s &= F(D = 0) \end{aligned} \quad (1.1)$$

with  $D$  being accumulated total dose of artificial radiation. Then linear non-threshold (LNT) expressed as,

$$LNT: E_{LNT}(D) = \alpha D \quad (1.2)$$

Nowadays instead of LNT model, LQM has been most commonly used:

$$LQM: E_{LQM}(D) = \alpha D + \beta D^2 \quad (1.3)$$

with  $D$  squared term added to LNT in order to reproduce existing experimental data. Apparently in the above formula, we have neither time dependence nor dose rate dependence (Rühm et al., 2015). Instead, the notion of dose and dose rate effectiveness factor (DDREF) was introduced, which is a factor initially introduced by the International Commission on Radiological Protection (ICRP, 1959a,b, 1975, 1977, 1991a,b, 1999, 2001) to apply to risk estimates derived from moderate- to-high dose and high dose-rate data to the one derived from low dose or low dose- rate. Note that the knowledge on DDREF changes with time [see e.g. (Rühm, 2015)]. It seems, however, to have failed in making clear the difference of dose and dose rate. Indeed, in the expressions of  $E_{LNT}$  or  $E_{LQM}$ , there is no explicit dose rate dependence or time  $t$ .

However, we should understand to what extent people have been aiming within the above LQM framework. One way of such approach can be seen from the discussion done by Niwa, who assumed that dose rate effects are clearly visible at higher dose  $D$  region: while the linear term is independent of dose rate, the quadratic term is dose rate sensitive. Then the biological effect for high-dose-rate exposures (H) and low-dose-rate exposures (L) can be described as,

$$\begin{aligned} E_H &= \alpha D + \beta D^2 \\ E_L &= \alpha D \end{aligned} \quad (1.4)$$

then DDREF is defined as,

$$DDREF = \frac{E_H}{E_L} = 1 + \frac{\beta}{\alpha} D \quad (1.5)$$

which is actually the same expression of DDREF index as follows,

$$DDREF = \frac{E_{LQM}}{E_{LNT}} = 1 + \frac{\beta}{\alpha} D \quad (1.6)$$

From the above discussion we understand that the notion of DDREF was indeed introduced not only to account for dose rate effect but also to add correction term to handle the data for high dose region. Provably people might naively imagine high  $D$  and low  $D$  correspond to high and low dose rate, respectively. However, if we encounter the situation of long-term low dose exposure seen in some area of Fukushima prefecture, for example, the correspondence is not justified, which we shall see in the separate ICRP publications. Moreover, the above complicated discussion further added several notations, such as dose rate effectiveness factor (DREF), defined as the ratio of the effect at a given acute dose to that of a chronic exposure to

the same total dose, and low dose effectiveness factor (LDEF), which are used here and there in estimating radiation protection reports but they are of almost similar meaning, and may bring somewhat confusion in their scientific discussion. More confusing notion may be what is called ‘Committed effective dose’ which is defined as the time integral of the equivalent dose rate in a particular tissue or organ that will be received by an individual following intake of radioactive material into the body, where the integration time is 50 years for adults. ICRP actually told how to calculate this committed effective dose.

$$\begin{aligned} \text{LDEF} &= \frac{\alpha D + \beta D^2}{\alpha D} = 1 + \frac{\beta}{\alpha} D \rightarrow \frac{E(D)}{E'(D)D} \\ \text{DREF} &= \frac{\alpha D + \beta D^2}{D} \rightarrow \frac{E(D)}{D} \end{aligned} \quad (1.7)$$

## 2. FRACTIONATION EFFECT IN LQM FRAMEWORK

Here is an important comment on the notion of ‘fractionation effect’ derived from LQM which leads us to serious pitfalls. The fractionation effects are utilised especially in the treatment of radiation therapy as well as the radiation risk estimation. When the total dose of radiation is divided into several smaller doses, people experienced that the radiation risk becomes lower.

However unfortunately, as for the experiments in radiation biology, especially in the mega mouse experiments done by Russell (Russell, 1951, 1963, 1965, 2013; Russell et al., 1958; Russell and Kelly, 1982a,b), they did not mention about the details of time schedule for the fractionated case, because people believed that mutation frequency depends only on total dose and did not care about its time dependence. In LQM the treatment of fractionation case is formulated as follows,

$$\text{Fractionation}(n\text{-fold})\text{def: } E_{frac}(D:n) = nE\left(\frac{D}{n}\right) = \alpha D + \frac{\beta}{n} D^2 \quad (2.1)$$

indicating that the above procedure changes the coefficient of  $D$  squared term, which becomes smaller and smaller for larger  $n$ . We can see an apparent inconsistency just by the following thought experiment. If we imagine the case where the time interval during the irradiation stop-and switch is extremely short, namely almost instantaneously, there is no difference of such fractionation procedure from continuous irradiation case. However, those two cases yield different prediction. Moreover, if we continue to do this procedure to take  $n$  to infinity, we have:

$$\begin{aligned} \lim_{n \rightarrow \infty} E_{frac}(D:n) &= \lim_{n \rightarrow \infty} n \left( \alpha \frac{D}{n} + \beta \left( \frac{D}{n} \right)^2 \right) = \alpha D \\ \text{DDREF} &= \lim_{n \rightarrow \infty} \frac{\alpha D + \beta D^2}{n \left( \alpha \frac{D}{n} + \beta \left( \frac{D}{n} \right)^2 \right)} = 1 + \frac{\beta}{\alpha} D \rightarrow \lim_{n \rightarrow \infty} \frac{E(D)}{nE\left(\frac{D}{n}\right)} \end{aligned} \quad (2.2)$$

where text books say that the DDREF can be derived. However, the inconsistency can be immediately understood because there should be no difference between two cases if the fractionation case with zero intermission times, leading to serious inconsistency. Why does it happen? The answer is simple; in the framework of LQM we have no information on the time dependence. Thus,  $E$  depends only on the total dose,  $D$ , which means that  $E$  stands constant so far as  $D$  does not change. However, everyone was aware that the actual data will change over time due to the recovery mechanism (Emami et al., 2015). Taking account of such repairing effects, we have constructed a model which we name ‘Whack-A-Mole’ (WAM) (Manabe et

al., 2013, 2015; Nakamura et al., 2014; Wada, 2015; Bando et al., 2019; Tsunoyama et al., 2019). We shall explain the essence of WAM and its extended version shall be presented in a separate ICTP report. Here we just demonstrate how the calculated results of our WAM reproduce consistent explanation by introducing reasonable time dependence.

In concluding this report, we add a comment on the question, ‘Why was the dose rate dependence observed only in mouse data (Russel group) while the accumulated fruit fly data (Mueller et al., 1927, 1932) clearly indicated LNT without any dose rate dependence?’. WAM will shed new light not only on the radioprotection principle but also on the clinical planning of radiotherapy.

### 2.1. Figure Typical example of Fractionation Effects

Examples the results of the radiation frequency vs, time, calculated by WAM and LQ fractionation formula. Two times schedule of radiation exposure, dose rate  $d = 0.01\text{Gy h}^{-1}$ , total time  $T = 250\text{ h}$  (total dose  $D = 5\text{ Gy}$ ) with different fractionation schedule, schedule 1 (blue colour) and schedule 2 (red colour)

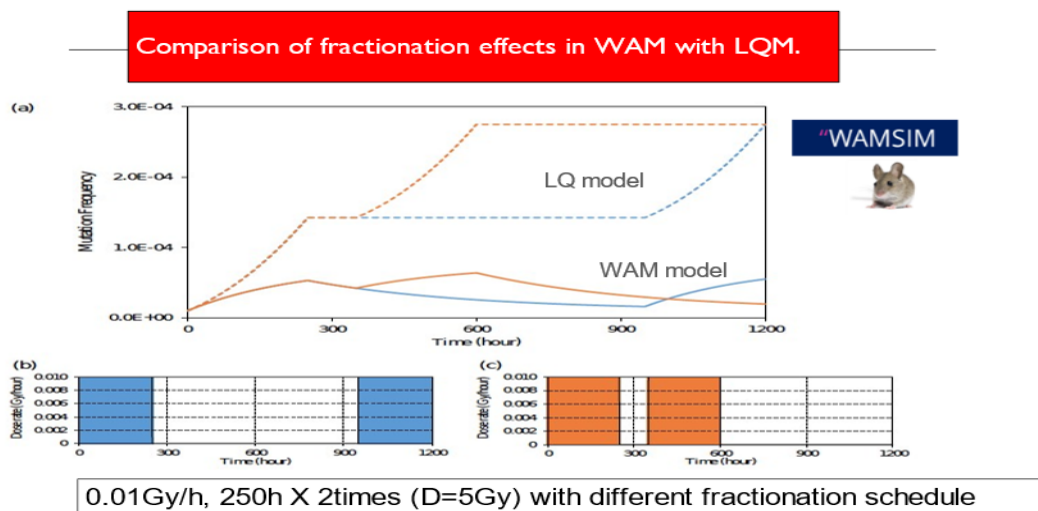


Fig.1. Comparison of fractionation effects of ‘Whack-A-Mole’ (WAM) with the linear quadratic model (LQM) with different time schedules; Case 1 two irradiation periods are indicated by blue regions ( $0 < t < 250\text{ h}$ ,  $950\text{ h} < t < 1200\text{ h}$ ) and red regions ( $0 < t < 250\text{ h}$ ,  $350\text{ h} < t < 600$ ). In the interval with no irradiation, the WAM shows decreasing effects while we see no decreasing effect in the usual LQ treatment.

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# The Review of the ICRP System of Radiological Protection – practical feedback from members of the Australasian Radiation Protection Society

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**Abstract**–The Australasian Radiation Protection Society (ARPS) has surveyed members for their personal and practical comments on the upcoming review of the ICRP system of radiological protection. A summary of the feedback was collated and formed the basis of ARPS contributions to the International Radiation Protection Association’s (IRPA’s) formal submission to the review. The comments from members ranged from detailed examples of where the current ICRP system fails to provide clear direction for applying a practical and risk-based system of management, through to broader themes that ARPS believes need significant work. As practitioners, ARPS has provided positive suggestions for changes and improvements pertinent to the future of applied radiation protection.

*Keywords:* ARPS; Australasian; System of Protection; Feedback; Review; ICRP *Publication 103*

## 1. THE AUSTRALASIAN RADITION PROTECTION SOCIETY

The Australasian Radiation Protection Society (ARPS) is a professional society of members engaged in one or more aspects of radiation protection, generally in New Zealand and Australia. Members come from various industries and sectors. These include regulatory, medical, research, environmental protection, industrial, mining, resources and nuclear. ARPS is an Associate Society of the International Radiation Protection Association (IRPA).

## 2. REVIEW AND REVISION OF THE SYSTEM OF RADIOLOGICAL PROTECTION

### 2.1. IRPA Task Group

The International Commission on Radiological Protection (ICRP) produced the paper titled ‘Keeping the ICRP Recommendations Fit for Purpose’ (Clement et al., 2021). This initiated the process of revising the system of radiological protection to update the 2007 general recommendations in ICRP *Publication 103* (ICRP, 2007). IRPA has convened a task group to promulgate the paper and to encourage feedback from Associate Societies. ARPS is represented on the task group and has provided feedback to the task group chair on specific aspects of the paper, as well as top priorities including challenges encountered in practical applications.

ARPS solicited feedback from its members as well as from other professional societies within Australia and New Zealand whose members have roles and responsibilities related to radiation protection. Feedback was received and shared within ARPS to foster discussions and

formulate a collective perspective. A summary of the most pertinent aspects is reported herein. It is worth noting that not all members contributed and not all members share the same concern for change.

## **2.2. Comments on the Principles of Radiological Protection**

### **2.2.1. Justification**

ARPS members note that ‘justification’ should remain a core pillar of the System and note that the justification process may involve more than just the costs or benefits of the radiation component. Any justified practice is predicted to (by virtue of the linear no-threshold model) do harm; the question is whether such harm remains acceptably low for the benefit derived. It was also noted that the ‘justification’ process for, as an example, a nuclear facility is very different from a medical procedure.

### **2.2.2. Optimisation**

Clement et al. (2021) emphasises a focus on risk and risk assessments. The nuclear industry has moved from risk (defined as ‘consequence’ x ‘likelihood of consequence being realised’) to deterministic assessments, which focus on consequence from postulated initiating events and controls to prevent the event leading to the consequence or mitigate the consequence to an acceptable level. Ergo, nuclear risk models have a strong focus on fail safes. In contrast, the medical and health sector consider beneficial outcomes, where the health benefit and health detriment are directly compared. Risk models are also influenced by considerations of legal liability. Clement et al. (2021) proffer consideration of promoting ‘reasonable caution whilst avoiding undue conservatism’ but ARPS members note that on a practical level this is difficult to implement in a legislative process. In cases where the dose may be significant, but the likelihood is assessed as low, the subjectivity or contextualisation of the assessment of likelihood is important.

Overall, clear guidance is required on how to assess radiological risk to properly apply the principle of optimisation which relies on risk assessment and radiation related risks need to be kept in perspective with the broader set of risks that apply in any situation.

ARPS also suggests that consideration be given to developing tools and accreditation standards for the competency of radiation professionals, as assessments of justification and optimisation increasingly require a case-by-case approach by competent radiation professionals using a uniform and methodical approach.

### **2.2.3. Application of Dose Limits**

Given the risk at low doses is highly uncertain, there needs to be a balance in managing risks at low doses, so that the efforts of regulatory governance and financial burden is commensurate with comparable other risks. It is important to recognise that many industries and sectors with ionising radiation hazards also have a range of other health hazards, such as biological, chemical, and musculoskeletal, among others. There should be consistency in the risk appetite across different types of health hazards.

Highly specific dose determinations that incorporate age and gender is not warranted at low doses given that there is negligible impact upon managing radiation exposures. Moreover, it implies an unwarranted degree of precision. Such additional complexity can be a barrier to beneficial practices and compound public anxiety.

ARPS considers the incorporation of potential response modifiers as a significant ethical challenge. It is not clear how this can be integrated into a system of protection. Care must be taken to ensure that individual dose limits do not become the norm as this would be impractical.

### **2.3. Comments on a Holistic System of Radiological Protection**

While the remit of the ICRP is radiation protection, caution must be exercised when considering aspects other than radiation protection. Introducing concepts such as environmental sustainability and a holistic definition of human health, such as that by the World Health Organization (WHO, 1946) of ‘a state of complete physical, mental and social well-being...’ into radiation protection requirements is considered overreaching for radiation protection specialists. The concept permits the possibility of sustainability and social well-being aspects dominating public radiation protection discussions. Moreover, these aspects would take radiation protection into areas where radiation protection specialists do not have the skill sets to inform decisions or advice. The wider context of aligning ‘sustainable development’ and ‘quality of life’ goals with radiation protection has merit, however the system of radiation protection should not extend beyond alerting governments and policy and decision makers to such considerations.

### **2.4. Unduly Conservative Application of the System of Radiological Protection**

In practice, the System promotes a prevalence of excessive risk mitigation, whereby radiation practitioners strive to minimise exposure risks beyond what is reasonable. It is a matter of applying the ALARA principle without a sound basis of what is reasonably achievable. A recent IRPA publication on reasonableness states ‘in practice there is a wide consensus that at low exposure levels typically around ‘a few mSv’ or less, all we know is that if there is a risk, then it is very small and is equivalent to many risks in situations commonly accepted in society’ (IRPA, 2021). Despite this consensus, practitioners find that low levels become the norm, either through regulation, industry standards, or application of the ALARA principle. Therefore, it is commonplace for unreasonable efforts to be expended in circumstances where such efforts are not justified when considering the potential effective dose alongside factors such as cost and actual risk. Further guidance in this area by the ICRP would be immeasurably valuable.

ARPS members provided the following examples where, in their opinion, interpretation of the System by regulators and radiation protection professionals results in mitigations that are unduly conservative.

#### **2.4.1. Management and Remediation of Contaminated Land**

The management and remediation of land contaminated with radioactive material begins with defining what is ‘contaminant material’. This is often based on applying reference levels comparable to exposures for planned exposure situations such as a dose limit of 1 mSv year<sup>-1</sup>, or a dose constraint of 0.3 mSv year<sup>-1</sup>; then using those values to derive measurable parameters such as activity concentration or associated exposure rates. Despite a correspondingly very low health risk, practitioners often apply these values conservatively, for example using worst case exposure rates and occupancy factors. The outcome can be restrictive, resulting in excessive expense to manage or remediate ‘contaminant material’ that has a low likelihood of significant exposure. Although exposures on legacy sites are justified on a case-by-case basis, the risk averse nature of environmental consultancy and the influence of public perception, results in unduly conservative outcomes where the trade-off between optimisation and reasonableness becomes unbalanced.



### 2.4.2. Lead Aprons for Diagnostic Radiology

Some regulatory processes require nurses to wear lead aprons during diagnostic radiology procedures and veterinary radiology. Furthermore, some regulatory jurisdictions require nurses to have personal monitoring despite most nurses involved being more than 2 m from the x-ray tube or outside the exposure room during exposures. This is evidenced by personal monitoring results that are routinely below minimum reportable doses. Conservatism in this situation imposes costs through the provision and maintenance of additional items of personal protective equipment and individual monitoring where workplace monitoring could suffice. Wearing lead aprons also introduces the risk of musculoskeletal injury.

### 2.4.3. Linear Accelerator Bunkers

Shielding assessments are routinely conducted prior to installing a medical linear accelerator. The implications of conducting shielding assessments on a conservative basis compared to a real case basis are substantial. A conservative assessment that overestimates the number of treatments and assumes full radiation output results in overengineered bunkers and can deem existing bunkers unsuitable for new linear accelerators resulting in the unnecessary construction of new bunkers.

## 3. CONCLUDING REMARKS

ARPS members support a review of the system of radiological protection. Although the current System is complex, it is considered to be effective and robust, therefore future recommendations should be evolutionary rather than revolutionary. Developments in the System should be based upon experiential learnings from application of the current system. ARPS members desire a system of radiological protection that is clear, logical and fosters simple practical implementation with clear guidance for uniform implementation across the industry when aligning optimisation and reasonableness to low dose exposure situations.

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## Protection of the environment from exposure to ionising radiation: why and how evolution is timely for the ICRP system

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**Abstract**—Currently, several task groups are addressing complementary aspects in support of improved ICRP’s recommendations and ultimately, a more robust approach to protection of the environment from deleterious effects of exposure to ionising radiation. In this context, ongoing developments are briefly presented, with some examples of new methods that have been conceived and implemented (e.g. statistical extrapolation models to quantify the range of radiosensitivity within a taxonomic class and derive transparently and systematically benchmark values or ranges such as the Derived Consideration Reference levels- DCRLs). This paper also addresses the main goals of the ongoing task groups dealing with various aspects of Environmental Radiological Protection (ERP) and their interactions, and the potential need for reformulation of the goal(s) for ERP. The approaches taken by the task groups and the outcomes of their work are expected to inform an inclusive and holistic justification and optimisation process to be considered in the review of the general recommendations of the ICRP.

**Keywords:** Environmental radiological protection; ICRP framework, Endpoint sensitivity distributions; Sustainable development goals; Ecosystem services

### 1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) introduced a specific objective for the protection of the environment against the harmful effects of exposure to ionising radiation as part of its 2007 General Recommendations (ICRP, 2007). The ICRP’s environmental protection framework was subsequently defined in *Publication 108* (ICRP, 2008), and its application in different exposure situations was outlined in *Publication 124* (ICRP, 2014). The framework aimed to, as far as possible, be consistent with the ICRP approach to human health protection and with existing frameworks for management of environmental risks from non-radioactive agents such as chemicals. The ICRP’s current objective of environmental radiological protection (ERP) is *to prevent or reduce 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).

However, as pointed out by the (then) ICRP Main Commission and Secretariat (Clement et al., 2021), the approach to ERP taken by ICRP may require reconsideration and expansion in

order to enable a holistic approach to protection and thereby also to justification, optimisation and the setting of dose (rate) benchmarks that guide the practical application of the system. It was considered that *while the work already undertaken by ICRP will remain a cornerstone, inclusion of more global considerations of environmental protection in the context of 'sustainable development' and concerns about the 'quality of life', including the services provided by the environment and ecosystems as well as the impacts of the implementation of protective actions, may be considered for inclusion in future General Recommendations*. This direction could help better respond to the current challenges of society.

To ensure that the radiological protection system continues to be fit for purpose in protecting the environment, several complementary ICRP Task Groups (TG) are reviewing, either directly or as part of their broader mandate, the framework for ERP. This includes the established TGs 99, 105 and 114, as well as the new TG 125 set up to explore how the concept of ecosystem services could be used in ERP and how the framework for ERP might contribute to the achievement of United Nations Sustainable Development Goals (SDG) agreed upon in the 2030 development agenda of the United Nations (UN, 2015). Additionally, the environment is included in the considerations of other ongoing Task Groups, even if not the specific focus (e.g. TG 97 Application of the Commission's recommendations for surface and near surface disposal of solid radioactive waste; TG 98 Radiological protection in the management of exposure in areas contaminated by past activities). Of relevance is also the TG 124 on justification, although it is considered premature to reflect on its work, which has just commenced, in this paper. Collectively, all mentioned TGs can be expected to have a significant impact on the ICRP approach to ERP as it may be laid out in the general recommendations that are likely to in due course replace *Publication 103* (ICRP, 2007).

This paper gives a brief overview of the main goals and methods developed by the ongoing task groups in dealing with various aspects of ERP and its links to human health and sustainable development. A collaborative approach by the relevant TGs is important. The paper concludes by outlining the next steps in the development of a more holistic and sustainable justification and optimisation process for the next set of ICRP general recommendations.

## **2. ONGOING WORK ON ENVIRONMENTAL RADIOLOGICAL PROTECTION**

Three ICRP task groups, TG 99 RAP Monographs, TG 105 Considering the Environment when Applying the System of Radiological Protection as well as portion of TG 114 Reasonableness and Tolerability in the System of Radiological Protection, were set up several years ago to clarify, update and improve various components of the ICRP approach to ERP (although the TG 114 scope-of-work extends beyond ERP). Their respective objectives, progress and achievements are briefly described in this section. Section 2.4 introduces the newly established TG 125 Ecosystem Services in Environmental Radiological Protection which was created to explore the potential use of the ecosystem services concept as part of consideration of the links to the UN Sustainable Development Goals (SDGs).

### **2.1. Task Group 99 to update and enhance the exposure criteria for reference animals and plants**

A graded approach to the demonstration of ERP has been developed and adopted, supported by *Publication 108* (ICRP, 2008) and *124* (ICRP, 2014), complemented by a series of technical documents and datasets on radionuclide transfer coefficients (ICRP, 2009), dose coefficients (ICRP, 2017) and weighting factors for different radiation qualities (ICRP, 2021). The framework and datasets enshrined in these publications, primarily support actions aimed at maintaining of biodiversity and conservation of species. Assessing whether these protection

targets are met requires simplification and the use of representative taxonomic groups through the use of two key concepts (Real and Garnier-Laplace, 2020):

- Twelve Reference Animals and Plants (RAPs), defined at the taxonomic level of family, aiming at representing fauna and flora in terrestrial, marine and freshwater ecosystems, to assess exposure and effects; and
- their related Derived Consideration Reference Levels (DCRLs) - as benchmark ranges of dose rates for assessing radiological risk to fauna and flora and to help optimise protection. As with any ecological risk assessment approach, comparison of dose rate estimates with DCRLs evaluates the likelihood and severity of adverse effects for that RAP.

The limitations of this approach are due to the patchiness of data, given the enormous diversity of wildlife species. These limitations were quickly recognised through the application of the approach to actual ecosystems, and extrapolation criteria have been explored, for example in *Publication 114* (ICRP, 2009) for radionuclide transfer factors. However, the development of extrapolation methods to infer interspecies variation in radiosensitivity has been lacking to justify DCRL values with improved underlying datasets and systematic methods that reduce the use of expert judgement. Therefore, knowing the existence of effects datasets on non-human biota beyond the twelve RAP families, TG 99 is exploring broadening the taxonomic representativeness of Reference Animals and Plants (RAP) from the family to the class level (e.g. the current RAP rat and deer would be grouped together under mammals (Class Mammalia); duck as bird (Class Aves)). To this end, TG 99 proposes to review and improve the quality of the Derived Consideration Reference Levels (DCRLs) by conceiving and implementing a systematic, generic, reproducible and transparent statistical method for their derivation. Statistical extrapolation models to quantify the range of radiosensitivity of population-relevant endpoints within a taxonomic class, named Endpoint Sensitivity Distributions (ESD), were developed, making the best use of existing effects data, so that the scientific evidence is improved and the remaining uncertainties are quantified as far as possible. Fig. 1 illustrates how ESD was developed as a basis to derive DCRL for a given class, such as mammals.

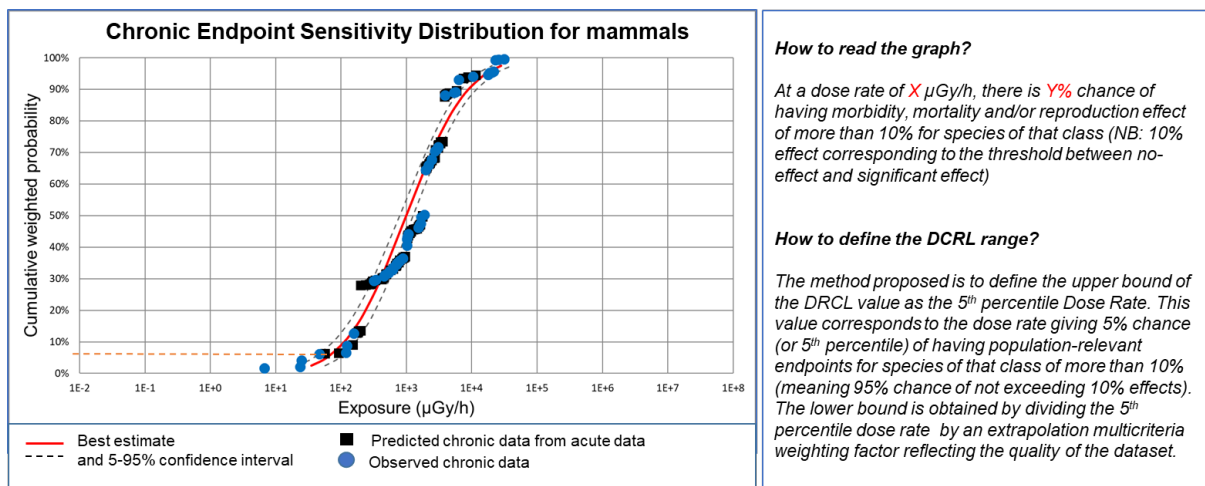


Fig. 1. Example of chronic Endpoint Sensitivity Distribution developed for classes of organism.

## 2.2. Task Group 105: Considering the environment when applying the system of radiological protection

Task Group 105 (TG 105) is considering how the system of radiological protection can be applied to protect the environment in its widest sense across different exposure situations. In all three exposure situations, the release of radionuclides into the environment leads to exposures of non-human biota, as well as having the potential for exposures of the public and impacting on environmental and ecosystem services quality. It is working closely with TG 99 and TG 125 in particular as these groups will help inform TG 105's considerations.

TG 105 is building on *Publication 124* (ICRP, 2014) and makes use of case studies to illustrate how the protection principles apply in the context of both humans and non-human biota. The case studies being considered include operational sites, uranium mine sites, former weapons testing sites, NORM contaminated sites and past accidents. The TG is aiming to deliver advice on: (i) site specific decision making; (ii) situations where biota may potentially be more limiting than humans; (iii) making decisions on human and non-human biota assessments in an integrated manner; and (iv) how the application of the Derived Consideration Reference Levels may support communication and decision-making. Considerations will include whether DCRLs should continue to be expressed as a radiation dose rate band or a single value, and testing the applicability of the approach at the taxonomic level of class.

TG 105 will deliver a report that provides supplementary advice to that given in *Publication 124* with an emphasis on how protective actions can ensure we do more good than harm to the environment as a whole.

The analysis can also serve as a test case addressing the question of *if*, and in that case *how*, the concepts of reasonableness and tolerability of risks were considered in the decisions relevant to the different scenarios. This discussion could be based on schematics and lines of reasoning that currently are under development by TG 114.

## 2.3. Task Group 114: Reasonableness and tolerability in the system of radiological protection

Recent reflections on the application of the principles/concepts of tolerability of risk and reasonableness for the different types of exposure situations have emphasised the importance of their multi-dimensional characteristics. Further consideration will examine the influence of well-being and societal issues in addition to individual risk.

Application to ERP is not straightforward and opens the question of identifying the components of tolerability as well as reasonableness for the environment in different types of exposure situations. DCRLs are derived on the basis of scientific evidence but do DCRLs adequately respond to concerns on tolerability in all exposure situations? Tolerability is a combination of a risk that is bearable in a specific context based on the current values of society and qualitative judgement (depending on various components and on the specific exposure situation and context).

Applying the framework for reasonableness implies a deliberative process taking into account various scientific, societal, economic and ethical considerations to identify the level of concentration of radionuclides in the environment judged as reasonable for the concerned stakeholders. In this context, reasonableness refers to good judgement, fairness, practicability, moderateness, and appropriateness. Optimisation relies therefore on a deliberative process to achieve a reasonable 'compromise' with all (informed) stakeholders.

The questions to be further investigated for applying reasonableness for ERP are notably to identify the meaningful quantitative and qualitative criteria to evaluate reasonableness and to make the link with the initial reflections of TG 125 on the concept of 'ecosystem services'.

The challenge is therefore to strike a good balance between the scientific results on the radiobiological impacts on the environment and the selection of relevant criteria including societal and ethical considerations for the protection of the environment as mentioned in *Publication 91* (ICRP, 2003).

#### **2.4. Task Group 125: analysing the ecosystem services concept**

Task Group 125, recently formed, will be analysing whether and how ecosystem services can support a holistic approach to environmental radiological protection. Sustainable development is recognised as an important component of ERP (e.g. ICRP, 2003) but the Commission's recommendations and approach have largely focused on conservation (Clement et al., 2021) which could be expanded upon to support sustainable development more broadly and explicitly. There is the potential for an ecosystem services approach to help meet this objective.

Ecosystem services refer generally the benefits people derive from nature, whether food, recreation opportunities, inspiration for art, local climate control, or a host of other benefits. A brief introduction to ecosystem services is available in this issue (Martinez et al., 2022). Although there is broad agreement that a natural environment is essential for human well-being and also valuable in its own right, there is not complete consensus on how to incorporate ecosystem-level endpoints into environmental protection and management decisions. TG 125 will consider the various arguments related to ecosystem services, which will include a review of lessons learned from evaluation of ecosystem services in practice. The outcome of this work will be a summary of ecosystem services along with recommendations for if and how ecosystem services should be used within a holistic approach to ERP with particular consideration of the link to sustainable development.

#### **2.5. Co-ordination between Task Groups**

Because of the integrated systems nature of environmental and human health protection the TGs are co-ordinating their work programmes and working collaboratively with each other and with other TGs where appropriate. Fig. 2 describes the outcome-oriented interactions between the groups. Combined, these TGs provide an opportunity to integrate the 'science-base' in terms of biological effects and sensitivity, and the principles, ethics and application of radiological protection for the purpose of environmental radiological protection.

		TG 99	TG 105	TG 125	TG 114
TG outputs and impacts on the next set of recommendations	<b>Main goals and Outputs</b>	Broaden RAPs representativeness at the class level Methods for effect data processing with Endpoint Sensitivity Distribution for the 3 types of exposure situations	Lessons from case studies to illustrate how protection principles should apply in the context of both humans and biota.	Analysis of the relationship between ERP, ecosystem services, promotion of well-being, and sustainable development with practical examples.	Revisit the framework of tolerability/reasonableness and provide rationale for the selection of radiological criteria taking into account ethical considerations
	<b>Potential expected changes</b>	Predefined DCRL per class and guidance for their use in PES and EES Guidance to support dialogue with stakeholders in specific cases of EES and emergencies	Refined guidance for integration of radiological protection of the environment into the system of protection	Clearer link between ERP and sustainable development; robust review of ecosystem services and recommendation on if and how to incorporate in holistic ERP	Propose approach for applying tolerability and reasonableness for ERP including consideration of environmental quality from the point of view of stakeholders
Interactions between TGs	<b>TG 99</b>	N/A			
	<b>TG 105</b>	Test new DCRL values/ranges Advice on use of DCRLs and other criteria	N/A		
	<b>TG 125</b>	Explore the applicability of the method to derive dose(rate) criteria for ecosystem services	Shared case studies; TG 125 to potentially expand scope considered in TG 105	N/A	
	<b>TG 114</b>	Consistency with the tolerability/reasonableness Framework	Explore the application of the approach for tolerability and reasonableness on selected case studies	Ethics and consideration on the application of an holistic approach for the quality of the environment	N/A

Fig. 2. Overview of goals and potential expected changes in the new set of ICRP General Recommendations for the ongoing task groups addressing Environmental Radiological Protection (top table). The bottom table is a schematic representation of the interactions between them.

### 3. CONCLUSION

Since the publication of the current set of general recommendations in 2007, the world has changed profoundly. Global climate, socio-economic, health and environmental challenges have increased, and the pace of change has accelerated (Mayall, 2022). It is important that the system of radiological protection responds to this change including ERP.

The current ICRP objective for ERP is focussed upon the potentially harmful biological effects of radiation on non-human organisms. The environment in its widest sense (e.g. the definition in the Oxford English Definition is *the physical surroundings or conditions in which a person or other organism lives, develops, etc., or in which a thing exists; the external conditions in general affecting the life, existence, or properties of an organism or object*) is clearly a very complex system and it is important that an integrated systems approach to protection is taken if we are to avoid unintended consequences of adopting a narrowly targeted (or ‘silo’) approach. Systems thinking recognises that events are separated by distance and time and that small initiating events can cause large changes in complex systems. An apparent improvement in part of a system can adversely affect another area of the system. It is therefore important that the radiological protection system promotes integration and communication at all levels to avoid the potential ‘silo effect’ of focussing only on discrete parts of the system, or on discrete impacts such as on effects to non-human biota and overlooking the impact of protection measures themselves. The justification and optimisation principles combined with an ‘all-hazards’ approach provide for a means of ensuring that the holistic picture is taken into account in radiological protection in order to maximise good over harm.

To keep the system fit for purpose and to respond to societal, economic, environmental and cultural developments, it is suggested that greater consideration is given to greater citizen participation and closer working with other bodies responsible for health, sustainable development and nature and biodiversity conservation. Greater consideration should also be given to a more holistic approach (with qualitative/quantitative considerations of reasonableness and tolerability, including deliberative processes and broader stakeholder involvement), for all exposure situations.

## ACKNOWLEDGEMENT

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# Protecting animals within a revised radiological protection framework

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**Abstract**–The ICRP’s current strapline is that of ‘*Protecting people, animals and the environment around the world from the harmful effects of radiation*’. But if that is the case, what revisions to its overall framework are necessary in order fully to achieve it? This paper briefly attempts to identify and address some of these questions.

*Keywords:* Protection of animals; Veterinary medicine; DRLAs

## 1. INTRODUCTION

Since its inception almost a century ago, in relation to medical practice, radiological protection has gone through many phases. And yet the only major change since the introduction of the concept of collective dose has been that of a sub-framework to enable sensible decisions to be made in relation to the protection of fauna and flora under different exposure situations, thus enabling the nuclear industries to be regulated on the same environmental-impact basis, as any other. Now, for much of the western world, medicine is once again the principal source of additional exposures for humans, and virtually all of the radiation sources used in diagnostic, interventional, and therapeutic medicine are increasingly being applied in veterinary practice. Because of this, the issue of the protection of ‘animal as patient’ was raised a few years ago and an ICRP Task Group (Pentreath et al., 2020) then explored the subject in some detail. It is now being further addressed by a TG considering veterinary practice as a whole. Thus in expanding the ICRP system even further in order to meet the objective of ‘*Protecting people, animals and the environment around the world from the harmful effects of radiation*’ it is therefore important to do so in a manner that complements and reflects the elements that the current radiological protection framework already contains.

## 2. SCOPE, ETHICS, AND THEIR RELEVANCE TO RADIOLOGICAL PRINCIPLES IN THE CONTEXT OF PROTECTING ANIMALS

Adding the protection of animals to the existing framework raises interesting questions about its overall scope. Animals are not only subject to ionising radiation in veterinary practice for medical reasons, but asymptomatic animals are frequently subject to screening programmes relating to their sale, insurance, or breeding potential. Animals are also exposed to radiation for purely ‘commercial’ reasons, such as the CT scanning of sheep to determine their meat content. And large numbers of animals are used in experiments under laboratory conditions to learn more about the effects of radiation. All of these exposures may well be reasonably defensible within a revised framework but, if so, it is important to be able to explain *why* – essentially their ‘justification’, a key component of the radiological protection framework. Alternatively, some may remain outside a revised framework; but again such a decision needs to be based on a reasoned argument, not just by default.

All of which, in turn, relates to the underlying assumptions being made in relation to the framework as a whole. The practical application of radiological protection has evolved in parallel with consideration of the morals and ethics relating to it. Thus the current primary aim of radiological protection (ICRP, 2007) is that of “...*contributing to an appropriate level of protection for both people and the environment against the detrimental effects of radiation exposures without unduly limiting the desirable human actions that may be associated with such exposures....*”. Behind these principles lie ethical values relating to individual human protection, and to protection of the environment - the focus on the latter usually being that of attempting to protect populations of animals rather than specific individuals within them.

The ethical bases underpinning veterinary practice, however, are different, and the focus is on the protection of individual animals. There are also issues arising from ‘animal ethics’ and ‘animal welfare’, plus the fact that there are always three ‘parties’ involved (the veterinarian, the animal as patient, and the animal’s owner) and differences of opinion may exist as to who reaps the benefit, and why. In many countries a person may hold ‘*property rights*’ over animals, which implies that such persons may own animals as private goods, make use of them for economic gains, and dispose of them in a manner deemed ‘fit’ within the law. An owner may demand that the veterinarians’ opinion should be secondary, and may thus ask them to comply with *their* decision. Different again is recognition of the extremely strong bonding between owners and their pet animals that may create a psychological barrier between the veterinarian and the client. And yet a further consideration may be the owners’ willingness or ability to pay. A clear, comprehensive, and overarching ethical basis therefore needs to be developed to encompass and explain what exposures are included (or excluded) from any expanded radiological protection framework and, just as importantly, how they are accommodated within the principles of justification, optimisation, and the application of dose limits in a practical way.

### 3. EFFECTS AND RISKS OF RADIATION FOR DOMESTIC ANIMALS

As with humans, the principal concern with regard to exposures of animals is that of cancer. Unfortunately, there do not appear to be any international registers of such information, although there are a number of national data compilations, particularly on dogs. Thus a UK study of purebred dogs by Adams et al. (2010) found that cancer was one of the major causes of death, accounting for > 25% overall, and increasing with age. And as observed by Dobson (2013), there are some interesting similarities and differences when compared with human data. Thus mammary glands are a common site for tumour development in bitches, although the risk is reduced in those that have been spayed at a young age, inferring the importance of endogenous hormones in the development of this disease. But in contrast, carcinomas of the prostate, a common condition in men and also associated with hormonal stimulation, appear to be relatively uncommon in dogs and occur more frequently in neutered animals. It also seems that carcinomas of the large bowel, which are fairly common in humans, do not feature highly in dogs, whereas some tissue sarcomas that are rare in humans, are relatively common. A rough ranking order for malignant cancer in dogs is that of mast cell tumours, soft tissue carcinoma, lymphoma, osteosarcoma and mammary sarcoma. Dogs have also been considered to be interesting models for the development of cancer (Gardner et al., 2016), and they are of interest, genetically. Becoming domesticated some 20,000 to 30,000 years ago, probably from grey wolves, they have, in fairly recent times, been subject to selective breeding practices that have resulted in over 300 discrete breeds worldwide, and the more recent establishment of breed ‘standards’ has resulted in reduced genetic diversity within breeds and greater genetic divergence amongst breeds. Thus although the average nucleotide heterozygosity across all dog breeds is comparable to that of the human population (Lindblad-Toh et al., 2005) the level

of genetic diversity within any single breed is considerably less than the species as a whole. Indeed, it has been estimated that whilst domestication of wild canid populations resulted in a 5% loss of nucleotide diversity, the establishment of specific breeds conforming to strict standards caused a 35% loss (Gray et al., 2009). In view of the fact that mutations in a small number of genes are responsible for many breed characteristics, selective breeding for exaggerated traits further reduces genetic diversity, and perhaps risks the selection of mutations that predispose to disease, for it is certainly the case that differences exist amongst breeds of dog and their risk of developing certain types of cancer, although there are few large scale studies that document such variations.

With respect to other animals, cancer is common in domestic cats, though less commonly reported upon than for dogs. There are, however, some interesting differences. The vast majority of mammary gland tumours in cats are malignant, and multiple tumours and metastasis are common at diagnosis. There also appears to be a breed predisposition in Siamese cats, which are more likely to develop mammary tumours, and at a younger age, than in other cat breeds. And, in contrast to breast cancer in women, feline mammary tumours are more likely to be hormone (oestrogen and progesterone) receptor negative (Cannon, 2015). Horses are different again: particularly common are squamous cell carcinomas that can affect the eyes and eye lids, melanomas, sarcoid tumours, lymphosarcoma, and cancers of the reproductive system.

It is therefore clear that, for at least dogs, cats, and horses, not only is increasing use likely to be made of radiation sources to treat cancer, for which advice and guidance will be necessary, but that the risks of developing cancer as a result of diagnostic techniques need also to be assessed. For other vertebrates, assessing the risks of radiation effects is far from straightforward. Interest has usually focused on stem cells. It seems that the lifetime risk of cancer correlates reasonably well with the total number of divisions of the normal ‘self-renewing’ cells that maintain any particular tissue’s homeostasis. But there are many other factors to consider, as discussed elsewhere (Pentreath, 2021) including metabolic rate, the number of different stages in the life cycle and how they transform from one to another, or even just the total life span.

#### 4. EXTENDING THE SCIENTIFIC FRAMEWORK

The scientific framework upon which human radiological protection is based makes use of various quantities, and uses specific points of reference: phantom models and data sets that are used to relate exposure to dose and dose to risk of biological effect. A similar and complementary ‘reference’ approach has also been developed to help manage radiation exposures in the context of protection of the natural environment (ICRP, 2008) for which a number of Reference Animals and Plants (RAPs) have been described at the taxonomic level of Family. The reference dosimetric models initially used were simple, but some voxel phantoms have since been developed. Data on biological effects for RAPs have also been reviewed in order to compile Derived Consideration Reference Levels (DCRLs) to help optimise the appropriate response to different environmental exposure situations (ICRP, 2008). This systematic approach now clearly needs to be extended to help formulate advice with regard to veterinary practice. There are several computational models available that are suitable for dosimetric modelling (Zaidi, 2018), including at least five for canines (Padilla et al., 2008; Kramer et al., 2012; Stabin et al., 2015). And there are many data sets relating to radiation effects at different doses. But with regard to enumerating risks to individual animals, there is no equivalent to the Sv. Radiation doses for any animal can thus only be expressed in terms of absorbed dose (Gy), and there are no parallels to the equivalent or effective dose. Recommendations have however recently been made by the ICRP to the effect that an RBE

weighted absorbed dose should be used for radiological protection purposes for biota in an environmental context (ICRP, 2021). If the system is to be extended to the protection of animals at an individual level in veterinary practice, then this discrepancy needs to be resolved, quickly, before confusion sets in – as, for example, in recording doses received in CT scans.

If such initiatives as these were pursued, then it would be possible to convert the ICRP's current good intentions into sound numerical advice, and the obvious place to start would be to complement the DRLs for humans in medicine with Diagnostic Reference Levels for Animals (DRLAs) - at least for canines - as an optimisation tool for exposures to individual animals. There is a vast and seemingly untapped data base to enable this to be done. Literally thousands of dogs, primarily beagles, have been sacrificed to obtain data on radiation effects for the benefit of the protection of humans (Spatola et al., 2021). From 1952 to 1983 at least 7,000 beagles were used in just six laboratories in the USA alone. Dogs were irradiated by intravenous injection, inhalation, ingestion, external irradiation, implants and so on. Large numbers were exposed to <sup>60</sup>Co and x rays at dose rates from a few mGy day<sup>-1</sup> to several Gy, under different exposure regimes, from continual, multiple, to single exposures. One large scale study involved 1,500 dogs exposed *in utero*, exposure terminating at various ages up to a year post-conception. The occurrence of various cancers were then recorded later in life. Frequent effects in all of these experiments were haematological changes, infertility, and cancers of the bone, liver and lung. None of these data have been interpreted with regard to their potential utility for providing advice on the consequences of exposures to dogs in the context of veterinary practice (or in any other context) and it would seem that, in view of their sacrifice, there is now a moral duty to do so. Indeed many of the data have probably never been freely released, or else currently lie forgotten. Many other countries had similar experimental programmes, so the number of dogs sacrificed may run into the tens of thousands worldwide. The derivation of such a data base could also be used to advise on limits for the use of radiation on asymptomatic animals.

Guidance is also needed on the therapeutic use of radiation. Linear accelerators are now routinely used in veterinary practice. The doses delivered can be up to 70 Gy (to dogs) (Coomer et al., 2009), and there is already some concern about the inadequate knowledge upon which such treatment is based, particularly because there are not many published scientific reviews of the damage incurred to healthy tissues, and even fewer of the consequences of errors in therapeutic treatment (Arkans et al., 2015; Vu Bezin et al., 2017).

## 5. CONCLUSION

In conclusion, therefore, it is clearly opportune to revise the current ICRP radiological protection framework, both to reflect the changes that have already occurred since 2007, and to prepare for the future. In order to do so, one obviously needs to reconsider its scope with regard to what practices are included and which, if any, are not included, and why. Such decisions need to be based on a clear rationale, and thus transparent ethical basis, particularly with regard to justification of exposure. There is no doubt, however, that it will include protection of the animal as patient in veterinary practice, and this alone brings with it many challenges with respect to optimisation, both in diagnostic and therapeutic applications. But such challenges can readily be addressed by expanding the current system and creating a sound numerical basis founded on reference models and data bases that can be used in a practical and useful way. It also surely makes sense to view the subject of exposure to radiation and its subsequent effects on all animals (but particularly mammals) in a more collective way, and to learn how this knowledge can be used for the protection of humans and animals in medical and veterinary science. There are data that can only arise from experience with animals that could be of value to improve human radiological protection, and vice versa, but this is only likely to

arise within a framework that has a sound numerical basis. There is so much that could be learned from each other, and the combined data arising would be highly beneficial to all.

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## How to start a network? Experience in networking and achievements of the IRPA Young Generation Network

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**Abstract**—Since its establishment in 2018, the IRPA Young Generation Network (YGN) has created several dynamics under the framework of its Strategic Agenda to promote the representation of the young generation, professional development, experience transfer, relationship and communication of students, young professionals and scientists in radiation protection and its allied fields. This article first reports on the activities performed from 2018 until today, with highlights on some important events, collaborations and publications. The IRPA YGN have made these achievements with the essential support of its Leadership Committee, the various national Young Generation Networks, and the IRPA organization and its Associate Societies. Then, the insights and experiences obtained from these activities are discussed and used to inform how the IRPA YGN aims to achieve its on-going activities and continue to follow the ways paved in the Strategic Agenda 2022–2024. It is expected that the identification of the backbone elements supporting a young generation network and also the very specific challenges can be useful for the future management of the IRPA YGN and existing national YGN and inspire the creation of other young generation networks.

**Keywords:** IRPA; Young Generation Network; International collaboration; Networking

## 1. INTRODUCTION

The Young Generation Network of the International Radiation Protection Association (IRPA YGN) was officially established as part of the IRPA in the spring of 2018. The IRPA YGN is an international network of young professionals across the field of radiation protection, and its primary function is to promote communication, collaboration and professional development of students and young professionals in the area of radiation protection and its allied fields. Membership is open to all members of YGN in national radiation protection societies (IRPA's Associate Societies, AS) and, where a national YGN is not in place, to students or professionals working within the first 10 years of their career in the fields of radiation protection (Leadership Committee, 2022).

The objectives of this paper are to present the variety of activities performed by the network during its (few) years of existence building upon previous reports (Leadership Committee, 2020; Sakoda et al., 2021) and to discuss some of the specificities associated with the activities of an international network of young professionals in radiation protection. It is expected that these experiences can be useful for the future management of the IRPA YGN and existing national YGN, inspire the creation of other young generation networks (be they in IRPA organization or not), and to help them to organise and drive their activities.

## 2. THE IRPA YOUNG GENERATION NETWORK

### 2.1. The origins

The IRPA YGN was proposed at the 13<sup>th</sup> international IRPA congress in Glasgow (2012), and its formation agreed at the 14<sup>th</sup> congress in Cape Town (2016) based on the observation that '*support for young practitioners and scientists in their work, education and membership to IRPA AS*' was needed (IRPA, 2016). In December 2017, the Executive Council (EC) of IRPA supported the constitution of a Leadership Committee (LC) of a few young professionals from Austria, France, Japan and United Kingdom YGN whose primary objectives were to set up effectively the IRPA YGN and drive its growth and development.

Meanwhile, several young professionals from the Young Club of the French Society for Radiation Protection (SFRP) and the Rising Generation Group (RGG) of the UK Society for Radiological Protection (SRP) disseminated a survey addressed to the young professionals in radiation protection worldwide to gather elements of information about this generation, identify ways to foster them, and to encourage initiatives and common actions.

Beginning 2018, the IRPA YGN ran an international competition for the design of its logo. The proposition from the SFRP won the competition. The IRPA YGN was officially launched at the IRPA Regional Congresses that took place in 2018: Latin America (Havana, Cuba, April), Asia (Melbourne, Australia, May), Europe (The Hague, The Netherlands, June) and Africa (Tunis, Tunisia, September).

### 2.2. The development

After the launch, the LC had extended and included 11 countries and proposed a mission statement: '*To encourage, inspire and develop the next generation of radiation protection professionals across the world and promote the communication and collaboration of our members*' and core objectives.

At the end of 2018, the LC established the Terms and Conditions for the operation of the IRPA YGN (Leadership Committee, 2018a) and completed a Strategic Agenda for the 2018–

2020 period aiming to drive the growth of the network in line with its Mission and Objectives (Leadership Committee, 2018b). The Strategic Agenda gave priority to the specific challenges identified from the analysis of the results of the international survey (§ 2.1) (Andresz et al., 2019) and also the synthesis of the discussions at the launch events at the Regional Congresses (Leadership Committee, 2018c).

Concretely, the Strategic Agenda was developed with five keys themes: (1) representation of the young generation, (2) professional development, (3) experience transfer, (4) relationship and (5) communication. Several comments from participants to the international survey indicated that some questions were ambiguous and difficult to understand, and that the objectives of the survey (therefore the interest to participate) were not apparent enough; as such, the LC was encouraged to promote clarity of the messages, motivation and engagement in all its future actions (although it was not formally included in the Strategic Agenda).

The EC supported the creation of a public website (<https://www.irpa.net/ypn/index.asp>) which was set up with the help of the IRPA Webmaster and the Platform on European Training and Education in Radiation Protection (EUTERP) provided the LC a private blog to store documents and exchange ideas (<http://irpaygn.posthaven.com>). The first post (March 2019) was about ‘The future of the profession’.

### 3. RESULTS

#### 3.1. Activities performed during the 2018–2021 period

Sakoda et al. published a report of the activities performed by the IRPA YGN from 2018 to 2021 (Sakoda et al., 2021). This report was based on earlier reports of activities (Sakoda et al., 2019; Leadership Committee, 2020) and integrated updates and new information. Several items are highlighted:

- A joint KARP (Korean Association for Radiation Protection), JHPS (Japan Health Physics Society) and SRP workshop held in December 2019 in Sendai, Japan, whose purpose was to encourage the active participation of young professionals and promote the interaction between nationals YGN to share their programme of activities, present research performed by young professionals and held a discussion session to explore substantive topics such as shortage of young professionals, motivations to enter in the radiation protection and stay.
- The contribution to the Nuclear Energy Agency (NEA) workshop on Optimization: Rethinking the Art of Reasonable (January 2020, Lisbon, Portugal) where the young generation explored the use of innovation and cutting-edge tools for optimization purposes, notably: social media, crowdsourcing and artificial intelligence.
- The early results of a survey on the impact of the COVID-19 pandemic on radiation protection among IRPA YGN members (the survey started in March 2020);
- The contribution to IRPA15 (15<sup>th</sup> International Congress of the IRPA; January-February 2021, online) via the participation in Women in RP session, co-chairing of the Future of RP profession session and the organization of a special session as well as the management of the IRPA Young Professional & Scientist Award.

#### 3.2. Continuation and expansion

The activities presented above have continued and extended in the following years. Here are some details:

The joint workshops were reconducted on an annual basis and while the participants have evolved with the inclusion of the Chinese Society for Radiation Protection (CSRPA) and the



topics have re-oriented on the challenges posed by the release of treated water from the Fukushima accident (Ha et al., 2021) and research in measurement and dosimetry (Kono et al., 2022), the YGN has remained the grassroot of the workshop and the involvement of young professionals has not faltered. This joint workshop concept has demonstrated that it can nurture collaboration of young professionals of the AS in a given world region to share knowledge and ideas and will certainly be reiterated.

Since the NEA workshop, the connection between the NEA and the IRPA YGN has strengthened: for example, NEA young professionals are invited to LC meetings as Observers and the announcement of the annual NEA International Radiation Protection School (IRPS) is broadcast through the IRPA YGN mailing list. Moreover, the topics raised at the NEA workshop ignited further reflections at the IRPA YGN and national YGN levels:

1. In March 2021, the IRPA YGN collaborated with EUTERP and SCK•CEN to investigate through an online survey the use of social media by members of the young generation in radiation protection. It was also the opportunity to collect early feedback about the generalization of online learning. The results were presented at the ETRAP 2021 conference before being published (Andresz et al., 2022a) and show that the young generation can play a role in supporting the extra- and intra-communication activities of the RP community.
2. The topic of artificial intelligence was later examined by the IRPA YGN during the special session: ‘Does Artificial Intelligence has a place in radiation protection?’ organised during IRPA-15 congress (January 2021) and fuelled a working group of the Young Club of SFRP who analysed through bibliometric analysis and interviews with experts the current trend of the uses of artificial intelligence in radiation protection and the early feedback (Andresz, et al. 2022b).

An IRPA YGN initiative being source of inspiration for a national YGN has been reproduced with the investigations of the impacts of COVID-19 on the young generation. While the IRPA YGN was publishing the results of its survey, showing a significant impact on the working conditions of radiation protection experts, especially of those from hospitals (Andresz et al., 2021a), the Spanish YGN (J-SEPR) was using this experience to evaluate the impacts of the different phases of the pandemic in Spain (García-Baonza et al., 2021; 2022).

The Members of the IRPA YGN have used the results of their contribution to the organization of IRPA-15 congress to put forward the network in the regional IRPA congresses that took place in 2022 (Europe, Africa and Latin-America). All these experiences and associated good practices have been compiled by D. Jakab et al. (Jakab et al., 2022) and published for consideration by the programme committees of future IRPA congresses.

### **3.3. Intra-YGN networking**

The Leadership Committee is now composed with 19 Members (Table 1) and met regularly to drive the activities of IRPA YGN in line with the objectives stated in the Strategic Agenda which has been renewed in 2022 (Leadership Committee, 2022), to exchange about their YGN activities and leverage networking activities. A position of Treasurer has been created to collaborate with the IRPA Treasurer for the management of the dedicated budget granted by the EC. A new Secretary has been elected and has successfully began her term.

Since 2019, the Portrait of a Generation initiative aims to collect and advertise portraits from young professional and scientist members of IRPA AS. The Portrait layout has been drafted with questions about the daily job, how this fit into initial training, potential career paths, and their views and reflections on the future of the profession. The six portraits already collected are available on the IRPA YGN website and the objective is to add new portraits regularly.

Table 1. Members of IRPA YGN Leadership Committee\* in December 2022.

Region	Country
Africa	Ghana
	Nigeria
	Tunisia
America	Canada
	United States of America
	Argentina
Asia	China
	India
	Japan
	Philippines
	South Korea
Europe	Armenia
	Austria
	Croatia
	Czech Republic
	France
	Germany-Swiss
	Spain
	United Kingdom

\*The IRPA YGN has also established privileged contact with national YGN in Belgium, Denmark, Italy, Romania and The Netherlands who indicated they would not take an active part in the LC and will position themselves as relay and contributor to the LC actions:

In 2020, six national young generation networks competed for the best Identity Card (ID) that present their activities in a comprehensive and photogenic manner. Besides the stylistic exercise, the objective of this contest was incidentally to encourage YGN to take a step back from their activities, to explain them to others YGN and eventually get information about what the others do and how. The ID card from the Austrian YGN won the competition and all the cards are presented on the IRPA YGN website.

It is becoming clear that the young generation has a role to play in capturing and retaining the professionals in the field (Bryant, 2021) and a new contest has been addressed to the YGN: the objective being to record a short movie presenting ‘the benefits for young professionals to join and to stay in their national radiation protection society’. Taking into account the difficulties to meet in-person associated with the COVID-19 situation, the deadline of this movie contest had been extended until February 2023.

## 4. DISCUSSION ON EXPERIENCES IN NETWORKING

### 4.1. The backbone

Written terms and conditions were essential to establish the ground rules of the operation of the IRPA YGN. For example, it was important to define what a ‘young’ individual is, to decide the procedures to join the LC, and to manage the budget. A Strategic Agenda (or equivalent) aligned with the strategic plan of the umbrella organization (IRPA) was utterly needed to make clear to all the intentions of the network, set targets and the means of how and when to realise it. To that extent, the operation of a YGN is comparable to any other long-term management project.

A YGN cannot work isolated and standalone: it shall be formally embedded in its umbrella organization and part of its activities: e.g. the IRPA YGN is included in the strategic plan of

IRPA (IRPA, 2021a), regularly invited to EC meetings to present its activities, and endeavour to have a representative in the IRPA working groups.

At the same time, a YGN should find its own path and create added value within the organization. § 3 *infra* has described how the IRPA YGN have addressed specific ‘young’ topics like social media and AI, established new contacts, and supported inter- and intra-networking activities as formulated in the Strategic Agenda. Other manners and orientations were possible and the IRPA YGN shall remain adaptive and open to the practices of other young generation networks, whether they are national, international, focused on radiation protection, or otherwise.

There is no need to be continuously innovative, and the YGN can take advantage of the conventional tools for networking: website/blog, contests, raffles and online surveys have all worked well, especially if they were supported with graphic flyers clearly conveying their purposes and the interest to participate. For a group of young professionals/researchers, publication in peer-review radiation protection journals was one of the most emulating, motivating, and rewarding achievements.

Finally, a YGN shall attain a ‘critical mass’ in size for being recognised as ‘*the voice of the [young] radiation profession*’ to paraphrase the IRPA motto and being labelled as such and regarded as a valid counterpart by the radiation protection organizations with an interest in the young generation. During the last years, various LC Members have represented the IRPA YGN at conferences organised by IRPA, IRPA AS, EUTERP, NEA, ISORD, IAEA and ICRP.

#### 4.2. Some puzzling issues

If the network needs a ‘critical mass’, it most surely needs active and engaged members, not members for counting. Additionally, a large expansion might require new forms of interaction and organization to manage emerging practical difficulties: meeting dates and times are hard to find, there is less time for everyone to participate in the discussion, rich and inclusive conversation are difficult to establish and participants may not feel a sense of belonging. These challenges might be more acute remotely, which has been the setting of the IRPA YGN meetings since its creation.

Another difficulty is the level of information transmitted to and from members: it is a good ambition to make everyone informed about all the activities, but in practice this could lead to excess of information sent with collective emails, potentially leading to an information overload for which negative consequences have been largely documented (Hoq, 2016; Roetzel, 2019). In addition, some Members are representing larger and more established YGN while others are battling to set up their own, therefore some information might be interesting for some and not for others.

Meetings with smaller (e.g. regional) groups and more personalization in the exchange of information are a way to overcome these difficulties, but shall be implemented without undermining the objectives of IRPA YGN in communication, relationship or experience transfer. Either way, the future IRPA YGN LC might wish to consider some forms of adaptation for its operation and meetings.

It should be recognised that participating to an international network needs a bit of a time and some activities will require a budget, both resources becoming scarcer and their usage for networking activities could be questioned by Managers. Although this is not mandatory, animating a network required some communication skills, which is not part of the initial training of most RP professionals and will be learned on the fly.

Another point is that a young network is by definition on ‘open-cycle network’, meaning that the Members join for a few years at most and then have to leave because they have reached the age limit. These circumstances are extremely peculiar and are making the questions about

how to generate interest to join the IRPA YGN, engage in the activities and keep the momentum after the individuals leave the network even more vivid. A robust Strategic Agenda and good hand-over between the outgoing Members and the new ones is key to ensure the continuation of the activities (and less subject to individuals), but these can make the IRPA YGN looks more programmatic than human.

## 5. PERSPECTIVES

The IRPA YGN continues to generate interest, and new applications for membership have been reported recently to the Leadership Committee. Under the IRPA EC auspice, the IRPA YGN has recently constituted a Task Group on mentorship and a survey is currently circulating to collect the practices of the AS in the field of mentorship. The analysis of these data will be carried out in early 2023 and the results could be useful for IRPA AS and at IRPA level. The release of the movies recorded for the movie contest will be another highlight of the year.

The next important chronological milestone for the IRPA YGN is IRPA16 congress (Orlando, United States of America, 7–12 July 2024) where the IRPA YGN can play a role in the organization and during the event. The end of 2024 will provide an opportunity to rethink the Strategic Agenda on the basis of the previous years and what the young generation wants for the future.

## 6. LIST OF ACRONYMS

**AS:** Associate Society (affiliated to IRPA); **CSRFP:** Chinese Society for Radiation Protection; **EC:** Executive Council (of IRPA); **EUTERP:** Platform on European Training and Education in Radiation Protection; **IAEA:** International Agency for Energy Agency; **ICRP:** International Commission on radiological Protection; **IRPA:** International Radiation Protection Association; **ISORD:** International Symposium On Radiation Safety And Detection; **JHPS:** Japanese Health Physics Society; **KARP:** Korean Association for Radiation Protection; **LC:** Leadership Committee; **NEA:** Nuclear Energy Agency; **NEA:** Nuclear Energy Agency; **RGG:** Rising Generation Group (of UK SRP); **RP:** Radiation/Radiological Protection; **SEPR:** Spanish Society of Radiological Protection; **SFRP:** French Society for Radiation Protection; **SRP:** Society for Radiological Protection (United Kingdom); **YGN:** (national) Young Generation Network.

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## Experiences of one mentee – the ICRP Mentorship Program and beyond

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**Abstract**—Mentoring is a powerful way to help people grow personally and professionally – to guide them throughout their careers. Mentoring provides insights to support another person's understanding of a specific area in career or life. The same can be said about research collaboration – it not only benefits the scientific community or research group, but it benefits tremendously the individual researcher. As an early career scientist, I have the privilege of being a mentee in the new International Commission on Radiological Protection (ICRP) Mentorship Program and member of Task Group 111: Factors Governing the Individual Response of Humans to Ionising Radiation (TG 111). In this article, I will expand on the presentation that I provided during the “Involving Young Professionals” session during the ICRP 2021+1 Symposium in Vancouver. I will describe the ICRP Mentorship Programme and briefly describe some of the work that I am conducting for TG 111.

*Keywords:* Mentorship, Sex differences, Systematic review

### 1. THE IMPORTANCE OF CAREER DEVELOPMENT OPPORTUNITIES IN RP

Concerns regarding labour shortages and knowledge management in nuclear and radiation protection occupy many organisations in these fields, including the Nuclear Energy Agency, the International Atomic Energy Agency and the International Commission on Radiological Protection (Clement et al., 2021; IAEA, 2022; NEA, 2022). The need for more radiation protection (RP) professionals continues to grow with advancements in new technologies and within the nuclear and medical sectors. Many professionals are retiring, and fostering youth interest in the nuclear sector and capacity building are key to building an effective and capable nuclear workforce. There is a need for investment in training, education, research and infrastructure in this area to continue to protect the health and safety of people and the environment.

The nuclear sector, including RP professionals, must maintain and build its expertise to properly manage radiation risks and improve how it communicates and engages with the public to build trust.

Through the many activities undertaken by the ICRP, it has contributed to the effort of building and fostering RP expertise. One of these activities is the ICRP Mentorship Programme, which will be the focus of this article.

#### 1.1. Mentorship programmes and the ICRP

Increasingly, mentorship programmes are being launched by many organisations. This is one tool that can empower, teach, and overall, strengthen diverse and inclusive culture, and address knowledge management.

In the Canadian nuclear and government sector, many mentorship programmes have been designed to address the lack of representation and promotion of various equity seeking groups,

and in some cases, specifically working in Science, Technology, Engineering and Mathematics (STEM) (Government of Canada, 2022; Leblanc, 2022; Women in Nuclear Canada, 2022).

In the case of gender equity in the nuclear sector, results from surveys conducted within Canada (Strategic Policy Economics, 2020) and internationally (Maher, 2021) have identified a need for such programs to help strengthen the metaphoric leaky pipeline (way in which women become underrepresented in STEM throughout their education and career). This is a strategic approach – it is, first, the right thing to do, but second, it also enables organisations to build trust and in so doing, improve its ability to attract and retain talent.

Mentorship programmes do not need to be specifically aimed at equity seeking groups to deliver beneficial impact.

The ICRP Mentorship Programme established in 2019 is aimed at university students, early-career professionals and scientists (ICRP, 2022). The Programme pairs mentees with mentors from within ICRP task groups. Mentees are members of the task group and conduct specific tasks for the group. Benefits are for mentees, mentors and task groups alike. The task group receives more resources to conduct their work, new knowledge and perspectives, and broadens their geographical representation and diversity.

## **2. ICRP TASK GROUP 111: FACTORS GOVERNING THE INDIVIDUAL RESPONSE OF HUMANS TO IONISING RADIATION**

Our experience with the ICRP Mentorship Programme began with Task Group 111. The Task Group was created to develop a report for publication in the Annals of the ICRP that presents a review of the current science relevant to the topic of individual response to radiation – this informing the next set of ICRP recommendations. Currently, the annual dose limit for occupational exposure as recommended by the ICRP does not distinguish between individual characteristics of the exposed workers such as age and sex. This is justified in order to develop a simple, economical and practical framework of radiological protection. Yet, in some situations, this may be too simplistic – for example, in individualised medicine and space exploration (Applegate et al., 2020).

To evaluate how individual characteristics could impact the system of RP, the ICRP conducted a sensitivity analysis, which aimed to assess potential developments that could improve the calculation of radiation cancer detriment. Amongst other important findings, it highlighted the fact that sex had a large impact on the estimate of detriment (Zhang et al., 2020).

These findings form the basis for the rationale of the task of evaluating the current evidence on how sex modifies the risks of ionising radiation-induced health effects to identify research gaps and inform the evolution of radiation protection standards.

### **2.1. A brief overview of a systematic review - How does biological sex modify radiation-induced health effects?**

#### **2.1.1. Methods**

The systematic review focuses on late tissue injuries (cardiovascular/circulatory/cerebrovascular diseases, cognitive effects and cataracts), stochastic effects (cancer incidence and cancer mortality) and their related mechanisms in irradiated human, animal and tissues/cells. A more detailed description of the systematic review methodology can be found in the PROSPERO registry (Leblanc, 2021) (CRD#: 42020207563).

#### **2.1.2. Results**

After duplications were removed, the search identified 9678 records. After level 1 (title and abstract) and level 2 (full-text) screening by pairs of reviewers, 385 records were identified for data extraction (Fig. 1).

Records have been divided by category: human, animal and in vitro. Data extraction and risk of bias assessment are ongoing (Table 1). A review of the records indicate that cancer consists of the majority outcome studied for each category, followed by circulatory and related diseases under “human” and cognitive effects under “animal”.

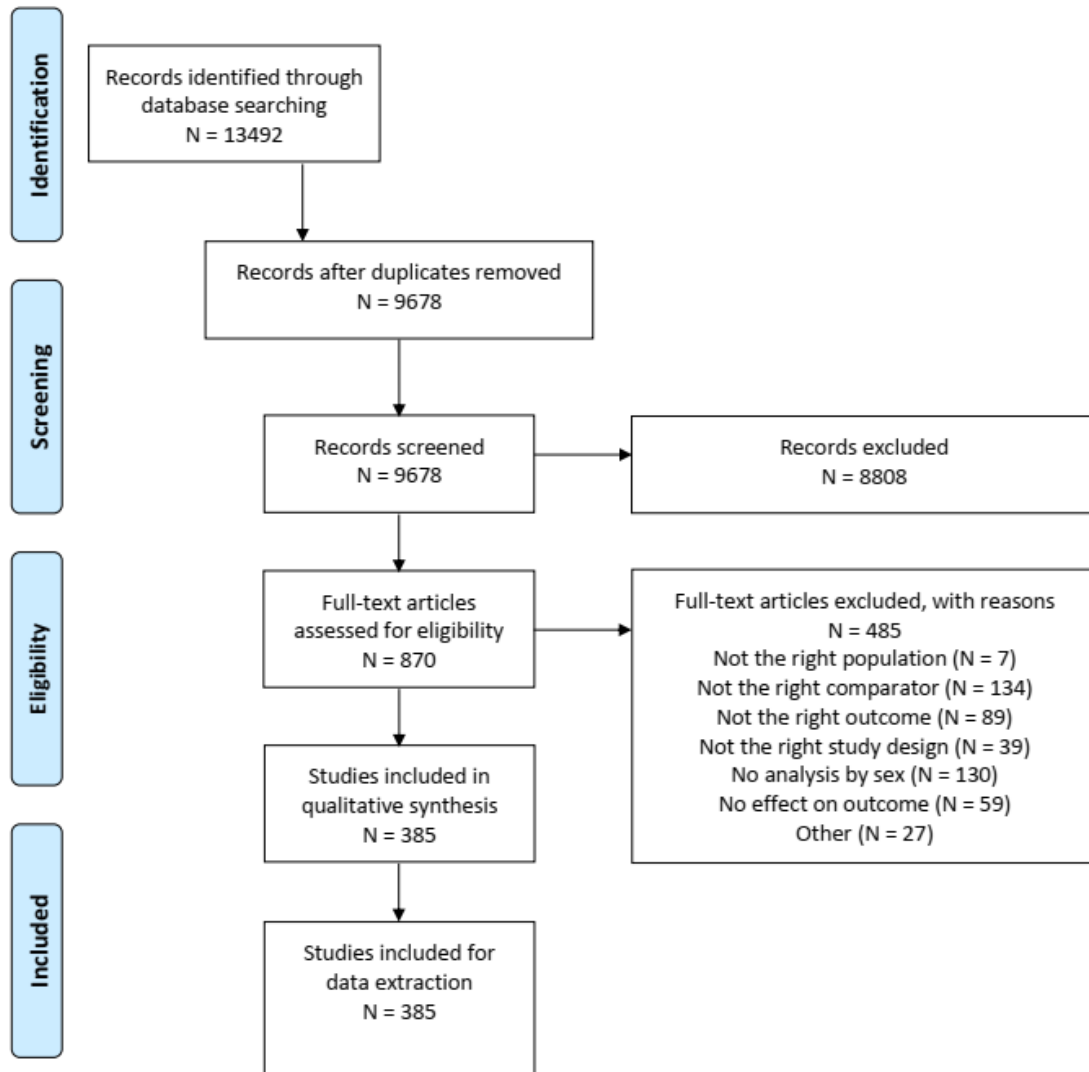


Fig. 1. PRISMA flow diagram.

Table 1. Data extraction status update (as of December 18, 2022).

Study category	No. of references left to extract
Human*	198
Animal	141
In vitro	37
Total	376

\*Human studies include cross sectional, case control, and cohort studies.



### 2.1.3. Discussion and Conclusion

Once completed, the systematic review will inform the task group report and provide the basis for future ICRP recommendations, and it is achieving much more than that. A systematic review is an approach that uses explicit methods to search and critically appraise and synthesise the relevant literature on a specific subject. Building capacity in this approach at the Canadian Nuclear Safety Commission (CNSC) and the ICRP ultimately exposes these organisations to another tool that produces reliable and accurate results which can be easily reproduced. A systematic review protocol is made publicly available making its methodology transparent – a characteristic important to both the CNSC and the ICRP from a scientific integrity and trust perspective.

The ICRP continues to show its leadership and commitment towards the future of RP – through information sharing, research, development of system of RP, and importantly in investment into the next generation of RP professionals. The ICRP publicises its mentorship opportunities through its website ([www.icrp.org](http://www.icrp.org)) and through social media channels; any suitably qualified persons are encouraged to apply. It is important that we continue to support initiatives like the ICRP Mentorship Programme. The programme enriches mentees' careers. It teaches fundamentally how the ICRP delivers its mandate, provides opportunities to impact the evolution of radiation protection standards and provides an excellent opportunity to collaborate on an international stage. We encourage those in a position to sponsor and mentor to do so – benefits are gained by the ICRP, the mentor, the mentee, the sponsoring-organisation and the broader RP community. Fostering the leadership of tomorrow benefits all!

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## Ethical aspects in the use of radiation in medicine: public consultation of the report from ICRP Task Group 109

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**Abstract**—ICRP *Publication 138* defines the ethical foundations of the System of radiological protection, based on four core values (beneficence/non-maleficence, dignity, justice and prudence) and three procedural values (accountability, transparency and inclusiveness). The mission of Task Group 109 mission was to propose a practical application in the medical field. As this field was already infused with a strong culture of biomedical ethics, the first action was to identify the values and define a common language. The core values are very similar, with the autonomy of biomedical ethics, which can be seen as a corollary of dignity, and the precautionary principle, which can be understood as the implementation of prudence. In recent years, medicine has been experiencing an emphasis on the values of solidarity, honesty, and empathy. We therefore proposed a grouping of these values in order to allow a structured review of practical situations from an ethical perspective. For the sake of concreteness, the report proposes 21 realistic scenarios (11 in imaging and 10 in therapy), which are all presented and analysed in a one-page format. Sensitising questions are provided to stimulate reflection. We hope that this report will allow all professionals in the medical and radiological protection fields to discuss situations and dilemma on a common ground. To achieve this, we also propose a strategy for the implementation of education and training, based on the Bloom taxonomy. In order to assist the reader in a theoretically complex subject, key messages are distributed throughout the text, as fixed points that can easily be understood. The report will soon be made available for public consultation and we look forward to any suggestions for improvement.

**Keywords:** Ethics; Medicine; Radiation; ICRP report

### 1. INTRODUCTION

In radiological protection, decisions can often be made on the basis of the three principles of justification, optimisation and dose limitation. In many situations, the measurable quantities

associated with these principles (dose criteria or financial implications) are not sufficient to make a decision. In addition to questions such as "Does it do more good than harm?", "Are the risks (un)acceptable?", "Is it legal?", "Is it economical?", "Would it stand up to public and media scrutiny?", "Do we retain our credibility?", we should ask ourselves "Can we give a rational ethical justification to our decision?"

To help answer this last question, ICRP *Publication 138* (ICRP, 2018) has identified the ethical values associated with radiological protection, with four core values (beneficence/non-maleficence, justice, dignity and prudence) and three procedural values (transparency, accountability and inclusiveness). This publication provides a basis for rational discussion to justify decisions based on shared values. However, it is not intended to deal with specific situations.

As a follow-up to this publication, the ICRP Task Group 109 (TG109) was mandated to prepare a report on the application of ethical values in the context of ionising radiation used in medical diagnosis and therapy. The issue of medical research was deliberately excluded. It will be addressed in a subsequent report.

With the report now ready for public consultation, the purpose of the Vancouver presentation was to elicit comments by focusing on three aspects: (1) What is the specificity of biomedical ethics? (2) What practical method can be used to take into account ethical values in medical radiological protection? and (3) How can ethics be taken into account in a medical radiological protection training curriculum?

Table 1. Synoptic view of the ethical values identified in the System of radiological protection (ICRP, 2018) and in biomedical ethics. Each line of the table corresponds to the pairing of values.

Values specific to <i>Publication 138</i>	Common values	Values emphasised in biomedical ethics
	beneficence / non-maleficence	
	justice	solidarity
dignity		autonomy
prudence		precaution
transparency / accountability		honesty
inclusiveness		empathy

## 2. EVALUATION METHOD

Medicine has an ethical tradition that predates the discovery of ionising radiation. Biomedical ethics is well codified with "principles" that are very close to the core values described in *Publication 138*: the autonomy principle of biomedical ethics can be seen as a corollary of dignity, and the precautionary principle can be understood as the implementation of prudence. In addition, the literature review identified four other values that have become particularly prominent in recent years: solidarity, precaution, empathy and honesty.

In order to facilitate the interaction between radiological protection and medical professionals, the report proposes to pair the ethical values of both fields. Table 1 shows how this was done. On this basis of common values, the report suggests a method for analysing real-life scenarios or situations (Malone et al., 2019). In a nutshell, the method is an invitation to review each "pair" of values in Table 1, assessing separately the compliance and non-

compliance of the scenario under consideration. An overview of the scenario is obtained by assigning smiley faces to a table whose boxes correspond to the values and their (non-)compliance. As shown in Figure 1, the method indicates to put 😊😊 if the compliance is good, and 😊 if it is partially present. At the same time, 😞😞 is used if the non-compliance is particularly important, and 😞 if some non-compliance is identified. This approach allows for easy identification of possible dilemmas.

In order to make this approach meaningful, the report presents various examples of scenarios from the field of medical imaging and therapy (see Figure 2). Each scenario is presented on one page of the size of this article. The first part contains a description of the scenario and the last part a proposal for an analysis of the values. In between, a summary table shows the overall view.

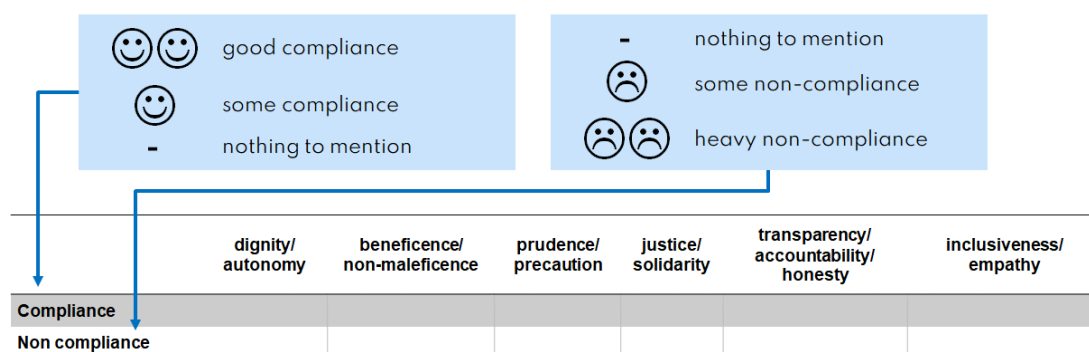


Fig. 1. Each scenario is evaluated from the perspective of a pair of ethical values. The method proposes to separately identify the compliance and the non-compliance of each pair of values.

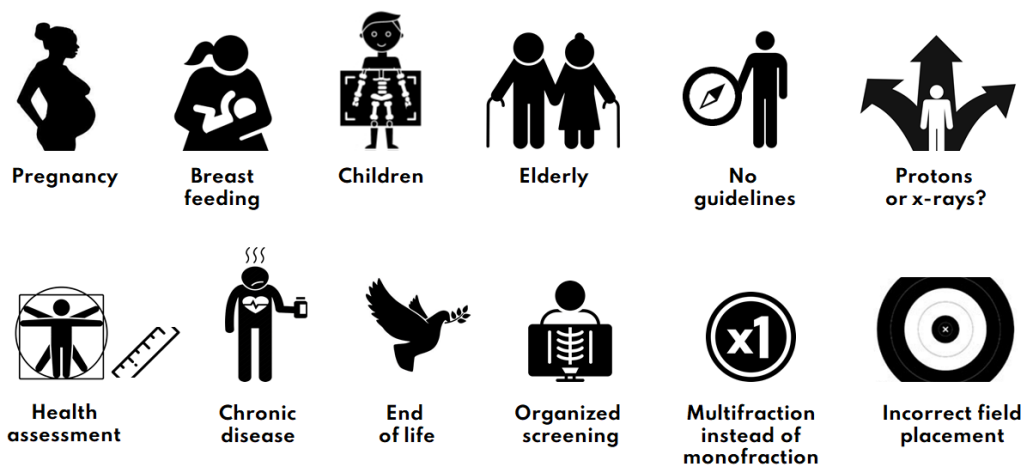


Fig. 2. Examples of subjects dealt with in the scenarios involving typical and realistic diagnostics and therapy situations. The report proposes 11 imaging and 10 therapy scenarios.

### 3. EDUCATION AND TRAINING

#### 3.1. Motivations for ethics training

To ensure that ethics is fully integrated into the clinical use of ionising radiation, an effective and balanced education and training programme for health professionals is needed. This programme should be practice-oriented to help patients, relatives and healthcare providers understand the procedures, their importance and also the risks. Whether requesting or

performing radiological procedures, health professionals have a shared responsibility to ensure that the procedure is appropriate and will benefit the patient (Image Gently, 2022). Ethics can help to achieve the greatest possible good with the lowest possible risk.

Patients can also benefit from ethical education, but it must be acquired within a wider framework, aimed at changing the culture and improving radiation health literacy. The various campaigns on this topic do not explicitly mention ethical values, but they are implicitly integrated (Image Gently, 2007; Eurosafe Imaging, 2022; AfroSafe, 2015–2018; ArabSafe, 2021).

Other personnel who interact with patients also need ethics education and training. This is particularly the case for those in positions of authority as their decisions often have a significant impact on a large number of people. It includes ensuring equity of access to resources, ensuring that health professionals are educated and trained, as well as monitoring professional training and public education programmes. The quality of hospital managers' work is also influenced by their ethical skills. For example, they must ensure that staff are sufficiently trained to respond to the ethical dilemmas they encounter and to communicate appropriately with patients and the public. Clerical personnel, as well as care assistants and porters are often the people to whom patients bring their questions. Many of these employees do not receive education and training in ethics and communication, which can have an impact on their care.

### 3.2. Establishing a curriculum

Ethics and radiological protection are difficult and complex topics that require a solid knowledge base before they can be applied in clinical situations. In this context, TG109 proposes to base education and training on Bloom's hierarchical taxonomy of learning (Bloom, 1956). This approach allows learning to be approached at an increasing level of complexity, from simple recollection of facts to the process of analysis and evaluation (ACGME, 1999; European Parliament, 2008; UNESCO, 2018). Table 2 shows the five levels of complexity of Bloom's taxonomy, as recommended in the report submitted for consultation.

Bloom's taxonomy allows the educator to define student learning outcomes based on the knowledge, skills and competences needed by health professionals to make informed ethical decisions in the clinical environment. The report gives some examples of how knowledge, skills and competence (KSC) can be defined. This allows for the development of education and training modules as part of an education programme.

Table 2. Taxonomy of Learning Definitions in Anderson and Krathwohl's updated Bloom Hierarchical Taxonomy (Anderson and Krathwohl, 2001).

Level of complexity	Explanation
Remembering	is retrieving information from long-term memory
Understanding	is constructing meaning from instructional messages including oral, written and graphic communication
Applying	is carrying out a procedure in a given situation
Analysing	is breaking the material into its constituent parts and determining how the parts relate to one another and to the overall structure or purpose
Evaluating	is making judgements based on criteria and standards
Creating	is putting elements together to form a coherent whole function: reorganising elements into new patterns of structure

#### 4. CONCLUSION

The TG109 report will soon be available for consultation. In order to assist the reader in a theoretically complex subject, key messages are distributed throughout the text, as fixed points that can easily be understood as such. The report required some extension of the ethical values of *Publication 138* to include those commonly established in medicine. This should therefore help medical and radiological protection professionals to interact in a common language. In order to demonstrate the practical usefulness of ethics, the report proposes an evaluation method that can be used to analyse real cases and identify ethical dilemmas.

The 21 scenarios proposed provide examples of the application of the evaluation method. They can be used for education and training purposes. In addition to giving an example of a curriculum based on Bloom's taxonomy, the report stresses the need to train all actors: not only those directly in contact with patients, but also regulators, vendors, managers and clerical personnel. Without forgetting the patient, who must remain at the heart of the informed decision-making process.

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# A comparative time-series analysis and deep learning projection of innate radon gas risk in Canadian and Swedish residential buildings

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**Abstract**—Accumulation of radioactive radon gas in indoor air poses a serious risk to human health by increasing the lifetime risk of lung cancer and is classified by IARC as a category one carcinogen. Radon exposure risks are a function of geologic, geographic, building design, and human behavioural variables, and can change over time. Using time series and deep machine learning modelling, we analyzed long-term radon test outcomes as a function of building metrics from 25,489 Canadian and 38,596 Swedish residential properties constructed between 1945 to 2020. While Canadian and Swedish properties built between 1970 and 1980 are comparable (96–103 Bq/m<sup>3</sup>), innate radon risks subsequently diverge, rising in Canada and falling in Sweden such that 21<sup>st</sup> Century Canadian houses show 467% greater average radon (131 Bq/m<sup>3</sup>) relative to Swedish equivalents (28 Bq/m<sup>3</sup>). These trends are consistent across housing types and regions within each country. The introduction of energy efficiency measures within Canadian and Swedish building codes coincided with opposing radon level trajectories in each nation. Deep machine learning modelling predicts that, without intervention, average Canadian residential radon levels will increase to 176 Bq/m<sup>3</sup> by 2050, emphasizing the importance and urgency of future building code intervention to achieve systemic radon reduction in Canada.

