IRPA Statement on 'Reasonableness' in Optimisation of Protection

Optimisation of protection, including the inherent judgement on what is 'reasonable', is a cornerstone of radiation protection. There is a very wide experience of its application in practice across all fields of protection. However, there are some concerns that the interpretation of what is 'reasonable' in applying the ALARA concept has in some cases become too cautious and limiting, with a tendency towards an approach of minimisation of exposure rather than exercising a balanced judgement on what is 'reasonable'.

These concerns were expressed in the IRPA consultation on the system of protection[1], and since then there have been several workshops and exercises to deliberate on 'Reasonableness'. The French radiation protection society (SFRP) held two workshops on this topic, and published the proceedings[2]. The European ALARA Network has published guidance on optimisation[3], and recently the NEA held a workshop on 'Rethinking the Art of Reasonableness' (Lisbon, January 2020).

In general terms these workshops and deliberations have been based around specific exposure scenarios for the optimisation of protection, and the conclusions relate principally to the specifics of the chosen scenario. Whilst these outcomes are indeed very valuable, IRPA believes that it is necessary to learn wider generic lessons which underpin the process of optimisation of protection for all situations. To this end we have committed to preparing an "IRPA Statement on Reasonableness in Optimisation of Protection", for which we seek the widest review and comment by the IRPA Associate Societies. Following this review within the IRPA family we intend to go out for wider consultation with other key international parties in the field of radiation protection.

The draft statement is attached, and Associate Societies are invited to review and comment on this draft. The closing date for such comment is **13 September 2020**.

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Optimisation of protection is a fundamental principle of radiation protection. It is often referred to as ALARA – keeping exposures As Low As Reasonably Achievable, taking account of economic and social factors. Optimisation of protection is a wider picture than just consideration of dose or exposure, although exposure is a key parameter in the concept. Experience has demonstrated that the optimisation principle is the central pillar for the practical implementation of radiation protection, and is the dominant factor controlling exposures in any well-developed system of protection.

Whilst noting the successes in the application of optimisation, there are concerns in the profession that we are moving to an expectation of 'ever lower doses' and an emphasis on minimisation of exposure, irrespective of judgements on what is 'reasonable'. Perhaps this results from an ingrained conservatism within practitioners, and also from a reaction by some regulatory authorities to a broad public perception that 'any dose is dangerous', which consequently influences required protection standards.

Consumption of huge resources to reduce trivial harm is easily judged to be unreasonable. However, as the cost reduces or the harm increases, the judgment of reasonableness becomes fuzzier and faces challenges. It is therefore helpful to seek broad agreement on how to judge what is 'reasonable' in how we approach optimisation of protection.

What is 'Reasonableness'?

ICRP Publication 138 defines Reasonableness as "To make rational, informed, and impartial decisions that respect other views, goals, and conflicting interests". In IRPA's view the following key factors should be taken into account in seeking reasonableness in protection.

1. Optimisation of protection is a **judgement call** which is essentially situation-based, often termed 'taking account of the prevailing circumstances' (which of course is how all decisions in life should be made). What is judged reasonable in one situation does not automatically determine, or necessarily strongly influence, what may be reasonable in another situation. Whilst it is helpful to follow a structured approach to assessing optimisation, none the less there can be no automatic judgement-free process which leads to a decision. It is important that local circumstances are always taken into account, and an uncritical assertion that the lowest exposure for a particular activity is 'best practice', and should therefore be achieved by all relevant practitioners, should not be made without proper justification.

2. It is widely acknowledged that the effort and resources allocated to optimisation should in broad terms be **proportionate to the level of risk** (which may be judged in terms of individual dose, collective dose as well as issues of perceived risk). This aligns with common sense approaches generally across society, and also with the regulatory principle of a graded approach.

3. Protection judgements must **take account of the balancing of key ethical values**, and the balance point will depend on circumstances:

- Prudence: this is the ability to make informed and carefully considered choices without the full knowledge of the scope and consequences of actions. Whilst in many ways this is a neutral concept, in practice it is often interpreted as a need for precaution, which in turn requires

judgement. In practical implementation the weight given to prudence should reflect the level of risk. The relative emphasis given to prudence at say tens of µSv should be lower than at tens of mSv, where risks are at least a factor of one thousand higher.

- Dignity and Justice: these values are reflected in the need to involve stakeholders in the judgement process

- Beneficence (in association with Non Maleficence) - 'to increase the direct and indirect benefits for individual, community and the environment' (ICRP 138): in broad terms this implies that we strive for the best value for society, with an expectation that the use of resources should be seen to deliver appropriate benefits.

Looked at in broad terms, the ethical values in radiation protection support the concept of proportionality in the approach to reasonableness and in the use of resources.

4. It is important that optimisation processes are based on **realistic assessments of dose**s. The use of multiple conservative assumptions in assessments, which result in significant over-estimates of exposure, or the use of 'worst case scenarios', can lead to a misallocation of resources.

5. It is essential to involve all those parties potentially impacted by the outcome, usually termed **'stakeholders'**, in the process of reaching agreement on the judgement of what is reasonable in the particular circumstances. In doing this it must be recognised that it might not be possible to reach a full consensus on what is reasonable, but it is important that the stakeholder process is open and fair, with clarity on the responsibility for making the final decision. Stakeholder involvement should also be educative for all parties. A key to informed decision making is a shared understanding of the science, related policies and perceived and actual risks. The ideal objective should be that all parties agree that what is to be implemented is 'safe enough'.

