Risks of Exposure to Low-Level Ionizing Radiation

Background Information, Position Statement 41

Introduction

In November 2020, the American Nuclear Society (ANS) updated Position Statement #41, which addresses the risks of exposure to low-level ionizing radiation. Through this position statement, ANS states that the linear-no-threshold (LNT) model may not adequately describe the relationship between harm and exposure, that research about the impacts of low-dose radiation continues to evolve, and that there is a desire to incorporate these research findings into risk-informed decision-making. Furthermore, Position Statement #41 notes that the implementation of the as low as reasonably achievable (ALARA) principle often results in a practice of dose minimization instead of risk-informed optimization. Finally, it is the position of ANS that regulatory bodies and those administering radiation protection programs ensure ALARA is properly applied; that an independent, credible national scientific organization review radiation protection regulations and practices to ensure harmonization; that radiation risk communication and outreach be prioritized; and that a robustly funded, internationally integrated, long-term low-dose radiation research program be established. The purpose of this document is to provide interested readers with additional background information supporting the November 2020 revision of Position Statement #41.

Linear No-Threshold Model

Exposure to low doses of ionizing radiation is hypothesized to cause negative health outcomes, including circulatory diseases and cancer.[1] Extended epidemiological follow-up of groups of people exposed to ionizing radiation has shown that doses[2] *more than* about 100 mSv are associated with statistically significant increases in cancer rates and that a linear or linear-quadratic dose-response model is appropriate for higher doses.[3,4,5] However, the risk *below* 100 mSv is uncertain. Since occupational and public exposures are typically far smaller than 100 mSv in magnitude, this lack of knowledge requires the use of models in this dose domain for radiation protection purposes. The LNT model serves this purpose and is integral to current radiation protection regulations and practices in the United States and around the world.

The LNT model is a linear extrapolation, anchored at the origin, of population excess risk associated with ionizing radiation exposures from doses where radiation has been determined to cause statistically significant increases in risk. The linear model is assumed down to zero dose above background, even where existing epidemiological methods are incapable of distinguishing increased risk from no excess risk.[6,7] Typically, a dose and dose rate effectiveness factor (DDREF) is used to account for reduced damage due to the action of cellular repair mechanisms, if the data anchoring the model were derived from a population exposed to high doses and dose rates. In practice, the slope of the linear extrapolation is reduced by the DDREF when calculating the population excess risk associated with exposures delivered at lower doses and dose rates. Although LNT-based organ-specific risk models with unique age- and sex-dependence have been published,[3,8] a "whole-body" risk model applicable to an average population is often utilized when a distribution of ages and both biological sexes are considered.

Use of the LNT model has been criticized for a variety of reasons, including the following:

- It does not explicitly account for the complexities of the physical-chemical-biological processes associated with ionizing radiation exposure that occur over vastly different timescales (picoseconds to decades).
- It is thought by some to be overly conservative.
- It has been used to justify very large expenditure of resources to avoid very small doses.
- It can be misapplied by calculating population collective doses and associated statistical outcomes without regard for the overall magnitude and distribution of individual doses, a practice explicitly discouraged by the International Commission on Radiological Protection (ICRP).[9]
- When the context, benefits, and costs/risks of an exposure are not properly weighed, it can lead to a fear of radiation exposures, particularly those of anthropogenic origin.

These criticisms are certainly important and must be explored; however, the most severe are not endemic to the model itself but rather to inappropriate application of the model or inadequate communication of what the model results represent. Additionally, results from radiation epidemiology studies are generally consistent with the LNT model,[4] and the model is simple, which is attractive for risk management applications. Furthermore, the LNT model has been used to successfully administer radiation protection worldwide for many decades, as evidenced by the low doses incurred by the public and radiation workers. Crucially, no other alternative model has been clearly defined, proposed for use, and recommended for adoption by national or international radiation protection organizations.

From a science perspective, there is no *a priori* reason to hypothesize that a simple linear extrapolation anchored at the origin is likely to be the most accurate descriptor of the relationship between exposure and radiological risk for all possible exposures. Apart from the previously mentioned statistical limitations, individual variability further limits the appropriateness of translating population-based risk estimates to any single person, and so use of the LNT model for *risk assessment* at very small organ equivalent doses or effective doses (on the order of background) should be discouraged, particularly when the associated uncertainty in those assessments is not clearly communicated and understood. However, while risk assessment is optional for these exposures, *risk management* is required for all radiation exposures. To consider the benefits and costs/risks of an exposure, some estimate of the associated radiological risk is required. If the exposure is low, the corresponding cost associated with the estimated risk is also low, and thus a smaller benefit must be realized to achieve a favorable cost-benefit ratio. Although inappropriate for risk assessment, these calculations are required to determine the "best estimate" of benefits associated with any action taken to reduce exposures below regulatory limits.