*Keywords:* Radon health risk; Time-series; Deep machine learning; Lung cancer; Canada; Sweden

## 1. INTRODUCTION

This article represents a condensed summary of an already peer-reviewed and published study (Khan et al., 2021) and has been prepared as part of proceedings from the International Commission for Radiological Protection (ICRP2021<sup>+1</sup>) conference that was held in Vancouver, Canada on November 7–10<sup>th</sup>, 2022, having been delayed one year due to the widespread consequences of the COVID-19 pandemic. The complete version of this work was published in Scientific Reports in September 2021.

Among global cancer-related deaths, lung cancer in people who do not smoke tobacco ranks 7<sup>th</sup> worldwide, and this trend is rising (Corrales et al., 2020; Subramanian and Govindan, 2007; Grundy et al., 2017). Radioactive radon (<sup>222</sup>Rn) is classified as a category 1 carcinogen by the International Agency for Research on Cancer (Pearson et al., 2021; Moore et al., 2014). This carcinogenicity is due to the bombardment of lung epithelial cells by alpha particle ionising radiation that takes place during the inhalation of decaying radon and its progeny such as <sup>218</sup>Po, <sup>214</sup>Po and long-lived <sup>210</sup>Pb, which can accumulate within the body (Pearson et al., 2021; Chen, 2019; Gaskin et al., 2018; Grundy et al., 2017; Kim et al., 2016; Stanley et al., 2017). Exposure to alpha particle radiation triggers a self-propagating cycle of genomic instability and genetic mutation in lung cells that increases cancer risk. Besides being the main cause of lung cancer in people who do not use tobacco, radon exposure can synergise with tobacco smoke



carcinogens to multiply lung cancer risks (Pearson et al., 2021; Lorenzo-González et al., 2019; Chen, 2019; Gaskin et al., 2018; Grundy et al., 2017; Stanley et al., 2017; Kim et al., 2016). An additive 16% increase in relative lifetime risk of lung cancer is incurred per 100 Bq/m<sup>3</sup> of long-term radon exposure (Darby et al., 2005; Krewski et al., 2005). The global radon exposure problem within the residential built environment is thought to be a relatively recent and human-made problem that has arisen as a function of building design, and construction practices of the mid to late 20<sup>th</sup> and 21<sup>st</sup> centuries (Gaskin et al., 2018; Grundy et al., 2017; Simms et al., 2021). From a population health perspective, exposure to indoor air carcinogens is an important consideration in the long-term health of populations, especially those who occupy cold-climate regions in which the majority of people spent most of their life within indoor environments (Klepeis et al., 2001).

North American residential radon exposure has worsened over time, while the opposite trend has taken place in Nordic countries (Stanley et al., 2017; Kim et al., 2016; Simms et al., 2021; Lagarde et al., 2001; Pershagen et al., 1994; Smethurst et al., 2008; Swedjemark and Åkerblom, 1994). Given the general similarities in climates, design trends, construction practices, technology, education, and radon awareness of both regions, it is not immediately clear why they have diverged so substantially in terms of residential radon exposure. It is important to acknowledge that there are also major differences between these regions in the prevalence of lung cancer. Primary lung cancer caused ~25% of Canadian cancer-related deaths in 2019, with one in five of the 29,800 new Canadian lung cancer cases in that year occurring in people who do not smoke tobacco. By contrast, Sweden reported 4325 new lung cancers in 2019. Demographic standardization shows that Canada's annual rate of new lung cancers is currently 163% greater than that of Sweden, at 28.9 versus 17.7 per 100,000 annually (Bray et al., 2018). These differences are unlikely to be explained by regional tobacco smoking rates, which are comparable at 11–13%, and have fallen in both countries with similar trajectories over recent decades (Pader et al., 2021; Hemminki et al., 2022). Considering the 10 to 30-year latency period between an initiating exposure and the detection of lung cancer, one plausible explanation for the disparity (between Canadian and Swedish age-adjusted lung cancer incidence) is that it has been driven by differences over the past several decades in exposure to other prevalent and potent lung carcinogens such as radon gas.

Regional population growth projections for 2050 indicate a need to expand current housing stocks by an additional 75% or more (Gazdar et al., 2007; Statistics Canada, 2019). Hence, understanding and incorporating new radon-reducing measures within the new construction design are important to avoid a continuation or worsening of the current lung cancer public health crisis. The objective of this study was to better understand factors underlying temporal and regional differences in innate radon risk within the built environment, in order to better develop systematic interventions that can be applied to future building codes to ensure performance-based outcomes.

## 2. METHODS AND MATERIALS

This research was conducted as part of the Evict Radon National Study ([www.evictradon.org](http://www.evictradon.org)) and was approved by the University of Calgary's Conjoint Health Research Ethics Board (REB17-2239, REB19-1522). For full details on all original consent and methodologies, please see (Khan et al., 2021). Informed consent was obtained, and study participants (SP) were permitted to withdraw from the study at any time. This work was conducted using the guiding principles of citizen science, wherein participants volunteered to purchase at-cost alpha track radon detectors curated by the research team, which were then delivered to participants who deployed these for a 90-day or more testing period, returned for analysis, and received results in a confidential manner while consenting for deidentified radon

readings (and property metrics) to be shared with and used by the study team. Recruitment was convenience-based, and open to all adult homeowners and renters of all residential building types anywhere within the study region. Selection biases were minimised since radon levels cannot be predicted by an individual prior to radon testing. Commercial offices or hospitality service buildings were not considered. Retrospective analysis of Canadian property types, occupants, and region indicated that the study cohort reflected the general distribution of the population (discussed in detail in Stanley et al., 2019; Simms et al., 2021; Cholowsky et al., 2021; Irvine et al., 2022). All radon tests were conducted with the closed passive etched track detectors made from CR-39 plastic film inside antistatic and electrically conductive housing with filtered openings to permit gas diffusion, with a typical linear range of 0.96.

### 3. ANALYSIS

We conducted descriptive, sensitivity, and comparative analyses of radon test results over matching time periods and geographical regions. We linked all test results to the property metrics including the year of construction, ventilation type, building type (and materials), and mitigation methods (building code interventions, HRV). We exploited machine (deep) learning modelling to project how radon exposure might evolve further by 2050. We also reviewed 20<sup>th</sup> to 21<sup>st</sup>-century build practices, energy efficiency provisions, house heating methods, and related policies for both regions, to determine possible causative factors in diverging radon exposure trends.

#### 3.1. Statistical Analysis

Statistical analysis was conducted in MS Excel 2016, SPSS, Prism 9.0 and R (4.0.2). One-way ANOVAs tested the differences between groups (year of construction, occupant age, mSv), Bonferroni–Holm post-hoc testing characterised group differences for pairwise comparisons if the ANOVA reached significance.

#### 3.2. Timeseries ARIMA and Deep Machine Learning Analysis

Predictive time-series analyses were conducted using both traditional Autoregressive Integrated Moving Average (ARIMA), and the new generation deep learning time series forecasting toolsets in MATLAB2020b using Python codes as well as the TSFA econometric platform. Descriptive, sensitivity, filtration, and random fluctuations tests were performed to train the models; once optimised, they forecasted comparative radon levels in the recent past (1990–2020) and near future (2020–2050) in Canada and Sweden. Both Canadian and Swedish datasets were non-stationary as shown by ADF tests (having trends and seasonality), and so we removed these through differential filtering and decomposition to get the stationary data suitable to assign to an ARIMA model. We used Fourier Transformation (that provides spikes in the frequency domain corresponding to the number of harmonics) to multiply the signal to remove seasonality. We used autocorrelation (AC) and partial autocorrelation (PAC) to determine autoregression. In our data, AC and PAC tailed off gradually, so we integrated both AR(p) and MA(q) models into ARIMA model. Our loaded case data contained a time series where the time steps corresponded to year of construction and values corresponded to the radon test results. The output was a cell array, where each element was a single time step. We trained the first 90% of the sequence and tested on the last 10% for the sequence-to-sequence regression network.

Deep learning is a type of machine learning based on artificial neural networks, in which multiple layers of processing can progressively extract higher-level features from large, often

complex datasets without losing memory. We previously developed a deep learning method applicable to understanding radon in the built environment (Khan et al., 2020) and applied a refinement of that initial technique to the datasets in this study. Briefly, this involved a long short-term memory (LSTM) network, a type of artificial, recurrent neural network with feedback connections capable of learning order dependence in sequence prediction problems (see methods for details). Our model had 200 hidden neuronal layers; we ran it up to 500 epochs, setting the gradient threshold at 1 and piecewise initial learning rate at 0.005 with a 20% drop factor from the midpoint (numFeatures=1; numResponses=1; numHiddenUnits=200; 'MaxEpochs', 500, 'GradientTreshold', 1, 'InitialLearnRate', 0.005, 'LearnRateSchedule', 'piecewise', 'LearnRateDropPeriod', 125, LearnRateDropFactor',0.2). The training progress plot reported the root-mean-square error (RMSE) calculated from the standardised data. Once the model was trained, we tested it to predict forecasted values and compared that with the test data. To forecast the values of future time steps of a sequence, our trained LSTM model produced responses with the sequenced values shifted by a one-time step. Where, at each time step of the input sequence, the model learned to predict the value of the next time step. To forecast the values of multiple time steps in the future, we used the 'predictAndUpdateState' function to predict time steps one at a time and update the network state at each prediction. We applied the model to display the recent past 1991–2020 and projected future 2021–2050 radon levels. This model performed better in dealing with the large volume of data and produced more accurate (94%) outcomes in terms of prediction errors as measured with RMSE which is the standard deviation of the residuals showing how close the data points are from the best fit regression line compared to that in the traditional ARIMA model.

## 4. RESULTS

### 4.1. Study Region and Cohort Analysis

Study regions included Canada and Sweden. These nations were chosen as both countries are in 'cold climate' regions with comparable built environments and demographic trends that have well documented over the past 75 years. We obtained long term (82–131 days) radon test outcomes for residential properties across three sub-regions (Fig. 1.A) for both countries, using identical alpha track detectors between 2004 and 2020. Already radon-mitigated properties were excluded from this analysis, as were multi-story apartment buildings, as the Canadian dataset did not contain enough properties of this type to perform a statistically meaningful comparison. The final dataset comprised 25,489 Canadian residential properties having an arithmetic mean radon of 149 Bq/m<sup>3</sup> (geometric mean 98 Bq/m<sup>3</sup>, CI95% [96.6, 98.7], min=1, max=32,321), and 38,596 Swedish properties containing 124 Bq/m<sup>3</sup> (geometric mean 66 Bq/m<sup>3</sup>, CI95% [65.6, 67.1], min=1, max=13,325).

To display generalised regional risks within each country, we determined the percentage of properties that were <100 Bq/m<sup>3</sup>, 100–199 Bq/m<sup>3</sup>, or ≥200 Bq/m<sup>3</sup> as a function of geography (Fig. 1.B). While there were some regional risk differences within each nation, the overall percentage of properties having the innate radon risk was comparable within each country and were considerably higher than global averages 12. We next compared three distinct housing types common to both countries. Single detached houses contained the highest average radon in both countries, with row housing being the lowest, and duplex (side-by-side) being variably higher in Canada or lower in Sweden (Fig. 1.C).

#### 4.2. Time Series Analysis of Radon Levels as a Function of the Construction Period

We observed clear differences in the distribution of Swedish and Canadian residential radon levels as a function of property age. To better measure these trends, we clustered test outcomes into 10-year groups of property construction (Fig. 1.D). We then calculated the geometric mean radon level observed within each period and considered this value to reflect the changing ‘innate radon risk’ within the built environment of each region. The trends demonstrated a striking convergence and divergence of residential radon exposure in Canada and Sweden. Residential radon levels are consistently and significantly ( $p < 0.0001$ ) greater in Swedish houses compared to Canadian houses built between 1951 and 1970. For properties built in the 1970s, however, radon levels between each nation converge, were analogous ( $96 \text{ Bq/m}^3$  in Canada,  $103 \text{ Bq/m}^3$  in Sweden) and not statistically ( $p > 0.05$ ) different. After 1980, the trends between these regions diverged substantially, and by the 2011–2020 period had risen in new Canadian builds to  $131 \text{ Bq/m}^3$ , while decreased steadily in Sweden to  $28 \text{ Bq/m}^3$ , equating with an innate radon risk gap of 467% between the two countries at this time.

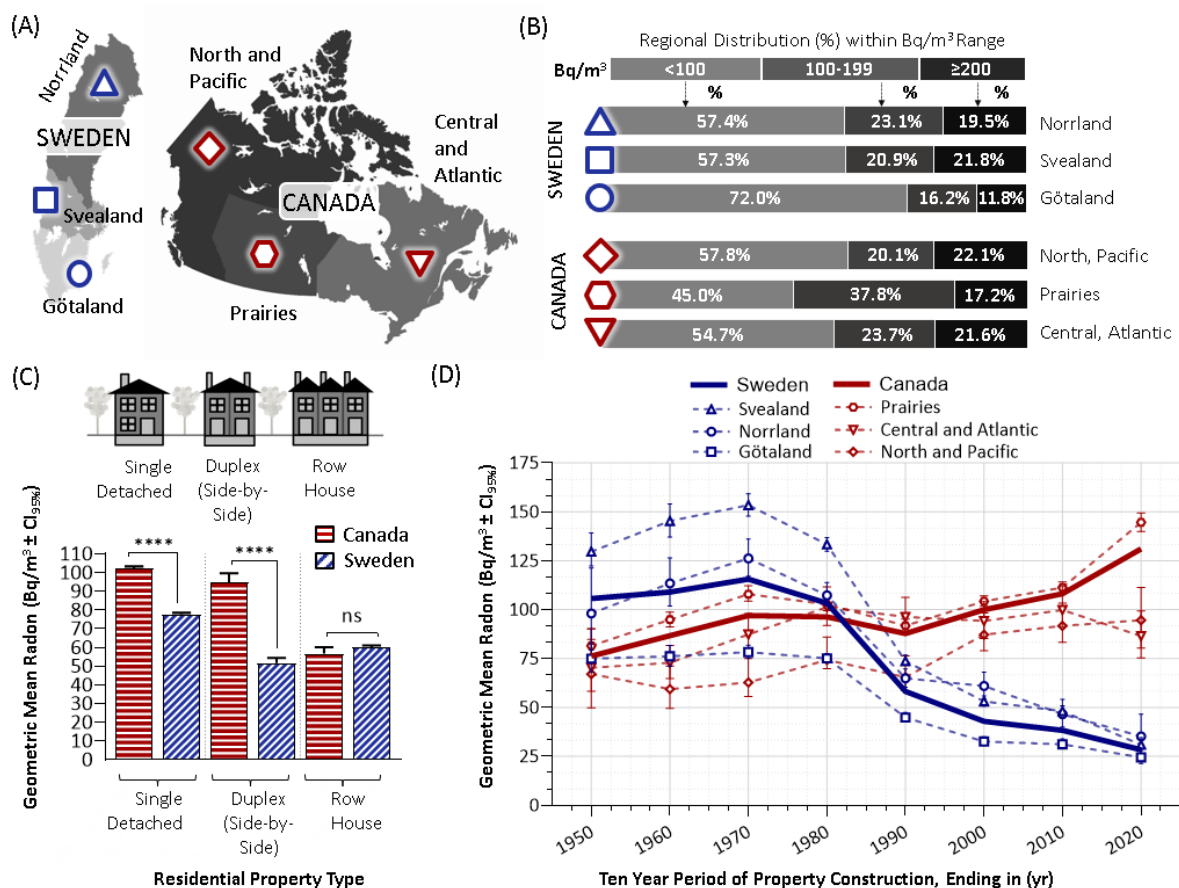


Fig. 1. (A) Three sub-regions of Sweden and Canada. (B) Regional distribution of radon in the three range brackets ( $<100$ ,  $100\text{--}199$ ,  $\geq 200 \text{ Bq/m}^3$ ) in both Sweden and Canada. (C) Comparative radon levels in three housing types of Canada and Sweden. (D) Geometric mean radon distribution over a 70-year timeline in Sweden and Canada along with the regional trends.

The decline in innate radon risk in Swedish properties occurred in an equivalent manner across all regions examined, with Svealand and Norrland experiencing the largest relative decrease (Fig. 1.D). In Canada, all regions also experienced a rise in radon over most of the twentieth to the twenty-first century, with this being proportionately largest in the Prairie

region. We note that residential indoor air radon levels in other regions of Canada, although not significantly decreasing from 2001 to 2020, also did not experience the same, large rises in innate radon risk that occurred over between 2001 to 2020 in Prairie Canada. The reasons for this are not clear and warrant future investigation. However, as these trends are consistent across different property types in both Sweden and Canada (Fig. 1.C), we suggest that the aetiology of regional trend differences is not related to any gross disparities in property type distribution.

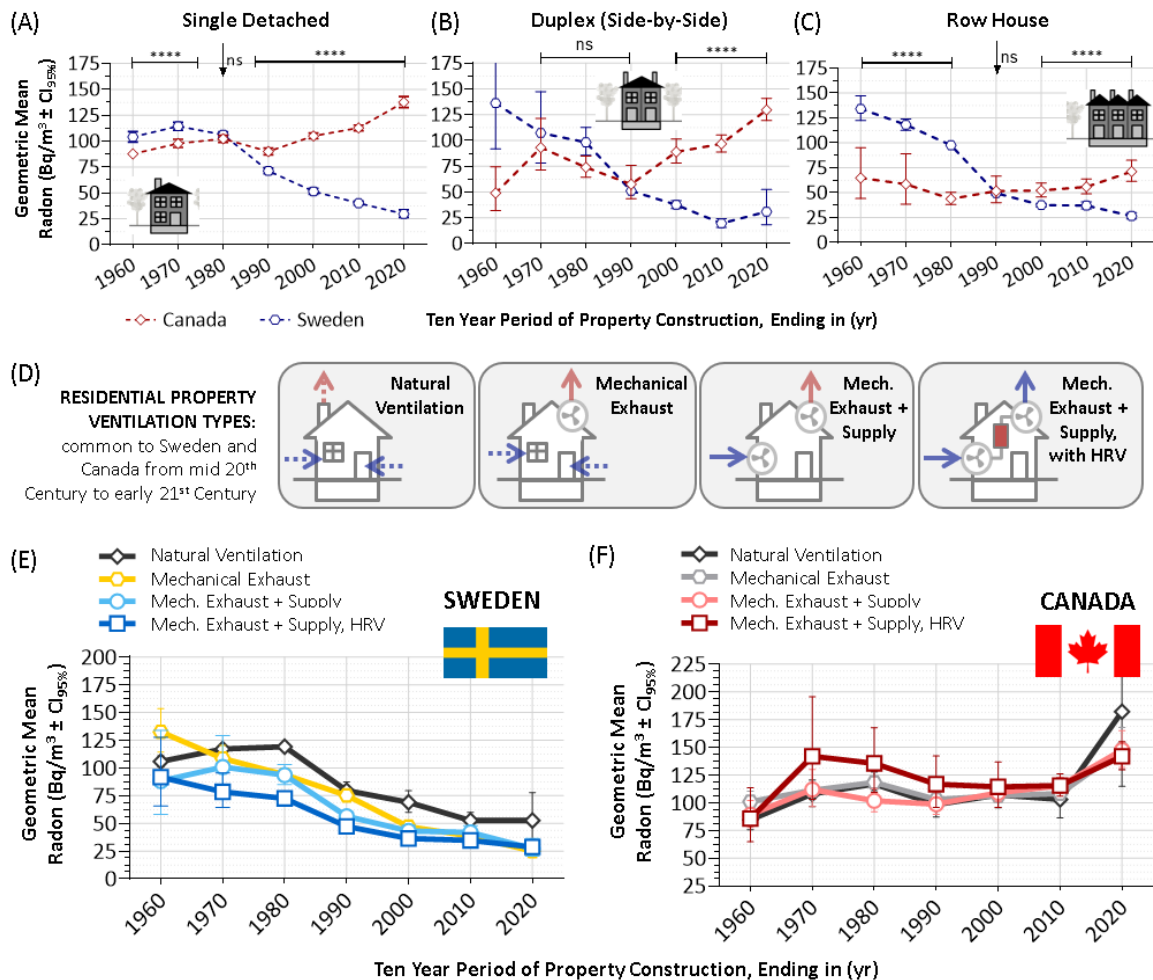


Fig. 2. Geometric mean radon trends over the decades in (A) Single Detached, (B) Duplex (Side-by-Side), and (C) Row house in Sweden and Canada. (D) Diagrammatic representation of the different residential properties' ventilation types. Radon trends over the decades as a function of ventilation types in (E) Sweden and (F) Canada.

#### 4.3. Swedish and Canadian radon in relation to building code and energy efficiency policies over time

While the innate radon risks of a residential property built in Canada and Sweden in 1980 were the same, the data outlined in Fig. 2. demonstrate strikingly different outcomes for all three types of houses over time. It is reasonable to hypothesise that subsequent changes in design trends and/or building codes over the following 40 years (1981–2020) underlie the significant increase in Canadian radon, and the opposing situation in Sweden. It is important to note that Canadian national building codes have no legal status until they are accepted by

the provincial legislatures and municipal government bylaws (CELA, 2018), a process that can take up to five years (NRC, 2010, 2015). This means that realised changes in Canadian build practices are typically spread out over time. In contrast, Swedish national building codes are mandated from their inception and result in more immediate changes in practice (Meacham et al., 2005; Meacham, 2016; Foliente, 2000; Boverket, 2019).

#### **4.4. Swedish and Canadian radon as a function of energy efficiency-related ventilation changes**

In both Sweden and Canada, new functional requirements relating to residential energy efficiency coincided with the introduction of performance-based build practices. These changes intentionally produced more air-tight properties and, in turn, necessitated more sophisticated controls over building ventilation to ensure a healthy balance between fresh and stale air. To determine how shifts in property ventilation impacted radon, we analyzed innate radon risks over time as a function of four ventilation types (Fig. 2.D): (1) natural ventilation, (2) mechanical exhaust, (3) mechanical exhaust and supply, and (4) mechanical exhaust and supply with heat recovery ventilation (HRV) technology. In Sweden, there were significant differences ( $p < 0.05$ ) between natural ventilation and those with mechanical exhaust and/or supply. To examine this more closely, we monitored the relative prevalence of each ventilation type over time in Sweden and Canada (Fig. 2.E,F) and found that they reflected the known timeline of adoption within each nation build code, with HRV-based ventilation rising in prominence in Sweden after 1980 and in Canada only after 2010. On the surface, HRV adoption in Sweden during the 1980s correlated with the most substantial period of reduced radon risk in that nation, while the opposite is true in Canada during the 2010s. This suggests that the adoption of these ventilation types into a given region's building code is independent of innate radon risk of properties. This idea is supported by our observation that these region-specific trends occurred for all four ventilation types, either all rising (Canada) or all falling (Sweden) in relative synchrony. We also conclude from this that the adoption of heat recovery ventilation, of itself, is also not a fundamental driver of radon risk.

#### **4.5. Deep-learning time series prediction of future residential property innate radon risks to 2050**

Finally, we used ARIMA and modelling via deep machine learning to project how the innate radon risk of residential properties in Canada and Sweden might evolve over the next 30 years. We used property metrics from the 30-year period immediately before 2020 only, to predict forward three decades to 2050. This model assumes that no radon-specific changes to future building codes, beyond what has already occurred (and were trending over the previous 30-year period), will be introduced. This was by design, so that we could estimate the consequences of future inaction on radon within the building codes might be. Each model was performed a maximum of 500 times and then aggregated together to develop a consolidated prediction of innate radon risk per year (Fig. 3). The models predict that Swedish innate radon risk may continue a modest decline to background levels ( $< 15 \text{ Bq/m}^3$ ), while Canadian levels might rise such that a residential property built in 2050 would contain an average of  $175 \text{ Bq/m}^3$ .

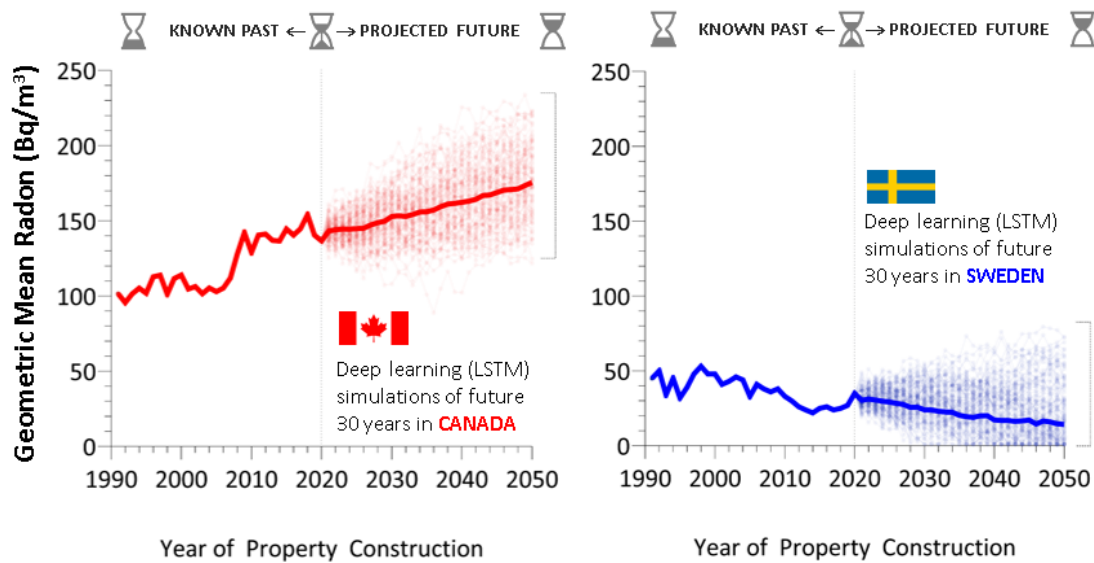


Fig. 3. Deep machine learning simulation predicted radon levels till 2050 in Canada and Sweden

## 5. DISCUSSION

For a complete discussion of the full, original dataset presented within this conference proceedings, including policy recommendations, and a more exhaustive description of study strengths and weaknesses, we refer the reader to the originally published version of this work that was released in 2021 in Scientific Reports (Khan et al., 2021).

The factors underlying opposing trends as identified between Canadian and Swedish innate residential radon risks are many, and likely to interplay with one another in complex ways. As such, we cannot conclude that any single, ‘obvious’ event or building code change or intervention either reduced or increased innate radon levels within the residential built environment of either Canada or Sweden. As far as we have been able to determine from available building codes, Sweden has not introduced any specific code change that explicitly incorporates radon reduction provisions; however, it certainly has detailed ventilation codes, radon testing guidelines, and provisions regarding the discontinued use of radon-emitting ‘blue concrete’ (Boverket, 2019).

In contrast, Canada introduced several radon reduction-specific measures as part of its 2010 building code (NRC, 2010). These measures included (1) a sub-(concrete) slab depressurization ‘rough-in’ to all building foundations, (2) increased washing required of sub-foundation gravel layers (to eliminate fine particulate that reduces gas communication below the slab), and (3) the inclusion of a plastic vapour barrier between the gravel and concrete foundations. Our analyses covered the periods before and after these measures were introduced, and we were able to compare radon levels in Canadian properties built using the 2010 code (NRC, 2010, 2015; CELA, 2018) to those built in the preceding (up to) 10-year period. We note that Canadian provinces variably adopted the 2010 code between 2011 and 2015, and so the cut-off we used for each before and after (code adoption) period was set in a regionally specific manner for the greatest sensitivity. In short, we found no statistically significant effect on innate radon risk, meaning that all properties constructed after the adoption of the 2010 Canada build code contain the same overall innate radon risk as those built during the previous decade. This was not entirely surprising, given that the radon-related provisions introduced to the 2010 code would not, in and of themselves, suppress radon entry. Rather, these measures were intended

more to make it easier for professionals to mitigate a property for high radon at a future date. This indicates that novel changes to future Canadian build codes are still required to effectively reduce innate radon risk in the new residential properties.

Performance-based design requires property builders meet measurable conditions, such as energy efficiency and air ventilation. This contrasts with prescriptive-based building practices, which require them to satisfy specified (often numeric) standards for individual building features or operational characteristics. Sweden introduced performance-based objective building code regulations in 1967, while the same style of build code was only implemented in Canada in 2005 (and took up to 2010 to be fully adopted). Based on our observation that innate radon risks in Canada and Sweden diverged with opposite trajectories as performance-based build code practices were adopted, we conclude that the adoption of this philosophy is unlikely to be directly correlative or causative with radon in the built environment.

While some research has found heat recovery ventilation technology to directly influence radon levels (25–75%) (Khan et al., 2019), we observed opposing outcomes on residential radon levels produced by HRV introduction in Canada and Sweden. We note, however, that there are now major differences between Canada and Sweden in terms of how a majority of residential properties are heated, with natural gas-based furnaces (57%), electric baseboard heaters (27%), and boilers (radiators) (5%) encompassing most of the heating in Canada (Government of Canada, 2017). By contrast, Sweden had largely phased out these heating methods by the late 20<sup>th</sup> century, replacing them with district heating, which uses the combustion of biomass fuels in a centralised facility to produce steam forced through a pipe network to individual properties for radiant heat distribution (Werner, 2017). By the 2010s, district heating accounted for >70% of heating in Sweden, while natural gas-based heating was only used in 10% of cases. As natural gas-based furnaces typically use forced air ventilation to distribute heat, the use of this technology has major implications on air dynamics within a given building, and we speculate that widespread use of this heating type in Canada could contribute to (or even underlie) why greater radon levels coincide with the adoption of HRV and other energy efficiency measures.

Canadian radon control public health practices typically aim to convince homeowners to test for radon and personally invest in post-construction radon mitigation if the radon level exceeds a certain threshold. The overall success of this strategy relies on an individual's psychological, sociological, economic, and behavioral factors - a process that is neither inclusive nor equitable on the basis of socioeconomic (Irvine et al., 2022). By contrast, a future-forward systemic approach to reduced innate radon levels in all houses is likely to be more equitable and impactful. We suggest that one near-term effective solution to this issue is the inclusion of a complete sub-slab depressurization (radon mitigation) system in all new builds. If installed at construction, costs are transferred from property owners to builders but are counterbalanced by the economy of scale that make systemic radon reduction far more economical versus ad hoc retrofits to already completed buildings. A complete economic cost-benefit analysis of this is warranted. The next Canadian build code is due to be published in 2025, and so there is a near-term opportunity to introduce such measures that would be expected to take effect across the nation by 2030.

## 6. CONCLUSION

Our study finds that the North American and Scandinavian residential property innate radon risks have diverged significantly over the last 40 years, where the new Canadian houses have 467% greater radon compared to their Swedish counterparts. Future research should address whether the different modes of heating houses in Sweden and Canada could have a diverse effect on indoor radon levels. Our research finds there is no basis to assign either blame nor



credit to any parties or persons for rising Canadian and falling Swedish innate radon risks. That said, meaningful future intervention to reduce high Canadian radon exposure should be addressed as fast as achievable by all those in a position to do so. Until then, radon in residential properties will continue to inflict human suffering from radon-induced lung cancers.

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## CONFLICTS OF INTEREST

All authors explicitly state they have no financial stake in the radon mitigation or construction industry within either Canada, Sweden, or any other nation. The third author of this study (TR) is a staff scientist at Radonova Laboratories, a private company that supplies radon test devices; however, his role and salary within Radonova Laboratories are independent of this study, and the management of Radonova Laboratories have not influenced the design, analysis, interpretation, or final submission of this study in any way. The other authors declare NO competing (financial or non-financial) interests or other conflicts of any kind. The funders of the study also had no role in study design, data collection, analysis, interpretation, or preparing the study manuscript or figures.

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## ICRU Report 95: new operational quantities for external radiation exposure

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**Abstract**—Measurable operational dose quantities approximate the protection quantities for external exposure, which can generally not be measured directly. In 2020, the International Commission on Radiological Protection (ICRP) and the International Commission on Radiation Units and Measurements (ICRU) have jointly published ICRU Report 95 with improved definitions for operational quantities, and with conversion coefficients for a wide range of particles and energies. For whole-body exposure, personal dose  $H_p$  and ambient dose  $H^*$  are the new operational quantities approximating effective dose  $E$ . They are based on the same phantoms and weighting coefficients as  $E$  and provide a better approximation of the protection quantity as well as a simplification of the system of radiation protection dose quantities. The paper briefly explains the definition of the new operational quantities. It then analyses which changes in practical radiation protection and dosimetry are implied by the future introduction of these quantities.

*Keywords:* Radiation protection dosimetry; Operational quantities; Ambient dose; Personal dose

### 1. PROTECTION QUANTITIES

In 1990, the International Commission on Radiological Protection (ICRP) introduced so-called ‘protection quantities’ for ionising radiation. The most used protection quantity, the effective dose  $E$ , serves to estimate the risk of stochastic radiation effects after whole-body exposure. The definition of  $E$  is based on a weighted average of absorbed doses in specified tissues and organs in the ICRP-ICRU reference phantom (ICRP, 2009). The organ doses are weighted for radiation quality ( $w_R$ ) and for the relative sensitivity of the tissues to develop stochastic effects ( $w_T$ ). Weighting factors were derived from epidemiological data. Effective dose is then (ICRP, 1991, 2007):

$$E = \sum_T w_T \sum_R w_R D_{R,T}$$

Effective dose is universally applicable to all types of radiation and to external as well as to internal radiation. The concept of effective dose is well established in practice for almost four decades. Legal exposure limits, constraints and guidelines are set in units of effective dose, and in operational radiation protection  $E$  is the objective of the optimisation process. Radiation exposure quantified in terms of  $E$  has to be reduced as much as reasonably achievable, after the as low as reasonably achievable (ALARA) principle.

For external radiation, values of the effective dose are calculated for simple directions of incidence of the radiation field using numerical anthropomorphic phantoms (ICRP 2009, 2010). The result are so-called conversion coefficients, which are the values of effective dose per unit of particle fluence or, alternatively for photons, per air kerma.

## 2. CURRENT OPERATIONAL QUANTITIES

Effective dose is not measurable in practice. This is the reason why the International Commission on Radiation Units and Measurements (ICRU) defined ‘operational (or measurable) quantities’ for the calibration of dosimeters and radiation measurement instruments. Operational quantities are defined in a point and are intended to provide the best possible approximation of the protection values.

The current operational quantities personal dose equivalent  $H_p(10,\alpha)$  and ambient dose equivalent  $H^*(10)$  (ICRU, 1985, 1993) are used to provide approximate values for effective dose  $E$ .

Personal dose equivalent  $H_p(10,\alpha)$  is used to calibrate personal dosimeters, i.e. for the retrospective assessment of effective dose of a person potentially exposed to radiation. It is defined as the absorbed dose at a depth of 10 mm at a representative position of the body, multiplied with the quality factor  $Q(L)$ , defined as a function of the unrestricted linear energy transfer  $L$ . A rectangular phantom made from ICRU four-component tissue is used for the calculation of conversion coefficients of the personal dose equivalent (ICRP, 1996; ICRU, 1998).

Radiation protection monitors are calibrated in ambient dose equivalent  $H^*(10)$  for prospective radiation protection measurements and for environmental measurements. Ambient dose equivalent is defined as the product of absorbed dose at 10 mm depth in the fictitious ICRU sphere and the quality factor  $Q(L)$ , in the extended and aligned radiation field. This concept assumes an isotropic homogeneous response of the monitor. The present operational quantities were defined in the 1980s, when the nuclear industry was the most important field of radiation protection. In the typical radiation fields of this industry, these quantities provided very good estimates of the effective dose  $E$  for exposure to photons and sufficiently good estimates for neutrons. With new applications of ionising radiation, the shortcomings of today’s operational quantities became evident: at high radiation field energies, occurring for example at accelerators, effective dose can be either over- or underestimated. Effective dose is overestimated in radiation fields with very low photon energies, occurring at some workplaces in medical diagnostics or treatment.

## 3. OPERATIONAL QUANTITIES IN ICRU REPORT 95

The ICRU set up a working group to test and evaluate alternatives to a revision of  $H_p(10)$  and  $H^*(10)$  and finally agreed on the quantities personal dose  $H_p(\alpha)$  and ambient dose  $H^*$ . Instead of basing the definition on the absorbed dose in a phantom, the new quantities are defined directly as the product of a physical field quantity such as particle fluence, or air kerma for photons, and a conversion coefficient. The definition can symbolically be expressed as:

$$H^*(E) = h^*(E) \cdot \phi(E)$$

$$H_p(E, \alpha) = h_p(E, \alpha) \cdot \phi(E)$$

In these formulae,  $E$  denotes particle energy. The conversion coefficients  $h_p$  and  $h^*$  are calculated using the same phantoms and the same weighting coefficients  $w_R$  and  $w_T$  as for the calculation of effective dose  $E$ .

The new definitions and the associated conversion coefficients were published jointly with the ICRP in ICRU Report 95 (ICRU, 2020). Personal dose  $H_p(\alpha)$  is defined for specific angles of incidence, while the definition of ambient dose  $H^*$  contains a maximisation of the quantity value over the direction of incidence. Based on their definition alone, these two quantities

provide a better estimate of the protection quantities; for some combinations of energy and angle of incidence, the numerical values of the operational and protection quantities are even identical.

Fig. 1 shows the energy dependence of the personal dose for photons expressed as a conversion coefficient from kerma in air. For the characteristic energy range of photons emitted by radionuclides, 100 keV–3 MeV, the measured quantity personal dose results in somewhat lower values than the personal dose equivalent. At very low photon energies, as encountered for example in interventional radiology or in mammography, the results for the personal dose are significantly lower. This is because at these low energies, personal dose equivalent  $H_p(10)$  overestimates effective dose  $E$  by a factor of up to 5. This large overestimation is avoided by personal dose (Otto, 2019b; Behrens and Otto, 2022).

For neutron radiation, Fig. 2 shows the energy-dependent conversion coefficients from fluence to effective dose  $E$  for different incident directions, to ambient dose equivalent  $H^*(10)$  and to ambient dose  $H^*$ . At each energy, the value of ambient dose is equal to the maximal value of effective dose over all incident directions. It thus forms a smooth envelope function of effective dose.

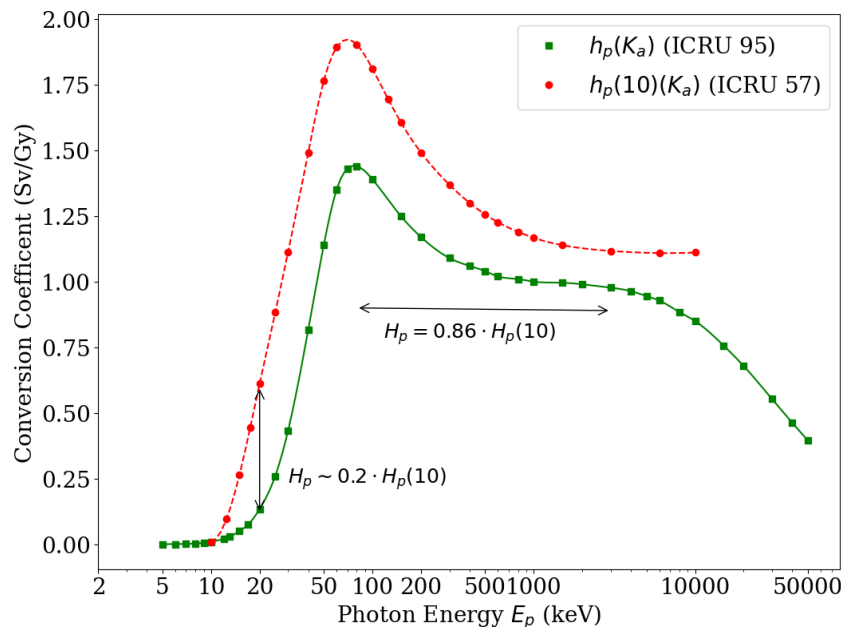


Fig. 1. Energy dependence of the conversion coefficients from kerma in air to personal dose equivalent  $h_p(10)$  (red circles, dashed) and of personal dose  $h_p$  (green squares, continuous) for photons. In the energy range of radionuclides, the new quantity delivers only slightly lower results. At low photon energies, the differences are more pronounced.

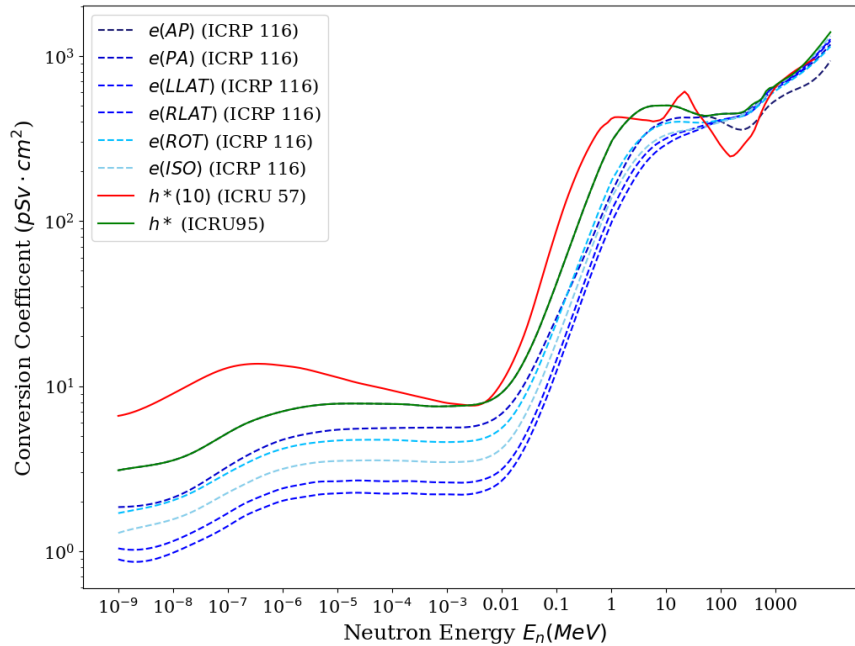


Fig. 2. Energy dependence of the conversion coefficients from neutron fluence to effective dose in six different irradiation directions  $e(\text{DIR})$  (blue, dashed lines), to ambient dose equivalent  $h^*(10)$  (red line) and to ambient dose  $h^*$  (green line).

#### 4. OPERATIONAL DOSIMETRY IN REALISTIC RADIATION FIELDS

When a new operational quantity for ionising radiation is introduced, one has to investigate how results obtained from it compare to those from the current operational quantities, in the same radiation fields. Here, we limit ourselves to photon radiation fields, in which the majority of occupational exposure happens.

Gamma- and beta-radiation from activation products at accelerators was investigated by Otto and Widorski (2021). As observed above, the dominant photon emissions of many radionuclides fall into the energy range where the numerical values of personal or ambient dose  $H_p$  or  $H^*$  are about 86 % of personal or ambient dose equivalent  $H_p(10)$  or  $H^*(10)$ . The impact of the new quantities on measurements in radiation fields from activation products is therefore small. The contribution of the beta-component of the radiation field to the whole-body quantities has been underestimated by the present quantities by about a factor of two. The practical consequences of this are probably minor: beta radiation is usually negligible for whole-body exposure, and the new operational quantities for the exposure of skin and extremities are nearly unchanged with respect to the present quantities.

X-ray qualities from the RQR and RQA series, used to determine the characteristics of medical X-ray equipment (IEC, 2005), are taken as a surrogate for workplace radiation spectra at medical workplaces (Otto, 2019b; Behrens and Otto, 2022). Here one finds that operational dose values measured by the new quantities are about a factor of two lower than with the current quantities. The reason for this is the overestimation of effective dose  $E$  by the current operational quantities for low-energy x rays. It may point to an overestimation of effective doses for personnel operating in these radiation fields. This observation requires more research.

Further investigations into the impact of the new operational quantities on predictions or measurement results in known radiation fields are currently carried out. They include radiation fields in medical practice, in the nuclear industry and at particle accelerators.

## 5. RESPONSE OF DOSIMETERS AND MONITORS TO THE NEW QUANTITIES

The principal use of operational quantities is the calibration of personal dosimeters and radiation protection monitors. The suitability of existing and currently used radiation instruments calibrated in the new quantities and their continued use for radiation protection measurements depends on the type of the dosimeter or instrument, and the area of application (Otto, 2019a; Ekendahl et al., 2020).

Fig. 3 shows the relative response for two radiation dosimeters. In a common Geiger-Müller counter-based instrument for photon radiation, the shielding effect of the solid housing ensures that the device is blind to photons with an energy below 50 keV. Such and similar dose rate monitors can continue to be used after recalibration to the new operational quantity ambient dose. This will not be possible for a modern personal dosimeter. According to the requirements, it correctly determines the personal dose equivalent  $H_p(10)$  for photon energies down to 15 or 20 keV. In doing so, however, it overestimates the effective dose of the photons and thus the new quantity personal dose  $H_p$ . A simple recalibration is not possible, and innovative dosimeter developments are required to correctly record radiation exposure in terms of the new dosimetric quantity (Eakins and Tanner, 2019; Hoedlmoser et al., 2020). Rem-counters, widely used as area monitors for neutrons, deliver dose values within broad acceptance limits defined by the IEC. The change to operational quantities recommended in ICRU Report 95 will at the most require a recalibration and a slight adjustment of the acceptance limits (Eakins et al., 2018).

The new quantities can and will not be introduced as legally and regulatory valid before the publication of the next general recommendations of the ICRP in 2031. That implies a generous duration for the adjustment phase in which the current quantities remain valid. This timetable will leave ample time to assess the consequences in all relevant radiation fields and, where necessary, to develop suitable radiation monitors and personal dosimeters.

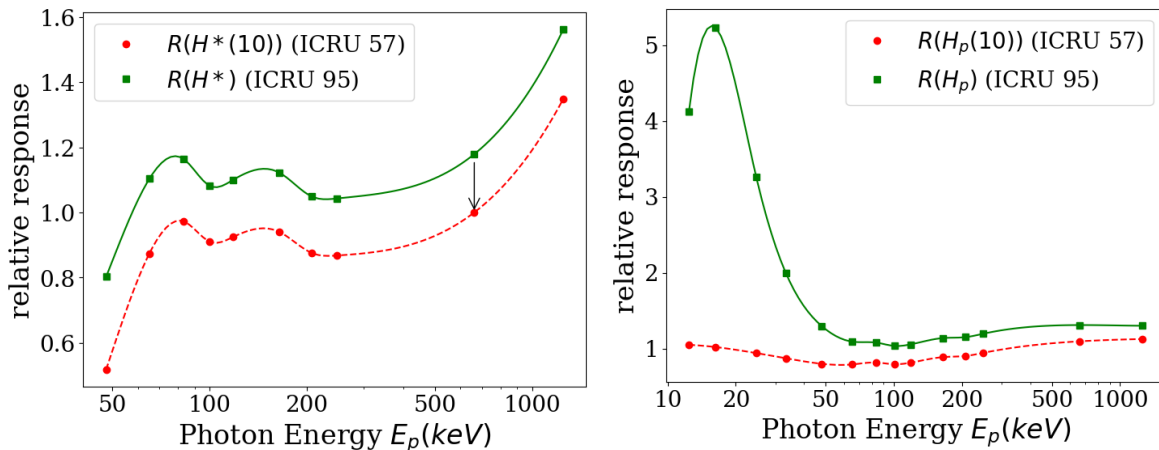


Fig. 3. Relative response of radiation dosimeters. Left: a Geiger-Müller tube-based radiation protection monitor. The robust housing cuts off low-energy photon radiation and a simple recalibration at the reference energy of 662 keV (arrow) would correct the overestimation of the ambient dose  $H^*$  by approx. 15%. Right: a modern personal dosimeter. A simple recalibration would not suffice to correct the response of the dosimeter to personal dose  $H_p$  over the full energy range.



## 6. CONCLUSION

ICRU and ICRP have introduced new operational quantities for the dosimetry of external radiation. Their definition is based on the protection quantities, notably the effective dose  $E$ . The proposed operational quantities simplify the system of radiation protection quantities by removing the difference of the current concepts in the definitions of protection and operational quantities. Changes in the measured values are to be expected at low photon energies, where the overestimation of the effective dose by current operational quantities is avoided. In this energy range, an adjustment of personal dosimeters will become necessary. The consequences of introducing the new operational quantities in other radiation fields and on different dosimeter types are currently examined by various institutions. It is estimated that it will take 15–20 years before the new quantities become legally mandatory, which is sufficient time for research and development and related adjustments for instrumentation.

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## Case study on occupational exposures to radiation with possible co-exposure to heavy metals

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**Abstract**—Biodosimetry is a valuable tool for determining the ionising radiation dose received by exposed individuals. The dicentric chromosome assay and translocation analysis are both standardised methods of biodosimetry which analyse chromosome damage. The dicentric chromosome assay is most suitable for acute exposures in the recent past as the dicentric frequency decreases with time after exposure. Translocation analysis is more appropriate for chronic exposures and older exposures as the translocations are considered stable and long-lasting. For both, analysis of low doses is difficult due to the stochastic nature of the damage and high levels of uncertainty. Complicating matters, confounding factors, such as medical exposures or exposures to heavy metals, have been shown to have an additive or synergistic effect to damage from radiation. For the situation described here, the individuals were welders who were also potentially exposed to both radiation and heavy metals. Biodosimetry was performed on 8 welders who were potentially exposed to ionising radiation during an industrial radiographic procedure using <sup>192</sup>Ir for non-destructive testing. Analysis was performed 4–6 years after the suspected exposures and chromosome damage above expected background levels was detected. Here we discuss the analysis performed, the methods used to estimate whole-body doses and the involvement of confounding factors.

*Keywords:* Biodosimetry, Dicentric assay, Translocations, Accidental exposure, Confounding factors

### 1. INTRODUCTION

This investigation was prompted by a radiation protection incident reported to the Canadian Nuclear Safety Commission (CNSC) on 23 March 2011. During non-destructive structural imaging using <sup>192</sup>Ir, a radiographer failed to observe many basic safety requirements while several non-radiation workers were conducting welding-related activities nearby. The original investigation by the CNSC conservatively evaluated the exposure to the non-radiation workers (welders) to be 1.5 mSv. These workers were informed of the low risk involved, the radiographer lost his licence, and the case was closed.

This incident would have remained closed, however one of the exposed welders developed health problems in the months following. When consulting a specialist, he realised that his health problems might have been caused by exposure to ionising radiation. He contacted the CNSC who referred him to Health Canada's Consumer and Clinical Radiation Protection Bureau, which is positioned to conduct biodosimetric analysis for the CNSC through a Memorandum of Understanding.

Following analysis of his blood sample, the dose was estimated to be 200 mSv calculated based on the presence of dicentric chromosomes and 100 mSv based on translocation analysis using Fluorescence *In Situ* Hybridisation (FISH). The number of dicentrics was corrected for

a typical temporal decay expected after 36 months. From this information, the investigators concluded that the dose received was between 100 and 200 mSv, which is well beyond the previously estimated dose (100 to 200 times higher). These results have been reported in Beaton-Green et al. 2016 where details on the methodology can be found.

Since the dose estimated by biodosimetric methods was much higher than the expected dose, the CNSC resumed the investigation and consulted other witnesses. On 18 February 2016, a new incident report was produced that noted that the unsafe conditions caused by the radiographer were likely to have been repeated several times in the past resulting in higher exposures for the welders. They concluded that this could help explain the biodosimetry results.

Following this finding, other employees were contacted and offered biodosimetric tests. On 13 November 2017, seven additional workers provided blood samples with all indicating cytogenetic damage above background. However, the interpretation of these results presented a significant challenge due to the length of time between exposure and testing in addition to possible confounding factors that further complicated the analysis.

### 1.1. Biodosimetry

Confirmation of radiation exposure and evaluation of the dose using biodosimetry is a standard approach if significant overexposure (>100 mSv) is suspected (Aleksanin et al., 2011; IAEA 2013). This technique was first used to study the case of individuals exposed to the Recuplex criticality accident on 7 April 1962, in Hanford, Washington (Bender and Gooch, 1966). In addition, biodosimetry methods are internationally standardised according to ISO 19238:2014 and ISO 20046:2019 (ISO, 2014, 2019).

This approach is based on measuring the incorrect repair of DNA damage that results from exposure to ionising radiation. By comparing the amount of damage in an individual's blood sample to calibration curves generated by measuring damage in *in vitro* irradiated blood cells, it is possible to estimate the radiation dose received by that person. In practice, this measurement is made on lymphocytes in peripheral blood. In this case, the analysis used two different techniques based on two types of chromosomal aberrations: a) the measurement of dicentric chromosomes [dicentric chromosome assay (DCA)] and b) the measurement of translocations using FISH.

Each technique has its advantages and disadvantages. Since dicentric chromosomes are unstable, this signal disappears over time, however, this method offers the advantage of being relatively simple and inexpensive to implement. Moreover, since the signal disappears over time, the background levels are very low (Hoffmann and Schmitz-Feuerhake, 1999). In addition, dicentric chromosomes are very radiation specific (Hoffmann and Schmitz-Feuerhake, 1999) and have been admitted as a sufficient legal proof of radiation exposure in some cases (Aleksanin et al., 2011).

Alternatively, the FISH method examines stable damage (translocations), so it can be used long after exposures. However, since this damage is stable, it also accumulates throughout life, therefore, it is necessary to subtract the background level of these mutations by comparison with reference subjects. Furthermore, clastogens other than ionising radiation can produce this type of damage (Bender et al., 1988; Grégoire et al., 2010a,b). This damage can also be observed both in cells that have been irradiated and their progeny. This poses certain challenges in interpreting the effect of time on this measurement (Pressl et al., 1999; Simon et al., 2007; IAEA, 2013).

## 2. MATERIALS AND METHODS

The sample processing, slide staining, scoring and analysis are described in Beaton-Green et al. (2016). It is briefly described here.

### 2.1. Sample Collection

Venous blood samples were drawn from individuals and shipped to Health Canada (HC) while maintained at room temperature and according to the appropriate Transportation of Dangerous Good protocols. The individuals gave signed consent for the analysis to be conducted.

### 2.2. Sample processing

Immediately upon receipt of the blood, samples were processed for cell counts, FISH and DCA according to the same HC protocols used for the calibration curves. Whole blood cultures were initiated as described by the IAEA (2013). Whole blood was added at a 1:10 ratio to culture medium (RPMI1640, Invitrogen, Burlington, ON, Canada) which was supplemented with heat-inactivated 15% fetal bovine serum (Sigma-Aldrich, Oakville, ON, Canada), 2 mM L-glutamine-penicillin-streptomycin (Sigma-Aldrich), 5  $\mu\text{g mL}^{-1}$  5-Bromo-2'-deoxyuridine (BrdU, Sigma Aldrich) and stimulated with 2% phytohemagglutinin (Invitrogen). Cultures were incubated at 37°C and 5% CO<sub>2</sub> for 48 h. After 44 h, the cultures were treated with 0.1  $\mu\text{g mL}^{-1}$  Colcemid block (Invitrogen) to restrict the lymphocytes to first metaphase. Cells were harvested after treatment with 0.075 mM potassium chloride and fixed with fresh Carnoy's fixative (3:1 methanol:acetic acid) and placed in a -20°C freezer overnight prior to slide preparation.

### 2.3. DCA Slide Preparation and staining

The DCA was performed according to a standard protocol with Fluorescence-plus-Giemsa-staining, which allowed for the analysis of dicentric chromosomes in first metaphase cells (ISO, 2014). Slides were prepared by dropping the cell suspension onto glass microscope slides (Fisher Scientific, Ottawa, ON) in a Hanabi metaphase spreader (Adstec, Funabashi-city, Chiba Japan) and then placed on a slide warmer at 37°C overnight. The slides were then stained for 2 minutes in 20  $\mu\text{g mL}^{-1}$  Hoechst 33258, placed on a slide warmer at 60°C and flooded with 0.6 M Na<sub>2</sub>HPO<sub>4</sub> (pH 9) before being mounted with glass coverslips. After being incubated under 365 nm UV light for 8 mins, the coverslips were removed and the slides were stained with Giemsa and mounted and sealed under glass coverslips with Permount.

### 2.4. FISH Slide Preparation and Hybridisation

Three-colour FISH was performed according to the protocol described by Beaton-Green et al. (2016). The following premixed probes were used: chromosome 1 (Texas Red spectrum), chromosome 2 [Fluorescein-Isothiocyanate (FITC) spectrum] and chromosome 4 (Texas Red and FITC combined). Staining was carried out according to the standard protocol provided by the probe manufacturers (Cytocell 1, 2, 4 DirectProbe, Rainbow Scientific; Windsor CT, USA or XCP Probe Mix 1-2-4, Metasystems Group Inc, Newton, MA, USA). The slides were mounted and sealed under glass coverslips, sealed and stored at -20°C.

## 2.5. Scoring and analysis

The slides were visualised under bright field or fluorescent microscopy (DCA or FISH, respectively) on a Metafer Slide Scanning System (Metasystems Group Inc., Watertown, MA, USA). Spreads were scored using the IAEA and ISO guidelines. All damage was recorded and verified by a second scorer. For dose estimation, the number of dicentrics (dics) or the number of translocations (trans) were used for DCA or FISH respectively (Table 1).

The translocation results were adjusted for age-related background by subtracting the expected age-related number of translocations from the observed numbers of translocations. This was carried out using the results from Sigurdson et al. (2008) and allowed the dose to be calculated by comparison with the age-related background-adjusted HC calibration curve (Beaton-Green et al., 2016). Since only 3 pairs of chromosomes were painted, the number of cells evaluated were converted to the equivalent number of cells scored that would have resulted in the number of translocations detected, if the whole genome had been painted (genome equivalent cells) by dividing by 2.46.

Table 1. Biodosimetric measurements.

Worker	Dicentric Analysis		Translocation analysis					Excess frequency (trans/1000 cells)
	Cells	Dics	Cells	Genome equivalent cells	Trans	Background trans	Excess trans	
W1	970	9	8001	3248	35	21.0	14.0	4.3
W2	983	5	10,038	4075	58	37.9	20.1	4.9
W3	983	7	10,012	4065	43	27.2	15.8	3.9
W4	991	5	10,046	4079	45	26.5	18.5	4.5
W5	987	5	10,111	4105	41	38.2	2.8	0.68
W6	990	7	10,020	4068	45	37.8	7.2	1.8
W7	978	7	10,072	4089	47	33.9	13.1	3.2
W8	987	9	10,177	4123	32	27.7	4.3	1.0

## 3. RESULTS

Examination of dicentric chromosomes showed a frequency of 5 to 9 dicentrics per 1000 cells, which is well above their natural frequency of between 0.5 and 1.0 dicentric per 1000 cells (Lloyd et al., 1980; Aleksanin et al., 2011; IAEA, 2013). Note that in some jurisdictions, this number of dicentrics alone constitutes evidence of exposure to ionising radiation over 100 mSv (Aleksanin et al., 2011). Excess translocations are expected to be produced at the same frequency as dicentrics, since they are governed by the same biophysical process. The frequencies varied from 0.7 to 4.9 excess translocations per 1000 cell equivalents. These values are significantly lower than those reported for dicentrics, which is the opposite of what is expected since dicentrics are unstable.

### 3.1. Incident dose calculation

The dicentric frequency was compared to the HC 250 kVp x-ray calibration curve to calculate dose, standard error, 95% confidence limits, adherence to the Poisson distribution and minimum detectable dose for this assay, using the Dose Estimate software (doses shown in Table 2). An independent statistical analysis, which agreed with the HC analysis, was

performed with the Radir R package (Higuera et al., 2015; Moraña et al., 2015) as the full statistical distribution was needed for legal purposes.

It should be noted that these are raw data not corrected for the effect of time or exposure to medical radiation and represent an equivalent whole-body dose. In order to account for the dose from medical procedures, an estimate of the whole-body dose equivalent for each individual was made based on their medical records and was corrected for the passage of time until the time of the biodosimetry analysis. The approach used for dose calculation depended on the modality. Typical diagnostic radiological exams present negligible doses, however, for the examination of the digestive tract we used a value of 3 mSv, for the examination of the lumbar spine, 1 mSv and for the examination of the sacroiliac region, 0.4 mSv (ICRP, 2007). For computed tomography, we used the dose length product (DLP), expressed in mGy·cm and converted it to mSv using a coefficient adopted by Association des physiciens et ingénieurs biomédicaux du Québec (APIBQ, 2009), which was largely based on the work of Shrimpton and Jones (1993), as recommended by the European Commission (EC, 2000), the International Commission on Radiological Protection (ICRP, 2007), the American Association of Physicists in Medicine (AAPM, 2008) and the National Council on Radiation Protection (NCRP, 2019). For nuclear medicine examinations, the quantity of radioisotopes injected was converted to an effective dose using the coefficients given in *publication 128* of the ICRP (ICRP, 2015). A dose of 1 mSv associated with the radiation produced by the computed tomography examination was added (Charest and Asselin, 2018). A two-population decay model for medical radiation exposure was used: One with a half-life ( $t_{1/2}$ )  $\cong$  5 months and the other with  $t_{1/2} \cong$  36 months, the breakpoint occurring at 14.5 months. This model-fit was based on a meta-analysis of the data available in the literature on the temporal evolution of the concentration of dicentric chromosomes following overexposures (Dutil et al., 2022).

We then obtained a residual dose that could not be explained by medical examinations. This dose was then corrected for the temporal decrease in the number of dicentric chromosomes since 23 March 2011. For this correction, we only used the slow decay term ( $t_{1/2} \cong$  36 months) (Simon et al., 2007; IAEA, 2013) since the dose rate was much lower for the potential worker exposures (few mGy h<sup>-1</sup>). It is recognised that there are large uncertainties in the dose estimates based on these calculations that are impossible to consider in the current state of science.

Table 2. Dose calculations.

Worker	Dose (raw)		Dose medical initial	Dose medical aged	Residual DCA	Dose incident DCA
	FISH	DCA				
	mSv					
W1	51	84	38	5	79	192
W2	59	33	41	8	25	118
W3	46	58	1	0	58	273
W4	54	32	0	0	32	151
W5	8	33	43	21	12	57
W6	21	57	13	10	46	217
W7	38	58	25	4	55	257
W8	12	82	22	9	73	346

#### 4. DISCUSSION

The interpretation of biodosimetry results is problematic when the measurements are taken after a significant delay in time, especially if only a fraction of the body is exposed. Vinnikov et al. (2010) have produced a review of the various associated issues. This is compounded by

the relatively high threshold of the FISH method (IAEA, 2013), which is close to the dose estimated from the dicentric.

In addition, even when taking into consideration previous medical exposures, once corrected for the decrease in the number of dicentric chromosomes over time, the doses calculated for the time of the incident (23 March 2011) are significant and higher than the physical dose estimates based on the exposure scenario. Alternative exposure scenarios were examined: Lost sources, metal contaminated by radioactive material, thorium welding rods and radon exposure. None could explain the observed genetic damage. This left the ionising radiation as a main culprit, with possible contributions from others clastogenic agents.

#### 4.1. Other clastogenic agents

A review of the scientific literature shows that the number of dicentrics observed in these individuals is much higher than expected during typical occupational exposure for welders (Bloom et al., 1980; Koshi et al., 1984; Jelmert et al., 1994, 1995; Yadav et al., 2001) and that the observed level is more compatible with exposure to radiation than to chemicals. It is important to note that the authors often mention that these are acute exposures which are not necessarily representative of normal work situations.

For example, the exposure of welders to metal fumes is common in their work (especially manganese, chromium and nickel) (Antonini, 2003). Benzene vapours could also have been present in the air. It is also possible that workers have been exposed to lead, manganese or arsenic in drinking water, at home or at work (Turcotte, 2006; Ibanez, 2008).

The additive effects of radiation and other contaminants is recognised by UNSCEAR (2000). However, only limited data are available for combined radiation and metal exposures in human populations and strong evidence of interactions has not been observed. Also, metals and ionising radiation have been shown to produce combined effects in many other biological systems. In humans, the best-documented case of a combined effect with radiation is the synergistic effect of radon and cigarettes (Musili et al., 2017; Lee and Kim, 2019). However, Manti and D'Arco (2010) noted that there is only limited data on the effects of low levels of naturally occurring chemicals on ionising radiation damage.

A potential explanation for this phenomenon is of a physical nature: The presence of metals near the nucleus of the cell would allow more efficient absorption of radiation (Coppola et al., 1986; Busby, 2019), a property that is also used in radiotherapy (Chithrani et al., 2010; Su et al., 2014; Martinov et al., 2017; Li et al., 2020; Higashi et al., 2021; Kim et al., 2021). In addition, the presence of metals leads to oxidative stress and disrupts the molecular machinery responsible for repairing DNA damage in the cell (Au et al., 1994; Kawanishi et al., 2002; Takahashi et al., 2000, 2002a,b; Jomova and Valko, 2011; Graczyk et al., 2015; Pesch et al., 2015; Guo et al., 2019; Su et al., 2019).

An important technical detail that should not be overlooked is that the clastogenic effects of chemical compounds do not necessarily affect all chromosomes in the same way (Grégoire et al., 2010a,b), unlike ionising radiation. This may have an impact on biodosimetry calculations as only a fraction of the chromosomes is examined by the FISH method but all of them for DCA.

It is clear that the additive, even synergetic, interaction between ionising radiation and heavy metals is a significant phenomenon. However, it is equally clear that it is very difficult to quantify the impact of the combined effects.

##### 4.1.1. Genetic Signature of a Clastogenic Agent

There is a genetic signature of the clastogenic effects of heavy metals and chemicals: The presence of an overabundance of acentric fragments. The formation of dicentrics and

translocations requires the presence of two duplicate breaks close to each other to build a composite chromosome. In the case of ionising radiation, this happens naturally, because the breaks are clustered in space and time. However, in the case of chemical compounds, this is much less likely, as fractures rarely occur and are randomly spaced. Instead, the formation of acentric fragments is observed (Coppola et al., 1986; Vulpis and Coppola, 1990; Nuta et al., 2014). However, no excess acentric fragments were observed among the worker samples. A possible explanation for the lack of acentric fragments would be their preferential elimination compared to dicentrics. We explored the scientific literature to find out if this was plausible. Norman et al. (1966) indeed observed faster decay for acentrics than dicentrics. Likewise, Awa et al. (1978) observed that, 20–25 years after the atomic bombing, the number of acentrics in the group of survivors who received a dose of less than 100 cGy (~1 Sv) was similar to the control group while the number of dicentrics was significantly higher.

Since the biodosimetric tests have been carried out 3.8 years (W1) and 6.6 years (W2–W8) after the expected exposure period, it is likely that the concentration of acentric fragments has reached or is close to having reached its lowest level, rendering any trace undetectable. This should also be interpreted as an absence of exposure to chemical clastogens affecting lymphocytes close to the time of the biodosimetric test.

## 5. CONCLUSION

In this communication, we report the results of biodosimetry carried out years after an incident. The results presented were difficult to interpret due to the lag-time between the incident and the test. An apparent discrepancy between the dose estimated by biodosimetry and the physically reconstructed dose might be explained by co-exposure to heavy metals.

This illustrates the importance of biodosimetry in cases where there is little information available, but also the inherent limitation of the method as the time passes after the event particularly when there could be co-exposures to other clastogenic agents.

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# Lifetime of dicentric chromosomes for biodosimetry applications

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**Abstract**—In this study, data on the evolution of dicentric chromosomes population over time following a whole body exposure has been gathered and normalised starting from a scientific literature review. A decay curve has been established and finds applications in dose assessments based on dicentric chromosome frequencies inferred for a specified time following acute exposure. Further analysis has been done to characterise the observed variability between cases, which is an important factor to consider for error propagation. Adequate knowledge of the uncertainties is needed for appropriate interpretation, particularly when biodosimetry results may be correlated with other sources of information such as a physical dose reconstruction. It is also important for legal purposes in a worker compensation scheme.

*Keywords:* Biodosimetry; Dicentric assay; Accidental exposure

## 1. INTRODUCTION

Radiation-induced chromosomal aberrations are one of the hallmarks of exposure to ionising radiation and are fundamental to biodosimetry methods. Such methods can be applied to assess doses following acute exposures, particularly in the context of radiological and nuclear accidents, where it can be an essential complement to other information sources, such as physical dose reconstruction. The original method of biodosimetry based on dicentric chromosomes assay (DCA) dates from 1960 (Moorhead et al., 1960). And has been used for the first time during the Recuplex criticality accident (Bender and Gooch, 1966).

Dicentric chromosome assay (DCA) using blood lymphocytes is among the most frequently used methods of biodosimetry for whole-body dose assessment, notably because of its relative simplicity and sensitivity to low doses (from acute photon equivalent doses of 0.1 Gy). It is also very specific to radiation as two chromosomes breaks must occur close in time (<2 h) and space (<100 nm) must occur to them (Hoffmann and Schmitz-Feuerhake, 1999). It is based on a laboratory-established dose reference curve and on dicentric yield measurements from blood lymphocytes samples prepared under standard conditions based on ISO 21243:2008 and ISO 19238:2014 (ISO, 2008, 2014).

While applying DCA is relatively straightforward, dicentric chromosomes are unstable aberrations, hence they cannot divide and have a limited lifetime. Therefore, a corresponding knowledge of the decay curve is needed to assess the actual dose if a significant amount of time has passed between exposure and measurement. Dose estimation is an essential element in the analysis of claims for compensation in the event of illness caused by radiation (ILO, 2010; IAEA, 2021). Nevertheless, for legal purpose, the uncertainty attached this average decay curve must also be characterised (Vuille et al., 2017).

## 2. DATA SELECTION

Scientific literature was searched using combination of keyword like ‘biodosimetry+accident’, ‘Dicentric+lifetime’, etc in Google Scholar. Manual search was also carried for citation of each paper in an attempt to cover as extensively as possible the scientific literature, with a minimum amount of bias. This leads to the identification of 117 publications with biodosimetry measurements following radiation exposure.

Of these 48 were withdrawn because they did not use dicentric. In this sample, data from medical exposures (20) were removed because they were often very local. This also includes the classical work of Buckton et al. (1967) on ankylosing spondylitis patient, which is the core of the current estimate of dicentric lifetime. Work on animal (2) and cases of internal exposure (2) were also removed.

In addition, only cases with individual measurements were kept. Duplicate measurements were removed. Finally, only cases with one data point in the first 18 months were kept. After all these steps, only 23 cases matched the criteria. Reported doses varied between 0.35 and 5.3 Sv, with a median of 1.9 Sv. This must be kept in mind as in most cases, significant leukopenia is likely to have occurred. Therefore, for application in the low dose range (<500 mSv) these results must be taken with caution.

## 3. DATA ANALYSIS

To normalise the decay curve to a common reference, a linear regression was applied to the decay curve on the initial curve and the calculated intercept was used as the normalisation factor as done by Hoffmann and Schmitz-Feuerhake (1999). By trial and error, a time span of 18 months was found to produce the least dispersion on the average slope and was therefore adopted for this procedure.

The normalised data were then fitted with two slopes segmented linear regression using the R package, segmented, version 1.6-0 Muggeo (2008). It should be noted that the linear regression was carried on the log of the dicentric fraction to ensure the linearity.

Through this exploration of the dataset, two additional criteria for data selection were added. Non-detection of dicentric were removed from the data set to avoid distortion in the data. In addition, only follow-up to 90 months were conserved, since they were very few data points past this time, which made them have an excessive weight on the final result. At the end, only 109 data points survived the screening process.

The best model had two slopes: a short decay time  $t_{1/2} = 4.8 \pm 0.5$  months, and a long one  $t_{1/2} = 39 \pm 6$  months. Break between the two regimes is set at 14.8 months (CI 95% 11.5–18.2 months). Fig. 1 presents the results of this fit.

### 3.1. Error analysis

While the determination of the average curve is important, the dispersion around the average is also very important. In addition, it is essential to determine the internal uncertainty of the model to avoid double counting of statistical errors. Residual dispersion around the mean is the sum of the Poisson noise, biological dispersion and undermodelling error. Model uncertainty, which is relevant for error propagation is equal to the total dispersion minus the Poisson noise on individual data points, which can be evaluated from the number of dicentric in the sample.

Following this analysis, two dispersion regimes appear to be present. The first one applies to the first 10.5 months. In this period, the internal model dispersion is very low ( $\sigma \cong 4\%$ ). After this period the model uncertainty increases sharply ( $\sigma \cong 60\%$ ). Separate linear fitting of each

individual components indicates that apparent cause of this increase of dispersion is the variable ratio between the slow and fast decay component.

It should be also note that as far as can be told based on this data set the dispersion is constant within each section (homoscedasticity). This could be interpreted to as the indication that the decay slopes are universal.

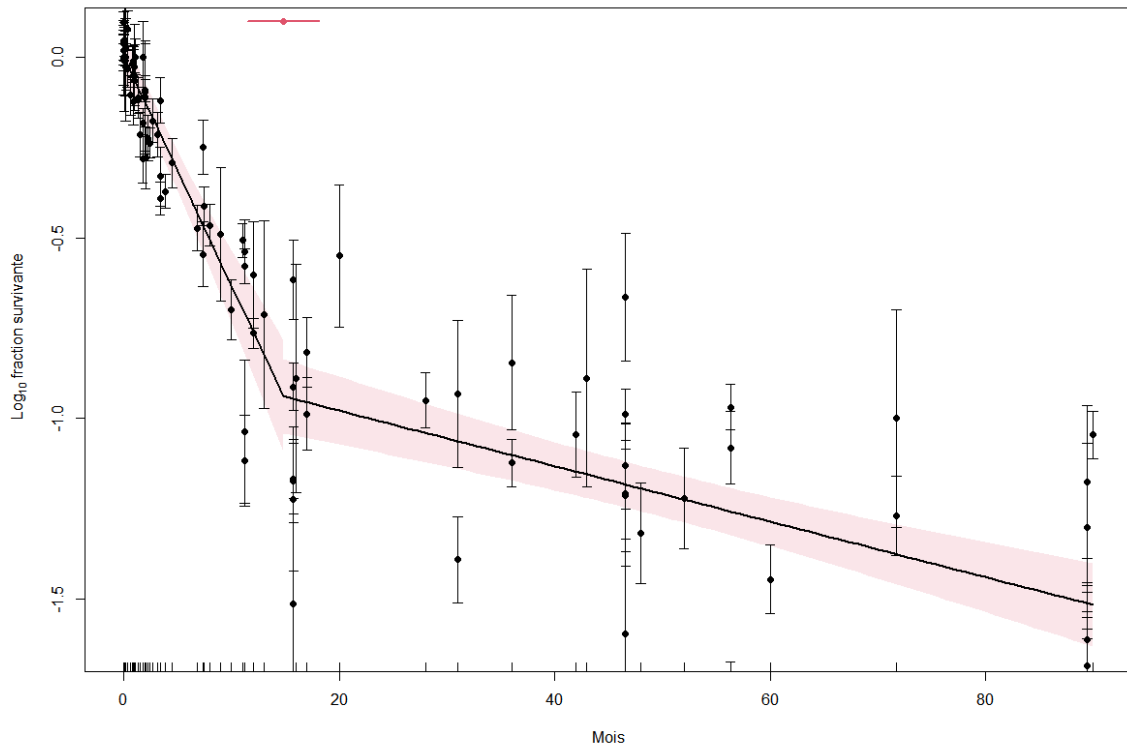


Fig. 1. An example figure with the caption fully justified, in a font size slightly smaller than the main text, in sentence case, and with a period at the end.

#### 4. DISCUSSION

The same decay curve is observed in many contexts Goiânia (Natarajan et al., 1998), Chernobyl (Sevan'kaev et al., 2005), and other accidents (Brewen et al., 1972; Voisin et al., 2000; Liu et al., 2013; Li et al., 2016).

The ratio between the slow and fast component does not appear to be related to age or dose. The fundamental cause of the presence of these two populations is unknown. This might be related to the nature of the genetic damage or the severity of the leukopenia. In addition, maybe there is two population of lymphocytes, each one with its own lifetime.

Nevertheless, some cases we have uncovered appears to not follow this general curve. The cause is unknown. Inspection of these cases raises the possibility this might be caused by the poor quality of the original data, an undocumented protracted or partial exposure or genetic instability. It is also possible that for some of them, the fast decay curve is not observed or represent a very small fraction.

It should be noted, a short-term increase of the number of dicentric following the initial measurement just after the exposure was observed. Therefore, the very first measurement following an accident might not be representative of the true dose. Follow-up measurements can be recommended on this basis.

## 5. CONCLUSION

A standard decay curve for the dicentric signal following accident whole body exposure. This curve appears to be composed of two components in a variable proportion. Not explanation was found for the variation of this ratio. This is still under investigation. Still, within the first 10 months post exposure, this appears to be inconsequential.

We also noted that the very first measurement might be not representative since an increase of the number of dicentric is sometime observed. Therefore, as a good practice a few data point should be taken within the first month post exposure. Then follow-up test should be carried (e.g. 3, 6, 12, 18, and 24 months later) and carried as long as practical.

It is obvious that more data are needed. Any data unpublished would be unvaluable to improve the data set. Please to communicate with us if it is the case. In addition, more data are needed for the low dose range (<500 mSv), which would be also relevant to most overexposure cases.

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# Modeling of heavy charged particle tracks overlap by pair of Al<sub>2</sub>O<sub>3</sub>:C, Mg dosimeters

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**Abstract**—Ion beam therapy (IBT) is the medical use of heavy charged particles to treat cancer due to their physical and biological properties, and damage the tumor at a given physical dose without causing damage to healthy tissues. The aim of this study was to investigate the ion track overlap (TO) from aluminium oxide doped with carbon and magnesium (Al<sub>2</sub>O<sub>3</sub>:C-Mg) dosimeters as a probability function. The dosimeters were exposed to proton 3 MeV u<sup>-1</sup> and carbon 26 MeV u<sup>-1</sup> heavy charged particle (HCP) beams-dosimeters in the interval of fluencies from  $2.23 \times 10^6$  to  $8.93 \times 10^7$  (ion cm<sup>-2</sup>). The TO occurs for fluencies higher than 10<sup>6</sup> cm<sup>2</sup> for all radiation types. A model for the TO process was developed, considering the dependence of the quantity of TO on the number of simulated tracks by a probability function, also the number of total induced tracks was determined. As the particle fluence increases, TO also increases, leading to increasing the number of track per spot. Therefore, the HCP fluence or dose at which the histogram starts to change may be an indication of onset of TO. It was observed that, TO starts from the fluence above 10<sup>6</sup> cm<sup>2</sup>, also the number of track per spot was increased with the increase of the fluence and the probability of getting one track per spot is approximately 100% for the very low fluence.

*Keywords:* FNTD; IBT; Track Overlap

## 1. INTRODUCTION

The radiation dosimetry community looked for a dosimeter that overcomes the limitations of current passive detector technology, and capable to be used in dosimetry of neutrons, protons and other heavy charged particles. Such a passive integrating detector would be sensitive to charged particles over a broad range of linear energy transfer (LET), require no post-exposure chemical processing, capable of multiple readouts using fully automated equipment, and possess the potential of being erased and reused.

Landauer Inc. has developed a passive integrating fluorescent nuclear track detector (FNTD) based on a single crystal of aluminium oxide doped with carbon and magnesium (Al<sub>2</sub>O<sub>3</sub>:C-Mg) and its readout technology, and have aggregate oxygen vacancy defects (Akselrod et al., 2003; Sanyal and Akselrod, 2005; Akselrod and Sykora, 2011). The FNTDs have demonstrated a promising performance for dosimetry of neutrons, protons and other heavy charged particles. FNTDs show a low-LET threshold of at least 0.4 keV μm<sup>-1</sup>, do not saturate at LET in water as high as 1800 keV μm<sup>-1</sup>, and are capable of irradiation to fluencies in excess of 10<sup>6</sup> cm<sup>-2</sup> without saturation (track overlap). FNTD may be a passive integrating sort of detector that doesn't require wires, electronics or batteries during irradiation. This detector is immune to electromagnetic interference and can measure doses at a very high dose rate (was successfully tested at 108 Gy s<sup>-1</sup>). FNTDs are made of sapphire and provide extremely good temperature and environmental stability, no light sensitivity or thermal fading. The detectors are produced in different sizes and shapes depending on the final application (Fig.1). Thin, 500 μm, polished wafers with 60 mm diameter were recently produced for radiation field imaging.

The tracks of recoil protons, heavy charge particles, or overlapping tracks of photoelectrons and secondary (delta) electrons generated in a crystalline detector are imaged using high resolution readout system based on the confocal laser scanning fluorescence microscopy technique (Diaspro, 2002). And they are appearing as bright objects on dark background in fluorescent contrast.



Fig. 1.  $\text{Al}_2\text{O}_3\text{:C-Mg}$  crystal and  $4 \times 6 \times 0.5 \text{ mm}^3$  FNTD (Akselrod et al., 2003).

## 2. METHODOLOGY

### 2.1. Dosimeter preparation and experiments

#### 2.1.1. Dosimeter preparation

In all experiments FNTD produced by Landure Inc was used in the form of rectangular chips having the dimensions of  $4 \times 8 \times 0.5 \text{ mm}^3$ , with the long side cut along the optical c-axis and with one large surface polished to optical quality.

The FNTD have been stick to LAB TEK cover slip with its polished surface faced to the radiation source.

#### 2.1.2. Dosimeter experiments

The dosimeters (FNTDs) were exposed to heavy charged particle (HCP) beams, proton with energy  $3 \text{ MeV u}^{-1}$ , LET  $14 \text{ keV } \mu\text{m}^{-1}$ , and Carbon with energy  $26 \text{ MeV u}^{-1}$ , LET  $73 \text{ KeV } \mu\text{m}^{-1}$  in the interval of fluencies from  $2.23 \times 10^6$  ( $\text{ion cm}^{-2}$ ) up to  $8.93 \times 10^7$  ( $\text{ion cm}^{-2}$ ) and at a  $2 \text{ Gy min}^{-1}$  flow-rate. Table 1. Explain the dose which is corresponds to the fluence for each radiation type. The proton irradiation had been done at the Van de Graaff accelerator in the Institute of nuclear physics of Lyon (IPNL), France, while the Carbon irradiation have been done at Grand Accélérateur National d'Ions Lourds (GANIL) facility in Caen, France.

All FNTDs were placed in homogeneous, mono-energetic particle fields.

Table 1. The dose corresponds to the fluence for certain radiation types with image size  $101.41 \times 101.41$  ( $\mu\text{m}^2$ ).

LET (Kev/ $\mu\text{m}$ )	14	73
Fluence (ions $\text{cm}^{-2}$ )	Dose (Gy)	
	Proton	Carbon
$2.23 \times 10^6$	0.05	0.26
$4.46 \times 10^6$	0.1	0.52
$8.93 \times 10^6$	0.2	1.04
$1.34 \times 10^7$	0.3	1.56
$2.23 \times 10^7$	0.5	2.60
$4.46 \times 10^7$	1	5.20
$8.93 \times 10^7$	2	10.40

## 2.2. Ion track detection

For ion track counting the following formula was used:

$$N = F \times S$$

where  $N$  is the number of tracks;  $F$  is the radiation fluence (ion  $\text{cm}^{-2}$ ); and  $S$  is the image size ( $\mu\text{m}^2$ ).

Ion tracks can be visualised with the confocal microscope over the entire ion range (from the FNTD surface to end of range). And the image processing was done using Matlab.

## 2.3. Track overlap

The track overlap occurs for fluencies higher than  $10^6 \text{ cm}^{-2}$  for all radiation types. This is an indication that number of track overlap per spot is increases for  $\text{Al}_2\text{O}_3$ : C-Mg dosimeters as the HCP fluence increases. A model for the track overlapping process was developed, considering the dependence of the quantity of overlapped tracks on the number of simulated tracks by probability function, and by a successive approximations, the number of total induced tracks (which is proportional to particle fluence) is determined from the knowledge of the radiation fluence, dimensions of the field of view and average track radius, it would be advantageous to develop a method to determine the number of tracks per spot on a detector from the knowledge of the total number of tracks and the track intensity.

Based on the HCP fluencies and analytical model of track overlapping by pair, we estimated that the probability  $P(n, i)$  that  $n_\Delta = n$  knowing the intensity  $i_\Delta = i$ . From the probability theory:

$$P(n, i) = PT(n/i) \times PI(i) = PI(i/n) \times PT(n)$$

where  $n_\Delta$  is number of ion tracks per spot and  $i$  is the intensity.

Then

$$PT(n/i) = (PI(i/n) \times PT(n)) / PI(i)$$

Determination of  $P(i)$ :

We considered an image (or as set of images on the same FNTD) for which the surface is S and the fluence of irradiation is F.

$$PI(i) = h(i) / \sum h(i)$$

where  $h(i)$  is the histogram of the spot intensities.

### 3. RESULTS

As the particle fluence increases, track overlap (TO) also increases, leading to increasing the number of tracks per spot. Therefore, the HCP fluence or dose at which the histogram starts to change may be an indication of onset of TO as shown in Fig. 2 and 3. It was observed that, TO starts from the fluence above  $10^6 \text{ cm}^2$ , based on the fluence and the model of the probability which determine the number of tracks per spot, also the number of tracks per spot is increased with the increasing of the fluence and the probability of getting one track per spot is approximately 100% for the very low fluence, as shown in Table. 2 and 3 for both proton and carbon ion irradiation.

