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OPINION ARTICLE

Radiological protection, optimisation and regulatory reform

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Abstract

The principle of optimisation of protection is a cornerstone of the system of radiological protection (RP). The practical implementation and interpretation of optimisation, particularly at low doses and dose rates, is a long-recognised challenge and has often been subject to robust and spirited debate. At present, we seem to have unprecedented interest and momentum for reflection on RP recommendations and standards, and with it the opportunity to collaboratively develop creative solutions to such challenges in support of a sustainable future. Potential solutions should be informed by science as well as a wide range of social and economic factors and be thoroughly and critically evaluated accordingly. In the United States (US), Executive Orders have led to relevant proposed rule changes from the US Nuclear Regulatory Commission (NRC), including one entitled 'Reforming and Modernizing the NRC's Radiation Protection Framework'. This paper argues that the proposal is rushed, imprecise and insufficient by highlighting a few illustrative examples of how the proposed rule change as written is inconsistent with international (e.g. International Commission on Radiological Protection) and national (e.g. US National Council on Radiation Protection and Measurements) recommendations and guidance. For example, the proposal claims that adherence to regulatory dose limits provides a sufficient level of protection and that beyond prescribed actions at certain thresholds, there is no need for further incorporation of the prevailing circumstances (i.e. no need to optimise protection) below these dose limits. National authorities of course have the purview to decide what is most appropriate and effective from a regulatory standpoint, but diverging from the broader consensus requires a clear, thoughtful, thorough and transparent argument that is missing from the current proposal.

1. Optimisation in the system of radiological protection

The International Commission on Radiological Protection (ICRP) describes the principle of optimisation of protection as ensuring that the likelihood of exposure, the number of people exposed, and the magnitude of their doses are kept as low as reasonably achievable, taking into account economic, societal, and environmental factors [1, 2]. The most recent ICRP publication dedicated to (general) optimisation, Publication 101B (2006), observes that its implementation 'is a process that is at the heart of a successful radiological protection programme' [3]. The optimisation principle rests alongside the principles of justification and application of dose limits in the ICRP's system of radiological protection (RP) [2]. The three fundamental principles are echoed by various other organisations including the International Atomic Energy Agency (IAEA), e.g. in the General Safety Requirements (GSR Part 3)[1], and the United States (US) National Council on Radiation Protection and Measurements (NCRP) (noting that dose limitation is referred to as 'numeric protection criteria' by NCRP) [4, 5].

[1] Of note is that GSR Part 3 is jointly sponsored by: European Commission, Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Organization, OECD Nuclear Energy Agency, Pan American Health Organization, United Nations Environment Programme and World Health Organization

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Table 1. Illustrative definitions of optimisation and ALARA.

Formulation	Definition	References
Principle of optimisation of protection	The likelihood of incurring exposure, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors.	ICRP Publication 103 [2]
Optimization of protection	The likelihood of incurring exposures, the number of individuals exposed, and the magnitude of the dose to an individual should be kept as low as reasonably achievable, taking into account societal, economic and environmental factors. More generally, the optimization of protection is satisfied when the expenditure of further resources would be unwarranted by improvement in health and safety (both radiological and nonradiological). The level of protection should be the best under the prevailing circumstances, maximising the margin of benefit over harm.	NCRP Report 180 [5]
Optimization (of protection and safety)	1. The process of determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being as low as reasonably achievable, economic and social factors being taken into account (ALARA). 2. The management of the radiation dose to the patient commensurate with the medical purpose.	IAEA Nuclear Safety and Security Glossary, 2022 (Interim) Edition [13]
ALARA	means 'As Low As is Reasonably Achievable,' which is the approach to radiation protection to manage and control exposures (both individual and collective) to the work force and to the general public to as low as is reasonable, taking into account social, technical, economic, practical, and public policy considerations. As used in this part, ALARA is not a dose limit but a process which has the objective of attaining doses as far below the applicable limits of this part as is reasonably achievable.	US Department of Energy [12]
ALARA	(acronym for 'as low as is reasonably achievable') means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licenced activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licenced materials in the public interest.	US Nuclear Regulatory Commission [11]