6. **The party ultimately responsible for associated expenditure of resources** in implementing the outcome must be fully engaged and represented in the stakeholder engagement process, and must accede to the outcome. This may involve careful consideration of who is really paying the true costs, especially where it may involve imposed costs to customers/consumers or the use of wider society resources.

7. The optimisation process should **take account of all relevant hazards** and not necessarily focus solely on radiation – i.e adopt an 'All Hazards' approach. Indeed, a complete consideration should address not just all hazards, but all negative considerations (detriments) such as expense or loss of income, decrease or loss of services, social disruption, discrimination, and so on. Furthermore, it must consider all benefits, not just the abatement of hazards or other negative considerations. In some situations the total risk could be increased if only radiation hazards are considered. Radiation is often not the most significant hazard, although it often receives the most regulatory attention.

8. Some consideration has previously been given to **the concept of a minimum cut-off**, below which no further efforts to address optimisation are necessary. Various proposals for such a threshold have covered the range from 10µSv/a up to doses around 5-10% of a dose limit. Whilst this sentiment is understandable and has some rationale, it is difficult to apply in practice:

- The simple declaration of a fixed 'de minimis' value carries an imputation that above this value it would indeed be necessary to take action, which may be totally inappropriate.

- Exposure situations are so varied that a single numerical minimum does not seem appropriate.
- Experience has shown that even at low doses there are often simple, realistic and inexpensive actions that can still be taken to improve the exposure situation.

IRPA's view is that at small fractions of a dose limit, or significantly below reference levels, there should be no 'a priori' expectation of dose reduction measures or formal demonstration of ALARA. However, it would still be reasonable to implement actions arising from stakeholder engagement where these improve stakeholder confidence, even if there is no significant benefit in direct safety terms, provided that these do not impose a disproportionate burden on society's resources.

9. The concept of wider **societal 'value for money'** (VFM) in the use of society's resources, as introduced above, should always be taken into consideration in optimisation judgements. Based on general principles of good governance as noted in ICRP104, regulators and governments have obligations to pursue the optimal use of societal resources. Previously in international recommendations there was an emphasis on Cost Benefit Analysis, with a monetary value placed on the manSv as a part of the judgement process. This was aimed at aligning societal VFM across different options for resource spending. Whilst such quantitative analysis can provide important information, in practice the technique has been limited both in scope and application, and rarely makes a significant contribution to optimisation judgements. It is recognised that VFM judgements are in practice quite difficult, but this is still an essential factor that stakeholders, regulators and authorities must consider. This would be consistent with a 'graded approach' to optimisation and with the ethical principle of beneficence.

10. Most radiation protection decisions involve doses less than 'a few' mSv/a, or indeed much lower. The overwhelming majority of exposures are well within the **variability of natural background exposure**, and hence make very little difference to the total dose received by any individual, with total exposure from all sources remaining within the normal range of natural background. In this low dose exposure range there is little direct evidence of harm, hence giving uncertainty over the true risk, although for protection purposes we prudently assume an LNT relationship. Whilst we cannot ignore the optimisation of such exposures, we should none the less be cognisant of society's 'common sense' approach to these variations of background exposure levels. In normal day to day life the many individual decisions (and associated allocation of resources) contributing to such exposure variations are not generally based on concerns or considerations of radiation risks. Whilst such reflection may well not apply in all situations, it does none the less reinforce the need to ensure that the radiation protection decisions we make are seen to result in reasonable value for society.

11. Especially in the cases of occupational and medical exposures there is a very strong alignment between the key aspects of an **ALARA process and the key attributes of a wider safety culture** which should be an inherent feature of any organisation. The common essential components include:

- Engaging with all parties involved in the activity
- Implementing appropriate education and training
- Maintaining an environment allowing openness and challenge
- Learning and sharing from experience
- Strong commitment from the leadership
- Integration of the above commitments into a clear management system

These fundamental safety culture attributes apply irrespective of the level of risk/dose, and they therefore provide a platform for ensuring appropriate attention in those lower dose situations where a more formal assessment of optimisation is not necessary.

These basic commonalities are also applicable in many situations involving public exposure, especially where longer term stakeholder engagement is necessary. In such situations it is often necessary to give greater attention to the process of engagement, due to the unfamiliarity of many stakeholders with the concepts of radiation protection.

12. The above list of factors which should be taken into account in the optimisation of protection is not exhaustive. In the various scenarios there are many other considerations which are appropriate, but IRPA believes that the above factors represent the key generic issues.

Conclusions – What is 'Reasonable' in Optimisation of Protection?

Optimisation of protection is an essential component of radiation protection, and usually is the dominant factor controlling exposures in any well-developed system of protection.

Based on the principles of proportionality and the graded approach, the greatest attention should be focussed on the higher levels of exposure. Lower levels of exposure are also subject to optimisation, but the considerations should be proportionate and integrated into a broader picture of all hazards, ideally within a general safety culture approach, and not focussed around specific expectations of reducing exposures.

Optimisation of protection should always take account of ensuring reasonable value for the use of society's resources.

The effective engagement of stakeholders, i.e. those persons impacted by the exposure and the decisions to be made, is a key to success.