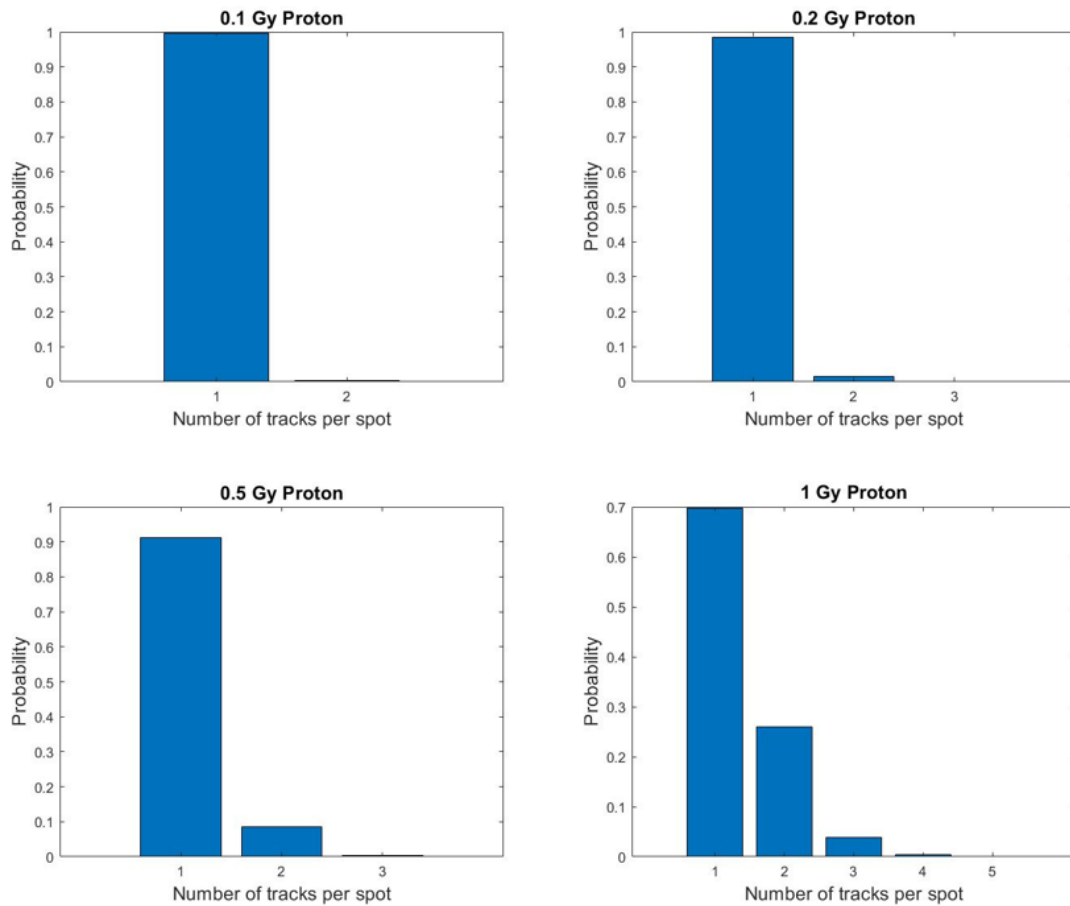


Fig.2. Shows overlapped Proton ion tracks per spot for different fluencies.

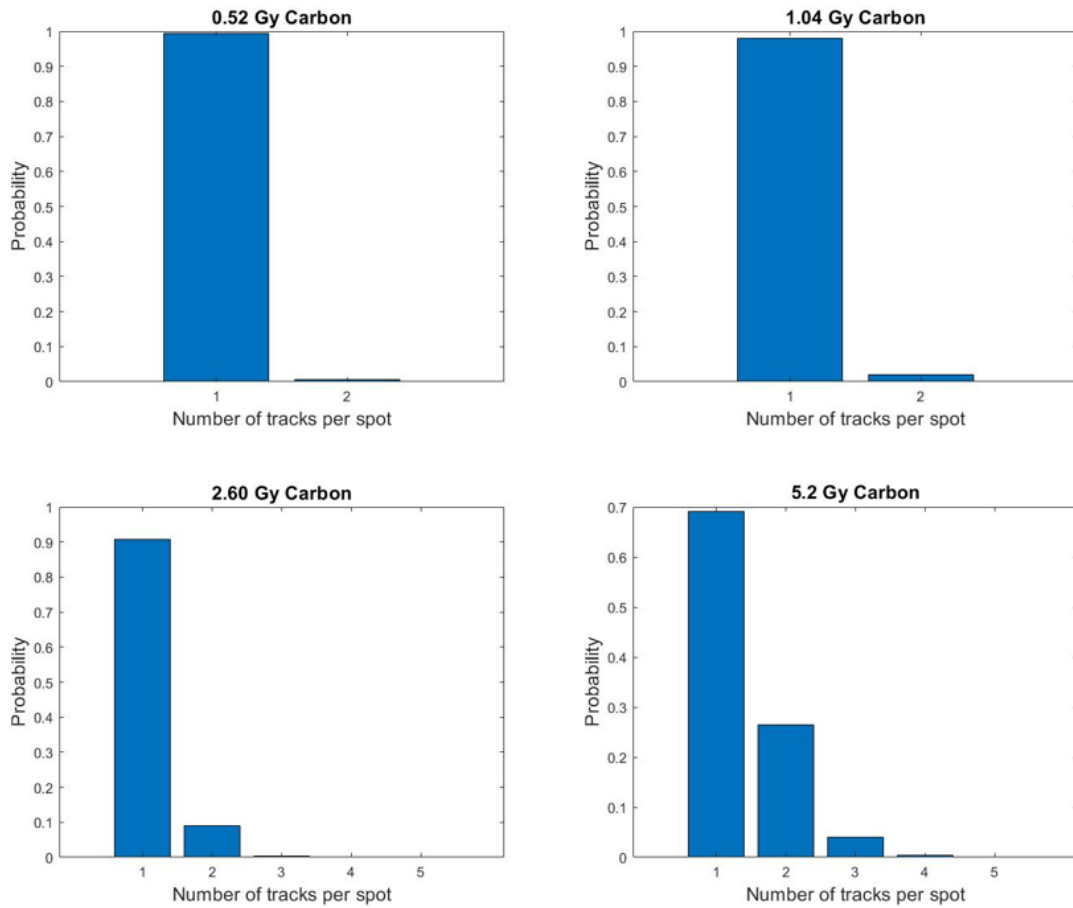


Fig.3. Shows overlapped Carbon ion tracks per spot for different fluencies.

Table 2. Explain the probability of ion track overlap per spot corresponding to proton irradiation fluence.

Dose (Gy)	Fluence ions cm <sup>-2</sup>	No track per spot	The probability
0.1	4.46×10 <sup>6</sup>	1	0.994
		2	0.005
		3	0.000
		4	0.000
0.2	8.93×10 <sup>6</sup>	1	0.984
		2	0.015
		3	0.000
		4	0.000
0.5	2.23×10 <sup>7</sup>	1	0.912
		2	0.084
		3	0.003
		4	0.000
1	4.46×10 <sup>7</sup>	1	0.69
		2	0.27
		3	0.04
		4	0.003

Table 3. Explain the probability of ion track overlap per spot corresponding to Carbon irradiation fluence.

Dose (Gy)	Fluence ions cm <sup>-2</sup>	No track per spot	The probability
0.52	4.46×10 <sup>6</sup>	1	0.996
		2	0.004
		3	0.000
		4	0.000
1.04	8.93×10 <sup>6</sup>	1	0.985
		2	0.014
		3	0.000
		4	0.000
2.6	2.23×10 <sup>7</sup>	1	0.913
		2	0.084
		3	0.003
		4	0.000
5.2	4.46×10 <sup>7</sup>	1	0.691
		2	0.268
		3	0.038
		4	0.003

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# External exposure of the public to radionuclides deposited in the terrestrial environments after the accident at the Fukushima Daiichi Nuclear Power Station: the UNSCEAR Model 2020

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**Abstract**—Assessments and forecasts of doses of external exposure to radionuclides deposited in the terrestrial natural and anthropogenic environments are often challenged by diverse environmental and social factors, which are unknown at the time of a nuclear emergency or shortly after but may substantially increase uncertainty of dosimetric estimates. The decade passed since the accident at the Fukushima Daiichi Nuclear Power Station (FDNPS) in 2011 demonstrated that the observed dynamics of ambient dose rates and the long-term forecasts of external exposures in Japan vary from those earlier observed after nuclear weapon tests, radiation accidents and other events of radiological emergency. Those earlier events provided the foundation for the model of external exposure in the UNSCEAR 2013 Report ‘Levels and effects of radiation exposure due to the nuclear accident after the 2011 great east-Japan earthquake and tsunami’. For the new UNSCEAR 2020/2021 Report vol. II ‘Levels and effects of radiation exposure due to the accident at the Fukushima Daiichi Nuclear Power Station: implications of information published since the UNSCEAR 2013 Report’, this model has been critically reviewed and further developed, using results of extensive systematic radiation monitoring in various environments and population-based studies with personal dosimeters conducted by experts in Japan. The new monitoring data created a supporting framework for validation of the improved models for estimation of population external doses from radionuclides deposited on the ground. The revised model follows the generic framework compatible to existing approaches, while considering country-specific features important for the public dose assessment. The model has been applied for forecasting external doses and their uncertainties due to unknown future trends of dose rate dynamics or population behaviour. The new model can be effectively applied for assessment of cumulative external doses and related uncertainties for various exposure scenarios, e.g. for evacuated members of the public returning to their homes, members of population born after the accident, environmental changes occurring as a result of countermeasures or remedial actions.

*Keywords:* External exposure; Deposited radionuclides; Nuclear accident; Fukushima Daiichi Nuclear Power Station (NPS)

## 1. INTRODUCTION

The nuclear accident at the Fukushima Daiichi Nuclear Power Station (FDNPS) in March 2011 was a major nuclear accident in the 21<sup>st</sup> century (IAEA, 2015) and, due to this, it was shortly addressed by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and the World Health Organization (WHO) in their reports (WHO, 2012, 2013; UNSCEAR, 2014). The decade since the accident at the FDNPS had resulted in collection of a substantial amount of radiological and radioecological data in Japan, thus motivating the UNSCEAR to review its earlier estimates of radiological impact on the population and the environment of Japan (UNSCEAR, 2014) and to critically re-evaluate these

estimates and forecasts of possible radiation effects. This work had resulted in the new UNSCEAR Report 2020/2021, Annex B (UNSCEAR, 2022).

To facilitate development of a new report, the UNSCEAR created in 2019 a dedicated task group focused on population exposure via different pathways, including external exposure from radionuclides deposited in the terrestrial environments. The model for external exposure of Japanese population in the previous UNSCEAR 2013 Report (UNSCEAR, 2014), termed here the model M2013, was largely based on the Chernobyl-specific data. Given the vast amount of radioecological information collected in Japan in 2011–2019, the model M2013 was carefully reviewed and tested using contemporary radiation monitoring results and country-specific population data. Correspondingly, the new UNSCEAR model, termed here the model M2020, had been developed and thoroughly validated using radiation monitoring and individual dosimetry data, thus providing a computational basis for the new estimates of the external exposure of the population in Japan.

This paper outlines distinctive features of the new UNSCEAR model M2020 for external exposure, describes its independent validation using personal dosimetry data and discusses country-specific changes in the dose computation methodology.

## 2. EXTERNAL EXPOSURE DUE TO RADIONUCLIDES ON THE GROUND

Inheriting from external dosimetry techniques developed since 1960s following atmospheric tests of nuclear weapons and nuclear accidents, which resulted in radioactive fallouts in the environment throughout the globe (see, e.g. Beck and de Planque, 1968; Jacob and Paretzke, 1986; Jacob and Meckbach, 1987; Golikov et al., 2002; Likhtarev et al., 2002; Minenko et al., 2006), the model M2020 estimates the cumulative effective and organ-specific equivalent doses, given specific age and lifestyle information for a population group of interest. Practically, it is achieved by integration of effective or organ equivalent dose rates for a specific personal age at the time of accident (UNSCEAR, 2022) taking into account:

- temporal changes of the ambient dose rates due to processes of radioactive decay, radionuclides' redistribution by downward migration in soil, weathering and runoff;
- the varying activity ratios for shorter-lived radionuclides and <sup>137</sup>Cs deposited on the ground;
- the location factors which express variation of the ambient dose rates at various places in various environments (e.g. outdoor in natural environment and in populated areas, indoor in diverse types of houses);
- the occupancy factors which describe human behaviour and represent average time shares spent by different population groups (e.g. school or pre-school children, office or outdoor workers, etc) in various locations;
- age- and sex-dependent dose coefficients (ICRP, 2020) from various radioactive sources distributed in soil.

The integral effective or organ equivalent dose  $D(t_1, t_2|a, s)$  (mSv) during the period from  $t_1$  to  $t_2$  for a person of sex  $s$  and age  $a$  at time of the main deposition in 2011 can be expressed, as follows:

$$D(t_1, t_2|a, s) = q_{137} \int_{t_1}^{t_2} \sum_m \rho_m e^{-\lambda_m t} \dot{D}_m(a + t, s) \sum_j f_j(t) p_j(a + t) dt, \quad (1)$$

where  $q_{137}$  is the <sup>137</sup>Cs deposition density (kBq m<sup>-2</sup>) on 15 March 2011;  $\rho_m = q_m/q_{137}$  is the ratio of deposition density  $q_m$  (kBq m<sup>-2</sup>) of radionuclide  $m$  to that of <sup>137</sup>Cs, corrected to the same date of 15 March 2011;  $\lambda_m$  is the decay rate of the radionuclide  $m$  (year<sup>-1</sup>);  $f_i(t)$  is the



‘location factor’, i.e. time-dependent dose rate reduction factor in location  $j$  in comparison to dose rate above undisturbed open flat area with the same deposition density (unitless);  $p_j(a + t)$  is the occupancy factor, i.e. a share of time spent by a person of age  $a + t$  (year) in location  $j$ ;  $\dot{D}_m(a + t, s)$  is the dose rate (mSv year<sup>-1</sup> kBq<sup>-1</sup> m<sup>2</sup>) per unit deposition density of the radionuclide  $m$  for a person of age  $a + t$  and sex  $s$ .

The dose rate per unit deposition density changes with time due to redistribution of radionuclides and, in the model M2020, can be expressed using dose coefficients for either the planar source in soil at depth 0.5 g cm<sup>-2</sup> or the source exponentially distributed in soil depth with the time-dependent relaxation mass per unit area  $\beta(t)$  (ICRU, 1994). The former method uses the empirical function  $r(t)$  to express reduction of the dose rate with time:

$$\dot{D}_m(a + t, s) = C_m^p(a + t, s) r(t), \quad (2)$$

where  $C_m^p$  is the dose coefficient (mSv year<sup>-1</sup> kBq<sup>-1</sup> m<sup>2</sup>) for the planar source at depth 0.5 g cm<sup>-2</sup> from ICRP *Publication 144* (ICRP, 2020) and the function  $r(t)$  is conventionally approximated by a weighted sum of two exponentially decreasing terms reflecting fast and slow reduction of dose rates (Golikov et al., 2002; Likhtarev et al., 2002):

$$r(t) = A e^{-\frac{\ln 2}{T_A} t} + B e^{-\frac{\ln 2}{T_B} t}, \quad (3)$$

where the coefficients  $A$  and  $B$  add up to one, and time after deposition  $t$  and effective half-lives  $T_A$  and  $T_B$  are expressed in years.

Alternatively, the dose rate reduction with time can be represented by the dose coefficients for exponentially distributed sources with time-dependent relaxation mass per unit area  $\beta(t)$  (see, e.g. Minenko et al., 2006; Mikami et al., 2019):

$$\dot{D}_m(a + t, s) = C_m^e(a + t, s, \beta(t)), \quad (4)$$

where  $C_m^e(a + t, s, \beta(t))$  is the dose coefficient (mSv year<sup>-1</sup> kBq<sup>-1</sup> m<sup>2</sup>) for the source exponentially distributed in soil depth with the relaxation mass per unit area  $\beta(t)$  (ICRU, 1994; ICRP, 2020). This method requires interpolation of the tabulated dose coefficients but better represent changes of ambient radiation fields created by radionuclides deposited on undisturbed soil due to subsequent migration into the soil depth.

The both methods, however, assume that all deposited radionuclides follow time-dependent migration patterns identical to those for isotopes of caesium. This assumption is plausible for radiological conditions found after the Chernobyl accident in 1986 and the accident at the FDNPS in 2011, because most of the released gamma-emitting radionuclides substantially decayed within the first year, thus the long-term dependence of the ambient dose rate was determined by the caesium isotopes <sup>134,137</sup>Cs, only.

### 3. DETAILS OF THE UNSCEAR MODEL 2020

#### 3.1. Isotopic composition of the deposited radioactivity

Isotopic composition of radioactive fallouts following the accident at the FDNPS varied across the country and both UNSCEAR reports (UNSCEAR, 2014, 2022) consider differently the whole territory of Japan and the, so-called, South Trace, where significantly higher ratios of activity concentrations of <sup>131,132</sup>I and <sup>129m</sup>Te to that of <sup>137</sup>Cs were detected. Both models, M2013 and M2020, account for contributions to the ambient dose from gamma-emitting radionuclides <sup>110m,110</sup>Ag, <sup>129,129m,132</sup>Te, <sup>131,132,133</sup>I, <sup>134,136,137</sup>Cs, and their progeny. The model M2013 assumes constant ratios of activities of these radionuclides to that of <sup>137</sup>Cs, while the

model M2020 for isotopes of iodine and tellurium uses non-linear relationships derived from available data on radionuclide composition of the fallout. For remaining gamma-emitting isotopes of caesium and silver, the activity ratios in the model M2020 are the same as in the preceding model M2013.

The isotopic composition of the deposited radionuclides was estimated using data of the Japan Atomic Energy Agency (Saito et al., 2019), extended with  $^{131}\text{I}$  data reconstructed by Muramatsu et al. (2015) from data on  $^{129}\text{I}$  deposition. The values of activity ratios, accepted in the model M2020, are shown in Table 1, where ranges for the isotopes of iodine and tellurium indicate application of the non-linear relationships, using a power function (see details in Attachment A-1 of UNSCEAR, 2022). The non-linear relationships for ratios of activities of iodine and tellurium to activity of  $^{137}\text{Cs}$  in the deposited radioactive materials reflected an observation that in the South Trace locations higher ratios were observed for low and moderate  $^{137}\text{Cs}$  deposition densities, up to  $0.3 \text{ MBq m}^{-2}$ , than those observed at other territories. The measured ratios increased with the decrease in  $^{137}\text{Cs}$  deposition density. Correspondingly, this resulted in higher doses per unit deposition density of  $^{137}\text{Cs}$  in areas of South Trace with low absolute deposition density of  $^{137}\text{Cs}$ . For higher deposition density of  $^{137}\text{Cs}$ , the ratios are reducing and approaching those observed over all other territories.

Table 1. Activity ratios of the deposited radionuclides and  $^{137}\text{Cs}$  used in the model M2020.

Territory	Radionuclide activity relative to $^{137}\text{Cs}$ on 15 March 2011					
	$^{134}\text{Cs}$	$^{136}\text{Cs}$	$^{131}\text{I}$	$^{129\text{m}}\text{Te}$	$^{132}\text{Te}$ ( $^{132}\text{I}$ )*	$^{110\text{m}}\text{Ag}$
All of Japan excluding the South Trace <sup>†</sup>	1.0	0.17	8.3–37 <sup>‡</sup>	1.1–1.9 <sup>‡</sup>	7.6–13 <sup>‡</sup>	0.0028
The South Trace	1.0	0.17	25–250 <sup>‡</sup>	1.7–28 <sup>‡</sup>	12–190 <sup>‡</sup>	0.0028

\* Activity of the daughter  $^{132}\text{I}$  was assumed equal to that of the parent  $^{132}\text{Te}$  at the time of deposition.

<sup>†</sup> The towns of Naraha, Hirono, Yamatsuri, Iwaki City of Fukushima Prefecture, the towns of Kitaibaraki, Takahagi of Ibaraki Prefecture.

<sup>‡</sup> The ratio of the radionuclide activities was modelled by a non-linear power function (see Attachment A-1 of UNSCEAR, 2022 for details).

### 3.2. Dynamics of ambient dose rates

Dynamics of ambient dose rates is a crucial parameter for estimating cumulative external doses, especially, for forecasting doses in the situations of changing radioecological conditions due to natural or anthropogenic activities, migration of the population (evacuation or return), or dose assessment for those born years after the accident.

Phenomenological factor  $r(t)$ , describing relative reduction of the ambient dose rates in air due to processes of migration, weathering and runoff, was pragmatically approximated by a two-exponential expression with the half-lives representing fast and slow components in the observed data. The model M2013 was based on the experience gained after the Chernobyl accident (Golikov et al., 2002; Likhtarev et al., 2002) and used equal weights for two components with half-lives 1.5 and 50 years. Based on the measurements of the ambient dose rates above undisturbed sites (Mikami et al., 2019), a different parameterisation was selected for the model M2020, namely, expressing the relative reduction of the dose rate as a result of processes with half-lives of 2.8 and 20.7 years with relative weights 37 and 63%, respectively. The long-term modelled dynamics was found compatible with global fallout data (Miller et al., 1990; Schimmak et al., 1998) for the period 25–30 years after deposition. Overall, the relative time dependence of the ambient dose rate in the model M2020 complies with observations and differs from that in the preceding model M2013.

Changes of the ambient radiation field above flat undisturbed site, not counting for radioactive decay, are mainly due to migration of radionuclides into soil depth. This process can be effectively represented by radiation field created by time-dependent exponential sources in soil (Beck and de Planque, 1968; Minenko et al., 2006; Saito and Petoussi-Henss, 2014). For the post-Fukushima experience, Mikami et al. (2019) reported values of the effective relaxation mass per unit area for undisturbed sites, mostly, in the 80-km zone around the FDNPS during the period 2011–2017. From their data, the initial value of the relaxation mass per unit area  $\beta_0 = 0.8 \text{ g cm}^{-2}$  with the annual change  $0.415 \text{ g cm}^{-2} \text{ year}^{-1}$  were deduced to describe transformation of an exponential source with time. These parameters result in relative reduction of the ambient dose rates, which was found in a good agreement with the empirically derived dose reduction function  $r(t)$  and the estimates based on the analysis of the global fallout data (Miller et al., 1990; Schimmak et al., 1998) (see Fig. A-1.III in Attachment A-1 of UNSCEAR, 2022).

The relative reduction of ambient dose rates in Japan appeared slower during the first decade than it could be inferred from the Chernobyl-based experience and predicted by the model M2013. This effect can be attributed to stronger fixation and reduced mobility of caesium in Japanese soils (IAEA, 2020; UNSCEAR, 2022).

### 3.3. Location factors

The model M2013 was mostly based on the experience gained after the Chernobyl accident in 1986. At that time in the former USSR, the standard procedure of determination of radionuclides' deposition densities requested to collect soil samples at reference sites, represented by undisturbed open flat areas, free from strong vegetation and anthropogenic impact. Such sampling sites were regarded as reference ones in the model M2013 (see Attachment C-12 in UNSCEAR, 2014). Based on the post-Chernobyl experience, it was found that the ambient dose rate per unit deposition density in settlements and anthropogenically affected places is less than the dose rates per unit deposition density above undisturbed reference grasslands. The dose rates per unit deposition density for unpaved areas in settlements were shown to be less than dose rates at the reference sites by, at least, factor 1.3–1.7 (see, e.g. Meckbach and Jacob, 1988; Golikov et al., 2002). In the model M2013, this consideration resulted in the value of initial location factor 0.75 or less for transition from a reference site to an unpaved area in a populated place.

At the time when the model M2020 was under development, extensive data on ambient dose rates in diverse environments, including streets, roads, paved and unpaved areas in settlements, had been collected in Japan (see, e.g. Kinase et al., 2017; Andoh et al., 2018), thus providing an opportunity to check and validate the model parameters using country-specific datasets. The analysis has shown that the Japan-specific data does not suggest the same initial location factor for unpaved populated area, as it was assumed in the model M2013. Instead, the data for the reference sites were found to be very close to that for the unpaved areas in populated places. This was attributed (Attachment A-1 of UNSCEAR, 2022) to a specificity of the Japanese environment, comprising forested mountains and strongly anthropogenically affected flatlands, unlike the environmental conditions found in the Chernobyl-affected areas of Belarus, the Russian Federation and Ukraine. Correspondingly, the model M2020 treats location factors differently than the preceding model M2013, thus reflecting effect of terrains and landscapes in the anthropogenic and semi-natural terrestrial environments of Japan.

### 3.4. Dose coefficients

ICRP *Publication 144* (ICRP, 2020) introduced dose coefficients for human external exposure to environmental sources of radiation, and the model M2020 took advantage to use

these. The dose coefficients of *Publication 144* are for ‘effective’ planar source as well as for various exponential sources in soil for six reference ages from a newborn to an adult. For use in M2020, the dose coefficients were smoothly interpolated on age and relaxation mass per unit area, thus allowing for accurate automated integration of a time-dependent dose rate functional. The dose coefficients of *Publication 144* are presented in terms of effective and organ equivalent doses as well as ambient dose equivalent and kerma in air (ICRP, 2020), thus facilitating correct conversion between diverse quantities and comparisons to measured data.

A possibility of using the dose coefficients for the ‘effective’ planar source in combination with the empirical time-dependent dose reduction function  $r(t)$  remained in the model M2020, providing a practical and simple approach for dose assessment and assuring back compatibility with methodology of the previous UNSCEAR 2013 Report and existing dose assessment and prediction approaches in Japan and worldwide.

### 3.5. Shielding from external radiation by houses and buildings

The model M2020 considers the same types of Japanese houses, as in the model M2013, for computation of the external doses during indoor residence: a wooden house, a wooden fireproof house and a concrete house or building. However, unlike the model M2013, where indoor location factors are presented with their own time dependencies, the model M2020 uses the time-dependent location factor for residential areas multiplied by a constant shielding factor. For the considered types of houses, these shielding factors have been selected equal to 0.4 for wooden houses, 0.2 for wooden fireproof houses and 0.1 for concrete buildings. These values agree with earlier studies (Meckbach and Jacob, 1988; Golikov et al., 2002; Likhtarev et al., 2002; UNSCEAR, 2014) as well as with recent observations in Japan. For example, Matsuda et al. (2017) reported the values of shielding factors for one/two-storey wooden or light steel frame houses in range 0.38–0.49 and the values for concrete building not exceeding 0.15.

### 3.6. Occupancy factors

Computation of population-averaged external doses requires to account for behavioural patterns of various social groups. Given age-dependence of dose coefficients and distinctively different location factors for indoor and outdoor exposures, the population was represented by children aged 1 and 10 years, two groups of adults, working outdoor and indoor, and retired people. The latter group was not explicitly considered in the UNSCEAR 2020/2021 Report (UNSCEAR, 2022) due to its occupancy factors being equal to that of an adult indoor worker. The occupancy factors for different population groups were selected based on the Japan national demographic statistics and surveys and are summarised in Table 2.

Table 2. Occupancy factors for representative population groups as used in the model M2020.

Type of location	Share of time spent by:			
	children aged		adult working	
	1 year	10 years	outdoor	indoor
Indoor, including:	0.9	0.9	0.7	0.9
at home and others	0.7	0.7	0.7	0.6
at work, school, kindergarten, etc.	0.2	0.2	—	0.3
Outdoor, including:	0.1	0.1	0.3	0.1
residential areas	0.1	0.1	0.2	0.1
unpaved surfaces	—	—	0.1	—

#### 4. VALIDATION OF THE MODEL

The model M2020 was developed and validated using extensive radioecological information systematically collected by Japanese experts in 2011–2019. Additionally, predictive capacity of the model was independently checked using results of personal dosimetry studies with wearable TL dosimeters, using them as an independent benchmark to test performance of the model M2020. Outcomes of the several personal dosimetry population studies (Harada et al., 2014; Takahara et al., 2014; Nomura et al., 2015, 2016; Tsubokura et al., 2015, 2017, 2018) were used to create the validation scenarios and to independently calculate the effective doses for the corresponding representative individuals.

Additionally to the published data, the anonymised individual dosimetry data were provided by the municipalities of Minamisoma City and Naraha Town in Fukushima Prefecture. These data were independently analysed by the UNSCEAR task group, taking into account statistical properties of the data, missing values and potential multimodality of distributions. Details of the validation scenarios, statistical analysis and performance of the models M2013 and M2020 can be found elsewhere (Attachment A-1 of UNSCEAR, 2022).

The summary of the results is shown in Fig. 1, where the average ratios of the model-calculated and inferred from TLD measurements effective doses for representative individuals are shown for all analysed scenarios and datasets. As seen from the figure, the estimates obtained with the model M2020 vary within the range 0.25–2 with the mean value of 0.98 and 95% CI (0.53, 1.67). At the same time, the estimates made with the preceding model M2013 demonstrate tendency to underestimate the personal dosimetry data, having the mean value 0.52 and 95% CI (0.20, 0.99), as shown in Table 3. It can be concluded that, for the considered validation scenarios, the model M2020 clearly outperforms the preceding model M2013.

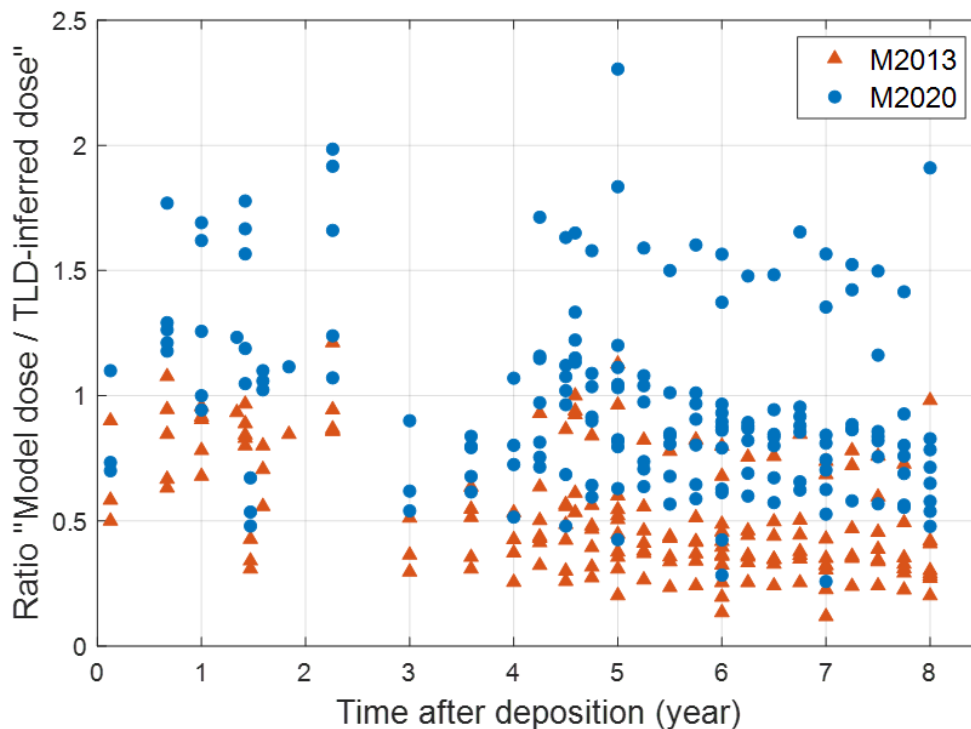


Fig. 1. Ratio of effective doses computed with the models M2013 and M2020 and the average effective doses derived from various personal dosimetry studies in Japan in 2011–2019 (see text).

Table 3. Statistics of the ratios of the model doses and the doses inferred from personal dosimetry surveys in Japan in 2011–2019 (Takahara et al., 2014; Harada et al., 2014; Nomura et al., 2015, 2016; Tsubokura et al., 2015, 2017, 2018; data provided by the municipalities of Minamisoma City and Naraha Town in Fukushima Prefecture).

Model variant	Statistics				
	AM	SD	GM	GSD	95% CI
M2013	0.52	0.24	0.47	1.58	(0.20, 0.99)
M2020	0.98	0.38	0.91	1.46	(0.47, 1.85)

## 5. RESULTS

External exposure to radionuclides deposited in the environment makes the largest contribution to the cumulative radiation doses for most of the population of Japan after the FDNPS accident (UNSCEAR, 2022). Correspondingly, this subject was carefully considered by the UNSCEAR task group, resulting in development of the new variant M2020 of the UNSCEAR model for assessment of the population external exposure. Changes in the model M2020 resulted in changes of assessed cumulative doses when compared to the preceding estimates in UNSCEAR (2014). Example of changes is given by Fig. 2, where cumulative doses for typical adult for  $^{137}\text{Cs}$  deposition density equal to  $150 \text{ kBq m}^{-2}$  are shown for the South Trace and the rest of Japan using the models M2013 and M2020. Typical adult was defined as an adult living in wooden house and working indoor a concrete building (UNSCEAR, 2014).

As seen in Fig. 2, the models M2013 and M2020 demonstrate different dynamics of the cumulative doses after the first year. Specifically, the model M2013 underestimates doses for the rest of Japan after the first year, resulting in the integral lifetime dose, approximately, one third less than that computed using M2020.

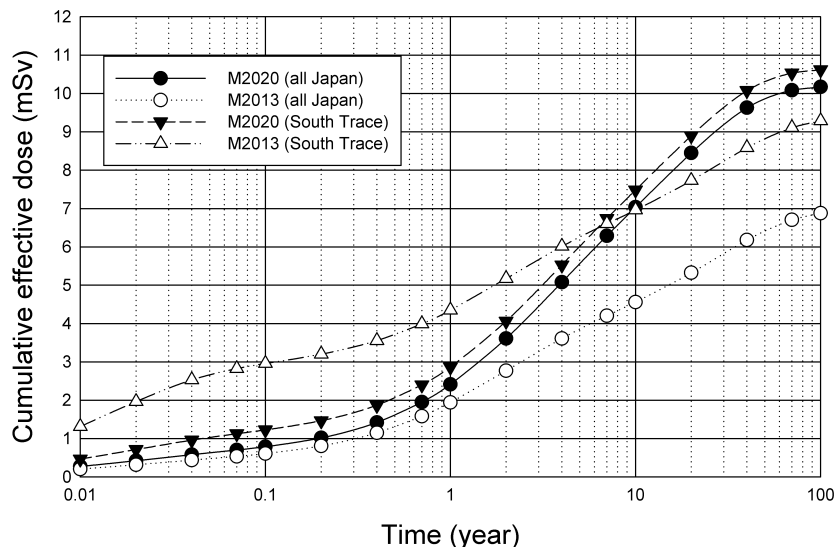


Fig. 2. Cumulative effective doses for a typical adult (see text) for  $^{137}\text{Cs}$  deposition density  $150 \text{ kBq m}^{-2}$  calculated using M2013 (UNSCEAR 2014, white symbols) and M2020 (UNSCEAR 2022, black symbols) for conditions of the South Trace (triangles) and the rest of Japan (circles).

At the same time, for conditions shown in Fig. 2, the model M2013 overestimates doses for places in the South Trace during the first decade and underestimates afterwards. This effect

results from use of constant activity ratios of shorter-living radionuclides of iodine and tellurium and <sup>137</sup>Cs in the model 2013. The higher activity ratios of the deposited iodine and tellurium were mostly detected in places with relatively low deposition density of <sup>137</sup>Cs, ranging from 1 to 100 kBq m<sup>-2</sup>. The data for the South Trace (Saito et al., 2019) demonstrated variation of ratios, reducing from high values at places with low <sup>137</sup>Cs deposition density to the values found in the rest of Japan in places with higher <sup>137</sup>Cs deposition density. Correspondingly, the model M2020 uses non-linear activity ratios for iodine and tellurium, which result in similar cumulative doses, as shown in Fig. 2, for <sup>137</sup>Cs deposition density 150 kBq m<sup>-2</sup>.

The model M2020 was used to assess and forecast doses of the population from external exposure to environmentally deposited radionuclides. The comprehensive description of the dose estimates and dose forecasts can be found in the UNSCEAR 2020/2021 Report, Annex B and Attachment A-1 (UNSCEAR, 2022). The exemplary values are shown in Table 4, where cumulative population-averaged effective doses are shown for population groups represented by 1- and 10-year-old children and adults for exposures during one and 10 years as well as for lifetime. The figures in the table are population averaged values for (a) non-evacuated municipalities of the Fukushima prefecture, (b) Ibaraki, Miyagi, Tochigi and Yamagata prefectures, (c) the rest of Japan, comprising Chiba, Gunma and Iwate and the remaining 39 prefectures. As seen from the table, the values of dose are low, ranging from the values below the typical doses from the natural background radiation to maximum 10–20 mSv of lifetime doses for residents of the most contaminated places in the non-evacuated municipalities of Fukushima Prefecture.

Table 4. Cumulative averaged effective doses of external exposure during 1 and 10 years after 2011 and lifetime for different population groups in non-evacuated municipalities of Fukushima Prefecture, in the neighbouring prefectures and in the rest of Japan (UNSCEAR, 2022).

Age group in March 2011	Averaged effective dose from external exposure (mSv)*		
	Fukushima prefecture <sup>†</sup>	Proximal prefectures <sup>‡</sup>	The rest of Japan <sup>§</sup>
1-year exposure			
Adult	0.04–3.6	0.09–0.74	0.0–0.35
10-year old	0.05–4.2	0.10–0.88	0.0–0.42
1-year old	0.06–5.0	0.12–1.0	0.0–0.50
10-year exposure			
Adult	0.12–10.6	0.22–2.1	0.0–1.0
10-year old	0.13–12.0	0.25–2.3	0.0–1.1
1-year old	0.16–14.1	0.29–2.7	0.0–1.3
Lifetime exposure to age 80 years			
Adult <sup>¶</sup>	0.17–15.1	0.30–2.9	0.0–1.4
10-year old	0.18–16.7	0.34–3.2	0.0–1.6
1-year old	0.21–19.0	0.38–3.7	0.0–1.8

\* The dose values in the table are ranges of municipality-average doses for Fukushima and neighbouring prefectures and ranges of prefecture-average doses for the rest of Japan. The ranges represent variability of the average values across a municipality or a prefecture and do not reflect individual variability within a specified population group.

<sup>†</sup> Non-evacuated municipalities of Fukushima Prefecture.

<sup>‡</sup> Ibaraki, Miyagi, Tochigi and Yamagata prefectures.

<sup>§</sup> Chiba, Gunma, and Iwate and the remaining 39 prefectures.

<sup>¶</sup> Assumed to be 20-year-old.

## 6. CONCLUSIONS

Substantial amount of detailed radioecological and dosimetric data accumulated in Japan during the decade since the accident at the Fukushima Daiichi Nuclear Power Station (FDNPS) in 2011 allowed the UNSCEAR to review and improve its estimates of radiation doses of the population of Japan due to external exposure to radiation of radionuclides deposited in the terrestrial environments. The improved model M2020 was developed by the UNSCEAR task group and thoroughly tested using the results of the environmental monitoring and population-based personal dosimetry surveys.

The new model M2020 received the modified dynamics of ambient dose rates, which better reflects the country-specific conditions and differs from those observed earlier after nuclear weapon tests, radiation accidents and other events of radiological emergency. Specifically, the new dynamics resulted in higher cumulative doses after the first year than it was predicted by the preceding model M2013, mostly based on post-Chernobyl experience.

For the model M2022, the revised activity ratios of the radionuclides deposited on the ground were derived from the environmental monitoring data, which resulted in substantial improvement of the doses assessed for the higher contaminated areas located south of the FDNPS (the South Trace), where the model M2013 overestimated the contribution of shorter-living isotopes of iodine and tellurium to the total external dose. The new non-linear relationships improved estimates of the external doses for such places.

Extensive data collected by Japanese scientists from large-scale systematic monitoring of ambient radiation fields allowed to modify and improve the model parameters, which describe reduction of external doses in populated places and indoor. The new location factors applied in the model M2020 reflect the specificity of the Japanese terrain, where open flat areas, suitable for selection as reference sites, are close to populated places or under strong anthropogenic influence.

The model M2020 received updated occupancy factors, better representing country-specific population structure and behaviour. Shielding properties of houses and buildings were reviewed and found compatible to those assumed in the model M2013 and earlier studies. The new model M2020 was independently validated by comparison with outcomes of the population-based individual dosimetry studies. The comparison demonstrated improved performance of the model M2020 in comparison to its predecessor, the model M2013.

The new model M2020 for assessment of external exposure takes into account vast data and experience gained after the FDNPS accident and brings higher confidence in the dose estimates presented in the UNSCEAR 2020/2021 Report on exposures and effects for the population and environment in Japan after the accident (UNSCEAR, 2022).

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## Equivalent dose reading for unregistered TLD card with calibration curve

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**Abstract**—The equivalent dose of body surface can be calculated using a thermoluminescence dosimeter (TLD). The TLD must be calibrated during the initial testing process using the TLD Reader and this process will zero the dose which means the equivalent dose in it will be erased. This study is to read doses for TLD that have not been registered/calibrated in TLD Reader. The sample is 40 calibration cards of TLD Harshaw's shared in 5 sets testing with different dose, so every sets consists of 8 calibration cards. The calibration card was irradiated with <sup>137</sup>Cs source at a dose of 2 mSv, 3 mSv, 5 mSv, 7.5 mSv, and 10 mSv. The calibration curve was created by comparing the irradiation dose with the response calibration readings of the TLD Reader. The best calibration curve is the calibration curve on the polynomial/ quadratic model with  $R^2 = 0.9968$  its mean pass the reference that good calibration curve have value of  $R^2 \geq 0.990$ . The standard deviation of the dose measurement results at  $-3.87\%$  to  $21.98\%$ , which means that the value is still in the range of  $-30\%$  to  $50\%$  or not to exceed  $-30\%$  to  $50\%$ . Equivalent dose in uncalibrated TLD can read using a polynomial calibration curve formula as evidenced by the value of  $R^2 \geq 0.990$  and a standard deviation that does not exceed  $-30\%$  to  $50\%$ .

**Keywords:** Dose calibration; Calibration of TLD Reader; TLD; Calibration TLD; Radiation Doses

### 1. INTRODUCTION

Radiology activities, apart from providing benefits, can also pose a danger to radiation workers. The magnitude of the effect of radiation on the human body is expressed in equivalent doses that cannot be directly measured in body tissues. To prevent this, it can be done by implementing aspects of radiation safety management. In order to support radiation safety, an individual or an institution is obliged to comply with the radiation protection that has been determined by the existing authorised institution. One of the fulfillment of radiation protection is the use of individual dose monitoring equipment that must be used by officers in carrying out radiology activities. An individual dose monitoring device or commonly known as a dosimeter consists of an active dosimeter and a passive dosimeter. An active dosimeter is an individual dosimeter that can be read directly, while a passive dosimeter is a dosimeter that must be evaluated by an accredited or designated external dosimetry laboratory. Passive dosimeters in accordance with Nuclear Energy Regulatory Agency include film dosimeters, thermoluminescence dosimeters (TLD) and radio-photoluminescence dosimeters (RPL) (Nuclear Energy Regulatory Agency, 2020).

The passive dosimeter used by radiation workers after evaluation will provide an equivalent dose that can be used as a radiation protection report. The requirement to provide dosimeter measurement services by an authorised party must always refer to the performance / quality of performance of the dose meter/reader and its evaluation system. A quality control program should be in place and implemented to monitor the performance of the dose measurement and

evaluation system. To be an effective tool in limiting exposure, these dosimetry must meet adequate quality standards which generally means cards must be used issued by a service approved by the relevant agency (Nuclear Energy Regulatory Agency, 2015).

Fulfillment of the quality standards of an External Dosimetry Laboratory that must be carried out to determine the performance quality of a dose measuring device such as calibration, inter-laboratory comparison tests and method validation that must be carried out regularly and continuously. Calibration itself aims to achieve a traceability of the numbers produced by a measuring instrument. The standard for performing calibrations aimed at radiation protection in the radiology field refers to ISO-4037 which was just published in 2019 and specifically discusses the photon energy response to personal cards / dosimetry. The latest card/dosimetry system standard for passive dosimetry refers to IEC-62387 edition 2 which was published in 2020 and discusses overall quality assurance for External Dosimetry Laboratories. ISO-4037 and IEC-62387 recommended the photon radiation sources are <sup>241</sup>Am, <sup>137</sup>Cs, and <sup>60</sup>Co. ISO-4037 and IEC-62387 also provide a reference for the dose used to calibrate the TLD Reader using <sup>137</sup>Cs at doses of 3 mSv and 10 mSv. External irradiation using a <sup>137</sup>Cs beam is carried out by an accredited Secondary Dosimetry Laboratory that is traceable to the Primary Dosimetry Laboratory, namely the IAEA (International Atomic Energy Agency) (ISO, 2019; IEC, 2020).

When calibrating the TLD Reader, the standard used by the External Dosimetry Laboratory in Indonesia is one dose value and generally in dose 5 mSv. Research on TLD Reader calibration using a single dose variation has been carried out by Luay in 2019 and Akintayo in 2021 using dose at 2 mSv (Rasool, 2019; Omojola et al., 2021), Ling Luo in 2017 using dose at 3 mSv (Luo et al., 2017) and Hiaty in 2013 using a dose at 5 mSv (Lrasoul, 2013).

Previous studies used calibration dose in mSv units. The calibration in mSv units compared with the calibration response readings from the TLD Reader in nC units can be used as a calibration curve to show a performance quality of the TLD Reader. The calibration curve will be considered good if the level of linearity of the curve has a correlation coefficient value close to 1. This calibration curve will have a calculation formula that can be used to manually calculate the dose if there is already TLD card response data in nC units. This nC unit is not only a response unit from the TLD Reader calibration, it is also a residual reading response from the TLD card. TLD cards that have not been calibrated/registered can only be read by removing residues in nC units, so according to the author, if this calibration curve has good linearity, it will be able to read TLD cards without registration/calibration.

## 2. METHODS

The type of research used in the preparation of this thesis is a quasi-experimental design using a factorial experiment. This experimental design is a development of the previous true experimental that has been implemented. Previous studies used a variation of one calibration dose, while in this study, a development will be carried out using a variation of five calibration doses. The sample is 40 calibration cards of TLD Harshaw's shared in 5 sets testing with different dose, so every sets consists of 8 calibration cards. The calibration card was irradiated with <sup>137</sup>Cs source at a dose of 2 mSv, 3 mSv, 5 mSv, 7.5 mSv and 10 mSv.

## 3. RESULT

Calibration is an important step in analytical methods to have a good understanding of how to set up calibration experiments and how to evaluate the results obtained. In order for the predictions made by the calibration curve to have a small measurement uncertainty, the value of regression must be very close to 1 (Prichard and Barwick, 2003). Calibration curve is made

by comparing the TLD calibration response in nC units with the correct dose in mSv units. To get the best calibration curve, the calibration curve can be made in two models, linear and polynomial. Regression (R) analysis was obtained from the performance of the TLD response with the correct dose. The calibration curve used is the calibration curve with the regression value closest to the 1 (Liuzzi et al., 2020).

The value of regression (R) on the calibration curve indicates whether the measurement is close to the resulting data. The value of regression (R) that is closer to 1 means the more accurate the calibration curve represents the response of the detector or instrument. In general, the value of  $R \geq 0.995$  and the value of  $R^2 \geq 0.990$  is stated to have a good relationship (Rigdon, 2016). Table 1 is the response to reading the TLD card using the Calibrate Reader acquisition at each different dose variation

The response data for TLD Reader calibration readings can be used as a calibration curve to determine the level of linearity of the readings from the TLD Reader where if the dose of irradiation given is greater, the response of the calibration card reading (nC) should also be greater. A calibration curve can be made by comparing the average response of the TLD Reader Calibration in nano Coulomb units in Table 1 with the calibration dose and shown in Fig. 1.

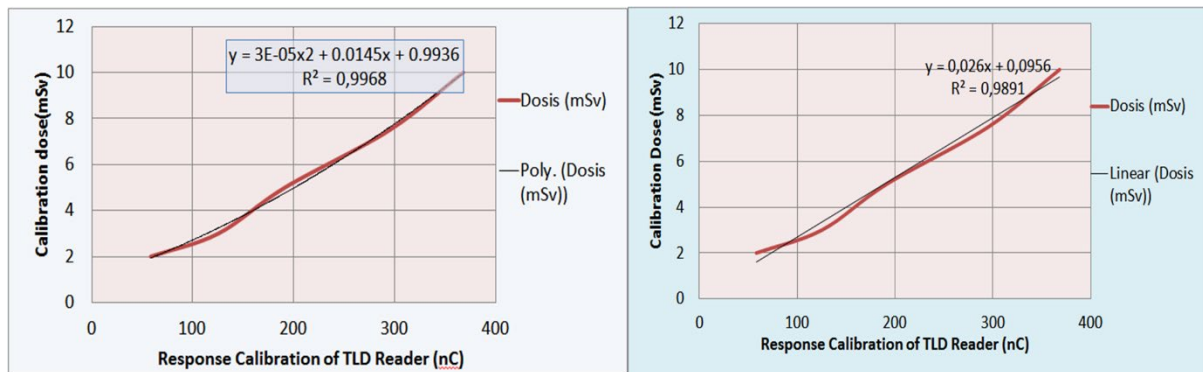


Fig. 1. TLD Reader Calibration Curve polynomial model (left) and TLD Reader Calibration Curve Linear model (right).

Table 1. Response of TLD Reader calibration.

Calibration TLD Card	2 mSv	3 mSv	5 mSv	7.5 mSv	10 mSv
	Response Calibration of TLD Reader (nC)				
1	57.10	121.7	190.8	286.6	372.1
2	57.77	123.8	192.3	288.2	362.9
3	59.28	120.9	192.6	283.5	375.9
4	58.05	121.8	190.4	287.5	369.0
5	58.47	117.9	191.9	279.8	369.0
6	57.28	118.6	190.0	276.5	361.6
7	58.81	140.5	192.3	333.0	367.9
8	58.36	137.3	190.0	326.9	365.9
Average response	58.23	125.31	191.29	295.25	368.04

Based on Fig 1, the  $R^2$  value in the polynomial model is 0.9968 while the linear model is 0.9891. Polynomial and linear model curves have different calculation formulas but have the same meaning where y represents dose in mSv units while x represents TLD response in nano Coulomb units. Uncalibrated TLD card dose readings can use the results of the calibration curve criteria on the TLD Reader's performance quality. The best calibration curve is the

calibration curve on the polynomial/ quadratic model. A good calibration curve is produced by a polynomial model calibration curve with a value of  $R^2 \geq 0.990$ , namely  $R^2 = 0.9968$ , with a quadratic model formula that is  $y = 3 \times 10^{-5} x^2 + 0.0145x + 0.9936$ .

According to Rasool, (2019) in a journal entitled "Linearity Test for Harshaw TLD (Type: TLD-100H) Base on Individual Calibration Method" after calculating the linearity of the calibration curve which produces the value of  $R^2$ , it is necessary to calculate the standard deviation of the measurement results to compare doses correct and calculated dose with an acceptance rate of  $-30\%$  or  $50\%$  (Marriott, 2005; IAEA, 2018; Rasool, 2019).

The  $R^2$  value in the polynomial model is 0.9968 which is closer to the value 1 compared to the  $R^2$  value in the linear curve model. So it is necessary to calculate the linearity of the calibration curve of the polynomial model to see the value of the standard deviation of the measurement results. The standard deviation of the measurement can be calculated by comparing the correct dose / calibration dose and the calculated dose with an acceptable level according to ICRP is  $-30\%$  or  $50\%$ . Table 2 below is the calculation of the standard deviation of comparing the true dose value and the measured dose.

Table 2. Calculation of the standard deviation of dose measurement.

No.	True dose (mSv)	Response Calibrate Reader (nC)	Measured dose (mSv)	Standard Deviation (%)	No.	True dose (mSv)	Response Calibrate Reader (nC)	Measured dose (mSv)	Standard Deviation (%)
1	2	57.81	1.93	-3.39	25	7.5	286.6	7.61	1.51
2		57.77	1.93	-3.43	26		288.2	7.66	2.19
3		59.28	1.96	-2.07	27		283.5	7.52	0.21
4		58.05	1.94	-3.18	28		287.5	7.64	1.89
5		58.47	1.94	-2.80	29		279.8	7.40	-1.34
6		57.28	1.92	-3.87	30		276.5	7.30	-2.71
7		58.81	1.95	-2.49	31		333.0	9.15	21.98
8		58.36	1.94	-2.90	32		326.9	8.94	19.19
9	3	121.7	3.20	6.75	33	10	372.1	10.54	5.43
10		123.8	3.25	8.28	34		362.9	10.21	2.07
11		120.9	3.19	6.17	35		375.9	10.68	6.83
12		121.8	3.20	6.83	36		369.0	10.43	4.29
13		117.9	3.12	4.01	37		369.0	10.43	4.29
14		118.6	3.14	4.51	38		361.6	10.16	1.59
15		140.5	3.62	20.77	39		367.9	10.39	3.89
16		137.3	3.55	18.33	40		365.9	10.32	3.16
17	5	190.8	4.85	-2.95					
18		192.3	4.89	-2.17					
19		192.6	4.90	-2.02					
20		190.4	4.84	-3.16					
21		191.9	4.88	-2.38					
22		190.0	4.83	-3.37					
23		192.3	4.89	-2.17					
24		190.0	4.83	-3.37					

Table 2 describes the standard deviation of the response of each TLD card at each calibration dose. The calculated dose is obtained from the polynomial curve formula, with  $y = 3 \times 10^{-5} x^2 + 0.0145x + 0.9936$ , where  $y$  is the calculated dose and  $x$  is the TLD response in nC readings. Based on the table above, the standard deviation values are in the range of  $-3.87\%$  and  $21.98\%$  which are still in the range of  $-30\%$  or  $50\%$ .

#### 4. CONCLUSION

Dose readings for uncalibrated TLD cards / TLD cards with nanoCoulomb reading responses can be generated using a polynomial calibration curve formula / quadratic formula as evidenced by the value of  $R^2 \geq 0.990$  and a standard deviation that does not exceed –30% to 50%.

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## Nuclear industry experiences in radiation exposures

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**Abstract**—The ‘As Low As Reasonably Achievable’ (ALARA) principle is one of the 3 fundamental elements of radiation protection. Noting that ionising radiation is both encountered naturally in the environment as part of everyday life, and artificially as part of a range of practices, the ALARA principle aims to provide a means of optimising radiation exposures. Since the introduction of the principle the nuclear industry has had a good track record of progressively reducing occupational and environmental exposures across the nuclear fuel cycle. However, recent industry feedback has highlighted that as the exposures continue to decline, there is evidence that its application in the purest sense can result in a disproportionate outcome in terms of wider non-radiological hazards, and / or use of resources both physical and human. This is leading to a general push for day-to-day exposures in nuclear power generation to be far lower than other forms of energy generation, sectors such as medical or minerals refinement, or compared to exposures we get from natural sources of radioactivity. This is at great cost for what is a negligible improvement in public protection. With the ongoing concerns of climate change, many countries have made a commitment to embrace low carbon energy systems. In support of this ambition new nuclear power has been identified as a key part of the energy mix, highlighting the need to further develop the ALARA concept, to ensure a fair treatment of the perceived ‘unique’ radiological risk of nuclear power. This paper explores feedback from industry in relation to optimising radiation exposures in the Nuclear Industry. This includes the need for the evolution of the ALARA principle to ensure it embeds ‘ALL Hazards’, ensures a sustainable outcome, and is informed by stakeholder engagement, along with the need for a graded approach to radiological protection, to ensure that improvement plans are based on clearly defined-value benefits based on judgements of reasonableness, and not in response to external pressures to ‘minimise exposure’. Feedback also highlighted the need to ensure we continue to tackle the Radiation Protection ‘Skills Gap’ and have sufficient skilled resources to meet the current and future needs of the industry in the context of climate change.

*Keywords:* ALARA; Optimisation; Nuclear; Radiation Exposures

### 1. INTRODUCTION

The optimisation principle is at the core of international radiation protection standards and legislation. It is referred to as ALARA, short for keeping the likelihood of incurring exposure, the number of people exposed and the magnitude of their individual doses ‘As Low As Reasonably Achievable’ taking social and economic factors into consideration, *Publication 103* (ICRP, 2007).

Since its introduction in the late 1970’s, *Publication 26* (ICRP, 1977), the nuclear industry has had an impressive record of controlling and reducing both its occupational and public exposures, in terms of average individual exposure and collective dose. As an example, Fig. 1 shows the average annual collective dose per reactor, showing a steady decline from 1980 to the present day.



Whilst there are variations across the individual parts of the nuclear fuel cycle, the industry has been able to demonstrate the central importance of exposure optimisation, with the current average workers doses being around 1 mSv per year across the entire fuel cycle, which is broadly within the variability of natural background radiation. Central to the success of this outcome has been:

- The development of structured approaches to reach ALARA, that emphasises the need for clear balance between the reduction in the magnitude of the exposure or dose, the cost of that reduction and societal impact, and
- A positive will to pursue the ALARA principle, or as it is now more commonly known nuclear safety culture.

However, the success, comes with a caution, with feedback from the industry highlighting concerns that as the exposures continue to decline, the application of ALARA principle is leading to the minimisation of exposures, rather than optimisation of radiological protection.

In the context of climate change, with several countries having made a commitment to new nuclear power as a key part of the future low carbon energy mix, this emphasises the need to further develop the ALARA concept, to ensure it remains fit for purpose ensuring a fair treatment of the radiological risk of nuclear power and the move to a sustainable outcome.

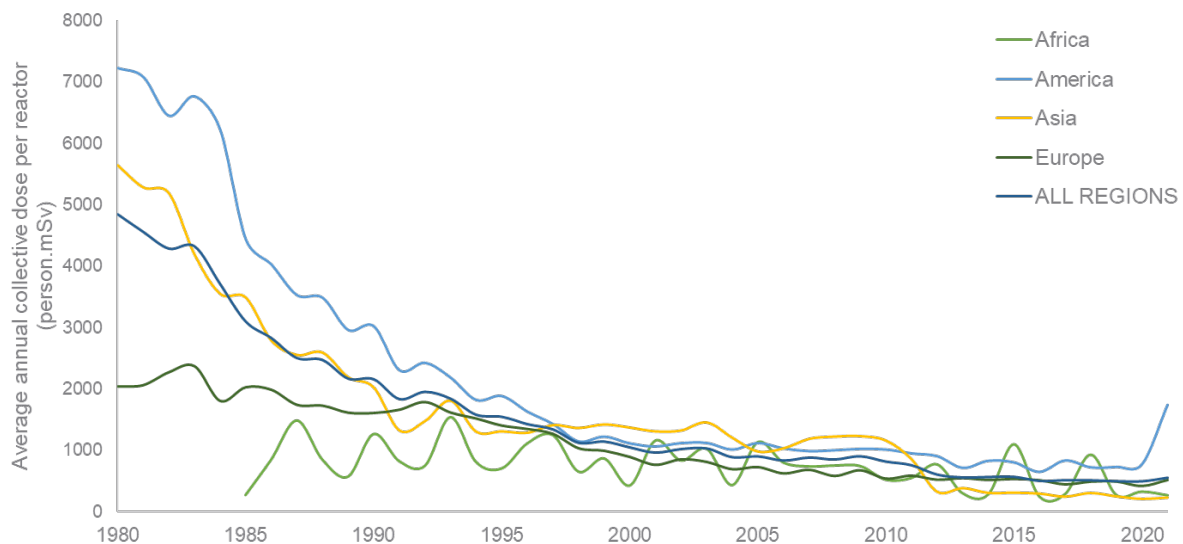


Fig. 1. Average annual collective dose per reactor by geographical region (man.mSv) - Data extracted from the Information System of Occupational Exposure, ISOE (2022).

## 2. DEVELOPMENT OF SAFETY CULTURE

Whilst ALARA was recognised as a desirable outcome, throughout the 1980's and early 1990's little was done to practically implement it, with the focus remaining on keeping doses below dose limits. By the late 1980's it was noted that whilst the development of structured approaches by the Commission of the European Communities (CEC) to reach the ALARA outcome was important, without a positive will to pursue the ALARA principle, these did not necessarily achieve anything in practice.

This led to the formation of radiation safety culture or as it is now more commonly known nuclear safety culture, recognising more strongly than in any other sectors that this has become an integral element of the approach.

The development of nuclear safety culture has been an area of increasing focus, following such global events at the Fukushima Daiichi nuclear power plant and Chernobyl. A healthy safety culture is created in an organisation by the collective commitment of leaders and individuals to emphasise safety over competing goals, to ensure protection of people and the environment.

This can be broken down further into several characteristics a few of which are presented in Fig.2.

The continued commitment of the nuclear industry, re-enforced by a strong independent regulatory regime, has been instrumental in driving the implementation of the ALARA principle, and reduction in radiological exposures.

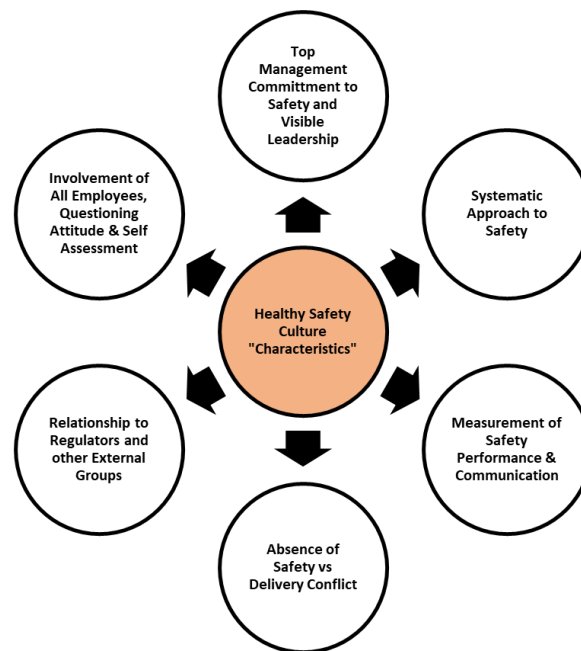


Fig. 2. Healthy Safety Culture Characteristics [adapted from (IAEA, 2002; WANO, 2013)].

### 3. DEVELOPMENT OF STRUCTURED APPROACHES TO THE TREATMENT OF ALARA

The ALARA principle ultimately tries to allow for an optimised and balanced treatment of the risk associated with exposure to ionising radiation. This is summarised in Fig. 3(a).

Following the introduction of the ALARA principle the initial projects focused on developing quantitative decision-making techniques (Bryant, 2018), to support the application of ALARA. This included the development of cost-benefit analysis which aimed to quantify the cost of the ‘man-sievert’ implicitly assuming that the radiation detriment was completely characterised by the collective effective dose equivalent.

However, by its very definition the ALARA principle is focused on driving the protection of individuals from ionising radiation, and as the exposures across the nuclear industry continue to decline, we are seeing evidence that its application in the purest sense can result in a disproportionate outcome in terms of wider non-radiological hazards, and / or use of resources both physical and human.

This has been leading to an increased shift in view that to correctly apply the principle, consideration must be given to all hazards, not only radiation, along with focusing on both

people and the environment, to allow a balanced and sustainable outcome to be reached. This is summarised in Fig. 3(b).

In addition, experiences of our new nuclear operators have shown that even where levels of exposure are trivial, a thousand time less than background, the perceived risk of ionising radiation in the context of nuclear power can additionally drive the misapplication of the ALARA principle with the need to implement further measures to reassure the public or stakeholders at a disproportionate cost and use of resources compared to the radiological risk.

One example is discussed (Bryant, 2021a) in which the dredging of non-hazardous sediment in the United Kingdom near a now decommissioned nuclear power station raised substantial public concern about radiological exposure. This turned what was a straightforward construction activity into a complex public engagement and reassurance task, at a significant cost disproportionate to the level of radiological risk.

Learning from this case study highlights the importance of public engagement as part of the ALARA process. Only by explicitly considering societal stress and perceived risk within the ALARA journey, do we truly reach a balanced treatment of the radiological risk based on a common understanding between stakeholders. This is summarised in Fig. 3 (c).

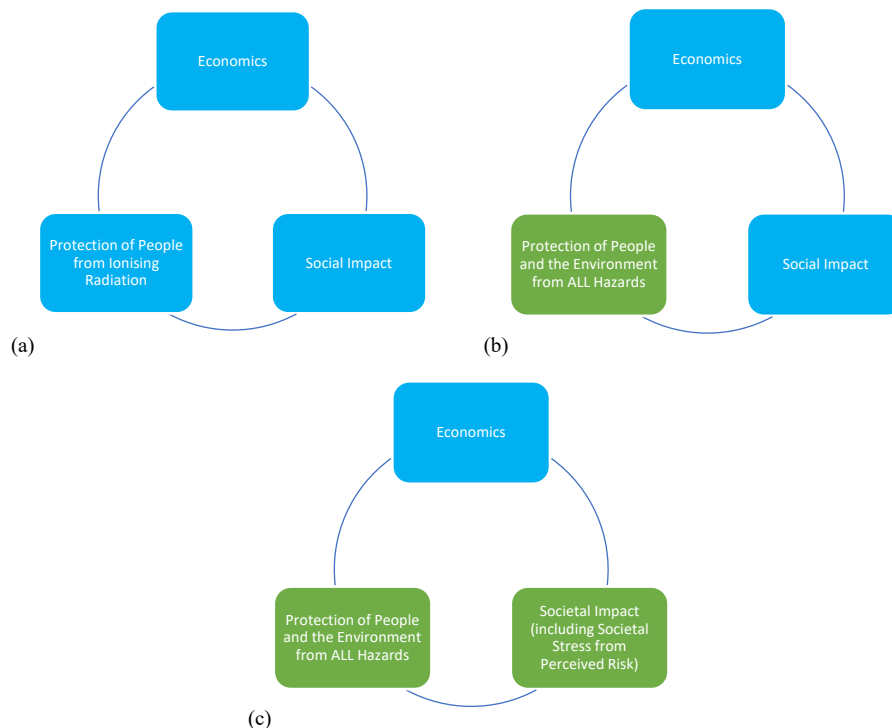


Fig. 3. (a) Summary of the competing factors within the ALARA principle, (b) ‘ALL Hazards’ interpretation of the competing factors within the ALARA principle (c) Modern interpretation of the competing factors within the ALARA principle

#### 4. FUTURE CHALLENGES TO RADIOLOGICAL EXPOSURES IN THE NUCLEAR INDUSTRY

To maintain the nuclear industries strong track record in optimising radiological exposures, whilst ensuring this done in a risk informed, proportionate, and sustainable manner, there are several key futures challenges that require focus and consideration going forward. These are summarised below:

- Continue to develop and embed a ‘ALL Hazards’, Sustainable, and Stakeholder Informed Approach to the implementation of ALARA, ensuring alignment with International and Domestic Standards and Regulatory Expectations. This is key to support not only the role of New Nuclear in tackling climate change but also the wider Nuclear Fuel Cycle e.g.:
  - There is increasing engagement on decommissioning, with less repetitive routine work and more hands-on intervention, which could lead to increasing exposures. This also results in an emphasis on waste management and the need for efficient waste processes, including effective clearance systems. Clearance provides additional options for management of material which supports sustainability through providing for recycling and re-use of material and reducing the amount of radioactive waste to be managed. This helps to efficiently decrease occupational exposure received during handling bulk waste.
  - Mining and uranium production has a different set of exposure conditions, resulting in worker total doses of the order of one to a few mSv. This is higher than for the rest of the nuclear fuel cycle; however, the doses remain very low and well controlled. For this sector it is critical to ensure that the low doses remain in perspective with other workplace hazards and hence a balanced all-hazards approach is necessary. The challenge is that any push to further reduce doses unnecessarily imbalances the safety focus.
- Continuing to develop and embed a strong safety culture across all parts of the nuclear fuel cycle and activities, in particular those areas that have not traditionally been required to address significant radiation protection issues, which have been the historical focus.
- Introduction of a ‘graded approach’ keeping the focus on reduction of high doses and risks. For example, some of the highest exposures are incurred by nuclear power plant outage workers, who move from site to site, undertaking high dose rate activities. A graded approach would ensure we focus our optimization efforts on such groups and not on the administration of worker doses with minimal exposure.
- Tackling the Skills Gap (both within Radiation Protection and wider Industry) - Over the last 10 years there have been increasing concerns raised about a potential skills gap in the field of radiation protection (RP). The initial results of a survey undertaken by the UK Society for Radiological Protection (second largest Radiation Protection Professional Body) (Bryant, 2021b), show that over 50% of their membership retires in the next 10–15 years, coupled with an increase in RP demand across the nuclear fuel cycle, medical sector and advancement of new technologies or applications requiring RP advice. This provides strong evidence supporting the concerns of a future skills gap. To help tackle this skills gap there is a need for global harmonization of competency standard, to facilitate the movement of key skilled workers across borders.
- Continuing to adapt our practices to take advantage of evolving technology to optimise the radiological risk of our activities for instance:
  - Ensuring ongoing consideration of radiation protection in design (where proportionate), through such approaches as remotely controlled operations, inherent and passive safety features, ease of maintenance and smart design, which progressively minimise workplace hazards.
  - Continuing to adapt operational and radiation practices to fully take advantage of technological advances, such as in remote sensing, computing, and Artificial Intelligence.

## 5. CONCLUSIONS

Since the introduction of the ALARA principle the nuclear industry has had a good track record of progressively reducing occupational and environmental exposures across the nuclear fuel cycle. This has been driven by a combination of a healthy nuclear safety culture, coupled with the development of structured approaches to reach ALARA.

However, as the exposures across the industry continue to decline, we are seeing evidence that its application in the purest sense can result in a disproportionate outcome in terms of wider non-radiological hazards, and / or use of resources both physical and human.

This is further heightened due to a generally negative public perception of ionising radiation in the context of nuclear power, because of the incidents at the Chernobyl and Fukushima Daiichi nuclear power station, and concerns over radioactive discharges and safe management of radioactive waste (Bryant, 2020).

These issues are leading to a general push for day-to-day exposures in nuclear power generation to be far lower than other forms of energy generation, sectors such as medical or minerals refinement, or compared to exposures we get from natural sources of radioactivity (Lecomte, 2019). This is at great cost for what is a negligible improvement in public protection.

Feedback from industry highlights the need for the evolution of the ALARA principle to ensure it embeds 'ALL Hazards', ensures a sustainable outcome, and is informed by stakeholder engagement.

Other challenges identified by the industry going forward is the need for a graded approach to radiological protection to ensure that improvement plans are based on clearly defined-value benefits based on judgements of reasonableness, and not in response to external pressures to 'minimise exposure', and the need to ensure we continue to tackle the 'Skills Gap' and have sufficient skilled resources to meet the current and future needs of the industry in the context of climate change.

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## Radiological protection and the public - NORM and communicating the risks

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**Abstract**—Naturally Occurring Radioactive Materials (NORM) is a complex area, covering a range of industries and practices that do not normally associate with radioactivity. In these industries and practices, risks need to be managed in perspective in order to ensure that appropriate resources are allocated to the right risks. However, due to the perceptions already associated with the term ‘radioactivity’ and the uncertainty in the international approach to NORM, there are many practical difficulties. In recognition of the widespread difficulties with management of NORM, in 2019, the IRPA Executive established a task group (TG), with the aim of providing advice, guidance and assistance for the everyday practitioner on NORM in industry. The TG has brought together some of the world’s leading experts in the area of NORM, and one of the key objectives of the TG is to produce a clear and simple handbook for practitioners. While this work is progressing, the TG has also been considering its role in providing international guidance on NORM and in providing input to the upcoming review of the ICRP system of protection and to provide practical thoughts to improve the ICRP system of protection.

*Keywords:* Communication; IRPA; NORM; Practical application

### 1. BACKGROUND

This paper is based on a presentation provided as part of an International Radiation Protection Association (IRPA) topical session on ‘Radiation Protection and the Public’ at the ICRP symposium ‘6th International Symposium on the System of Radiological Protection’. The intent of the presentation was to focus on issues associated with communicating the radiation-related risks of naturally occurring radioactive material (NORM) to the public. However, to do this, and to achieve effective communication, the information that is being communicated needs to be understandable, logical, consistent and technically relevant. The underlying assumption is that the integrity of the information is more important than the communication method.

The paper is therefore focussed on some of the practical aspects of the existing ICRP system of protection that require consideration for improved effective communications. The paper has been prepared by the IRPA NORM Task Group (TG), which consists of radiation protection practitioners with expertise and experience in the field of NORM from around the world.

Based on the views of the TG members, it was agreed that while the ICRP system of protection is generally fit for purpose, the system is complex, and it is the interpretation of the system and practical implementation of the system that generates most of the difficulties. A particular problem arises from the prejudices and perspectives of the public and lay persons towards radioactivity in general. An easy and well-communicable system is required to prevent these prejudices adversely affecting industrial activities or otherwise resulting in inadequate radiation protection.

An important conclusion from our TG discussion is that development or changes in the system of radiation protection should focus on its practical implementation and also its simplification to allow it to be more widely understood.

This paper also highlights the importance that the voice of the practitioner brings to the review of the ICRP system of protection, who are ultimately responsible for the implementation of the System. The key message is that for effective communications of NORM (and more broadly radiation protection issues) for the public, the ICRP system of protection needs to be clear, consistent and practical.

## **2. IRPA NORM TASK GROUP**

NORM is present in many industries and areas of society, and there is a growing understanding of its importance, particularly in:

- industry sectors not normally associated with radioactivity;
- legacy sites from previous industrial activities and, more broadly; and
- in areas of naturally evaluated radiation levels.

For NORM, unlike the nuclear industry or medical uses of radiation, the broader community are generally unaware of the real picture of hazards and tends to think the worst.

Accordingly, in 2019 IRPA implemented a TG of practitioners from around the world to consider the issues with NORM, with the aims of:

- Increase awareness about NORM around the world.
- Developing a common understanding of requirements for the safe and appropriate management of NORM.
- Development of a library of good practice documents.
- Support countries which are new to NORM.
- Networking between practitioners and sharing existing and good practices.

All TG members are radiation protection practitioners including: six from operations, six regulators and six from professional institutes. The Task Group has a unique balance of skills and experience and has formed a practical international network of practitioners.

A key task of the TG is to develop a handbook of good radiation protection practices for NORM. The regular contact via web-based meetings has worked to establish a productive exchange.

In their work, TG members are often confronted with issues arising from views and opinions of the public on radioactivity and ionising radiation. These issues arise when workers first learn of radioactivity in their personal workplaces, but they also arise when local residents learn of radioactivity at an industrial plant in their neighbourhood or when commercial consumers learn of radioactivity in products. In all these cases the complex system of radiation protection needs to be interpreted consistently because the radiological risks of NORM tend to always be outweighed by other risks. However, decisions are frequently made based on emotions and various inconsistent interpretations of the system of protection.

## **3. IMPROVEMENT OPPORTUNITIES**

The IRPA NORM TG identified a number of areas for potential improvement in the ICRP System of Protection that would lead to improved communications with the public. Three main

areas are highlighted in this paper, and it is suggested that engagement of the practitioners in the resolution of the issues would be beneficial.

It is important to note that the IRPA NORM TG considers the principles, systems or definitions themselves to be less problematic; it is their complexity in details or the way that they are inconsistently interpreted that leads to difficulties with the effective communication of risk. Any development of the system of protection needs to take this into account and ensure that complexity or ambiguity is reduced.

### **3.1. Radiation risk messaging**

In radiation protection, there is a range of terms that are used when working with and when communicating about radiation. For professionals engaged in the field, these terms are commonly used and sometimes mis-used when the interpretation of the terms and their application is different. This results in difficulties when communicating with people outside the profession, such as the public, and is both a barrier to effectively delivering any messages and can undermine the intent of the message being delivered. Another layer of complexity arises when words or terms are translated into different languages, which again results in different interpretations of the terms.

Examples, where terms are interpreted in different ways, include:

- Practical application of the terms, such as, ‘limit’, ‘constraint’, and ‘reference levels’. While the terms are sometimes used interchangeably, more importantly, in some situations, they are seen to have the same meaning.
- Inconsistent use of the term NORM itself. IAEA recommends using this term only if naturally occurring radioactive materials are under a regulatory regime, but the term is also applied to all materials that contain natural radionuclides. In the latter case, NORM becomes part of the background.
- Consideration of the impacts of background radiation. Background radiation levels vary around the world and depend upon a range of factors. Because ‘genuine’ background radiation is not amenable to control, it is excluded from radiation protection. Consequently, radiation risks in radiation protection refer to additional doses to a variable background. But in communication with the public, the doses from this background are used for comparison purposes. Moreover, in the case of radon, the background is included in the risk assessments as far as activity concentration is used for radiation protection.
- In some cases, radiation levels must be controlled (in existing exposure situations) and in other cases, the levels do not need to be controlled (planned exposure situations).
- Equating the terms NORM, nuclear and radioactivity. In practice, the terms NORM nuclear and radioactivity are used interchangeably. In some situations, this is formalised in legislation where, in some situations, NORM facilities are classified as nuclear facilities.

When there is a lack of clarity, especially regarding radiation, then a conservative stance is adopted leading to claims such as ‘all radiation is harmful’. With unclear information and despite the best communication methods, it is quite reasonable for individuals to adopt this conservative stance.

### **3.2. Graded approach in practice**

The principle of the graded approach is logical and sound and is widely supported by practitioners. It aims to ensure that the levels of control for a radiation risk are commensurate with the size of the risk. It is a risk-based approach that is used more broadly in everyday life



and applied to many non-radiological day-to-day situations, such as decisions to cross busy roads or the type of vehicle to purchase.

International guidance on the graded approach has been developed and, in general, national legislation incorporates the concept of a graded approach, however, in practice, when it comes to radiation, it is usual for the graded approach to collapse to simple compliance requirements which are usually based on overly conservative factors. In almost all cases, NORM that contains more than 1 Bq g<sup>-1</sup> of naturally occurring uranium and thorium series radionuclides, are seen to require regulation, regardless of the risk and despite the fact that there may be national legislation in place to do otherwise. One reason for this is that for NORM, no exemption values of the total activity are defined, and consequently, any small amount of NORM may be considered a risk/danger/hazard.

An example of where the graded approach in practice exists is some countries where there is a 'pre-requirement' to assess activity concentration of a material being handled and if it exceeds a prescribed concentration, then a dose assessment is required.

A common and bizarre example of the consequences of lack of implementation of the graded approach is that in some jurisdictions, when a material containing NORM exceeds the prescribed criteria concentration, then the material is legally considered to be a 'nuclear material' and therefore subject to controls and assessment that would normally only be associated with nuclear fuel cycle activities. In these cases, a practical graded approach would not allow this to occur and would be able to ensure that the controls are actually commensurate with the risk.

The IRPA NORM TG suggest that more practical and common guidance should be developed, that includes real life examples. This could provide confidence for decision-makers.

### 3.3. Inconsistencies in interpretation of exposure situations

The requirements for Planned Exposure Situations (PES) and Existing Exposure Situations (EES) are fundamental to the ICRP System of Protection. However, in practice, the type of exposure situation for a particular operation, activity or industry with NORM may be challenging. At first glance this may seem to be minor, however, it is critically important because PES and EES are managed differently – basically, PES are managed via dose assessment and radiation protection programs, while EES are (partly) managed separately by operational quantities, such as radon concentration and activity concentration.

Generally, according to ICRP activities with NORM are meant to be EES, however, the regulatory and practical implementation is often confusing. There are some situations where the appropriate controls should be as per PES; however, the requirements for EES apply (due to interpretation), which offer a lower level of protection.

There are also radon-related aspects that need careful consideration from a PES and EES perspective.

The IRPA NORM TG considers that fundamental and practical research work that collects and summarises practical experiences in this area would be beneficial.

## 4. SUMMARY

Communication of the radiological risks from NORM to the public is complex, mainly because the broader system of protection itself is complex. This can lead to inconsistent interpretation and application of the system and, therefore, difficulties with communication.

Efforts to simplify the system would be beneficial, and the IRPA NORM TG considers that the ICRP System of Protection is sound, however, there are improvement opportunities that ensure more effective communications.

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## Developing the system of radiological protection to enhance its contribution to sustainable development

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**Abstract**–The ICRP stated in 2007 that the primary aim of its recommendations is to contribute to an appropriate level of protection for people and the environment from the detrimental effects of radiation exposure without unduly limiting the desirable human actions which lead to such exposure. We face climate, humanitarian, biodiversity, health, pollution, and other crises. This rapidly changing context has potential implications for: the radiological protection system; views on what constitutes desirable human actions; and for how societies view the risks and benefits of technologies. The United Nations Sustainable Development Goals (SDGs) are an ideal framework for facilitating a balanced approach to socio-economic development, good health and wellbeing and environmental protection. The SDGs could be used to guide the development and application of the radiological protection system to ensure that it is fit for the 21st century. This paper considers the fundamental purposes of sustainable development and radiological protection and their underpinning values and principles. It considers how radiological protection contributes to sustainable development and how this might be enhanced; and whether the primary aim of radiological protection should be amended to make its contribution to sustainable development explicit.

*Keywords:* Sustainable; Development; System; Radiological; Protection

### 1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) has embarked on a review and revision of the System of Radiological Protection that will update the 2007 General Recommendations in ICRP *Publication 103*. This is a process that will take several years, involving open and transparent engagement with organisations and individuals around the world. While the System is robust and has performed well, it must adapt to address changes in science and society to remain fit for purpose (Clement et al., 2021).

This paper considers the strategic enabling role of radiological protection in a changing world in areas such as energy, healthcare, industry, space travel and research - in other words in sustainable development. It considers this in the context of the primary aim of the radiological protection system and suggests some potential areas for enhancement (Mayall et al., 2021).

### 2. CHANGING CONTEXT

Since the publication of the existing set of General Recommendations in 2007 the world has changed profoundly. Global climate, socio-economic, health and environmental challenges have increased, and the pace of change has accelerated. This is alongside the major changes in the way people communicate and obtain their information through social media and the internet. There is now a wealth of information, accurate and not so accurate, available to

everyone. This growth in the use of IT provides an increased opportunity to engage with citizens about technologies and their risks and benefits like never before.

The review of the system of radiological protection needs to respond to this changing environment to ensure that it continues to make a positive and enabling contribution to social, economic and environmental developments, ensuring that it does more good than harm and does not result in unintended consequences. The review should include consideration of how the system is designed, described, engaged upon, and applied, so that it continues to fulfil its primary aim and objectives.

### 3. PRIMARY AIM AND SUSTAINABLE DEVELOPMENT

The primary aim of the system of radiological protection is 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, 2007). There are more detailed objectives for human health and the environment.

What do ‘appropriate level of protection’ and ‘unduly limiting desirable human actions’ mean in practice, who decides, and should citizens help determine them? Is there scope for a more aspirational and inspirational aim which goes beyond ‘unduly limiting desirable human actions’ to make a more positive contribution?

An alternative approach is to frame the primary aim in the context of sustainable development. Sustainable development (and sustainability) is not a new concept and several ICRP documents already refer to it but often as an additional consideration among many others, when in fact it is central and fundamental to the system’s purpose.

The 17 United Nations Sustainable Development Goals (SDGs) (Fig. 1) agreed in 2015 are an ideal framework for facilitating a balanced approach to socio-economic development and environmental protection and enhancement. They recognise that ending poverty and other deprivations must go together with improving health and education, reducing inequality, and promoting economic growth – all while tackling climate change and preserving our environment (United Nations, 2015a). Sustainable Development Goals that are particularly relevant to radiological protection include SDG 3 (Good Health and Wellbeing), 7 (Affordable and Clean Energy), 8 (Decent Work and Economic Growth), 9 (Industry, Innovation and Infrastructure), 10 (Reduced Inequalities), 13 (Climate Action), 14 (Life Below Water), 15 (Life on Land), 16 (Peace, Justice and Strong Institutions) and 17 (Partnerships for the Goals).



Fig. 1. The United Nations Sustainable Development Goals.

#### 4. SUSTAINABLE DEVELOPMENT, ETHICS AND PRINCIPLES

In considering the relationship of the radiological protection system to sustainable development it is helpful to begin by exploring their shared values and ethical underpinning. As with sustainable development the practice of radiological protection is not only about science but also about philosophy and ethics.

ICRP *Publication 138* (ICRP, 2018) discusses the core ethical values that underpin radiological protection:

- *Beneficence/non-maleficence*: promoting or doing good, and avoiding doing harm.
- *Prudence*: making informed and carefully considered choices without full knowledge of the scope and consequences of an action. Prudence is reflected, for example, in the consideration of uncertainty of radiation risks for both humans and the environment and the use of the linear no-threshold model. This is not the same as conservatism or never taking risks.
- *Justice*: fairness in the distribution of advantages and disadvantages. Justice is a key value underlying, for example, restrictions on dose to individuals that aim to prevent any person from receiving an unfair burden of risk. This includes intergenerational distributive justice and restorative and procedural justice, which are also relevant to sustainable development.
- *Dignity*: the unconditional respect that every human deserves. This underlies, for example, the importance placed on stakeholder participation and the empowerment of individuals.

Three procedural values are also described to assist with the practical implementation of radiological protection:

- *Accountability*: this relates to decision makers such as regulatory bodies being held accountable and can also be applied to the present generation being accountable to future generations.
- *Transparency*: relates to procedural justice and is not only about communication and consultation but importantly about having a system that is intelligible to a wide cross section of society.
- *Inclusiveness*: relates to the importance of engaging with and taking proper account of a wide range of perspectives and knowledge.

These values are consistent with the universal values that underpin the UN SDGs (United Nations, 2015b):

*We envisage a world of universal respect for human rights and human dignity, the rule of law, justice, equality and non-discrimination; of respect for race, ethnicity and cultural diversity... A just, equitable, tolerant, open and socially inclusive world in which the needs of the most vulnerable are met.*

##### 4.1. Relationship of fundamental principles to values and sustainable development goals

We can consider how the fundamental principles of radiological protection relate to ethical values and SDGs. Justification is related principally to the ethical value of beneficence. For example in coming to justification decisions, it may be necessary to consider wide spatial and temporal domains in line with intergenerational equity. Optimisation and the quest for reasonableness is perhaps more complex and relates to several underpinning values. ICRP has

said that a broad range of factors should be considered in optimisation depending on the nature and scale of the decision being made and the prevailing circumstances, including social values such as sustainability and intergenerational equity (*Publication 101b*, ICRP, 2006).

