13 September 2020

Roger Coates
IRPA President

Eric Goldin
HPS President
Health Physics Society

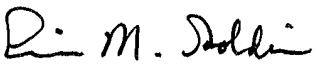
Subject: Comments "IPRA Statement on 'Reasonableness' in Optimisation of Protection'

As an Associate Society of IRPA, the Health Physics Society[1] (HPS) appreciates the opportunity to provide comments on the May 2020 request of the "IPRA Statement on 'Reasonableness' in Optimisation of Protection".

In preparing our response, we reviewed our respective Position Statements related to this topic and provide a brief summary below. We also sought input from several of our standing committees, sections, and invited input from individual HPS members through a public notice in our monthly HPS Newsletter. (https://hps.org/membersonly/publications/newsletter/hpnewsvol48no07.pdf) We believe this review effort is consistent with IRPA's desire to seek the widest review and comment to support your efforts in seeking further consultation with other key international parties in the field of radiation protection.

If you have any questions regarding these comments, please feel free to contact me at +1-760-271-1280 or emgoldin@yahoo.com.

Sincerely,



Eric Goldin, CHP
President, Health Physics Society

cc:
John Cardarelli II, PhD, CHP, CIH, PE, President-Elect
Eric Abelquist, PhD, CHP, HPS Past-President
Robert Cherry, Jr, CHP, HPS Past-President
Brett Burk, HPS Executive Director

[1] The HPS is a nonprofit scientific professional organization whose mission is excellence in the science and practice of radiation safety. Since its formation in 1956, the Society has represented the largest radiation safety society in the world, with a membership that includes scientists, safety professionals, physicists, engineers, attorneys, and other professionals from academia, industry, medical institutions, state and federal government, the national laboratories, the military, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits.

Summary of key HPS Position Statements

The position statement on the Intentional Nonmedical Radiation Exposure of the Public (https://hps.org/documents/intentionalnonmedicalexposure_ps028-0.pdf) addresses bioethical issues and states that *"No member of the public should be intentionally exposed to ionizing radiation without his or her knowledge."* We believe this condition is fundamental to gaining public trust and accepting recommendations that may challenge their initial fears or negative perceptions associated with unnecessary or unwanted exposure to ionizing radiation.

Our position statement, Radiation Risk in Perspective (https://hps.org/documents/radiationrisk.pdf) advises against estimating health risks to people from exposure to ionizing radiation that are near or less than natural background levels because of the large statistical uncertainties at these low levels. We state *"...below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero*." Also *"...the LNT hypothesis cannot provide reliable projection of future cancer incidence from low-level radiation exposure*." This position is based on known scientific evidence that (1) molecular-level radiation effects are non-linear, (2) radiogenic health effects have not been consistently demonstrated below 100 mSv, (3) dose-rate is a known factor that has demonstrated non-linear responses, and (4) misuse of collective dose in radiation protection planning and risk assessment decisions where "*...the multiplication of small risk coefficients by large population numbers leads inevitably to unsupportable claims of cancer risk from ionizing radiation.*" The last factor is central to much of the regulatory problems encountered in the United States, and noted in the IRPA statement, regarding cleanup of contaminated sites.

Our position statement, Uncertainty in Risk Assessment (https://hps.org/documents/riskassessment_ps008-2.pdf) states "…*the expenditure of public and private funds to mitigate these risks should be commensurate with the public health benefits expected to be achieved"* Examples of problem areas include (1) 100- to 1,000-fold discrepancies in permissible exposure levels among various regulations, all based on much the same scientific risk-assessment data, (2) proposed expenditures of billions of public and private dollars to clean up radioactively contaminated federal and commercial sites without careful consideration of the proportionality of costs to the public health benefits to be achieved, and (3) extensive delays in licensing facilities for the disposal of radioactive wastes and other applications of nuclear technologies. Perhaps most notable is the acknowledgement that cancer and other health effects have not been observed consistently at low doses (< 0.1 Gy), much less at the even lower doses (< 0.01 Gy) typical of most occupational and environmental exposures. We continue to recommend that regulations intended to achieve very low levels of radiation exposure should take full account of the uncertainties in risk estimates; otherwise, they may result in enormous expenditure of limited resources with no demonstrable public health benefits. In fact, some regulatory positions may increase overall public health risk when extreme measures, such as population relocation, to avoid effective doses of 50 mSv are imposed, due to physical injuries, mental health, and somatic illness induced by the stress of relocation, as appears to have occurred at Fukushima.