The concept of optimisation has been around for decades, albeit in slightly different formulations [6]. ICRP Publication 22 (1973) introduced the phrase 'as low as is reasonably achievable' (where 'reasonable' replaced 'readily' from ICRP Publication 9 [1966]) in the context of doses, acknowledging that 'economic and social considerations' (among others) should be taken into account in associated decision-making [7]. The corresponding acronym 'ALARA,' although not used in ICRP Publication 22 or in subsequent general recommendations, gained wide popularity and 'the ALARA principle' or simply 'ALARA' has often been used as shorthand for optimisation [8], notably in older NCRP publications and the US Code of Federal Regulations (i.e. 10 CFR Part 20 and 10 CFR Part 835) [9–12]. Table 1 summarises various definitions of optimisation and ALARA. These definitions are in clear agreement that the implementation of the optimisation process should lead to decisions that reasonably balance benefits and disbenefits in the context of the prevailing circumstances.

2. Contextualising regulatory reform

There is international agreement that the principle of optimisation of protection is, and should remain, a cornerstone of the system of RP [14–16]. There is also recognition, though, that its implementation needs broader, more holistic consideration [17]. For example, the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development recently observed that 'optimisation in radiological protection needs to be seen as part of a wider overall optimisation process and recognised as such in regulatory activity' [14]. Indeed, regular reflection is essential to consider whether the mechanism to achieve the aforementioned balance is effective. Such reflection should be informed by science as well as a wide range of social and economic factors. The potential revision to US regulations related to RP, for example [18], can be seen in that vein, with positive potential for collaboratively developing creative solutions to modern RP challenges in support of a sustainable future.

It is important that such proposals are considered in the broader sociopolitical context of the USA, including the current approach to science. The civil service workforce of federal agencies has been gutted [19–21]. Numerous national scientific advisory groups have been disbanded [22]. Research grants have been terminated for political reasons [23]. A recent rule change was proposed to move away from merit review and politicise how research proposals are reviewed and implemented in the USA; the editorial board of the *New England Journal of Medicine* summarises problems with this proposal, from the logistical to the ethical, also observing that there 'are too many objectionable aspects of these proposals to discuss here' [24]. An exasperated chemist, writing for *Science*, highlights the political use of empty buzzwords like 'gold standard science' and 'transformational breakthroughs' as smokescreens for 'complete miscomprehension of how science actually works and a reflexive hostility to it when [seen]' [25, 26]. Taken together, such issues in the USA demand a deep and critical reflection on the content of proposed rule changes, rather than accepting claims at face value.

It is normal for sociopolitical and cultural issues to influence regulatory decisions [3, 27] and politically motivated changes do not necessarily lead to poor outcomes. However, as pointed out by Huff *et al* in response to recent US Executive Orders (EOs), '[f]ailure to maintain regulatory independence from commercial, political and ideological influence is not accountability. It is instead regulatory capture' [28]. Given the context then, statements in the US Nuclear Regulatory Commission (NRC) proposed rule change entitled 'Reforming and Modernizing the NRC's Radiation Protection Framework' [18] should be vigorously challenged to help ensure a strong, balanced and science-informed outcome.

Concerning such a critical challenge, the proposal does not 'remain[] in harmony with scientific consensus' [18] as claimed. Precisely how is discussed elsewhere [29]. It additionally provides little confidence that the NRC spent the time and consideration in review that the situation demands, presumably due to the tight timeline prescribed by the EOs, ultimately resulting in what appears to be a rushed, imprecise and insufficient proposal. Here, I highlight a few illustrative points to that end.

3. Illustrative observations

3.1. Optimisation is about the greatest overall benefit

The proposed rule change states the intention 'to restore to the NRC's regulations the original intent of the ALARA principle, which is to ensure that dose reductions below the dose limits are only required to the extent that they are reasonable and are supportive of compliance with those dose limits' [18]. Under this incorrect premise (elaborated below), the NRC exchanges 'ALARA' for a 'graded approach to dose management'. The phrase 'graded approach' is consistent with how the IAEA describes the implementation of the system of protection (and safety), where a graded approach is such that the 'application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation' [4]. The proposed rule directly diverges from the IAEA's meaning, though, first in claiming that the 'graded approach to dose management… would ensure risk of stochastic effects is adequately controlled by ensuring that regulatory dose limits are not exceeded' and second by suggesting that 'compliance with regulatory dose limits is sufficient to provide reasonable assurance of adequate protection for individuals' [18]. The original intent of optimisation or ALARA was not to ensure adherence to dose limits, but rather to 'achieve the greatest overall benefit' in a situation [1, 2]. Dose limits are a boundary for the optimisation process (see also section 3.4) [2, 30] and the idea of applying a graded approach to optimisation is to account for the prevailing circumstances in a proportionate way, which in turn necessitates the use of professional judgement (technical, societal, economic, etc) [3, 31].