The limitation principle is aimed at protecting individuals from tissue reactions and reducing the probability of stochastic effects to a tolerable level. But tolerability is a multi-attribute judgement which addresses several ethical and procedural values. Should that judgement be informed by perspectives wider than that of radiological protection specialists? Public acceptance or tolerance of risk is highly variable as demonstrated by the response to the Covid pandemic and to its vaccines. We cannot assume we know what citizens want unless we ask.

Limits can in theory be set too high and not protect wellbeing sufficiently, or too restrictive and hinder activity associated with significant wellbeing or sustainable development benefit. A disproportionate and exclusive focus on controlling radiation risk may result in other forms of greater harms (which may be remote in time and space from the radiation harm averted) such as the significant harm to physical and mental health following the evacuation and relocation of citizens from around Fukushima (Hasagawa et al., 2016; Tsuboi et al., 2022; and Tsubokura, 2022).

## 5. CONCLUSIONS AND POTENTIAL AREAS FOR ENHANCEMENT

Radiological protection has an important role in enabling sustainable development. The use of the fundamental principles of radiological protection and their ethical basis may have been ahead of its time. However, to keep the system fit for purpose and to respond to societal, economic, environmental and cultural developments it is suggested that greater consideration is given to:

- *Amending the primary aim of radiological protection* to recognise explicitly the contribution of the radiological protection system to enabling sustainable development.
- *Integrating and learning* from other practices and disciplines to broaden optimisation and justification practices including psychological and social impacts, ecosystems services, Covid and vaccine experience.
- *Properly valuing and accounting* for costs/detriments (harm) and benefits (good) over space, time and generations combined with a better understanding of what constitutes good and harm linked to effective communication/understanding, citizen participation and mapping to the UNSDGs.
- *Improving citizen participation* in the development of the system and in its application, taking greater account of the need for better informed, integrated, inclusive and holistic risk management in society.
- *Reviewing the application of the fundamental principles to ensure that they are being applied in a way that supports sustainable development.* For example, the application of the optimisation principle would benefit from further clarification to reinforce its purpose to optimise overall protection and maximise net benefit, and not to minimise radiation exposure.

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## Reframing the inadvertent human intrusion scenario to improve public understanding of repository safety

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**Abstract**—The Nuclear Waste Management Organization (NWMO) is responsible for implementing Adaptive Phased Management (APM), the federally approved plan for the safe long-term management of Canada’s used nuclear fuel. Under this plan, used nuclear fuel will ultimately be placed within a deep geological repository in a suitable host rock formation. The primary objective of a deep geological repository is the long-term containment and isolation of used nuclear fuel. The long-term safety of the repository is based on a combination of the properties of the waste material, engineered barriers, and geology. As the project moves toward site selection and in preparation for the licensing process, the NWMO is performing preliminary post-closure safety assessments of the potential sites. These assessments help determine the potential effects of the repository on the health and safety of people and the environment in the long term after repository closure. In alignment with national and international guidance, these safety assessments consider potential effects during the normal evolution of the repository and disruptive event scenarios, including inadvertent human intrusion scenarios. Such scenarios, in which future humans are assumed to inadvertently drill into the repository and bring fuel and radioactive debris to the surface environment, are used for illustrative purposes. Inadvertent human intrusion scenarios where all repository barriers are bypassed often assume no precautions. Evaluations of these scenarios can lead to high estimates of dose consequences, which do not reflect the repository’s safety. This paper frames the human intrusion scenario in a way that aligns with national and international guidance and strengthens public understanding of the safety of the repository.

*Keywords:* Public communication; Deep geological repository; Safety assessment; Human intrusion

### 1. INTRODUCTION

The Nuclear Waste Management Organization (NWMO) is implementing Adaptive Phased Management (APM), Canada’s plan for the long-term management of its used nuclear fuel. The APM approach encompasses centralised containment and isolation of the used fuel in a Deep Geological Repository (DGR) in a suitable rock geosphere with an informed and willing host community. Fig. 1 shows, for illustration purposes, one conceptual design for the repository. The long-term safety of the repository is based on a combination of the properties of the waste material, engineered barriers, and geology.

### 2. SAFETY ASSESSMENT

The NWMO is currently in the siting process, working towards site selection in 2024. In preparation for the licensing process, the NWMO is performing preliminary post-closure safety assessments of the potential sites, which are part of an iterative process that will inform future assessments, engineering design and site characterisation work. These assessments help determine the potential effects of the repository on the health and safety of people and the environment in the long term after repository closure.



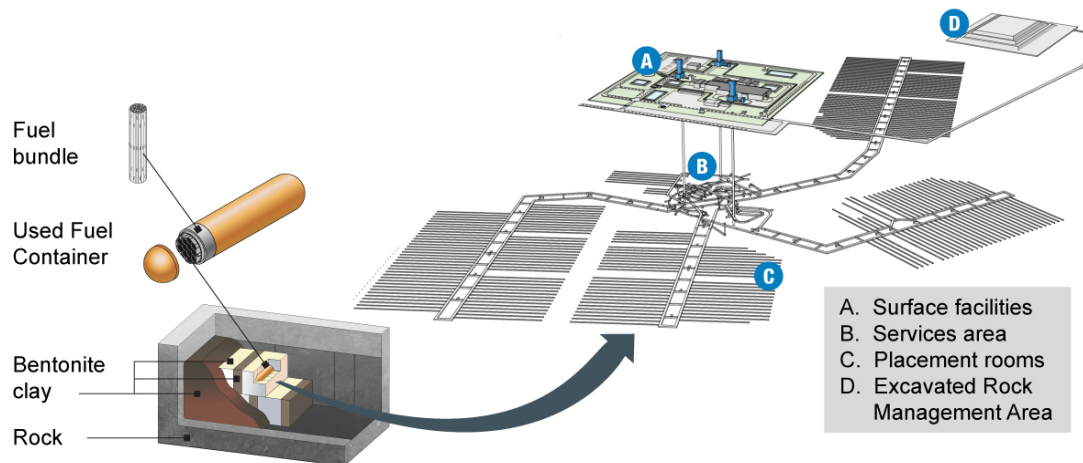


Fig. 1. Deep Geological Repository Conceptual Design.

## 2.1. Safety Assessment Scenarios

A post-closure safety assessment considers whether the deep geological repository will meet the applicable safety requirements, including acceptance criteria designed to protect people and the environment. The assessments include numerical modelling of potential future scenarios (normal evolution scenarios and disruptive event scenarios), describing possible alternative evolutions of the repository systems. Normal evolution scenarios consider the repository system evolution scenarios that are possible within the assessment timeframe. In contrast, disruptive event scenarios consider repository system evolution scenarios that are unlikely within the repository timeframe.

The reference case of the normal evolution scenario is where all repository barriers perform as expected, with no environmental releases and, therefore, no human or environmental exposures. This scenario demonstrates the repository concept's safety (i.e. when all barriers are functioning as expected, the repository safely contains and isolates the used nuclear fuel). All other normal evolution and all disruptive event scenarios challenge the barriers' performance and estimate potential dose consequences to human and non-human receptors. Comparison of these doses to acceptance criteria provides a measure of the repository's safety.

In some disruptive event scenarios, repository barriers are bypassed. Inadvertent human intrusion scenarios are disruptive event scenarios where some or all the repository's barriers have been bypassed.

## 2.2. Inadvertent Human Intrusion Scenario

Fig. 2 presents an event tree that defines events leading to inadvertent human intrusion, with the endpoint being an intrusion that bypasses all barriers. In this scenario, an exploratory borehole is drilled through the geosphere and into the repository, with the drill bit intersecting a used fuel container.

Some inadvertent human intrusion scenarios only bypass some barriers. Evaluation of hypothetical dose consequences from these scenarios provides a metric of repository safety since it demonstrates the principle of defence in depth from the remaining barriers. Those scenarios are not the focus of this paper; they are evaluated similarly to other disruptive event scenarios.

An intrusion that bypasses all barriers can lead to various types of exposure to the drill crew or residents in the vicinity of the drill site. Doses from these types of human intrusion scenarios are very sensitive to input parameters that are difficult to parameterise. For example, the total dose is directly related to the length of exposure. However, it is hard to quantify the extent to

which a future human would recognise the hazard and adopt protective measures or continue working unaware of the hazard.

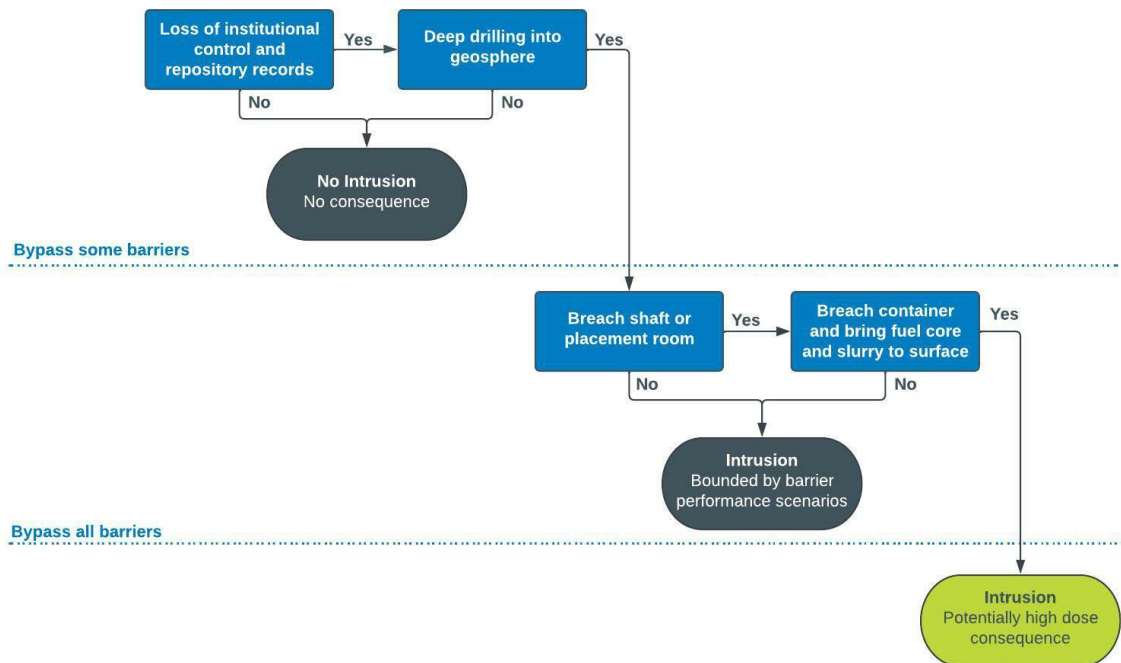


Fig. 2. Event tree leading to inadvertent human intrusion.

### 2.3. National and International Guidance

The assessment of consequences of inadvertent human intrusion into a radioactive waste disposal system is used to optimise facility design. The IAEA (2011, 2012) provides dose constraints to be used in the graded approach to optimising the design of radioactive waste disposal facilities. Annual doses below 1 mSv from inadvertent human intrusion do not warrant efforts to reduce the probability of intrusion. For doses between 1–20 mSv, ‘reasonable efforts are warranted at the stage of development to reduce the probability of intrusion and to limit its consequences [...]’. Further optimisation measures are recommended for annual doses above 20 mSv, such as waste disposal below ground.

Therefore, a deep geological repository is warranted when inadvertent human intrusion doses are estimated to be above 20 mSv. According to the ICRP, ‘disposal in deep geologic formations has the potential to provide a very long period of isolation from the accessible environment and a greatly reduced possibility of inadvertent human intrusion if proper characteristics are selected for both the natural and the engineered barriers within the disposal system’ (ICRP, 1998).

In other words, deep geological repositories are designed and sited to minimise the risk of human intrusion.

National (Canadian) and international guidance indicate that scenarios considering inadvertent human intrusion into deep geological repositories should be treated differently than other disruptive event scenarios. Canadian regulations indicate that dose consequences and event likelihood should be reported ‘for illustrative purposes only’ (CNSC, 2021) because the site characteristics, depth and design of deep geological repositories are optimised to reduce the likelihood of intrusion. The ICRP indicates that dose constraints do not apply to inadvertent human intrusion scenarios (ICRP, 1998) because, by definition, intrusion will have bypassed the barriers which were considered in the optimisation of the repository (ICRP, 1998).

In summary, national and international guidance for deep geological repositories indicate that results from inadvertent human intrusion scenarios should be reported but that they do not measure repository performance or are not a tool for optimising protection.

### 3. PUBLIC MESSAGING

Despite not being an indication of repository barrier performance, consideration of inadvertent human intrusion scenarios is essential to the safety case for a repository, and they must be appropriately framed within the ‘safety story’ to improve public understanding of repository safety.

Table 1 presents two safety narratives that discuss inadvertent human intrusion; one coupled and the other de-coupled from safety assessment scenarios. Though both narratives consider that the consequences of inadvertent human intrusion can be high, and the likelihood is low, the first narrative may lead a public reader to view the repository as an environmental problem rather than an environmental solution.

With the second narrative, the public focuses on one of the key purposes of the repository: to minimise the risk of human intrusion into the used fuel waste. In this narrative, the repository is presented as an environmental solution as opposed to a potential environmental problem.

Table 1. Safety narratives for inadvertent human intrusion scenarios.

Narrative	Arguments	Public Interpretation
<b>Coupled to Safety Assessment Scenarios</b>	<ol style="list-style-type: none"> <li>1) Safety assessments are quantitative assessments of the ability of the repository to contain and isolate the used fuel hazard. They consider a range of scenarios that characterise the uncertainties in the repository system.</li> <li>2) Inadvertent human intrusion scenarios are included among these scenarios. These scenarios are very uncertain and difficult to parametrise, and the consequences are typically high.</li> <li>3) Because the likelihood of inadvertent human intrusion is very low, the repository is safe.</li> </ol>	<p>‘Inadvertent human intrusion is a possibility and the consequences are bad. The repository is an <b>environmental problem.</b>’</p>
<b>De-Coupled from Safety Assessment Scenarios</b>	<ol style="list-style-type: none"> <li>1) Interim storage is safe while institutional controls are in place but these controls cannot be guaranteed for the long term.</li> <li>2) The consequences of inadvertent human intrusion are high and the risk of human intrusion into used fuel during interim storage increases over the long term. However, a deep geological repository makes the risk of inadvertent human intrusion as low as possible.</li> <li>3) The repository safely contains and isolates the waste while minimising the risk of inadvertent human intrusion.</li> </ol>	<p>‘The repository makes the risk of inadvertent human intrusion as low as possible. The repository is an <b>environmental solution.</b>’</p>

### 4. SUMMARY

Safety assessments for deep geological repositories consider potential impacts from the normal evolution of the repository and disruptive event scenarios, including inadvertent human intrusion scenarios. Assessment of these scenarios provides a measure of repository safety. However, inadvertent human intrusion scenarios that bypass all repository barriers and lead to

high estimates of dose consequences do not provide a measure of repository safety. Coupling these inadvertent human intrusion scenarios with other safety assessment scenarios may lead the public to consider the risk of inadvertent human intrusion as an environmental liability introduced by the repository. However, one of the fundamental purposes of a deep repository is to minimise the risk of human intrusion into used fuel waste. De-coupling the inadvertent human intrusion scenario from other safety assessment scenarios and illustrating the repository as a defence against intrusion into used fuel waste clarifies that the repository is an environmental solution.

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## Communication with patients on radiological procedures

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**Abstract**—In recent years, radiological procedures in medical practice have been increased dramatically. The average radiation exposure from medical procedures and nuclear medicine was estimated to be 3.0 mSv year<sup>-1</sup> in the United States, and 2.1 mSv year<sup>-1</sup> in South Korea. Radiotherapy and radioisotope therapy are also increasing with the rising incidence of various cancers. Most of patients and physicians understand the concept of risk-benefit assessment and accept the benefit of such procedures that exceed the risk from radiation exposure. However, some patients and their caregivers have overconcern about the radiation exposure. On the other hand, a few do not pay any attention to the radiation protection. Thus, appropriate communication between the physicians, patients and their caregivers are required for optimal patient care and radiation protection. The communication should be based on scientifically appropriate risk assessment. Currently, dosimetry schemes for radiological procedures are well established, and there are considerable epidemiological data about the radiation effect on human health. A physician should be aware of the radiation dose and its effect, when performing a radiological procedure. Also, the purpose and need for radiological diagnosis or treatment should be discussed between the physician and the patient. Reliable quantitative assessment of risk and benefit is the beginning of the communication. In communication with those who have overconcern about radiation exposure, some principles need to be noted to improve emotional perception of the risk, such as high understanding, self-decision, and self-control. For better understanding of the radiation hazard, its amount needs to be understood in comparison with those of other well-known risk factors, such as traffic accident, surgical anaesthesia, and bike riding. Exaggerated or even false information from media or film should be avoided. It is also necessary to give sufficient information on the disease status and other available diagnostic and therapeutic options, except radiological procedures. When the decision for a certain radiological procedure is made by patient, the emotional perception would be improved. Additionally, it is also good to provide guidance for self-controlling radiation dose, if available. In case of radioisotope treatment, there are several preparation methods and guidance for patients to reduce radiation exposure of themselves and their caregiver. In summary, physicians' communication with patients on radiation risk should be based on scientific data, sufficient information, and sharing of decision and control with patients.

*Keywords:* Radiological procedure; Patients; Radiation exposure; Communication

### 1. INTRODUCTION

Radiological procedures in medical practice have been dramatically increased in recent years, with the increasing use of x ray, CT, radiological intervention, and radiotherapy. Medical procedures are the largest part of manmade source of radiation, and the average radiation exposure from medical procedures and nuclear medicine was estimated to be 3.0 mSv year<sup>-1</sup> in 2009 in the United States (U.S.NRC, 2009). Use of radiotherapy and radioisotope therapy are also increasing continuously. Radioligand therapy agents for neuroendocrine tumour or prostate cancer were recently approved by regulatory authorities of some countries. There are many other radioactive drugs that are under development for cancer therapy (Hermann et al., 2020). Based on this trend, some authors reported that cancer incidences caused by medical radiation exposure are considerably high, particularly in developed countries where more

radiological procedures are used in clinical practice than developing countries (de González and Darby, 2004; Brenner and Hall, 2007). However, most of the studies are based on statistical assumptions, rather than direct observation. There are few studies that have directly assessed the effects of low-dose radiation from radiological procedures.

The key in radiation protection is justification. Both patients and physicians are familiar with the concept of risk-benefit assessment. Patients generally accept a radiological procedure as its benefit outweighs the risk from radiation exposure. However, some patients and their caregivers may have an excessive concern about the risks, while others may not be aware of the risks at all. Thus, effective communication between physicians, patients and their caregivers are necessary for optimal patient care and radiation protection.

## **2. JUSTIFICATION OF RADIOLOGICAL PROCEDURES**

In many cases, radiological procedures in medical practice are justified with no doubt. For example, diagnosis and monitoring of cancer patients using CT, radioiodine therapy for metastatic differentiated thyroid cancer, and radiotherapy for inoperable lung cancer are definitely necessary for patients' benefit. However, there are also some equivocal cases. Is CT required for a 5-year-old boy who experienced uncertain head trauma? Is radioiodine therapy required for an 11-year-old boy who has intermediate-risk thyroid cancer? Is low-dose screening CT required for an asymptomatic 60-year-old man for cancer screening? Patients and their caregiver may be willing to undergo such procedures of little value due to the concerns about their diseases. However, they may refuse the procedures for an overconcern about the radiation exposure.

The first step in the communication regarding radiation risk in a medical radiological procedure is the appropriate risk-benefit assessment. It is recommended to provide the risk of radiation in quantitative values. Radiation dose quantity in medicine and its biological effect have been well established by several authoritative organisations such as ICRP (ICRP, 2007a,b; ICRP, 2015; ICRP, 2017). However, even when the quantity is provided, it can still be misunderstood by those who do not have a basic understanding of the radiation and its effect. Thus, it is recommended to present the radiation risk in combination with other risks that are more familiar to patients in daily lives. Additionally, it is also important to inform patients about the risks of their specific disease and the expected effect of the radiological procedure, as this information is crucial for assessing the benefit of the procedure. This process is similar to informed consent process for other medical procedures, as it involves providing patients with sufficient information about their disease and the procedures.

## **3. FACILITATING CORRECT RISK PERCEPTION**

In practice, it is more common for patients and caregivers to have excessive concerns about radiation exposure, rather than not being concerned enough. In this case, science-based justification may not be enough to reduce their concern, and effective communication skill is necessary. One of such skills is to provide them with self-decision and self-control. A patient may have alternative options for a radiological procedure, which have no or low radiation exposure. In most cases, the alternative options would be less effective than the initially considered radiological procedures. However, when patients are making their own decisions about the radiological procedure to undergo, they can have better risk perception. It should be noted that patients need to be provided with information on strengths, weakness, and effectiveness of not only for a radiological procedure being considered, but also for all other alternative options.

It is also helpful to provide a patient with self-control methods to reduce radiation exposure. In case of radioiodine therapy for thyroid cancer, use of recombinant thyroid stimulating hormone (rhTSH) can be considered for patient preparation, instead of conventional thyroid hormone withdrawal. As renal function is preserved by rhTSH use, radioactivity retention and radiation exposure would be reduced (Menzel et al., 2003). Additionally, following a strict low-iodine diet can improve efficacy of radioiodine therapy and may prevent the need for additional radioiodine treatment (Sohn et al., 2013). The participation and action of patients in reducing radiation exposure would be beneficial to correct risk perception of radiological procedure. However, the most fundamental principle in such communication is patients' trust in their physicians. Physicians need to provide patients with accurate, reliable and understandable scientific data, so that patients can make a more reasonable decision.

#### 4. SUMMARY

With increasing use of radiological procedures in medical practice, it is important to prevent unnecessary patients' overconcern about radiation exposure. Effective communication between physicians, patients, and their caregivers is essential for ensuring patients to have correct perception of the risks. The communication needs to be based on accurate and understandable information, self-control and self-decision, and most of all, trust of patients in physicians.

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# A comprehensive biokinetic model for the dose to embryo and fetus due to radon intakes by the mother – Part I: the state of the art

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**Abstract**–RadoNorm is a European project that aims to support the European Union Member States, Associated Countries, and the European Commission to implement the Council Directive 2013/59/EURATOM regarding radon and NORM risk management, ensuring effective radiation protection based on most recent scientific studies and societal aspects. The Work Package 3 is focused on dosimetry and its subtask 3.3.1 targets on the design of a comprehensive model for the dose to embryo and fetus following radon intakes by the mother. The first part of the subtask consisted in gathering information on the state of the art on biokinetic models for embryo and fetus, and searching for animal and human data that could be useful to build a specific biokinetic model. This paper reports on the literature review on the identified data that are relevant to perform the task. Publications of the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), and the U.S. Nuclear Regulatory Commission were reviewed with regard to how doses from radon and radon progeny to the embryo and fetus have been calculated so far. Currently, a general approach for the calculation of the concentration of a radionuclide in embryonic and fetal tissues ( $C_F$ ) is based on the ratio to the concentration of that radionuclide in the mother's body ( $C_M$ ) as given in *Publication 88* of the ICRP. However, no biokinetic model specific for radon and radon progeny is presented there. The challenging task of defining a specific biokinetic model for radon faces the lack of experimental data and the scarcity of recent works, especially regarding transfer of radionuclides through the placenta. Nevertheless, some results of animal studies on radon, radon progeny, and other noble gases can be used as a starting point to build the biokinetic model as well as some recent assumptions considering the concentration of radon in the fetus following intakes by the mother as being the same as in the mother's muscle, because fetal tissues do not contain much fat. Using the most recent adult model describing the biokinetics of radon in the mother and assuming the hypothesis of radon concentration in fetus being the same as in the mother's muscle are reasonable approaches to the biokinetic model. Animal studies provide useful information for a more realistic modelling of radon progeny biokinetics, with regard to lead and bismuth placental transfer and direct translocation of lead from maternal skeleton to fetal tissues.

**Keywords:** Internal dosimetry; Radon; Fetal exposure; Biokinetic model

## 1. INTRODUCTION

In 2013 the European Atomic Energy Community (EURATOM) in its Directive 2013/59/EURATOM (EURATOM, 2014) established new Basic Safety Standards (BSS) regarding radon and Naturally Occurring Radioactive Materials (NORM). To support the European Union Member States, Associated Countries and the European Commission in the implementation of these new BSS, the RadoNorm project (Kulka, 2022), entitled “Towards effective radiation protection based on improved scientific evidence and social considerations – focus on Radon and NORM” was funded in the frame of the EURATOM Research and Training Program, which covers nuclear research and innovation in the more general research



program Horizon 2020. The project started in September 2020 and is expected to finish in August 2025.

The RadoNorm work package 3 (WP3, dosimetry) aims to calculate absorbed doses with updated biokinetic and dosimetric models based on the most recent recommendations of the International Commission on Radiological Protection (ICRP). The subtask 3.3.1 targets on the design of a comprehensive model for the dose to embryo and fetus following radon intakes by the mother. To this end, the first part of the subtask consisted in gathering information on the state of the art for biokinetic models for embryo and fetus in general, and search for animal and human data that could be useful to build a specific model for radon and its progeny. To accomplish this task, publications of the International Commission on Radiological Protection (ICRP) and the U.S. Nuclear Regulatory Commission were reviewed with regard to how doses from radon and radon progeny to the embryo and fetus have been calculated so far.

## **2. A COMPREHENSIVE BIOKINETIC MODEL FOR THE DOSE TO EMBRYO AND FETUS DUE TO RADON INTAKES BY THE MOTHER**

### **2.1. Internal dosimetry and the use of biokinetic models**

A biokinetic model is a scheme that describes the distribution of a radionuclide in the whole body, organs or tissues as function of time. Such models are applied to calculate the total number or transformations in each source region within the body during a given period of time [time-integrated activity (Paquet, 2019)]. These models are usually represented by a compartmental structure consisting of a finite number of units (the compartments) with interconnections that illustrate the flux of the radionuclide transported either physiologically or chemically from one compartment to another. The mathematical description of such models is expressed by a system of differential equations. According to the ICRP, a compartment typifies an organ, a part of an organ, a tissue, a part of a tissue, or another substance of the body. The radionuclide activity is considered to be uniformly distributed in a compartment and depends on its physical and biological half-lives, and its biodistribution into the body (ICRP, 2015). In general, the material transferred between compartments is assumed to be proportional to the material in the parent compartment. This simple assumption of first-order kinetics neglects more complex physiological and chemical mechanisms, but is in general sufficient for the purposes of dosimetry and radiation protection (Giussani, 2011).

### **2.2. Considerations for a biokinetic model for radon**

Radon ( $^{222}\text{Rn}$ ) is a noble gas originating from the decay of  $^{226}\text{Ra}$  in the soil, rocks, and other materials. Because of its gaseous form, radon escapes from the physical matrix containing  $^{226}\text{Ra}$ . When outdoors, radon mixes with the ambient air, diluting its concentration. Nonetheless, when indoors, high concentrations of radon emanating from soil or building material can be reached, especially in case of poor ventilation. Radon is also found in drinking water, due to water contact with soil rich in uranium and its progeny. Therefore, in this study we consider that the pathways of intake are either through inhalation or ingestion. According to Sakoda et al. (2010), approximately 1% of the inhaled radon is absorbed into the blood and distributed all over the body, accumulating in organs with more fat content like other noble gases do. Although most part of the inhaled radon gas is readily exhaled from the lungs, radon progeny remains there. Consequently, radon progeny (consisting of alpha and beta emitters) is known to deliver the largest component to the dose, mostly to the lungs (Kendall and Smith, 2002). In contrast, in case of ingested radon the highest dose tends to be delivered to the stomach, once it stays there for a while before being transferred to the intestines and finally to

the blood (Khursheed, 2000). A biokinetic model for systemic radon proposed by Leggett et al. (2013) is used by ICRP to estimate intake and doses to workers (ICRP, 2017). Leggett's publication contains also a tabulation of parameter values for adult females that can be used for the exposure of members of the public.

In the case of an intake by a pregnant woman, one has to consider how the incorporated radionuclides are distributed among the maternal organs and the fetoplacental unit, taking into account the placental transfer of the radionuclide. The biggest challenge is to predict and establish the impact of the growth of the fetus on the radionuclide accumulation.

ICRP *publication 88* (ICRP, 2011) recommends that the calculations of absorbed dose to the conceptus during embryonic phase (up to 8 weeks after the conception) should be taken to be the same as the absorbed dose to the uterus wall. During the fetal phase, from the 9<sup>th</sup> week after conception up to term, the external dose to the fetus is averaged over the volume of the fetus and all fetal tissues are assumed to receive the same dose from the activity in the maternal tissues. For the internal component, there is a generic model based on the concentration of the radionuclide in the mother's body ( $C_F : C_M$ ). Using this generic approach, the activity in the fetus  $q_F(t)$  at time  $t$  is:

$$q_F(t) = (C_F : C_M) \cdot \left( \frac{m_F(t)}{m_M(t)} \right) \cdot q_M(t) \quad (1)$$

Being  $q_F(t)$  the activity in the fetus; ( $C_F : C_M$ ) the concentration ratio of the radionuclide in fetal and in the respective maternal tissue/organ;  $m_F(t)$  and  $m_M(t)$  the masses of the fetus and the mother respectively, and  $q_M(t)$  the maternal systemic activity. The activity in the placenta,  $q_{Pl}(t)$ , is calculated with a similar equation to (1), considering the concentration ratio between placenta and maternal tissues ( $C_{pl} : C_M$ ) (ICRP, 2001). ICRP *publication 88* (ICRP, 2001) does not provide specific values of the ratios ( $C_F : C_M$ ) and ( $C_{pl} : C_M$ ) for radon gas incorporated by the mother, but there are ratios provided for radon in case of intake of uranium and radium by the mother. Radon as a progeny is assumed to be uniformly distributed throughout fetal tissues. Both ratios, ( $C_F : C_M$ ) and ( $C_{pl} : C_M$ ), are considered to be 1.

In 1996 the US Nuclear Regulatory Commission issued the publication entitled 'Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses' (Sikov and Hui, 1996). Based on data derived from the experimental studies of Bagg (1922) and Sikov et al (1984, 1990), the author traced a correlation between the behavior of radon and that of other noble gases, especially <sup>85</sup>Kr.

In the study with <sup>222</sup>Rn, both the control group of 29 mated rats and the radon-exposed group of 48 mated rats were exposed 18h-per-day in a chamber from the 6<sup>th</sup> to the 19<sup>th</sup> gestational day (dg). The control group was exposed to filtered air atmosphere, while the study group was exposed to radon atmosphere at a <sup>222</sup>Rn concentration of  $1.25 \times 10^7$  Bq m<sup>-3</sup>. The equivalent dose rate in the placenta was found to be similar to that in the femur and liver and the equivalent dose rate in the fetuses was about one third of that in the placenta (Sikov et al., 1990). These results were compared with previous studies on rats exposed to <sup>85</sup>Kr, in which study groups of pregnant rats in different gestational days (dg) were exposed to a recirculated <sup>85</sup>Kr atmosphere, one group with exposure times of 4 to 6 hours to 37–40 nCi mL<sup>-1</sup> to determine krypton biodistribution and dosimetry, and another group with an exposure time of 5 days to krypton level of 40 pCi mL<sup>-1</sup> to evaluate developmental toxicity. Control groups were exposed to air atmosphere. The concentrations of <sup>85</sup>Kr in most fetal tissues were similar to the respective maternal tissues. They concluded that <sup>85</sup>Kr from atmosphere inhaled by pregnant rats reaches the placenta and fetus and that the radiation dose received by the fetus would be equivalent to the dose to maternal visceral organs, except to the lungs. These organs corresponded to 1% of maternal lung dose (Sikov, 1984). From the comparison of the two studies, they observed that

$^{85}\text{Kr}$  concentrations were more uniform than radon concentrations and that the fetoplacental radiation doses were similar to those received by the pregnant rats in krypton exposures (Sikov et al., 1990). In addition, they also concluded that radon tends to cross the placenta in both directions (mother to fetus and fetus to mother). This may also happen with other radon decay products, except polonium that has minimal accessibility to the fetus from maternal blood and tends to be deposited in placental structures (Sikov and Hui, 1996).

With regard to dosimetric calculations for radon in humans, Kendall and Smith resorted to the model offered by Marsh and Birchall (1999) and to the ICRP generic concentration ratios model ( $C_F : C_M$ ) to estimate doses in many organs and also in fetus after intakes by the mother in two different scenarios: inhalation of radon gas and its progeny and ingestion of radon and its progeny in drinking water. For polonium and bismuth, ( $C_F : C_M$ ) was taken to be 0.1, as ICRP makes no recommendation to radon gas and its progeny. They assume the dose to the fetus is similar to that to maternal muscle, since the fat content of the fetus is low. They concluded that the largest contribution to the dose to fetus after inhalation of radon and its progeny was actually caused by unattached particles of radon progeny. Doses following ingestion of radon in drinking water were higher than doses following inhalation due to radon exhalation by the lungs (Kendall and Smith, 2002).

### 2.3. Important considerations for radon progeny

Regarding radon progeny studies, Richardson proposed a model for predicting the in-utero activity of  $^{210}\text{Po}$  as a decay product of  $^{210}\text{Pb}$  (Richardson, 1994). Stable lead is known to cross the placenta, so it is assumed that the radioisotope  $^{210}\text{Pb}$  is also capable of crossing it, even  $^{210}\text{Pb}$  deposited in the mother's skeleton. In his model (Fig. 1), the ingrowth of  $^{210}\text{Po}$  in the fetal tissues from  $^{210}\text{Pb}$  transferred through the placenta was considered, and the skeletal activity concentration of  $^{210}\text{Pb}$  in the fetus was taken to be proportional either to the concentration of stable calcium in the whole body of the fetus, the concentration of stable lead in the whole body of the fetus, or the concentration of stable lead in fetal bone.

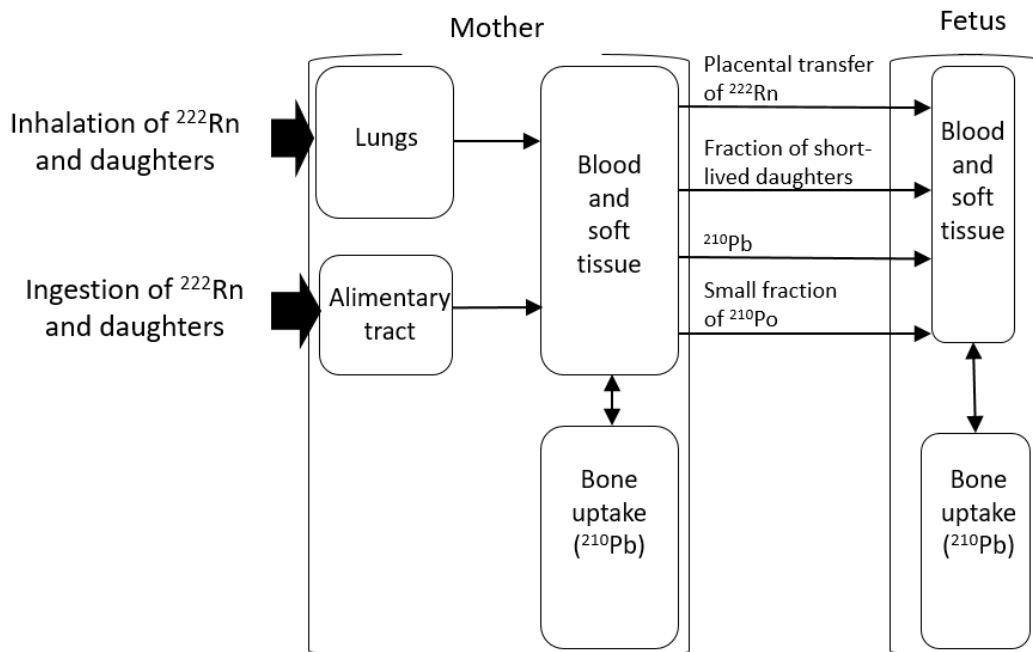


Fig. 1. Model proposed by Richardson considering the placental transfer of  $^{210}\text{Po}$  and  $^{210}\text{Pb}$  (Adapted from Richardson, 1994).

Finally, for bismuth, an experimental study conducted in guinea-pigs to assess the uptake of  $^{214}\text{Bi}$  in fetal organs after intravenous administration to the mother showed that the radionuclide would be poorly transferred across the placenta, once little activity was found to cross the placental barrier, being the activity found in fetoplacental unit less than 1% of the injected activity (Richardson, 1992).

### 3. OUTLOOK AND CONCLUSIONS

The proposed solutions for this biokinetic model involve using the most recent radon model for the mother's biokinetic from the upcoming ICRP publication on the exposures of the public. Following information from the literature search will be considered:

- Radon gas tends to accumulate less in the fetus since it has less fat. However, the bone marrow contains fat and radon would accumulate there.
- $^{210}\text{Pb}$  behaves as stable Pb and its translocation from maternal skeleton should be considered.
- $^{210}\text{Bi}$  tends not to cross the placenta.
- The external dose to the fetus due to radon concentration in maternal organs is the same as the dose to the mother's muscle, consistent with Kendall and Smith's hypothesis.

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# The novel terminology ‘discernible’ undiscerned conclusions: a critical review of UNSCEAR 2020/21 Fukushima Report

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**Abstract**—On March 2022, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) released the updated Fukushima Report 2020/21. Through this critical review, I identified serious problems. (1) The Report introduced the novel terminology ‘discernible’ that is equivalent to statistically enough power to detect increases in cancer. The Report explains that “‘no discernible increase’ did not equate to an absence of risk (Para. 213)’. In fact, for ‘females of ages in utero to five years at initial exposure, about 16 to 50 cases of thyroid cancer attributable to radiation could be inferred (snip) A statistical power analysis showed that an excess of 50 cases or less would be undetectable (Para. 222)’. However, UNSCEAR’s news releases and briefings do not explain the meaning of ‘discernible’, leading reporters and the general public to misinterpret ‘no discernible’ is ‘no risk’. That is a fatal failure in risk communication. (2) For thyroid cancers identified in Fukushima Ultrasound Examination (TUE), the Report concludes ‘the excess does not appear to be associated with radiation exposure, but rather a result of the application of highly sensitive ultrasound screening procedures (Para. 246)’. Because compared to Chernobyl, where a significant increase was observed among children under five years after four years of the accident, in Fukushima, a large part of thyroid cancer was detected in adolescents within three years. The report missed the context of TUEs in Chernobyl and Fukushima: TUE in Chernobyl started in the 1990s or after 4–5 years of the accident; in Fukushima, TUE started after a half year. Moreover, the literature review in the Report does not understand the limitations of the studies that reported insignificant relationships between radiation and thyroid cancer, suffered a lack of statistical power, and/or improper analysis. (3) For solid cancer (excluding melanoma and thyroid cancer), UNSCEAR’s statistical power analysis in Attachment A-23 indicated a lifetime increase likely to be detectable (LFR is 1.2% for 10-year-old girls subpopulation with a statistical power of 0.80). On the contrary, the report describes, ‘the levels of exposure of members of the public have been too low for the Committee to expect distinctive increases in the incidence of breast cancer or other solid cancers (Para. 247)’. A Critical review revealed severe problems in the UNSCEAR2020/21 Fukushima Report; thus the Report must be corrected or updated accordingly.

*Keywords:* Fukushima nuclear disaster; UNSCEAR; Thyroid cancer; Statistical power analysis

## 1. INTRODUCTION

UNSCEAR published its 2013 Report on the Fukushima nuclear disaster in 2014 (UNSCEAR, 2014) and has since periodically released white papers that review the published Fukushima-related papers. The UNSCEAR 2020/21 report (UNSCEAR, 2022b) is a revised version that reflects findings since the 2013 report. Due to space limitations, this study critically examines ‘Health implications for the public’ of the Report in terms of risk communication, thyroid ultrasound examination, and power analysis.

## 2. RESULTS

### 2.1. Serious failure of risk communication: Misinterpretation caused by failure to explain the meaning of the ambiguous word ‘discernible’

UNSCEAR released a draft version of the updated Fukushima report (UNSCEAR, 2021b) in March 2021. The press release at the time was titled ‘Radiation-linked increases in cancer rates not expected to be seen’ (UNSCEAR, 2021a). It reads as if the report denies the future occurrence of cancer. Moreover, the press release describes that ‘UNSCEAR said that future health effects, e.g., cancer directly related to radiation exposure are unlikely to be discernible’ without estimation method. Here, the unfamiliar word ‘discernible’ is utilised, that was introduced in the 2013 Report, describing it as (UNSCEAR, 2022b):

*213. The Committee explained that, in estimating values of the risk of stochastic effects due to exposure for members of various exposed groups, it has used the term “discernible” for cases where the estimated risk of the disease was sufficiently large in a large enough population to be detectable, compared to the normal statistical variability in the baseline incidence of the disease in that population. Conversely, when risks may be inferred from existing knowledge (i.e., using models), but the level of the inferred risk is low and/or the number of people exposed is small, the Committee has used the phrase “no discernible increase” to express the idea that currently available methods would most likely not be able to demonstrate an increased incidence in the future disease statistics due to irradiation (that is, the attributable risk is too small compared to the baseline levels of risk to be detected). The Committee emphasized that its use of the term “no discernible increase” did not equate to an absence of risk or rule out the possibility of excess cases of disease due to irradiation, nor the possibility of detection of a biomarker for certain types of cancer in certain subgroups being identified in the future that could be associated with radiation exposure. Nor was it intended to disregard the suffering associated with any such cases should they occur.*

According to this explanation, ‘discernible’ seems to have a meaning similar to that of ‘statistical significance’. Just as an ‘insignificant relationship between radiation dose and incidents of cancer’ does not necessarily mean ‘no risk’, not discernible doesn’t mean ‘no risk’. In fact, the report describes the possible risk of developing thyroid cancer as follows (UNSCEAR, 2022b, Para. 222):

*females of ages in utero to five years at initial exposure comprise the most susceptible subgroup. For this subgroup, about 16 to 50 cases of thyroid cancer attributable to radiation could be inferred from the estimated exposure, depending on the risk model assumed. (snip) A statistical power analysis showed that an excess of 50 cases or less would be undetectable.*

As explained, the risk of developing thyroid cancer is predicted but can not be detected because of noise. The meaning of ‘discernible’ is explained in the report but not in the press release, which caused a misunderstanding of ‘no risk’ of radiation.

In March 2022, UNSCEAR released the finalised Fukushima report 2020/21 (UNSCEAR, 2022b) and conducted an outreach in Japan in July 2022. The press release of outreach also

failed to explain the meaning of ‘discernible’<sup>1</sup>. Unfortunately, the meaning of ‘discernible’<sup>2</sup> was not explained during UNSCEAR outreach. This led to news reports misinterpreting ‘undiscernible’ as ‘no risk’. For example, one newspaper reported that ‘it is unlikely that there will be an increase in cancer and other health effects from exposure’<sup>3</sup>. Another TV station reported that ‘On July 20, the former chairman of the United Nations Scientific Committee visited Governor Uchibori of Fukushima Prefecture and reported the results of the report that there were no health effects from radiation exposure’<sup>4</sup>. In both cases, ‘discernible’ was omitted, leading to the misunderstanding that UNSCEAR concluded ‘unconditionally’ that there were or will be no adverse health effects from radiation exposure.

‘No risk’ and ‘risk is possible but not detectable’ are completely different situations. In the latter case, health examination should be enhanced to detect health risk, and medical responses should be prepared when it becomes apparent. If a ‘risk is possible but not detectable’ situation was misinterpreted as ‘no risk’, the harm could not be detected, and the damage could be magnified.

According to WHO, ‘The purpose of risk communication is to enable people at risk to make informed decisions to mitigate the effects of a threat (hazard) – such as a disease outbreak – and take protective and preventive measures.’ (WHO, 2022). The use of the novel word ‘discernible’ and the failure to fully explain its meaning, causing misunderstanding, is a fatal failure of UNSCEAR’s risk communication. UNSCEAR should explain the meaning of ‘discernible’ and strengthen testing and medical response.

## 2.2. Concluding on thyroid cancer without understanding the examination protocol

In Fukushima Prefecture, about 300,000 children and young adults under the age of 18 at the time of the Fukushima nuclear disaster were screened for thyroid cancer by ultrasound, and about 300 cases of thyroid cancer, including suspicious, have been detected so far. For thyroid cancer detected through thyroid ultrasound examination, the report concludes (UNSCEAR, 2022b):

*the excess does not appear to be associated with radiation exposure, but rather a result of the application of highly sensitive ultrasound screening procedures. (snip) (Because) (a) no excess of thyroid cancer has been observed in those exposed before age 5, in contrast to the large excess observed in the same age group exposed as a result of the Chernobyl accident; and (b) thyroid cancers were observed within 1 to 3 years after exposure following the FDNPS accident rather than beginning 4 to 5 years after exposure as in Chernobyl and other radiation studies.*

<sup>1</sup> no adverse health effects due to radiation exposure have been documented in the residents of Fukushima that could be directly attributed to radiation exposure from the accident, and it is unlikely that any such effects will be observed in the future.

<sup>2</sup> During outreach in Japan, the UNSCEAR team held briefing at the Japan Press Club, Tokyo Institute of Technology (TIT), Fukushima Medical University, and Iwaki City. The present author posted the following question and comment at the Tokyo Institute of Technology Scientific meeting held on 7/19/2022.

*Could you elaborate meaning of ‘discernible’? According to my understanding of the description in paragraph 222, you expect 16 to 50 excess thyroid cancer for under 5 years old girls. But you estimated you can not identify them because of noise and small sample size. Is it right? If it was right, it is completely different from ‘no risk of cancer’. You should explain, ‘there is a certain risk of cancer, but we expect we can not detect them’.*

Dr. Balonov replied that ‘It is difficult to determine significance level.’ that was not reply to my question and comment.

<sup>3</sup> Yomiuri Shinbun 2022/7/19 “UNSCEAR says no health damage caused by radiation exposure is not recognized after Fukushima nuclear” disaster. Available at <https://www.yomiuri.co.jp/science/20220719-OYT1T50202/> (in Japanese) (last accessed 31 December 2022)

<sup>4</sup> TV You Fukushima “The United Nations Scientific Committee visits Fukushima.” <https://web.archive.org/web/20220720133407/> and <https://newsdig.tbs.co.jp/articles/-/100709?display=1> (last accessed 31 December 2022) (in Japanese).



UNSCEAR missed the results and the protocol of TUE in Fukushima. Although in the first round of TUE, no cancer was detected among children exposed before age 5, from the second to the fifth rounds of TUE in Fukushima, 16 thyroid cancers were detected in the group (POC for FHMS, 2022). Moreover, as UNSCEAR 2008 Chernobyl Report recognises, ‘the number of ultrasound examinations increased dramatically in all oblasts between 1990 and 2002, over 20-fold in Chernihiv and Zhytomyr Oblasts’ (Likhtarov et al., 2006). Thus, part of the increase in the observed thyroid cancer incidence may be attributable to the improved detection of cancers because of the greater use of ultrasonography (UNSCEAR, 2008 Para. D82). The increase after four years of the Chernobyl accident is attributable to an increase in screening rather than latency.

Furthermore, although the target of screening in Belarus by Sasakawa Zaidan were 0–9 years old at the time of the accident (Yamashita and Shibata, 1997), the participants were concentrated 0–5 years old (see Table 1). Thyroid cancer was found more frequently in children under the age of five at the accident, starting four years after the accident was attributed by biased TUE. In Fukushima, by contrast, 0–18 year-old are examined six months after the accident. Although the participation rate is slightly lower among high school students aged 15 and older, the age distribution of participants is not as distorted as in Chernobyl. UNSCEAR failed to understand the differences in the examination context in Chernobyl and Fukushima.

Table 1. Result of thyroid screening in Belarus by Sasakawa Project during 1991-1996\*.

	Age at the accident	Participants			Thyroid Anomalies			Thyroid Cancer		
		Boys	Girls	Total	Boys	Girls	Total	Boys	Girls	Total
Number	0	1383	1391	2774	73	86	159	0	5	5
	1	1350	1361	2711	69	107	176	2	9	11
	2	1284	1300	2584	64	102	166	2	2	4
	3	1211	1267	2478	75	115	190	4	3	7
	4	1115	1257	2372	87	146	233	2	1	3
	5	938	1073	2011	58	143	201	0	1	1
	6	719	817	1536	64	116	180	1	2	3
	7	434	452	886	40	53	93	0	1	1
	8	257	300	557	14	36	50	0	0	0
	9	163	195	358	0	10	10	1	1	2
	Total	8854	9413	18267	544	914	1458	12	25	37
Cases per 100,000 participants	0				5278.4	6182.6	5731.8	0.0	359.5	180.2
	1				5111.1	7861.9	6492.1	148.1	661.3	405.8
	2				4984.4	7846.2	6424.1	155.8	153.8	154.8
	3				6193.2	9076.6	7667.5	330.3	236.8	282.5
	4				7802.7	11,615.0	9822.9	179.4	79.6	126.5
	5				6183.4	13,327.1	9995.0	0.0	93.2	49.7
	6				8901.3	14,198.3	11,718.8	139.1	244.8	195.3
	7				9216.6	11,725.7	10,496.6	0.0	221.2	112.9
	8				5447.5	12,000.0	8976.7	0.0	0.0	0.0
	9				0.0	5128.2	2793.3	613.5	512.8	558.7
	Total				6144.1	9710.0	7981.6	135.5	265.6	202.6

\*Source) Table A15-T01, Table A17-T01, and A19-T01 in Yamashita and Shibata (1997).

### 2.3. Concluding on thyroid cancer without understanding the limitations in previous studies

In addition, although the UNSCEAR compiles a list of previous studies that analysed thyroid cancer in Fukushima (Table 16 in UNSCEAR, 2022b), they do not understand their limitations. For example, Suzuki et al. (2016) and Ohira et al. (2016), which reported no regional differences in cancer detection rates, lack the statistical power at a detection rate of 0.03% as criticised by the present author (Hamaoka, 2016, 2017). Ohira et al. (2020), that excluded children aged five years or younger at the time of the accident from their analysis and analysed the remaining samples separately for those aged 6–14 years and those aged 15 years or older, found *a negative and significant* relationship between the UNSCEAR estimated thyroid absorbed dose and the detection rate of thyroid cancer in the latter group. Their results contradicted common knowledge of radiation epidemiology that identified linear dose-response with positive slope (NCRP, 2018), and the validity of the analysis should be questioned. Unfortunately, UNSCEAR 2020/21 report missed these limitations.

Thus, the conclusions of the UNSCEAR report, which does not understand the context of TUE in Fukushima, and which does not thoroughly examine the previous studies on thyroid in Fukushima, are hardly plausible.

### 2.4. Descriptions that differ from the analysis results

The UNSCEAR 2020/21 Report (Para. 247) summarises the results of health implications:

*Likewise, the levels of exposure of members of the public have been too low for the Committee to expect distinctive increases in the incidence of breast cancer or other solid cancers.*

This is against the result of Attachment-23 that conducted power analysis (UNSCEAR, 2022a), in which the lifetime risk of all solid cancer (excluding thyroid cancer and nonmelanoma skin cancer) for female 10 years old age subpopulation is estimated at 1.8% with a statistical power of 0.80 for a municipal average dose (Table A 23.9 in Attachment-23). The results are explained in the Attachment as follows (UNSCEAR, 2022a):

*A potential exception to this occurred for females initially exposed at age 10, with a related value for both sexes: statistical power achieved the 80% criterion for the mean dose, indicating that one might potentially see a radiation-associated excess in this subpopulation (but see caveats in the next paragraph).*

As mentioned within parentheses, four caveats are described in paragraph 46 of Attachment-23, which is not convincing. For example, for reason (a), even 'very small', possible risks must be avoided to protect the general public. Reason (b) missed Japanese cancer statistics experts confirmed that the Japanese cancer registry is sufficiently accurate to detect the effect of radiation exposure-caused cancers<sup>5</sup>. For reason (c), if the uncertainty of the parameters were evaluated, much higher power would be obtained for the upper bound of the parameter. Furthermore, reason (d) ignores the fact that the statistical power exceeds 80% not only in the upper 95% dose but also in the average dose population.

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<sup>5</sup> Dr. Katanoda (Chief, Division of Surveillance and Policy Evaluation, Institute for Cancer Control, National Cancer Center and member of the Thyroid Examination Evaluation Committee of Fukushima Health Management Survey) explained. "The cancer registry data [in Fukushima Prefecture] is sufficiently accurate [to detect an increase in thyroid cancer]," Minutes of 16th Thyroid Examination Evaluation Committee of FHMS (2021/3/22) in Japanese. Available at <https://www.pref.fukushima.lg.jp/uploaded/attachment/454168.pdf>.

The Report's conclusion (Para. 247) failed to understand that strong statistical power was obtained even with 'too low level of exposure'.

### 3. SUMMARY AND CONCLUSIONS

In this short paper, I reported the results of a critical review on Health Implications: General Public. A review revealed severe problems in the UNSCEAR 2020/21 Report. The descriptions in the report contradict the analysis results; the Report must be corrected or updated accordingly. As I pointed out, risk communication must also be improved, which caused a misunderstanding of the results of the Report.

Due to space limitations, in this short paper, three limitations are summarised. Other problems that include methods of statistical power analysis, estimation of thyroid absorbed dose, and others will be reported elsewhere.

### ACKNOWLEDGEMENT

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## Beyond radiation anxiety and country borders: applying health literacy in the field after the Fukushima nuclear disaster

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**Abstract**—The 2011 Fukushima nuclear disaster placed health professionals and the public in the centre of an ‘infodemic’. We introduced health literacy training for health professionals to improve communication skills when facing a health crisis. By 2019, one in four public health nurses – our gatekeepers of community health – had been trained in Fukushima. Follow-up evaluations showed that the trained nurses applied their newly learned skills in practice, with more positive attitudes toward – and increased confidence in – their interactions with community residents. We also found that older residents and those unfamiliar with health services were more likely to notice improvements in written health information from the trained health workers. Health literacy training enhances communication between professionals and the public and makes health information more equitably accessible. This training has been incorporated into medical and nursing education, and also into primary school education, with participatory health-related activities for children in Fukushima and beyond. Our health literacy initiative covers the two arcs of health literacy: health professionals’ ability to communicate health information and people’s (including children’s) ability to use the information.

*Keywords:* Health literacy; Fukushima

### 1. NEED FOR HEALTH LITERACY PROMOTION

Two arcs of health literacy are health professionals’ ability to communicate health information and people’s ability to use the information. An ‘infodemic’ that emerged after Fukushima’s 2011 nuclear disaster affected both arcs. This dual impact came to light in a previous study that analysed the voices of mothers in parenting counselling and those of public health nurses (PHNs), who are the gatekeepers of community health in Japan (Goto et al., 2014). Mothers asked PHNs about technical issues, including radiation measurement procedures, e.g. ‘What does it mean to measure a parent’s exposure level? Another city introduced a machine that a child can get into (and be measured directly)’. In response, PHNs showed a strong concern about explaining scientific and medical information, recognising that it was not only a matter of improving access to information, but also about taking its psychological impact into account: ‘I understood how to read the (thyroid cancer) screening results, but I am not confident in explaining them to residents’. This paper summarises our past achievements in implementing health literacy training for health professionals and how our health literacy initiative has reached out to younger generations in Fukushima and beyond.

## 2. HEALTH LITERACY TRAINING FOR HEALTH PROFESSIONALS

Table 1 summarises the achievements of our health literacy promotion activities among health professionals, using a ‘logframe’ (logical framework) evaluation model (Armstrong and Barsion, 2006). Initially, we prepared front-line PHNs by adapting an American health literacy training model to the Japanese language and context (Goto et al., 2015, 2018). By 2019, one in four PHNs in Fukushima had been trained (Honda et al., 2022). Post-training evaluations showed that: nearly half had applied their newly learned skills within a month (Goto et al., 2015); they showed more positive attitudes toward feedback from community residents (Yumiya et al., 2020); and self-evaluation of risk communication competencies improved (Honda et al., 2022). We also found that older residents and those not seeing doctors regularly were more likely to notice improvements in written health information from the trained health workers (Goto et al., 2021). These data show that health literacy training enhances communication between professionals and the public and makes health information more equitably accessible.

Table 1. Achievements of health literacy training.

<b>Project goal levels</b>	<b>Achievements</b>	<b>References</b>
Impacts	<ul style="list-style-type: none"> <li>• The training was incorporated into medical and nursing education within and outside Fukushima.</li> <li>• In-class exercises showed that among university students, data shown with a pictogram was preferred and trusted more than with a bar graph.</li> </ul>	Murakami and Goto (2019) Machida et al. (2022)
Outcomes	<ul style="list-style-type: none"> <li>• Trained PHNs showed more positive attitudes toward feedback from community residents.</li> <li>• Trained PHNs’ self-evaluation of risk communication competencies (responding to residents’ concerns, alleviating residents’ distress, building trust, supporting health-related self-efficacy) improved.</li> <li>• From the intended audience’s perspective, older residents and those not seeing doctors regularly were more likely to notice improvements in written health information from the trained health workers.</li> </ul>	Yumiya et al. (2020) Honda et al. (2022) Goto et al. (2021)
Outputs	<ul style="list-style-type: none"> <li>• One in four PHNs in Fukushima were trained.</li> <li>• Nearly half of trained PHNs had applied their newly learned skills within a month, and nearly 70% in a year.</li> </ul>	Honda et al. (2022) Goto et al. (2015, 2016)
Inputs	<ul style="list-style-type: none"> <li>• American health literacy training was adapted to a Japanese public health setting and implemented mainly for PHNs.</li> <li>• Subsequently, a health literacy toolkit, in booklet form, was developed for teaching.</li> </ul>	Goto et al. (2015, 2018)

This health literacy training has been incorporated into medical and nursing curricula at Fukushima Medical University (FMU) (Murakami and Goto, 2019). For example, medical students at FMU have collected data from their peers to compare how risk perception depends on the style of presentation graphics. Subsequent analysis showed that data presented in pictogram form, in contrast to a traditional bar graph, was preferred in general and trusted more

among those with a lower health literacy level (Machida et al., 2022). Requests from other schools and universities within and outside the prefecture, including those serving international students, have led us to modify sessions to meet specific needs while continuing to be highly interactive with exercises, group discussions, and presentations.

### 3. HEALTH LITERACY PROMOTION FOR THE NEXT GENERATION IN COMMUNITY

More recently, our ‘Creative Health’ project for elementary school students facilitates their scientific and creative thinking, working in teams, presenting, and expressing their opinions (Goto et al., 2021). The project consists of three workshops: BODY, FOOD, and ACT. In the BODY workshop, students share simple statements of what they know about their body, continue by presenting scripted storyboards about medical discoveries, and then create a histogram from their own heart rate measurements. In the FOOD workshop, students learn through cooking, quizzes, and drawing how their body depends on what they eat and how their community produces or otherwise provides the food they eat. In the ACT workshop, students use participatory theatre methods to express their ideas about food and health in their local community (Lloyd Williams and Goto, 2022). Participating children appreciated presenting, measuring, connecting new topics, and working collaboratively with peers. Teachers have learned ways to promote children’s creativity and capacity to express their opinions. Beyond Fukushima, we are partnering with teachers in Indonesia, Cambodia, and Rwanda. Under travel constraints due to the COVID-19 pandemic, we conducted online training for local facilitators including medical school faculty and students, NPO staff, and primary school teachers. Fig. 1 shows an online training session for the Indonesian team and representative opinions from students, parents, and teachers after implementation at local schools (Muniroh, 2022). Similar to our Japanese experience, teachers in other countries learned to accept students’ opinions and recognise their abilities. This ‘Creative Health’ approach may enhance children’s autonomy as agents of change in their community.

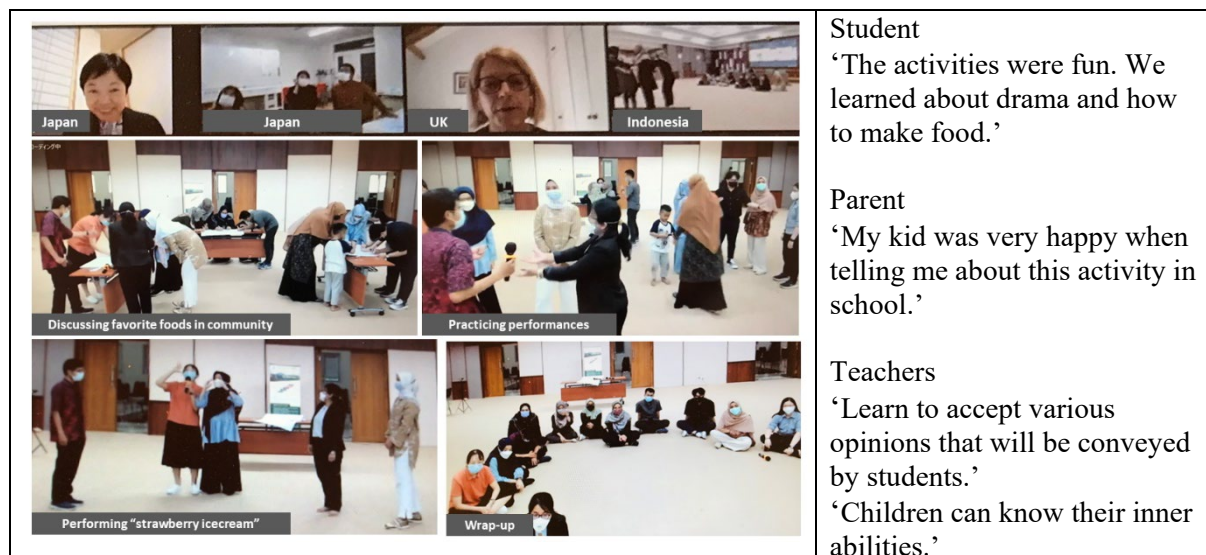


Fig. 1. Online facilitator training and opinions collected after implementation at a local school.

### 4. CONCLUSION

In summary, health literacy training – developed for health professionals after the Fukushima nuclear disaster – has been adapted to educate university students and engage

children in communities, thus covering two arcs of health literacy and outreaching to the next generation within and outside Japan. The evolution of our health literacy initiatives serves as a ‘build back better’ model after a major crisis.

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## Don't throw out too many babies with the bathwater, and remember old ideas!

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**Abstract**—The retraction in ICRP *Publication 103* of assessments of genetic effects after the 2nd generation needs to be corrected, for reasons of public trust at least. The medical management of persons exposed to high doses of radiation needs to be addressed. Experts' desire to achieve ever increasing precision in dose coefficients (unfortunately much appreciated by some regulators) may be at variance with the intention to achieve a comprehensible, defensible practical system. Repeated examinations of patients may lead to excessively high doses and should be investigated. Ethical considerations require that basic philosophical principles of ethics are taken into account, calls for reasonableness are an important theme but some of the most absurd examples of 'excessive protection', such as the gold-plated waste handling of 'spent' nuclear fuel, will be hard to address. Many good older suggestions are worth re-visiting – e.g. giving greater weight to relatively high doses and to doses incurred now rather than in the far future. ICRP should also re-assess its remit and consider non-ionising radiation [in conjunction with the International Commission on Non-Ionizing Radiation Protection (ICNIRP)], safety and security [with the International Nuclear Safety Advisory Group (INSAG), and general regulatory philosophy.

*Keywords:* Next ICRP Recommendations; Genetic risk; DCs; Ethics; Scope

### 1. INTRODUCTION

Having served in the capacity of the then Scientific Secretary of ICRP, and thus as the Editor of ICRP *Publication 103* (2007), I commend the Commission's ambition to produce in due course an updated set of fundamental recommendations, and am following with great interest this project and the related debate, e.g. Clement et al. (2021); Laurier et al. (2021); and Rühm et al. (2022). New scientific developments and accumulated practical experience of the existing recommendations necessitate regular updating of the ICRP Recommendations. An additional reason for updating is that there are also some flaws in the existing recommendations, partly reflecting my own shortcomings as an editor.

However, in order to ensure that the System of Radiological Protection remains fit for purpose, it is important not to be overzealous when revising the system (e.g. in the context of 'reasonableness', as further argued below in Section 2.4.2). That is not to be construed as advice against the revision as such. At the present Symposium, both P. Johnston and M. Pinak (2022) voiced concerns on behalf of the International Atomic Energy Agency (IAEA), claiming that the Agency would be unlikely to update its IAEA (2014) Basic Safety Standards unless the new ICRP Recommendations contain vitally important and new conclusions. Similar views are often aired when new ICRP Recommendations are presented or contemplated, often with the added observation that the process of updating ICRP recommendations usually begins before the national legal implementation of any particular generation of ICRP recommendations is completed. However, while that observation may hint that revisions should not occur too frequently, ICRP certainly needs to issue new fundamental

recommendations at least every 20 years – even if only to re-iterate the previous version, the Commission must clarify what recommendations and which reports are still valid.

## 2. SPECIFIC ISSUES NEEDING ATTENTION

### 2.1. Committee 1 issues

These are issues concerning the medical and biological effects of ionising radiation.

#### 2.1.1. Genetic risk estimates

In the ICRP (1977a) Recommendations, *Publication 26*, the estimate of risk due to genetic effects of radiation for radiological protection purposes covered just two generations, while the total population detriment for all generations was ‘considered to be about twice that which is expressed in the first two generations only’. *Publication 26* offers no rationale for the actual risk estimates given, nor for the choice of including just the first two generations in a radiological protection context. Instead, explanations are given in the accompanying ICRP (1977b) report. This still does not give a proper explanation of how the genetic risk was computed, but the estimate had been provided by a Committee 1 Task Group, the results of which were published only as Oftedal and Searle (1980) and which was inexplicably not referred to in the ICRP (1977a,b) reports. The choice of including just two generations in the estimate for radiological protection purposes seems to be based on what, in the Commission’s view, an average worker is likely to consider important.

In ICRP (1991a), the 1990 Recommendations, the estimate was extended to genetic equilibrium, i.e. essentially an infinite risk integral. The reason given for this was that ‘In assessing the consequences for exposed individuals, the Commission has previously taken account of the hereditary effects that might occur in their children and grandchildren. This left the effects in later generations to be considered as part of the consequences for society. The Commission now attributes the whole detriment to the dose received by the exposed individual, thus avoiding the need for a two-stage assessment’. A full and amply referenced explanation of the calculation of the risk estimate was provided in ‘Supporting Guidance 1’, ICRP (1991b).

However, in 2007 ICRP reverted to just 2 generations, which was in my opinion a big mistake for credibility and psychology. The reason given was that ‘In *Publication 60* genetic risks were expressed at a theoretical equilibrium between mutation and selection. In the light of further knowledge, the Commission judges that many of the underlying assumptions in such calculations are no longer sustainable. The same view has been expressed by United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (UNSCEAR, 2001) and National Academy of Sciences/ National Research Council (NAS/NRC) (NAS/NRC, 2006). Accordingly, the Commission now expresses genetic risks up to the second generation only’. In Annex A of *Publication 103*, it is also argued, based on UNSCEAR calculations, that the majority of the hereditary effects would be manifested in the first two generations, such that an estimate up to equilibrium would not differ materially from a two-generation estimate.

I fully accept that the assumptions behind the equilibrium estimate are no longer sustainable – but I feel that the assumptions and the flaws in them need to be discussed more prominently in the main text of the next recommendations. Furthermore, I do not find the *Publication 103* reference to UNSCEAR calculations regarding a longer-period risk estimate convincing. In my opinion, the next recommendations should include a table presenting risk estimates computed for, say, 5, 10, 20, 30, and 50 generations, and the choice of the number of generations chosen for the radiological protection estimate (which may be 2, 5, 10, or whatever) should be carefully motivated.

An additional problem with the *Publication 103* assessment of genetic risk is that in spite of seemingly clear and precise descriptions, it is difficult to follow the method and logic of the calculations and not possible, with the numbers and sources given, to replicate in exact detail the calculation results for the risk estimates. A similar problem exists for the calculation of detriment where cancer risks are included. My understanding is that these problems are being addressed by an ICRP Task Group.

And for the record, I advise against the *Publication 103* terminology of ‘heritable’ effects or risks – in my opinion, it would be better to talk about genetic effects, or hereditary effects.

### **2.1.2. Medical management of persons exposed to high doses of radiation**

High doses of ionising radiation will cause significant harm to the human body. Various kinds of medical treatment can reduce the harmful effects of a high-dose event and increase the probability of survival. While high-dose events keep recurring, cases in any given country are rare. The average physician has never seen, let alone treated, a victim of a high dose of radiation.

Because high-dose radiation events are rare, education and training regarding the symptoms and possible treatments tend to be at a disadvantage when universities plan their curriculum. The relevant textbooks are getting out-of-date. Reports describing cases, treatments, and results are scattered in widely different journals. Emergency preparedness planning rarely takes sufficient account of victims of high radiation doses. Radiological protection experts, medical physicists, and medical staff are all insufficiently educated and trained in this area. However, not only do the rare events continue to occur, but possible malevolent events could lead to high doses to many victims and the possibility of exposures from a new nuclear weapon explosion (intentional or otherwise) cannot be excluded.

Therefore, ICRP has an important task to fulfil. The Commission must go back to its 1920s roots of protection against serious/fatal tissue reactions and explain how we should manage patients with serious overexposures (accidents, nuclear explosions, etc). But a lot of the legwork has been done already, in the shape of two recent collections of papers on this topic: Valentin and Stenke (2022) from the Karolinska Institute, and Carr, Wilkins and Reyes. (Carr et al., 2022) from the World Health Organization’s Radiation Emergency Medical Preparedness and Assistance Network (WHO REMPAN). Together, these two Special Issues should comprise all the basic information an ICRP Task Group may need to provide pertinent advice.

It could be argued that this is a Committee 3 task, but in my opinion, since this deals very much with the medical effects of ionising radiation, it is primarily a Committee 1 responsibility.

## **2.2. Committee 2 issues**

These issues concern the dose-per-unit-intake coefficients painstakingly produced by the Committee’s Task Groups.

### **2.2.1. Timely publishing of dose coefficients**

The 1977, 1990, and 2007 Recommendations of ICRP were all dependent on new dose coefficients – which however became available only several years later than the recommendations. ICRP must not again, for the fourth time, issue dose coefficients long after the corresponding Recommendations. This is not a criticism of the hard-working experts of Committee 2. Rather, the Main Commission must learn to wait until all the building blocks which are required for the full use of the recommendations are available.

### **2.2.2. Proper presentation and use of dose coefficients**

This could be viewed primarily as a communication problem. It is important that compilations of dose coefficients really highlight only the major changes. Otherwise, they may tempt regulators and operators to fall into the trap of over-interpreting minute differences, thus encouraging the fallacy of forgetting that with a linear-no-threshold dose response model, limits do not separate ‘dangerous’ from ‘safe’ (which means of course that minor dose variations, for instance due to minor modifications of dose coefficients, are not desperately significant).

## **2.3. Committee 3 issues**

These issues concern the protection of patients and staff in medical usage of radiation, an area where ICRP has really been taking the lead in recent years. However, improvements are always possible!

### **2.3.1. Cumulative doses due to recurrent procedures**

Repeated imaging can lead to quite high patient doses. This is a theme that has attracted recent attention; see e.g. IAEA (2021) and Brower and Rehani (2021). Martin and Barnard (2021, 2022) do not seem to be very worried by this problem. I believe that they may be underestimating the problem because their data refer to UK patients – but medical radiological protection is exceptionally good in the UK, so the frequency of patients getting really high doses may be higher in other countries. Also, the problem perhaps is not just the risk of cancer induction, there might be serious tissue reactions in some cases.

In the discussion after the oral presentation of this paper, it was argued that automatic dose registration during imaging might be more important than keeping track of patient doses. I would agree that having automatic dose registration on all imaging equipment is very important and may be a requisite in order to address cumulative doses, but I still maintain that Committee 3 should launch a Task Group on repeated exposures.

## **2.4. Committee 4 issues**

These refer to the practical implementation of ICRP advice, where scientific information must be blended with common-sense judgements, and therefore ethical issues are very important.

### **2.4.1. Ethical considerations require application of ethical principles**

ICRP (2018) is a very important overview of the ethical foundations of the System of Radiological Protection, but it treats the philosophical theory of ethics too grudgingly. As a practical tool for ethical considerations, it focuses on the core values of beneficence/non-maleficence, prudence, justice, and dignity. These core values, while important, really just say that we must be ‘good’ and behave ‘nicely’, which does not help with the difficult ethical problems.

Some worked examples of ethical conflicts and how they are resolved are required, not just for medical radiological protection where such examples are already in the offing, but also for other areas.

#### **2.4.2. Low-dose decision-making must be reviewed *cautiously***

IRPA (2021) and in particular Coates (2022) offer very convincing and at times derisive reasons to address non-sensical ‘over-protection, such as in the use of clearance values. However, when fixing such flaws we must not discard important protection achievements. It is not possible to optimise too much – if protection is too costly it is not optimised!

Having been raised in Bo Lindell’s very utilitarian atmosphere, he often said that ‘if it does not cost any, it’s useful if it saves a statistical life’.

And perhaps the worst, most expensive waste of resources is for spent nuclear fuel, but so many even in our community have invested so much in absurdly over-safe solutions that it will be very difficult to change things.

#### **2.4.3. Revive good old NRPB ideas!**

The UK National Radiological Protection Board was once pronounced in an international assessment to be ‘the best organisation of its kind in the world’. A year later, in a politically motivated re-organisation NRPB was merged with other bodies and no longer exists in its former glory. However, long before those events, it was a hot-house for new ideas. One of those ideas was that it might be sensible to give greater weight to high doses than to low doses (a concept which was also put forward by Lips (2022) at this symposium).

Another such ideas were that it might be relevant to give more weight to current doses than to doses assessed to occur in the far future. Both of these ideas were also repeated as food for future thought by ICRP (2007).

Of course, both of these ideas sound controversial. However, I am convinced that it is possible to find logical and ethical support in favour of these ideas, and I suggest that Committee 4 should launch the necessary Task Group(s) to pursue them.

### **3. THE SCOPE OF ICRP**

Here, I am referring to the remit of the organisation as such which I think could be widened, not to the scope of radiological protection.

#### **3.1. Non-ionising radiation**

The Commission’s worst mistake ever was to refuse to take on NIR when WHO requested that. ICNIRP, the International Commission on non-ionizing radiation protection, does a brilliant job, but both our customers and the ICNIRP experts would benefit from a merger of the two Commissions, or at least, a much closer continuous collaboration.

#### **3.2. Safety and security, not just protection**

INSAG, the International Nuclear Safety Advisory Group at IAEA, was intended to mimic ICRP but is a failure in that respect, since it is not independent. Furthermore, INSAG is not very productive. Again, I believe a merger, or at least a much closer collaboration, would be most valuable for both organisations. As an early task in this context, ICRP should develop advice regarding risk constraints – ICRP (1997) cannot remain the last word on this important topic!

### 3.3. Regulatory philosophy

Here I have no specific counterpart in mind – apparently no similar international advisory organisation exists, which means that the need for advice is great and ICRP would do a very useful service if a Committee specifically on this topic were launched. Expertise from the aviation sector, from toxicology, and from the nuclear sector would be well placed here,

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## NTW role in nuclear safety and transparency

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**Abstract**—Nuclear Transparency Watch (NTW) is a non-governmental organisation, based on French law from 1905, devoted to nuclear safety and transparency, organised as network of NGOs and experts in almost all European countries. Building on the Aarhus Convention, NTW works to ensure that civil society is present at the heart of expertise and decision-making on nuclear safety and security in the European Union. The network's activities cover the entire nuclear cycle, with a particular focus on operational safety, including issues such as life extension of old nuclear power plants, emergency preparedness and response (EP&R), post-accident management, radioactive waste management (RWM), decommissioning and environmental issues. In parallel, the topic of transparency is constantly followed, at the national or European level. Some more important activities included: organisation of thematic Aarhus Convention and Nuclear round tables on important topics like EP&R and RWM with European partners, follow-up of the implementation of the Radioactive Waste Directive (2011/70/EURATOM), participation in the research RWM programme EURAD (The European Joint Programme on Radioactive Waste Management) to access the expertise based on the double wing model utilised, assessment of the independence of nuclear regulators in the different national contexts of the EU, development of rolling stewardship in the context of long term RWM. NTW builds a strong institutional presence and visibility at the European and UN level [links with the European institutions, International Atomic Energy Agency (IAEA), the Convention for the Protection of the Marine Environment of the North-East Atlantic (the OSPAR Convention)] and coordinate its members in activities. The main results will be described and discussed.

*Keywords:* Transparency; Nuclear; Safety

### 1. NUCLEAR TRANSPARENCY WATCH OVERVIEW

Nuclear Transparency Watch (NTW)<sup>1</sup> is a non-governmental organisation, based on French law from 1905, devoted to nuclear safety and transparency, organised as network of NGOs and experts in almost all European countries. NTW promotes the conditions for democratic transparency and effective public participation in the nuclear sector. It supports and assists national and local initiatives and civil society organisations seeing to promote transparency of nuclear activities. It favours the sharing of information among participants and the building of participatory review of nuclear safety arrangements when appropriate. Finally, it raises the voice of civil society in the European and national decision-making processes on nuclear activities and provide information to the European Union institutions and Members of Parliament. Currently we have 55 members, organisations and individual experts from across Europe. The Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters defines the bases for NTW activities and it is transversal to all our actions (UNECE, 1998).

The network's activities cover the entire nuclear cycle, with a particular focus on operational safety of nuclear facilities, including issues such as lifetime extension of old nuclear power plants, emergency preparedness and response (EP&R) in case of nuclear accidents, post-

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<sup>1</sup> <https://www.nuclear-transparency-watch.eu/>



accident management, radioactive waste management (RWM) devoted to different types of radioactive waste, decommissioning of nuclear facilities and environmental issues of nuclear sector. In parallel, the questions of transparency are constantly followed, at the national, European, and international level. From year to year, NTW participate to more activities, lately we focused also on the development of our own actions.

The radiation protection is included in our work implicitly, as the fundamental safety objective is *'to protect people and the environment from harmful effects of ionizing radiation'* (IAEA, 2006). This fundamental safety objective of protecting people and the environment has to be achieved for all nuclear facilities and activities using ionising radiation. Some measures have to be taken, such as control of the radiation exposure of people and the release of radioactive material to the environment, restriction of the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation and mitigation of the consequences of such events if they were to occur.

## 2. MAIN ACTIVITIES OF NTW

NTW organised several topical areas in which main efforts are directed and include nuclear safety of Nuclear Power Plants (NPP), RWM, and EP&R. In addition to these areas, we currently organise the new area devoted to the Environmental Impacts. The transparency as defined in the Aarhus convention is cross cutting to all topics and constantly monitored.

NTW builds a strong institutional presence and visibility at the European and the United Nations (UN) level and has links with the European institutions, [like the European Commission (EC), the European Nuclear Safety Regulators Group (ENSREG), Heads of the European Radiological Protection Competent Authorities (HERCA)], but also to International Atomic Energy Agency (IAEA) and different commissions based on important conventions (the Convention for the Protection of the Marine Environment of the North-East Atlantic (the OSPAR Convention), the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention), Convention on Environmental Impact Assessment in a Transboundary Context (the ESPOO Convention)] and coordinate its members' participation in related activities.

Some activities which also related to the radiation protection are reported here in order to present the content and also the approaches with methods and tools as they are used for interactions.

### 2.1. Emergency preparedness and response (EP&R)

NTW did perform EP&R assessment from civil society (CS) view (NTW, 2015): this was a past project but with large impact, proving that the current arrangements in case of nuclear accident are not addressing many concerns of society, specially local inhabitants (e.g. topics where improvement is needed include iodine prophylaxis, involvement of public in planning and management at local, national and trans-boundary levels, harmonisation of emergency provisions, reconsideration of evacuation process in the case of large urban area,...). Based on findings NTW started with different dissemination activities, such as presentation at different events and conferences (NTW, 2022a), but also with development of EP&R leaflet which will be translated in national languages: simple information with suggestions what to do.

Among the latest activities, NTW with collaboration of the European Commission organised an Aarhus Convention and Nuclear Round Table in January 2022 to assess the implementation of the Aarhus Convention in the preparation and cross-border management of nuclear accidents. Divided into three sessions, the round table focused on taking stock of the

implementation of European and national regulations on cross-border nuclear crisis management. It then set up small discussion groups based on a dialogue methodology (serious games) on concrete accident scenarios. The round table ended with a reflection on the lessons learned from the COVID crisis for nuclear accident and post-accident management. A report has then been done by NTW after the European Commission's request to assess the results of this round table.

NTW also took part as an observer in the project for the European Commission led by NucAvisor on the Implementation of nuclear and radiological emergency preparedness and response requirements in EU Member States and neighbouring countries. A lack of minimal discourse between the authors and members of civil society as well as a lack of civil society viewpoints inclusion had unfortunately to be reported.

## 2.2. Radioactive waste management

NTW is involved in European research programme EURAD (The European Joint Programme on Radioactive Waste Management)<sup>2</sup> dealing with radioactive waste management, where NTW represents CS in a double wing model: on one side CS experts are directly involved in work packages, on the other side the larger group of CS members, representing different more and less advanced radioactive waste programmes/countries are engaged in the programme to exchange, comment and suggest on the outcomes from the programme. The CS experts are mainly involved in two strategic studies on uncertainty managements and radioactive waste management from cradle to grave. NTW contributes with CS experts addressing important questions for society: what questions are brought in case of shared RW solutions, what lessons can be learnt in the development of national radioactive waste solutions for transparency, how to address the remaining uncertainties in RW management, what would be approach in the longer period for governance after closure of RW disposal.

In this context, it appeared important to take advantage of EURAD to develop within NTW a broader reflection on the legal, scientific, social and financial conditions for a continuous, very long-term citizen monitoring of radioactive waste management activities (notion of 'Rolling Stewardship' first developed in North America, of long-term intergenerational monitoring). NTW is organising a set of webinars on the subject and now introduce it into discussion in the EURAD programme (NTW, 2022b,c).

## 2.3. Environmental Impact

A new group on 'Environmental Impact' was created in 2022 with aim to report on the various types of radionuclides discharges throughout Europe. In the frame of this group several project can be reported:

- Open Radiation project which was launched in cooperation with French technical support organisation IRSN to measure radioactivity in the environment, started in 2021 and attracted several NTW members in the European Union (EU). In addition, in partnership with NTW member Cumbria Trust in Sellafield (UK), a school project was initiated in which students under the supervision of the science professor perform the measurement in local environment. Now the plans are to broaden the project and to engage local population in areas where local partnerships will be formed for geological repository of high-level radioactive waste to be involved in measurements. This way NTW enables to empower the citizens and also provides options for increased awareness on the radioactivity.

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<sup>2</sup> <https://www.ejp-eurad.eu/>

- NTW support and coordinate the members in the participation to the Environmental Impact Assessments (EIA) for life-time extension (LTE) of existing NPPs and other facilities as well as for new RWM facilities. The contributions were applied in case of LTE Doel, Loviisa, Krsko nuclear power plants and in case of Onkalo repository in Finland. Within the framework of the Espoo Convention, NTW will keep asking for real public participation opportunities despite the outcomes as this will still enable public participation for all registered.

## 2.4. Transparency

NTW continuously work on the implementation of transparency in relation to the nuclear. In this context we organise debates in the form of Round Tables devoted to specific topics (like RWM, EP&R, LTE for NPPs) and discussion how the Aarhus convention has been implemented and if there are any uncertainties, challenges or problems and how to solve them.

We also work on individual studies, like study on the independence of regulators which started in the summer of 2020 and was due finalised recently. The aim is to examine governance of regulators and compliance gaps with the independence as defined in the Independence in Regulatory Decision Making (IAEA, 2003)<sup>3</sup>. In the framework of this project, several activities will be carried out, like research on the development of a whistleblower platform, an overview of the independence mechanisms in place as a first step in the reform and a legal overview of nuclear regulatory authorities in the EU Member States.

The first results of this study show that the problem of regulator independence is more sociological than legal. They highlight strong national differences in the independence of nuclear regulators, depending on the political and social contexts.

Also, new tools for interaction of different actors have been developed in collaboration with different networks. In the frame of SITEX.Network<sup>4</sup> the PEP - Pathway Evaluation Process 'serious game' was developed with intention to foster dialogue around concrete topics, like radioactive waste management scenarios, EP&R, environmental legacies. The PEP methodology has the ambition to create the conditions of a fair dialogue on different topics among various pluralistic societal components, providing them with equitable opportunities to contribute to the framing of the purpose and content of the exchanges.

## 3. CONCLUSIONS

NTW addresses the question of radiation protection only indirectly for now as we are focused on nuclear safety and transparency. However, as part of the nuclear safety also the radiation protection is investigated. We develop a number of methods and tools for the civil society representatives to be involved and engaged and provide for independent evaluation of nuclear practices.

NTW also discusses the issues of sustainability of our organisation and therefore we have regular strategic seminars with NTW members: we exchange positions on our future directions, the focus of necessary attention, the context which is evolving, and investigate also how to

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<sup>3</sup> Key features of independence in regulatory decision making in the area of nuclear safety include (IAEA, 2003):

- Insusceptibility to unwarranted external influences, but the existence of appropriate mechanisms for external professional dialogue and consultation, with both licensees and independent experts, along with appropriate mechanisms for dialogue with the public;
- Decisions taken on the basis of science and proven technology and relevant experience, accompanied by clear explanations of the reasoning underpinning the decisions;
- Consistency and predictability, in relation to clear safety objectives and related legal and technical criteria;
- Transparency and traceability.

<sup>4</sup> [http://sitexproject.eu/index\\_2.html](http://sitexproject.eu/index_2.html)

organise to be present in longer period. One of the challenges is for sure resources: human and financial. We try to find solutions to this. One of concrete action is for example the project ‘rolling stewardship’ for post closure radioactive waste repository governance. We hosted several webinars with key actors in last year and now we introduce this concept also to other actors which contribute to adoption of new practices.

