



HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

31 January 2021

Roger Coates
IRPA President

Eric Goldin
HPS President
Health Physics Society

Subject: Comments “IRPA Guiding Principles on ‘Reasonableness’ in the Optimisation of Radiation Protection’

As an Associate Society of IRPA, the Health Physics Society¹ (HPS) appreciates the opportunity to provide comments on the second version of IRPA’s Statement on Guiding Principles on “Reasonableness” in Optimisation of Radiation Protection.”

In our initial comments, we summarized the HPS Position Statements related to this topic (https://hps.org/govtrelations/documents/hps_irpa_response_to_r_in_alara_9-11-2020.pdf). Similarly, during this second round of comments, we 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/hpnewsvol48no12.pdf>). We are encouraged by many improvements in this second version but differences remain between our respective organizations. Although IRPA’s second draft provided no additional information that would alter our original position and we offer the following comments and supporting documentation for further consideration and look forward to a continuing scientific exchange on this topic.

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.

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. 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 our previous comments, there are many consistencies noted in the IRPA revised document. 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.

Introduction and Background

The HPS generally supports the language in this section, especially the statement when expenditure of huge resources to reduce trivial harm is easily judged to be unreasonable. We offer our concern that sound science must be fundamental factor for including “public-concern” as a significant factor in this decision. Lessons learned from Fukushima and other large scale environmental radiological accidents/disasters have shown that significant public concerns, driven mostly by fear, have resulted in unwarranted and harmful public health decisions. The primary source of that fear is derived from the application of the linear no-threshold (LNT) theory in risk assessments and its use to establish ultra-low environmental cleanup levels that demonstrate no public health benefit. We encourage IRPA to reconsider its endorsement of the LNT for low-dose environments and adopt ICRP recommendations based on 1 mSv to 20 mSv per year when weighing public concerns as part of the optimization process.

Underpinning Considerations and Context

We concur with the introductory language and subsection a) and are pleased to see IRPA acknowledged alternative risk models (e.g., Threshold and Hormesis). However, we continue to disagree with IRPA’s position expressed in subsection b) LNT/Threshold. This section states that there is “*scientific uncertainty in the risk posed by radiation in the key dose range of around a few mSv/a....*” 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.*”

We suggest IRPA revise the statement that there is “some limited scientific support” for the threshold model

since it may give a false impression that thousands of scientific publications on this subject were pre-judged and dismissed as “limited” in nature. Thousands of scientific publications also support a hormetic effect in the low-dose, low-dose rate exposure scenario. Further, the HPS recognizes that the current radiation protection paradigm is based on the LNT hypothesis and is “widely accepted” among regulatory agencies, mainly due to the slow promulgation process and reliance on outdated scientific information. IRPA’s statement on LNT continues to be “widely accepted” and that there is “consensus” among practicing radiation professionals has been challenged in the current scientific literature² and suffers from a logical fallacy as it appeals to authority rather than more recent scientific facts. Statements that appear dismissive or suffer from logical fallacies without a stronger scientific justification can affect the credibility of any organization. The HPS respectfully requests IRPA provide the scientific evidence from which the “widely accepted basis” and “consensus” arguments are concluded. Perhaps this could be a starting point to resolve our differences.

c) Ethical Values

Regarding subsection on “prudence”, the IRPA guidance continues to suggest that a dose of “tens of mSv” results in an adverse risk at least a factor of one thousand times higher than “tens of μ Sv”. We continue to disagree with this statement and suggest it be deleted or modified 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.

d) Context of risk and natural background

The HPS position statement, “Radiation Risk in Perspective” mentioned above, states risks are no different from zero at exposures consistent with natural background levels. The IRPA guidance states that there is “...*little direct evidence of harm, hence giving uncertainty of the true risk.*” We suggest IRPA provide references that support their statement which implies there is direct evidence, no matter how limited, where natural background exposures pose a risk. A critical evaluation of that evidence is warranted as it would affect our position and strengthen IRPA’s guidance.

Guiding Principles on ‘Reasonableness’, 2) Proportionality

The conventional view of “collective dose” is that it can be used to compare policy options. HPS continues to recommend IRPA remove the term “collective dose” in reference to determining the level of risk.

In the final paragraph of this section, IRPA is assuming that all dose reduction results in a lower risk. This implicitly ignores the volumes of scientific literature demonstrating a beneficial effect from low-level radiation exposures. We suggest this statement be revised especially given the uncertainty in the dose-response at low doses.

5) Avoidance of Over-Conservatism

The first sentence may be a bit confusing to the reader by using dose and risk interchangeably. We suggest revising this statement to something like “...realistic assessments of radiation risks and other risks.”

6) Value for Society

We support the message in this section, especially the ICRP 104 guidance that the optimal use of societal “resources not be squandered on unproductive legislation and fruitless regulatory control.” This is where applying LNT becomes problematic. There is zero value to society when we expend resources to reduce risk from zero to zero. Applying the ICRP recommendation of 1 mSv to 20 mSv per year is a reasonable approach to judge value to society.

² Cardarelli J. and Ulsh B. “It is time to move beyond the linear no-threshold theory for low dose radiation protection.” <https://doi.org/10.1177%2F1559325818779651>

7) De Minimis cut-off

We recommend the arguments to support the IRPA conclusion be strengthened or revised. For example, in the first bullet, we believe this is a misinterpretation of de minimis application. It does not imply the need to take action above the de minimis. It only means there is no demonstrable benefit to reducing doses below the de minimis value. Above the de minimis value, optimisation applies.

In the second bullet, the justification seems a bit contrived. Perhaps providing a clearer explanation of the “lowest common denominator approach” would clarify the intent. The HPS and much of this IRPA guidance supports the message that there is little to no benefit in reducing doses that are already in the noise of natural background, regardless of the exposure situation.³

In the third bullet, if there is no demonstrable benefit to reduction of trivial doses, how can the exposure situation be “improved”? When benefits cannot be demonstrated, it is not possible to justify costs. Further, safety culture can be justified without resorting to the argument of further reducing trivial doses, implying zero dose is the safest environment. The basis for safety culture is to instill good practices and habits that minimize the likelihood of consequential exposures.

We believe the example that states actions arising from safety-culture or from stakeholder engagement that improves overall confidence appear to be driven more by public relations than sound scientific principles. Safety culture and stakeholder engagement should not be conflated when making public health decisions. Safety culture deals directly with increasing safety. Stakeholder engagement indirectly deals with a perception of safety that our respective organisations must ensure is grounded in sound science. We suggest IRPA rephrase this example for clarity and to re-enforce the concept that these guidelines are scientifically based with an acknowledgement that other social, economic, and political factors are considered. From a strictly scientific perspective, IRPA should consider acknowledging the absence of risk at low doses based on an abundance of credible science and strongly support a de minimis value.

³ Abelquist, E. To mitigate the LNT model’s unintended consequences—a proposed stopping point for as low as reasonably achievable. DOI: 10.1097/HP.0000000000001096