The ICRP's general recommendations of 1977 (ICRP Publication 26) succinctly describe the interaction of optimisation with the other two fundamental principles as: '[t]he limitation of stochastic effects is achieved by keeping all justifiable exposures as low as is reasonably achievable, economic and social factors being taken into account, subject always to the boundary condition that the appropriate dose-equivalent limits shall not be exceeded'. ICRP Publication 101B built on earlier publications on optimisation, including ICRP Publications 37 (1983) and 55 (1989) [3, 32, 33]. Publication 37 notes that optimisation is an important attitude to maintain due to 'the fact that it may not be good enough to operate just below the dose limits' [32] and Publication 55 reiterates that 'limits are a constraint on optimization' [33]. IAEA Safety Report Series No. 21 (2002) states that optimisation is essential to the RP system since 'reliance on dose limits is not enough to achieve an acceptable level of protection' and that '[d]oses just below the limits can … only be tolerated if nothing reasonable can be done to reduce them' [34]. NCRP Statement 8 (1999) specifies that '[t]hrough the inclusion of the ALARA principle, the NCRP wished to emphasize that adherence only to dose limits was not sufficient' [10]. NCRP Report 180 (2018) states that '… the first objective is to meet that numeric protection criterion [if exceeded], then optimization of protection should be applied' [5].

Of course, the NRC is under no obligation to follow the ICRP or NCRP; it is the NRC's purview to independently decide what is most appropriate and effective from a regulatory standpoint. However, it does have an ethical obligation of due diligence and to honestly and transparently communicate the proposed changes, motivation and justification for those changes, and the associated potential implications of changes.

3.2. Optimisation is not minimisation

The proposed rule change additionally claims that 'the radiation protection community has taken a layered precautionary approach, traditionally seeking to minimize radiation exposure in order to minimize the risk of stochastic health effects' [18]. However, the RP community has sought to optimise protection rather than minimise exposure or dose [2, 3, 5]. ICRP Publication 103 (2007), the most recent general recommendations, specifies explicitly that 'optimisation of protection is not minimization of dose' [2], reiterating a statement in ICRP Publication 101B that it 'should be stressed that optimisation is not minimization' [1]. Similarly, NCRP Report 180 states that 'optimization of protection is not minimization of exposure' [5] and US DOE Standard 1098 (2017) states that 'the ALARA process does not require that exposures to radiological hazards be minimized' [35]. It has been well-noted by practitioners that minimization is an enemy of optimisation [16, 36].

It is also worth noting that the ICRP approach is technically considered prudent (i.e. 'informed and carefully considered' under uncertainty) rather than precautionary *per se*, although the terms have similar meaning [1, 2, 37]. ICRP Publication 138 (2018) further elaborates that '[n]either prudence nor the precautionary principle should be interpreted as demanding zero risk, choosing the least risky option, or requiring action just for the sake of action' [37]. Of course, there are certainly examples of the disproportionate use of resources [36, 38] and the misapplication of the principle of optimisation is a widely acknowledged challenge [17, 39, 40], but it is disingenuous to claim the RP community seeks to minimise exposure.

3.3. Justification goes beyond following the law

The proposed rule change also does not adequately describe the remaining two principles of protection: justification and application of dose limits. Justification is defined in the proposed rule change as 'ensuring that decisions resulting in radiation exposure do more good than harm', with the claim that justification 'is satisfied by the NRC's enacting legislation, NRC regulations, and the licencing process' [18]. This description of justification meaningfully differs from 'any decision that alters the radiation exposure situation should do more good than harm' [2]. Moreover, justification plays a role in the management of day-to-day exposures as part of best practices and is not always met simply by following the law. For example, remediation may reduce exposure but would not be justified if it would result in more harm than good. Physicians make decisions daily regarding whether a medical exposure is justified based on professional judgement.