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# SMARP: A 3D ALARA planning tool based on the virtual reality technology

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**Abstract**—The SMARP, a 3D ALARA planning tool, is developed to improve the efficiency of nuclear installation operations and reduce the radiation exposure of radiation practitioners. The tool is an integration of multiple technologies, including virtual reality, 3D model reconstruction, radiation monitoring, radiation field calculation and visualisation. Based on the radiation field, it allows a dose assessment by integrating radiological information with 3D models of the actual environments. This paper will address some of the key techniques and applications of the tool.

*Keywords:* Nuclear protection; Virtual reality; Visualisation; Dose assessment; Radiation Monitoring

## 1. INTRODUCTION

Nuclear energy has developed rapidly as clean and economic energy since the 1950s. The radiation exposure control of employees in the nuclear industry is an important issue for radiation protection. In recent years, the radiation protection management tool based on visualisation technology has become one of the important development directions of the as low as reasonably achievable (ALARA) concept. The Belgium Nuclear Research Centre (SCK CEN) has developed the VISIPLAN based on the point kernel method to calculate dose distribution and evaluate the personnel dose (Vermeersch, 2005). The Hitachi Group in Japan has also developed a radiation dose field calculation and visualisation system for nuclear power plant maintenance support (Ohga, 2005).

In this respect, China Institute for Radiation Protection (CIRP) developed SMARP (Smart ALARA system for Radiation Protection, also called CIRPDose), which can visualise the radiation field with virtual reality technology. The spatial radiation data can be visually displayed by colour and transparency in a three-dimensional way so that the information about the distribution and the variation in radiation levels can be directly presented. This tool also allows dose calculation and simulation of radiation risk operations, which can provide practical suggestions and safety guarantees in personnel training.

## 2. TECHNOLOGY AND METHODOLOGY DESCRIPTION

### 2.1. System overall frame design

According to the analysis of the functional requirements, the existing technical solutions, the software and hardware equipment used in the development process and other factors, we have formulated the overall frame of the 3D ALARA planning tool, as shown in Fig. 1.

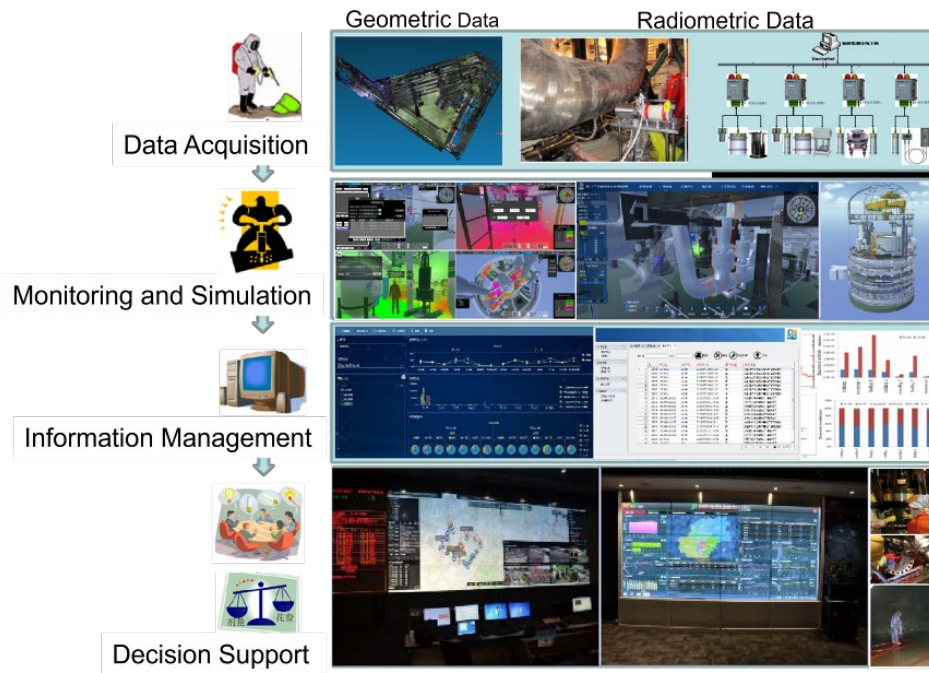


Fig. 1. Overall frame of the 3D ALARA planning tool.

## 2.2. Research on key technologies

### 2.2.1. 3D model optimisation technology

The geometric conditions of a nuclear power plant are very complex, with many rooms, equipment, and piping. To solve these problems, 3D laser scanning and computerised inverse modelling techniques are used. The point cloud model from laser scanning is used to obtain the standard format by algorithms of feature point extraction, parameter identification, and mapping. Then it is rendered into the display model considering texture mapping, lighting, baking, etc., refer to Fig. 2. For the areas where laser scanning does not work, the solution is the computerised inverse modelling technique. A special interface was developed to generate a standard 3D format from a computer aided design (CAD) drawing. Components with weak shielding effects will be automatically excluded to reduce modelling time.

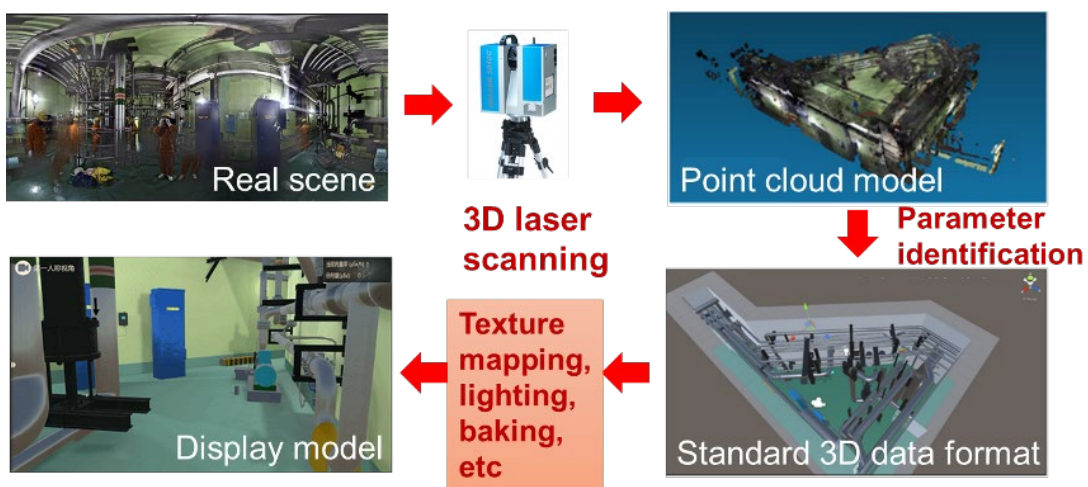


Fig. 2. 3D laser scanning transforms a real scene into a display model.

### 2.2.2. Source term evaluation and 3D radiation field measurement technology

Building a radiometric model needs to rely on radiological measurements. For radiological measurement methods, a combination of on-site source term evaluation and 3D radiation field measurement is used to obtain accurate radiation field data. We have a complete evaluation process for source terms that supports the analysis and acquisition of information on radionuclide species, activity, and dose rate contribution in the pipeline of interest.

However, in previous experiments, it was found that calculating the radiation field from source term information alone is highly inaccurate. It also needs to be combined with the 3D radiation field measurement data. The specific solutions are as follows:

- A total station was used as the 3D positioning means.
- Reconstruct the portable dosimeter to realise wireless data transmission.
- Develop a system to realise the synchronous measurement of total station and dosimeter.
- Data recording and storage.



Fig. 3. Radiological on-site measurement. (a)(b)(c) HPGe detector-based gamma radiation source term measurement system and (d) total station for coordinate measurement.

### 2.2.3. 3D radiation field reconstruction algorithm

Using the technique of point-kernel integration and solid modelling, the study on the reconstruction algorithm of the gamma radiation field is carried out systematically. The algorithm modifies the gamma-photon accumulation factor, which improves the accuracy of the dose calculation results by about 10%. The computational speed is improved by nearly 10 times from the aspects of weight discretisation for the body source, nonuniform meshing for the radiation field and multithread parallel computation.

Additionally, a source inference technique is implemented to estimate the source strengths based on dose mapping and the knowledge of the source positions and the isotopic composition of the sources (Sharma, 2016). The calculation of the source activity is realised by combining the least squares theory and iterative algorithm. The algorithm can solve the problem of inversion calculation of source activity for multiple individual sources, surface sources, line sources and point source combinations in 3D complex geometric space. It also considers the cases with weights and constraints to enhance its ability to solve practical problems.

### 3. THE APPLICATIONS OF 3D ALARA SYSTEM IN THE NUCLEAR INDUSTRY

#### 3.1. Visualisation of the 3D radiation field

Based on the technologies mentioned above, SMARP has the outstanding feature of taking model data and measurement data as input to realise rapid calculation and visualisation of the radiation field. A mapping relationship between dose rate and colour is established. SMARP supports roaming and perspective switching. These allow the user to view any location in the plant and quickly detect high-dose rate areas. Fig. 4 shows the radiation field visualisation of a pressurised water reactor (PWR).

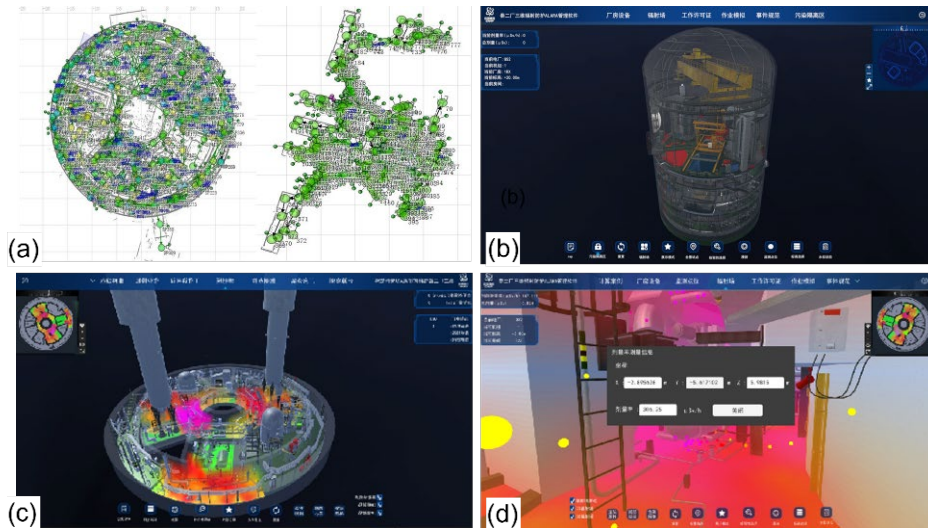


Fig. 4. 3D radiation field Visualisation of a PWR. (a) More than 1700 effective scanning points, (b) Three-dimensional geometric model, (c) overall radiation field demonstration in the 5-meter layer of the island, and (d) dose rate information viewing.

#### 3.2. Operational plan simulation and personnel dose assessment

SMARP can pre-set several operation plans for typical operation processes, especially for high radiation-risk operations. These plans include information involving the task description, the path planning and the duration. Based on the known radiation field, the accumulated dose of personnel and group in each plan is calculated. Then from the perspective of shielding settings, path avoidance, and operation plan optimisation, to achieve optimal radiation protection during the operation. Fig. 5 shows a case.

#### 3.3. Digital management of nuclear power operation

A database is created for daily management and virtual training, including radiation monitoring data and information on plant and equipment. It allows users to acquire information on dose rate, source term contribution and accumulated dose related to location and time. SMARP supports queries on rooms and equipment, with database information associated with the 3D model. After querying a room or device, the view can immediately jump to the corresponding location, or the tool can automatically generate a navigation path. SMARP also has functions such as radiation safety marking management, contamination isolation zone setting, radiation work permit (RWP) association, etc., which can be visualised and located in real-time. Fig. 6 shows more functions.



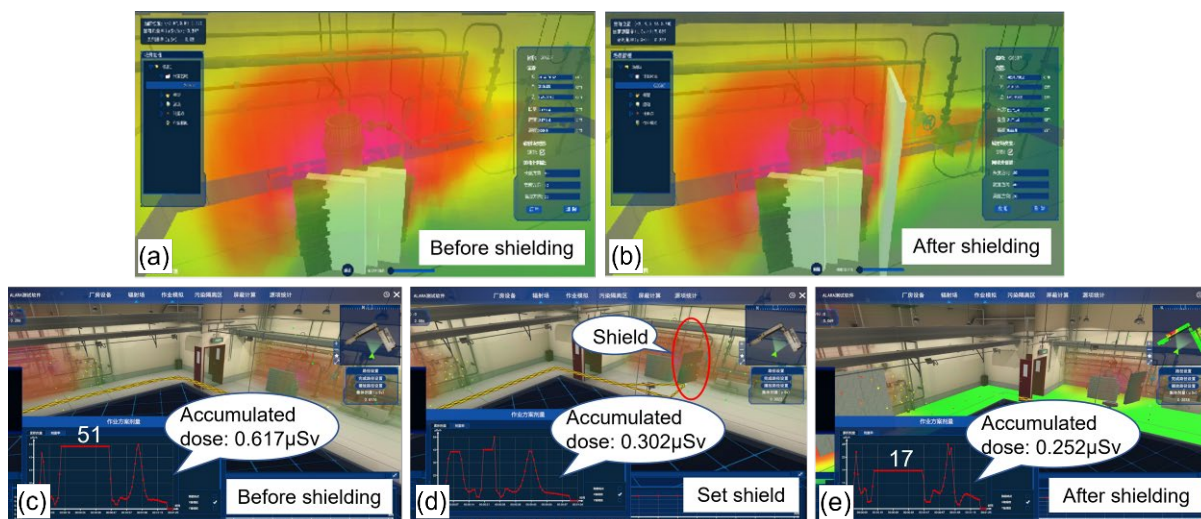


Fig. 5. Dose assessment of two operation plans for a valve repair case. (a) and (b) are the comparison of radiation fields before and after shielding. Plan 1: (c) Without shielding, the accumulated dose is 0.617  $\mu\text{Sv}$ . Plan 2: (d) Set shielding first, (e) then repair the case, total accumulated dose is 0.554  $\mu\text{Sv}$ .

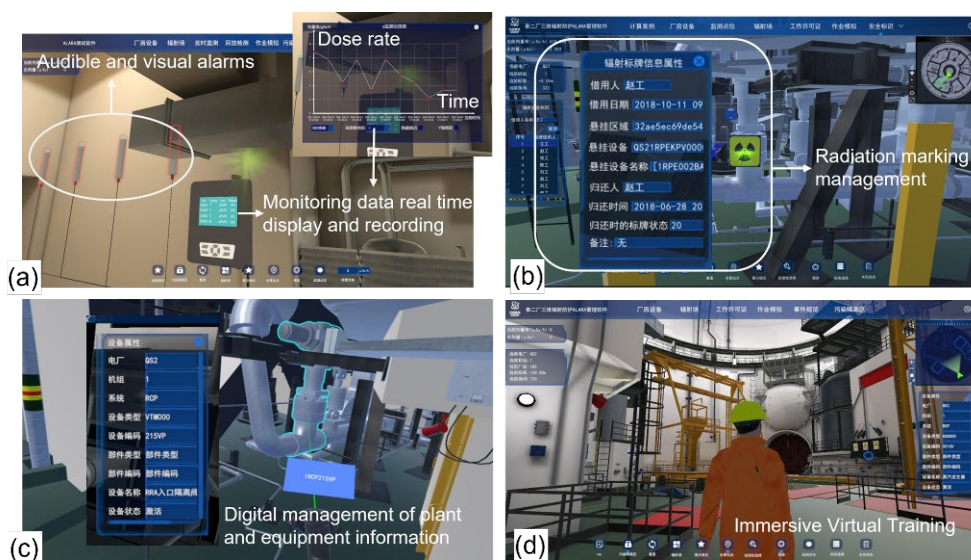


Fig. 6. SMARP has practical functions, such as (a) radiation monitoring, (b) radiation safety marking management, (c) digital management of equipment, and (d) virtual training.

#### 4. CONCLUSION

To solve nuclear radiation safety and protection issues, we developed the SMARP ALARA planning tool. The tool rapidly calculates and visualises the dose rate distribution through the integration of multiple techniques and algorithms. It is also an important tool for radiation high-risk operations protection and digital management. The tool has been applied to the Uint1 in Qinshan Phase II NPP since December 2020 and has also been promoted and applied in spent fuel reprocessing, plant decommissioning, etc.

For future work, a more intelligent radiation monitoring system is needed to obtain radiation data more quickly, in real-time, and in a comprehensive manner. In addition, we will fully mine the massive monitoring data accumulated during the operation and maintenance to obtain effective information and feedback to guide the implementation of the ALARA approach.

## ACKNOWLEDGMENTS

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## Enhance justification of medical exposures: a case study of completeness and vetting of CT requisitions for children and young adults in sub-Saharan Africa

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**Abstract**—Clinical information is of importance for justification of imaging procedures, strengthening radiation protection and improving appropriate utilisation of imaging resources. The purpose of this study was to assess the level of completeness of clinical information and vetting computerised tomography requisition forms (CTRFs). This was a retrospective review of all consecutive CTRFs for patients 35 years and below performed from 1 July through 31 December 2018 from six hospitals. Hard copies of CTRFs were reviewed for completeness of clinical information against a ‘standardised’ check list and whether vetted by a medical imaging practitioner (MIP). Data was descriptively analysed using STATA-14. The results were presented as proportions / frequencies / tables. Of the 972 CTRFs assessed, 464(47.7%) were from PNFH, 408(42%) public hospitals and 100 (10.3%) from PFP hospitals. All the CTRFs had incomplete clinical information. The fields with 100% information included patient’s name, age and anatomical region to be scanned. Pregnancy status, renal functional tests and allergy status were the worst fields with no information at all and Only 18 (1.9%) CRFs were vetted by a MIP. There are low levels for clinical information completeness in sub-Saharan Africa. Strengthening justification of medical exposures and radiation protection is a shared responsibility by both the users and providers yet underestimated.

**Keywords:** Justification, Computed Tomography, Clinical information, Imaging requisition forms, Radiation protection

### 1. BACKGROUND

'Data! data! data!' he cried impatiently. 'I can't make bricks without clay'. This expression of dissatisfaction was from the most famous fictional detective author Sherlock Holmes, who needed 'Data' to conclude a case (Doyle and Macaluso, 2016). This is almost the same way medical imaging practitioners (MIPs) feel when presented with incomplete computerised tomography request forms (CTRFs). Incomplete Request Forms are those forms which lack basic clinical information containing details regarding the problem that prompted the examination. Such information has been cited to enhance radiologists to provide better and more relevant differential diagnosis (Gunderman et al., 2001). 'Trying to practice radiology in the absence of relevant clinical information is like driving without a map. You will sometimes get to where you want to get but you will inevitably get lost at some point' (Fatahi et al., 2019).

Currently, it is not uncommon for a radiologist to view more than 100–400 images in a single investigation. This is because of advance in computed tomography (CT) technology that has seen the introduction of multi-detector computed tomography (MDCT) which provides for simultaneous examination of multiple systems and/or dual or triple phase acquisitions. This comes with voluminous number of cross-sectional images for the radiologist to interpret and

as of such patient clinical history comes in handy to focus the radiologists for an accurate report (Kalra et al., 2004).

Request forms with inadequate clinical information are a precursor to inappropriate imaging procedures because then, such procedures lack justification and complicate the process to determine the most appropriate examination protocol to use (Horner, 2017). The process of justification in the field of radiology is a shared responsibility between several stakeholders, but importantly medical imaging referrer (MIR) and medical imaging practitioner (MIP). The MIR is under the obligation to provide sufficient clinical details when requesting for a computerised tomography (CT) procedures while the MIP is the gate keeper of radiation protection. The MIP has the professional responsibility to review all CT requests for justification and appropriateness given a clinical question and the individual patient. They have the lee-way to reject a procedure with reasons in non-offensive manner in case of insufficient clinical history, advise modification or recommend other investigations in consultation with the referring clinician (Remedios et al., 2014; IAEA, 2017).

World over, a CT request form (CTRF) has been recognised as a legal communication tool between the MIR and MIP since little face-to-face communication occurs and thus its quality which includes completeness is of importance for this role and for the process of care (Khorasani, 2001; Rawoo, 2018). Complete and adequate clinical information guides the MIP in planning, choosing an appropriate imaging modality, protocol selection and optimisation, improves quality of radiology report, and appropriate utilisation of radiology resources (Naik, et al., 2001; Triantopoulou et al., 2005). Additionally, incomplete requisitions can lead to errors in interpretation, risk of complications for patients, waste of time and money for the hospital and patient (Clement, 2005; Smith et al., 2005; Alkasab et al., 2009).

Much as there are neither agreed standards on the format nor the content for an adequately completed CTRF, the Royal College of Radiologists (RCR), and the Royal Australian and New Zealand College of Radiologist, have defined a minimum criteria for such to include but not limited to the following: clear and legible referral, Identity of the patient, identity of the imaging referrer, and sufficient clinical information (Depasquale and Crockford, 2005; Radiologists LRC, 2007; Pitman, 2017). Even with such guidance and standards, studies have found rates of inadequate or incomplete requisitions ranging from 2% to 29% (Khorasani, 2001; Cohen et al., 2006; Rawoo, 2018). A study of radiologist's perceived need of clinical information, by Boon et al found 72% of the time radiologists needed more clinical information than they received, and 87% noted additional clinical information could change or modify the final report (Boonn and Langlotz, 2009).

To the best of authors' knowledge, little attention has been paid to this issue and no investigation done to generate reliable evidence that such a problem exists in this setting. The purpose of this study was to determine the proportion of completed and vetted CT requisitions among children and young adults, as precursor in developing targeted intervention to enhance justification of CT services

Advancement in knowledge; The findings of this study can be capitalised as guide to explore determinants of inappropriate CT requisitions and develop tailored interventions to improve quality of CT requisitions.

## 2. MATERIALS AND METHODS

The study ethical approval and waiver of consent was obtained from the School of Medicine Research Ethics Committee (SOMREC) and Uganda National Council for Science and Technology (UNCST). Administrative clearance was also obtained from all the participating hospitals before data collection.

This was a cross sectional study that reviewed request forms for common CT examinations performed during a 6month period at the six participating hospitals. The selection of the participating hospitals was based on availability of functional CT scan services, with a geographical representation. These included: 2 Public (National and regional referrals and teaching hospitals (KR and MBR), 2 Private for profit (PFP- KH and MB) and 2 Private Not For Profit (PNFP- MH and NS). The sample selection of the hospitals was also a representation of the National CT scan service delivery in the study setting. There were 22 functional CT scans at the time of the study, 6 (27%) were public, 4 (18%) private not for profit (PNFP) and 12 (55%) private for profit (PFP).

All hard copies of paper-based CTRFs scan requests for patients 35 years and below performed from 1 July 2018 to 31 December 2018 were collected from the respective radiology departments for the participating hospitals. The upper limit of 35 years was chosen since attributable risk of cancer from low dose radiation in adults plateaus beyond this age (Brenner and Hall, 2007).

Unreadable records, duplicates, cancelled examination, electronic medical records and requests from prescribers outside the participating hospital were excluded. A ‘standard’ check list (appendix 1) against which local practice for completeness of CTRFs were evaluated was developed based on literature (De Lacey and Manhire, 1996), locally available template and International Basic Safety Standards (EC F and IAEA I, 2014).

Additional clinical history such as laboratory results, prior imaging findings, use of metformin was noted but not required for the clinical history to be considered adequate. The standard for this audit was defined by the presence or absence of each of the items on a ‘yes’ or ‘no’ basis respectively. The indicator was the percentage of each type of mandatory and secondary items and percentage of CTRFs with presence of mandatory fields. Data was descriptively analysed using STATA-14. The results were presented as proportions/frequencies/tables/figures. The proportion of missing fields were compared with similar studies published in literature.

### 3. RESULTS

We evaluated 972 CTRFs which were collected for a 6-month period and met the inclusion criteria from the six participating hospitals. A total of 464(47.7%) were from PNFP, 408 (42%) public hospitals and 100 (10.3%) from PFP hospitals.

Table 1 below shows the level of completeness of clinical information for children and young adults referred for CT procedures across the six participating hospitals.

It is apparent from this table that all CTRFs were incompletely filled. However, name (KH, ME, NS), age (MB) and anatomical region to be scanned (KH, ME) were 100% filled in some facilities. The least items to be filled included allergy to contrast media or drugs and RFTs 38 (11.8%) for those that needed intravenous contrast media (2.4%) respectively in addition to pregnancy status for those in reproductive age of 11 CTRFs (7%). Less than 50% CTRs had Referrers telephone contact and only 18 CTRFs (1.9%) vetted by a radiologist.

Table 1. Completeness of 972 CT requisitions among children and young adults across the six participating hospitals.

	Participating Hospitals						TOTAL (N = 972)
	KHL (n = 62)	KR (n = 259)	MH (n = 98)	MB (n = 38)	MBR (n = 149)	NS (n = 366)	
Request form template (%)							
Yes	80.7	99	5.1	16	47.7	80.6	70.2
No	19.3	0.39	94.9	83.8	52.3	19.4	9.6
Patient study number							
Yes	32.2	66.8	57(58.2)	32.4	8.8	69.3	54.5
No	67.7	33.2	41(41.8)	65.6	91.2	30.7	45.5
Patient location at the time of referral (%)							
Yes	27.7	93.8	52.0	60.5	58.4	63.1	67.1
No	2.6	6.2	48.0	39.5	41.6	36.9	32.9
Name of the patient written (%)							
Yes	100	99.2	100	97.4	98.0	100	99.4
No	0.00	0.77	0.00	0.6	2.01	0.00	0.6
Patient age stated (%)							
Yes	93.6	98.5	98.0	100.0	94.6	99.5	97.9
No	6.5	1.5	2.04	0.00	5.4	0.55	2.1
Sex of patient indicated (%)							
Yes	90.3	97.7	98.0	81.6	91.3	97.5	95.6
No	9.7	2.3	2.04	18.4	8.7	2.5	4.4
Request Hand written (%)							
Yes	85.3	98.5	98.0	100.0	100.0	79.4	90.8
No	14.7	1.5	2.04	0.00	0.00	20.6	9.2

*(continued on next page)*

Table 1. (continued)

	Participating Hospitals						TOTAL (N = 972)
	KHL (n = 62)	KR (n = 259)	MH (n = 98)	MB (n = 38)	MBR (n = 149)	NS (n = 366)	
If hand written request, is it legible (%)							
Yes	98.0	99.2	100	94.7	99.3	97.9	98.6
No	2.0	0.80	0.00	5.3	0.7	2.1	1.4
Clinical question asked or adequate clinical history given (%)							
Yes	96.7	99.6	97.9	70.3	91.9	97.5	96.2
No	3.33	0.4	2.1	29.7	8.1	2.5	3.8
Anatomical region to be scanned indicated (%)							
Yes	100.0	97.5	100.0	89.5	97.9	98.9	98.2
No	0.00	2.5	0.00	10.5	2.1	1.1	1.8
Order of CT-examination in the current investigation of the patient (%)							
First radiological	95.2	85.0	94.9	91.9	87.1	90.4	89.3
A check on the progress of a disease	3.2	1.6	4.1	5.4	4.8	3.3	3.2
Effect of treatment.	0.00	0.4	0.00	0.00	0.8	0.00	0.2
A further step in an ongoing investigation.	1.6	13.0	1.0	2.7	7.5	6.3	7.3
If child bearing age female, (n = 271) pregnancy status given (%)							
Yes	4.2	8.3	0.00	33.3	0.00	9.2	7.0
No	95.8	91.7	100.0	66.7	100.0	90.8	93.0
Allergy status given (n= 329), (%)							
Yes	4.0	3.2	0.00	0.00	0.00	3.1	2.4
No	96.0	96.8	100.0	100.0	100.0	96.9	97.6

(continued on next page)

Table 1. (continued)

	Participating Hospitals						TOTAL (N = 972)
	KHL (n = 62)	KR (n = 259)	MH (n = 98)	MB (n = 38)	MBR (n = 149)	NS (n = 366)	
<b>Renal function given (n=329), (%)</b>							
Yes	4.0	20.1	0.00	0.00	0.00	12.2	11.6
No	96.0	79.8	100.0	100.0	100.0	87.8	88.4
<b>Referrer name given (%)</b>							
Yes	80.7	95.0	96.9	73.7	83.8	96.4	92.3
No	19.3	5.0	3.1	26.3	16.2	3.6	7.7
<b>Referrers contact details given (%)</b>							
Yes	23.0	5.5	3.1	44.7	53.1	73.6	41.0
No	77.0	94.5	96.9	55.3	46.9	26.4	59.0
<b>Is the form signed (%)</b>							
Yes	77.4	96.5	26.6	71.0	83.9	95.1	84.8
No	22.6	3.5	73.5	29.0	16.1	4.9	15.2
<b>Form sanctioned by a radiologist (%)</b>							
Yes	1.7	0.4	3.2	0.00	2.0	2.7	1.9
No	98.3	99.6	96.8	100.0	98.0	97.3	98.1

CT, Computerised Tomography; LNMP, Last Normal Menstrual Period; RFTs, Renal Functional Tests



Table 2. Comparison of findings with other studies with similar objective.

Clinical information	Published studies and year of publication						
Author, year of publication	Current Study	Muna Badu, 2020	Zafar, 2018	Chitwiset, 2019	Chanda, 2021	Humaira Anjum, 2016	Chia DM, 2022
Country	Uganda	Nepal	Pakistan	Bangkok Thailand	Zambia	Pakistan	Nigeria
Study design	Retrospective	descriptive cross section	Not stated	retrospective	retrospective	Not stated	Retrospective
Study setting(s), number and type	University teaching National referral, public, PNFP, PFP	medical college and teaching hospital	Tertiary care center	Rajavithi Hospital. Rangsit University, hospital	Cancer Diseases Hospital	Teaching Hospital	University teaching hospital
Sample Size	972	196	300	1000	80	444	303
Patient hospital Number (% of complete)	54.5	-	-	100	-	-	92.7
Patient location at the time of request (%)	67.1	46.9	100	53.7	43.75	13	100%
Patient name (%)	99.4	100	100, 27.66	100	100	100	100
Age (%)	97.9	99.5	77.33	100	97.5	72	94.7
Sex (%)	95.6	98.5	64.33	100	100	67	94.1

*(continued on next page)*

Table 2. (continued)

Clinical information	Published studies and year of publication									
Illegible (hand written requests)	1.4	2.6	5.5	6.92	2 (2.5%)	-8.6	-			
Clinical Information/ Clinical Question/ Differential Diagnosis	96.2	91.3	50.7	99.7	96.25	79.5	84.5			
Anatomical region to be scanned	98.2	-	99.7	18.86	--		100			
LNMP/pregnancy status (271) %	7	-	0				8.1			
Allergies/Contrast allergies%	2.4	-	0	45.80/1.1	2.5		5.9			
Renal Function tests %	1.6	-	53.5	56.8	5	1.5	-			
Referrers Name, %	92.3	30.6	100	93.7	17.5	18	89.8			
Referrers Signature %	84.8	68.9	0	-	91.25	89	89.8			
Referrers Contact/ Tel/pager %	41	-	0	31.4	10%	-	0			
Date form generated%	68.4	93.4	99.6	-	75 (93.75%)	-	95.7			

#### 4. DISCUSSION

From our study, we found that all the CTRFs reviewed were incompletely filled. This is consistent with findings of previous studies, which registered 0–4% (Chia et al., 2022). This finding may be explained by the fact that although inadequate, age, name and anatomical region are regarded to be the most important information while writing CTRFs that. The adequacy of clinical information availed in imaging requisition is very important in the process of care, especially for patients requiring multiple or complex procedures, procedures for conditions that not included in the local clinical guidelines or those procedures associated with high radiation exposures (Khorasani, 2001). Other peculiar circumstances such as paediatric age group, pregnant women, costs and availability, expertise of the radiological practitioner, comorbidities of the patient which put the patient at a higher risk of side effects from the investigation, chronic conditions warranting frequent radiological procedures, cumulative doses from previous imaging, and patients preferences and adverse effects of the procedure, should be considered.

Additionally, we also found that less than 2% CTRFs were vetted by a radiologist for justification and appropriateness. The low numbers of CTRFs vetted by a radiologist reflect a gap in the process of in their role as 'gate keepers' of radiation safety. This could partly due to shortage of radiologists (radiologist-to-population ratios in Africa: 1:67,000 in Egypt, 1:1,600,000 in Uganda and 1:8,000,000 in Malawi) (Kawooya et al., 2022). With those appalling ratios, it is impossible for radiologists to review all the CTRFs for every patient. The process of vetting imaging examinations is an important step of ensuring justification at the level of the imaging department, certifying that the correct investigation is performed and correct scan protocol are used (Remedios et al., 2014). The radiologist should have the lee-way to reject a procedure, advise modification or recommend other investigations in consultation with the referring clinician. Vetting has been demonstrated to improve the overall efficiency, cost-effectiveness, safety and appropriate utilisation of radiology resources with improved patients' health outcomes (Harrison et al., 2000). According to the Ionizing radiation (Medical exposure) Regulation 2017 (IR (ME) IR), the radiologist is under the obligation to justify and authorise a medical exposure considering the clinical question and the individual patient (Walker and Tuck, 2001).

We also found that only 1.4% of the CTRFs had illegible hand writing. This finding is in contrast with those in studies done in Nepal, Pakistan, Zambia and Thailand where levels of illegibility were found to be higher at 2.6%, (8.6%, 5.5%), 2.6% and 6.92% respectively (Ahmad and Anjum, 2016; Zafar et al., 2018; Chitwiset, 2019; Badu, 2020; Chanda et al., 2020). Illegible requisitions can cause delays in conducting the appropriate examination since clarification needs to be got from the MIR. In addition, wrong examinations or repeat examinations may be performed exposing patient to unnecessary radiation and wastage of resources.

The date when the CTRF was generated was missing in almost 30% of the reviewed CTRFs. This result is higher compared to previous studies by Muna et al, Zafar et al and Chia et al who had less than 7%. The discrepancies could be due lack of awareness by the referrers as to the relevance of such information in timely patient management in our setting. The date is a useful reference point for radiology report turnaround time, an important measure and indicator of quality of radiology service (Agarwal et al., 2009; Khorasani, 2009; Zafar et al., 2018; Chitwiset, 2019, Badu, 2020).

Patient's identification including name, age and sex had the lowest proportion of missing information across all the study centres with only 6 CTRFs missing names, and less than 5% having age and sex not filled. Although this seems to be a small proportion, there is room for improvement to 100% as achieved in other studies (Troude et al., 2014; Ahmad and Anjum,

2016; Chitwiset, 2019; Badu, 2020; Chanda et al., 2020). Patient's biodata is important especially for procedures emitting ionising radiation such as MDCT, the risk of radiation induced cancers depends on patient factors in particular the age, sex, location, extent and body part exposed, nature of examination and imaging protocol used to perform the procedure and because of this fact, referrers are keen to ensure that they are well filled in during the writing of the CTRFs. The missing demographics information may be explained by the fact that some cases are brought in unconscious and unknown while others are Road Traffic accidents. In our setting over 70 % indications for CT scans are due head trauma. Work over load may be the other contributing factor. MIRs, especially junior doctors are in hurry to finish the line and probably feel that the request form is too long, delegation of responsibilities (Sometimes the MIR aren't the ones who fill or write the CTRFs but the nurses or interns or students who also may not understand the importance of such information).

Out of the 972 CTRFs 37 CTRFs (3.8%) lacked Clinical history. This proportion was lower than those found in studies by Ahmad and Anjum, Chia et al.(2022) and Zafar et al.(2018) at 19.5%, 15.5% and 49.3% respectively. The differences could be due to the way we defined "adequate clinical information", as any one of the three components "Clinical history/differential diagnosis /clinical question". This could have erroneously raised the proportion of completeness of this particular item in our study. Ahmad and Anjum defined clinical history to include clinical history and specific question, Chia et al clinical information included indication of the study and provisional diagnosis, while Zafar et al included provisional diagnosis, brief clinical history, detailed history, past surgical history, physical examination. Additionally, paper based request forms are tedious to fill and is likely to be incomplete or inaccurate. In our setting it's not uncommon for patients to be referred for CT scan before proper clerking, even setting with EMR, a busy clinical practice it's a challenge for imaging referrers to fill out long requisitions forms for every patient with CT study.

Anatomical region to be scanned was not filled in only 7 CTRFs, a finding almost similar to other studies by Zafar et al. (2018) and Chia et al. (2022). Standardisation of adequate clinical information across various types of scans is difficult since appropriate clinical information varies with anatomical region and clinical indication. The situation is worsened by non-focused requests. For example, adult male acute abdominal pain "R/o cholecystitis, appendicitis, ureteric stone" as a standalone request are very common. Information on the anatomical site to be scanned and order of CT-examination in the current investigation of the patient is important for protocol dose optimisation during CT scan.

Female patients in the child bearing age group should be evaluated for possibility of pregnant, gestation age, whether the fetus will be in the direct beam and whether the procedure is relatively high dose. These accounted for almost 30% of the total requests but only 19 (7%) CTRFs indicated the pregnancy status. The findings are consistent with previous studies with ranges of 0-19% filled (Ahmad and Anjum, 2016; Zafar et al., 2018; Chia et al., 2022). Although prenatal doses from most properly performed diagnostic procedures present no measurable increase risk, special precaution should be taken during the organogenesis and early foetal period, which are more sensitive to the cancer-causing effects of radiation. A 10-day rule is applied to examinations with the potential to deliver a high dose to the lower abdomen and pelvis, such as CT of the abdomen or pelvis and 28-day rule for all other examinations (Brent et al., 2001).

Allergic status and Renal Function tests were documented in Only 8 (2.4%) CTRFs and 38 (11.6%) CTRFs respectively out of almost the 34% patients who required intravenous contrast media. The findings are consistent with those found in literature (Agarwal et al., 2009; Khorasani, 2009; Zafar et al., 2018; Chitwiset, 2019; Badu, 2020). The use of intravenous contrast media improves CT image quality and new clinical applications such as CT angiography, cardiac CT instead of Conventional catheter-based diagnostic angiographic

examinations and CT urography are on the increase. However, intravenous contrast media (ICM) can cause various adverse effects, ranging from mild to fatal type reactions or contrast induced nephropathy (Murphy et al., 2000). MIR need to indicate prior allergy like hypersensitivity reaction to ICM, atopy, asthma, dehydration, heart disease, existing renal disease, hematologic disease (e.g., sickle-cell anemia), age less than 1 year or more than 65 years, and use of  $\beta$ -blockers or non-steroidal anti-inflammatory drugs (Fatahi et al., 2019).

The signature which authenticates the request was found on average in 85% CRFs which is almost similar to previous studies Chanda et al. (2020) and Chia et al.(2022), Chitwiset(2019), but higher than Muna Badu (69%) and Zafer (10%) (Zafar et al., 2018). The variation could be due to the way CTRFs are generated. In our setting junior doctors and interns generate imaging requests on behalf of senior doctors and consultant. The consultant is supposed to sign the CTRFs verifying that the availed clinical information is correct and appropriate. Mobile telephone platform is the most efficient way of communication between the MIR and MIP in our setting and although this is the case, less than 50% of CTRFs indicated a referrer's telephone number. The findings are consistent with what is in the literature rates of 0%–41% (31%) and Chanda et al (10%), whereas Zafar et al and Chia et al.

In a survey to ascertain clinicians' knowledge of their patients when requesting radiological investigation, Bosanquet et all found in 30% of the radiological requests, doctors had not seen patients to be investigated (Bosanquet, et al., 2013). The deficiency was contributed to shift working patterns. Additionally, the low staffing levels in public health facilities is below acceptable standard at 72%, in our setting (UBOS U, 2017). The Doctor-patient ratio in Uganda is estimated at 1:25,725 compared to (WHO recommendation 1:1000), and this ratio is worse for the consultants and specialists. There is lack of supervision, missed learning opportunities for junior doctors, errors of inappropriate requisitions, and exposing patients to unnecessary radiation. Imaging referrer's identification is required for consultation in case of insufficient history, option of alternative imaging modalities or timely communication of feedback of emergency or unexpected findings.

## 5. LIMITATION OF THE STUDY

There is neither a consensus on the format nor what constitute adequate CT requisition nor the format to be used. The generated criteria were from literature, most of which is from the developed countries.

### Strength:

The strength of this study is the multicentre and geographical representation of common CT examination representation of both MIRs and MIPs clinical behaviours and practices. This can be used as a baseline to ascertain determinants of appropriate utilisation of CT services in the country and develop targeted behaviours' change interventions

### Conclusion:

The findings of this study are consistent with what is published in literature, showing generally a deficiency in both availed clinical information by the imaging users and vetted CTRFs by the providers.

Future research to explore the determinants of health workers' behaviours in justification of CT requisitions among children and young adults with the aim of developing behaviour targeted interventions is recommended.

## Practical interventions:

- Develop a tailored template with check list for vital clinical information for common CT procedures
- Utilise Continuous Medical Education platforms to enhance communication (dialogue & feedback), awareness, materials on radiation safety, e.g. posters, leaflets
- Review training curriculum and incorporate radiation safety knowledge, skills and competence
- Orientation and induction of new staffs, interns and resident doctors on appropriate imaging requisitions
- Regular Audits on quality and vetting of CT requisitions
- Invest in newer electronic medical records system -with and include alerts and reminders such as hard-stops that prevent providers from moving forward in the medical chart, simple educational pop-up windows or banners that automatically inform the clinician of a specific action and providing real-time feedback
- Delegate a designated person to vet imaging requisitions and reject inappropriate ones with reasons

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# Radiological training for the defence sciences: a unique playing field

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**Abstract**—Defence Research and Development Canada (DRDC), part of the Department of National Defence, comprises seven research centres and forty-seven research and development (R&D) capabilities across Canada. Of these centres, the Suffield Research Centre, located in Alberta, provides training and expertise on radiological and nuclear technology through the Radiological and Nuclear Technologies Group (RNTG). Housed within the Canadian Forces Base, which includes a vast experimental proving ground facility, the RNTG is tasked with providing radiological training to various members and clients including Canadian Armed Forces Members, NATO allies, foreign nationals as arranged by Global Affairs Canada, and First Responders in the safe handling and remediation of radiological and nuclear material. The expansive inventory of various sources (in terms of activity (up to several TBq of material) and forms of ionising radiation), the Department of National Defence specific regulatory body, and the procurement and use of more novel isotopes, give it the unique capability to deliver specialised radiological training within the NATO partner nations. The RNTG's Radiological and Nuclear (RN) Defence program goes beyond field radiation training. Existing as a group of subject matter experts, the RNTG also conducts research and can provide expertise, advice and reach-back support to both Canadians and non-Canadian partners alike.

*Keywords:* Radiation; Defence Science; Defence Research and Development Canada; Training; Nuclear

## 1. DEFENCE RESEARCH AND DEVELOPMENT CANADA

Defence Research and Development Canada (DRDC) is the science and technology research portion of the Department of National Defence with forty-seven research and development (R&D) capabilities across seven research centres in Canada (Government of Canada, 2022a). While each research centre has its own unique expertise within the defence science and security milieu, the mandate, vision, and role remains the same across all centres. The mission of DRDC is 'to enhance Canada's defence and security posture through excellence in science and technology' (Government of Canada, 2022b). In essence, DRDC provides a knowledge and technology advantage to support defence and security at home and abroad. It also ensures that the Canadian Armed Forces (CAF) remain technologically prepared and operationally relevant. This is accomplished through various leadership roles, engagements, collaborations, partnerships and investments across all centres in order to offer the best scientific support to the Department of National Defence (DND) and the CAF. Of the seven DRDC research centres, it is the Suffield research centre, located at the Canadian Forces Base in Suffield, Alberta, that houses the speciality of radiological and nuclear technology. This radiological and nuclear (RN) speciality is delivered under the RN program by the RNTG.

### 1.1. Radiation and Nuclear Technology Group (RNTG)

DRDC has conducted research in RN Defence for more than 75 years. Initially housed at DRDC Ottawa Research Centre, the program moved to the Suffield Research Centre in 2017, resulting in the establishment of the RNTG. Today, the RNTG is comprised of defence



scientists, research technologists and an engineer working to provide expertise and radiological and nuclear training to various members and clients. In line with DRDC's mission, the RN defence program has several priorities which include:

- provision of immediate reach-back support for the CAF
- knowledge transfer and advice for the CAF (including live radiological training)
- provision of evidence-based advice to the CAF

Evidence based advice to the CAF includes topics such as: (i) procurement and assessment of detection equipment, (ii) protection of RN hazards through hazard and risk assessments, (iii) decontamination research, and (iv) emerging technologies and threat analysis.

The delivery of these priorities are enhanced by unique capabilities and resources. CFB Suffield is the largest military base in Canada and one of the advantages of being housed at CFB Suffield is access to a 470 km<sup>2</sup> experimental proving ground (EPG). Combined with a vast and unique inventory of radionuclides, and the ability of the RNTG to procure and use radiological materials in large quantities, access to this area of land allows for the performance of large scale field trials (Green et al., 2016; Beckman et al., 2020). In addition to large scale radiological field trial capabilities, the RNTG also has GEANT modelling and radiological decontamination capabilities. The RNTG currently houses a gamma spectroscopy lab and a small containment lab, allowing for smaller scaled experiments to be performed with unsealed sources. Using these facilities, the RNTG also provides scientific support. An example of this is a research collaboration currently underway on a remote detection project involving aerial autonomous systems.

Of special note, adding to the unique resources and capabilities, is the fact that, unlike civilian groups or the remainder of the Government of Canada, DND has its own nuclear regulatory body called the Directorate of Nuclear Safety (D N Safe) due to the nature and requirements of the CAF. Rather than being regulated by the federal, civilian nuclear regulatory body, the Canadian Nuclear Safety Commission (CNSC), D N Safe regulates and oversees radiological and nuclear activities within DND and the CAF as discussed in the next section.

## **1.2. Unique regulatory body: D N Safe**

Due to the nature of military operations and equipment, DND is exempt from the Nuclear Safety and Control Act (NSCA) and is self-regulated by D N Safe rather than the CNSC (Government of Canada, 2017). As stated, in the Defence Administrative Orders and Directives 4002-0: 'Nuclear and Ionizing Radiation Safety Management' (Government of Canada, 2017), D N Safe has several roles overseeing DND, including:

- establishing and maintaining a comprehensive nuclear safety program, including compliance-related activities;
- issuing authorisations or waivers for nuclear activities, other than visits and associated transits of nuclear-powered or nuclear-capable military platforms of foreign countries;
- issuing nuclear safety standards;
- approving the disposal of ionising radiation sources and emitting devices;
- approving the radiological decommissioning of real property and immovable assets involved in the conduct of nuclear activities; and
- advising on DND and CAF compliance with Canada's international obligations with respect to nuclear non-proliferation and associated safeguard regimes.

It should be noted that, despite having its own regulatory body, the DND radiological principles and practices generally follow those as recommended by both the CNSC and IAEA, including annual radiation dose limits. This oversight body has contributed to the strong safety record at DRDC SRC.

### **1.3. Live radiological and nuclear training**

The requirement to provide unique and specialised training required by the CAF due to their potential mission abroad cannot be accomplished effectively by normal civilian government agencies, industry partners, or academia. The RNTG is tasked with providing radiological training to CAF members and external clients such as NATO allies, foreign nationals as arranged by Global Affairs Canada, and Canadian First Responders in the topics of safe handling and remediation of radiological and nuclear material. To accomplish this task, live radiological training is performed using a variety of sources on the order of mBq to the order of a TBq in different scenarios. Novel training done includes:

- Training in support of International obligations including NATO CBRN Battalion Exercise PRECISE RESPONSE, the German Army Medical Group and International group training sponsored by Global Affairs Canada;
- Training in support of Public Safety and Security including advanced first responder training, National Nuclear Response team training, and Federal Radiological Assessment Team (FRAT) training; and
- CAF RN training and doctrine development

These radiation training field exercises are designed to meet specific training objectives and exercise specific response actions such as:

- scene surveying;
- reconnaissance;
- risk assessment;
- use of radiation detection equipment;
- explosive ordnance device (EOD) and radiological dispersal devices (RDD) assessment and disposal;
- sampling and identification;
- mitigation and site remediation;
- operating in radiological fields; and
- decontamination.

These exercises often include both theoretical and practical components involving a mixture of classroom lectures and field exercises. Furthermore, as the defence sciences and security of the RN training falls under the CBRNE umbrella, the radiological scenarios are designed to reflect real-life radiological and nuclear threat scenario conditions, and as such these include a specific selection of sources that cannot normally be procured and acquired by most non-DND agencies, making the capability to deliver such training unique to the RN Defence Program at SRC.

## **2. RADIOLOGICAL TRAINING WITHIN THE DEFENCE SCIENCES: CHALLENGES AND CONSIDERATIONS**

### **2.1. Sources**

In designing scenarios, while for security purposes the inventory of sources and its use cannot be identified, what makes the RN defence program stand out is the ability to procure and use sources that are typically not possessed by an organisation outside of DND. The inventory of sources include both sealed and unsealed forms in a range of sizes from check sources to sources on the order of a TBq. With such a breadth of inventory, there is a wide range of creative and real-life radiological scenario settings that can be designed and delivered for the CAF and other clients. This is enhanced by the knowledge and expertise of the RNTG members to work with these sources within a defence science and security environment and mindset.

### **2.2. Types of training**

Given unique resources such as the EPG, sources, and expertise under the CBRNE umbrella, the RNTG is capable of delivering numerous different types of radiological training scenarios to match the needs and requirements of the CAF and our clients. The variety of training includes:

- led training: specifically designed training in pro forma fashion;
- ‘In and Out’ style training: task-based operation style training;
- assessment scenarios: includes operator testing and decontamination line testing;
- full exploitation scenarios: more complex scenarios that may run over multiple days typically involving designations of radiological zones, intelligence briefings and analysis; and
- special request scenarios: these are custom request-designed scenarios that are created, incorporating explosive radiological devices, chemical and/or biological hazards, and other similar threat environments.

It should be noted here that radiological training may also occur on external sites beyond CFB Suffield or other CAF owned properties. In this case, there are more considerations that are factored in which include: risk and hazard assessments and, for externally owned non-DND sites, approval from both the D N Safe and the CNSC.

### **2.3. Other considerations**

Other considerations that are factored in to deliver the specialised radiological training include:

- material transport;
- training group size: various group sizes have been accommodated and as such, training can be customised according to skill level and competency of participants;
- time of year;
- use of Neutrons: capability to procure specific detectors and create neutron based scenarios; and
- shared facilities between multiple groups: With a variety of scenarios, the RN Defence program has hosted simultaneous training activities between multiple groups.

Such considerations in delivering radiological training may also include the expertise and collaborations of other sections within DRDC Suffield Research Centre, all of whom work together to deliver a successful and safe radiological training experience. In sum, having the RN defence program and the RNTG on a site combined with other CBRNE sections makes for a unique Canadian capability and asset.

### **3. RADIOLOGICAL AND NUCLEAR TECHNOLOGY GROUP: BEYOND RADIOLOGICAL TRAINING**

While the RNTG provides the capability to deliver a unique radiological training experience to the CAF and clients, the RNTG also plays a major role beyond training.

#### **3.1. Research and expertise**

The RNTG has staff with expertise in radiation physics, health physics, radiochemistry, instrumentation, and scientific measurement. The RNTG conducts research in various radiological areas that include: radiological dispersal, decontamination, gamma spectrometry, rapid field dosimetry, and radiation detection and detector development. The strong research component and expertise has allowed for the RNTG to work with, foster, and develop partnerships, and to perform research collaboration with external academics, other government departments, and allied nations providing scientific expertise and reach-back capability.

#### **3.2. Impact**

The capabilities of DRDC SRC to provide and deliver radiological training to both Canadian and non-Canadian military members and civilian partners combined with subject matter expertise allow it to produce an impact in several ways:

- Knowledge- transition of scientific and technological knowledge to CAF operations.
- Increased level of preparedness of the Canadian Forces, our Allies, National and International First Responder community towards CBRNE events.
- Providing scientific expertise and reachback capability.

As radiological and nuclear threats evolve in the future along with technological developments, the mission, vision, mandate, and objectives of the RN Defence program continues to focus on its assets, and capabilities to meet these changing challenges in the future.

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## Preliminary analysis of certified disaster-related death in the affected area of the Fukushima Daiichi nuclear power plant accident following the Great East Japan Earthquake: an observational study

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**Abstract**—The Fukushima Daiichi nuclear power plant (FDNPP) accident in 2011 primarily caused indirect adverse effects. Even the indirect adverse effects of radiation/nuclear disasters sometimes lead to death. Japan compensates for disaster-related deaths under the legally enshrined disaster condolence grant system. Studies on disaster-related deaths in areas heavily affected by radiation/nuclear disasters have been limited. We investigated 520 fatalities in Minamisoma City, Fukushima Prefecture, located near the FDNPP, that were certified as disaster-related by the Minamisoma City Committee for Certification of Disaster-Related Deaths. The most common reason for certification of death as disaster-related was ‘displacement owing to evacuation’ (25.8%) followed by ‘lack of appropriate treatment’ (20.4%). Disaster-related deaths that occurred more than 6 months since the incident accounted for 37.8%. According to the Nagaoka criterion, which is one of the current guidelines for disaster-related deaths in Japan, a death must occur within 6 months to be recognised as disaster-related. However, the results of this study suggest that delayed deaths occurring more than 6 months after the incident may still be disaster-related particularly when involving nuclear/radiation disasters. Compared to common disasters, radiation/nuclear disasters may have more long-term effects on affected people owing to measures such as evacuation. This suggests that long-term measures are needed to prevent unnecessary deaths.

**Keywords:** Disaster-related death; Radiation disasters; FDNPP; Evacuation; Nagaoka criterion

### 1. INTRODUCTION

The adverse health effects of radiation/nuclear disasters can take various forms, including direct consequences due to radiation exposure (such as acute radiation syndrome and an increased long-term risk of cancer) as well as indirect repercussions caused by evacuations, disruptions of the health care system, and changes in social structure. The Chernobyl nuclear power plant accident of 1986 resulted in direct adverse events, including acute radiation syndrome among those exposed and a long-term increase in thyroid cancer rates among individuals who were children at the time of the incident (Christodouleas et al., 2011). On the other hand, the Fukushima Daiichi nuclear power plant (FDNPP) accident in 2011 primarily

caused indirect adverse effects such as an increase in lifestyle-related diseases and mental health problems due to changes in living environments following the post-accident evacuations (Niwa, 2014; Nomura et al., 2016; Sun et al., 2022). Delays in treating patients with cancer were also noted (Ozaki et al., 2017).

The indirect adverse effects of radiation disasters may sometimes result in death. After the FDNPP accident, hospitals in the surrounding area faced a lack of medical staff and reduced access to medical infrastructure (Sonoda et al., 2019; Sawano et al., 2021a; Sawano et al., 2021b); therefore, providing adequate medical care became extremely difficult. Following the accident, some hospitalised patients died due to reduced access to medical care, changes in living conditions, and psychological and physical stress. Furthermore, the physical and mental strain of prolonged displacement following radiation/nuclear accidents has been shown to have adverse health impacts on the elderly, disabled, and other vulnerable health populations (Morita et al., 2017; Sawano et al., 2019). Therefore, understanding the nature of indirect disaster-related deaths is important in preventing casualties.

Japan compensates for disaster-related deaths under the legally enshrined disaster condolence grant system, wherein grants are paid to bereaved families after their municipality certifies that the person has died from the indirect effects of a disaster. Although this system may not cover all disaster-related fatalities, compiling a list of certified recipients can be useful in portraying a more complete picture of these deaths. Several studies have been conducted to that end; for example, Tsuboi et al. performed a detailed study on disaster-related deaths in Ishinomaki City (Miyagi Prefecture) after it was severely damaged by the tsunami that followed the Great East Japan Earthquake (Tsuboi et al., 2022). On the other hand, studies on disaster-related deaths in areas heavily affected by nuclear power plant accidents have been limited, and there have been no detailed investigations of the demographics of disaster-related deaths in these areas using mass data.

The Great East Japan Earthquake that occurred on 11 March 2011, registered a magnitude of 9.0 on the Richter scale. The resulting tsunami triggered an accident at the Tokyo Electric Power Company's FDNPP located in Okuma Town and Futaba Town, Futaba County, Fukushima Prefecture. Owing to concerns about radiation exposure, the 20 km radius of the FDNPP was designated as an evacuation order zone, while an additional 10 km radius beyond it was designated as an emergency evacuation preparation and planned evacuation zone. Minamisoma City in Fukushima Prefecture, which is located 13 to 38 km north of the FDNPP, was severely affected. Several disaster-related deaths among its residents were recorded as a result. The purpose of this study was to identify the characteristics of individuals who died indirectly from the effects of this large-scale radiation disaster by analysing data from Minamisoma City. The results of this study ought to provide future guidance on reducing the number of disaster-related deaths which often follow such large-scale catastrophes.

## **2. MATERIALS AND METHODS**

### **2.1. Study Design and Setting**

This was a retrospective observational study of the residents of Minamisoma City, Fukushima Prefecture, who were certified as having disaster-related deaths between 11 March 2011 and 31 March 2022.

The tsunami caused by the Great East Japan Earthquake killed 636 people in Minamisoma City. The southern part of Minamisoma City, including most of Odaka Ward and southern part of Haramachi Ward was designated as the Restricted Area. The central part, consisting of a large part of the Haramachi Ward, the southern part of Kashima Ward, and the northern tip of Odaka Ward, was classified as the Evacuation-Prepared Area in case of Emergency. The

western part, mostly Haramachi Ward was categorised as the Deliberate Evacuation Area (Fig. 1.). As of 14 February 2022, 520 disaster-related deaths had occurred owing to long-term mass displacement (Minamisoma City, 2022).

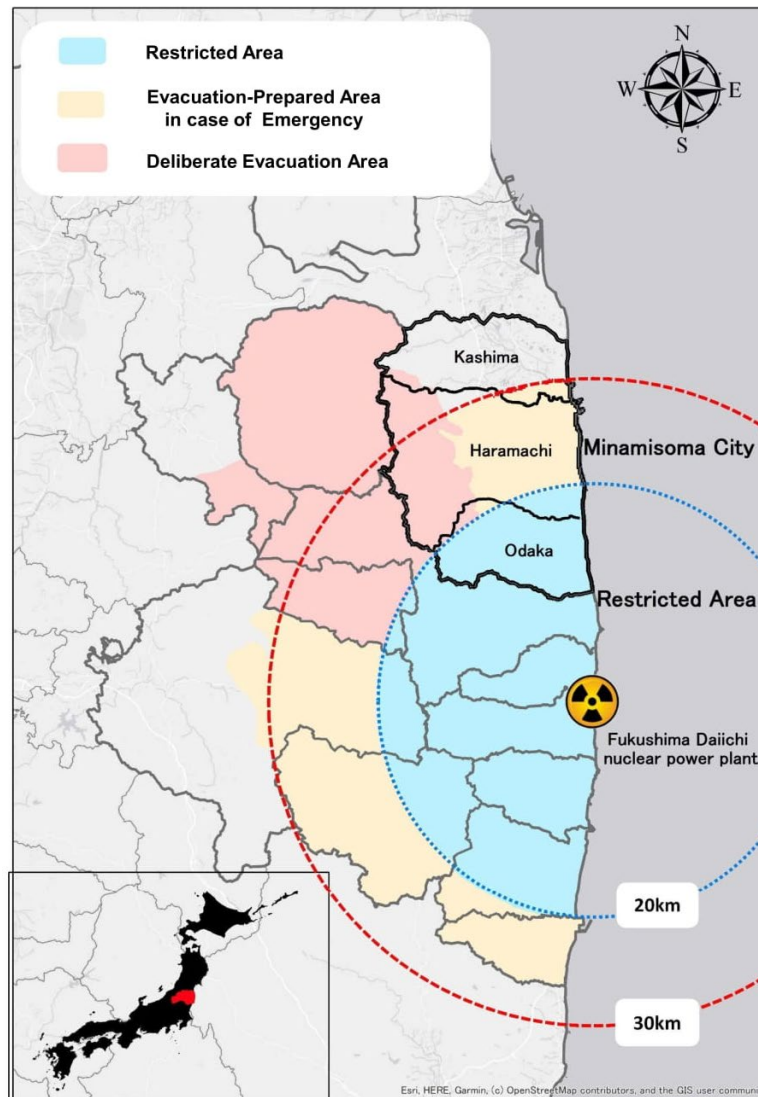


Fig. 1. Location of Minamisoma City, Fukushima Prefecture, Japan and the detail of evacuation areas as of 22 April 2011. Minamisoma City, Fukushima Prefecture, Japan is located 13 to 38 km north of the Fukushima Daiichi nuclear power plant. The southern part of Minamisoma City, most of Odaka Ward was designated as the Restricted Area, the large part of Haramachi Ward was classified as the Evacuation-Preparation Area in case of Emergency, and the western part, mostly Haramachi Ward was categorised as the Deliberate Evacuation Area as of 22 April 2011.

## 2.2. Study subjects

The 520 fatalities among Minamisoma residents who were present in the city at the time of the earthquake and whose deaths were certified as disaster-related by the Minamisoma City Committee for Certification of Disaster-Related Deaths were investigated.

The definition of disaster-related death in Japan is ‘a person who died owing to the aggravation of injuries caused by the disaster, or of illness caused by the physical burden of life as an evacuee, and whose death is recognised as caused by the disaster in accordance with the Act on Provision of Disaster Condolence Grants (Act No. 82 of 1973), including those for



whom no disaster condolence payment was actually made but excluding those whose whereabouts were unknown in the aftermath of the disaster’.

The municipality of the population centre where the disaster occurred certifies the death as disaster-related only when its own certification committee examines the application based on the information provided by the bereaved family. This committee also determines that the death is related to the event. However, there is currently no nationwide unified standard for certifying disaster-related deaths by Japanese municipalities. Furthermore, there is no publicly available information on the criteria for certification or on the frequency of certification committee meetings in each municipality.

### **2.3. Data collection**

Data on individuals whose deaths were certified to have been from disaster-related causes in Minamisoma City were collected. Application forms and other documents completed by the bereaved families were allowed to be summarised in the Minamisoma City Hall Office in Fukushima Prefecture.

### **2.4. Data analysis**

Variables such as age, sex, duration from disaster to death, residential area, and reason for certification were analyzed using descriptive statistics.

### **2.5. Ethics statement**

This study was approved by the Minamisoma Municipal General Hospital Ethics Committee (approval number: 2-21) and the Fukushima Medical University Ethics Committee (reference number: 2020-297). Informed consent was waived due to the retrospective and anonymised nature of the investigation. The study was performed in accordance with the principles of the Helsinki Declaration.

## **3. RESULTS**

The characteristics of the individuals with certified disaster-related deaths in Minamisoma City between March 2011 and February 2022 are shown in Table 1. Overall, the mean age of the deceased was 82.69 years; 51.3% were male and 48.7% were female. An average of 230.6 days passed between the disaster and death; 62.2% of all deaths occurred within 6 months of the disaster (Fig. 2.). Most individuals (94.8%) had been evacuated; 77.1% lived within 20 km of the FDNPP. At the time of the disaster, 25.6% lived in Odaka, 10.8% lived in Kashima, and 61.7% lived in Haramachi.

The most common reason for certification of death as disaster-related was ‘displacement owing to evacuation’ (25.8%) followed by ‘lack of appropriate treatment’ (20.4%). Additionally, 11.3% of the cases had ‘influence of stress’ as the reason for certification.

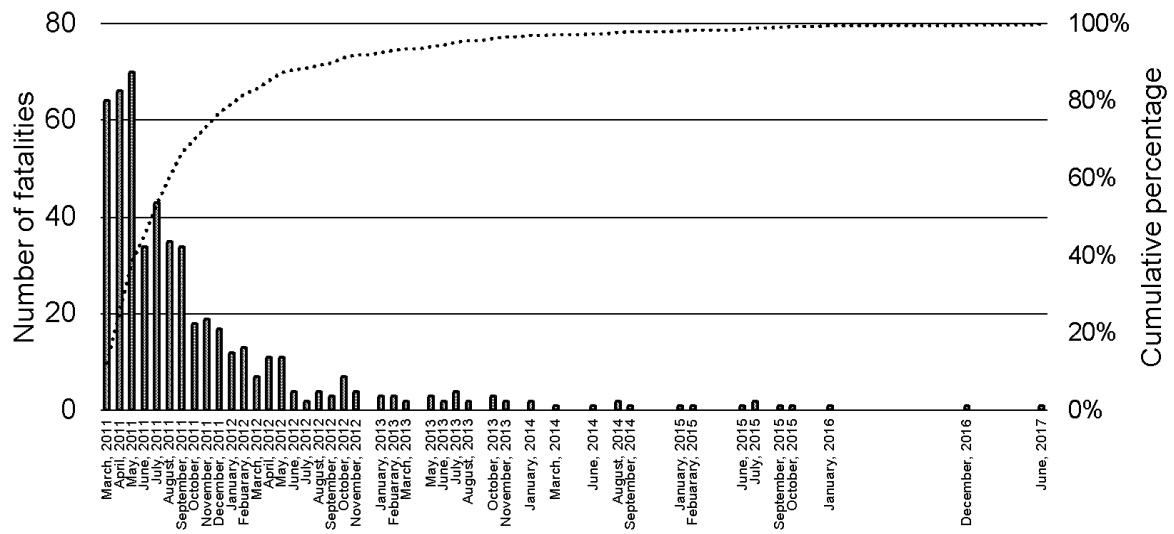


Fig. 2. Time course of occurrence of disaster-related deaths in Minamisoma City since the Fukushima Daiichi nuclear power plant accident. Description of number of disaster-related deaths in Minamisoma City since the Fukushima Daiichi nuclear power plant accident based on the time of the month. The bar indicates a total count of fatalities per month while the dotted line indicates the trend of cumulative percentage.

Table 1. Characteristics of certified disaster-related deaths in Minamisoma City

Variables	Overall (n = 520)
Age, mean (SD)	82.7 (11.9)
Sex, n (%) Male/Female	267 (51.3)/253 (48.3)
Presence of evacuation after the disaster, n (%)	493 (94.8)
Duration from the disaster to death (days)*, mean (SD)	230.6 (310.2)
Distance between FDNPP and residence, n (%)	
Within 20 km	400 (77.1)
Within 30 km	119 (22.9)
Residential area at the time of disaster, n (%)	
Odaka	133 (25.6)
Kashima	56 (10.8)
Haramachi	321 (61.7)
Other	9 (1.7)
Reason for the certification of death as disaster-related, n (%)	
Displacement owing to evacuation	134 (25.8)
Lack of appropriate treatment	65 (12.7)
Decline of physical strength	63 (12.1)
Influence of stress	59 (11.3)
Other	199 (38.3)

FDNPP, Fukushima Daiichi nuclear power plant.

\*Excluded an individual lacking data on the interval between the disaster and death.

#### 4. DISCUSSION

The best of the authors' knowledge, this study is the first investigation of disaster-related deaths in a large evacuation area after a radiation/nuclear accident caused by an earthquake and tsunami.

As shown in Fig. 1, 41.0% of the disaster-related deaths in Minamisoma City occurred within 3 months of the disaster, 21.2% within 3–6 months, and 37.8% over 6 months later. In a study on disaster-related deaths in Ishinomaki City after the Great East Japan Earthquake, approximately 80% of deaths were found to have occurred within 3 months of the disaster. According to the Nagaoka criterion (one of the current guidelines for disaster-related deaths in Japan), a death must occur within 6 months to be recognised as disaster-related, yet the results of this study suggest that many deaths beyond this 6-month cut-off may be disaster-related as well. We previously reported that evacuations that last over a period of years can significantly impact the health of disaster victims (Sawano et al., 2019). The 'effects of evacuation' were cited as the most common causes of disaster-certified deaths; the period of evacuation appeared to be prolonged owing to the wide-area in need of evacuation given the concerns about radiation exposure. The results of this study again highlight the fact that the indirect health effects (including death) of radiation/nuclear disasters can be long-term, and that appropriate measures ought to be taken in this respect.

#### 5. LIMITATION

There were some limitations to this study. First, the number of disaster-related deaths analysed only included those wherein certification was sought or applied for. Those that were not applied for were therefore not included in the study. Second, the data used in this study were mainly based on information from bereaved families and may lack medical accuracy. Third, due to the limit of the paper's length, we could not investigate the exact causes of deaths, so further research is needed.

#### 6. CONCLUSION

Preliminary analysis of disaster-related deaths in the severely affected area by the FDNPP accident revealed that such fatalities continued to occur over a long time. This indicates that radiation/nuclear disasters have long-term effects owing to measures such as evacuation. This suggests that long-term measures are needed to prevent unnecessary deaths following radiation/nuclear disasters. However, the current study was limited to a descriptive level, and additional in-depth analyses are needed to determine more specific measures that could be employed.

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## Significance of stem cell competition in the dose-rate effects

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**Abstract**—The system of radiological protection has been functioning well and is sufficiently robust. However, it needs to be further improved by new scientific findings. At low dose and low dose rate, which are the main areas of radiological protection, carcinogenesis is regarded as the main risk and its biological mechanisms need to be elucidated. Biological effect of a given dose generally decreases with a decreasing radiation dose rate, which is known as a ‘dose-rate effect’. Tissue stem cells are considered as targets for radiation-induced carcinogenesis. In tissues exposed to low dose of radiation, non-irradiated cells begin to appear when irradiation doses are approximately lower than the elemental dose. Under heterogeneous exposure conditions, biological effects could be reduced if damaged stem cells are eliminated by ‘stem cell competition’. Here we showed that proliferation of irradiated intestinal stem cells was inhibited by the presence of surrounding non-irradiated stem cells in the intestinal organoid, which is three-dimensional cultured tissue model generated from intestinal stem cells. Additionally, we found that x-ray-microbeam-irradiated stem cell and its daughter cells were excluded from the organoid. These results suggest that stem cell competition would play an important role in suppression of carcinogenesis under very low-dose-rate irradiation condition.

**Keywords:** Dose-rate effects; Stem cell competition; High background radiation area (HBRA); Low dose-rate; Microbeams

### 1. INTRODUCTION

The system of radiological protection of the International Commission on Radiological Protection (ICRP) has been functioning well and is still sufficiently robust. However, almost 15 years have passed since the last ICRP General Recommendations (ICRP, 2007), and during this time there have been significant new scientific advances as recently reviewed by ICRP (Clement et al., 2021; Laurier et al., 2021; Rühm et al., 2022) and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR, 2021). The system of radiological protection should adapt to changes in advanced science to remain fit for purpose.

Low doses and low dose rates are recently defined as <100 mGy of low-linear energy transfer (LET) radiation to organs and tissues and as <5 or 6 mGy h<sup>-1</sup>, respectively (UNSCEAR, 2021; ICRP, 2021). On the other hand, there is another definition of low dose in terms of microdosimetry. Elemental dose is the lowest dose given by a single track of radiation to the nucleus of a cell. The elemental dose of <sup>137</sup>Cs gamma rays is 0.95 mGy when the target is set to a sphere with a diameter of 8 μm (Watanabe, 2012). Assuming that the acceptable relative standard deviation (RSD) of the energy deposition due to stochastic effects is 20%, the minimum dose of <sup>137</sup>Cs gamma rays to provide that RSD can be calculated as a dose 23.8 mGy by ICRU Report 86 (ICRU, 2011). In other words, when the average absorbed dose is less than 23.8 mGy, irradiation can be considered heterogeneous. At a given dose rate, the mean time between two events is proportional to the mean specific energy for a single event. If the dose rate is very low, all radiation-damaged molecules and unstable reaction products of one charged particle will have progressed to their stable products before the next event occurs, and the only

interactions between unstable molecules will be those within an individual track (ICRU, 2011). Furthermore, under these very low-dose-rate irradiation conditions, hit stem cells will compete with surrounding non-hit stem cells in the niche at any time (ICRP, 2015).

Tissue stem cells are maintained in stem cell niches in some tissues and are considered as targets for radiation-induced carcinogenesis. If the elemental dose affects the stemness, the hit stem cell will be preferentially eliminated by ‘stem cell competition’ from the tissue stem cell niche. This elimination theory lowers the linear term. Hence, stem cell competition at the tissue level leaves an ample possibility for a dose-rate effectiveness factor (DREF) value larger than unity, as in the case of the current dose and dose-rate effectiveness factor (DDREF) value used by ICRP (2015). In our presentation, we reviewed a recent epidemiological study of cancer incidence in the high natural background radiation area (HBRA) in Kerala, India, with extended observation period and expanded cohort size. Next, we presented our important results of radiation-induced stem cell competition using intestinal organoids and x-ray microbeams, suggesting that stem cell competition would play an important role in suppressing carcinogenesis under low-dose-rate irradiation condition.

## 2. A CANCER INCIDENCE STUDY OF THE KARUNAGAPPALLY COHORT

The coastal belt of Karunagappally, Kerala, India is well-known as one of HBRA from thorium-containing monazite sand, where are discovered in 1909. The radiation dose in terms of air kerma ranges from <1 to 45 mGy year<sup>-1</sup> (UNSCEAR, 2018). A cohort of all 385,103 residents in Karunagappally was established in the 1990s to evaluate health effects. In the first report of the cohort study (Nair et al., 2009), 69,958 residents were followed for an average 10.5 years, and 1379 cancer cases, including 30 cases of leukaemia, were identified by the end of 2005. The results of this study were reviewed by UNSCEAR (2018), which described that while the findings in this study were reasonably robust, the confidence intervals obtained from the study were still wide and could not convincingly discount risks similar to those reported from the Life Span Study (LSS).

Recently, the cancer incidence excluding leukaemia in relation to the cumulative dose of natural background radiation in Kerala, during 1990–2017 was reported (Jayalekshmi et al., 2021). The cohort of 149,585 residents aged 30 to 84 years were followed for an average of 19.1 years. Using Karunagappally cancer registry, 6,804 cancer cases excluding leukaemia were identified by the end of 2017. The excess relative risk (ERR) of cancer excluding leukaemia was estimated to be  $-0.05 \text{ Gy}^{-1}$  (95% CI:  $-0.33, 0.29$ ). The confidence interval obtained from the present study is much narrower than that in the previous study [the ERR was  $-0.13 \text{ Gy}^{-1}$  (95% CI:  $-0.58, 0.46$ )] (Nair et al., 2009).

As shown in Fig. 1, recent result of Karunagappally cohort study (Jayalekshmi et al., 2021) suggests the possibility that the solid cancer risk associated with the continuous exposure to very low-dose-rate radiation is significantly lower than that associated with acute exposure obtained by the LSS (Grant et al., 2017). A radiation biological effect of a given dose generally decreases with decreasing radiation dose rate, which is formally known as a ‘dose-rate effect’. But a biological mechanism of dose-rate effect, especially in vivo, has not yet been fully elucidated. To elucidate the biological mechanism of the dose-rate effect, we focus on the radiation-induced stem cell competition.

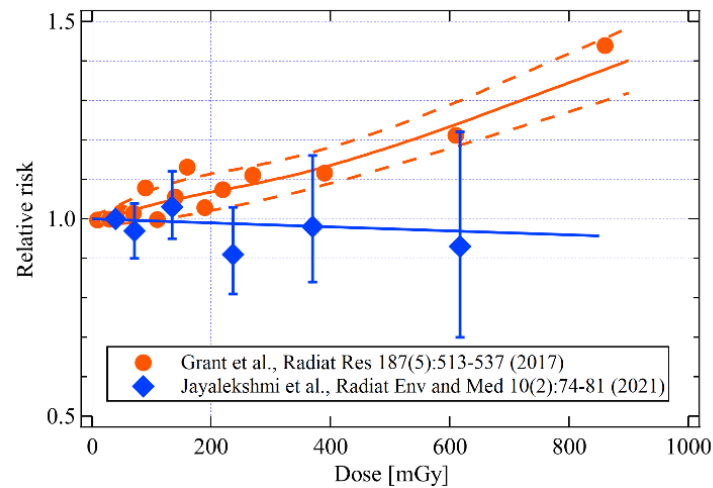


Fig. 1. Comparison of the relative risks between Karunagappally cohort study (very low dose rate) (Jayalekshmi et al., 2021) and LSS (high dose rate) (Grant et al., 2017).

### 3. RADIATION-INDUCED STEM CELL COMPETITION

#### 3.1. Mixed-organoids to evaluate radiation-induced stem cell competition

Cells expressing leucine-rich-repeat containing G-protein-coupled receptor 5 (Lgr5) are one of the major components of intestinal stem cells and exist at the bottom of crypts (Hendry and Otsuka, 2016). Intestinal organoids are three-dimensional cultured tissue models generated from intestinal stem cells and contain all-types of intestinal epithelial cells. To evaluate a radiation-induced stem cell competition, we established a quantitative method using mixed organoid derived from Lgr5 stem cells expressing two fluorescent proteins (EGFP and tdTomato) (Fujimichi et al., 2019). Mixture of irradiated and non-irradiated stem cells expressing different fluorescent colours in a single organoid could simulate heterogeneous exposure situation. To assess which fluorescent-coloured cells grew more preferentially within the mixed organoids, cells were isolated from the mixed organoids after they had grown sufficiently, and the fluorescence intensity of each cell was measured by flow cytometry.

In this study, stem cell competition was quantitatively evaluated by forming two-colour organoids derived from tdTomato<sup>+</sup> non-irradiated stem cells and EGFP<sup>+</sup> (tdTomato<sup>-</sup>) stem cells immediately after exposure to 1 Gy of x rays (Fujimichi et al., 2019). The organoid-forming potential (OFP) is one of the indicators of the abilities of self-renewal, proliferation, and differentiation of stem cells. We found that irradiated stem cells exhibited a growth disadvantage in the mixed organoid, whereas the OFP of irradiated cells per se did not decrease significantly from that of non-irradiated cells. Obtained results suggest that irradiated stem cells are more likely to be eliminated from the stem cell population than non-irradiated stem cells.

#### 3.2. Visualisation of radiation-induced stem cell competition using x-ray microbeam

Next, to directly observe radiation-induced stem cell competition, we performed microbeam irradiation experiments. Microbeam X-ray Irradiation System was developed at the Central Research Institute of Electric Power Industry in Tokyo, Japan, and this system is characterised by tabletop size and an x-ray focusing system using Fresnel zone plate (FZP). Titanium K-shell (TiK) characteristic x ray (4.5 keV) was generated by the focused electron bombardment of the titanium target, and the beam size focused through FZP was 5–10  $\mu\text{m}$ .

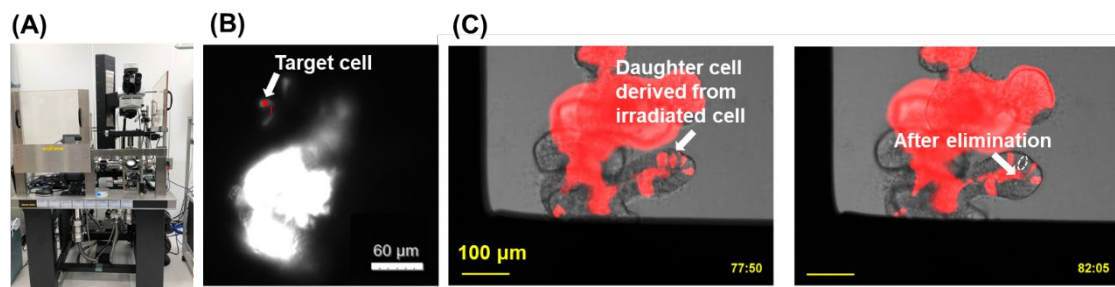


Fig. 2. Microbeam irradiation and elimination of irradiated cell. (A) Microbeam X-ray Irradiation System at CRIEPI. (B) Target irradiation of stem cell by x-ray microbeam (180-degree rotated image of (C)). The red square indicates the microbeam irradiation position. (C) Elimination of daughter cell derived from irradiated cell into lumen.

The attenuation length ( $1/e$ ) of  $TiK$  x ray in water is  $171 \mu\text{m}$ , which is sufficient to irradiate cells in the intestinal organoid.

To observe stem cell competition, this single  $tdTomato^+$  stem cell in the intestinal organoid was targeted with 1 Gy of  $TiK$  x-ray microbeam (Fujimichi et al., 2022). The irradiated  $tdTomato^+$  cell divided and underwent cell death and fragmentation, and their debris was eliminated into lumen (Fig. 2). In contrast, non-irradiated  $tdTomato^+$  cells continued to grow without disappearing. This was the first time that the moment of elimination of irradiated stem cell in the organoid was successfully captured.

#### 4. CONCLUSION

The obtained results suggested that radiation-induced stem cell competition can occur between x-ray irradiated and non-irradiated stem cells and that irradiated stem cells are eliminated after cell division. Recently, Kohda et al. (2022) reported that the frequencies of translocations and of dicentric chromosomes in the splenic lymphocytes from female mice continuously exposed to gamma rays at  $18.25 \text{ mGy year}^{-1}$  (6.25–35 mGy) and that the frequencies were significantly lower in the irradiated mice, although the frequencies increased over time in both irradiated and non-irradiated control mice. Considering the results of carcinogenic risk in HBRA, it is possible that stem cell competition plays an important role in suppression of accumulation of mutations and carcinogenesis under very low-dose-rate irradiation condition. Reflecting the content of stem cell competition by ICRP *Publication 131* (ICRP, 2015) in the discussion of the future of radiological protection system is important for building a consistent and robust system based on biological mechanisms.

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## The radiation epidemiology of cancer – where do we stand now?

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**Abstract**—Much has been learnt from epidemiological studies about the risk of cancer consequent to exposure to ionising radiation. These studies have investigated the influence of radiation exposure upon cancer risk in the Japanese atomic bomb survivors, patients exposed for medical reasons, workers exposed occupationally, and members of the public receiving doses from various environmental sources of radiation. Findings from radiation epidemiology continue to be published, casting light on many aspects of radiation-related cancer risks. Continued follow-up of the bomb survivors has revealed excess cancer risks among those exposed at a young age many years later, and there is emerging evidence of upward curvature in the dose-response for all solid cancers combined. The rise of computed tomography (CT) examinations in medical diagnostic investigations presents an opportunity to study low dose risks, although caution is required in the interpretation of medical studies. Analyses of pooled nuclear worker data provide increasingly powerful investigations of the risks of protracted low-level exposures, particularly because lengthening follow-up has led to an expanding database for early workers who tended to accumulate higher doses than later workers. This paper reviews recent findings of epidemiological studies of radiation exposure and cancer risk that were available at the end of 2022.

*Keywords:* Low-level radiation; Cancer risk; Epidemiology; Recent studies; Review

### 1. INTRODUCTION

Epidemiology is the scientific study of groups of (primarily) humans that investigates the distributions of health effects and the factors that influence these effects in these groups, and is predominantly an observational (i.e. non-experimental) science (Ahrens and Pigeot, 2014). Observational studies cannot constrain the impact of extraneous factors to the same extent that can be achieved in an experimental set-up, and this can distort data to produce misleading findings. For example, the randomisation of study subjects between exposure levels is not possible in non-experimental investigations, so this powerful tool that is so effective in the design of clinical trials is not available to the great majority of epidemiological studies. Observational epidemiology must make the best use of data generated by the uncontrolled conditions of everyday life. In consequence, a major consideration in the interpretation of the results of epidemiological studies is the assessment of how large might be the potential impact of systematic errors and confounding factors. This led Austin Bradford Hill (among others) to propose a framework of guidance as to whether or not an epidemiological association should be inferred as representing an underlying cause-and-effect relationship (Hill, 2015; Wakeford, 2015). From this background, it will be appreciated that in radiation epidemiology, evidence from a broad range of studies is desirable to arrive at conclusions that can be regarded as reliable (Wakeford, 2004; NRC, 2006; UNSCEAR, 2008; Kamiya et al., 2015; McLean et al., 2017).

For convenience, studies in radiation epidemiology may be grouped into four categories:

- the Japanese survivors of the atomic bombings of Hiroshima and Nagasaki in 1945;
- patients exposed to radiation for diagnostic or therapeutic purposes;

- members of the general public who are exposed to radiation from a variety of environmental sources; and
- workers exposed to radiation in the course of their employment.

This paper will examine recent advances made by epidemiological studies in the understanding of the relationship between exposure to ionising radiation and the consequent risk of developing cancer, particularly in the context of low-level exposures. Other diseases, such as heritable effects or eye cataracts, are not addressed in the paper. Results of recent studies that were available at the end of 2022 will be briefly reviewed.

## 2. JAPANESE ATOMIC BOMB SURVIVORS

### 2.1. Introductory remarks

Following the atomic bombings of Hiroshima and Nagasaki in 1945, substantial effort has been devoted to the study of health effects in the Japanese survivors and their offspring, originally by the Atomic Bomb Casualty Commission (ABCC) and then from 1975 the Radiation Effects Research Foundation (RERF) (Ozasa et al., 2019). The Life Span Study (LSS) is a cohort study of 120,321 people, which includes 93,741 survivors present in either city during the bombings and 26,850 people who were residents of the two cities but were not present at the time of the bombings (Brenner et al., 2022). Cohort members have been followed since 1 October 1950 to identify deaths throughout Japan and their causes, and incident cases of cancer among residents of Hiroshima and Nagasaki have been recorded in specialist registries since 1950 for leukaemia, lymphoma and multiple myeloma, and since 1958 for solid cancers. The retrospective estimation of organ/tissue-specific doses received during the bombings is a notable feature of the LSS. Several dosimetry systems have been generated over the years, and the latest version is the Dosimetry System 2002 Revision 1 (DS02R1), which includes absorbed dose components from gamma radiation and neutrons; 86,720 (92.5%) of survivors in the LSS have DS02R1 dose estimates (Cullings et al., 2017).

