IRPA Guiding Principles on 'Reasonableness' in the Optimisation of Radiation Protection

Introduction and Background

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 in many situations towards an approach of minimisation of exposure rather than exercising a balanced judgement on what is 'reasonable'. This is perhaps reflective of an embedded conservatism within the profession, including within the regulatory community, and it is now very timely to reconsider our fundamental approach to optimisation.

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) arranged two internationally-oriented 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)[4].

In general terms these workshops and deliberations have been based around specific exposure scenarios for the optimisation of protection, and many of the conclusions relate to the specifics of the chosen scenario. Whilst these outcomes are indeed very valuable, IRPA believes that it is also necessary to have a clear understanding of the wider generic issues which underpin the process of optimisation of protection for all situations. IRPA has therefore prepared these Guiding Principles, which have been developed through consultation with the Associate Societies, and which therefore reflect the views of a wide range of radiation protection professionals and practitioners. The views of many other international organisations have also been taken into account in the development of the guidance.

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 societal 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.

Expenditure of huge resources to reduce trivial harm is easily judged to be unreasonable. However, as the cost reduces, or the risk increases, or public concern becomes a significant factor, the judgment of reasonableness becomes much less clear. The complexity of optimisation can also depend on the exposure situations, with emergency and existing exposure situations often being more challenging than planned exposure. Every scenario needs its own specific considerations, but It is also important to have a broad understanding on how to judge what is 'reasonable' in optimisation of protection across all situations – i.e. the common underpinning factors and principles.

This IRPA guidance is addressed to all organisations and radiation protection professionals involved across all fields of protection, including operators, medical specialists, regulators, governmental officials and advisers.

Underpinning Considerations and Context

Optimisation of protection has been a fundamental component of the system of protection for many years, and the concept of 'reasonableness' is integral to this approach. ICRP Publication 101[5] outlines some basic tenets of the approach, noting in particular the increasing role given to considerations of equity, safety culture and stakeholder involvement. It emphasises that optimisation is not minimisation, and thus the best option is not necessarily the one with the lowest dose. ICRP Publication 138[6] defines reasonableness as 'to make rational, informed, and impartial decisions that respect other views, goals, and conflicting interests'.

In working towards a consensus on reasonableness it is helpful to provide for ongoing dialogues between regulators, industry/sector groups and relevant professional bodies such as radiation protection societies. This can provide a supporting national framework for the judgement and decision-making process.

Before defining the key guiding principles for reasonableness it is helpful to explore some underpinning considerations on which any guiding principles are based.

a) Radiation Protection Principles

Optimisation is the second of the three principles underpinning the system of protection - Justification, Optimisation and Limitation - and cannot be seen in isolation. We must first demonstrate that the exposure is justified: namely that it does more benefit than harm. The optimisation process needs to note that this justification has already taken place, and not re-open that fundamental question.

It can also be helpful to note the role of dose reference levels, diagnostic reference levels and dose constraints in the optimisation process. These are aimed at limiting the range of exposures in the interest of ensuring equity amongst the exposed population. They are not direct limits, and must never be considered as such, but can be very useful in the optimisation process and helpful to the understanding of stakeholders.

b) LNT/Threshold

There is scientific uncertainty in the risk posed by radiation in the key dose range of around a few mSv/a, which is the situation where almost all practical decisions of protection are made. Recognising this uncertainty, the system of protection in general use is based on the Linear No Threshold (LNT) model, which assumes for the purposes of protection that the risks identifiable at higher doses (typically down to several tens of mSv) are extrapolated pro-rata to the low dose region. There are other alternative concepts for the risk model for which there is some limited scientific support, in particular the concept of a threshold below which the risk would be zero (or even there could be a hormetic benefit from such exposure).

It is clear that the concept of optimisation at low doses would not be applicable in a threshold model. Whilst there are some strongly-held views in favour of such an approach, the widely accepted basis for the system of protection adopts the LNT model. This IRPA guidance follows this approach.

In practice there is a wide consensus that at these relevant low exposure levels, all we know is that if there is a risk, then it is very small and is equivalent to risks that would normally be accepted in society. In recognition of this we should accept that it is necessary at these low exposure levels to give careful thought before allocating significant effort and resources to the pursuit of even lower doses.

c) Ethical Values

Protection judgements must take account of the balancing of key ethical values as outlined in ICRP Publication 138[6], 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 this is an important and essential concept, in practice it is often interpreted as a need for precaution, which in turn requires careful judgement. In Publication 138 ICRP notes that prudence should not be taken to be synonymous with caution, conservatism or never taking risks. In practical situations where it is necessary to seek a balance between the ethical values, the weight given to prudence and precaution should reflect the level of risk: the relative emphasis given to precaution at for example 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 related to fairness and limiting inequity, which lead to the need to involve stakeholders in the judgement process, and also support the general principle of optimisation. The values therefore support the introduction of equity and fairness in the distribution of exposure among people exposed, which must be taken into account during optimisation.

- Beneficence (in association with Non-Maleficence) - 'To increase the direct and indirect benefits for individual, community and the environment' (ICRP 138[6]). 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.

