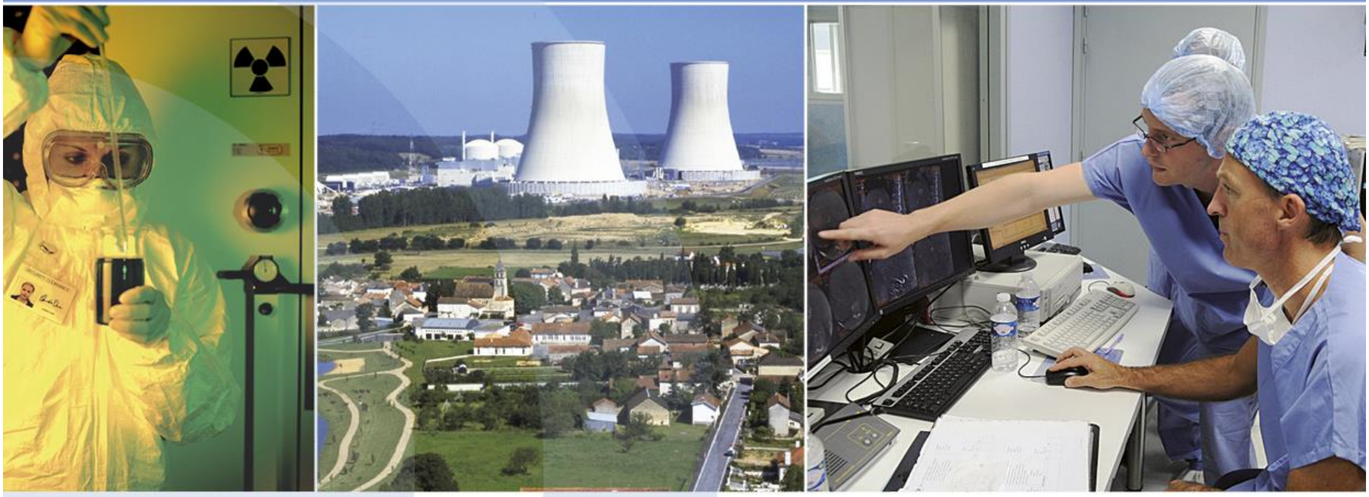
IRPA

INTERNATIONAL RADIATION PROTECTION ASSOCIATION

IRPA PERSPECTIVE ON ‘REASONABLENESS’ IN THE OPTIMISATION OF RADIATION PROTECTION



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AN IRPA PERSPECTIVE ON 'REASONABLENESS' IN THE OPTIMISATION OF RADIATION PROTECTION

Table of Contents

1. Introduction and Background

Optimisation of protection, including the inherent judgement on what is 'reasonable', is a cornerstone of radiation protection for ionising radiation. There is a very broad experience of its application in practice across all fields of protection. However, as expressed in the IRPA consultation on the system of protection[1], there are some concerns that the interpretation of what is 'reasonable' in applying the ALARA concept has led to 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.

Because 'reasonableness' is so central to practical protection there have been many workshops and exercises at an international level to deliberate on this topic. For example, following the IRPA system of protection consultation the French Radiation Protection Society (SFRP) arranged two internationally-oriented workshops on this topic[2], the European ALARA Network (EAN) has published guidance on optimisation[3], and the Nuclear Energy Agency (NEA) held a workshop on 'Rethinking the Art of Reasonableness'[4]. Hence there is much information regarding specific exposure scenarios for the optimisation of protection, and many conclusions relating to the specifics of the chosen scenario. In addition, some general conclusions on the approach to optimisation have also been identified.

Whilst these outcomes are indeed very valuable, it is inevitable that international considerations will continue on this important topic, for example with ongoing work planned by ICRP, NEA and many other organisations. IRPA strongly supports these developments and believes that it is necessary to have a clear understanding of the wider generic issues which provide a common underpinning of the process of optimisation of protection across all exposure situations and scenarios. Noting this, we believe it is essential that ongoing considerations take account of the experience of those professionals who have to implement radiation protection on a day-to-day basis – i.e., the perspective of the IRPA practitioner. IRPA has therefore prepared this document, which has been developed through consultation with the Associate Societies, and which therefore reflects the views of a wide range of radiation protection professionals and practitioners (see appendix). In taking this approach we also invited input from other international organisations so that we could be informed from a wider perspective, although it must be stated that this document is principally reflecting the views of the practitioner community.