A second cohort consists of 1878 survivors who were exposed in utero during the atomic bombings and 585 persons whose mothers were residents of one of the two cities and pregnant but not present in the cities at the times of the bombings (Sugiyama et al., 2021). Excluded from the in utero cohort are 879 persons because either maternal doses could not be estimated or maternal exposure status was unknown; people in this latter group, numbering around 600, have been assumed to be unexposed, but this is not clear (Preston et al., 2008). Embryo/fetus doses have yet to be estimated in the dosimetry system, so maternal uterine doses are used as surrogate doses.

A third cohort (the F1 cohort) is composed of 75,327 offspring born during 1946–1984 to residents of Hiroshima and Nagasaki; approximately 23,700 mothers and 36,500 fathers (and for nearly 17,000 cohort members, both parents) were not present in the cities at the times of the bombings (Grant et al., 2015). For study subjects with at least one exposed parent, gonadal (DS02) doses are available for around 39,700 mothers (~23,300 having non-zero doses) and 27,600 fathers (~16,400 having non-zero doses), and about 13,000 people have two exposed parents with dose estimates.

Subgroups of these three cohorts have been invited to participate in clinical programmes (Ozasa et al., 2019). Those selected from the LSS take part in the Adult Health Study (AHS), and certain members of the in utero cohort have also been invited to participate in the AHS. Those selected from the F1 cohort participate in the F1 Offspring Clinical Study (FOCS).

## 2.2. The Life Span Study (LSS)

Although the upward curving dose-response for leukaemia has been recognised for some time (Pierce et al., 1996), until 2017 the evidence that the dose-response for all solid cancers combined departed from linearity was unconvincing. However, in an examination of 22,538 incident cases of solid cancer during 1958–2009, using DS02R1 weighted (by a factor of 10 for the neutron component) absorbed doses to the colon, Grant et al. (2017) found that the best description of the variation of the excess relative risk (ERR) of all solid cancer incidence with dose for female survivors was linear, with an adjusted (for smoking and other risk modifying factors) ERR Gy<sup>-1</sup> at an attained age of 70 years following exposure at an age of 30 years of 0.64 (95% CI: 0.52, 0.77), while that for male survivors was linear-quadratic, with an ERR at 1 Gy at an attained age of 70 years after exposure at an age of 30 years of 0.20 (95% CI: 0.12, 0.28). The significant ( $p = 0.02$ ) difference in the shapes of the dose-responses between males and females was not readily explicable (Grant et al., 2017).

Brenner et al. (2022) further investigated the shapes of the dose-responses for all solid cancer incidence, and compared these with the shapes obtained from a parallel analysis of 15,419 cancer deaths during the same 1958–2009 period and using DS02R1 doses. The resulting dose-responses are shown in Fig. 1. As will be seen, the findings are, at least at first sight, somewhat perplexing: for the dose-responses over the 0–4 Gy colon dose range, for males, highly significant upward curvature was found for incidence accompanied by borderline non-significant upward curvature for mortality, while for females, there was little evidence for any departure from linearity for incidence but significant upward curvature for mortality. The difference in the curvatures between the sexes was significant for incidence, but not for mortality. Findings did not change notably when the dose range was restricted to 0–2 Gy.

It would be surprising if the nature of the dose-response (e.g. its curvature) was exactly the same for all types of solid cancer, and perhaps what is being seen in the findings of Brenner et al. (2022) when the most recent data are available for analysis is the impact of such underlying heterogeneity upon the dose-responses for all solid cancers combined. Indeed, Brenner et al. (2022) propose that their findings strengthen the evidence for upward curvature in the dose-response for all solid cancers combined, with the strength of evidence depending on the types of cancer contributing to the aggregation of all solid cancers: the composition of the incidence and mortality groupings will depend, inter alia, on the lethality of the type of solid cancer and on variations with sex, age-at-exposure and calendar period. Of interest in this respect is that the data accumulating from more recent periods of follow-up primarily involve those exposed at a young age who are diagnosed with cancer several decades since exposure, and at a time when survival for many cancer types has improved significantly in the more than half a century since solid cancers were observed to be in excess among the bomb survivors.

The analysis of all solid cancers combined as a single grouping has been conducted to increase the statistical power of investigating features of the dose-response such as curvature and the existence of any dose threshold. It may be, however, that the time has now come when the usefulness of such a single grouping is outweighed by the difficulties identified by the study of Brenner et al. (2022). Specific sites of solid cancer have been studied using the latest incidence data from 1958–2009, such as prostate cancer (Mabuchi et al., 2021) and central nervous system (CNS) tumours (Brenner et al., 2020) among others, and continuing analysis of updated data for specific solid cancer types is likely to shed light on the dose-responses and how they vary. It should be borne in mind that the last follow-up of cancer incidence was to the end of 2009, and at that time 37.7% of survivors were still alive, so there is substantial information still to be come, predominantly from cancers occurring many years after exposure at a young age. In any event, the 2007 Recommendations of the ICRP (ICRP, 2007) do not make use of the category of all solid cancers combined in the derivation of cancer incidence risk

estimates, but rather employ risk models for specific sites of cancer (albeit based on solid cancer incidence during 1958–1998); cancer risk models for use in the next ICRP recommendations are being assessed by ICRP Task Group 122.

### All Solid Cancers Combined

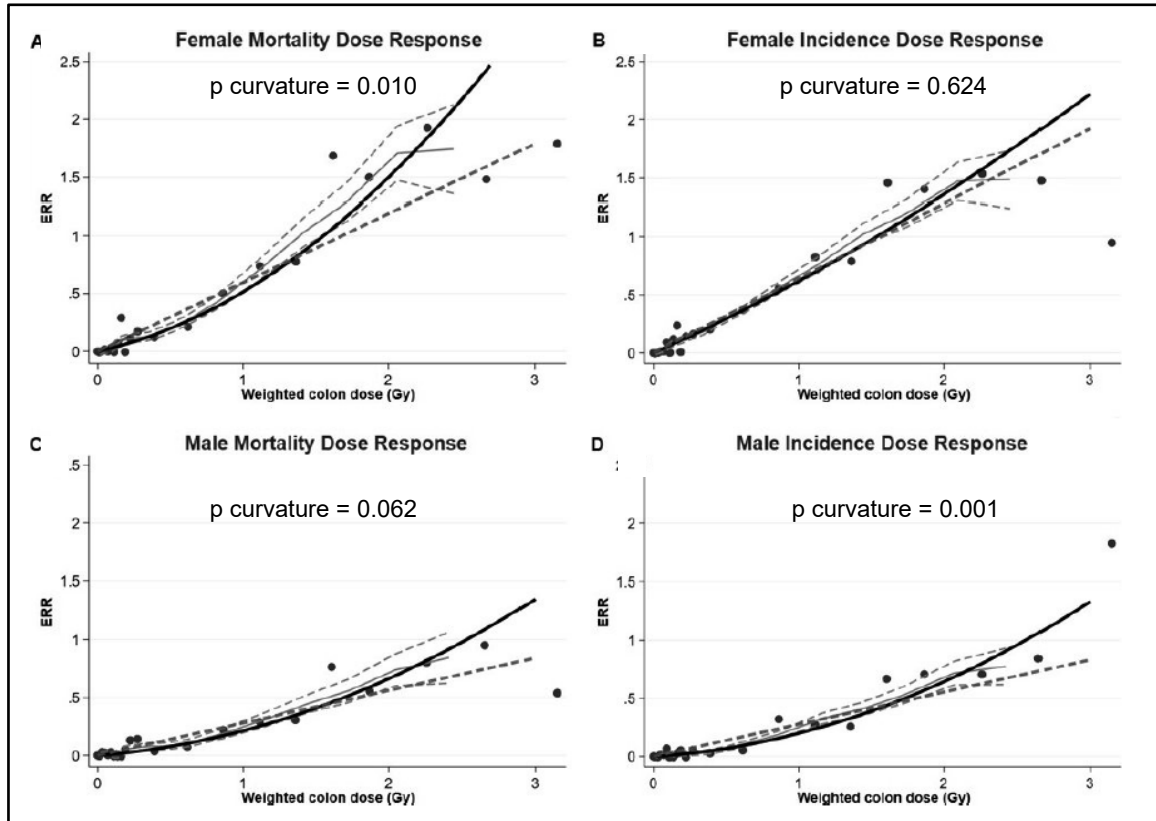


Fig. 1. Dose-responses for the incidence of, and mortality from, all solid cancers combined, Excess Relative Risk (ERR) with respect to DS02R1 weighted colon dose, for each sex. Incident cases and deaths during 1958–2009 in the Life Span Study. The ERR estimates are for a survivor 70 years of age following exposure at 30 years of age. Figure adapted from Fig. 2 of Brenner et al. (2022) where further details may be found.

### 2.3. Exposure in utero

Sugiyama et al. (2021) have updated the study of mortality in the cohort of survivors irradiated in utero with follow-up to the end of 2012. Based on a total of 137 solid cancer deaths, they reported an  $\text{ERR Gy}^{-1} = 2.10$  (95% CI: 0.26, 5.61) for women and an  $\text{ERR Gy}^{-1} = -0.08$  (95% CI:  $<-0.82$ , 1.36) for men. This difference in the sex-specific risk estimates must be viewed in the light of just 15% of the exposed members of the cohort having died by the end of 2012. Longer follow-up will provide more information on the risk of cancer in later life following exposure in utero, and this cohort represents one of the few sources of data on this topic.

Given the clear excess risk of leukaemia among survivors exposed after birth at a young age, which started to appear just a few years after exposure, the absence of evidence for a similar excess risk among survivors exposed in utero has been the subject of much comment [see, for example, (Boice and Miller, 1999)]. However, the small expected number of incident cases of, and deaths from, childhood leukaemia in the cohort exposed in utero precludes a reliable interpretation (Wakeford and Little, 2003). Ohtaki et al. (2004) presented the results of

a study of stable chromosome translocations in the peripheral blood lymphocytes of 150 survivors exposed in utero, the blood samples being taken at an age of 40 years. There was a small excess frequency of translocations at DS86 maternal uterine doses <100 mGy, but at doses >100 mGy there was no increase in frequency with increasing dose. In contrast, translocation frequencies in blood sampled from a small number of mothers showed the expected increase with dose. Cologne et al. (2022) refined the analysis conducted by Ohtaki et al. (2004), in particular, by adjusting for smoking and using DS02R1 uterine doses, and the original findings were broadly confirmed. The explanation for this surprising pattern of results may lie in intrauterine doses as low as a few 100 mGy damaging lymphocytes to a sufficient extent that they are eliminated and replaced by the progeny of unaffected haematopoietic stem cells, and this may also account for the absence of excess cases of leukaemia in the cohort of survivors exposed in utero. Studies of the phenomenon using experimental animals continue (Hamasaki et al., 2022). Further investigations are desirable, especially whether or not the use of embryo/fetus doses rather than maternal uterine doses affect the results in any material way, and whether the effect persists after birth and if so, for how long.

#### **2.4. Offspring of the survivors**

Until recently, there was little evidence from the F1 cohort for parental exposure during the atomic bombings affecting the health of subsequently conceived offspring when followed up to the end of 2009 (Grant et al., 2015). However, Yamada et al. (2021) have re-examined the data for major congenital malformations and perinatal mortality among 71,603 births during 1948–1953, using refined analytical methods and, in particular, DS02 gonadal doses. They reported positive associations between gonadal doses received by parents and an increased risk in offspring of major congenital malformations and perinatal death, although most of the associations were not statistically significant. Yamada et al. (2021) opined that the imprecision of the associations imply that the findings should be interpreted cautiously, and as remarked upon by Lie (2021), the evidence for a radiation-related risk remains weak. As the F1 cohort ages it will be important to ascertain whether preconceptional exposure has a detectable impact on the multifactorial diseases of old age.

### **3. MEDICAL EXPOSURES**

#### **3.1. Introductory remarks**

Patients exposed to radiation for diagnostic or therapeutic reasons offer an opportunity to study groups of people who have experienced a wide range of exposure circumstances, which is a valuable complement to the studies of the Japanese atomic bomb survivors. Indeed, it was a study of British ankylosing spondylitis patients in the 1950s, who had been irradiated with x rays for therapeutic purposes, that provided support for the early findings from the bomb survivors of an excess risk of leukaemia (Court-Brown and Doll, 2007; Smith, 2007). Early medical studies were mainly of patients treated with external photon radiotherapy for a variety of medical conditions, although some groups received internal exposures for therapeutic [e.g. injections of <sup>224</sup>Ra (Spiess, 2010)] or diagnostic [e.g. injections of the <sup>232</sup>Th-based contrast medium Thorotrast (Grosche et al., 2016)] purposes. In recent years, the rise of diagnostic examinations, in particular, the use of computed tomography (CT), has led to openings for the study of the effects of the receipt of low doses, or a series of low doses, upon the subsequent risk of cancer (and other diseases).

There exist a number of difficulties in the interpretation of the results of studies of radiation exposure for medical reasons. Fundamentally, medical exposures occur because people are ill,

have been ill, or are suspected of being ill. This gives rise to the potential for reverse causation and confounding by indication. Reverse causation occurs when a diagnostic examination is conducted because of symptoms of a disease that is only diagnosed later, perhaps much later, so that whereas it could appear that a CT scan might have caused a subsequently diagnosed cancer, in fact the cancer was already present, but undetected, when the CT scan was carried out. Confounding by indication occurs when some underlying medical condition leads to a higher risk of a disease such as cancer, but that this condition may, in itself, also lead to an increased requirement for diagnostic examinations, which may manifest as an association between CT scanning and cancer. Various approaches to these difficulties have been made, such as increasing the period between exposure and a relevant cancer diagnosis, which decreases the likelihood of reverse causation, and omitting from studies those suffering from known conditions predisposing to cancer, but confidently excluding explanations other than direct cause-and-effect is difficult (Boice, 2015). There have been certain studies reporting positive associations between CT scans at a young age and subsequent cancer diagnoses in which reverse causation and confounding by indication are likely to play a role, perhaps a considerable role (Walsh et al., 2014).

A further problem with medical studies is that exposures are generally heterogeneous, leading to variations of doses between organs/tissues (or even within organs/tissues) that can be substantial. This makes the determination of the organ/tissue-specific doses required for epidemiological studies difficult, especially the dose reconstructions often necessary for the reliable interpretation of historical studies. Moreover, therapeutic exposures occur with the intention of killing diseased cells, accompanied by the unintentional irradiation of healthy cells that is, to a variable extent, inevitable, particularly when addressing radiotherapy regimens in earlier years. Not only does this lead to complications in dose assessment, but the competing effects of malignant transformation and sterilisation of cells in irradiated tissues could affect the shape of the dose-response, and this is certainly a consideration for the risk of second primary cancers resulting from cancer treatment with radiation (Wakeford and Hauptmann, 2022).

### 3.2. CT studies

Recently, Berrington de Gonzalez et al. (2021, 2022) conducted a meta-analysis of studies of the incidence of leukaemia and brain tumours following a CT scan at a young age, that is,  $\leq 21$  years of age at first exposure, but with the age range at exposure (and at diagnosis) varying between studies. The results of this meta-analysis are presented in Fig. 2.

Berrington de Gonzalez et al. (2021, 2022) found an overall estimate of the ERR of leukaemia per 100 mGy dose to the active bone marrow (ABM) of 1.05 (95% CI: -0.58, 2.69), and an overall estimate of the ERR of brain tumours per 100 mGy dose to the brain of 0.79 (95% CI: 0.47, 1.11). Of note is that the analytical approach taken in the individual studies is not consistent in a number of respects, so that, for example, the period of exclusion of cases of brain tumours after first exposure is five years in the British and Dutch studies and two years for the French and German studies; Berrington de Gonzalez et al. (2021) were of the view that the summary risk estimate for brain tumours could be overestimated due to reverse causation. In a similar vein is the role of myelodysplastic syndrome (MDS) in the risk estimates for leukaemia derived from the studies contributing to the meta-analysis. In general, cases of MDS are included with cases of leukaemia in the results presented in the studies, but in the British and Dutch studies results are available with and without MDS included with leukaemia: in the British study the ERR per 100 mGy estimate with MDS included is 3.6 (95% CI: 0.5, 12.0) while with MDS excluded it reduces to a statistically non-significant 1.9 (95% CI: -1.2, 7.9), and in the Dutch study the ERR per 100 mGy estimate with MDS included is 0.04 (95% CI:

−0.12, 1.61) while with MDS excluded it increases to (a still non-significant) 0.21 (95% CI: −0.12, 2.40). As Berrington de Gonzalez et al. (2021) opine, comparison of the findings of different studies is challenging.

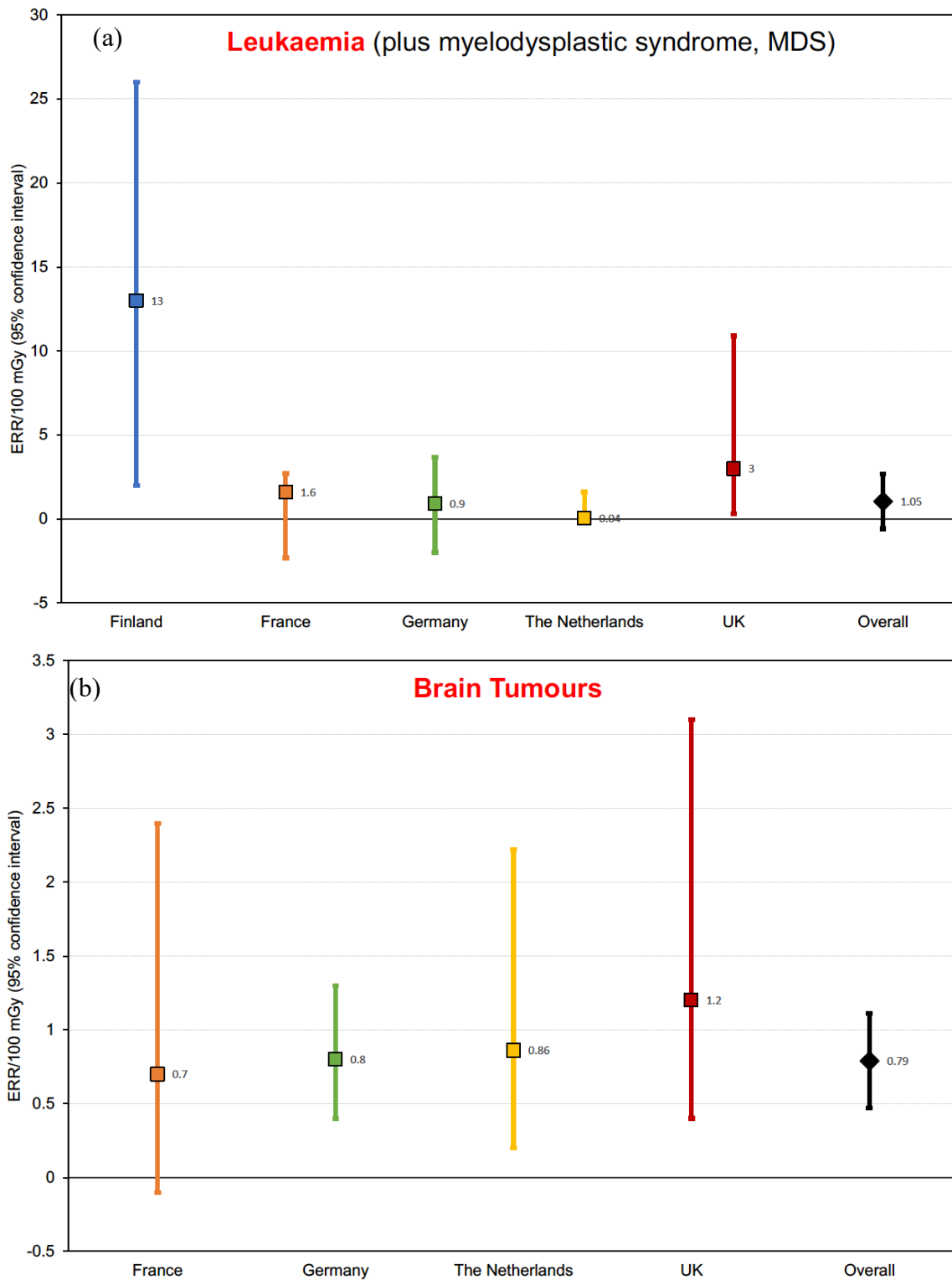


Fig. 2. Estimates of the Excess Relative Risk (ERR) per 100 mGy organ dose obtained from cohort studies of young people exposed to x rays during CT scans for the incidence of (a) leukaemia (plus myelodysplastic syndrome, MDS) and (b) brain tumours, and the summary ERR per 100 mGy estimates obtained from meta-analyses conducted by Berrington de Gonzalez et al. (2021, 2022).



The French study included in the meta-analysis of Berrington de Gonzalez et al. (2021) has recently been updated by Foucault et al. (2022), who reported an ERR per 100 mGy estimate for leukaemia (plus MDS) of 1.6 (95% CI: 0.7, 2.6) and an ERR per 100 mGy estimate for brain tumours of 0.6 (95% CI: 0.2, 0.9); a case exclusion period of two years after first exposure was used for both leukaemia and brain tumours. Inclusion of this updated French study in the meta-analysis would have little impact on the overall point estimates of risk, but would narrow the summary interval estimates. However, basic interpretational issues remain.

Towards the end of 2022, the first results of the EPI-CT collaborative project analysing pooled data from cohort studies of CT scans of young people in nine European countries was published: Hauptmann et al. (2022) reported a linear dose-response for brain cancer incidence and brain dose of ERR per 100 mGy = 1.27 (95% CI: 0.51, 2.69). Country-specific results were ‘somewhat heterogeneous’, although this was not quantified, and although the UK data were influential [the British study having been the first large cohort study to report a significant dose-response for brain tumours (Pearce et al. 2012)], a significant dose-response was found if the UK data were excluded from the analysis: ERR per 100 mGy = 0.91 (95% CI: 0.12, 2.83). Of interest is the (statistically non-significant) tendency for ERR per 100 mGy to increase with increasing age-at-exposure, which is in the opposite direction to that found in the LSS, although this trend was also non-significant (Brenner et al., 2020). The study of Hauptmann et al. (2022) is a valuable addition to the CT scan and cancer literature, although further investigations are required to address the remaining questions on the impact of reverse causation and confounding by indication.

### 3.3. Antenatal x-ray examinations

It was in the mid-1950s that Stewart et al. (1956, 1958) first reported an association between childhood cancer mortality and an abdominal x-ray examination of the pregnant mother, from a case-control study of childhood cancer mortality and a number of potential risk factors; the association was present both for leukaemia and for all other childhood cancers combined. The interpretation of the association was controversial when these results were reported over 65 years ago and has remained so, not least because the dose received by the fetus from such an examination would have been of the order of 10 mGy and it was thought unlikely that doses this low could cause cancer. The study of Stewart et al. (1956, 1958) became known as the Oxford Survey of Childhood Cancers (OSCC) and continued into the early-1980s (Gilman et al., 1989). Some of the criticisms levelled at the early findings of Stewart et al. (1956, 1958) were met by a case-cohort study based solely upon medical records conducted in the north-east USA by MacMahon (1962), which confirmed the association between childhood cancer mortality and an antenatal x-ray examination. With other studies carried out around the world also tending to support the OSCC findings, the reality of the statistical association is no longer seriously doubted, although its interpretation continues to be debated (Doll and Wakeford, 1997; Boice and Miller, 1999; Brent, 2014).

Obtaining an estimate of the risk of childhood cancer in terms of the fetal dose is not straightforward due to the lack of information on fetal doses delivered during an antenatal x-ray examination in the period covered by the OSCC (Mole, 1990a,b). However, data from the OSCC and a British nationwide survey of fetal doses in 1958 (Mole, 1990a) may be used to derive an estimate of the ERR at 10 mGy of 0.5 (95% CI: 0.3, 0.8) (Bithell, 1992), although the confidence interval reflects sampling errors only and the inevitable presence of other uncertainties associated with this estimate (dosimetry, modelling, etc.) needs to be emphasised (Doll and Wakeford, 1997; Wakeford and Little, 2003).

As noted in the Introduction, a statistical association established by epidemiological studies is not necessarily causal and confounding by indication has been suggested as an explanation

for the association between childhood cancer and radiation exposure in utero in that, for example, the poor health of the mother during pregnancy may lead to an abdominal x-ray examination, but this maternal poor health might also increase the risk of childhood cancer. There are suggestions that raised birthweight may increase the risk of childhood cancer, and it is plausible that a large fetus may have an increased probability of an obstetric x-ray examination, although this potential source of confounding does not appear to provide an explanation for the association between an antenatal x-ray examination and childhood cancer (Wakeford and Bithell, 2015).

One aspect of the OSCC results that has provoked comment is the uniformity of the raised relative risk found for almost all types of childhood cancer (Bithell and Stewart, 1975), which is not what would be expected from the evidence following postnatal exposure (Boice and Miller, 1999). To assess whether this pattern of results was confined to the OSCC or was more general, Wakeford and Bithell (2021) compared the findings of the OSCC with the summary estimates obtained from appropriately combining the data from all other case-control/case-cohort studies in a meta-analysis. The relative risks for the various types of childhood cancer obtained from the OSCC are compared with those derived from the meta-analysis in Fig. 3.

Fig. 3 demonstrates the broad consistency of the two sets of results. For the rarer types of childhood cancer, such as peripheral neural tumours and kidney tumours, lack of data from the combined studies other than the OSCC leads to imprecise estimates that are compatible with both the findings of the OSCC and no raised risk, but in general, the combined other studies support the raised risks generated by the OSCC. Of interest is the consistent lack of a significant association for bone tumours, which are not typical cancers of childhood. While confounding by indication is difficult to rule out as a possible explanation for the association, this analysis shows that the pattern of (almost) uniform raised risks is not a feature confined to the OSCC.

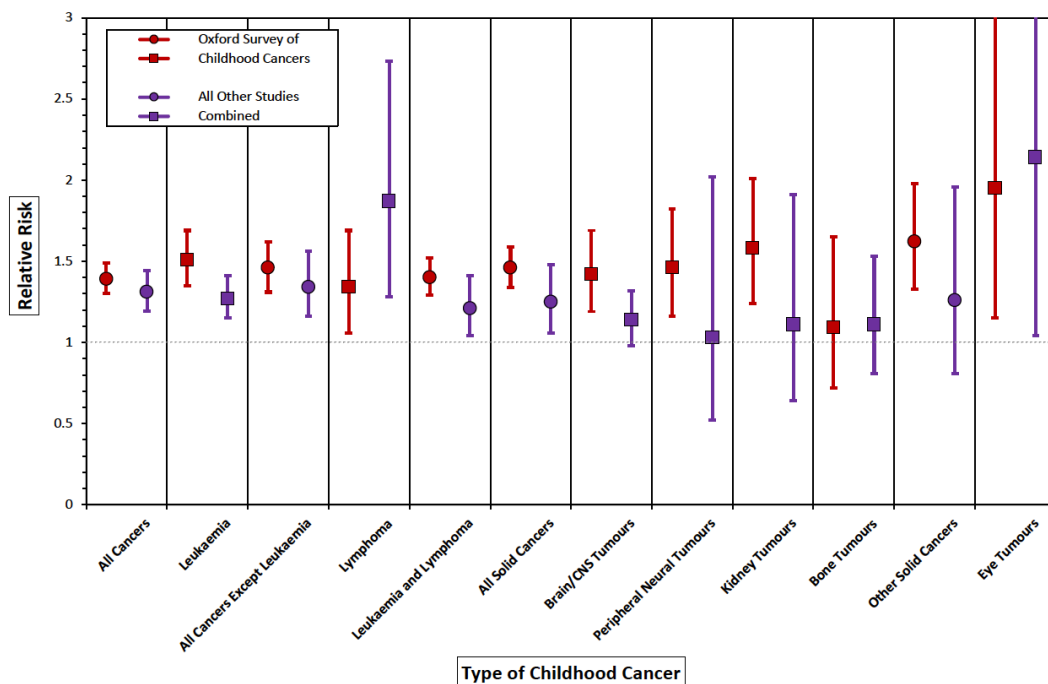


Fig. 3. The relative risk of childhood cancer associated with an antenatal x-ray examination, for various types and groups of types of childhood cancer, obtained from the Oxford Survey of Childhood Cancers (OSCC) and from all other case-control/case-cohort studies appropriately combined in a meta-analysis (Wakeford and Bithell, 2021). Circular markers show groupings of some of the specific cancer types indicated by square markers [although not all studies of specific cancer types are necessarily included in the studies of the relevant groupings of cancer types (Wakeford and Bithell, 2021)], and error bars show 95% confidence intervals. CNS = central nervous system.

Little et al. (2022) conducted a meta-analysis of studies of (predominantly childhood) cancer and exposure in utero to x rays for diagnostic reasons, which included the OSCC and the great majority of the other studies considered by Wakeford and Bithell (2021). The results of the meta-analysis showed no significant inter-study heterogeneity and significantly raised summary relative risk estimates for leukaemia, lymphoma, brain/CNS tumours and all other solid cancers combined, and when these four relative risks were appropriately combined an overall relative risk for all cancers of 1.32 (95% CI: 1.25, 1.40) was obtained. For all cancers combined, a trend of decreasing relative risk with advancing calendar period was apparent.

### 3.4. Pooled data analyses

Increased statistical power may be obtained by appropriately pooling data from similar studies for suitable analyses, and such studies have recently been undertaken. Lubin et al. (2017) analysed the subset of data for thyroid doses <200 mGy in data pooled from nine cohorts (Veiga et al., 2016) to examine the risk of incident thyroid cancer following low doses from external sources of photons; eight of the cohorts were those exposed at a young age for therapeutic purposes, but survivors from the LSS were also included. No departure from a linear dose-response was detected and Lubin et al. (2017) reported an ERR Gy<sup>-1</sup> of 11.1 (95% CI: 6.6, 19.7) for a thyroid dose range of 0–200 mGy, and an ERR Gy<sup>-1</sup> of 9.6 (95% CI: 3.7, 17.0) for a thyroid dose range of 0–100 mGy. The upper 95% confidence limit for a threshold dose for thyroid cancer was 40 mGy. The pooled data study of Lubin et al. (2017) provides impressive evidence of an increased risk of thyroid cancer following the receipt at young ages of low doses of photons from external sources by the thyroid gland.

Little et al. (2018) conducted an analysis of pooled data from nine cohorts to examine the dose-response for leukaemia following cumulative ABM doses <100 mGy received at a young age from external sources of photons. The LLS was one of the cohorts included, but otherwise the cohorts consisted of patients exposed for therapeutic or diagnostic reasons; one of the diagnostically exposed cohorts was the British CT scan cohort of Pearce et al. (2012). No departure from a linear dose-response was found for the major types of leukaemia, and significantly increased dose-responses were reported for acute myeloid leukaemia (AML), ERR per 100 mGy = 15.6 (95% CI: 0.9, 40.6), and acute lymphoblastic leukaemia (ALL), ERR per 100 mGy = 46.6 (95% CI: 3.5, 187.1), but not for chronic myeloid leukaemia (CML), ERR Gy<sup>-1</sup> = -6.4 (95% CI: <-6.4, 13.6). The results were heavily influenced by the LSS and British CT scan data (Little et al., 2018). When an equivalent pooled data analysis was carried out for the lymphomas and multiple myeloma, but with no restriction on the doses received, no significantly raised dose-responses were found using ABM doses, but rather limited indications of some positive dose-responses using lymphatic tissue doses (Little et al., 2021). The pooled data analysis of Little et al. (2018) indicates that raised risks of acute leukaemias are apparent after low cumulative doses received by the ABM of young people from external sources of photons.

### 3.5. Survivors of diseases treated with radiation

A brief mention should be made of studies of patients treated with radiation for a variety of medical conditions who received (predominantly) localised high, or very high, doses of radiation. Studies of cancer following radiotherapy for benign diseases in the early- and mid-20th century offered valuable evidence that complemented the early findings of cancer in the atomic bomb survivors, and Boice (2006) has reviewed these studies. With the increasing success of treatments for cancer, studies of second primary cancers in cancer survivors have become a further important source of information on the effects of high-level radiation exposure (although tissues remote from the target of radiation treatment will have received

lower doses from scattering and leakage). The study of second primary cancers in women treated with radiation for cancer of the uterine cervix is a particularly notable example of a large study of cancer survivors from the late-twentieth century (Boice et al., 1988). The literature on the risk of second primary cancers from radiation treatment has recently been reviewed by Wakeford and Hauptmann (2022). A challenge for those managing cancer treatment is maintaining control of the risk of second primary cancers as radiotherapy regimens continue to evolve and improve in efficacy (Wakeford and Hauptmann, 2022).

## 4. EXPOSURES IN THE ENVIRONMENT

### 4.1. Introductory remarks

People exposed at various levels to radiation in the environment are of interest because, *inter alia*, unlike patients and workers, they are generally unselected for exposure, but like the Japanese atomic bomb survivors, may have received high exposures because they just happened to be present in the wrong place at the wrong time. Several groups relevant to environmental radiation epidemiology have been studied, and these studies form a useful complement to the other categories of studies. The groups consist of those exposed to natural background radiation (such as residential radon and terrestrial gamma radiation) and to radiation from radioactive contamination (such as nuclear weapons testing fallout, arial releases from the Chernobyl and Fukushima reactor accidents, and liquid discharges from the Russian Mayak nuclear facility into the Techa River). However, affected people are often difficult to identify unambiguously, their vital/health status can be difficult to establish reliably, and the reconstruction of the doses received is a particular problem.

The UNSCEAR 2017 Report, Annex B (UNSCEAR, 2017), provides a valuable recent summary of the findings of epidemiological studies of groups exposed environmentally. The report included reviews of studies of the Techa River cohort, those exposed from <sup>60</sup>Co contaminated steel in Taiwan, and those exposed to elevated levels of natural background gamma radiation. The UNSCEAR 2017 Report, Annex B (UNSCEAR, 2017) does not address studies of the general public affected by the Chernobyl or Fukushima releases or of residential radon because these were considered in other UNSCEAR reports, but these important sets of studies are reviewed briefly below.

### 4.2. Residential radon

Despite the problems of design and conduct, case-control studies of lung cancer and residential exposure to radon and its decay products have demonstrated that inhalation of these radionuclides is a cause of lung cancer (ICRP, 2010). These studies must not only measure radon concentrations in the homes (and ideally in previous homes) of cases and controls, and the length of residence in the measured homes, but also establish the tobacco smoking histories of the study subjects, given the importance of smoking as a cause of lung cancer, and appropriately account for smoking in the analyses. Obtaining comprehensive and unbiased information in these case-control studies is a challenge – see discussion of Kendall et al. (2015). Pooled analyses of data from studies in China (Lubin et al., 2004), North America (Krewski et al., 2006) and Europe (Darby et al., 2005, 2006) have been conducted, although there would appear to be scope for further pooling of case-control studies to provide greater statistical power.

These studies are expressed in terms of the ERR of lung cancer per measured radon concentration ( $\text{Bq m}^{-3}$ ) in the home, but efforts to derive excess risks in terms of cumulative exposures ( $\text{Bq m}^{-3} \text{ h}$ ) would be of value when comparing with studies of underground hard-

rock miners (see Section 5.2), which usually report risk in terms of cumulative exposure to radon decay products. Ultimately, expressing risk per unit absorbed dose to the relevant target cells in the lung should be the aim, although this is not straightforward (Marsh et al., 2021; Harrison, 2021).

Of interest is the American Cancer Society cohort established in 1982 and the investigation of lung cancer in terms of residential radon exposure within a cohort of >800,000 persons, which found an association compatible with the results of the case-control studies, an adjusted hazard ratio of 1.15 (95% CI: 1.01, 1.31) per 100 Bq m<sup>-3</sup> (Turner et al., 2011). This cohort study considered lung cancer deaths during 1982–1988 and used individual smoking data gathered prospectively in 1982, but also used the mean residential radon concentration available from measurements in the US county of residence rather than in the homes of the study subjects, which would not be possible in a cohort study this large. Whether a case-control study nested within this cohort, using radon measurements specific to the homes of study subjects for cases occurring in a later period might be feasible is unknown, but this is an interesting prospective cohort that looks to provide support for the case-control studies. It would be useful to investigate whether further studies using this cohort would be possible.

### 4.3. Releases from the Chernobyl and Fukushima accidents

Within a spectrum of radionuclides, ~1.8 EBq of <sup>131</sup>I was released to atmosphere during the Chernobyl reactor accident of 1986 (UNSCEAR, 2011). UNSCEAR (2018) estimated that during 1991–2015, ~5000 cases of thyroid cancer (range, ~1400 to ~10,000) in the highly contaminated regions of the former Union of Soviet Socialist Republics (USSR) were attributable to this release (and other radioisotopes of iodine), principally due to in excess of 10,000 children drinking heavily contaminated milk and receiving doses to the thyroid of 1 Gy or more (UNSCEAR, 2011). This level of exposure provided an opportunity to compare the risk of thyroid cancer from radioiodine deposited in the thyroid gland with that from external photons (see Section 3.4), and a number of studies were initiated in the 1990s (UNSCEAR, 2011). Most reliable are two cohort studies of ~12,000–13,000 persons exposed while <18 years of age, with thyroid radioactivity measurements made soon after the accident and who participated in a programme of screening for thyroid cancer and other thyroid anomalies; the Ukrainian and Belarusian cohorts produced linear ERR Gy<sup>-1</sup> estimates of, respectively, 4.93 (95% CI: 1.67, 19.90) (Little et al. 2014) and 1.48 (95% CI: 0.53, 3.87) (Little et al., 2015). There was some evidence of downturns in the dose-responses, and linear-exponential models provide linear ERR Gy<sup>-1</sup> components of 7.97 (95% CI: 2.32, 49.81) and 2.79 (95% CI: 0.83, 9.05) for the respective cohorts. Efforts continue to improve the accuracy of thyroid dose estimates (Masiuk et al., 2023).

In general, doses to organs/tissues other than the thyroid were much less than those to the thyroid and so evidence for any excess of cancers other than of the thyroid is less certain. However, recently some studies have indicated an increased risk of breast cancer (Rivkind et al., 2020; Cahoon et al., 2022; Vij et al., 2022), but not all studies (Zupunski et al. 2021).

At the time of writing this paper, at the end of 2022, whether geopolitical circumstances will permit the continuation of Chernobyl studies remains to be seen. This would be an unfortunate loss of evidence, but may be unavoidable.

The accident at the Fukushima Daiichi nuclear power station in 2011 led to a release of radioiodine (and other radionuclides, such as radioisotopes of caesium) that was substantially less than that released during the Chernobyl accident (UNSCEAR, 2022). Further, those responsible for radiological protection following the Fukushima accident were aware of what had happened after Chernobyl and imposed measures that would restrict the intake of radioiodine by children. The Japanese authorities established the Fukushima Health

Management Survey, which included ultrasound screening of the thyroid glands of ~300,000 people who were <19 years of age at the time of the accident (Yasumura et al., 2022; Shimura et al., 2022). In the first round of screening during 2011–2015, conducted to provide a baseline of prevalence of thyroid tumours in the study population, 116 cases of thyroid cancer were found, which is much higher than the rate of incidence of thyroid cancer occurring in other areas of Japan (UNSCEAR, 2022). Tsuda et al. (2016) argued that these cases were the result of radiation exposure following the Fukushima accident, but Wakeford et al. (2016) pointed out a number of flaws in this claim, including that the prevalent cases found by the highly sensitive screening technique in Fukushima Prefecture were not distributed according to the radioactive contamination caused by the accident. Further, the age-at-exposure distribution of the cases of thyroid cancer detected in Fukushima was quite different from that observed around Chernobyl, with only one case occurring among the <5 year age-at-exposure group (UNSCEAR, 2022). It would appear that ultrasound screening detects small thyroid tumours that would not be found by routine thyroid examination, and similar ‘overdiagnosis’ of thyroid cancer had previously been found in South Korea (Ahn et al., 2014). This led the International Agency for Research on Cancer to recommend that thyroid screening at the population level should not be carried out after a nuclear accident because the harm outweighs the benefit (IARC, 2018). Investigations into the incidence of thyroid tumours (and other health effects) in Fukushima Prefecture continue, with little evidence that radioactive releases from the accident have produced a discernible increase in thyroid cancer incidence or other health conditions (Yasumura et al., 2022; Shimura et al., 2022; Nakaya et al., 2022).

#### 4.4. High natural background gamma radiation

A number of studies of populations exposed to high natural background gamma radiation have been conducted; these studies have been reviewed by UNSCEAR (2017). The study of cancer incidence in Karunagappally, Kerala, where areas of high gamma radiation can be found because of the presence of monazite (thorium-bearing) sands, has recently been updated by Jayalekshmi et al. (2021), who reported that using incidence data for adults during 1990–2017, the ERR Gy<sup>-1</sup> for all cancers excluding leukaemia (6804 cases) was -0.05 (95% CI: -0.33, 0.29). Somewhat perplexing is that although 135 cases of leukaemia were available for study, no quantification of the radiation-associated risk of leukaemia was presented by Jayalekshmi et al. (2021). No explanation for this omission of results for leukaemia was given, although it might be expected that leukaemia would be one of the types of cancer most influenced by comparatively high levels of gamma radiation, and of note is that in the previous report of this study, Nair et al. (2009) presented detailed results for leukaemia, even though these were based on just 30 cases of leukaemia (of which 10 cases were of chronic lymphocytic leukaemia, CLL). Further, Jayalekshmi et al. (2021) did not report separate results for other cancer types of particular interest, such as female breast cancer (705 cases) and thyroid cancer (137 cases in women). Nonetheless, this interesting study should be continued as it has a number of valuable features, such as the availability of cancer incidence data from a local registry. However, additional information would be helpful, such as any differences [e.g. dietary habits, data for which were collected in a survey (Jayalekshmi et al. 2021)] between higher exposure areas on the coast or estuaries and lower exposure areas inland.

Although not specifically addressing populations from identified areas of high natural background gamma radiation, of note is that conventional leukaemia risk models indicate that perhaps one-fifth of childhood leukaemia cases in Great Britain are attributable to natural background gamma radiation (Wakeford, 2004, 2013; Wakeford et al., 2009). Large case-control studies are required to have enough power to be able to detect this predicted risk (Little et al., 2010), but an appropriate British database of 27,447 childhood cancer cases is available

and preliminary results from a case-control study using this database were promising in that a gamma-radiation-associated risk of childhood leukaemia was indicated, but not for other childhood cancers (Kendall et al., 2013). However, a large study of acute leukaemia cases in France has not confirmed this association (Demoury et al., 2017; Berlivet et al., 2021) so consistent inferences currently cannot be drawn about the risk of childhood leukaemia arising from natural background radiation. A central difficulty in conducting such studies is assigning doses to cases and controls when individual dose measurements cannot be made for such large numbers of children so that doses must be estimated from general radiation survey data. Studies of childhood cancer and natural background radiation have recently been reviewed by Mazzei-Abba et al. (2020) and Kendall et al. (2021).

The last four decades has seen intermittent heightened interest in childhood leukaemia and nuclear installations, initially a putative link with radioactive discharges and then with occupational exposure of fathers prior to the conception of their children. This interest was prompted by reports of ‘clusters’ of cases near some installations. At times, these reports seemed to challenge the conventional scientific basis of radiological protection, but these ‘clusters’ now appear to be part of a more general pattern of childhood leukaemia incidence and a role for radiation exposure has effectively been abandoned (COMARE, 2016).

## 5. OCCUPATIONAL EXPOSURES

### 5.1. Introductory remarks

Those exposed to radiation in the course of their employment provide valuable groups for study for a number of reasons. Indeed, radiologists provided the first tentative evidence that sufficiently high exposure to radiation could cause leukaemia (Henshaw et al., 1944; March, 1944; Ulrich, 1946). A fundamental issue with studies of workers is that they are selected for employment on the basis of their ability to work and, as a consequence, tend to be healthier than the general population, leading to a selection bias known as the ‘healthy worker effect’. Further, those workers employed for longer durations tend to be healthier than those employed for shorter periods, leading to a further selection bias known as the ‘healthy worker survivor effect’. Consequently, age-sex standardised mortality rates using reference rates for the general population are unlikely to give a true picture of any adverse effect due to employment. Therefore, most emphasis in occupational studies is on disease incidence or mortality rates by degree of exposure to potentially harmful agents, and cumulative radiation dose received occupationally is often used when available. Nonetheless, selection effects for workers need to be borne in mind; for example, cumulative dose is most likely to be positively correlated with duration of employment and this should be taken into account in analyses.

An advantage of occupational studies of radiation exposure is that personnel records for workers are usually good so that linkage to mortality or incidence registries is less prone to ambiguous matching. Also, dose information is likely to be available from personal dosimeters worn to detect and measure radiation from external sources, and urinalysis or other bioassay data may also be available to measure intakes of radionuclides. However, occupational dose records are kept for the purposes of radiological protection and cannot be used directly in epidemiological studies without due consideration being given as to whether adjustments to dose records may be necessary to obtain the most accurate (organ/tissue) dose estimates ideally required for such studies [see, for example, the discussion of Fix et al. (1997)].

## 5.2. Exposure to radon

Studies of underground hard-rock miners (such as uranium, tin and iron miners) have provided definitive evidence for the inhalation of radon-222 and its radioactive decay products causing lung cancer (NRC, 1999; ICRP, 2010). Analyses using pooled data from studies of various groups of miners have produced estimates of the risk of lung cancer per unit exposure to radon decay products that are the basis of radiological protection against radon in occupational and residential settings. Of note is that radiological protection against radon exposure does not depend directly on the results of studies of the Japanese atomic bomb survivors. However, studies of hard-rock miners are complicated because account must be taken of tobacco smoking (and most miners were smokers) and smoking records are often unavailable. Further, exposure levels in the earlier years of mining were high (frequently very high) but records of radon concentrations from this period may not be good, and the doses to the sensitive cells of the lung from alpha-particle-emitting  $^{218}\text{Po}$  and  $^{214}\text{Po}$  in the  $^{222}\text{Rn}$  decay chain are not straightforward to derive. This last issue has led to risk usually being expressed in terms of working level months (WLM), where WLM is a measure of the cumulative exposure to alpha-particle-emitting  $^{222}\text{Rn}$  progeny (1 WLM =  $3.54 \text{ mJ m}^{-3} \text{ h}$  cumulative potential alpha-particle energy concentration =  $638 \text{ kBq m}^{-3} \text{ h}$ ).

In a pooled analysis of data from 11 cohorts of underground miners, Lubin et al. (1995) derived an estimate for lung cancer mortality of  $\text{ERR/WLM} = 0.0049$  (95% CI: 0.002, 0.10) from a linear fit to the data with a 5-year exposure lag. Cumulative exposures ranged up to 2500 WLM and beyond, which is a large dose to the lung and the exposure-response could be influenced by cell-killing effects. Further, there is evidence of an inverse exposure-rate effect, such that a higher exposure-rate leads to a lower risk per unit exposure, although this could be related to the impact of high lung doses. To address the difficulties surrounding earlier, high exposure studies, Richardson et al. (2022) conducted the Pooled Uranium Miner Analysis (PUMA) consisting of a pooled analysis of data from 7 cohorts of uranium miners employed from 1960 onwards. Nearly 58,000 miners were included in PUMA, with just over 1200 lung cancer deaths included in the analysis. The overall  $\text{ERR/WLM} = 0.013$  (95% CI: 0.009, 0.019) using an exposure lag of 5 years; the risk estimate is notably higher than the estimate obtained by Lubin et al. (1995). The radon-related risk of lung cancer was modified by age-at-exposure, attained age and annual exposure rate – for those miners who were exposed at  $\geq 35$  years of age at annual exposure rates  $< 0.5$  working levels, at attained ages  $< 55$  years the  $\text{ERR/WLM} = 0.084$  (95% CI: 0.033, 0.19). PUMA could not make a quantitative assessment of the effect of smoking on the radon-related lung cancer risk.

What is eventually needed is an excess risk estimate in terms of the absorbed dose to the irradiated cells that are the target for lung cancer so that, inter alia, a comparison may be made with the lung cancer risk estimate from the atomic bomb survivors, but such estimations of absorbed doses are far from straightforward to calculate (Marsh et al., 2021; Harrison, 2021). Of interest is that an earlier analysis of PUMA data in terms of standardised mortality ratios (Richardson et al., 2021), showed a clear excess risk of lung cancer and some indication of lesser raised risks of cancers of the liver and gallbladder, larynx and stomach, so provided little suggestion that inhalation of radon and its progeny has a discernible effect on the risks of cancer at sites beyond the respiratory tract.

## 5.3. Nuclear industry workers

### 5.3.1. Introductory remarks

Studies of workers in the nuclear industry have been undertaken over the past 45 years and provide a good opportunity to study people exposed to a series of low external doses received



at a low dose-rate. Those employed in the early years of the nuclear industry are particularly important because many workers received annual doses that were higher than would be considered tolerable today and accumulated working lifetime doses that provide much of the power of nuclear worker studies. However, even though workers may have accumulated occupational doses in excess of 100 or 500 mGy, or even in excess of 1 Gy, it needs to be borne in mind that such doses consist of many small doses received at a low dose-rate. Large collaborative studies are generally required to provide the power necessary to detect the excess risks of cancer predicted by standard risk models, and a number of international collaborations have been undertaken, the most recent of which is the International Nuclear Workers Study (INWORKS) (Leuraud et al., 2015; Richardson et al., 2015).

### 5.3.2. International Nuclear Workers Study (INWORKS)

INWORKS consists of ~308,300 workers from France, the UK and five sites in the USA. Largely because INWORKS includes workers from early nuclear sites, the study includes some 20,000 workers (6%) with cumulative  $H_p(10)$  photon doses >100 mSv, and more than 1000 workers who accumulated doses >500 mSv, which provides the study with reasonable power to detect the predicted excesses of leukaemia and solid cancer (Hamra et al., 2016). The principal analyses have been of 531 deaths from leukaemia excluding CLL (Leuraud et al., 2015) and 19,064 deaths from all cancers excluding leukaemia (Richardson et al., 2015), in terms of, respectively, 2-year-lagged photon doses to the ABM and 10-year-lagged photon doses to the colon. Doses from other radiation types, such as neutrons from external sources and alpha-particles from internally deposited radionuclides, are not included in the analyses although some adjustments are made for monitoring for such exposures. How ABM and colon doses were obtained for individual workers from dose records maintained for radiological protection purposes has been described by Thierry-Chef et al. (2015).

The main findings from INWORKS, for leukaemia excluding CLL and all cancers excluding leukaemia, are illustrated in Fig. 4. Also shown in Fig. 4 are the dose-responses obtained from adult male atomic bomb survivors included in the LSS, for leukaemia and all solid cancers (Cardis et al., 2007).

Statistically significant dose-responses were found for mortality from leukaemia excluding CLL,  $ERR\ Gy^{-1} = 2.96$  (95% CI: 0.83, 5.64) [largely due to chronic myeloid leukaemia (CML),  $ERR\ Gy^{-1} = 10.45$  (95% CI: 3.34, 21.41)] and for all cancers excluding leukaemia,  $ERR\ Gy^{-1} = 0.48$  (95% CI: 0.15, 0.85). No significant departures from linearity were found. Dose-responses from analyses of appropriate data from the LSS are statistically compatible with the findings of INWORKS (Fig. 4). Even for a worker study as large as INWORKS, the numbers of deaths from specific types of solid cancer are presently insufficient to provide reliable evidence for an effect of radiation exposure, although lung cancer is a possible exception (Richardson et al., 2018).

It is something of a disappointment that workers from only five sites in the USA could be included in INWORKS, given the length of time that multi-site nuclear worker studies have been underway in the USA (Gilbert et al., 1989), and that workforces from other countries, notably Canada (Zablotska et al., 2014; Wakeford 2014), could not be included. In the USA, the Million Person Study (MPS) of radiation workers and nuclear weapons test veterans will markedly improve the coverage of US radiation workers (Boice et al., 2022a), which will enhance the power of US worker studies and international collaborative projects. At the end of 2022, results from eight separate cohorts that form components of the MPS have been published (Boice et al., 2022a,b), and at the moment, a radiation-associated excess risk of leukaemia is indicated. More cohorts are being analysed, and the pooled MPS data should provide a valuable insight into risks from protracted exposure to low doses.

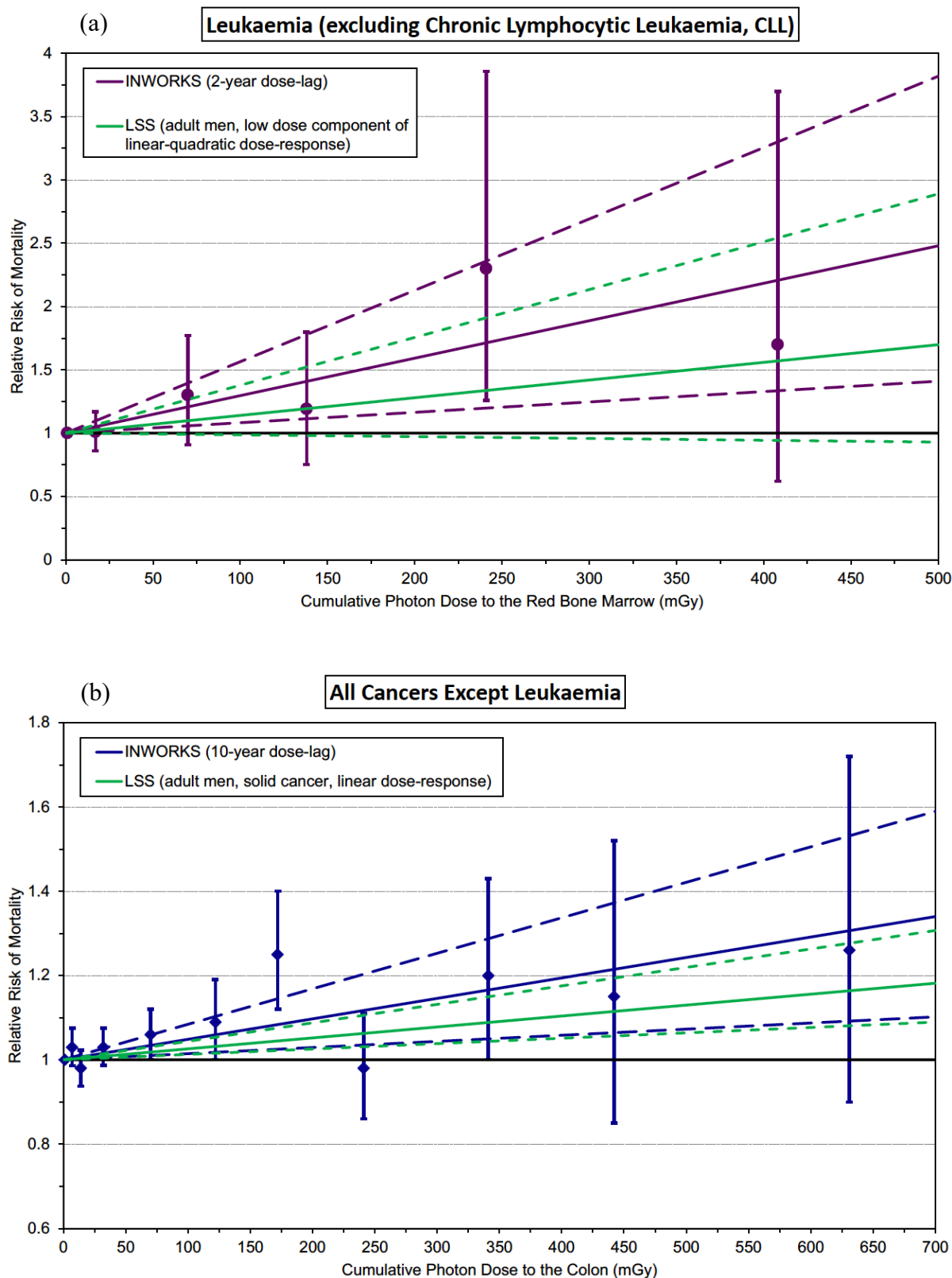


Fig. 4. Linear dose-responses ( $\text{ERR Gy}^{-1}$ ) obtained from INWORKS and adult males in the Life Span Study (LSS) of Japanese atomic bomb survivors for (a) mortality from leukaemia excluding chronic lymphocytic leukaemia (Cardis et al., 2007; Leuraud et al., 2015), and (b) mortality from all cancers except leukaemia (Cardis et al., 2007; Richardson et al., 2015) where the LSS data are for all solid cancers combined. Doses for the LSS include a weighted neutron component. Error bars and bands are 95% confidence intervals.

### 5.3.3. Russian Mayak nuclear complex

The Mayak nuclear complex in the Southern Urals of the Russian Federation started nuclear operations in 1948 to produce plutonium (and other materials) for the weapons programme of the former USSR. Conditions at the site were particularly harsh before 1960, leading to high doses from external sources of radiation and high intakes of plutonium. Of ~22,400 workers first employed at Mayak during 1948–1982 and included in a recent study (Azizova et al., 2018), around 14,500 workers had received lifetime photon  $H_p(10)$  doses exceeding 100 mSv and nearly 4000 of these workers had accumulated doses greater than 1 Sv. However, it must be borne in mind that these doses consist predominantly of many small doses received at a low dose-rate.

Fig. 5(a) shows the linear dose-response for 2-year-lagged cumulative photon doses received by the ABM and the incidence of leukaemia excluding CLL obtained from the Mayak worker cohort by Kuznetsova et al., (2016), and also shows the equivalent linear dose-response obtained from the LSS by Hsu et al. (2013). Fig. 5(b) shows the linear dose-response derived from Mayak worker data using 5-year-lagged cumulative photon doses to the colon and mortality from all solid cancers combined but excluding lung, liver and bone cancers (Sokolnikov et al., 2015); lung, liver and bone cancers were excluded from the analysis because these cancers are the most likely solid cancers to have mortality rates affected by intakes of plutonium. Also presented in Fig. 5(b) is the linear dose-response for mortality from all solid cancers combined excluding lung, liver and bone cancers obtained from the LSS data by Preston et al. (2017), and the lower slope of the Mayak dose-response will be noted (an issue discussed further in Section 5.3.5).

Kuznetsova et al., (2016) reported an ERR Gy<sup>-1</sup> for the incidence of leukaemia excluding CLL with respect to cumulative photon dose to the ABM of 3.57 (95% CI: 1.16, 9.11), when appropriately adjusting for the ABM dose from plutonium. Of interest is that the increased ERR Gy<sup>-1</sup> for leukaemia was due to acute myeloid leukaemia (AML), ERR Gy<sup>-1</sup> = 13.23 (95% CI: 2.53, 56.39), in contrast to the results from INWORKS, which showed that the raised ERR Gy<sup>-1</sup> estimate for leukaemia was due to CML (see Section 5.3.2). Sokolnikov et al. (2015) found an ERR Gy<sup>-1</sup> for mortality from all solid cancers excluding lung, liver and bone cancers in terms of cumulative photon dose to the colon of 0.12 (95% CI: 0.03, 0.21) following adjustment for internal plutonium exposure and plutonium monitoring status. The only cancer site to show a significant dose-response was the oesophagus, although that for stomach was marginally significant.

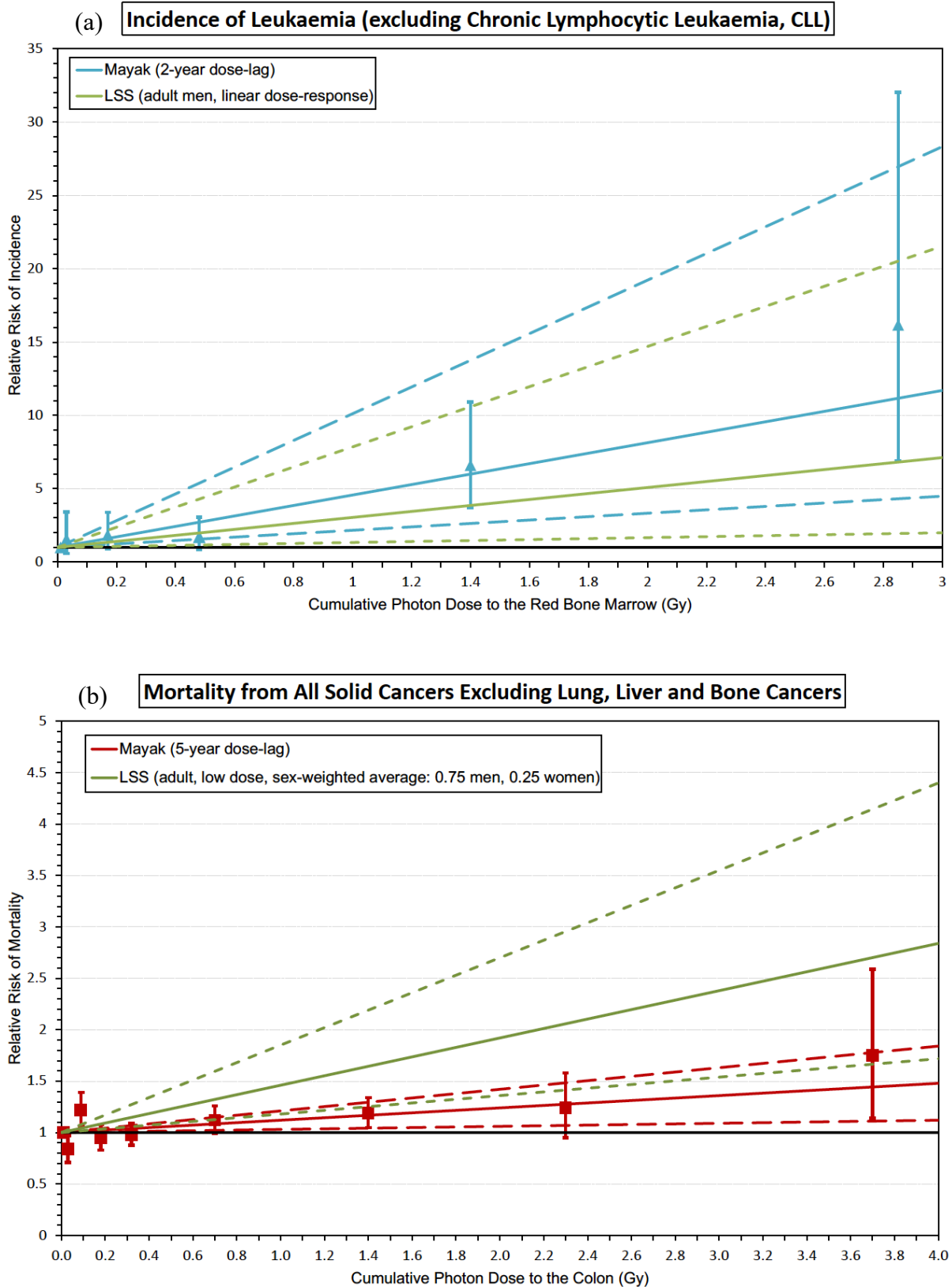


Fig. 5. Linear dose-responses (ERR Gy<sup>-1</sup>) obtained from the Mayak worker cohort and adults in the Life Span Study (LSS) of Japanese atomic bomb survivors for (a) the incidence of leukaemia excluding chronic lymphocytic leukaemia (Hsu et al. 2013; Kuznetsova et al., 2016), and (b) mortality from all solid cancers excluding lung, liver and bone cancers (Sokolnikov et al., 2015; Preston et al., 2017). Doses for the LSS include a weighted neutron component. Error bars and bands are 95% confidence intervals.

### 5.3.4. Recent nuclear worker studies

The British radiation worker data from the National Registry for Radiation Workers (NRRW), that were the UK contribution to INWORKS (Muirhead et al., 2009), have been updated in studies by Haylock et al. (2018), Gillies et al. (2019), Hunter and Haylock (2022) and Hunter et al. (2022). A positive linear dose-response for the incidence of leukaemia excluding CLL was reported,  $ERR\ Sv^{-1} = 1.38$  (95% CI: -0.22, 3.60), which was largely due to CML,  $ERR\ Sv^{-1} = 6.77$  (95% CI: 1.25, 17.10) (Gillies et al., 2019). Assuming a linear dose-response for solid cancer incidence (with a 10-year dose-lag and follow-up commencing 10 years after the start of radiation work) produced an  $ERR\ Sv^{-1} = 0.20$  (95% CI: -0.001, 0.43), but a striking feature of the latest NRRW results is that a linear-exponential model provided a significantly better fit to the dose-response for solid cancer incidence than a linear model, which was due to a flattening of the dose-response at cumulative external doses in excess of around 200 mSv (Hunter et al., 2022). This downturn in the dose-response was primarily attributable to the group of workers who had been monitored for potential intakes of radionuclides: a linear dose-response was adequate for those workers monitored only for exposure to external sources with an  $ERR\ Sv^{-1} = 0.52$  (95% CI: 0.11, 0.96), whereas a better fitting linear-exponential external-dose-response for those workers also monitored for internal exposure had a linear component that gave an  $ERR\ Sv^{-1} = 2.24$  (95% CI: 0.42, 4.83) (Hunter et al., 2022). Clearly, it is important to understand these results for a proper interpretation of the risks appropriate for low doses. This puzzling pattern of findings was previously found in a study of workers from British Nuclear Fuels Limited (BNFL, a major component of the NRRW) when a highly significant difference in the external-dose-responses for cancer mortality was found among workers monitored only for exposure to external radiation and those also monitored for internal exposure, which was especially marked for digestive cancers (Gillies and Haylock, 2014). This matter really does need to be investigated thoroughly.

Laurent et al. (2023) updated the study of mortality among French nuclear workers (Metz-Flamant et al., 2013) that was the contribution to INWORKS, with the follow-up extended to 2014. A significant association between leukaemia excluding CLL and 2-year-lagged cumulative photon dose to the ABM was reported: for males at an attained age of 65 years,  $ERR\ Gy^{-1} = 3.31$  (95% CI: 0.94, 13.38), which was largely due to AML,  $ERR\ Gy^{-1} = 5.26$  (95% CI: N/A, 24.17), in contrast to the NRRW findings (see above). A non-significant positive linear dose-response (with respect to 10-year-lagged cumulative colon dose from photons) was reported for mortality from solid cancers:  $ERR\ Gy^{-1} = 0.69$  (95% CI: -0.28, 1.77).

Beyond the nuclear workers in North America, UK, France and Mayak, there is the potential for studies of workers in other countries, and indeed, 11 other countries contributed data to the 15-country study (Cardis et al., 2005). A number of analyses of workers in the Japanese nuclear industry have been conducted, and recently Furuta et al. (2022), in a study of ~204,100 workers, reported  $ERR\ Gy^{-1}$  estimates of -0.42 (95% CI: -6.33, 9.12) for leukaemia excluding CLL and 1.22 (95% CI: 0.05, 2.46) for all cancers excluding leukaemia. Of interest is that the  $ERR\ Gy^{-1}$  for all cancers excluding leukaemia and lung cancer was 0.50 (95% CI: -0.76, 1.76) and that for lung cancer,  $ERR\ Gy^{-1} = 4.00$  (95% CI: 1.39, 6.97), indicative of potential confounding by smoking. For a subcohort of ~71,700 workers with smoking information the  $ERR\ Gy^{-1}$  for all cancers excluding leukaemia was 1.00 (95% CI: -0.85, 3.17) without a smoking adjustment and 0.25 (95% CI: -1.43, 2.24) with a smoking adjustment, while the  $ERR\ Gy^{-1}$  estimates for lung cancer were 3.09 (95% CI: -0.72, 8.15) and 1.56 (95% CI: -1.69, 5.96), respectively. Relatively small studies have been carried out in South Korea (Jeong et al. 2010) and Germany (Merzenich et al., 2014), but conspicuous by their absence are studies of nuclear workers in China, India and the Russian Federation other than Mayak. A naïve view would be that nuclear

workers in these last three countries could potentially contribute much to radiation epidemiology, although perhaps factors such as record keeping and linkage conspire to prevent such studies being undertaken.

### 5.3.5. Potential implications for the dose-rate effectiveness factor (DREF)

The comparisons of the dose-responses for solid cancers between the worker cohorts and the LSS cohort is informative as to the value of the dose-rate effectiveness factor (DREF), because the Japanese atomic bomb survivors were briefly exposed whereas nuclear workers were (in general) protractedly exposed, receiving many small doses at a low dose-rate (Rühm, et al., 2022; Lowe et al., 2022). In the current system of radiological protection (ICRP, 2007), a dose and dose-rate effectiveness factor (DDREF) of 2 is adopted for low-LET radiation exposure to reduce the estimates of the nominal risk coefficients for solid cancers obtained from the atomic bomb survivors exposed to moderate-to-high doses received at moderate-to-high dose-rates by a half when applied to exposures at either low dose-rates (a DREF of 2) or low doses (a low dose effectiveness factor, LDEF, of 2). Fig. 6 shows the linear dose-responses derived from the LSS and the INWORKS and Mayak studies for mortality from all solid cancers excluding lung cancer; for the Mayak workforce, a dose-response is only available for all solid cancers excluding lung, liver and bone cancers (Sokolnikov et al., 2015) so this dose-response is compared with the dose-responses for all solid cancers excluding lung cancer for INWORKS and the LSS (Leuraud et al., 2021).

It will be seen from Fig. 6 that there is broad statistical compatibility between the three dose-responses, so that no firm conclusions about the value of any DREF that might differ from unity can be drawn. Although both the INWORKS and Mayak dose-response slopes are compatible with that of the LSS dose-response, there is an indication of a lower slope for the Mayak workforce that is consistent with the DREF of two as currently assumed for the purposes of radiological protection (ICRP, 2007), but it is no more than an indication. This has also been observed by others (Shore et al., 2017; Hoel, 2018), and future studies with longer follow-up periods should shed further light on this issue. As noted by (Wakeford, 2021), attention must be paid to how the dose-responses have been generated because different slopes can be obtained from different approaches to the analyses, which could lead to different inferences as to the value of any DREF.

### 5.3.6. Doses from internal emitters

In addition to doses received from external sources of radiation, many nuclear workers also receive doses from radionuclides taken into the body, usually via inhalation. Radionuclides emitting short-range radiations, such as alpha particles, cannot be detected directly (unless also emitting penetrating radiations) and so indirect methods to determine doses from internal emitters have to be used, such as urinalysis. The interpretation of bioassay data in terms of tissue-specific doses is a complex process, and the only large-scale epidemiological studies to have been conducted are of inhalation of plutonium and lung cancer with respect to lung doses from deposited plutonium; lung cancer following inhalation of radon and its decay products has been studied in terms of exposure levels rather than lung doses.

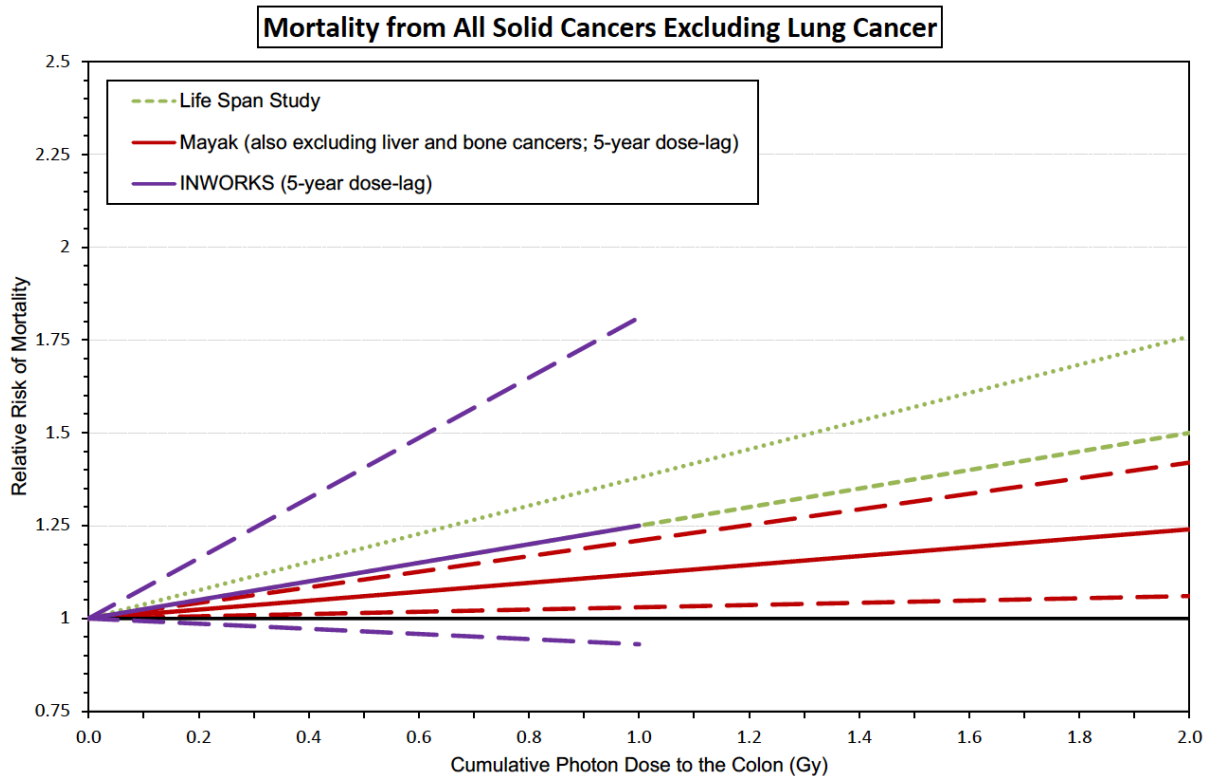


Fig. 6. Linear dose-responses ( $\text{ERR Gy}^{-1}$ ) obtained from the Mayak worker cohort, INWORKS and the Life Span Study (LSS) of Japanese atomic bomb survivors for mortality from all solid cancers excluding lung cancer (Sokolnikov et al., 2015; Leuraud et al., 2021); Mayak data also exclude liver and bone cancers (Sokolnikov et al., 2015). The INWORKS dose-response has been truncated at 1 Gy because very few workers included in the study accumulated photon doses  $>1$  Gy. Doses for the LSS include a weighted neutron component. Error bands are 95% confidence intervals.

Gillies et al. (2017) reported the results of a joint study of plutonium workers at Mayak and Sellafield, using estimates of the doses to the lung from inhaled plutonium that made use of urinalysis data and assumptions about the lung solubility of plutonium compounds. The mean lung dose from plutonium for Mayak workers was 129.0 mGy while that for Sellafield workers was 1.9 mGy (both assuming ‘fast’ solubility in the lung). For a ‘fast’ solubility assumption and a 10-year-lagged cumulative lung dose from plutonium, lung cancer incidence in the pooled data gave an  $\text{ERR Gy}^{-1} = 7.84$  (95% CI: 5.35, 11.16) assuming a linear dose-response model, from which there was no discernible deviation. Although smoking information was available for the Mayak workforce it was not for the Sellafield workforce, and so Gillies et al. (2017) could not adjust for the effects of smoking on lung cancer risk, although previous studies of Mayak plutonium workers had shown that smoking was not a confounding factor, but did act as an effect modifier, with non-smokers having higher  $\text{ERR Gy}^{-1}$  estimates than smokers (Gilbert et al., 2013).

ICRP *Publication 150* (ICRP, 2021) summarised the evidence on cancer risks from exposure to plutonium and uranium. For epidemiological evidence, the ICRP publication relied heavily on the study of Gillies et al. (2017).

Of interest is the recent study of mortality in 1746 French tritium workers during 1962–2011 based on 256 deaths (6% of workers) (Martin and Ségala, 2021). Urinalysis data were available from 1962. Significant trends with cumulative tritium doses (lagged by 10 years) were found for pancreatic and bladder cancers and non-Hodgkin lymphoma, but based on very few deaths. Given the intention to build nuclear fusion reactors, which will use large quantities

of tritium, further studies of tritium workers using tritium-specific doses, and pooled data analyses, would be desirable.

### 5.3.7. Some issues to be resolved

Sophisticated data linkage systems are required to unambiguously match large numbers of workers with entries in death registers, and sometimes with records in other databases, such as incident cancer registries. INWORKS is a study of mortality because, of the three countries included in the study, only in the UK is routine access to nationwide cancer registration data currently available. A study of mortality restricts the investigation of cancers with low lethality, such as thyroid cancer. Further, details of the disease entered on a death certificate may not be as accurate as that recorded in a cancer registry. Other limitations of pooled worker studies have been discussed by Blettner (2015) and Little (2015).

That there can be problems with data held in occupational databases is illustrated by the 15-country study, an earlier international collaborative project that investigated cancer mortality in nuclear workers (Cardis et al., 2005, 2007). It was pointed out (Wakeford, 2005, 2009) that the Canadian worker data have a surprisingly large influence on the results of the 15-country study, an issue investigated in detail by Ashmore et al., (2010). It transpired that the Canadian database contained inaccurate information that needed to be revised, and Zablotska et al. (2014) concluded that the erroneous Canadian data had had an important effect on the 15-country study results.

A detailed examination of the photon doses received by workers in INWORKS has been conducted (Thierry-Chef et al., 2015), and a similar examination of worker doses had been carried out for the 15-country study (Thierry-Chef et al., 2007). The 15-country study analysed cancer mortality risk in terms of cumulative photon dose, and workers with potential for >10% of their cumulative effective dose to be from neutrons or internal emitters (other than tritium) were excluded from the study because these doses 'have not been adequately measured' (Cardis et al., 2007). In INWORKS, cancer mortality risk was also analysed in terms of photon dose (Leuraud et al., 2015; Richardson et al., 2015), but in contrast to the 15-country study, all workers monitored for exposure to neutrons or internal emitters were included in the analysis, but were stratified by monitoring status. Some intriguing results were reported, such as the main ERR Gy<sup>-1</sup> estimate for all cancers excluding leukaemia of 0.48 (95% CI: 0.15, 0.85) that was adjusted for neutron exposure monitoring status reducing to 0.20 (95% CI: -0.07, 0.50) when no such adjustment is made.

Wakeford (2018, 2021) noted the substantial upwards adjustments made to recorded annual external doses in the early years of operations at two of the US sites included in INWORKS, Hanford and Savannah River, made for the purposes of the US worker compensation program. Undoubtedly, these upwards revisions will have been designed to be generous to claimants, possibly substantially so, but the question arises as to why it was felt to be necessary to amend doses in the early years of operations at these two sites and not in later years. What were the factors that led those reconstructing doses for the purposes of compensation to make these upwards revisions, and do these factors have implications for the doses used in epidemiological studies such as INWORKS? These are questions that need to be answered to have an appropriate understanding of dose uncertainties in the early years of operations at certain nuclear installations, and their potential effect on cancer risk estimates.

In the early years of operations at Mayak intakes of plutonium were high with little respiratory protection available for workers, but systematic collection of samples for urinalysis did not begin until the 1970s and less than half of Mayak workers potentially exposed to noteworthy levels of plutonium were monitored. In order to address this issue, six surrogate indices of plutonium exposure were constructed based on job and calendar period of



employment (Gillies et al., 2017). Further, when Stram et al. (2021) took account of uncertainties in plutonium doses they found that interval estimates for lung cancer mortality risks in terms of plutonium doses increased markedly, emphasising the need to address uncertainties in doses when conducting epidemiological studies. Similar, but less severe, difficulties with plutonium dosimetry existed at Sellafield in the early years of operations, so that several hundred Sellafield plutonium workers have had to be omitted from epidemiological analyses of plutonium exposures. These difficulties led to plutonium doses for these workers being estimated through a job-exposure matrix (de Vocht et al., 2019; Riddell et al., 2019) with the intention of including these workers in future epidemiological studies.

#### 5.4. Other radiation workers

There are other groups of radiation workers that have been the subject of epidemiological study, and notable among these are the >500,000 Chernobyl emergency and recovery workers ('liquidators') involved in response and clean-up operations during 1986–1990, and in particular the ~240,000 liquidators who worked in 1986–1987 when doses would have been highest (UNSCEAR, 2011). Studies of Ukrainian (Bazyka et al., 2018; Gudzenko et al., 2022), Russian (Ivanov et al., 2020) and Lithuanian (Smalyte et al., 2021) liquidators have been updated and summarised in the past few years, with excesses of a number of cancers being reported. Interpretation of these studies is not straightforward because of the difficulties of reliably linking large numbers of liquidators with mortality or cancer incidence databases, and the possibility of surveillance bias given the interest in the liquidators, especially those thought to have received the highest exposures. Dose uncertainties also pose problems for these studies, see for example (Drozdovitch et al., 2022).

Aircrew receive raised levels of exposure to cosmic radiation because of reduced shielding by the atmosphere, and of interest is the high-LET component of this exposure, in particular, neutron exposure (Scheibler et al., 2022). Studies of aircrew continue (Dreger et al., 2020) and although annual doses received by aircrew are low, at a few millisievert, large collaborative studies (Hammer et al., 2014) that continue into the future could include reasonable numbers of long-serving crew on intercontinental flights who have accumulated working lifetime doses >100 mSv. Accurate estimates of doses will be important (Wollschläger et al., 2018), especially the doses received from high-LET radiations.

Medical radiation workers have been studied since the mid-twentieth century because of the numbers exposed and the doses received in the first decades of the use of radiation in medicine (Linet et al., 2010). Recent studies of radiographers in the USA have found some evidence for an increase in the risk of female breast cancer (Preston et al., 2016) and possibly lung cancer (Velazquez-Kronen et al., 2020), but little evidence of excess risks of brain/CNS cancer (Kitahara et al., 2017), thyroid cancer (Kitahara et al., 2018) or leukaemia (Linet et al., 2020). Doses were highest in earlier years, but individual dose measurements were not available before 1960 and dose reconstruction is required, which is a limitation of these studies (Linet et al., 2020).

## 6. CONCLUSIONS

This review of progress in epidemiological investigations of the risk of cancer consequent to exposure to ionising radiation has demonstrated that there is still much work underway to improve understanding of the carcinogenic effects of exposure. We continue to learn from the experience of the Japanese atomic bomb survivors, more than six decades after the bombings, and nearly 40% of the survivors were still alive at the end of the last follow-up in 2009, so substantial data remain to be included in future studies. How the risk of cancer develops in

subsequent follow-up periods among survivors many years after they were exposed at a young age will be an important aspect of these studies.

Studies of large cohorts of patients who have been examined with CT as children or adolescents offer the potential of directly investigating the effects of low doses or a series of low doses. However, studies of medical exposures present various difficulties that must be addressed before a confident interpretation of findings can be made. Similarly, diverse weaknesses are inherent in studies of groups exposed to environmental sources and these need to be overcome, whenever possible, to produce sound results.

Occupational exposures offer a valuable opportunity to investigate protracted exposure to low dose-rates using, in general, reasonable quality personnel and dosimetry records, although records of exposure to radon and its decay products in underground mines are sometimes less than ideal. Even in the nuclear industry, records of doses received during the earlier years of operations, by those workers who tend to accumulate the highest working lifetime doses, have to be treated with caution, and this is especially so for doses from intakes of radionuclides.

A variety of epidemiological studies have generated a broad range of findings on cancer risks following radiation exposure. However, traps for the unwary lurk everywhere, and considerable care (and possibly also good fortune) is required to avoid misleading results – that is the nature of observational epidemiology. Nonetheless, a reasonable conclusion based on currently available findings from radiation epidemiology, complemented by an incomplete knowledge of radiobiological mechanisms (UNSCEAR, 2021), is that, overall, there is substantial evidence of an elevated risk of most forms of cancer following the receipt of moderate and high doses delivered briefly, and some evidence of some excess risk for some cancers consequent to low-level exposure. Epidemiological studies based on larger datasets will allow firmer conclusions to be drawn on the nature of cancer risks following low-level exposures. In terms of radiological protection against low doses or doses received at a low dose-rate, a prudent inference based on a careful evaluation of the present evidence is that even low-level exposures produce some small subsequent excess risk of cancer (NCRP, 2018; Shore et al., 2018). It is difficult to envisage how this conclusion cannot continue to be incorporated in the framework of radiological protection.

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# International horizon-style exercise (HSE): advancing the use of adverse outcome pathway (AOP) in radiation protection

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**Abstract**—The Adverse Outcome Pathway (AOP) framework provides a means to integrate radiobiological and epidemiological data across different levels of biological organisation for an adverse outcome of interest to regulatory decision-making. The AOP approach is envisioned to improve understanding of radiation-induced effects at low doses and dose-rates and decrease the uncertainty in radiation health risk assessment. To explore the challenges in the use of AOPs, an international horizon-style exercise (HSE) was initiated through the Nuclear Energy Agency (NEA) High-Level Group on Low Dose Research (HLG-LDR) Radiation/Chemical (Rad/Chem) AOP joint topical group. The HSE was completed in three phases. First, candidate research questions were solicited from radiation risk professionals via a dedicated website. Second, the over 250 questions submitted were refined by a dedicated steering committee using a best-worst scaling method. During a virtual 3-day workshop, the list of questions was further refined to the top 25 priority questions. Lastly, an internet-based survey of the broader radiation risk community led to an orderly ranking of the 25 priority questions, again using a best-worst scaling method. Major themes from the survey included the ability of AOPs to address different levels of biological organisation, radiation quality, dose or dose rate, time patterns, and confounding variables. Broadly, these efforts will help advance the use of AOP in radiation research and regulation.

**Keywords:** Adverse outcome pathway; Regulatory application; survey; Low dose radiation; Risk assessment

## 1. INTRODUCTION

As demonstrated in the chemical toxicology field (Ankley et al, 2010), the Adverse Outcome Pathway (AOP) framework provides a means to integrate radiobiological and epidemiological data across different levels of biological organisation for an adverse outcome of interest to regulatory decision-making – an aspect also of interest to the RP community. The AOP approach is

envisioned to improve understanding of radiation-induced effects at low doses and dose-rates and decrease the uncertainty in radiation health risk assessment. To assess the current understanding of the AOP framework in the field of radiation sciences a horizon-style exercise (HSE) was undertaken (Burt et al, 2022).