Regarding our position statement on Radiation Safety Culture (https://hps.org/documents/radiationsafetyculture_ps026-0.pdf) we offer a matrix of 9 traits derived with input from industry, scientific, and professional organizations that helps to create a protective radiation safety culture. This may benefit IRPA's overall communication of this topic to other international partners in the field of radiation protection.

Our position on Stakeholder Engagement (https://hps.org/documents/stakeholder_engagement_ps024-

0.pdf) endorses the Guiding Principles for Radiation Protection Professionals on Stakeholder Engagement developed by the International Radiation Protection Association (IRPA).

Finally, our position statement on Ionizing Radiation Safety Standards for the General Public (https://hps.org/documents/publicdose_ps005-3.pdf) states *"Public radiation safety standards should be based on specified values of dose rather than hypothetical estimates of risk."* This is an important factor to communicate reasonableness in any radiological environment because radiation exposure is measurable whereas risk is not. Dose estimates via exposure measurements represent a method whereby any individual can make a measurement using a properly calibrated instrument to decide the best action for themselves, while considering the guidance and recommendations from scientific and professional organizations.

Specific comments from HPS Committees and Members

The Scientific and Public Issues Committee (S&PIC) and the president carry out the duty of spokesman for the society. The following paragraphs summarize comments received from several HPS committees, sections, or individual members of the society. They were reviewed by the S&PIC which consists of the HPS President, President-Elect, and three of the most recent past presidents of the society. Comments were received from our Standards and International Coordinating Committees and several HPS Sections (Power Reactor; Academic, Industrial, Radiation Research; and Medical Physics). The comments are presented according to the format of the IRPA document and do not reflect attribution to a particular committee, section or individual HPS member as these represent the views of the society.

As noted in several of our HPS Position Statements, there are many consistencies noted in the 'IRPA Statement on 'Reasonableness' in Optimisation of Protection." These include (1) concerns of an expectation of 'ever-lower-doses' and an emphasis on minimization of exposure, (2) overly conservative assumptions used by some regulatory authorities (e.g., U.S. Environmental Protection Agency regarding environmental cleanup standards; see https://hps.org/documents/epa_hps_regulatory_reform_task_force_2017-05-15.pdf and the U.S. Nuclear Regulatory Commission, see https://hps.org/documents/hps_nrc_lnt_comments_2015-11-05.pdf), (3) consumption of huge expenditures to reduce trivial harm, and (4) ICRP Publication 138 definition of reasonableness, especially respecting the views of others, goals, and conflicting interests.

Before we provide specific comments, I would like to note that there is one key area where the society differs with the IRPA statement, and that is the reliance on the LNT relationship with **low-dose radiation exposure** as a prudent assumption for radiation protection. The HPS states in Radiation Risk in Perspective (PS010-4) that *"because of statistical uncertainties in biological response at or near background levels, the LNT hypothesis cannot provide reliable projections of future cancer incidence from low-level radiation exposures (NCRP 2001)."* The HPS recognizes that the current radiation protection paradigm is based on the LNT hypothesis and that provides the basis for ALARA. This paradigm was intended for setting occupational limits. It's application to establish environmental limits that fall at or near background is problematic for the reasons outlined our HPS position statement and in the IRPA statement. HPS continues to be concerned that the use of the LNT in this context is the root cause for the very challenges we face today. We continue to state that reliance on the LNT model tends to foment the public's fear of all types of radiation. Regarding this context, we offer the following comments:

1. In the first paragraph, IRPA states *"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."* The HPS believes it is important to recognize that there is nothing optimal about controlling exposures when those exposures convey no risk or deny potentially beneficial effects to the relevant target audience (i.e., workers, members of the public, patients, manufacturers of IR producing equipment, etc.). Optimization in this context should only be applied to doses and dose-rates known to have a strong scientifically-based foundation of deterministic and stochastic adverse health effects. However, it does not preclude the option of using optimization based on other economic, societal, or political factors. This distinction should be made clear that optimizing exposure below a known threshold or stochastic level is not scientifically justified but based on other factors.
2. The HPS concurs that the ALARA concept can be overly cautious & limiting, however, from a medical physics perspective, we understand the ALARA purpose is to minimize exposure to the patient while assuring the exposure is adequate to produce an efficacious result and avoid repetitive exposure of the patient. Concurrently, as stated in the final paragraph, it is necessary to learn *"wider generic lessons which underpin the process of optimization of protection for all situations"* is an important step and the HPS supports this mission and is glad to be involved in the process. Further we suggest the statement should state that a key stakeholder significantly impacted in this discussion is the patient. As written, the IRPA statement implies this but it is not stated. The concept of a 'Standard of Practice" based on this premise can be valuable to all stakeholders; especially the patient.
3. Factor 1: IRPA quotes ICRP Publication 138, which defines Reasonableness as *"To make rational, informed, and impartial decisions that* ***respect other views****, goals, and conflicting interests."* [emphasis added]. The HPS suggests the IRPA statement acknowledge and include other scientifically-based views regarding the effects of radiation exposures that point to a threshold or hormetic effect, especially from low level radiation exposures. Excluding this discussion is paramount to ignoring the volumes of scientifically-sound data that have demonstrated these effects and jeopardize the credibility of the association.
4. Factor 2: IRPA states *"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)."* HPS re-iterates our concern that the risk is non-detectable and possibly beneficial in these low dose, low dose-rate environments. Allocating resources should be based on the science unless economic, societal, or political forces eclipse the science.
5. Factor 2: HPS recommends IRPA remove the term "collective dose" in reference to determining the level of risk. Collective dose should never be used to assess risk to individuals.
6. Factor 3: Within the Prudence ethical value, IRPA suggests that a dose of "tens of mSv" results in an adverse risk at least a factor of one thousand times higher than "tens of μSv". The HPS disagrees with this statement because there are no adverse health effects consistently observed in the scientific literature at these low dose levels. Furthermore, it implies a linear relationship within this low dose range that is not supported in the scientific literature.
7. Factor 3. While we appreciate and agree with including the four key ethical values as a necessity for any decision on "reasonableness," HPS suggests this document should explain

them more clearly in the context of attempting to interpret the term “reasonable” for the health physics community and the general public. More specifically,

a. The HPS is concerned that "prudence," or reference thereto, often results in further optimization / dose reduction cycles via a series of conservative assumptions in exposure assessments. While we feel it is key in any decision related to optimization and radiological protection, it must not be used as a pretense for undue restrictions or limitations. “Prudence,” by its definition, does not necessarily imply that a planned action cannot be executed.

b. "Dignity" and "justice" most certainly are at the core of an appropriately designed and executed stakeholder process. However, both can be easily lost in this process if individual opinions or singular viewpoints are allowed to dominate the discussions (see more below also with respect to stakeholder "consensus") and if threats (regarding lawsuits) become a driving factor, or resort is taken to paternalism. The HPS believes that it should become clear in these bullets that “dignity” and “justice” do not necessarily imply action according to the smallest common denominator.

c. The HPS is concerned that the strongly Utilitarian approach in the bullet on "beneficence" could be misinterpreted which states *"...we strive for the best value for society, with an expectation that the use of resources should be seen to deliver appropriate benefits."* We agree, in principle, with this statement; however, one of the criticisms of utilitarian ethics is that the utmost benefit to the largest number of people (society) could lead to unacceptable detriment for individuals; or put differently, the greatest benefit to the majority may conflict with what is beneficial for certain individuals or the environment. We suggest revising this particular sentence.

8. Factor 4: The HPS agrees with the statement. However, in our experience, the *“...use of multiple conservative assumptions in assessments, which result in significant over-estimates of exposures”* appear to be a common practice in the health physics community, possibly under the guise of “prudence.” Over-estimates are not necessarily “significant” in all instances, but often are appreciated by the stakeholders and built into many health physics processes.
9. Factor 4: The HPS believes this represents a paradigm shift from the use of conservative assumptions (simple assumptions) to the use of realistic assumptions (complex assumptions). The whole system of radiation protection is currently built on radiological performance evaluated around worst case scenarios (simple and conservative assumptions); shifting to realistic assumptions will add a level of complexity that will have to be fully implemented and understood by each radiation protection system participant, from the affected stakeholders to the regulators. We acknowledge this is not a simple task to undertake; realistic assumptions may lead to unwanted tensions (e.g., lack of consensus) due to disagreements that are inevitably associated to the intrinsic meaning of “what’s real” and “what’s not real”. We generally support this statement.
10. Factor 5: HPS strongly supports the inclusion of stakeholders in the decision-making process. IRPA also states *“A key to informed decision making is a shared understanding of the science, related policies and perceived and actual risks.”* HPS encourages IRPA to acknowledge and include a statement about the state-of-the-science that supports a threshold and potential hormetic effect from low-dose and low-dose rate exposures to ionizing radiation. It is difficult to have a shared understanding without the full disclosure of our knowledge at the low-dose, low-dose-rate effects. Again, this should help to optimize decision-making where scientific

evidence supports it, otherwise, those decisions should be acknowledged as being driven by economic, societal, or political factors.