Because the IRPA community is so wide-reaching, both in terms of fields of experience and geographical cover, it is inevitable that on some issues there cannot be universal agreement. Where this divergence is reflected in responses from our membership, our approach is to seek out the widest possible consensus whilst accepting that there are some alternative perspectives. However, overall, there was broad agreement on the key issues under consideration.

Optimisation of protection is one of the three fundamental principles 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 a dominant factor controlling exposures in any well-developed system of protection.

The specific characteristics and complexity of optimisation can depend on the exposure situations, with different emphasis often given to various characteristics of approach. Emergency and existing exposure situations are often more challenging than planned exposure. Within the planned exposure situation there are significant differences in approach, for example relating to medical exposure, largely because for this case too low a dose is as inappropriate as too high a dose: the emphasis is on ensuring the lowest reasonable dose which meets the clinical requirements (e.g. in terms of image quality or cancer cell killing). In all situations every scenario needs its own specific considerations, but in recognising these differences it is also important to have a broad understanding of the key issues in judging what is 'reasonable' in optimisation of protection across all situations – i.e. the underpinning factors and principles which are common across all situations even if the emphasis varies from case to case.

This IRPA document is addressed to all radiation protection professionals and organisations involved across all fields of protection, as well as other interested parties involved in optimisation of protection.

2. Fundamental Considerations and Context

Optimisation of protection has been an essential 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 making 'rational, informed, and impartial decisions that respect other views, goals, and conflicting interests'.

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

Before defining the key generic issues for reasonableness it is helpful to explore some fundamental considerations on which any guidance is based.

2.1. Radiation Protection Principles

Optimisation is the second of the three principles underpinning the system of protection - Justification, Optimisation and Limitation - and cannot be considered in isolation. Firstly, it must be demonstrated that the exposure, or the proposed protection strategy, is justified: namely that it provides more benefit than harm. The optimisation process follows on from this justification and does not replace or second guess 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 upper end of 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.

2.2 Dose Response Model: LNT/Threshold

There is scientific uncertainty in the risk posed by radiation in the key dose range of around a few mSv/year, which is the situation of greatest importance for practical decisions on protection. 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 cancer risks identifiable at higher doses (typically down to around a hundred mSv or so) are extrapolated pro-rata to the low dose region. There are other alternative concepts for a risk model for which there is some scientific support, in particular the concept of a threshold below which the risk would be zero, or that there could even be an hormetic benefit from such exposure.

It is clear that in a threshold model the concept of optimisation for each potential contribution to the total individual dose would be complex and less clear, with there being virtually no role for such an approach where the total dose is below any declared threshold. Whilst there are some strongly-held views in favour of such an approach, including some of the IRPA practitioners contributing to this report, the internationally-accepted basis for the system of protection, as recommended by ICRP and endorsed by the principal international organisations, adopts the LNT model. This IRPA document follows this approach.

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. 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, where there would be little direct health benefit. It is also recognised that the acceptance of LNT can be seen to underpin the idea in the public consciousness that 'there is no safe level of radiation'. Whichever model (LNT or threshold) is assumed, what is common is the need to emphasise the importance of ongoing public information and interaction on radiation risks, both in general terms and within each specific engagement on optimisation.

2.3 Ethical Values

Protection judgements must take account of the key ethical values, as outlined in ICRP Publication 138[6], and the relative importance of each 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. It should also be recognised that characteristics of the exposure situation in addition to dose may also serve as a basis for action.

- 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, and the involvement of all interested parties in a transparent and inclusive process during optimisation.

- Beneficence (in association with Non-Maleficence): ICRP 138 notes that this aims 'to increase the direct and indirect benefits for individuals, community and the environment'. 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 respect these key ethical values, whilst noting that because the values are not absolute in nature it will be necessary to judge the most appropriate balance between them. 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.