### **1.1. Adverse Outcome Pathway (AOPs)**

An AOP approach is a conceptual framework with predictive utility that draws from publicly available scientific and epidemiological knowledge. It organises biological data into key events (KE) beginning with a molecular initiating event (MIE) leading to an adverse outcome (AO). The weight of evidence of AOPs is demonstrated through support of a modified Bradford hill criteria (Becker et al, 2015). Although AOPs were conceptualised to support chemical toxicology, the approach is now being considered in the radiation field to consolidate data and identify priorities for future research initiatives (Chauhan et al, 2020a,b,c, 2022a,b).

### **1.2. International Collaboration**

To explore the challenges in the uptake of AOPs within radiation protection and radiation research, the HSE was initiated through the Radiation/Chemical (Rad/Chem) AOP joint topical group under coordination of the Nuclear Energy Agency (NEA) High-Level Group on Low Dose Research (HLG-LDR). The work was guided by a steering committee (SC) with broad experience in radiation biology, epidemiology, and chemical toxicology research with international representation. Engaging the international community provided perspectives across various sectors of research and was instrumental in finalising the list of questions.

### **1.3. Methodology**

A horizon scan is a method of systematically searching for, and identifying emerging trends, opportunities, and limitations that might impact the future directions of a defined subject. This approach has been used in the chemical toxicology field (LaLone et al, 2017) and other fields (Rudd et al, 2014a,b), and its success was leveraged for this project. The HSE was completed in three phases. First, candidate research questions were solicited from radiation risk professionals via a dedicated website. Questions were compiled on the use of AOPs in radiation research including participants knowledge, interest, and even hesitation of using the AOP framework. The call for questions was circulated within the radiation community via social media posts, email distribution, and connections through steering committee networks. Second, the over 250 questions submitted by 99 individuals and 13 organisations globally were refined by the SC using a best-worst scaling methodology. During a virtual 3-day workshop, the list of questions was further refined to the top 25 priority questions by consensus. Lastly, an internet-based survey of the broader radiation risk community lead to an orderly ranking of the 25 priority questions, again using a best-worst scaling methodology (Burt et al, 2022). Approximately 100 individuals responded to the international survey.

### **1.4. Project Objective**

The overall objective of this HSE was to short-list a set of priority research questions that could, if answered, improve the description of the radiation dose-response relationship for low dose and

low dose-rate exposures as well as reduce uncertainties in estimating the risk of developing adverse health outcomes following such exposure.

## 2. RESULTS OF THE HORIZON STYLE-EXERCISE

Each phase of the project provided an opportunity to narrow and rank important research questions finally arriving at a list of 25 priority questions. Statistical analysis revealed that no one question was significantly ranked higher than another, indicating that all 25 of the priority questions are important and would benefit from collaborative research efforts and discussion. This is supported by the information captured in the survey, where respondents included comments to explain their rationale for each of the rankings they conducted.

### 2.1. Top 25 priority questions

The output of phase I of the project included over 250 questions, after selection criteria was applied. Criteria for inclusion of a question was that it would address important knowledge gaps, have a factual answer (not depending on value judgements), cover a spatial and temporal scale that can realistically be addressed by expert groups, and cannot be answered with yes, no, or it depends. The output of phase II of the project was an unranked list of 25 priority questions, developed by the steering committee during a 3-day virtual workshop. To facilitate discussion and optimise efficiency, the questions were grouped into the following categories: 1) mechanism of radiation injury, 2) AOP components, 3) radiation versus chemicals, 4) AOP challenges, 5) tools and approaches for integration, 6) data or weight of evidence, and 7) regulatory significance. The output of phase III of the project was a rank-ordered list of the top 25 questions (see Table 1).

Table 1. Top 25 priority questions decided by consensus following a 3-day virtual workshop.

Number	Question
1	How can all relevant data from different levels of biological organisation (e.g., molecular, cellular, tissue, individual, population) be optimally integrated in AOPs?
2	How can the complexity of biological damage correlated to time-effects, dose ranges and dose-rates of exposure be effectively captured in an AOP?
3	How can the AOP framework accurately reflect the effects of radiation with different exposure time patterns (e.g., acute, fractionated, and chronic radiation exposures) and deliveries (e.g., internal, external, partial, or whole body)?
4	How can AOPs be integrated with other approaches and/or techniques (e.g., modeling biologically based pathways, benchmark dose modeling) to support the formulation of dose-response models that alleviate uncertainty in quantitative risk estimates?
5	Which adverse outcomes (AOs) should be prioritised in the radiation field for reducing uncertainties related to low dose and low dose-rate effects?
6	How can the AOP approach be used to understand key factors of radiosensitivity to support individual (human) and species (biota) radiation risk assessments?
7	What are the relevant molecular initiating event(s) (MIEs) that need to be considered for radiation AOPs and why?
8	How can AOPs add value to the current radiation risk assessment methods?

*(continued on next page)*

Table 1. (continued)

Number	Question
9	For complex systemic biological processes (e.g., immune, endocrine responses, metabolic memory), what are the essential key events (KEs)?
10	How can the AOP framework accommodate confounding variables/modulators (e.g., dietary status, smoking, life stage/age, sex, and individual genetic and epigenetic variation) of adverse outcomes (AOs)?
11	How can the AOP framework be applied to delineate or decipher causation to an adverse outcome (AO) from exposure to multiple stressors?
12	How can the AOP framework accommodate different radiation-induced phenomena (e.g., bystander effects, genomic instability, adaptive responses)?
13	How can AOP networks accurately represent the interconnectivity in macromolecular and multi-organ responses leading to adverse outcome(s) (AO)?
14	How can the AOP framework accurately reflect the effects of radiation of different qualities (e.g., alpha, beta, gamma, neutron)?
15	What criteria and/or approaches should be used to identify the most relevant studies to support weight of evidence considerations in AOP development?
16	How can the AOP framework support strategies in prevention/mitigation of human health outcomes and/or field monitoring (e.g., biodosimetry) for accidental or intentional exposures where there are uncertainties about exposure dose, dose-rate, and radiation quality?
17	How can AOPs be used to decipher or discern the toxicity of a stressor that has both chemical and radiological properties (e.g., for radioactive elements such as uranium, diagnostic and therapeutic radiopharmaceuticals)?
18	Which approaches are suitable for quantitative AOP development and how can these be pragmatically used?
19	How could AOPs help identify research gaps compared to already existing methods (e.g., systematic reviews, expert panels, international reports)?
20	How can the latency between radiation exposure and adverse outcome (AO) development be delineated when constructing an AOP?
21	What proof of concept examples and/or endorsement processes can enhance interest and willingness of funding agencies to adopt AOPs as an asset to a research proposal?
22	How can the scientific and regulatory communities, including scientific journals, support capturing relevant data to be used for AOP development and reporting AOPs in a feasible format for dissemination and implementation into research and the regulatory framework?
23	How can AOPs support enhancing the understanding of possible multigenerational and transgenerational radiation effects?
24	How can AOPs support engagement and communication dialogs with stakeholders (including members of the public) for informed and sustainable decision-making?
25	What processes (e.g., self-organisation, workshops, training) and tools (e.g., AOP handbook, templates, common review tools) need to be considered for collaborative development of AOPs?

### 3. DISCUSSION

The international survey permitted respondents to provide additional comments explaining their rationale for the ranking, note any anticipated constraints, and add any open-ended comments or replacement questions. This information was valuable for understanding the various perspectives

and misperceptions on the scope of AOPs. The following describes select comments provided by the survey respondents. Many stated that the value of AOPs must be apparent, and that the framework must be actionable, and improve upon current predictive models. Several participants identified that MIEs other than radiation should be considered. Emphasis was placed on the importance of being able to demonstrate how a molecular event can lead to a population effect. A few individuals felt strongly about the term “Adverse Outcome” stating that a full understanding of the biology could not be obtained if positive outcomes were not considered in the AOP framework. Several people were hopeful that the framework could be used as a tool for public engagement. Three key constraints were repeatedly raised by survey respondents, touching on resources (i.e., availability of experts and funding), multi-disciplinary collaborative teams, and limitations of the AOP framework itself (e.g., discussion on radiation stressors, agreement on nomenclature). Many of the priority questions have already supported discussions for several case studies (Azimzadeh et al, 2022; Jaylet et al, 2022; Klokov et al, 2022; Tollefsen et al, 2022) dedicated scientific meetings and will be a source for future considerations of how AOPs may support radiation research and regulatory decision-making.

#### **4. IMPLICATIONS FOR RADIATION PROTECTION**

The HSE has met its objectives listed in section 1.4. Moving forward, the HLG-LDR will solicit advice from the broader radiation protection community on which research questions to prioritise and address first. In fact, the major themes from the survey, such as the ability of AOPs to address different levels of biological organisation, radiation quality, dose or dose rate, time patterns, and confounding variables are all important and common areas of uncertainty affecting the system of radiological protection for low dose (rate) health risk management. Further, many of the aspects within the top questions are listed as priorities for the International Commission on Radiological Protection (ICRP). Specific ICRP task groups (TGs) have either recently been formed, or may be formed in coming years, to address important radiation-related epidemiological outcomes like cardiovascular diseases, non-cancer effects beyond cardiovascular (immune response), protection of non-human biota, and individualisation of dose, risk, and projection (or stratification). Given the growing interest and use of AOPs, the upcoming efforts to prepare for the new ICRP recommendations, and the need for lower uncertainty in risk estimates at low doses and dose-rates, a call for collaboration is timely. The AOP framework is quickly becoming a tool that can address important knowledge gaps and provide a significant improvement of understanding of biological effects of radiation exposure, or reduction of uncertainties in risk estimates, with positive impact on the system of radiation protection and its communication to (and with) stakeholders.

#### **5. CONCLUSION**

This horizon-style exercise has allowed the collection of data to identify priority areas for radiation protection related AOP development. This work will facilitate the evolution of the OECD AOP programme from one that is focused on chemical toxicology to one that also supports adverse outcomes related to radiation exposures. Four case studies are under development will also support this evolution. Lastly, this work has encouraged participation of individuals to become AOP reviewers and identify projects in emerging areas where the AOP framework could support radiation risk assessment and ultimately radiation protection.

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## An introduction to ecosystem services for radiological protection

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**Abstract**—It is important that the system of radiological protection provides for an appropriate level of human and environmental protection without unduly limiting desirable human actions, adversely affecting sustainable development, or resulting in unintended consequences. As such, there has been increasing interest in incorporating monitoring and assessment of ecosystem services in many contexts related to environmental protection and policy making. Ecosystem services are the benefits humankind derives from the workings of the natural world, i.e., from ecosystems, and are crucial to human well-being by, for example, providing nutritious food and clean water; regulating air quality; supporting crop pollination and soil formation; and offering recreational, cultural, and spiritual benefits. The mandate of the recently formed Task Group 125 is to explore and share knowledge on ecosystem services by providing background and recommendations on if and how ecosystem services can support a more holistic approach to environmental radiological protection (ERP) and, as specifically relevant to ERP, explore how the system of radiological protection contributes to the delivery of sustainable development. This paper provides an overview of ecosystem services and an introduction to the ongoing work of Task Group 125.

**Keywords:** Ecosystem services; Sustainable development; Environmental radiological protection

### 1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) recently initiated the long-term process of revising the 2007 Recommendations for the System of Radiological Protection (the System) (ICRP, 2007). Several new task groups, including Task Group (TG) 125 on Ecosystem Services (ES) in Environmental Radiological Protection (ERP), have been formed in support of this objective. Additionally, the needs and challenges related to a new set of recommendations was a central theme of the 2022 symposium on the System from which these proceedings were developed. In this context, this paper provides a brief overview of ES along with the intended scope of work of TG 125.

In the current recommendations, the primary aim of the System 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, 2007). For radiological protection of the environment specifically, protection objectives include *preventing or reducing the frequency of deleterious radiation effects to a level where they would have a negligible impact on the maintenance of biological diversity, the conservation of species, or the health and status of natural habitats,*



*communities, and ecosystems*, recognising that radiation exposure is one factor to consider among many in environmental protection (ICRP, 2007).

A significant body of ERP work within the ICRP has been completed since the last set of recommendations (e.g., ICRP, 2008, 2009, 2014, 2017, 2020, 2021) that will help support a robust ERP approach in revised recommendations. Of note is that the historical approach to ERP has largely been rooted in conservation of species *with focus on organisms in the natural environment*, with an acknowledgement by Commission leadership that this *may not be sufficient when considering ecosystems that are created and managed by people for the purposes of delivering goods, services, and cultural value for human populations* (Clement et al., 2021). Moreover, there has generally been increasing interest in incorporating ES monitoring and assessment in many contexts related to environmental protection and policy making (Daily and Matson, 2008; Daily et al., 2009; Fisher et al., 2009; Costanza et al., 2017). Given this, TG 125 was formed with the mandate to explore and share knowledge on ES by providing background and recommendations on if and how ES could be used within a more holistic approach to ERP with consideration given to how the System contributes to sustainable development (e.g., UN, 2015; Mayall, this issue). *Publication 91* (ICRP, 2003) highlights sustainable development as an important principle in ERP, defining it as relating to *the need to recognise the interdependence of economic development, environmental protection, and social equity, and thus the obligation also to protect and provide for both the human and environmental needs of present and future generations*. Moreover, sustainable development has strong ties to System's core ethical values of prudence and justice (ICRP, 2018, 2022). Thus, sustainable development is not a new consideration within the System. However, related practical guidance and more robust discussion is warranted.

## 2. WHAT ARE ECOSYSTEM SERVICES?

Ecosystems provide numerous services that combined are critical to human well-being and are worthy of protection (MA, 2005; TEEB, 2010; IPBES, 2019). Although there are a variety of definitions and descriptions, simply put, ES are the benefits humankind derives from the workings of the natural world. The phrase 'ecosystem services' was popularised by the Millennium Ecosystem Assessment (MA), published in 2005, although the underlying science has been around since at least the late 1980s (MA, 2005; Costanza et al., 2017). ES can be loosely divided into four major categories that are highly interlinked: provisioning services, regulating services, cultural services, and supporting services (Fig. 1).

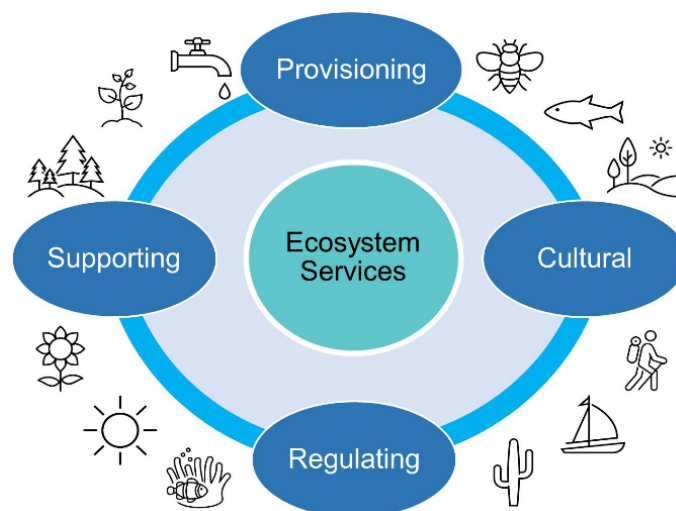


Fig. 1. Four categories of ecosystem services.

Provisioning services refer to the furnishing of direct, tangible ecosystem products. This would include food (e.g. fruits, vegetables, meat, eggs), drinking water, raw materials (e.g. timber, natural fibres, fuel sources), and biologically derived medicines and pharmaceuticals. Although beneficial to humans in the short term, excessive demand for provisioning services beyond the sustainable capacity of the ecosystem can result in degradation of ecosystem integrity and ultimately reduction in the services relied upon (Palacios-Agundez et al., 2015). Moreover, modification of one ecosystem service is also likely to impact other ecosystem services and trade-offs between ecosystem services (e.g., an increase in food production that is detrimental to water quality) should ideally be considered in associated decision-making.

Regulating services are the processes that moderate natural phenomena. This would include regulation of local climate, air quality, water flow, soil erosion and quality, pests, and disease. Pollination, water purification, carbon sequestration, and moderation of natural disasters are also regulating services. The degradation of regulating ecosystem services is of concern due to the expected cascading impacts on the other categories (Carpenter et al., 2009). Regulating services have proven difficult to quantify and remain largely unnoticed in the daily activities of the individuals they benefit, even though they consist of the majority of the total value in most ES economic valuations (TEEB, 2010).

Cultural services are those that contribute to the identity and cultural well-being of people, including the aesthetic beauty of the environment, outdoor recreational opportunities, and religious or spiritual benefits. These benefits are often non-material and include improved mental health, physical health, learning, inspiration, sense of control, identity, and more (Huynh et al., 2022). Cultural ES contribute to individual, indigenous, scientific, and societal knowledge of the environment and the individual's sense of connection to the natural world (Barbier et al., 2009; TEEB, 2010; Fish et al., 2016). Cultural ES are often augmented with human infrastructure to provide improved access and increased derived benefits (e.g. a trail and dock providing access to a lake) (Costanza et al., 2017).

Supporting services are those that enable and sustain the other ES. Supporting services include the natural, foundational processes of the planet (e.g. water, nutrient, carbon, and rock cycles; photosynthesis and primary production) as well as the structural and functional backbone of ecosystems (e.g. habitats) (MA, 2005; TEEB, 2010). Note that some services can be categorised as multiple types of services, and in some cases supporting services are classified under regulating services in a three-category organisational scheme (Carpenter et al., 2009). Supporting services typically impact people indirectly or over comparatively longer time periods, compared to other categories of services that may have more obvious or immediate impact.

This suite of ES can be impacted by radiological contamination of the environment as well as decisions made with respect to such contamination. Accidents or other events resulting in contamination of the environment have the obvious potential of impacting provisioning services through contamination of food and water. Environmental contamination can also influence provisioning services through interruption or prevention of the ability to processes, manufacture, and distribute environmentally derived products (Smith and Beresford 2005). Similarly, cultural services can be impacted by environmental contamination through, for example, loss of access to activities like swimming, hiking, foraging, or gardening (Mabon, 2019; Matsuura, 2021).

Responses to radiological contamination of the environment can also impact ES, and ideally, related decisions will consider potential cascading impacts associated with implemented interventions. Evacuation following a nuclear accident will impact cultural services for communities with strong ties to the land, which is an important aspect to consider when working towards rehabilitation. Where remediation strategies may be necessary to protect human health from potentially harmful radiation effects, remedial action(s) can often result in

environmental degradation or indirect harm to human well-being. For example, removal of topsoil can impact both regulating services, through reduction in erosion control and soil nutrient availability, and supporting services, through alteration of habitats. Remediation considerations are also discussed in TG 98, which is concerned with sites contaminated from past activities.

These are simple, non-comprehensive examples; real scenarios have much greater complexity and variability than described here. Additionally, an open question remains for TG 125 regarding the practical incorporation of ES concepts into the existing ERP framework, e.g., if and how metrics related to ES monitoring and assessment could be related to criteria such as Derived Consideration Reference Levels (DCRLs), or how inclusion of ES might differ between exposure situations (i.e., planned, existing, or emergency).

### **3. CONSIDERATIONS**

Although ES have become a popular research focus among ecologists and economists, many have not embraced the concept (Silvertown, 2015). Schröter et al. (2014) reviews several major critiques of the ES concept. First, a focus on ES could be considered regressive from an environmental ethics perspective due to the anthropocentric framing of the definition of ES. Second, the robust body of work on the economic valuation of ES highlight the suspect feasibility and ethics of the commodification of nature. Finally, the inconsistency of various ES definitions and classification systems may potentially impede ES research or prohibit comparisons among studies. These three major criticisms and respective counter arguments are elaborated further below.

#### **1.1. Environmental ethics**

Given that radiation can have deleterious effects on non-human species, the Commission recommends that an ethically-based radiological protection framework be applied to the environment (ICRP, 2003, 2018). This recommendation is motivated by substantial science showing that humanity is intertwined and dependent on nature whose resources are finite. Thus, there has been emphasis on moral and scientific grounds that justify policies to protect the environment. Since the 1960s, there has been a significant evolution of thought on environmental ethics toward realising the value of nature goes beyond just the resources it supplies to humans (anthropocentric view), but that nature contains an equal intrinsic value and is by itself worthy of protection (biocentric and ecocentric views).

Critics often label the ES concept as anthropocentric, a regressive perspective compared to the growing interest in protecting nature for nature's own sake and recognition of the overall intrinsic value of nature recently promoted in environmental protection (Gagnon Thompson and Baron, 1994; Schröter et al., 2014). For example, the integrity of nature may not be respected if the outcome of ecosystem services is specifically intended to be the promotion of human well-being (Islam et al., 2019); the impacts of environmental pollution (including radioactive materials) should be considered holistically and evaluated in terms of their effects not only on humans but equally on other components within impacted ecosystems.

Advocates of the ES concept reject this criticism as an over-simplification and emphasise that the intrinsic value of nature can be captured within the existing ES framework, as many of the services within the cultural services category rely upon the simple existence of nature (e.g., the aesthetic beauty of nature). Additionally, supporters argue that ES can encourage sustainable use of the biosphere by highlighting the connections between human populations and nature and reinforcing the knowledge that human well-being is dependent upon ES (Folke et al., 2011; Raymond et al., 2013; Schröter et al., 2014; Costanza et al., 2017).

## 1.2. Economic framing

In their seminal paper, Costanza et al. (1997) made an initial attempt at assigning a monetary value to the world's ES which garnered a significant amount of both admiration and criticism among ecologists, economists, and decision-makers (Turner et al., 1998; Parks and Gowdy, 2013). Debate surrounded the paper's methodology, the accuracy of the final calculated value (\$33 trillion USD in 1997), and ultimately the ethics of valuating the biosphere (Norgaard and Bode, 1998; Serafy, 1998). The authors and other proponents of economic valuation of ES readily acknowledged the paper's shortcomings, including assumptions of unrealistic homogeneity across biomes and large uncertainties in the quantitative values used, but maintained that the paper represented a much-needed preliminary effort at valuating the environment (Costanza et al., 1998). Certainly, the study succeeded in opening avenues of study within the context of ES and strengthening both positive and negative interest in ES.

Criticisms of the ES concept often include an overarching condemnation of the economic valuation of nature. Some authors argue that the value of nature is infinite, thwarting any attempt at valuation (McCauley, 2006). Others address that assigning monetary values to ES can result in the commodification of nature and the subsequent 'selling off' of ecosystems and biodiversity (Turnhout et al., 2013). Of particular concern is that commodification may create equity issues wherein disparate access to ES can cause a cascading decline in other economic well-being metrics among marginalised members of a community (Corbera et al., 2007; Gómez-Baggethun and Ruiz-Pérez, 2011). Additional criticisms of the economic framing of ES include assertions that the economic valuation methods commonly employed are inappropriate and that the results can be misleading for policy makers (Serafy, 1998; Toman, 1998).

In response, ES proponents maintain that valuation does not necessarily equate to monetisation and that monetary valuation is simply an additional tool used for environmental protection and decision-making and is not intended to be the sole guiding metric (Costanza et al., 2017). Additionally, ES supporters argue that valuation of nature occurs regardless of whether deliberate monetary valuation assignment occurs and that both individuals and organisations make environmental decisions and compromises based on their own internal value of the environment (Costanza et al., 1998). While valuation is useful in decision-making contexts, nonmarket indicators such as biophysical and social measurements could serve as alternatives to traditional monetary valuation (Schröter et al., 2014). Dasgupta (2021) argues that natural capital (i.e., natural assets or natural resources, stocks of which influence flows of ecosystem services over time; Maseyuk et al., 2016) into national accounting systems would be a critical step towards fully accounting for nature's worth to society as the true value of ES is not reflected in market prices leading to underinvestment in natural assets.

## 1.3. Clarity of ES concepts and approaches

The final major criticism is that many of the components of the ES concept are ambiguously defined and injudiciously used. Importantly, the underlying philosophy behind the definitions often differ, challenging the guiding principles behind the purpose of studying, assessing, and managing ES (Nahlik et al., 2012). In particular, there is a discrepancy between whether general ecosystem processes and functions or only human-derived benefits fall under the ES category. This is one contributing factor to the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) adopting the phrase 'nature's contributions to people', which is intended to be an expansion of the concept of ES (IPBES, 2019). Other criticisms regarding ES terminology are concerned with the distinction between services and goods, and whether the differentiation between the two is relevant when discussing

environmental protection. Vague definitions can be challenging from a regulatory perspective with respect to consistency and equity in interpretation and application.

Others have argued the ambiguous definitions and varied classification systems in ES have been beneficial, facilitating flexibility for contextualisation of various ES applications, interdisciplinary collaboration, and creativity (Schröter et al., 2014). There is significant overlap and similarities between some of the most common classification systems, permitting comparisons between them (MA, 2005; TEEB, 2010; IPBES 2019). Proponents of ES accept that the ambiguous definitions can make implementing ES ‘messy’ and suggest that the meanings selected must be tailored to particular contexts and stakeholders and made clear when applied to real-world scenario (Jax et al., 2018). The Environment Agency in England has developed ES Case Studies and consolidates a list of practical lessons learned, ultimately concluding that the ES can be a helpful tool within an overall assessment (EA 2009), in particular by adopting a natural capital approach (HMT, 2022).

#### 4. SCOPE OF ONGOING AND FUTURE WORK

The Commission recognises the importance of ecosystems and acknowledges that corresponding elaboration on the current System would be useful to help clarify the Commission’s philosophy toward protection of the environment beyond what is currently discussed in the most recent recommendations. Moreover, the role of sustainable development, recognised as an important ethical principle relevant in RP (ICRP, 2003, 2018), could use more explicit discussion and elaboration. This may include revisiting the definition of ‘environment’ to be more robust. For example, the International Atomic Energy Agency has a broad definition for protection of the environment (IAEA, 2022), consistent with ES and sustainable development: Protection and conservation of: non-human species, both animal and plant, and their biodiversity; environmental goods and services such as the production of food and feed; resources used in agriculture, forestry, fisheries and tourism; amenities used in spiritual, cultural and recreational activities; media such as soil, water and air; and natural processes such as carbon, nitrogen and water cycles. A simpler expression of these ideas would be that ERP refers broadly to protection of both natural and managed environments, prioritising but not limited to non-human life, from the detrimental effects of ionising radiation exposure in support of sustainable development and the overall well-being of humanity.

With respect to ERP, the System clearly seeks to support and promote good health and well-being, life below water, and life on land, which are three of the United Nations Sustainable Development Goals (3, 15, and 15 respectively; UN, 2015), although the question remains how the System can more clearly and robustly support specific aspects of these (and other) goals, e.g. sustainable use of resources. ES has the potential to serve as a bridge between incorporation of ecosystem endpoints and sustainable development. Of note is the role of the Commission is not to prescribe valuation methods or similar; this type of determination is for ecologists, economists, etc. Rather, the Commission is considering the potential for ES to be useful in RP in support of a more robust approach to ERP. To that end, several TGs are actively and collaboratively addressing complementary goals related to ERP (Garnier-Laplace, et al., this issue). Among them is TG 125, within which the scope of work is to:

- Define ecosystem services in the context of ERP based on currently accepted definitions;
- Review and describe practical examples in which ecosystem services have been incorporated into RP decision-making;
- Explore the link(s) between ERP, promotion of well-being, and sustainable development;
- Consult with organisations to understand how other similar protection frameworks consider ecosystem services and/or sustainable development; and

- Provide recommendations for if and how ecosystem services (and other environmental management tools or concepts as relevant) should be used to promote a holistic approach in ERP with consideration of sustainable development and practical application, e.g., the relationship to DCRLs or other potential assessment criteria.

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## Canadian Organization on Health Effects from Radiation Exposure (COHERE) strengthening co-operation within the Canadian Government on radiation research

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**Abstract**—The Canadian Organization on Health Effects from Radiation Exposure (COHERE) is a collaborative initiative between two federal organisations, Health Canada (HC) and the Canadian Nuclear Safety Commission (CNSC). COHERE will work to advance knowledge on biological mechanisms and human health risks from exposures to ionising radiation relevant to environmental and occupational settings. The objectives of the initiative include: better aligning Health Canada's and the CNSC's radiation science research priorities to focus and leverage resources; maintaining and enhancing expertise in radiobiology and epidemiology within the Government of Canada; providing an informed and consistent federal message to the public and stakeholders on matters involving low dose and low dose-rate ionising radiation; and strengthening Canada's contribution towards international efforts on the assessment of ionising radiation doses and health effects. These objectives support the application of international recommendations, Canadian regulations, and national guidance. COHERE's vision is to contribute knowledge to reduce scientific uncertainties from low dose and dose-rate exposures. It will advance our understanding by bridging the knowledge gap between human health outcomes, and linkages to molecular- and cellular-level responses to radiation. Research priorities focus on identifying sensitive, early, and key molecular events of relevance to risk assessment. The initiative will address questions of relevance to better apprise Canadians, including radiation workers, members of the public and indigenous peoples, on health risks from low dose and low dose-rate radiation exposure and inform radiation protection frameworks at a national and international level. Furthermore, it will support global efforts to conduct collaborative undertakings and better coordinate research. The strategic research agenda (SRA) developed by COHERE specifically considers the areas of research identified by many international radiation agencies to support the current and evolving system of radiological protection. The evolution of COHERE, its SRA and its activities since inception are discussed.

*Keywords:* Radiation; Low dose research; Health effects

### 1. INTRODUCTION

The Canadian Organization on Health Effects from Radiation Exposure (COHERE) is a joint initiative between Health Canada (HC) and the Canadian Nuclear Safety Commission (CNSC) who both lie within the Canadian Federal Government (Chauhan et al., 2021). Both organisations conduct and coordinate research on health effects from radiation exposure and

both recognise the importance of collaboration and coordination of research on important topics of interest to stakeholders. To this end, HC and CNSC launched COHERE to facilitate coordinated and collaborative application of Canadian scientific expertise on problems relevant to understanding the health risks from exposure to low dose and low dose-rate of ionising radiation. For practical reasons, COHERE began as an HC-CNSC partnership; however, efforts are now underway to develop a national hub for Canadian low dose radiation researchers and programs.

## 2. VISION

COHERE's vision is to contribute knowledge to reduce scientific uncertainties from low dose and dose-rate radiation exposures and to contribute information to help bridge the knowledge gap between human health outcomes and molecular- and cellular-level responses to radiation. To accomplish this, we need to:

- Align research priorities to focus and leverage resources;
- Maintain and enhance expertise in dosimetry, radiobiology, and epidemiology; and
- Produce clear, informed and consistent messaging to the public, indigenous and stakeholders on matters involving low dose/dose-rate ionising radiation.

## 3. STRUCTURAL FRAMEWORK

Currently, the structural framework is comprised of representatives from CNSC and HC (Fig. 1). Champions provide oversight to the scientific committee, and support and promote COHERE. The scientific committee is responsible for establishing a strategic research agenda (SRA) and work plan for conducting, presenting, and publishing high-quality research. Program coordinators interface with the Champions and the scientific and communication committees to ensure all COHERE activities are delivered. Lastly, the communication committee contributes to a communication plan, designs, and produces informational products, and a website presence.

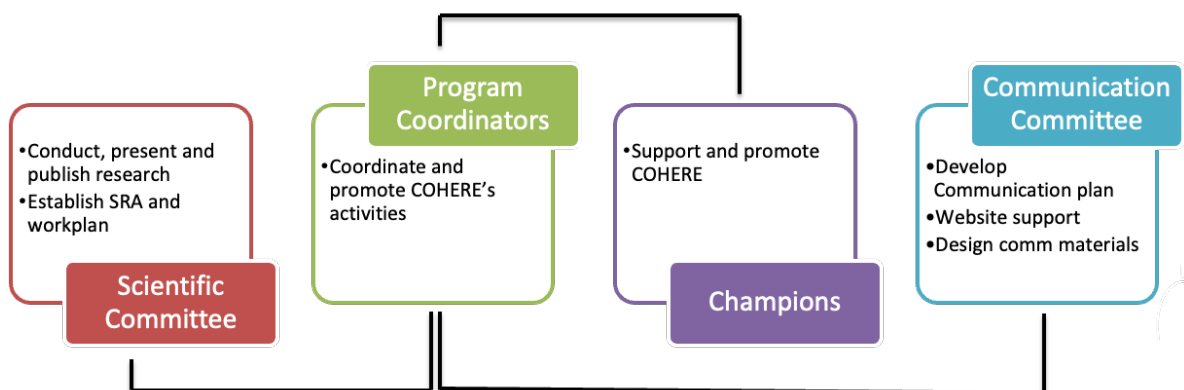


Fig. 1. COHERE structural framework.

## 4. STRATEGIC RESEARCH AGENDA

The SRA (Table 1) was developed to address the challenges and inconsistencies encountered by CNSC and HC when applying and updating current radiation protection regulations and recommendations, and when communicating with stakeholders. It also

considers stakeholder input as received through public and indigenous enquiries or, expressions of concern and requests from CNSC Commission members.

Themes and research lines were informed by priorities identified by the international community and other research platforms, including the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and the Multidisciplinary European Low Dose Initiative (MELODI). Priority areas narrow the scope of the agenda to focus on topics of primary concern in the Canadian landscape, as well as opportunities, tools and technologies that best leverage Canadian federal expertise. COHERE identified five key research themes as being best aligned with its priorities: cancer effects, non-cancer effects, globalised data-sharing/consolidation, capacity building, and epidemiological studies.

Current priority research questions include:

- How does chronic exposure to ionising radiation lead to disease progression and what are the key events and interconnectivities?
- Is the distribution of radionuclides and the subsequent energy deposition inside a tissue or cell homogeneous?
- Which biomarkers can best predict biological effects of low dose and low dose-rate exposures to ionising radiation and how can they support risk assessment activities?

Table 1. COHERE strategic research agenda.

Themes	Cancer Effects	Non-cancer effects	Globalised data-sharing/consolidation	Capacity building	Epidemiological studies
<b>Research lines</b>	Conduct mechanistic based studies to examine dose-response relationships and links to adverse outcomes		Develop expertise in the area of data management and interpretation	Test new technologies/approaches for identifying low dose response effects	Link occupational or medical data to cancer/mortality data
<b>Priority area</b>	Lung cancer (radon), kidney cancer (uranium), organ-level cancers (tritium)	Cataracts (high and low LET), kidney toxicity (uranium)	Adverse outcome pathway, systematic reviews, benchmark dose modelling	Optical spectroscopy, 3D organoid models, stem cell regeneration, phenotypic assays, dosimetry, omics technology	International pooled studies, uranium workers, nuclear energy workers, patients, other radon cohorts
<b>Benefits</b>	Mechanistic understanding of low-dose radiation exposures, improved risk communication, harmonised with international efforts, contributes to Canadian guidance on radiation protection standards				

Recent work has focused on the adverse outcome pathway (AOP) approach and developing an AOP to lung cancer, kidney toxicity, and health outcomes from space travel. This also involves modeling of radiation interactions with biological systems. Other efforts include cohort studies such as the Canadian fluoroscopy cohort study (CFCS) and Canadian uranium workers study (CANUWS). To facilitate these studies historical cohorts and the Canadian National Dose Registry (NDR) are being linked to cancer incidence and mortality outcomes.

The validation of these linkages is underway. We are also involved in a few systematic reviews, including one that is being conducted as part of the ICRP mentorship programme. The current systematic reviews will address how biological sex modifies radiation-induced health effects, the perceived risk of different outcomes associated with the exposure to ionising radiation, and the relationship between exposure to ionising radiation and thyroid diseases in adults. The COHERE workplan is reviewed annually.

COHERE's webpage is hosted on the CNSC website and includes further details on the SRA along with a more detailed list of ongoing projects (<http://nuclearsafety.gc.ca/eng/resources/research/cohere/index.cfm>). The progress of COHERE can also be followed through ResearchGate (CNSC, 2020).

## **5. NATIONAL COORDINATION OF LOW DOSE RESEARCH**

We are also partnering closely with other Canadian organisations and groups conducting low dose and low dose-rate research and working towards coordinating research at the national level. This would ideally be a collaborative effort between government, industry, and academia.

Better national-level coordination will allow us to work more effectively. Coordination will result in increased collaboration, coordination of proposals to funding agencies, support capacity building, thereby supporting international efforts. It would also improve knowledge transfer and consistent communications, enabling sharing of ideas, preventing duplication of projects, increasing the funding efficiency, sharing of resources and facilities, and identifying priority research. Finally, coordinated messaging on low-dose risks and new scientific research supports transparency and public confidence in scientific authorities.

Coordinating research at this level is challenging and we are always open to ideas and input on how to make this a success. We invite Canadian researchers conducting low dose research to contact current COHERE coordinators Dr Ruth Wilkins or Ms Kristi Randhawa to get involved.

## **6. CONCLUSION**

COHERE benefits the radiation protection community by 1) broadening the international profile of Canadian scientists and their research activities; 2) demonstrating leadership to the radiation protection community; and 3) creating a point of contact within the Government of Canada for more effective coordination and collaboration with national and international organisations.

Results from COHERE will contribute to standards and recommendations for radiological protection by adding to the body of evidence that informs the international radiation protection agencies (e.g. Nuclear Energy Agency, UNSCEAR, ICRP, and the International Atomic Energy Agency). COHERE looks forward to a future with national coordination of low dose radiation research.

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## Exposure of volunteers in medical research – justified and optimised?

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**Abstract**—Volunteers participating in medical research must be adequately protected. A volunteer can be a person undergoing treatment for an illness (a patient) or a healthy person. The radiological imaging and therapy procedures used could be routine or project-specific with different purposes. This contribution aims to explore the features and conditions of this planned exposure situation and to address some challenges. The result of a national study is presented. The main aspects covered in this presentation are justification, optimisation of radiation protection and the use of dose constraints. The guidelines in ICRP *Publication 62* were reflected upon.

**Keywords:** Medical research; Volunteers; Medical exposures; Optimisation; Justification; Dose constraint

### 1. AN INTRODUCTION TO EXPOSURES OF VOLUNTEERS

#### 1.1. The exposures and prerequisites

In medical research the need for the inclusion of humans is evident although there is often experimental research on animals prior to that of clinical research. The volunteers have to fulfil inclusion criteria and exclusion criteria in order to apply to the project. Therefore, the volunteers constitute assumingly healthy persons of all ages but also patients with known disease and in some cases limited lifetime expectancy. The research design may also require a certain number of volunteers to provide statistically significant results.

Medical research encompasses a wide range of research, applicable from preclinical investigations to clinical research to develop new pharmaceuticals and medical procedures or improve the application already available. This research could include that volunteers are exposed to ionising radiation, e.g. medical imaging to monitor the efficacy of the intervention. However, the area of application is huge, exemplified by two studies. Firstly, a study where the volunteers ingested a small amount of polonium, with an assessed effective dose of 20  $\mu$ Sv and a small group of male healthy volunteers participated (Rääf et al., 2015). Second, a study comprising the first-in-human Flash radiotherapy, comprising a patient with a known disease with a target absorbed dose of 19 Gy delivered in 19 ms (Bourhis et al., 2019). This illustrates the range of experiments and range of exposure levels possible.

In the system of radiological protection, this type of human research exposure is included in the concept of medical exposures (ICRP, 2007a), i.e. medical exposure does not only include patients that are assumed to individually benefit from the exposure but also exposures in medical research that could be beneficial to the society. The most obvious attribute of this specific exposure situation of volunteers in medical research is that dose limits do not apply.

## 1.2. International standards, recommendations and advice

International standards and recommendations include radiological protection for volunteers. ICRP *Publication 103* (ICRP, 2007a) and ICRP *Publication 105* (ICRP, 2007b) address the issue and recommend the use of dose constraints when no direct medical benefit of the exposure is obtained by the volunteer. The benefit is in this case directed towards society. The Commission also issued specific recommendations in the field, ICRP *Publication 62* (ICRP, 1991). The ethical and procedural aspects of the participation of volunteers in biomedical research and its justification are included. That report also gives suggestions on dose constraint for four levels based on the level of societal benefit. Note that the *Publication 62* preceded the two before-mentioned general recommendations publications.

The IAEA basic safety standards (IAEA, 2014) and safety guides (IAEA, 2018) adopt the Commission's recommendations. Requirements directed towards the ones performing the medical exposures, registrants and licensees, are issued. Prerequisites for justification are stated; should follow the Helsinki Declaration (WMA, 2013) and other international organisations (CIOMS, 2016) including ICRP *Publication 62* (ICRP, 1991). The IAEA standards further indicate the importance of an ethics committee, and the actual use of dose constraints in the optimisation of protection and safety in the clinics. The EU directive (EU, 2013) is in line with the above standards. The directive also addresses when a patient voluntarily accepts to undergo an experimental medical procedure and is expected to receive benefit, then the dose levels concerned should be considered on an individual basis before the exposure.

## 2. A NATIONAL EXPERIENCE

In Sweden, the issue was addressed in a national study (Almén, 2022). The system as a whole was illuminated from different points of view. In the investigations 100 applications using healthy volunteers? sent to the National Ethic Authority were included. It cannot be ruled out that the selection was biased if the researchers incorrectly assessed that the volunteers benefited from the exposure, which means that the exposure is not assessed and the radiation risk assessment not handled.

### 2.1. A short summary of the investigation

The considered projects constituted a variety of issues. A great percentage of the research was concerning treatment regimens (45%). Another large group was clinical trials of pharmaceuticals (35%). A smaller group was about the radiological procedures, diagnostic or radiotherapy, itself. A substantial part of the projects were not easy to categorise and some constituted projects that was not apparent in medical research. The exposure level, effective dose, was given for diagnostic examinations. The imaging modality and sometimes body part was given but the organ doses were seldom stated and in some cases, the given effective dose was wrong. Repeat exposures were usual. Details about the medical information required from the radiological examinations were seldom given. The most preferred imaging modality was computed tomography followed by conventional radiography. Fig. 1, summarises the number of volunteers included in projects and effective dose given in the applications. The few radiotherapy projects included were evaluated concerning additional imaging performed due to the research. The volunteers were of all ages, and about 15% of the projects included children. Several projects included patients with serious illnesses and expected shortened life expectancy.

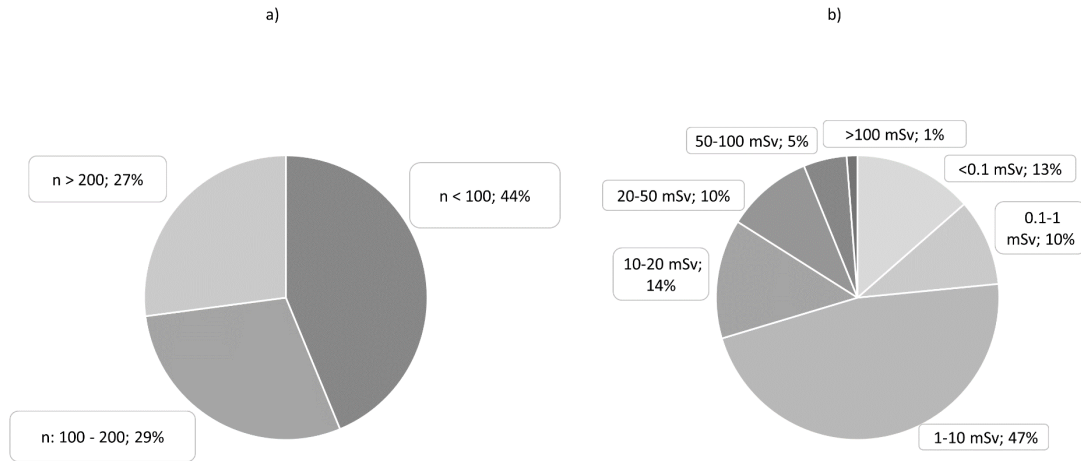


Fig. 1. a) The number of volunteers (n) included in each project, percentage in each interval. b) The percentage of projects in each range of effective dose given.

For each project, a dose constraint was assigned. The values in ICRP *Publication 62* (ICRP, 1991) were used, i.e. the value was chosen based on the societal benefit. The researcher indicated the societal benefit. The investigation shows that for similar projects the societal benefit were sometimes judged differently. Furthermore, it was obvious that the evaluation was sometimes about the importance of using ionising radiation and not the possible benefit of the research (societal benefit). The dose constraint was adjusted for age but not gender or life expectancy. Three age groups were used as indicated in ICRP *Publication 62*; 18 years and younger, above 50 years and older and one group between these two. The issue of pregnancy was not particularly addressed in the research application but in some of the projects, an exclusion criterion was pregnancy.

## 2.2. Main conclusions from the investigation

Radiation protection for volunteers depends on a number of factors from the time the projects are planned to their execution. The national experience indicates that the focus is on the ethics review where overall risks, dose constraints and information to the volunteers and to a less extent on the justification and appropriateness of the medical exposures as well as, the optimisation of radiological protection.

The risk assessment seems, to some extent, lack some information and this has a negative affect. The indicated organ dose and effective dose were also sometimes wrong. The assessment of organ dose is in some cases important component. It is also important for an appropriate estimation of effective dose. The risk assessment regarding tissue effects, not covered in the present use of dose constraints, need to be highlighted and clearly covered and potential exposures should also be considered. This becomes especially important for new radiological procedures when uncertainties have to be taken into account explicitly and handled. Therefore, it should be further investigated how risk assessments are performed.

The information on the radiological procedures was elementary. The justification of an imaging or therapy procedure could not be evaluated, e.g. requested medical information from imaging was not stated. In addition, the optimisation of radiation protection could not be assessed. This also requires specific competence that the researcher may not possess. The clinic responsible for the medical exposures, e.g. the radiology, nuclear medicine, or radiation oncology department, could be assumed to have this competence. This in turn indicates the

need for improved collaboration between researchers and the clinics. The need to guide on the different responsibilities and tasks between stakeholders was also identified.

The assessments of societal benefit varied between similar types of projects. The application of dose constraints particularly the assessment of societal benefits needs to be harmonised. It is also not obvious how to handle different subgroups, such as healthy volunteers and patients, multiple exposures or multiple participations.

The projects were sometimes not easy to characterise and sometimes it was questionable if the research could be characterised as medical research. It is also sometimes implied that the medical exposure is performed in the healthcare setting, with their competencies and resources, and that the research therefore could be defined as medical research. On review, it was apparent that this is not always the case. These miscellaneous projects have to be further investigated.

### 3. CHALLENGES

Based on this experience and taking into account international standards some challenges could be identified. The wide range of possible content of research project that is doubtful to be medical research situations. Medical exposure is carried out both in the health care settings and outside. Involving patients also raises the questions of benefit to the individual, there are tendencies to more consideration when healthy volunteers is considered. It is even more complex when it comes to experimental treatments including patients with assumed short life expectancy. Dose and risk assessment for non-standard procedures may be complex and the right competence could be missing when planning a project. There is also a type of research that uses medical imaging procedures but does not aim to improve health or use non-medical radiation sources. The current system needs to better evaluate these issues. Research outcome as such is uncertain and this makes value judgments even more complex. There are also special groups where specific issues are present, e.g. children unable to give consent, terminally ill patients, and the monetary incentives to volunteers, requiring specific ethical considerations.

The assessment of late stochastic effects may consider age, gender or life expectancy in a more detailed manner. Standard assessments may not be appropriate for specific cohorts. The risk assessment should also be done in conjunction with assessments of other risks and it should be investigated whether incidence or mortality should be used. The current system relies heavily on the concept of effective dose and there is a risk that tissue effects are overlooked. When managing an effective dose, specific considerations should also be taken when the effective dose exceeds 100 mSv because of the increased risk that the absorbed dose to a specific organ exceeds the level for tissue effects. Clarification on risk management is needed.

The societal benefit, the expected benefit of the research, is in the current system critical for the dose restriction that is employed. Guidance may be needed on how this benefit should be assessed. The purpose of the research may be e.g. to increase survival, but the probability that the project can provide this information also needs to be assessed.

The concept of justification is different from when the exposed directly receives the benefits and this is a challenge. The justification must then be based on the benefit of the project and an appropriate method for the project to be used. For diagnostic procedures, there is a need for competence in e.g. medical imaging to evaluate whether the medical method provides the information sought in the project or whether another method is more appropriate. Optimisation of radiological protection should also take into account the specificities of the project and that the dose constraints are used correctly. There could be a miss conception that dose constraint means a dose limit for the project and that optimisation of protection does not apply. The actual effective dose could of course be considerably lower compared with the set dose constraint. To facilitate proper radiation protection adequate competencies are included both in the planning and executing phases and this could constitute a challenge.



#### 4. CONCLUSIONS

Exposure of volunteers constitutes an exposure situation where radiation protection needs to be taken care of for each project but within a robust framework. The process shows both similarities and differences in where patients, who bear the benefit themselves, are exposed. It cannot be assumed that those who plan the project or those involved in the ethics review understand the conditions to ensure proper radiation protection. The right competence is required both in the planning and execution of the research project. It can be concluded that even within this area of radiation protection there is room for improvement regarding guidance to all stakeholders involved.

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## Development of guidance on radiological protection aspects of imaging in radiotherapy

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**Abstract**—Radiation therapy has the capability to conform radiation fields delivered to tumours much more accurately because of developments in therapy equipment in recent decades. This can help to reduce doses to normal tissues considerably. Successful delivery requires the patient to be in the same position on the couch as in the treatment plan. Therefore, images are taken at regular intervals, frequently at every treatment fraction and compared with images used for planning, and this is referred to as image guided radiation therapy (IGRT). If more imaging with x rays is carried out, this exposes patients to additional doses to tissues surrounding the tumour that carry a risk of inducing secondary cancers. The reductions in high dose treatment margins that can be achieved with IGRT need to be balanced against risks from greater imaging doses. ICRP Task Group 116 is preparing guidance on IGRT, and has used the ICRP mentorship programme to undertake surveys of imaging practices and to trial ways for measuring cone beam computed tomography (CBCT) doses that could be widely applied. Results from the projects are feeding into development of the report with recommendations to facilitate improvements in the application and optimisation of radiological protection in the use of imaging in radiotherapy.

*Keywords:* Image guided radiation therapy, Cone beam CT, Radiotherapy planning, Imaging in radiotherapy, Imaging dose

### 1. INTRODUCTION

The two main forms of radiotherapy deliver radiation to the tumour target to be treated either using beams of radiation from an external radiation source or by positioning radiation sources inside the body, close to the tumour, a technique known as brachytherapy. Tumours are treated in external beam therapy with high energy x-ray beams generated in linear accelerators (linacs) or gamma-ray beams from high activity sources in multiple fractions. The beams are delivered from multiple directions using gantries that move the source around the patient to build up a high dose at the position of the tumour target. The shape of the radiation beam from a linac is adjusted by a multi-leaf collimator with high density leaves to resemble the cross section of the target. The collimator shape is adjusted during treatment under control of a computer to conform the radiation field to the tumour target. Several techniques have been developed to improve the delivery, such as intensity modulated radiation therapy (IMRT), in which movement of the collimator blades modulates the intensity of beams delivered from different directions, and volumetric modulated arc therapy (VMAT), which allows additional degrees of freedom for beam fluence modulation through delivering radiation while the gantry is in motion. These new techniques allow the radiation dose to be conformed more effectively to the shape of the tumour target. The improvements in shaping the radiation field to the tumour can only be realised, if treatment delivery to the patient is performed with millimetre accuracy.

The size of the high dose region used for treatment will be set larger than the tumour to ensure that cells on the periphery are treated. This allows for variations in tumour shape, uncertainties in position of the patient during treatment, and to account for internal motion.

Therefore, there is a margin around the tumour, within which normal tissues are exposed to higher doses. Ensuring that the patient is in the correct position so that the precise dose distributions will be delivered to the correct tissues is essential for taking advantage of the improvements in technique. Courses of radiotherapy treatment are delivered in up to thirty fractions. Imaging immediately prior to treatment delivery to delineate tumour and normal tissue at each fraction enables better targeting of the tumour, so that the size of the high dose margin can be reduced. This allows a reduction in doses to normal tissues and may allow the dose delivered to the target to be increased, improving the effectiveness of the treatment.

This process of planning treatments using imaging coupled with further images at the time of treatment is called image guided radiation therapy (IGRT). Additional imaging may be undertaken during both planning and treatment to take account of motion from breathing and other motion cycles. IGRT has enabled more precise treatment delivery and led to better patient outcomes and is now regarded as essential for the optimal implementation of highly conformal radiotherapy (Webster et al., 2020). However, the cumulative doses from imaging will contribute to an increased risk of second cancers (Suit et al., 2007), so reduction in the high dose margin around the target must be balanced against the increased dose from imaging to surrounding normal tissues. For making judgements about potential harm from imaging information is required on doses received. Guidance has been produced on use of IGRT in high income countries, but the information is limited and optimal techniques are not yet established.

## **2. ICRP MENTORSHIP PROJECTS**

ICRP set up Task Group 116 to provide guidance on radiological protection aspects of IGRT. Because the information available on use of IGRT is limited, the Task Group set up a project through the ICRP mentorship programme to find out more about practices in different parts of the world. The countries included were determined by the residency and nationality of the mentees taking part in the project. The survey was conducted on-line in countries where the mentees were resident between July and November 2020, using the SurveyMonkey platform (San Mateo, California, USA). The questionnaire included 130 items of information about imaging practices in each radiotherapy centre. 143 RT centres registered to participate and 100 completed the full questionnaire. Data from 97 centres in nine countries in six continents were used in the analysis (Martin et al., 2021). The mentees collated data for their own countries and investigated any anomalous results. The main imaging modality used during treatment procedures was kV cone beam computed tomography (CBCT), but the measurement of imaging doses from CBCT was limited. Therefore, a second project was established through the ICRP mentorship programme to consider ways in which quantities relating to patient dose might be measured, and especially the options that might be employed in countries with limited funding.

## **3. SURVEY OF IGRT PRACTICES**

The Task Group required information on the use of IGRT across countries with varying funding levels, and so the data were analysed in terms of the Human Development Index (HDI) as defined by the United Nations Development Programme (UN, 2022). This combines measures of life expectancy, education, and per capita income, and values increase to a maximum of 1.0 with the level of development. Summary data for the countries are listed as A to I in order of decreasing HDI in Table 1. The survey showed that IGRT is employed in the major radiotherapy centres in all countries, but more frequently in those having higher HDIs. Treatment planning is done with CT scanning in all centres, but other imaging modalities, such as magnetic resonance imaging (MRI), positron emission tomography/CT, single photon

emission CT and ultrasound contribute information about location of diseased tissues. kV CBCT is the modality employed most widely for imaging during the treatment cycle, being used by all centres surveyed in countries (A–F) with values of HDI above 0.8. 86% and 89% of radiotherapy centres in countries G and H, respectively had at least one linac with kV imaging. Country I had only two from 13 linacs with kV imaging, and so MV imaging was the main option used, for which soft tissue contrast is poor and absorbed doses delivered to tissues are higher. Other imaging techniques employed were kV-kV pair, MV-MV pair and in a few centres MV CBCT. Optical surface guidance and/or ultrasound provided additional aids in checking alignments in about half of the centres and MRI in 10%–25%.

The choices that need to be made in optimising radiological protection for IGRT are the frequency at which imaging is being carried out and the exposure parameters used for image acquisition that determine the quality of the image. Most centres in countries A-F recorded images at every fraction during the course of treatment. Country G used imaging once per week and country I, once per week or even once per course of treatment, primarily because of limited availability of kV imaging equipment on linacs in these countries (Table 1). Most centres in country I only had MV imaging available, so the advantage gained with the poorer image quality together with the higher dose to the patient did not justify imaging more than once per week. An advantage of the more limited imaging is that it allowed more patients to be treated on each linac, providing an advantage for a country with fewer treatment resources.

Table 1. Information on radiotherapy centres in survey and their use of imaging during treatment. Each row contains data for one country and these are listed in order of Human Development Index (HDI).

HDI at time of survey*	Continent	No. of RT centres in survey	RT centres using IGRT <sup>†</sup> (%)	Most frequent options for imaging <sup>‡</sup>	Linacs with kV CBCT (%)	RT centres recording CBCT doses (%)
A 0.947	Europe	10	80	Once per fraction	85	50
B 0.944	Australasia	12	92	Once per fraction	96	0
C 0.926	N. America	30	80	Once per fraction	92	3
D 0.887	Europe	2 <sup>§</sup>	100	Once per fraction	100	50
E 0.854	Asia	4 <sup>§</sup>	50	Once per fraction	75	50
F 0.81	Asia	7 <sup>§</sup>	86	Once per fraction	89	14
G 0.767	S. America	14 <sup>§</sup>	79	Once per week, Once per fraction	71	15
H 0.748	Africa	9 <sup>§</sup>	67	Once per fraction	87	0
I 0.707	Africa	9	22	Once per week, Once per treatment	15	0

RT, Radiotherapy.

\*Data from IAEA (2021).

<sup>†</sup>Proportion of RT centres using IGRT for 75%–100% of treatments.

<sup>‡</sup>Option used for majority of treatments of the trunk. Where the main option is used for <50% of RT centres, the second choice is also given.

<sup>§</sup>Represents over 20% of RT centres in country.

With regard to optimisation of radiological protection, 90% of radiotherapy centres simply used exposure factors in imaging protocols provided by the vendor for CBCT in two thirds of the countries and fewer than 50% made adjustments to protocols for individual patients. The image quality required should be the minimum necessary for delineation of organs and

verifying alignments for accurate treatment delivery. Although vendor protocols provide a good starting point, they are likely to err on the side of better image quality. As exposures, which include normal tissues surrounding the tumour target, are often repeated many times, consideration of optimisation of radiological protection is important. The volume of normal tissue surrounding the tumour target that is irradiated should also be restricted to the minimum required to ensure accurate treatment. Centres in countries D, F and I used standard adult protocols with limited adjustment of field size for most patients. Between 38% and 60% of the radiotherapy centres in other countries adjusted the field size for individual patients.

Optimisation requires a knowledge of patient doses from imaging. However, the survey showed that although 50% of radiotherapy centres in European countries (A and D) and one Asian country (E) recorded patient doses, less than 10% of centres in other countries recorded them (Table 1). Most medical physicists working in radiotherapy do not have expertise in diagnostic imaging, so many centres involve diagnostic physicists, but this was limited to less than 30% of centres surveyed in six countries. Introducing measurements and surveys of patient imaging doses will require the involvement of diagnostic radiology medical physicists and training of radiotherapy imaging physicists in diagnostic radiology requirements for optimisation.

#### 4. CBCT DOSIMETRY MEASUREMENTS

Reasons behind the lack of attention to patient doses from imaging in radiotherapy are:

- 1) The doses from imaging are significantly less than those from radiotherapy treatment.
- 2) Many CBCT units do not display a dose quantity suitable for calibration.
- 3) The instruments and phantoms used for measurement of CT doses and calibration of CT dose displays are not available in many radiotherapy centres.

Current techniques for accurate measurement of dose quantities for CBCT proposed by the International Electrotechnical Commission (IEC, 2009), the International Atomic Agency (IAEA, 2011) and the American Association of physicists in medicine (AAPM, 2010, 2014) are complex, take significant lengths of time to carry out and require specialist equipment that is not available in radiotherapy centres in many parts of the world (ICRP, 2015). Therefore, a second project under the ICRP mentorship programme has been set up to determine the feasibility of measurement of CBCT dose with a wide beam as used in the clinics in a 150 mm CT phantom with either a 100 mm CT chamber or a 0.6 cc Farmer chamber, which is more widely available in many radiotherapy departments (Martin et al., 2023). The aim is to measure doses for single rotations of the x-ray source with the chambers at the centre and periphery of standard CT phantoms, 16 and 32 cm in diameter, representing the head and body respectively (Fig.1). This approach resembles the standard method for dose measurement in CT, but using wide beams from CBCT. The aim is to make measurements of cumulative doses with the same exposure parameters used for patient imaging. These measurements should be relatively easy to make, if centres can gain access to CT dosimetry equipment. It is hoped that use of a relatively simple approach will enable comparisons of performance to be made across a larger number of centres.

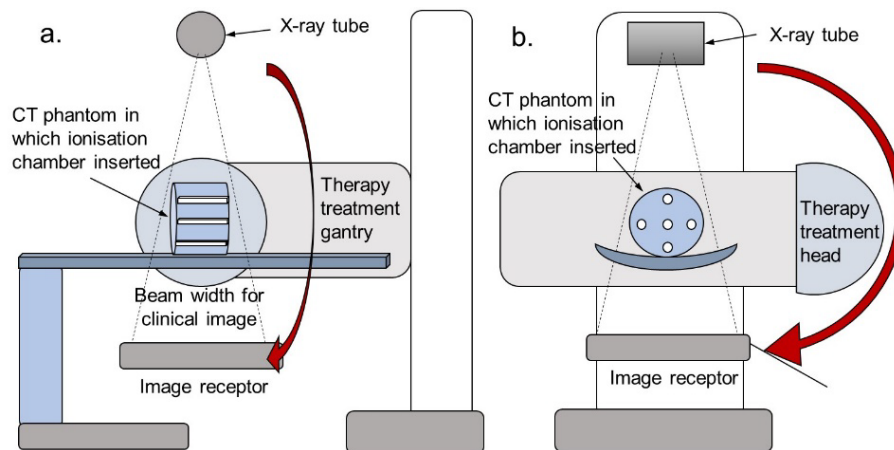


Fig. 1. Experimental setup (a) perpendicular and (b) parallel to the axis of rotation, used to measure CBCT dose with an ionisation chamber inside a standard CT phantom.

## 5. CONCLUSIONS

ICRP Task Group 116 is preparing a report on radiological protection aspects of imaging in radiotherapy. Two projects have been organised through the ICRP Mentorship Programme to obtain information about imaging practices in radiotherapy centres around the world. The programme has enabled data to be collected from countries through local contacts and, although the survey provided only a snapshot of practices, it has given a useful indication of approaches and techniques employed in different countries. Results show that imaging is used more frequently in countries with higher incomes, but is starting to be introduced elsewhere. The amount of effort put into optimisation of radiological protection for imaging in radiotherapy is limited at the present time. Optimisation requires a knowledge of patient doses from imaging, but few centres outside Europe record any information on patient doses. Awareness of doses to tissues surrounding the tumour target that result from imaging needs to be raised. Methods need to be developed to promote dose quantities that can be measured to calibrate displays on imaging equipment used in radiotherapy. It is important that sufficient expertise is available and appropriate training courses in diagnostic radiology techniques are developed for radiotherapy medical physicists. Consideration will be given to these points in preparation of the ICRP report.

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## Voxel-based analyses for paediatric outcomes research

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**Abstract**—Radiation therapy (RT) research increasingly recognises the critical limitations of historical knowledge regarding the relation between physical radiation exposures and their biologic effects, known as the dose response. Improved understanding of dose response is urgently needed to guide treatment-plan optimisation and enable continued increases in long-term survivorship. Advanced computational methods for survivorship research, like deep learning and data mining, offer opportunities to improve our understanding of dose response. Survivorship research is especially important for children, whose growing bodies are inherently vulnerable to radiation damage and for whom survival often spans decades. Much of the work to incorporate advanced computational techniques into survivorship research, however, has focused on adult patients. Two important applications of advanced computational methods to paediatric survivorship research include automatic contouring and voxel-based methods for identifying the most important parts of the anatomy driving toxicity. The latter is called image-based data mining. Both avenues are currently under investigation in our lab, and preliminary results are promising. The continued, safe integration of advanced computational methods into paediatric radiation oncology is needed to realise the full beneficial potential of radiation therapy and provide not only prolonged survival, but also superior outcomes with reduced toxicity for children with cancer.

*Keywords:* Radiation therapy; Childhood cancer; Deep learning; Data mining

### 1. INTRODUCTION

As cancer survival rates steadily improve (Howlader et al., 2018), radiation therapy (RT) research increasingly focuses on survivorship issues. Survivorship considerations are particularly critical in paediatric RT due to the inherent vulnerability of children to radiation damage and their particularly long duration of survival, which typically extends decades longer than for most adult cancer survivors. Studies aiming to mitigate or avoid morbidity and mortality after the completion of RT require a deep understanding of the relation between physical radiation exposure and its biologic effects, known as the dose-response relation (Langendijk et al., 2013; Rechner et al., 2015; Draguet et al., 2022; Kalendralis et al., 2022; Papp and Unkelbach, 2022). Critically, the dose-response relations are uncertain or unknown for many of the tissues and health effects that are relevant to RT for childhood cancer (Constine et al., 2019).

### 2. COMPUTATIONAL INNOVATIONS FOR RADIOTHERAPY

Advanced computational methods like data mining, deep learning, and other forms of artificial intelligence offer opportunities to uncover characteristics of dose-response relations that were previously undiscoverable by conventional analytical and manual methods. Contemporary computational innovations purport to consider the full data generated by and



relevant to RT to reveal insights and perform tasks that support both research and clinical activities. Here we review some emerging applications of advanced computational methods for paediatric RT: automatic contouring of medical images and discovery of the specific anatomy driving toxicity.

## 2.1. Automatic Contouring

RT treatment planning and survivorship research require patient images to be annotated with delineations that indicate which regions of the image represent specific anatomic structures and tissues. Structure delineations are used in treatment planning to guide plan optimisation algorithms that aim to deliver high doses of radiation to the target volume while keeping the dose in surrounding organs at risk below tolerance levels. Manual delineation, however, is time consuming and user-dependent, despite the implementation of guidelines designed to reduce interobserver variability (Brouwer et al., 2012). Variations in manual delineations can potentially reduce plan quality (Peng et al., 2018). Structure delineations are also used in conventional survivorship research to compare doses delivered to corresponding anatomic structures across patients. In clinical practice, however, many organs are not contoured because they were not considered to be at risk or specifically useful for guiding the plan optimisation. In other cases, organs may be contoured inconsistently, for instance the top of the brainstem. To be able to perform survivorship research, for which cohorts can number in the hundreds of patients, manual delineation is typically a prohibitive barrier. In paediatric research, multi-institution collaboration is often necessary due to small single-institution cohort sizes, so inter-institutional variation in contouring may further increase uncertainty of existing delineations.

Automatic contouring tools offer a means of reducing the burden of delineating images while also avoiding inter-observer variability. Several commercial (Xu et al., 2018) and open-source platforms for automatic structure delineation exist, especially for anatomy that is particularly cumbersome to manually contour, like brain substructures (Fischl, 2012; Jenkinson et al., 2012; Gaser and Dahnke, 2016). Deep-learning-based solutions, however, have been shown to deliver improved accuracy and higher time savings compared to conventional atlas-based platforms (Lustberg et al., 2018). Deep-learning algorithms for automatically contouring organs at risk (Henschel et al., 2020; Gibbons et al., in press) and target volumes (Kamnitsas et al., 2016; Ma et al., 2022) are emerging. The vast majority of existing algorithms, however, have been developed for and validated in data collected from adults. It is still unclear whether such algorithms are applicable to data collected from children, either healthy or with cancer. For example, several anatomic anomalies, like the presence of solid tumor and hydrocephalus, commonly accompany cancers of the central nervous system. Therefore, more work is needed to train and test automatic contouring tools on data collected from children, both healthy controls and those with disease. Our group is currently investigating the applicability of existing atlas-based and deep-learning automatic contouring platforms to data collected from children. Preliminary results suggest several popular automatic contouring platforms produce comparable segmentations, although they perform better in data collected from healthy children than in data from children with brain tumors (Bryce-Atkinson et al., 2022). Further work is needed, however, to validate the platforms with ground-truth contours and assess the relative computational costs. This work will be complicated by the large datasets needed to train deep-learning algorithms and so multi-institutional collaborations may be necessary.

## 2.2. Discovery of anatomical structures driving toxicity

Conventional methods of investigating the relation between physical exposures and their biologic effects rely on dose-volume analyses. Dose-volume techniques, however, have two important limitations. First, they rely on a priori structure selection, which can lead to the

omission of anatomy that has not yet been linked with an effect of interest. Second, they typically only consider whole organs as if they are functionally homogeneous, which can obfuscate sub-structure dependencies. Image-based data mining (IBDM) is a novel voxel-based method for analysing spatial associations between RT dose and biologic effects. Voxel-based methods like IBDM take an agnostic approach to identifying associations between RT dose and observed effects to overcome several limitations of conventional dose-volume analysis techniques. The associations revealed by IBDM highlight the anatomic structures that may be implicated in the exposure-to-effect pathway, thereby improving our understanding of the dose-response relation.

IBDM comprises two primary steps: spatial normalisation and dose analysis. The spatial normalisation step involves mapping individual patient anatomy to a reference anatomy, typically via deformable image registration (Palma et al., 2020). In children, the size and shape of the anatomy is more variable than in adults, posing an additional difficulty. The dose analysis in IBDM is vulnerable to a multiple-comparison problem, which is often addressed by establishing statistical significance using permutation testing. Permutation tests are a non-parametric method to conservatively correct for multiple comparisons based on a single test statistic that is derived from each case (Chen et al., 2013; Palma et al., 2020). Despite several applications of IBDM in adults (Monti et al., 2017; McWilliam et al., 2017; Beasley et al., 2018; Mylona et al., 2019; Palma et al., 2021; Cella et al., 2021), the feasibility of applying IBDM to data from children, encompassing the wide anatomic variability characteristic of childhood, is unclear. In addition, pediatric cohorts are often small and therefore methods have to be refined to be more economical; for instance, by considering continuous rather than binary outcome measures (Beasley et al., 2018). Recent work demonstrated the feasibility of spatially normalising images of children (Skaarup et al., 2021; Veiga et al., 2021) and performing dose comparisons using simulated dose distributions (Wilson et al., 2022). Our group is currently investigating the association between cranial RT doses and neurocognitive outcomes among survivors of childhood brain cancer using IBDM. Preliminary results suggest that IBDM results are consistent with those of conventional, dose-volume analyses (Acharya et al., 2022) and also reveal more comprehensive information regarding associations in organ sub-structures and in structures previously overlooked in dose-volume assessments. Further work is needed, however, to identify the causal links involved in the IBDM-identified associations. An example of causal inference research in radiotherapy research can be found in the recent study from van Amsterdam et al. (2022).

### 3. DISCUSSION

Dose-response relationships are a primary focus of modern RT research. Advanced computational methods are essential to improve dose-response studies via deep-learning-based automatic contouring and voxel-based analysis methods like image-based data mining. The incorporation of advanced computational methods into RT research can lower the barriers to leveraging and interpreting datasets that encompass higher numbers of patients who were treated over wide spans of time than was possible via conventional methods. Implementations tailored to adults, however, are unlikely to directly translate to data collected from children.

The new knowledge produced by the advanced computational methods discussed here will further open the door for other research and clinical applications. For example, with the ability to more comprehensively interpret dose-response associations with IBDM will come a need to more precisely know the delivered dose distribution. Current dose-response studies rely on the planned dose distribution, which can differ from that which is delivered to the patient in several important ways. Although the difference between planned and delivered radiation exposures poses an obstacle to both paediatric and adult survivorship studies (Shelley et al., 2017),

paediatric studies are particularly sensitive to dose variability caused by daily setup uncertainties and organ motion. Children's small bodies place organs at risk at much closer proximity to each other and to the steep dose gradients surrounding the target volume than is typical of adult anatomy. Therefore, small spatial perturbations may modify the dose delivered to the nearby organs at risk in magnitudes that are clinically meaningful. Furthermore, organ motion is less well-understood in children (Meijer et al., 2022). Deep-learning dose algorithms are emerging (Nguyen et al., 2019a,b; Guerreiro et al., 2021) and should in the future be extended to reconstruct and/or predict delivered dose distributions.

Advanced computational methods like data mining and deep learning present exciting opportunities to improve RT clinical and research workflows by making them smarter (i.e. by incorporating more data) and faster (i.e. by increasing automation). The deeper knowledge into dose-response revealed by advanced research techniques will be ripe for clinical translation, where it can guide treatment planning optimisation to minimise risk of side effects while maintaining therapeutic benefit (Wilson and Newhauser, 2021). Continued, safe integration of advanced computational methods into radiation oncology will allow us to realise the full beneficial potential of radiation therapy, and provide not only prolonged survival, but also superior outcomes with reduced toxicity to children with cancer.

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## Proposal of See-saw model - overcoming LQM difficulty

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**Abstract**—We propose the See-Saw (SS) model, which provides a unified description of the biological effect caused by radiation. This can be directly applied to clinical plans in radiotherapy and further provides the basic formula for radioprotection since it correctly describes the effects caused by radiation exposure by taking account of the dose rate effect without any additional concept of dose and dose rate effectiveness factor (DDREF). This can be done by introducing the cell exclusion effect. The model is very simple and intuitively acceptable by expressing the dose-rate effect and can be easily extended to the radiation clinic cases and overcomes the difficulties of the standard method using LQM-based biological equivalent dose (BED). The calculated result of our model reproduces the existing data of the time dependence of the cancer volume during the cancer treatment measurement. We demonstrate that different initial volumes, namely for the cases where irradiation starts with a smaller initial volume are more effective than a larger volume. Especially if the cancer volume is almost full in the tissue, the radiation effect of the cancer treatment is found to be less effective. On the other hand, for the smaller initial volume, the cancer treatment is found to work more effectively to reduce the cancer volume. After explaining the essential difference between our See-saw (SS) model and traditional LQ treatment with the BED index, we report the results of the SS model by displaying the comparison of our prediction with the relevant data. We are arranging the collaboration with the members of the radiation therapy sectional group of Osaka International Cancer Institute and will report detailed results in near future. We can also consider continuous but time-dependent irradiation cases and got interesting outcomes on the time dependence of the tumour volume for various clinic plans. Especially by choosing the value of the dose rate to be balanced with the total growth rate, the tumour volume is kept constant. Finally, I would like to emphasise that our SS model leads us not only with a unified description of radiation therapy but also indicates the misleading principle based on the LNT or LQM hypothesis which is still adopted in the society of radiation protection.

*Keywords:* Sea-Saw model; LNT; LQM; Radiotherapy; Radioprotection

### 1. DEFINITION OF BIOLOGICAL EQUIVALENT DOSE (BED) BASED ON LINEAR QUADRATIC MODEL (LQM)

There has been a growing trend to review the linear non-threshold model (LNT)/ linear quadratic model (LQM), which has been long established as a standard of radiation protection. The main difficulty is that the risk assessment is expressed as a function of only the total dose, and the time evolution is totally hidden, while the proliferation and risk recovery mechanisms are characteristics of living organisms, which can never be neglected. This is the apparent reason why formulations that can make time transitions explicit are necessary. In risk assessment, it is not only necessary to assess the frequency of risk due to accumulated stimuli, but also to incorporate the risk-reducing functions of the organism and the associated ‘dose-rate effect’. Especially, in the medical world, cancer cells grow abnormally. Even during

treatment, a rational radiotherapy plan cannot be developed without an accurate picture of the cancer growth process. There have been many attempts to incorporate the proliferative effects, although most of which are indeed inconsistent. The exception are Jack Fowler's modified 'biological equivalent dose' (BED) and 'PSI model' (Harpold, 2007). However, they are still based on LQM and are incomplete as they cannot provide accurate time procedures. The, which has been long established as a standard of radiation protection. The main difficulty of the standard formulae, LNT/LQM is that the risk assessment is expressed as a function of the total dose, and the time evolution is totally hidden, while the proliferation and risk recovery mechanisms are characteristic of living organisms. This is why there is an essential need for a formulation that can make time transitions explicit. In risk assessment, it is not only necessary to assess the frequency of risk due to accumulated stimuli, but also to incorporate the risk-reducing functions of the organism and the associated 'dose-rate effect'. Especially, in the medical world, cancer cells grow abnormally. Even during treatment, a rational radiotherapy plan cannot be developed without an accurate picture of the cancer growth process. There have been many attempts to incorporate the proliferative effects, although most of which are indeed inconsistent, with the exceptions being f Jack Fowler's BED (Biological Equivalent Dose) (Fowler, 2010) and 'PSI model' (Enderling, 2020, 2022). Although they are still based on LQM and incomplete as they cannot provide accurate time procedures.

First let us introduce the famous notion, BED. The simple LQM model is represented as follows, which is quite a bit different from original hit model but in any case, we introduce arbitrary parameters, usually expressed as  $\alpha$  and  $\beta$ , so we simply express it as:

$$\text{Survival function: } S(D) = \exp[-E(D)], \quad E(D) = \alpha D + \beta D^2 \quad (1.1)$$

From this LQM formula, the system including the number of cancer of cells or volume of tumour.  $N_c(D)$ , caused by radiation treatment with total dose D, some of cells are killed, remaining the original cells with the ratio:

$$\frac{dN_c(D)}{N_c} = [\alpha + 2\beta D]dD \Rightarrow N_c(D) = N(D=0) S(D) \quad (1.2)$$

Now in the case of radiotherapy, we want to know how the number of cancer cells,  $N_c$  or tumour volume is reduced by the time scheduled irradiation, namely the time schedule of the exposure program with total dose D divided into n fractional doses per day. Then according to the traditional fractionation treatment, we get<sup>1</sup>:

$$E_n(D) = nE\left(\frac{D}{n}\right) = n\left[\alpha\frac{D}{n} + \beta\left(\frac{D}{n}\right)^2\right] = D\left(\alpha + \frac{\beta D}{n}\right) \quad (1.3)$$

This is quite different from the one with the LNT case. The index, BED (Biological Effectiveness Dose) was introduced to compare the effectiveness of n fractionated treatment.

$$BED = \frac{E_n(D)}{LNT} = \frac{D(\alpha + \frac{\beta D}{n})}{\alpha D} = nd\left(1 + \frac{d}{\frac{\alpha}{\beta}}\right) \quad (1.4)$$

where:

$$d = \frac{D}{n}$$

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<sup>1</sup> For the detailed criticism of this formula, see the separate ICRP2021<sup>+1</sup> report titled 'Example of the misleading results caused by LQ model in calculating the Fractionation Effect in Radiation Therapy'

This index is thought to take account of the effect of fractionated irradiation on cancer cell viability based on the LQ model of radiation biology and radiation oncology, and allows comparison of the effects and impact of radiotherapy using different doses and irradiation frequencies. Now, what is missing of this formula? People realised that during the interval with no irradiation time, tumour surely grows. To stop worrying about the difficulty of LQM, Jack Fowler proposed (Fowler, 1989, 2010) the following corrected BED by adding time-Dose evaluations:

$$\text{BED Modified by Fowler : } BED = nd \left( 1 + \frac{d}{\alpha} \right) - \frac{\log 2(T - T_k)}{\alpha T_p} \quad (1.5)$$

by introducing the so-called ‘time growth factor’,  $T$  is overall time with fractionations with each dose  $d$  and  $T_k$  and  $T_p$  being kick-off time and cell doubling time, respectively.

However, it is still incomplete, since they start from LQM and cannot give an exact time procedure. All the above-complicated treatments in both cases can overcome the LQM difficulty if we correctly take into account of time dependence.

## 2. FROM WAM TO SS (SEE-SAW) MODEL

### 2.1. WAM model

Let us make a brief review of the ‘Whack-A-Mole’ (WAM) model which describes the fate of normal cells into mutated cells (Bando et al., 2017,2019). The normal-cells become mutated cells by the coefficient  $A$  in the WAM model, while the biological system has the cell exclusion process such as cell death and mutated cells are removed frequently, with reaction rate,  $B$ , as shown by Fig. 1 Let the numbers of the mutated cells in a tissue or organ be denoted by  $N_m(t)$  starting from the normal cell number,  $N_0$ , the mutation frequency denoted by  $F(t)$  defined as:

$$F(t) = N_m(t)/ N_0 \quad (2.1)$$

where  $N_0$  is the number of normal cells which is in most cases almost constant since the mutation rate is of order,  $10^{-5}$  locus<sup>-1</sup>. Mutated cells are produced from the initial total number  $N_0$  via radiation exposure. The dynamical equation of the WAM model is expressed in terms of differential equation as:

$$\frac{dF(t)}{dt} = A - BF(t) \quad (2.2)$$

with the transition rates  $A$  (from the normal to damaged cells) and the exclusion rate  $B$  by the cell death process. This expresses the time dependence caused by the stimulus-response relationship. More concretely, under the external stimuli of radiation exposure with its dose-rate  $d$ :

$$\begin{cases} A = \alpha_0 + \alpha_1 d \\ B = b_0 + b_1 d \end{cases} \quad (2.3)$$

with the coefficients,  $a_1$  and  $b_1$  in addition to the endogenous reaction rates,  $a_0$  and  $b_0$  caused by the internal stimuli. Note that  $B$  represents all the cell exclusion effects, which is completely different from the LQM. Indeed, the mutation frequency decreases over time even after the irradiation stops.



The explicit dose rate dependence is essentially needed, and this very dose rate dependence can answer the question of why the famous animal experimental data show quite different behaviours between *Drosophila* data (Muller, 1927, 1932) and Mouse experimental data (Russell, 1951, 1963, 1965; Russell et al., 1958; Russell and Kelly, 1982a,b), respectively. Here, let us notice the remarkable fact that the above parameters, the coefficients,  $a_1$  and  $b_1$  in addition to the endogenous reaction rates,  $a_0$ , and  $b_0$ , are almost of the same order commonly obtained in *Drosophila* and mouse cases (Bando, 2019).

## 2.2. SS model; Application to cancer therapy

The dynamical behaviour of cancer cells is obtained just in the same procedure as the previous case, except that the number  $N_c$  of cancer cells, or equivalently tumour volume  $V_0$ . Since cancer cell is not controlled (Hanahan, 2011), the growth of tumour (cancer colony) gives the dominant dynamical contribution to the cancer colony, which is usually caused by damage to an oncogene or tumour suppressor gene. However, in an actual case of a cancer colony in a biological body, we here neglect small input contribution due to cancer cell incidence after a cancer cell is generated. Although a variety of discussions on such growth behaviour are reported (see (Kühleitner, 2019) for example), we here take a most reliable example as follows: in an actual case of a cancer colony in a biological body, we here neglect small input contribution due to cancer cell incidence once cancer cell is generated.

Although a variety of discussions on such growth behaviour are reported (see (Kühleitner, 2019) for example), we here take a most reliable example as follows:

$$\frac{dN_c}{dt} = \lambda \left(1 - \frac{N_c}{N_m}\right) N_c \quad (2.4)$$

where  $N_m$  is the maximum number of cancer cells in a tumour. By combining the cell growth and the WAM equation, we have the following equation for cancer therapy,

$$\frac{dN_c}{dt} = (\lambda - B) N_c \left(1 - \frac{N_c}{N_m}\right) = (\lambda - B) N_c^{active} \quad (2.5)$$

Here we have neglected the small contribution coming from  $A$  which is negligibly small compared with proliferation rate  $\lambda$  with  $B$  term (2.3) coming from the dominant cancer therapy. Note that we have only 3 parameters to be determined from observed data,  $\lambda - b_0$ ,  $b_1$ , and  $N_m$ .

## 2.3. WAM and SS: Comparison conceptual diagram

Leaving the details in our paper, we here just compare two figures, WAM (left) with the system of mutated cells and SS with the one of cancer cells (right).

It is really interesting to have been led to a unified understanding of the biological effects caused by radiation exposure with the parameters can be almost of the same order irrespectively of the species of the organism. The SS model can follow tumour growth as well as the effect of radiation exposure over time describing tumour changes according to the irradiation plan. The essence is just to describe in terms of the differential equation.

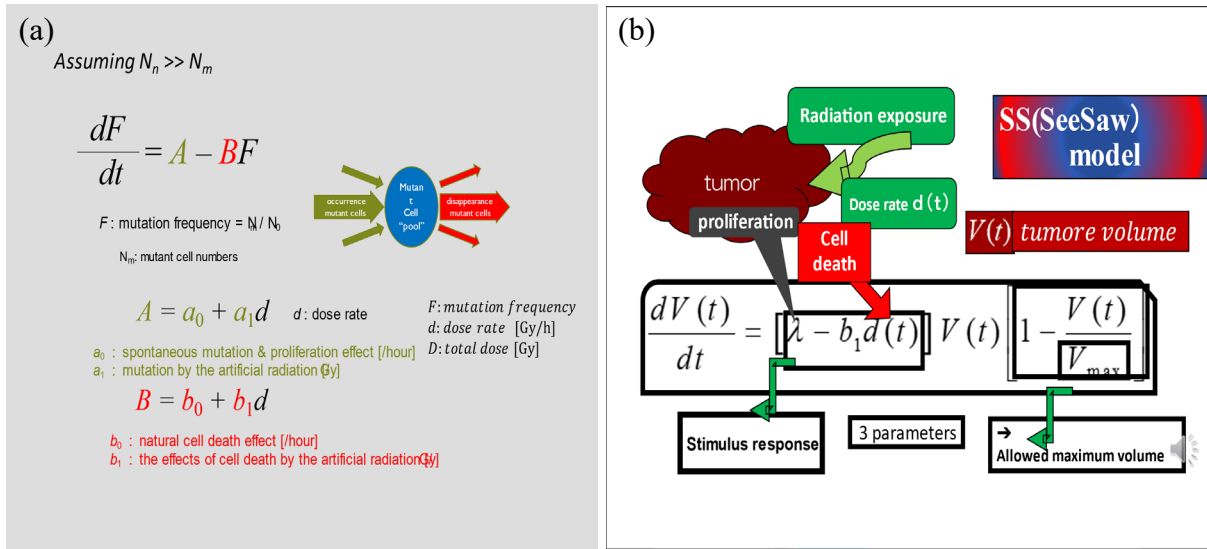


Fig. 1. (a) The schematic structure of ‘Whack-A-Mole’ (WAM), where the mutation frequency obeys the differential equation derived from stimulus response reaction process. A and B are the reaction rate from normal cell to mutated cell and cell exclusive rate (including cell death rate) of mutated cell, respectively. Those parameters include dose rate independent and dependent contributions. (b) The structure of See-saw (SS) formula, where the time dependence of tumour volume  $V(t)$  obeys the differential equation with respect to time  $t$ , proliferating according to the proliferation rate  $\lambda$  and decreasing due to the radiation exposure  $b_1$ . We introduce an additional suppression term because the tumour volume is known to stop proliferation when it approaches to its maximal volume.