In any specific optimisation situation it will be necessary to judge an appropriate balance between these key ethical values, none of which are absolute in nature. In summary it can be said that the ethical values in radiation protection support the concepts of proportionality, the engagement of interested parties, and the effective use of resources in the approach to reasonableness.

d) Context of risks and natural background exposure

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. As noted above, in this low dose exposure range there is little direct evidence of harm, hence giving uncertainty over the true risk.

Whilst we cannot ignore the optimisation of such low dose exposures, we should nevertheless be cognisant of society's pragmatic '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 exposures are often classed as 'voluntary', and as such are taken to be less sensitive than imposed risk, in practice for most situations the decisions are taken by individuals in the absence of knowledge regarding radiation exposure, and any associated risks are therefore implicitly deemed as acceptable by society.

Although such considerations may well not be universally applicable, it does nevertheless re-inforce the need to ensure that the radiation protection decisions we make are seen to result in reasonable value for society. It also emphasises that it would be helpful for all parties (stakeholders) engaged in the optimisation process to be aware of the context and perspective of natural background exposure.

Guiding Principles on 'Reasonableness'

1. Judgement Call

Optimisation of protection is a judgement call which is essentially situation-based, often termed 'taking account of the prevailing circumstances' (which of course applies to all decisions in life). What is considered 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, nevertheless there can be no automatic judgement-free process which leads to a decision. It is important that the specific circumstances are always taken into account; hence any generalised assertion that the lowest exposure for a particular activity is 'best practice', and must therefore be achieved by all relevant practitioners, should not be made without proper consideration of all relevant circumstances.

2. Proportionality

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 and collective dose as well as issues of perceived risk), and also take account of the potential degree of exposure reduction. This aligns with pragmatic common sense approaches generally across society, and also with the regulatory principle of a graded approach.

Collective dose can be a valuable factor, particularly in occupational exposure considerations, but its value in other situations may be limited – see further discussion in ICRP Publication 101[5].

As noted by IAEA[x], the incremental benefits to be obtained in terms of dose reduction decrease progressively as the associated expenditure increases. Even the cost of considering the ways in which doses can be reduced can become significant compared with the benefit to be achieved. At some stage, for low doses, the effort might not be worthwhile.

3. Stakeholder Engagement

It is essential to involve all those parties potentially impacted by the outcome, usually termed 'stakeholders', in judging what is reasonable in the particular circumstances. Stakeholder involvement should be educative for all parties, and where some participants are not familiar with radiation risk it

is essential to take enough time to explore and engage cooperatively in order to share understanding of both the science and perception issues involved. Such an approach can help to address what seems to be an inherent fear of radiation in some quarters. A key to informed decision-making is a shared understanding of the science, related policies and perceived and actual risks.

It must be recognised that it might not always be possible to reach a full consensus on what is reasonable, and whilst all stakeholders must have the opportunity to express their own expectations and concerns, it is important as far as possible to avoid strongly-held but singular opinions dominating the process. The stakeholder process must be seen as open and fair, with clarity on the responsibility for making the final decision – i.e. who has the decision authority, and what is the role of the other interested parties. The ideal objective of the stakeholder engagement process would be that all parties accept that what is to be implemented is a fair outcome that is appropriately safe.

It is important to ensure that the party ultimately responsible for associated expenditure of resources in implementing the decision outcome must be fully engaged and represented in the stakeholder engagement process. 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. The funding party's role and responsibilities in the optimisation process must be clearly defined.

ICRP 101[5] notes that the extent of stakeholder involvement will vary from one situation to another. Depending upon the circumstances, it may not be necessary to involve all stakeholders, or types of stakeholders, in every aspect or phase of the optimisation process. Many radiological protection decisions will not be complex or socially contentious, and thus will not need broad stakeholder involvement.

Further guidance is contained in IRPA 's Guiding Principles for Radiation Protection Professionals on Stakeholder Engagement[7].

4. All Hazards Approach

The optimisation process should take account of all relevant hazards, and not necessarily focus solely on radiation – i.e adopt an holistic '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, the health risks of <u>not</u> undertaking medical radiological interventions, 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 when only radiation hazards are considered. Radiation is often not the most significant hazard, although it often receives the most regulatory attention.

It is recognised that in some jurisdictions the scope/competence of a regulatory body may be limited to radiation safety, and hence not formally encompass other risks which should be taken into account in an All Hazards approach. In such situations it is important for the regulatory body to establish working relations and practical agreements with other relevant regulatory authorities.

5. Avoidance of Over-Conservatism

It is very important that optimisation processes are based on realistic assessments of doses and other risks. The use of multiple conservative assumptions in assessments, which result in significant over-

estimates of exposure, or the use of 'worst case scenarios', are a misinterpretation of reasonableness and can lead to a misallocation of resources. Where there is a range of possible outcomes for a scenario, then careful judgement is necessary to determine the basis for assessments so that the outcome may be considered as 'reasonable'.

It is noted that in some cases an exposure assessment is undertaken solely to demonstrate compliance with a defined criterion. In such cases it may be appropriate to use conservative parameters if this approach can easily demonstrate compliance. However, where it is important to determine the actual exposure levels, such as in an optimisation assessment, then it is important to avoid over-conservatisms.