2.4 Context of risks and natural background exposure

Although there are exceptions, particularly for some medical, existing and emergency situations, most radiation protection decisions involve doses less than 'a few' mSv/year. As such the majority of exposures are within or less than the unavoidable basic range of natural background exposure (typically say from 2 up to around 5 mSv/year), and hence make little difference to the total dose received by any individual, with total exposure from all sources remaining within this typical range of natural background. As noted above, in this low dose exposure range there is no definitive 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 variations of background exposure levels. In normal day-to-day life the many individual decisions which contribute to such exposure variations, such as where to live or go on holiday, what to eat, how to travel (etc), 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, they do nevertheless re-inforce the need to ensure that the radiation protection decisions we make at low doses are aligned with wider experiences and 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, ideally in the context of a wider risk-informed society. However, whilst providing helpful context, natural background exposure cannot be seen in itself as a justification for exposure from other sources.

3. Principal Underpinning Factors for 'Reasonableness'

3.1. 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. It is helpful to follow a structured deliberative process to assessing optimisation, without basing this on specific numerical criteria, and also to recall that optimisation has been described as 'a frame of mind'[7]. There is 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.

3.2. Proportionality

It is widely acknowledged that the effort and resources allocated to optimisation should in broad terms be proportionate to the level of risk, whilst also taking account of social perception aspects. The effort should also reflect 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, where the degree of resource allocation should take account of risks and both social and economic impact.

Taking due account of the number of persons exposed can be a relevant factor in some situations, for example in occupational exposure considerations. Whilst the concept of collective dose has been used in some optimisation situations, its value and use may be limited and must be carefully judged, especially when aggregating a large number of very small doses where the concept essentially becomes meaningless – see further discussion in ICRP Publication 101[5].

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.

3.3. Stakeholder Engagement

It is essential that all those parties potentially impacted by the outcome, usually termed 'stakeholders', are involved 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 provide helpful context for what seems to be an inherent fear of radiation in some quarters. A key to informed decision-making is moving to a shared understanding of the science, radiation protection concepts and principles, and perceived and actual risks and concerns, through a process of dialogue.

It must be recognised that it might not always be possible to reach a full consensus on what is reasonable. 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, fair and honest, and provide the basis for developing trust between the parties. It is important that there is clarity on the responsibility for making the final decision – i.e. who has the decision authority, and defining the role of the other interested parties. The ideal objective of the stakeholder engagement process would be that all parties agree that what is to be implemented is a fair outcome that is appropriately safe: this has been referred to as maximising overall well-being, which takes account of the full range of social considerations.

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 significant broad stakeholder involvement.

Further guidance is contained in IRPA's Guiding Principles for Radiation Protection Professionals on Stakeholder Engagement[8].

3.4. Holistic '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 not always the most significant hazard, although it often receives the most regulatory attention.

The optimisation principle applies to all exposure situations, including environmental exposure. This is a developing field which must be kept under review. Some experiences with the application of 'Best Available Technology' to environmental discharges have identified concerns over the perceived emphasis on minimisation rather than optimisation, and a lack of appropriate financial considerations in this approach. Optimisation also applies to situations involving potential exposures, where assessment of the likelihood of events is necessary as well as of the resulting exposures (individual doses and the numbers of persons potentially exposed).

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 holistic '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.

3.5. Avoidance of Over-Conservatism

It is very important that optimisation processes are based on realistic assessments of risks and benefits, including dose assessments and other relevant 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 optimisation assessments so that the outcome may be considered as 'reasonable'.

It is accepted that in some cases an exposure assessment is undertaken solely to demonstrate compliance with a defined criterion such as a limit or constraint. 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 undue conservatism.

3.6. Value for Society – Optimal Use of Societal Resources

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[9], 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[10, 11] there was an emphasis on Cost Benefit Analysis (CBA), with a monetary value placed on the person-Sv 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 the need to involve all stakeholders in the optimisation process as in the ethical considerations noted previously. These are important developments that are central to this report, 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[12].

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. Whilst recognising the importance of seeking an overall 'value for society' which encompasses a much wider range of attributes[2, 3, 4, 5, 6], IRPA believes that the contribution of the financial component of this deliberation merits a higher recognition than currently experienced.

3.7. De Minimis Approach

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/year[13] up to doses around 5-10% of the relevant worker or public dose limit[14]. Whilst this approach is understandable and has some rationale, it is challenging to apply in practice:

- The simple declaration of a fixed 'de minimis' value perhaps carries an imputation that even just above this value it is necessary to undertake optimisation, which could lead to inappropriate and unnecessary action.
- 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. A system of different de-minimis levels appropriate for different types of situations could be more 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 by resulting in greater overall well-being.