### 2.4. Typical figures of tumour volume change calculated from SS

The comparison of the SS prediction is shown for the cancer volume as a function of time due to the cancer treatment with the real hospital data. We here pick up two typical examples of the data of non-small cell lung cancer (NSCLC) patients, where the time dependence of the tumor volume of each patient is available, which are shown by points normalised to the initial volume (100%). One is named as ‘patient 6’ and the other is ‘patient 9’ (Sunassee et al., 2019). The time schedule of radiation exposed (yellow zone) with a total dose of 2 Gy per day in working days with no irradiation on weekends (blue zone). The parameters we take are the growth rate  $\lambda = 0.045 \text{ day}^{-1}$ , which is kept the same for these two cases, and  $b_1 = 0.045 \text{ Gy}^{-1}$  and  $V_m = 250\%$  of the initial volume for patient 9 (left figure), and  $b_1 = 0.085 \text{ Gy}^{-1}$  and  $V_m = 103\%$  of the initial volume for patient 6 (right figure). The tumour growth can be clearly recognised during the weekend.

## 3. TOWARDS BEYOND LQM

There have been many attempts to incorporate proliferative effects in the medical field, all of which are found to contain inconsistent treatments, except the ‘PSI model’ (Enderling, 2020, 2022) and Jack Fowler’s BED. From the scope of SS formulation; ‘PSI model’ (Enderling, 2020, 2022); This exactly describe t dependent cell Proliferation process while it adopts instant approximation by using traditional LQM to describe the radiation effects.; Jack Fowler’s BED (Fowler, 1989,2010) uses essentially time independent LQM formula and take overall proliferation effect through the time interval of clinical treatment. in this sense both are just approximate formula which can be applied to the limited cases and still incomplete so far as the formulation is based on LQM without the information of time procedure. On the other hand,

SS model can follow tumour growth over time and can describe tumour changes that accurately reflects the irradiation plan.

**Examples of Real clinical data :We can reproduce that the tumor grows during the weekend when radiation therapy stops.**

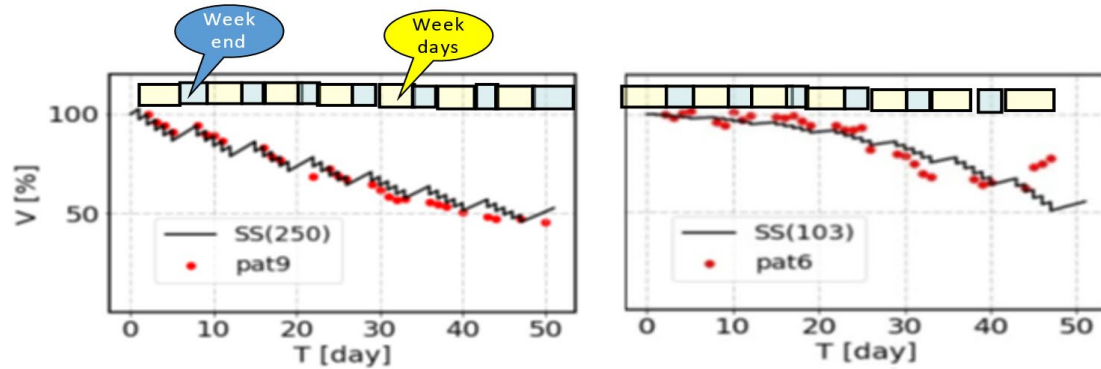


Fig. 2. Examples of clinical data on the time dependence of tumour volume caused by radiation therapy. The time schedules are shown in the upper parts of the figures with white and blue periods are irradiation and no radiation exposure in the weekends, respectively. Tumour growth can be recognised during the weekends with no radiation therapy. The predicted results derived by our model (black lines reproduce the observed data (red points).

We hope to organise an international network to validate the model and further pave the way for practical application. We would like to emphasise that our SS model leads us not only with a unified description of radiation therapy but also indicates the misleading principle based on LNT or LQM hypothesis which is still adopted in the society of radiation protection. In this sense, we think the important issues to be reviewed for LQM for the next ICRP Publications are:

- 1) It should take account of temporal changes of biological effects of radiation.
- 2) It must explain correct dose rate effects (DDREF is not sufficient).
- 3) We have not yet determined the reasonable value of the relation of RBE and radiation weighting factor (for protection) for high LET radiation.

Of course, there are still many issues to be considered. For example, our model assumes that cancer cell death is directly reflected in measured cancer volume immediately, but in reality, a time delay is required for cell death to be reflected in volume and we need to include that formulation as well (Yonekura et al., 2023). It is necessary to formulate a more accurate treatment plan through such precise consideration. Moreover, the biologically-based mechanism of carcinogenesis, especially from mutation (Maki, 2002) to carcinoma (Rühm et al., 2015), is not well understood. We are arranging the collaboration with the members of the radiation therapy sectional group of Osaka International Cancer Institute and will report detailed results in near future. Further we hope to organise an international network including Heiko group<sup>2</sup> to validate the model and pave further steps to find the way for practical application.

<sup>2</sup> <https://moffitt.org/research-science/researchers/heiko-enderling/>

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## Thyroid and lens absorbed dose assessment during different interventional and surgical procedures: a multicentre study

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**Abstract**—A priori estimation of staff exposure during medical interventional procedures involving the use of ionising radiation is essential to carry out an adequate risk assessment and, therefore, to define the maximum workloads, to choose appropriate dosimeters and additional shielding. To date, research activity has been mainly focused on cardiac procedures, which involve high dose rates, and much attention is paid to the optimisation of radiation protection in this field. The purpose of this retrospective study was to evaluate the dose exposure of different healthcare professionals starting from the Dose Area Products (DAPs) recorded after various interventional (non-cardiac) and surgical procedures. A total of 374 operators, 2829 interventional procedures and 4463 surgical procedures were considered. Estimated thyroid/lens absorbed dose (median-75%) for surgeons/interventionists were as follows ( $\mu\text{Sv/procedure}$ ). Interventional procedures: endoscopy (107–121)/(85–97) and urology (60–130)/(48–104); surgeries: vascular (68–73)/(55–60), general (28–35)/(22–28), orthopaedic (6–9)/(5–7). After grouping the data of all the procedures, the same estimations are reported for anesthesiologists (15–29)/(13–25), nurses (13–24)/(11–20) and radiographers (15–32)/(12–26).

**Keywords:** Thyroid; Lens absorbed dose; Interventional and surgery procedures

### 1. INTRODUCTION

The use of ionising radiation in medical imaging, both in diagnostic imaging and in support to interventional and surgical procedures, has been growing in the last years (Midulla, 2019). In general, it is difficult to a priori estimate the exposure of the staff involved in these procedures, as this exposure depends on many variables, like surgeon position, x-ray tube position, etc. Nonetheless, a priori staff exposure estimation is needed in order to define the maximum workload, to choose appropriate dosimeters and to provide appropriate additional shielding (i.e. lead apron, leaded ceiling, etc). To date, research activity has been mainly focused on cardiac procedures, which involve high dose rates, and much attention has been paid to the optimisation of radiation protection in this field (Betti, 2019). However, other procedures can involve significant exposures for workers (Vecchia, 2020). Given this background, the purpose of this retrospective study was to evaluate the dose exposure of different healthcare professionals starting from the Dose Area Products (DAPs) recorded after various interventional (non-cardiac) and surgical procedures, to estimate thyroid and lens absorbed dose for each procedure to be used in future risk assessments.

### 2. MATERIALS AND METHOD

The following parameters were recorded for each surgical and interventional procedure using an automatic software (OrmaWeb, Dedalus Italia s.p.a.): tube voltage, tube current,

exposure time, imaging technique, tube position, DAP. Staff composition (number of surgeons, nurses, etc.) was recorded as well. Data were collected from five different hospitals during all 2020. The following procedures were considered in the study: interventional gastrointestinal (GI) endoscopy, interventional urology; vascular, orthopaedic and general surgery. To estimate the radiation scattered by the patient, a scattering angle of  $140^\circ$  was considered (Fig. 1). Thyroid and lens absorbed dose were calculated for the surgeons/interventionists, anesthesiologists, nurses and radiographers, considering the recorded DAP, the average x-ray tube voltage and the average position during the procedure, following the method described in NCRP 147 (NCRP, 2004). The effects of additional shielding, like protective glasses, thyroid shielding, etc, are not considered in this dose estimation. For each type of procedure, descriptive statistic of surgeons/interventionists thyroid and lens exposure was finally obtained, while data recorded from different procedures were grouped together for anesthesiologists, nurses and radiographers statistical analysis on exposure data.

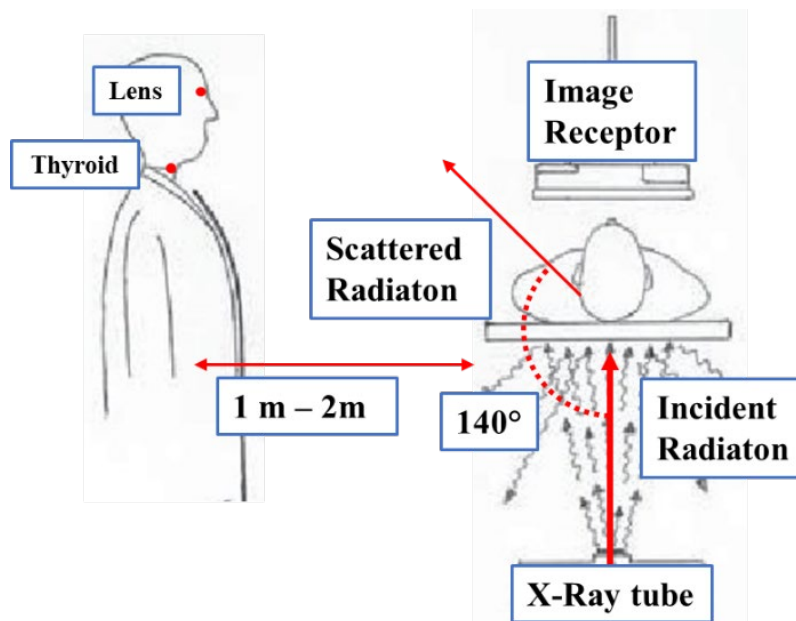


Fig. 1. Surgeon/interventionist, patient and X-ray tube considered positions for exposure assessment.

### 3. RESULTS

A total of 2829 interventional procedures, 4463 surgical procedures and 374 workers were considered in this study (Fig.2). Median and 95<sup>th</sup> percentile of thyroid and lens absorbed dose ( $\mu\text{Sv}/\text{procedure}$ ) for each healthcare professional and for each procedure are reported in Table 1, Table 2 and Figure 3. A large variation of lens absorbed dose both inter- and intra- procedure (especially in urological procedures and for radiographers) is shown. Large dose exposures were found in GI endoscopic procedures and vascular surgeries, with estimated values in agreement with literature [around  $60 \mu\text{Sv}/\text{procedure}$  (Martin, 2013)]. The lowest exposures were found in orthopaedic surgeries.

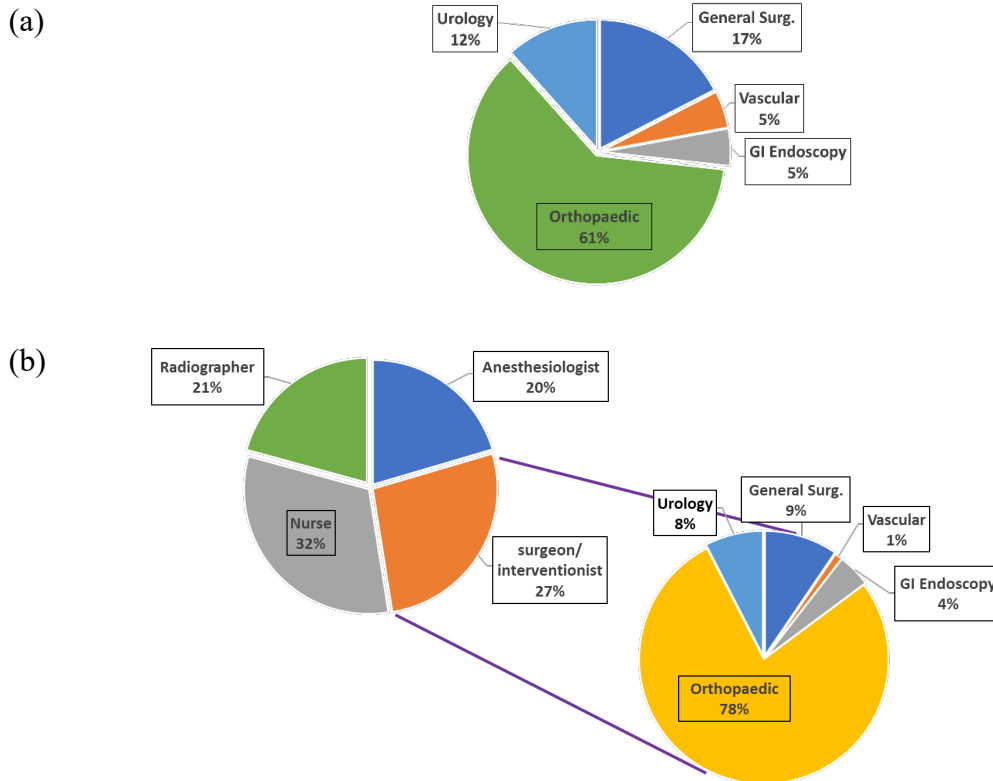


Fig. 2. Details on interventional/surgical procedures (a) and staff (b).

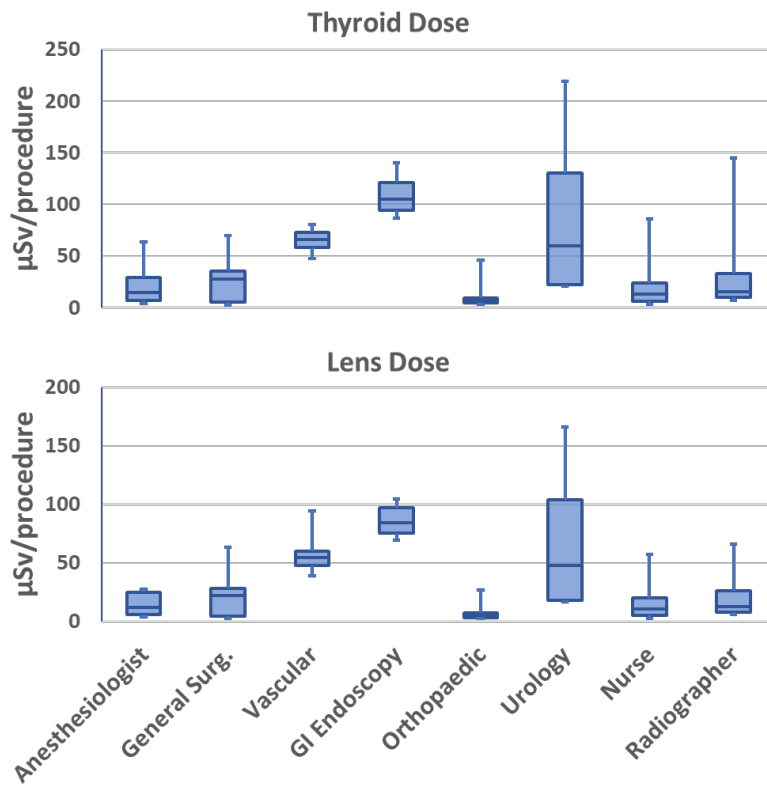


Fig. 3. Box plot showing thyroid and lens dose distributions for surgeons/interventionists for each procedure (general and vascular surgeries, GI endoscopy, orthopaedic and urological interventional procedures) and for anaesthesiologists, nurses and radiographers obtained grouping the data from all the considered procedures.

Table 1. Median and 95th percentile of the surgeon/interventionist estimated thyroid and lens absorbed dose for each procedure.

Surgical/interventional procedure	Median/95 <sup>th</sup> percentile ( $\mu\text{Sv/procedure}$ )	
	Thyroid Dose	Lens Dose
General Surg.	28/70	22/56
Vascular	68/81	55/65
GI Endoscopy	107/140	85/112
Orthopaedic	6/46	5/37
Urology	60/219	48/175

Table 2. Median and 95th percentile of the anesthesiologists, nurses and radiographers estimated thyroid and lens absorbed dose obtained grouping the data from all the considered procedures.

Operator	Median/95 <sup>th</sup> percentile ( $\mu\text{Sv/procedure}$ )	
	Thyroid Dose	Lens Dose
Anesthesiologist	15/64	13/51
Nurse	13/86	11/69
Radiographer	15/145	12/175

#### 4. DISCUSSION

The results obtained in this study are comparable to other reported in previously published articles (Martin, 2013; Betti, 2019; Vassileva, 2021; Meijer, 2022) and may represent a reference to carry out future a priori risk assessments. GI endoscopic and urological procedures can involve high exposures for healthcare professionals, albeit with a considerable variability, and therefore should be carefully optimised. Exposure of workers in vascular surgery is relevant, but lower than that in gastrointestinal endoscopic and urological procedures: the low number of considered vascular procedures (only 60) may limit this result.

#### 5. CONCLUSION

In general an accurate a priori exposure estimation is useful to evaluate the maximum allowed workload. Considering the reported 95<sup>th</sup> percentiles it is possible to estimate the maximum number of procedures that each operator can perform without exceeding annual dose limit to the lens (20 mSv). These values can be corrected if additional shielding (for example suspended ceiling or protective glasses) are employed.

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## Developing a system of protection that supports effective optimisation of exposures at low doses - the nuclear industry perspective

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**Abstract**—The nuclear industry has had an impressive record of reducing occupational exposure. With numerous optimisation processes radiation exposures became extremely low, with worker exposures comparable to natural background radiation and public exposures at tiny fractions of it. As radiation is only one among many risks we are exposed to, it should not be considered in isolation from other types of hazards. ICRP should make greater efforts to ensure that the system of protection recognises the full interaction between all relevant risks and benefits. The system of protection should aim to be understandable to non-specialists, and any proposed changes should avoid additional complexity, thereby reducing practicability. Most RP decisions in practice relate to low exposures at levels within the variability of natural background radiation. At these low levels the risks are uncertain, but at worst are what is generally regarded as very low. Whilst the need for prudence is recognised, there is also a need for proportionality and a wider context in decision-making which recognises the universal presence of natural background radiation. There is also a challenge of over-conservatism, both in approaches to dose assessments and in regulatory expectations. More emphasis is necessary on the practical application of a graded approach.

*Keywords:* Graded approach; All-hazards approach; Practicability; Optimisation; LNT

### 1. INTRODUCTION

With numerous processes for optimisation the international nuclear industry has for many years had an impressive record of controlling and reducing occupational exposure, as measured by average individual exposure and collective dose. Whilst there are variations across the individual sectors within the nuclear fuel cycle, the industry has been able to demonstrate the central importance of exposure optimisation, and the nuclear industry has in fact been the leading sector across all industries/employers in this respect. Current worker exposure levels are comparable to natural background radiation, average worker doses are well below 1 mSv year<sup>-1</sup> (UNSCEAR, 2010, 2022), which is within the variability of natural background radiation.

Impacts to the environment through radioactive releases or waste are very well controlled and ongoing monitoring show that radiological impacts remain well within acceptable regulatory standards. Exposures to the general public are in the order of a few microSv year<sup>-1</sup> at maximum for the most exposed persons (Rochedo, 2009) and make no real difference to the total individual exposure. They are about 3 orders of magnitude below mean natural background radiation and are less than the radiation dose of one return long-haul round-trip flight. Nevertheless, these doses are often questioned, whereas decisions impacting radiation exposure made on a day-to-day basis by individuals are mostly not challenged.

However, regulations derived from the system of protection tend to require operators to further reduce these low-level exposures to even lower levels, without there being a clear net health and safety benefit.

The Fukushima Daiichi nuclear power plant accident showed that even under accidental conditions doses to emergency responders were kept below levels where deterministic effects are likely to occur. With all actions taken, average effective doses to the general public were kept below 20 mSv in the first year (UNSCEAR, 2014), which corresponds to the upper level of annual natural background radiation. The same holds true for estimated lifetime exposures.

## 2. OPTIMISATION IN PRACTISE – THE RP PERSPECTIVE

With the current system of radiological protection, and its pillars of justification, optimisation and limitation, RP practitioners do have guidance on how to protect workers in their daily task. These might be very simple and easy actions like avoiding people standing close to a source. Even if such actions may only save a few microSv, with no effort they are still proportionate.

In other cases, and for workplaces that cannot be moved away from a source, single or combined actions are useful to reduce the corresponding radiation levels, like the use of shielding, such as specific lead shapes for nozzles (see Fig. 1), or a combination of water in and lead shields on plant components (see Fig. 2). Dose rate reductions of more than 1 order of magnitude can be achieved in many cases. For nuclear safety reasons, lead shielding often needs to be removed for power operation and re-mounted for inspection or maintenance.

Other types of engineering controls can be used to reduce radiation exposures. Adjusting water chemistry in nuclear power plants and ventilation in mines are examples of reducing the radiation source term. The use of remote technologies for inspection, non-destructive testing, maintenance or decommissioning can eliminate or reduce the time workers need to work in proximity to radiation sources and is a very effective dose reduction strategy. Digitisation is an upcoming new technology for further potential dose reductions as it will influence training and pre-job activities (virtual training).

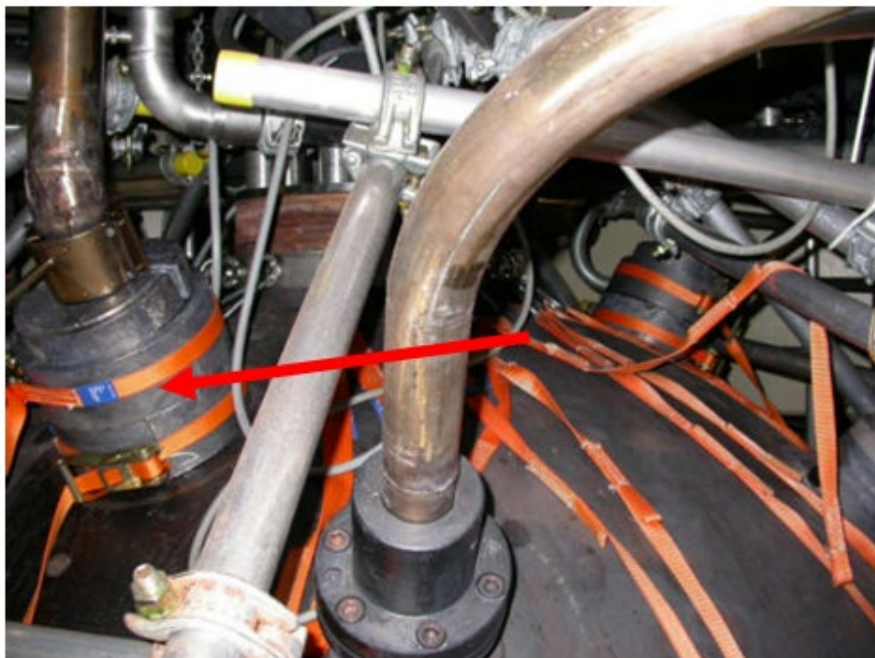


Fig. 1. Shielding of a pressuriser nozzle (Source: Goesgen NPP).

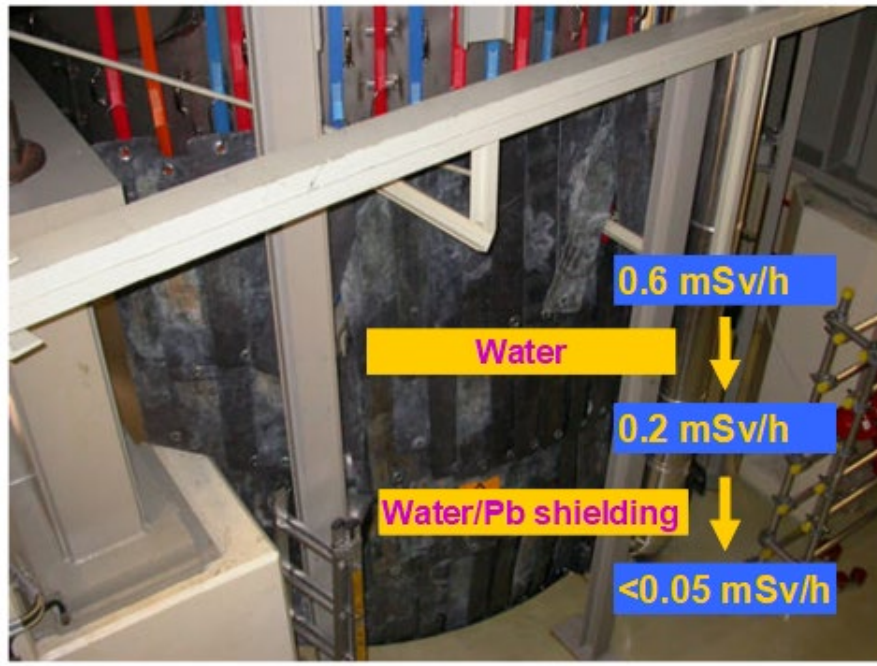


Fig. 2. ‘Water/lead’ shielding of a steam generator (Source: Goesgen NPP).

In total the continuous application of such processes led collective doses, maximal and average individual doses to drop significantly over the years (see Fig. 3 and 4) (UNSCEAR 2010, 2022; OECD-NEA, 1999, 2000, 2001, 2002, 2004, 2005, 2006, 2007, 2008, 2009, 2010a,b, 2011a,b, 2012, 2017a,b, 2018a,b, 2020, 2021).

Mean individual doses for workers dropped to a level which is less than the variability of natural background radiation. For the general public doses were always low and do not really affect their individual exposure. The only issues that have arisen for the general public were impacts in the vicinity of military installations in the very early use of nuclear technologies and the two accidents in Chernobyl and Fukushima.

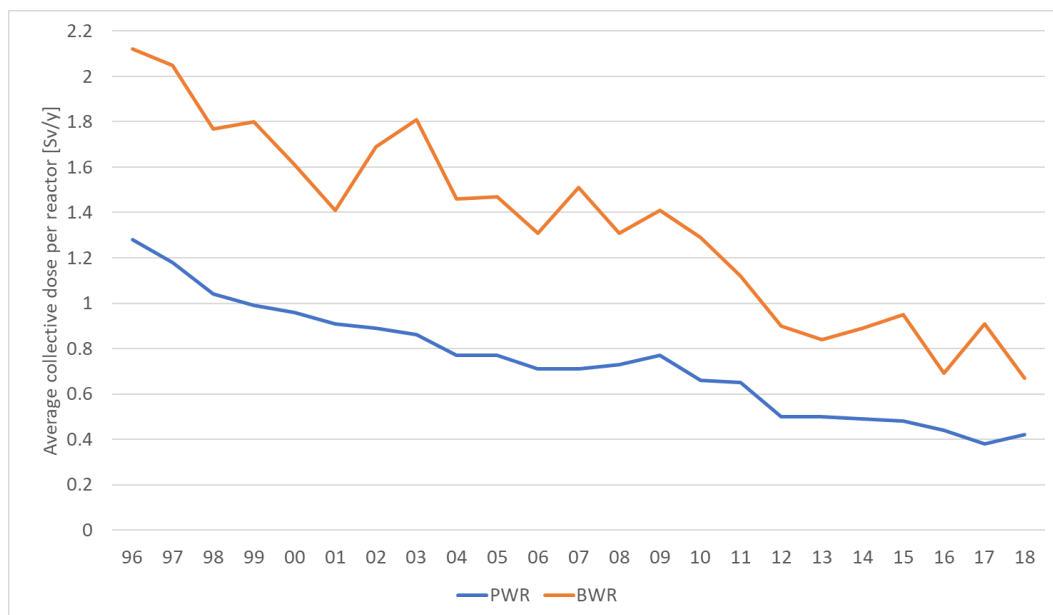


Fig. 3. Average collective dose per reactor (PWRs / BWRs) (Source: ISOE).

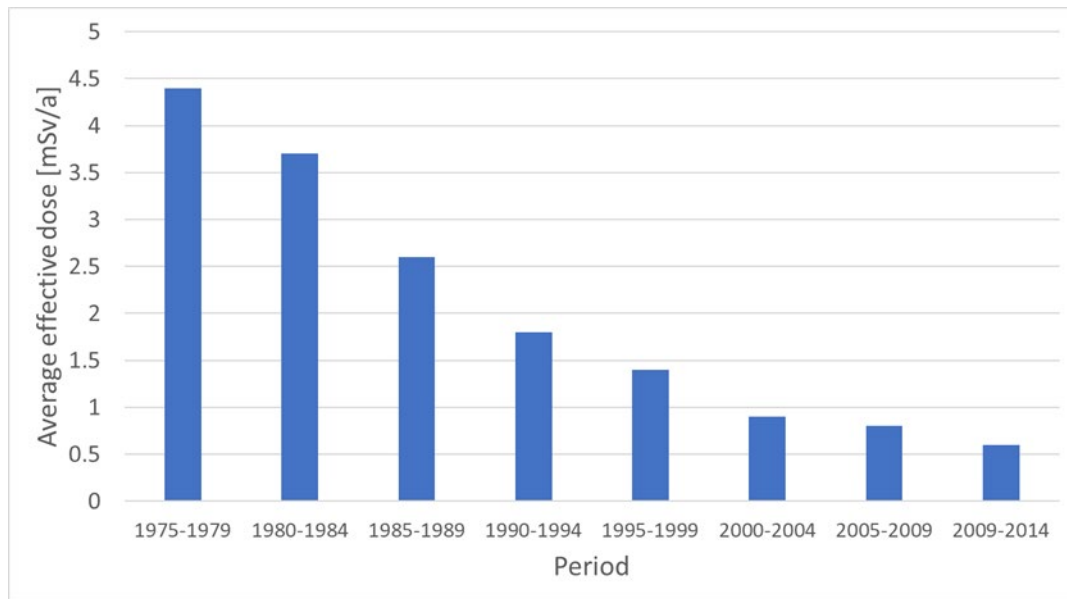


Fig. 4. Average doses to nuclear industry workers (Source: UNSCEAR).

### 3. PUBLIC PERSPECTIVE

The general public is often not aware about the existence of natural radiation sources and/or the use of radiation in medicine, but they are aware about ionising radiation from the nuclear industry. Combined with global cultural changes on how society is responding to a variety of risks, there is an ongoing pressure to further reduce radiation exposures. The initial ALARA philosophy is moving more and more towards a continuing expectation that optimisation is equivalent to reduction. Interestingly, such a public pressure is much less pronounced in other fields where ionising radiation is applied (medical sector for example). In fact, it seems that people are often questioning the radiation source that contributes the smallest fraction of their radiation exposures the most. There are numerous reasons for this, including inferences drawn from imbalanced and inconsistent regulatory requirements, overly conservative dose calculations and a general lack of awareness of some basic radiation science (e.g. existence and magnitude of natural background radiation).

Furthermore, for the public and to some extent even for RP practitioners, the system of protection has indeed become complex and not easily understood. For example, the use of dose limits, constraints, and reference levels and their varying applicability to normal, emergency and existing exposure situations are confusing even for RP practitioners and even more for those who are not regularly confronted with RP issues. Complexity also decreases practicability. Some degree of simplification could be envisaged to help promote a better understanding of the RP system, which in turn would contribute to better decision making. It is self-evident that the pillars of the RP system must remain intact.

### 4. OPTIMISATION – A BROADER VIEW

There is a need for wider acceptance and recognition that optimisation means optimisation of the total risk (and benefits) in any situation. Often it goes much wider than radiation considerations. Additionally, there are broader global and social hazards that need to be included in the discussion on optimisation.

With doses becoming lower and lower, radiation hazards have become less dominant, and optimisation needs to be seen increasingly in a broader view. As radiation is only one among

the many risks we are exposed to, it should not be considered in isolation of other types of hazards. The risks and benefits from any radiation source must be judged alongside all other types of risks and benefits which are relevant to any decision. For workforces, other hazards might be mechanical, biological, chemical, or simply a question of conventional industrial safety. For example, workers mounting and dismounting lead shields often need to do that manually and hence this radiation protection measure introduces ergonomic and conventional safety risks. These risks need to be balanced against the benefits from dose savings of other workers.

Different hazards for the general public include atmospheric pollution, climate change, flooding, drought, etc. Climate change is an example that is already creating upheaval in our society and is on course to cause a tremendous impact on our planet and human society, far more than any small change in radiation exposure ever will. Questions like 'is it sensible to phase out nuclear and as a consequence to increase greenhouse gas emissions by fossil fuel power production' need a more rational thinking. The link to achieving sustainability in our decision-making is an important dimension for the system of protection.

A general observation is that recommendations and standards do address optimisation but do mostly not address explicitly such a broader view and consequently regulation is focused solely on the radiation risks and not generally consider the broader health, safety and environment hazards.

ICRP should make greater efforts to ensure that the system of protection is not uniquely radiation-centric but recognises that a more fulsome 'all-hazards approach' that facilitates better comparisons and interactions between different types of hazards and their associated risks and benefits will stand for optimised overall safety. Interfaces are needed to other areas of expertise and other regulatory bodies.

## **5. CURRENT CHALLENGES WITH LOW DOSE OPTIMISATION**

Most RP decisions in practice relate to very low exposures at levels within the variability of natural background levels. At these low levels the risks are uncertain, but at worst are what is generally regarded as very low. Whilst the need for prudence is recognised, there is also a need for proportionality and a wider context in decision-making, recognising the universal presence of natural background radiation. Further work that better understand the variations in natural background may assist in proportionality in decision making.

There is currently also a challenge of over-conservatism. Assumptions, models or calculations, each of them derived conservatively and usually in combination, result in over-conservatism in recommendations. Often regulators and practitioners add additional conservatism to guarantee compliance. This leads to a misallocation of resources, especially when recommendations do not distinguish between application at levels of tens of mSv or a few microSv. The opportunity to use more accurate assumptions in dose modelling should be encouraged, rather than the continual desire to assess 'worst case', particularly when this is being done for such low doses.

The graded approach to regulation is potentially the however in practice, it is rarely used effectively. Work can be done to understand why and to provide guidance and tools that will improve decision making. More emphasis is necessary on a graded approach, and in particular its practical application. Doses and dose rates within or lower than the variability of natural background radiation need less focus.

The use of the linear-non-threshold (LNT) model builds the basis for protection, which is accepted by the relevant international organisations and forms the underpinning for regulation. For several reasons the World Nuclear Association (WNA) supports the LNT approach. But it is to note that LNT is not claimed as a scientific hypothesis – it is just a convenient model on

which to base a system of protection, given the current scientific uncertainties. It does not have to be scientifically correct, and there is no claim that every type of radiation causing any type of cancer is actually linear all the way down. Some types of radiation causing some types of cancer are likely to be more linear than others (and some may even have a threshold). This is why a simple model is necessary for protection purposes – scientific fact-finding is too uncertain for this purpose. However, LNT has the potential to reinforce the belief that risks at low doses are significant (‘there is no safe level of radiation’). But noting the current limitations of the science at low dose, a truer statement for low dose would be that ‘if there is a risk, then indeed it is very small and bounded, and well within the range of risk usually accepted in society’. On this basis WNA argues that, whilst accepting LNT in principle, there must be wider inputs to decision-making at low dose. For this purpose, WNA recommends a need to better implement a graded approach into the system in order to attain reasonable proportionality. This would help to concentrate optimisation where its benefit is biggest and will prevent practitioners from spending too much time in administrative paperwork when dealing with low or very low doses.

## 6. PRACTICABILITY

The system of protection should aim to be understandable to non-specialists, and any proposed changes should avoid additional complexity. Indeed, some degree of simplification should be envisaged. As mentioned above, the system of dose limits, constraints and reference levels is confusing for those who are not regularly confronted with RP issues. Any changes to the system of protection must result in a clear benefit to health and safety and be practicable and proportionate in implementation.

In the field, practitioners need a few simple variables to be able to give adequate protection in due time. A system more heavily based on gender, age or even individual sensitivity might be interesting from a scientific perspective but is not manageable in practice. For similar reasons the implementation of changes in dose quantities need to be considered carefully. Under laboratory conditions the new quantities may provide better accuracy in dose measurements, but in the field the benefits may well be much less and the additional expense significant, casting doubts on the real benefit. Any change to the system of protection must result in a clear benefit to health and safety and be practicable and proportionate in implementation. Here again, the quick and adequate response to an occurring situation is the underpinning pillar of optimisation and protection in practice.

## 7. CONCLUSIONS

In accepting responsibility, the nuclear industry has for years controlled and reduced occupational and public exposure to ionising radiation to sufficiently low levels such that any risk is uncertain and not verifiable. At the same time the system of protection has evolved according to new scientific insights and societal developments, thereby adding complexity to it.

The Linear No Threshold Model is still the best basis for developing a system for the purposes of protection but implies a weighted bias of unverifiable risks at low doses. Other risks might be more dominant but get less attention. From an overall safety perspective this is not optimised and needs adjustment. The nuclear industry therefore recommends an all-hazards approach for the future system of protection that allows an interaction between all relevant risks and benefits to ensure best overall safety for workers and the public.

While accepting the Linear No Threshold model as the best option for the purpose of protection, the nuclear industry recommends implementing a more realistic graded approach which is much more proportionate to risks and which results in less emphasis on low doses.

It is also recommended that a future system of protection applies primarily for applications in the field and should not focus on hypothetical laboratory situations.

Industry is committed to effective optimisation of the overall safety risk and is convinced that incorporating these recommendations into the next system of protection will attain a proportionate balance between risk and the use of societal resources.

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## Radiation protection strategies in high-grade underground uranium mines

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**Abstract**—Mining high-grade uranium ore in an underground environment presents a number of potential challenges and exposure sources that must be addressed and controlled. Specific sources include radon progeny, gamma, and long-lived radioactive dust (LLRD). Workplace conditions, including grade and proximity to ore, worker positioning, and shielding impact gamma exposure potential, while ground conditions and the presence of radon gas in water can create highly temporal and spatially variable radon progeny conditions. High-grade uranium ore grade also presents a strong source term for LLRD that must be controlled. Cameco has implemented numerous physical and administrative control strategies in an integrated fashion to address these hazards. These controls start at the design of the mine and extend into operational practices. The radiation protection program provides the overall framework that guides the various activities including training of workers and radiation protection staff, dosimetry and engineering monitoring programs, research into better characterisation of hazards, shielding design and administrative controls. Cameco has continued to optimise radiation protection strategies in high-grade underground uranium mining environments over the past two decades and has kept doses well below the national dose limits and implemented numerous ALARA initiatives to further lower doses where practical.

*Keywords:* Uranium mining; ALARA; Operation controls

### 1. BACKGROUND

Underground uranium mines in Canada's Athabasca Basin, located in the northern portion of Saskatchewan, are largest high-grade deposits in the world, with grades 10 to 100 times higher than those found in the rest of the world. Most of the world's uranium deposits have an average grade below 0.1% uranium, with a small number between 0.1% and 1% uranium. Cameco Corporation, located in Saskatoon, Saskatchewan, is the operator of three of the highest-grade underground mines in the world, shown in Fig. 1. First, the Eagle Point mine (part of the Rabbit Lake operation) began production in 1994, with annual average ore grades between 1994 and 1998 ranging from 0.9% to 2.2% uranium. In 1999, the McArthur River mine began production with planned ore grades of 15% uranium in the initial production years and with production grades of about 10% in its most recent full production year. Finally, the Cigar Lake mine began production in 2015 and became the world's highest grade mine, producing at over 15% uranium in its most recent production year.

High-grade mines present several challenges compared to lower-grade mines, in particular the magnitude and variability of the sources of radiation. Each of the sources, gamma, long-lived radioactive dust, radon progeny and radon gas, must be addressed and controlled in order to allow workers to safely operate these facilities. This paper will discuss those sources terms as well as key control strategies employed by these facilities, to manage and control doses to workers.



Fig. 1. The location of Cameco's three underground uranium mines, Rabbit Lake, McArthur River and Cigar Lake.

## 2. RADIATION SOURCES AND ENGINEERING CONTROLS

Uranium-238 ( $^{238}\text{U}$ ) is the head of a decay series that includes 14 radioactive decay products. These decay products are all present in equilibrium in uranium ore prior to it being extracted from the ground. Most of these decay products contribute to the gamma field produced by the ore. Of the 14 decay products, there are five long-lived alpha emitters that can contribute to internal dose. Finally, radium-226 ( $^{226}\text{Ra}$ ) and radon-222 ( $^{222}\text{Rn}$ ) are part of the  $^{238}\text{U}$  decay series, resulting in the presence of both radon gas and radon progeny in the air within the mines. Each of these sources must be controlled to ensure the safety of workers.

### 2.1. Gamma radiation

Gamma radiation coming from uranium ore is proportional to grade, with the general rule-of-thumb for large sources being  $45 \mu\text{Sv hr}^{-1}$  per %  $\text{U}_3\text{O}_8$  on contact. Large sources such as tanks, ore embedded within the walls of underground tunnels, or a large spill can have a dose rate of several 100 to more than  $1000 \mu\text{Sv hr}^{-1}$  on contact. As with other types of facilities, the primary control strategies for gamma radiation are time, distance and shielding. In terms of shielding, a common strategy in underground mines is a sprayable concrete-based material called shotcrete. It is applied to the surfaces (sides and ceiling) of underground tunnels to provide ground stability and to shield gamma being emitted from the ore behind it. In higher grade mines, such as McArthur River and Cigar Lake, the underground tunnels cannot transect the ore zone. They must be located outside the ore zone, typically above and below, with only the mining equipment entering the ore zone. When large tanks are needed to store high-grade ore, these tanks are typically encased in concrete to provide shielding. In cases where there are smaller sources, steel or sometimes even water can provide effective shielding. Distance is typically incorporated by using remote equipment. This can be line-of-site operated equipment or fully remote. Time is typically reduced through administrative controls such as working time limits

## 2.2. Long-lived radioactive dust (LLRD)

The  $^{238}\text{U}$  decay series contains five long-lived alpha emitters:  $^{238}\text{U}$ ,  $^{234}\text{U}$ ,  $^{230}\text{Th}$ ,  $^{226}\text{Ra}$ , and  $^{210}\text{Po}$ . These create an inhalation hazard, with the dose potential of 20% grade ore being comparable to pure uranium concentrates. LLRD is generally produced through physical or mechanical activities, such as blasting, drilling, grinding, or high-pressure washdowns. It is also possible for LLRD to be produced or aerosolised while doffing of personal protective equipment. Reduction strategies to prevent LLRD becoming airborne include wetting or misting of work areas and local ventilation to collect dusts. High-volume mine ventilation is the primary to control to collect and remove any airborne LLRD from the general mine air. Additional controls to address tasks where dusts are created include remote equipment and use of personal protective equipment.

## 2.3. Radon gas and radon progeny

Radium 226 ( $^{226}\text{Ra}$ ) is part of the  $^{238}\text{U}$  series. It decays into  $^{222}\text{Rn}$  within the rock matrix and some of that  $^{222}\text{Rn}$  can be transported via groundwater to the mine openings. While the  $^{222}\text{Rn}$  remains under pressure inside the rock, it remains in solution. Once it reaches the mine openings, the pressure is released, and most of the radon is released into the mine air. The  $^{222}\text{Rn}$  then begins to decay into its short-lived decay products, the radon progeny. In addition,  $^{222}\text{Rn}$  can be released directly from the rock through fractures within the rock and activities such as blasting.

$^{222}\text{Rn}$  and radon progeny are the most variable radiation sources within an underground uranium mine and are actively monitored with continuous detectors placed throughout the facilities. In high-grade mines,  $^{222}\text{Rn}$  concentrations in water can exceed  $10^9 \text{ Bq m}^{-3}$ . With this extremely high source term potential,  $^{222}\text{Rn}$  must be actively controlled to limit its concentration in air and the resulting radon progeny concentration. Ventilation is the primary control for  $^{222}\text{Rn}$  and radon progeny. These mines use very high volume, single-pass air to quickly remove the  $^{222}\text{Rn}$  before it can accumulate significantly or decay to radon progeny. Additional control strategies include grouting fractures in the rock to divert water, piping to collect it and direct it to a safe area and freezing to prevent groundwater movement. These strategies combine to limit radon progeny concentrations to below 0.1 working level (WL) in active work areas.

However, based on location, the activity occurring in an area, or during upset conditions it is possible for  $^{222}\text{Rn}$  to reach several 10s of thousands of  $\text{Bq m}^{-3}$  and radon progeny to reach several or even more than 100 WL. During these types of situations, additional controls are required, such as respiratory protection or remote equipment, to ensure worker safety.

## 2.4. Predictive modelling and mine design

Knowledge of the types, locations and magnitudes of the various sources is critical to mine design, planning, as well as mining method selection. Prior to starting a new mine or making significant changes, it is important to understand and predict, to the extent possible, what the radiological conditions will be to ensure the mine is designed to meet regulatory requirements and ensure worker safety. Shielding requirements are typically modelled using either MicroShield or MCNP, with key input parameters being grade, geometry and locations of sources, and nature of shielding.  $^{222}\text{Rn}$  and radon progeny are modelled using a custom-built software called Aquilo (named after a Greek god of the wind). Primary inputs to this model are mine layout, mine tunnel geometry (length, perimeter and cross-section), ventilation rates and radon gas emanation rates. The emanation rates are in turn based on an understanding of geology and ground fracturing, the resulting groundwater seepage rates, potential for localised

elevated water sources and radon in water content. LLRD cannot be modelled directly from first principles, but it is possible to base predications on measurements made while performing similar tasks or activities (e.g. drilling) at other facilities and scale the measurement by ore grade.

Predictive modelling is often statistical, using distributions for input variables and Monte Carlo techniques to make conservative choices and articulate the range of likely conditions. In addition to these predictions, the engineering and physical controls above are then integrated into design and the work planning, to ensure overall control of the sources of radiation.

### 3. PROGRAM AND ADMINISTRATIVE CONTROLS

All operations have radiation protection programs that meet regulatory requirements as well as the requirements of the corporate radiation protection program. These programs are ISO based and follow the overarching requirements of Cameco's Management System. The details of this program will not be discussed here, however it is worth mentioning the training component. Basic radiation training is provided to all workers, with additional training for supervisors and radiation department staff. Training is geared to help workers understand the role that each person plays in effectively implementing the radiation protection program and its controls, including teaching workers about things they can do to identify radiation sources and remediate them. For supervisors, there is additional focus on their responsibility for protecting their crews and the tools available for them to do so. The radiation staff training takes people from learning simple sampling techniques to being able to identify and remediate upset conditions, respond to emergencies and make decisions on how to best protect the people in the mine. As a collective, this training helps ensure there is active and ongoing assessment and implementation of our controls and control system.

In addition to the physical and engineering controls on radiation sources, there are key administrative controls within the radiation program, used to limit and monitor doses. Those discussed below are not the only controls but are of critical importance to dose control.

The first of these controls is a radiation work permit system. Whenever workers must enter an area or do a task with elevated radiation dose potential, they do it under radiation work permit. Radiation staff works with the supervisor and crews to determine where they will be working and what they will be doing, to assess the risks and controls required. They may employ additional ventilation, shielding, or PPE (e.g. respirators), and will also determine the appropriate dosimetry and ALARA monitoring requirements. The permit is also used to record and control who can enter the area, and to assess the dose received by each worker while performing the task.

Another control to mention is the Code of Practice. This is a standardised set of responses to increasing radiological conditions. It allows personnel to respond in a pre-planned, consistent way to radiological conditions as they rise. There is a Code of Practice for each of the radiation sources, however with radon progeny being the most variable source, it is the one that receives the most focus and communication to the workforce. The continuous radon progeny monitors, shown in Fig. 2, are linked to the Code of Practice. They are equipped with a light system that is visible to the workers from a distance, with each colour combination (green, amber/green, amber, amber/red, red) reflecting a different code of practice level with preassigned actions. Workers are extensively training on their importance and actions required at each light level, allowing for fast response by everyone in the mine to changing conditions.



Fig. 2. An image of a continuous radon progeny monitor and quick reference guide to key actions in the Code of Practice.

The radiation protection program also includes a full dosimetry system. Underground workers use personal dosimetry for gamma, radon progeny and LLRD, and an area/time system for radon gas. All personal dosimeters are licensed by the Canadian Nuclear Safety Commission. Dose to all workers remain well below dose limits with site average doses typically around or below 1 mSv year<sup>-1</sup>.

#### 4. CONCLUSION

Despite the many challenges presented by high-grade underground uranium mines, with appropriate planning and controls, it is possible to safely mine these deposits. Cameco uses a combination of engineering, physical and administrative controls to manage the radiation sources. We have significant dosimetry and workplace monitoring programs, including continuous monitors for radon progeny to maintain active awareness and control of workplace conditions. In the event of an upset or tasks that may need to be performed in elevated radiological conditions, additional controls are applied through radiation work permits. Pre-planned actions are known and trained to all workers to ensure upsets are responded to in an appropriate and consistent manner. All of these controls work together to maintain doses well below regulatory limits and ALARA.

## Future application of the ICRP system of radiological protection: views from UK professionals

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**Abstract**—The Society for Radiological Protection (SRP) and UK Partner Societies have formed a working group to consider ICRP proposals for new recommendations, helping to formulate responses to ICRP from the International Radiation Protection Association. SRP views have been summarised under three headings: (1) Science; (2) Applications; and (3) Communications. (1) Small changes in low dose (< 100 mSv) risk estimates may not warrant detailed revisions. Proposed changes to ICRP dose quantities and ICRU operational quantities are generally welcomed. However, it is noted that the present system works well and such changes do not of themselves appear to warrant the publication of new ICRP general recommendations. (2) An important focus for the practical application of the system is the promotion of reasonableness in the optimisation of protection at low doses in different circumstances of exposure. Experience has shown that in many cases, application of the ALARA principle over-emphasises the ‘as low as’ without due consideration of the ‘reasonably achievable’ and the caveat of ‘taking economic and social factors into account’. (3) ICRP recommendations are aimed principally at regulatory authorities, organisations and individuals who have responsibility for radiological protection. There is scope for improved coordination of the efforts of RP organisations in the development of the system, its dissemination to RP professionals and its communication to stakeholders affected by the application of the system.

**Keywords:** ICRP system; Risk estimates; Dose quantities; Reasonableness in optimisation; International cooperation on communication

### 1. INTRODUCTION

The International Commission on Radiological Protection (ICRP) has embarked on a review and revision of the system of radiological protection with the aim of updating the 2007 general recommendations (ICRP, 2007). As discussed by Clement et al. (2021), the 2007 recommendations replaced the 1990 recommendations (ICRP, 1991) and took about a decade to complete. ICRP therefore considers review and update to be timely, with the proposal that new recommendations might be published by around the end of this decade.

The UK Society for Radiological Protection (SRP) has set up a group to coordinate responses to ICRP proposals as they are formulated. The group includes representatives of UK Partner Societies: the Association of University Radiation Protection Officers, The British Institute of Radiology, British Nuclear Medicine Society, Institute of Physics and Engineering in Medicine, Royal College of Radiologists, and Society and College of Radiographers. The main conduit for the expression of UK views is through the International Radiation Protection Association (IRPA) but other opportunities will also be pursued, including responses to ICRP consultations on draft reports of relevance to the development of new recommendations.

This paper builds on submissions to IRPA during 2021/22, expressing early reactions to the proposals for new recommendations and considering some of the specific issues raised by Clement et al. (2021). We also refer to the paper from ICRP on research needed to support the system of protection (Laurier et al., 2021). Our main responses to IRPA have been delineated under three headings: (1) Science; (2) Applications; and (3) Communications.

## 2. SCIENCE AND THE SYSTEM

Clement et al. (2021) discussed, *inter alia*, ICRP views on the updating of risk estimates for stochastic effects based on the most recently available epidemiological data, considering whether to apply a Dose and Dose Rate Effectiveness Factor of two for solid cancers and whether low dose risks should include non-cancer effects, including diseases of the circulatory system. Proposals for agreed and possible future changes to dosimetric quantities are also presented. Laurier et al. (2021) provided a discourse on scientific research needs from an ICRP perspective.

On research needs, SRP supports research targeted on improving the system of protection, including the continuation of epidemiological studies, together with biological research and data reviews and analyses, identifying the following topics that require improved understanding and quantification:

- 1) The shape of dose-response relationships for cancer at low doses and/or low dose-rates.
- 2) Differences in cancer risks as a function of age at exposure and differences between males and females.
- 3) Risks from internal exposures.
- 4) The effect of modifying factors on cancer risks, including tobacco smoking.
- 5) Variation of cancer risk in populations resulting from genetic differences.
- 6) Methodology for the transfer of risks across populations with different background cancer rates.
- 7) Risks of circulatory diseases and other non-cancer disease at low doses and/or low dose rates.
- 8) Risks of heritable diseases.
- 9) Risks from exposures *in utero*.
- 10) Methodology for the calculation of detriment or an alternative, taking account of the severity of disease and years of life lost.
- 11) Risks to non-human biota at the population level.
- 12) Consideration of the formulation of the dosimetric quantities that are used as measures of risk.

It is difficult to reconcile, however, the need for a substantial continuing programme of research with the need to scope possible changes that will warrant the revision of ICRP's general recommendation. An early step in the consideration of the need for new recommendations will be an examination of the extent of the envisaged changes in risk estimates and in the use of dosimetric quantities. ICRP is encouraged to provide greater clarity on expected changes and their implications for protection practice, as the basis for discussion of the need to proceed with new general recommendations, recognising the substantial efforts that will be required to implement changes in international safety standards and national legislation.

It is noted that low dose (< 100 mSv) risk estimates will be updated, based on thorough review of all epidemiological evidence, with consideration of whether a DDREF of 2 should be applied to solid cancer risks and whether non-cancer diseases should be included in low-



dose detriment (or an alternative to detriment). It would be helpful if ICRP could provide an early indication of the likely outcome of these considerations. Is it likely that the population-averaged stochastic risk estimate of 5% Sv<sup>-1</sup> used at low doses will change appreciably and how might this affect the setting of reference levels and limits? Although ICRP expects to publish revised estimates of risk and detriment (or an alternative expression of harm), the necessity to frame these data as recommendations will depend on how different the estimates are from current values.

An important consideration for ICRP in planning new recommendations is that all ICRP organ and effective dose coefficients will require revision once new radiation and tissue weighting factors are published, applying revised risk estimates. Following from the 2007 Recommendations (ICRP, 2007), ICRP has published a series of reports providing revised dose coefficients for external exposures and intakes of radionuclides by workers (ICRP, 2010, 2015, 2016, 2017, 2019, 2022) and on external exposures of members of the public (ICRP, 2020). However, revised data are yet to be published for intakes of radionuclides by members of the public and for the diagnostic use of radiopharmaceuticals. ICRP should provide a timescale for these publications and consider whether further revision of all these data is justified, either in terms of the very substantial effort required by ICRP members to perform these calculations or the efforts required by users to implement the new data. Unless substantial changes in risk and dose coefficients are anticipated, it may be most appropriate to carry forward the *Publication 103* based data into any new recommendations since practical protection in the vast majority of circumstances would not be improved by further changes. In parallel, ICRP could encourage the more accurate calculation of doses and risks in circumstances where such considerations may be important – for example, in medical applications or in emergencies when the risks to individuals may need to be assessed more accurately than can be done using effective dose and nominal risk coefficients. Laurier et al. (2021) also mention the consideration of uncertainties in risk and dose coefficients as a research aim. Given the substantial uncertainties associated with risks at low doses (some unquantifiable), it will be sufficient in the majority of cases to use effective dose and the corresponding risk coefficient to provide a simple assessment of what the risk to an individual might be, as discussed in ICRP *Publication 147* (2021).

As discussed by Clement et al. (2021), ICRP *Publication 147* (2021) and ICRU Report 95 (ICRU 2020) present proposals for changes to protection and operational quantities, removing the quantities equivalent dose and dose equivalent. Instead, according to the proposals put forward, limits on organ/tissue doses to prevent tissue reactions will be set in absorbed dose, Gy, and the operational quantities relating to eye and skin doses will also be absorbed dose quantities. In addition, the operational quantities relating to effective dose will be calculated directly from maximum values of effective dose in the reference phantoms and renamed personal dose,  $H_p$ , and ambient dose,  $H^*$ . Possible changes to effective dose have also been suggested, including the use of sex- and age- specific tissue weighting factors. There is a clear need for work by ICRP, ICRU and others to develop an agreed plan, considering the scientific rationale and practical implementation of all agreed changes and their costs and benefits.

SRP is generally supportive of the proposed changes to ICRP dose quantities and ICRU operational quantities, including the increased clarity that will be provided by using absorbed dose (Gy) to organs / tissues in the control of tissue reactions and effective dose and operational dose quantities (Sv) in the control of stochastic effects (Clement et al., 2021; ICRP, 2021; ICRU, 2020). For example, emergency planning and operation will be aided by distinguishing between absorbed doses to the thyroid and effective doses from all contributing radionuclides. The cooperation between ICRP and ICRU in formulating complementary proposals is noted and welcomed. However, we also note that the present system works well and these changes do not of themselves appear to warrant the publication of new ICRP general recommendations. While we see the advantages of the proposed changes, we note that there have been concerns

among practitioners regarding the costs of implementation of changes to operational quantities in the workplace, which would arguably not be justified by significant benefit in terms of improved safety. Hence, there are challenges yet to be addressed regarding the practical implementation of the proposed changes.

Considering protection of the environment, a helpful focus would be a re-analysis and clarification of the derivation and practical application of Derived Consideration Reference Levels (DCRLs). Many of these values look low in the context of protection of populations and there needs to be a defined methodology for the calculation of doses to exposed populations. It is likely that there will be very few situations in which protection of non-human biota will be of importance. It would be good for ICRP to be clear about this (if correct) so that resources are directed most appropriately.

### 3. APPLICATION OF THE SYSTEM

SRP considers that an important focus for the practical application of the system is to promote reasonableness in the optimisation of protection at low doses in different circumstances of exposure. The principle of optimisation is defined by ICRP (2007) as the source related process of keeping the likelihood of incurring exposures (where these are not certain to be received), the number of people exposed, and the magnitude of individual doses, as low as reasonably achievable, taking economic and social factors into account. Experience has shown that in many cases, particularly when considering very low public exposures, application of this ALARA principle over-emphasises the ‘as low as’ without due consideration of the ‘reasonably achievable’ and the essential caveat of ‘taking economic and social factors into account’. There are concerns at an apparent lack of proportionality in decision-making at very low doses, resulting in poor value in the utilisation of society’s resources.

SRP would welcome improved contextualisation of very low dose exposures as an aid to understanding and consideration of what is reasonable in optimisation of protection. When consideration is being given to doses of a few millisievert or fractions of a mSv, it will be helpful to consider the context of natural background radiation and the variation in doses received by individuals (Coates and Czarwinski, 2018; IRPA, 2021). It is important to review the general basis for decision-making at low doses. ICRP and other international organisations, including IRPA, should work together to define what is considered to be a trivial dose under different circumstances. This is also important, for example, in the context of incidents and emergencies where the wider risks of interventions (e.g. evacuation) to further lower doses may be significantly greater than any resulting reduction in risk that can be achieved.

We also wish to stress the importance of ensuring a holistic approach to the optimisation process, whereby risks from different types of hazards potentially involved are taken into account in a balanced way. It would be helpful for ICRP to give further consideration to the importance of, and methods for, balancing risks from different types of hazard. However, we recognise that ICRP’s area of competency is limited to radiation, and that any expansion of the means to achieve this may be beyond its scope. But a clear top-tier statement of the importance of considering all hazards could encourage others with the relevant expertise to address this issue, especially the relevant stakeholders in local decisions. In particular, it is essential that regulators have the competency, capacity and willingness to take account of the non-radiation factors in achieving optimisation. A full holistic approach would also embrace considerations of sustainability, which is increasingly recognised as central to modern decision-making. This involves sustainable usage of our natural resources and minimising our impact on future generations.

Clement et al. (2021) make the point that while optimisation is intended to establish the best solution for society, dose limitation is required to protect individuals. As discussed by Coates

and Czarwinski (2018), one of the issues of greatest concern to Partner Societies is the strong perception that limits mark the boundary between safe and unsafe. It may be preferable to set limits solely for the prevention of serious tissue reactions at higher doses and use only reference levels in relation to the optimisation of protection against stochastic effects at low doses (Constraints are a sub-set of reference levels and it is not clear why two alternative words are required.)

It is not clear that such considerations of the optimisation of protection require new general recommendations from ICRP. It is important that all international stakeholders are involved in discussing and agreeing the best way forward and it may be that, rather than new ICRP recommendations, joint statements should be made by all organisations involved to help practitioners and regulators interpret and apply the existing system. IRPA will play a central role in this process.

Medical exposures represent a large contribution to public exposure, making optimisation of great importance in this field. New technologies are being designed and brought to market to increase the quality of diagnostic imaging. This needs to be supported by and balanced against an RP system that aims to keep doses as low as reasonably achievable whilst maintaining an adequate level of imaging quality. Diagnostic Reference Levels are a key tool for optimisation and are needed for the full range of examinations for children and adults, although greater clarity is needed on their intended use (not limits) and flexibility when considering clinical complexity.

Research and collation of information is needed in relation to the best use of ionising radiation and radiopharmaceuticals in medical diagnosis and treatment as different techniques are developed and require different dosimetric approaches. There are increasing numbers of patients undergoing multiple diagnostic procedures, with a need to consider cumulative dose and risks in their justification.

Procedures that have been highlighted for attention are:

- Proton beam radiotherapy, including outcomes, patient experience, techniques, cost effectiveness, delivery, training, and late effects.
- Adaptive radiotherapy, in relation to developing guidelines, improving treatment outcomes, and reducing side effects.
- How to implement individualised patient specific radiotherapy.
- Image Guided Radiotherapy (IGRT) - development of gold standard imaging regimes and image matching techniques, and consideration of dose.
- Targeted radiotherapy based on functional imaging.

There is also a need for audit of survivorship and late effects after radiotherapy and more work on the management of acute and late side effects of radiotherapy.

#### **4. COMMUNICATION**

There are a number of important aspects to the need for effective communication, including:

- communication between ICRP and other international organisations responsible for the development of the system;
- communication of the system and its application to radiation protection practitioners worldwide; and
- communication with stakeholders exposed to radiation and the wider public in the application of the system of protection.

ICRP (2007) makes clear that its recommendations are *aimed principally at regulatory authorities, organisations and individuals that have responsibility for radiological protection*. There is a close connection between ICRP Recommendations and the International Basic Safety Standards for Protection against Ionizing Radiation and the Safety of Radiation Sources, which are co-sponsored by UN international organisations and published by IAEA. The latest revision of these Basic Safety Standards (BSS) was published in 2014, following the ICRP 2007 Recommendations. Cosignatories of the BSS are the EC, FAO, IAEA, ILO, OECD/NEA, PAHO, UNEP and WHO (IAEA, 2014).

We suggest that there is a need to better coordinate the efforts of RP organisations in the development of the system, its dissemination to RP professionals and its communication to stakeholders who are or may be affected by the application of the system. At this critical stage of the consideration of the need for new ICRP recommendations, it would seem appropriate to seek a consensus from the responsible international organisations on this perceived need. More generally, greater delineation of the responsibilities of the various organisations would be helpful, to foster greater collaboration and reduce duplication of effort.

Communicating with stakeholders affected by the application of the system and the enhancement of public understanding of radiation risks and their control would seem to be best handled by the RP practitioners involved in application of the system at a national or local level. IRPA and its Partner Societies clearly have a central role in this process, as discussed by Coates and Czarwinski (2018) and in associated IRPA (2020) guidance. ICRP has a key role in ensuring that its recommendations are understandable and aligned with common sense, while other organisations, and principally practitioners, should lead on the day-to-day interactions with wider stakeholders. ICRPaedia(<http://icrpaedia.org/>) is noted as a very welcome initiative in this context.

Communication of radiation and risk is widely recognised as one of the key challenges within our profession. However, it is not clear what ICRP's role could be in this context, other than ensuring that the system of protection, as it evolves, is able to be presented in terms that are understandable and relatable to members of the public, and ensuring that those parts of the current system which seem to imply that low doses may carry significant risk are appropriately moderated. Part of the current concern could be addressed within the proposed review of the exposure situations and categories of exposure, together with a simplified approach to limitation of exposure (considering limits, constraints and reference levels). Important in the medical context, but also in other exposure situations, is further analyses and approaches to communication of the substantial benefits afforded by the use of radiation, so that low risks can be judged in their proper perspective. Clarity is needed in explaining what is known about radiation risks at low doses – that risks are inferred from observations of excess disease at higher doses with little direct evidence of risk at low doses.

## 5. DISCUSSION

Radiological protection has benefitted enormously from the work of ICRP in developing a system of protection that is recognised and applied worldwide. The periodic revision and updating of ICRP general recommendations have ensured that they keep pace with scientific and societal developments. ICRP is to be applauded for its open and inclusive approach to its current considerations of the need for change and update of the 2007 Recommendations.

There is an inevitable tension within ICRP and the RP profession between scientists seeking accuracy and practitioners seeking stability and clarity. There is no doubt that re-analysis of epidemiological data with an additional 20 years of accumulated information will lead to changes in cancer risk estimates, but will changes in estimates of stochastic risks at low doses

be sufficiently large to affect RP practices? A possible outcome of review might be to publish updated risk estimates but avoid fundamental changes to the definition and application of effective dose as the central tool for exposure control. ICRP could then also promote a more detailed consideration of doses and risks to individuals in situations where such precision is deemed appropriate, for example, for exposures in emergencies, in certain medical procedures, or by astronauts.

A number of features of the current system of protection have proved difficult to apply in practice, with major concerns being the appropriate application of ALARA within a holistic framework of risk control. A clear statement of the importance of considering all hazards could encourage others with the relevant expertise to address this issue, especially the relevant stakeholders in local decisions. Improved practical advice may be best provided by international organisations working together; new ICRP recommendations may not be a prerequisite for such clarifications of the application of the system

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## How do you solve a problem like conservatism?

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**Abstract**—The International Commission for Radiological Protection (ICRP) has commenced a review of the system of Radiological Protection. This review commenced with a discussion paper, Keeping the ICRP Recommendations Fit for Purpose, and workshop in October 2021. The review, planned to take ten years, is an opportune time to rethink the way we do radiation protection. Members of the Australasian Radiation Protection Society work at the leading edge of implementation of ICRP recommendations. As practitioners, we know there can be undue effort applied at low doses ( $< 1$  to  $5$  mSv  $y^{-1}$ ). This effort may, at times, divert resources from more significant radiation protection or workplace safety matters. Proactive consideration of the transition from reasonable protection measures to excessive conservatism will help to maximise benefit in radiation protection. This paper proposes practical approaches to the application of LNT for radiation protection at doses in the range of natural background levels. The proposals consider the IRPA position on reasonableness and aim to be consistent with the IAEA graded approach to regulation of radiation.

**Keywords:** Low dose; Implementation; Radiation protection; Holistic risk; Conservatism

### 1. BACKGROUND

The ICRP announced a review of the System of Radiological Protection (the System) in 2021 and published a discussion paper to *identify issues that may require attention*, Clement et al. (2021). This paper considers a range of matters to do with the ethical and scientific foundations underlying the System. The discussion paper noted that the existing dose response model was appropriate, however, it remains a subject of considerable discussion and even debate. Experience has shown that the dose response model can present challenges for practical implementation of the System, particularly at dose levels that are well within the normal variation of background radiation - in the region of 1 mSv to 5 mSv per annum. Such challenges are exacerbated by inclusion of additional layers of conservatism during implementation of ICRP recommendations without due consideration of costs and benefits.

Clement et al. (2021) provides a useful discussion of the dose response model currently in use, which is a linear no threshold (LNT) relationship. They make the case for continuing review of the science *to ensure that LNT is the most appropriate evidence-based assumption to use for radiological protection purposes*, although it is noted that at low doses the *risk for stochastic health effects is uncertain, and becomes increasingly uncertain as the dose decreases*. Clement et al. (2021) also presents the view of NCRP which notes that the LNT model represents a pragmatic interpretation of current epidemiological data.

However, experience gained in implementation of the ICRP recommendations has highlighted the need for a more pragmatic approach to radiological protection at low doses.

It is an understatement to say the use of an LNT model for radiation risk is subject to debate and this paper provides a number of examples of the unwitting conservative implications of the application of LNT in practical radiation protection measures.

## 2. RISK AT LOW DOSES

The logic for additional research on radiation risk at low doses is that there is no clear evidence of an effect. However, this is also true for normal radiation exposure levels, such as current occupational and public levels, which are well within the normal variation in background radiation exposure levels. Radiation risk studies present results for high radiation doses that are well beyond exposure levels encountered in normal circumstances. ‘Low dose’ results, presented in summary reports, are frequently in the range up to ~ 500 mSv, for example McLean et al. (2017).

Therefore, in practice, exposure levels which show an effect are not representative of typical exposures in everyday industries. The studies are looking for an effect somewhere in a fraction of a confidence interval; somewhere in the error bars. To add to the complexity and uncertainty, there also appears to be two competing approaches to low radiation dose risk, being, epidemiology and biological studies. Averbeck et al. (2018) suggest that radiation risk at low dose might require the combined effort of both epidemiology and biology. In this context, perhaps we should consider whether the risk of low dose radiation might never be clearly determined.

In keeping with the concept of ‘fit for purpose’ recommendations, the ICRP needs to be clear about the conservatism in protection at low radiation exposure levels where there is a lack of clear evidence. A pragmatic, regulator friendly model should not collapse to worst case, and create an imperative for consumption of significant protection resources.

## 3. CONSERVATISM IN PRACTICAL RADIATION PROTECTION

The adoption of the LNT tends to encourage a never ending iterative application of conservatism in the approach to radiation protection. This needs to be considered alongside the fact that the ICRP develops the System of Radiological Protection on the basis of conservative assumptions. For example, the dose model assumes the settings that result in the highest dose and the LNT model is applied to avoid under estimation of risk. This approach seems entirely reasonable at the level of the System of Radiological Protection.

However, the System has to be implemented via standards developed by the International Atomic Energy Agency (IAEA), which in turn are the model for the development of regional, and then national, radiation protection standards. In Australia, we add another layer of regulatory oversight that adopts national standards within state jurisdictions. There is a tendency to add conservatism at each layer of this process. Additional layers upon layers of conservatism can be problematic for practical implementation of radiation protection.

### 3.1. Applied Conservatism

The layers of additional conservatism impact radiation protection and broader occupational health and safety aspects in practice. Radiation safety regulations will often adopt a ‘belt and braces’ approach. Occupationally exposed persons in a medical setting are required to have personal radiation monitoring and also use Personal Protection Equipment (PPE). In some workgroups the PPE means greater than 95% of personal radiation monitoring results are less than the minimum detectable dose. In this situation, it should be sufficient to either use PPE or measure exposure. Requiring both PPE and monitoring is additional conservatism, which is hard to justify in terms of radiation risk.

Perversely, the use of PPE in these situations creates an additional risk of musculoskeletal injuries. Such injuries may have lifelong consequences depending on severity of the injury. Procurement and maintenance of PPE incurs additional expense for an organisation. A



theoretical review of attenuation suggests incurred occupational exposures may increase upto approximately 0.5 mSv if PPE was not used. (Jeffries, 2021)

There are many examples of conservatism in practice. Radiotherapy shielding is designed for maximum radiation output and maximum patient treatments, whereas the reality may be one quarter or one tenth of the values used in shielding models. This approach can lead to unnecessary radiation concern when upgrading existing equipment. (Jeffries et al., 2016)

The IAEA recommends that radiation dose ‘of the order of 10  $\mu\text{Sv year}^{-1}$ ’ should be considered trivial. Regulations often set this recommendation at precisely 10  $\mu\text{Sv year}^{-1}$ . A dose level that requires detailed modelling, but that is too small to measure.

In Australia, the drinking water guidelines have recently been reviewed to reduce the reference dose from 0.5 mSv year<sup>-1</sup> to 0.3 mSv year<sup>-1</sup>. This change is based on the concept of a dose constraint at approximately one-third of the dose limit. The dose from drinking water is modelled on daily consumption of 2 L day<sup>-1</sup>.

However, consumption of 6 L day<sup>-1</sup> would approach a lethal dose of water for humans. The reduced drinking water reference level provides no practical improvement in protection. Instead it appears to be a conservative application of a one third dose constraint without consideration of the protection situation.

### 3.2. IRPA Position on Reasonableness

These experiences of radiation protection in practice appear to arise from individual interpretation of the System, which is very complex. The System itself is sound at a fundamental level but the complexity may have unintended consequences for implementation. The International Radiation Protection Association (IRPA) has prepared a position on Reasonableness in the Optimisation of Radiation Protection to assist radiation protection practitioners (IRPA, 2021). The position is based around the following principles.

- Judgement Call
- Proportionality
- Stakeholder Engagement
- Holistic ‘All Hazards’ Approach
- Avoidance of Over-Conservatism
- Value for Society – Optimal Use of Societal Resources
- De Minimis Approach
- Alignment with Radiation Safety Culture

The IRPA position provides strong focus on a complex part of the System, optimisation. ICRP (2007) advice for optimisation is that *doses should all be kept as low as reasonably achievable, taking into account economic and societal factors*. This advice, while sound, leads to numerous pages of interpretation in guidelines and regulations. There is often a response to this complexity in trying to simplify ALARA to as low as possible or as little as possible. An expectation or demand for zero doses can result from such interpretation of ALARA, which does not appear to be the intention of ICRP.

## 4. PRACTICAL SUGGESTIONS FOR FUTURE RECOMMENDATIONS

This paper attempts to focus on the issues that are experienced with practical implementation of radiation protection. Current radiation protection practice involves conservatism that unintentionally diverts limited radiation protection resources away from medium and high radiation doses towards low doses where the *risk for stochastic health effects*

*is uncertain, and becomes increasingly uncertain as the dose decreases* (Clement et al., 2021). The recommendations have to be practical and support a risk based approach to protection to remain ‘fit for purpose’.

Future recommendations could more strongly advise against expending resources at low doses due to the uncertainty of risk. The presentation in Vancouver suggested a science based and pragmatic dose threshold as one means to encourage reasonableness. The current recommendations already include an implied lower dose of concern in the band of 1 mSv or less, *where individuals receive exposures – usually planned – that may be of no direct benefit to them but the exposure situation may be of benefit to society* (ICRP, 2007). A situation where there is little or no individual benefit suggests that doses of 1 mSv or less are of no concern.

Does this mean inherently safe? Radiation protection practitioners have to answer this question regularly. The question arises in a context of an assumption that all radiation is harmful and some use this hypothesis to our detriment. In practice, this means asking people for acceptance of the risk; *The risk of your radiation exposure at work is the same as your risk of a road accident. Do you think twice before getting into a car?*

Future recommendations could make a strong case for minimal or no effort at such low dose levels. Effectively imposing a lower limit on optimisation. ICRP has the expertise required to consider ethics, uncertainty, acceptance and a holistic risk approach for doses that represent a marginal increase above natural background. The goal should be to set dose constraints that consider the whole risk picture with consideration to factors that may already limit exposure.

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## Japanese translations of ICRP Publications on contract with the Nuclear Regulation Authority, Japan; activities in FY 2022

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**Abstract**—The project of Japanese translations of ICRP Publications is conducted by the Nuclear Regulation Authority of Japan (NRA) to share ICRP’s knowledge widely among those concerned and to assist in enhancing reliability of Japanese domestic regulations. To hear from a professional and objective standpoint, the ICRP Publications Japanese Translation Committee was established to offer suggestions to the NRA about the selection of the Publications to be translated and to approve the final version of the translation. The priority of selection is given to those Publications that deal with important and urgent issues deeply connected to Japanese domestic radiation safety regulations. To ensure quality of translations, 7-step procedure was adopted. In financial year (FY) 2022, Japanese translations of *Publications 129* and *135* will be published (by March 2023).

*Keywords:* ICRP Publications; Japanese translations; System of radiological protection; Regulations

### 1. OUTLINE OF THE PROJECT

Japanese experts have contributed significantly to create the scientific knowledge that forms the basis of the system of radiation protection and participated in discussions on the establishment and review of the system. Moreover, to respect the internationally agreed concepts of radiation protection at international organisations such as the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA), Japan has incorporated these concepts into its own regulations as technical standards for radiological protection.

The project of Japanese translations of ICRP Publications aims to widely share the findings of the ICRP among relevant parties, including the regulatory authorities so that it has contributed to the establishment of a system to collect, organise and evaluate the latest findings on radiological protection by investigating ICRP publications, translating those of high importance and conducting activities to promote understanding of the project by the public.

In financial year (FY) 2017, the Nuclear Regulation Authority of Japan (NRA) launched an outsourced project ‘Survey and translation of ICRP Publications for domestic radiation safety regulations in Japan’. The contractor of this NRA-led project is selected annually through a competitive bidding process, and JAPAN NUS Co., Ltd. has won the bids and set the secretariat in each year since FY 2020.

To carry out this project, the ICRP Publications Japanese Translation Committee (hereafter ‘JT committee’) was established. The committee offers suggestions to the NRA about the selection of the Publications to be translated and approves the final version of translation.

Table 5. Members of The Japanese Translation Committee of ICRP Publications FY 2022.

Name (without honorifics)	Affiliated Organization
Gen SUZUKI (Chair)	International University of Health and Welfare Clinic
Michiaki KAI (Vice-chair)	Nippon Bunri University
Michiya SASAKI (Vice-chair)	Central Research Institute of Electric Power Industry
Kazuko ONO	Kyoto College of Medical Science
Keiji ODA	Electron Science Institute
Isao KAWAGUCHI	National Institutes for Quantum Science and Technology
Sachiko SAKODA	Japan Radioisotope Association
Yasuhito SASAKI	Shonan Kamakura General Hospital
Hideki HANGAI	Japan Atomic Energy Agency
Hiroshi YASUDA	Hiroshima University

## 2. STEPS TO PREPARE A JAPANESE TRANSLATION

The following 7 steps are taken to ensure the quality of a Japanese translation to be published (Fig. 1).

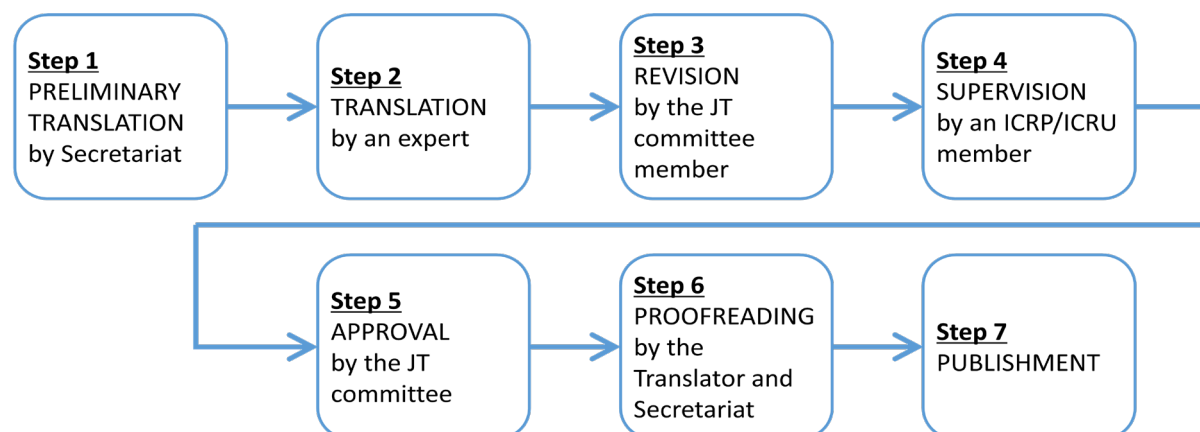


Fig. 1. 7 Steps to Prepare a Japanese Translation.

1. PRELIMINARY TRANSLATION (by secretariat)
  - The secretariat prepares a preliminary translation of the publication.
2. TRANSLATION (by experts)
  - Experts in the field selected by JT committee translate the Publication with their expertise, referring to the preliminary translation.
3. REVISION (by members of the JT committee)
  - JT Committee member experts use their expertise to give advice to the translator experts of Step-2.
4. SUPERVISION (by ICRP/ ICRU members or equivalent experts)
  - ICRP/ ICRU members and equivalent experts give advice based on discussions during the development of the original publication.

5. APPROVAL (by the JT committee)
  - The JT Committee confirms the entire texts of the Japanese translation and approves its publication.
6. PROOFREADING (by a translator and secretariat)
  - The translator and the secretariat carry out the proofreading process.
7. PUBLISHPMENT
  - The Japanese translations are published on the ICRP website.

### 2.1. Published Japanese Translations

Table 2 lists the Japanese translations carried out under the project of the Nuclear Regulation Authority. The other 89 publications not listed in this table were translated into Japanese by the Japan Radioisotope Association (JRIA) separately from the NRA project, and all Japanese translations can be found on the ICRP website (ICRP, 2022).

Twelve Japanese translations of the projects completed under the NRA are also available on the NRA website (NRA, 2022).

Table 6. Published Japanese translations.

<i>Publication</i>	Title
107	Nuclear Decay Data for Dosimetric Calculations
121	Radiological Protection in Paediatric Diagnostic and Interventional Radiology
124	Protection of the Environment under Different Exposure Situations
125	Radiological Protection in Security Screening
126	Radiological Protection against Radon Exposure
127	Radiological Protection in Ion Beam Radiotherapy
130	Occupational Intakes of Radionuclides: Part 1
131	Stem Cell Biology with Respect to Carcinogenesis Aspects of Radiological Protection
132	Radiological Protection from Cosmic Radiation in Aviation
138	Ethical Foundations of the System of Radiological Protection
146	Radiological protection of people and the environment in the event of a large nuclear accident: update of <i>ICRP Publications 109</i> and <i>111</i>

Table 3 provides the list of the Japanese translations to be published in FY 2022, and Table 4 presents the Japanese translation for which work is underway in FY 2022.

Table 7. Japanese translations to be published in financial 1 year (FY) 2022.

<i>Publication</i>	Title
129	Radiological Protection in Cone Beam Computed Tomography (CBCT)
135	Diagnostic Reference Levels in Medical Imaging

Table 8. Japanese translations for which work is underway in financial 1 year (FY) 2022.

<i>Publication</i>	<i>Title</i>	<i>Step</i>
123	Assessment of Radiation Exposure of Astronauts in Space	Step 2 (TRANSLATION)
133	The ICRP Computational Framework for Internal Dose Assessment for Reference Adults: Specific Absorbed Fractions	Step 1 (PRELIMINARY TRANSLATION)
139	Occupational Radiological Protection in Interventional Procedures	Step5 (APPROVAL)
140	Radiological Protection in Therapy with Radiopharmaceuticals	Step 4 (SUPERVISION)
142	Naturally Occurring Radioactive Material (NORM) in Industrial Processes	Step 4 (SUPERVISION)
144	Dose Coefficients for External Exposures to Environmental Sources	Step 2 (TRANSLATION)
147	Use of Dose Quantities in Radiological Protection	Step 3 (REVISION)
150	Cancer Risk from Exposure to Plutonium and Uranium	Step 1 (PRELIMINARY TRANSLATION)
ICRU Report 95*	Operational Quantities for External Radiation Exposure	Step 3 (REVISION)

\*Jointly issued with ICRP

## 2.2. Terminology Review

The JT Committee discusses and decides appropriate translations under consideration. Examples of the translations of specific terminologies discussed are given in Table 5.

Table 9. Terminology Review (Examples).

<i>Publication</i>	<i>Original terms</i>	<i>Background/description</i>
126	graded approach	There was a discussion on how to translate the term ‘graded’. It was decided to use the term ‘Graded Approach’ (as a phonetic transcription to Japanese characters), which is also used in nuclear power and other fields in Japan, without replacing it with another Japanese word.
130, 138	prevailing circumstances	Various candidates were mentioned, but the term ‘Prevailing circumstances’, used as a description of the Reference Level, was chosen to simply express “ubiquitous and widely-spread situations.”
127	length of life lost	In previous publications, the translation meaning ‘shortening of life expectancy’ had been adopted before it was changed to match the fields other than radiation, or the terms used in UNSCEAR and WHO’s Japanese translation, etc.
121	local DRL regional DRL national DRL	It was considered that ‘Local’ refers to a limited area compared to the national level and connotes a group of facilities with common elements such as fields of expertise, while ‘Regional’ is a group of countries, e.g. the European Union.

### 3. SUMMARY

Japanese translations of ICRP publications had been carried out by Japan Radioisotope Association for many years before the NRA took over this task in 2017.

The NRA established the ICRP Publications Translation Committee (the JT Committee) to ensure quality of translations with application of the 7-step procedure. To ensure high quality of translations, Step 4 of the 7 steps is supervised by ICRP members.

So far, 12 Japanese translations of the projects completed under the NRA are also available on the NRA website. In FY 2022, Japanese translation of *Publication 146* was published while *Publications 129* and *135* are due to be published by March 2023. Especially for *Publication 146*, which was of great interest in Japan, its Japanese translation was released two years after publication of the original ICRP document while ensuring the quality of the translation, allowing it to be widely disseminated to interested parties in Japan.

The project is supported by a number of experts in Japan. Through this project, we believe that the knowledge of the ICRP will be widely shared among those concerned in Japan.

This report is a part of the activities to promote understanding of the Nuclear Regulatory Authority's project 'Survey and translation of ICRP Publications for domestic radiation safety regulations in Japan'.

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