11. Factor 5: IRPA initially states that *"stakeholders [are involved] in the process of reaching agreement on the judgement of what is reasonable in the particular circumstances."* but follow-up with *"...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."* The HPS believes this may be somewhat of an idealistic outcome. Individuals or groups who do not agree with the final decision in the process might still utilize other means (e.g., lawsuits) to achieve an alternative outcome. This may change "reasonableness" after it has been established, or even preemptively if the stakeholder process is not completed until the most stringent demands are met. The question at the core of this discussion will always be the definition of "safe enough." One could concentrate on rendering the process educative and that decision making is properly informed for all stakeholders, while recognizing that all parties still may not agree on the final decision for a variety of reasons. Does IRPA have an opinion on how a course of action will be decided if such a consensus cannot be reached?

12. Factor 8: IRPA states *"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."* HPS acknowledges the practical realities that decisions may not be strictly scientifically based, but as a scientific organization, we recommend IPRA refrain from giving credence to decisions that allocate limited resources toward an activity that is not scientifically-grounded. If a decision is based on stakeholder input that is not consistent with our knowledge of the science, it is prudent and ethical to clearly state that such a decision is not based on science but being driven by other factors. It's critical that such a decision not be cloaked by a perception of being scientific based.

13. Factor 8: IPRA states *"Whilst [the concept of a minimum cut-off] is understandable and has some rationale, it is difficult to apply in practice."* The HPS believes that such a cut-off indeed might be valuable, as it could save a tremendous amount of time and resources. Regarding this point, the HPS notes that the NCRP has defined the negligible individual dose (NID) in 1993 as having a value of 0.01 mSv y^{-1} (1 mrem/y). A recent paper in Health Physics "To mitigate the LNT model's unintended consequences – A proposed stopping point for as low as reasonably achievable" [2] argues for increasing the negligible individual dose by a factor of 10. This would provide an ALARA stopping point of 0.1 mSv y^{-1}, and would be a practical step forward in recognizing the uncertainties in low-dose radiation health effects. However, we also realize the difficulty with reaching agreement on a single value. We recommend IRPA discuss future challenges with respect to risk management and risk perception in this context, and that they emphasize the need for further validation or research on the risk at low doses. Significant initiatives have been introduced on this particular topic (e.g., the 2018 Low Dose Conference – http://www.lowdoserad.org, and others).

14. Factor 9: The HPS understands and appreciates the concept of "value for money" (VFM) considerations; any rational "consumer" would utilize this process in their decision making. Our concern here is how to define "value" for an individual (which may very well be different from person to person) and how to address assumptions and uncertainties which certainly will influence the result. Is the radiation protection community setting ourselves up for any arbitrary outcome depending on what "values" and "costs" we ascribe to the variables in our equation?

[2] Abelquist, EA Health Physics; DOI: 10.1097/HP.0000000000001096; December 2019

Are we claiming a rigorous mathematical balance while not controlling the input variables? We agree, however, that placing a cost matrix on low dose exposures might help with risk management and risk communication. The ALARA principle, when applied properly, does not have to cost exorbitant amounts of resources, but could indeed be accomplished at times with appropriate attention to "safety culture" which could be as simple as changing individual (and collective) behaviors. We note the statement does not resolve any of the issues previously raised in some IAEA reports regarding the issue on 'reasonable value for society'.

15. Factor 10: The IRPA statement clearly demonstrates a reliance on the LNT by stating *"…although for protection purposes we prudently assume an LNT relationship."* As stated earlier, the HPS does not support the use the LNT in low dose and low dose rate environments, and believes that it is the root cause for the very challenges we face today. The scientific evidence is abundantly clear that there is no detectable adverse health effects from low-dose or low-dose rate exposures to ionizing radiation, which the IRPA statement is primarily addressing. Further, there is evidence of a threshold or even hormetic effect that is excluded from this statement. Lessons from Fukushima regarding evacuations are evidence that it was not prudent to do so.