6. Value for Society

The concept of wider 'value for society' in the use of resources, as introduced in the above discussion on ethical values and the risk context, should always be taken into consideration in optimisation judgements. As noted in ICRP104[8], based on general principles of good governance, governments have obligations to pursue 'the optimal use of societal resources' and 'not allow such resources to be squandered on unproductive legislation and fruitless regulatory control'. The concept of Value for Society must include the use of financial resources as well as other concepts of societal value.

Previously in ICRP recommendations[9, 10] there was an emphasis on Cost Benefit Analysis (CBA), with a monetary value placed on the personSv as a part of the judgement process. This was aimed at aligning societal Value for Money (VFM) across different options for resource spending. Over more recent times there has been a growing emphasis placed on the equity issue raised by the uneven distribution of benefits and detriments through society, and on a consequent need to involve all stakeholders in the optimisation process. These are important developments which are central to this guidance, but it does seem that the consideration of financial factors in judging a balanced value for society has become much less visible.

Whilst quantitative analysis such as CBA 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. There are other quantitative techniques which can assist in the judgement of value for society, such as Multi Attribute Utility Analysis and related systems, and these can be helpful.

There is evidence in other aspects of life where VFM considerations are quite central to societal decision-making. In the healthcare sector there are several examples where decisions are made on how to prioritise the spending of the national health budget. The use of the QALY concept (Quality Adjusted Life Year), which in many ways has analogies with a CBA approach, has been adopted in several countries and has been proven as a valuable approach.

It is recognised that VFM judgements are in practice quite difficult, but it is important that they are recognised as having a rightful place in the overall judgement of value for society. Financial considerations are 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 value of beneficence. The challenge is how to ensure that in practice these considerations are factored into optimisation assessments. IRPA believes that further deliberation is necessary in order to ensure that financial aspects are given due regard in the judgement of reasonableness.

7. De Minimis cut-off

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 the relevant worker or public dose limit. Whilst this approach is understandable and has some rationale, it is difficult to apply in practice:

- The simple declaration of a fixed 'de minimis' value can be seen to carry 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 realistic, and would be likely to lead to an inappropriate 'lowest common denominator' approach.
- 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, often based on the 'safety culture' concept.

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. The interpretation of the term 'small fraction' is inevitably judgemental, but would not exceed of the order of one tenth. This does not imply that exposures above these levels should always be considered for optimisation. Indeed, for many exposures this would be totally unrealistic.

However, as noted above, in some low dose situations there may be appropriate measures that could reasonably be taken. For example to implement actions arising from safety culture considerations or from stakeholder engagement, where these improve overall confidence without imposing a disproportionate burden on society's resources, even if there is no significant benefit in direct safety terms. In such cases it would be helpful overtly to recognise the basis on which the decision is made.

This issue of a De Minimis approach is of wide interest and importance. IRPA believes that further deliberation is necessary in order to further explore the concept.

8. Alignment with Radiation Protection Safety Culture

There is a very strong alignment between the key aspects of an ALARA process and the key attributes of a wider safety culture, of which radiation safety culture is an integral sub-set. A strong safety culture should be an inherent feature of any organisation, covering all contributions to risk, including radiation. The common essential components of a safety culture 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 appropriate.

There is good evidence for the success of safety culture approaches, especially in the cases of occupational exposure and for the totality of occupational and patient exposures in a healthcare setting. Culture-based approaches 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.

9. Audit Trail

In any specific optimisation scenario there are very many factors that need to be taken into account, and the outcome is often the result of a complex judgement process. As part of the process it is helpful to declare and record the key factors which determined the decision. This will help to decide if the optimisation process should be revisited when circumstances change, and it also makes visible whether it is radiation risk itself, perception issues or other factors that have been key to the outcome in those specific situations. This can help inform other situations and is important in seeking to avoid establishing inappropriate precedents, as well as ensuring that stakeholders are clearly aware of the decision drivers.

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. Each exposure situation is individual, and must be addressed as such, and there is a wide range of factors which should be taken into account. Some of these factors may be common, or particularly important, in specific exposure situations such as planned, emergency and existing exposures. Medical exposure also has a particular set of common factors, for example relating to optimising imaging practice around image quality. It is not possible for this IRPA guiding principles document to cover all these different detailed situations.

The above list of Guiding Principles covers principles that should be applicable in all, or most, scenarios and situations, but cannot be taken as a complete exhaustive set of factors. IRPA believes that the above principles represent the key generic issues. Taking these into account in judgements of reasonableness will lead to greater consistency in approach, greater confidence in the outcome and improved transparency.

Specific remarks for the consultation on this v2 draft

There are two particular issues where there was strong support from the IRPA Associate Societies in the first round of consultation, but where the way forward is not clear and it was considered that further reflection is important:

- *De Minimis Cut-off: There was agreement on the need to avoid unproductive effort at very low doses, as well as broad support for the de minimis concept, but there was a range of views on how best to proceed.*

- *Value for Society: Specifically on how best to ensure that financial considerations are properly taken into account.*

Further reflections on these two issues are particularly welcome.

References

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