3.4. Application of dose limits reflects the duty to protect individuals

With respect to the application of dose limits, 'limitation' is defined within the proposed rule change as 'the regulatory body establishing and enforcing dose limits' [18], which is unclear; ICRP Publication 103 defines the principle of application of dose limits as '[t]he total dose to any individual from regulated sources in planned exposure situations other than medical exposure of patients should not exceed the appropriate limits specified by the Commission' where '[r]egulatory dose limits are determined by the regulatory authority' [2]. The application of dose limits accounts for the 'duty to protect individuals' [17], reflecting a deontological perspective, whereas optimisation of protection addresses utilitarian (i.e. collective or societal) issues [27]. These combined ethical approaches, together with virtue ethics, underly the system of RP and are important to keep in mind when considering the system's implementation, e.g., in order 'to do more good than harm, avoid unnecessary risk, establish a fair distribution of exposures, and treat people with respect' [37, 41]. As written, the discussion of dose limits and extension(s) thereof does not adequately capture the responsibility to protect individuals nor the intent within the system of RP to 'avoid any serious inequities in the dose distribution' [42].

The proposed rule change claims that when 'an occupationally exposed individual receives an annual dose below the annual limit, that individual is experiencing a smaller risk than was originally assumed to be acceptable for a radiation worker in developing the annual dose limits' [18], which is not consistent with the modern ICRP approach. The current general recommendations maintain the dose limits in ICRP Publication 60 [2]; although earlier ICRP recommendations (ICRP Publication 26) considered numerical values for dose limits based on 'comparison with the rates of accidental death in industries not associated with radiation', currently recommended dose limits 'represent a selected boundary in

the region between 'unacceptable' and 'tolerable' for the situation to which the dose limit is to apply' [30]. Here, 'tolerable' means 'not welcome but can be reasonably tolerated', and 'acceptable' means 'can be accepted without further improvement i.e. when the protection has been optimised' [30]. Thus, based on the international standard, simply being below the dose limit is not necessarily acceptable, as mentioned above. Finally, the proposed rule argues that using 'additional workers to spread out the dose so as to maintain individual doses below limits' may not be 'commensurate with the risk associated with the dose' [18], which is in effect arguing for the removal of a boundary on what could potentially be serious inequity.

4. Final thoughts

NRC's proposed rule change claims that adherence to regulatory dose limits provides a sufficient level of protection and that beyond prescribed actions at certain thresholds there is otherwise no need for further reflection on, or incorporation of, the prevailing circumstances (i.e. no need to optimise protection) below these dose limits. As written, it also seems as if justification is considered unnecessary if exposures are below the dose limits and the prescribed actions are implemented. These claims (among others) seem to be predicated on misconceptions related to the system of RP and ultimately diverge considerably from international and national consensus. Justifying such divergence would require clear, thoughtful, thorough and transparent arguments, which are unfortunately absent from the proposal.

Furthermore, terminology throughout the proposed rule change is imprecise. For example, 'tissue effects' is used instead of 'tissue reactions', despite reference to ICRP Publication 118 (2012), which introduced the term [18, 43]. The discussion of dosimetric quantities describes introduction of 'several new quantities for measuring radiation dose (i.e. equivalent dose and effective dose)' [18] although neither of these quantities is measurable [2]. A 'dosimetry method (or system)' is described as 'an approach for calculating the biological effects of ionizing radiation exposure in humans' [18], but in the context of occupational and public dosimetry in the system of RP, dosimetry is not a calculation of effect. Such lack of attention to detail further erodes confidence that the NRC gave the task at hand the attention it deserves.

The NRC is a storied institution with a stellar international reputation. Simple mistakes and misconceptions as those described herein are not reflective of the historical commitment of the NRC to public health and safety. Why, then, are we presented with such an insufficient proposal? It seems likely due to excessive political influence, ranging from thoughtless reductions in workforce to overly aggressive timelines and prescriptive demands via EO. The Heads of the European Radiological Protection Competent Authorities observe that the independence of regulatory authorities 'is crucial for preserving public trust and ensuring the effectiveness of RP' [15], and I remain gravely concerned that both will suffer in the US over the coming years.

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Data availability statement

No new data were created or analysed in this study.

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