Whilst the above considerations identify challenges in applying the de-minimis concept, it is none the less appropriate to consider how the underpinning conceptual value of this approach could be manifested in a more practical way. IRPA therefore encourages authorities and regulatory bodies to have a very careful regard before setting expectations or requirements for optimisation assessments at low doses, unless there are significant and specific reasons for doing so. This approach should apply where exposures are significantly below relevant limits, constraints, or reference levels – which of course would be a matter of judgement and which could benefit from wider consideration. Such a course would align with the concept of a graded approach and support the effective use of society's resources.

However, as noted above, in some low dose situations below any implied de-minimis level there may be appropriate measures that could reasonably be taken by the respective local interested parties: for example, to implement actions arising from safety culture considerations, or from stakeholder engagement where these improve overall confidence and well-being 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.

3.8. Alignment with Radiation Safety Culture

There is a 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 attributes of a safety culture include:

- Engaging with all parties involved in the activity
- Implementing appropriate education and training
- Maintaining an environment supporting a questioning attitude, 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 both occupational and patient exposures in a healthcare setting. Radiation protection 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.

3.9. Audit Trail

In any specific optimisation scenario there are 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, especially in the more complex optimisation scenarios. 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.

4. 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, with a wide range of factors which need to be taken into account.

This IRPA perspective identifies the principal key factors which provide a common underpinning across all (or most) optimisation situations and scenarios. The relative importance of these factors may vary from situation to situation, especially across the different exposure situations (planned, existing and emergency) and exposure categories (occupational, public and medical). In addition, there will be many other factors that must be taken into account in each specific scenario, some of which may be common across a particular exposure situation or category. Because of the wide range of potential factors and influences, it is not possible for this document to cover all these different detailed situations. However, there is considerable literature and ongoing deliberations that can helpfully provide additional guidance in many specific situations.

IRPA believes that the above perspective represents the key generic issues relevant to the optimisation of protection. Taking these into account in judgements of reasonableness will lead to greater consistency in approach, greater confidence in the outcome and improved transparency.

Because of the central importance of optimisation, it is also recognised there will be ongoing considerations on reasonableness at both international and national levels. As well as providing valuable guidance for current practice, this IRPA document presents a practitioner's perspective into ongoing further developments

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Appendix: Responses to the IRPA Consultation on 'Reasonableness'

1- First Consultation for IRPA Associate Societies

- Australasia (ARPS)
- Austria (OVS)
- France (SFRP)
- Germany/Switzerland (FS)
- Italy (AIRP)
- Japan(JHPS)
- Korea (KARP)
- Netherlands (NVS)
- South Africa (SARPA)
- UK (SRP)
- US (HPS)

2- Second Consultation for IRPA Associate Societies

- Argentina (SAR)
- Belgium (BVS)
- France (SFRP)
- Japan (JHPS)
- Spain (SEPR)
- UK (SRP)
- US (HPS)

In total 14 Associate Societies responded to the AS consultations. These societies cover a wide geographical base (North America, Latin America, Europe, Africa, Asia, Australasia) and represent around 80% of the total IRPA membership of individual professionals. The full comments received from the Associate Societies are available on the IRPA website alongside this document.

3- Second Consultation: Other National/International Organisations

Several international/national organisations responded to invitations to comment on the second consultation draft guidance.

- American Nuclear Society (ANS)
- Iberoamerican Forum of Radiological and Nuclear Regulatory Organisations (FORO)
- International Commission on Non Ionising Radiation Protection (ICNIRP)
- International Commission on Radiological Protection (ICRP)
- International Organisation of Medical Physics (IOMP)
- Public Health England (PHE)
- Nuclear Energy Agency (NEA)
- World Nuclear Association (WNA)

In addition the following organisations presented preliminary comment on the draft document at the IRPA Side Event on Reasonableness during the IAEA International Conference on Radiation Safety (IAEA2020), November 2020:

- US Conference of Radiation Control Program Directors (CRCPD)
- Heads of European Radiological Protection Competent Authorities (HERCA)
- International Atomic Energy Agency (IAEA)

IRPA Executive Council

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