As Low As Reasonably Achievable Principle

The three principles of radiological protection, recently re-emphasized in ICRP Publication 103[9] and National Council on Radiation Protection and Measurements (NCRP) Report No. 180,[10] are *justification*, *optimization*, and individual *limitation* of ionizing radiation exposure. When considering the issues of low-level ionizing radiation, of particular interest are the principles of limitation and optimization, as the exposures are typically already justified. Radiation protection regulatory structures around the world are all built upon the recommendations of the ICRP and the NCRP. Within the United States, relevant regulations are implemented by bodies with jurisdiction, such as the Nuclear Regulatory Commission,[11] Department of Energy,[12] Department of Transportation,[13] Environmental Protection Agency (EPA),[14] and the states.[15]

At the core of reducing exposures below applicable limits is the assumption that there is some functional relationship between the dose and the associated estimated risk. While a great deal of attention has been given to the LNT model, support for actions that keep exposures ALARA would be justified in situations where some other function, such as a linear-quadratic or quadratic model, of dose response is considered. More complicated would be how to apply regulations derived from a threshold or hormetic model and whether such models would apply to specific organs, to single exposures, or to cumulative lifetime exposures. Typical radiation protection regulations are specified on an annual basis, but it is understood that the radiobiological processes are not linked to any amount of time or calendar dates. Radiation protection regulations also distinguish between anthropogenic radiation and natural background, and they further differentiate between medical exposures and other exposures. Thus, even for a threshold or hormetic model, the accumulation of exposures from a variety of sources could be problematic.

If exposures satisfy the principles of justification and limitation, then optimization drives radiation protection actions. The ICRP describes the optimization process as follows: "The likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors."[9] Within this definition is the acronym ALARA, the fundamental premise that it is prudent to reduce exposures *when it is reasonable to do so*; reasonableness is thus a prerequisite for any action taken to reduce exposure likelihood, the size of the exposed population, and individual doses. In the medical community, ALARA is modified to include the requirement that dose reductions be consistent with achieving the medical objective.

In practical, day-to-day work, ALARA is implemented by intentionally altering time of exposure, distance between source and receiver, and shielding. Reduced exposure results from decreasing time while increasing distance and shielding. The simplification, however, can easily overlook the question of what is reasonable to do in a particular situation by focusing on simply reducing the exposure at all costs. Optimization is not minimization or use of "best available technology," where an exposure is to be reduced if there are any technological measures available, irrespective of costs. Reasonableness implies a balancing of various factors, including social, economic, and environmental factors.

Chemical hazard management has similarities and differences with radiological protection. Chemical protection generally starts with the assumption that any exposure to a chemical toxicant should be avoided, and thus the goal is zero exposure. Factors of use are then considered to establish a preferred risk range for protection or remediation. For example, the EPA Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) program[16] establishes preliminary remediation goals, and initial goals may be modified based on exposure, uncertainty, and technical feasibility factors. In essence, the endpoint of radiological protection and chemical protection approaches is an agreed result, whether approached from the "top" (i.e., starting at the dose limit and working downward in exposure) in radiological protection, or from the bottom (i.e., working upward from initial goals) in chemical hazards. It is important to recognize that minimization of exposure without balancing other factors is inappropriate for both radiological and chemical protection practices.

Deciding whether to execute a particular action intended to reduce dose may involve both quantitative, cost-benefit analyses and qualitative analyses. For example, a generic approach might require that the "costs" to implement a shielding strategy be below a specified amount of money per person-rem avoided to implement the strategy. In occupational settings, accounting for costs may be relatively straightforward. In environmental remediations, analyses require that the social, economic, and environmental factors be translated into a common unit, usually dollars, making the analysis more difficult.

ALARA implementation in a routine occupational setting is analogous to quality assurance and control programs, which are characteristic of a good safety culture. After a facility design has incorporated ALARA in a cost-effective, reasonable manner, ALARA largely relies on tracking and trending of occupational and public exposure metrics related to the continued safe handling of radioactive materials and ionizing radiation fields. By providing all decision makers with an evaluation of historical trends, reports of “near-miss” occurrences, reportable events, and simple annual dose distributions, changes can be made, as appropriate, in operations and/or design.

In environmental radiological remediation, a different dynamic exists; many stakeholders have expectations and desires that are frequently at odds with one another. As zero risk is unattainable, optimization requires cost-effective solutions to enable work and results that appropriately balance these opposing expectations/desires. Without such balancing efforts, the extreme would mean spending countless resources to avoid trivial doses. Further research into the dose response at low doses and dose rates will help ensure that optimization, particularly in circumstances involving diverging interests, is based upon a solid scientific foundation.

Technical Research Coordination and Harmonization

The resources necessary to adequately interrogate the true shape of the dose-response curve for low-level ionizing radiation exposures are anticipated to be substantial, in terms of both time and financial resources, due to health outcomes present in background populations and relatively small radiation-induced detriment that is expected. However, since most exposures to ionizing radiation occur at low doses and low dose rates, it is imperative to understand this region of the dose-response curve to ensure that regulations and communication with stakeholders, including the public, are supported by the best possible scientific evidence. A robust understanding of the biological responses to these exposures allows for development of evidence-based models to inform appropriate regulatory and safety standards that appropriately balance risk and benefit.

While epidemiological cohorts have traditionally formed the basis of understanding health risks associated with radiation exposure in human populations, translational radiation biology needs to be leveraged to improve that understanding where epidemiological analysis cannot alone yield definitive results. Epidemiology and radiation biology provide different tools to support improved characterization of the impacts of radiation exposure. Thus, coordinated and integrated efforts in both human epidemiology and radiation biology are necessary for research to inform risk assessment effectively. Key research objectives that should be coordinated include the following:

- Characterization of relevant human health impacts.
    - Development of *data-driven models* of radiation quality, dose, and dose-rate effects based on human populations and radiation biology experiments.

    - Identification of *strategies to translate impacts* from radiation biology experiments to human populations where acquiring epidemiological data is either impossible or inappropriate.
- Identification of new paradigms to accelerate research.
    - Identification or development of sensitive and specific *predictive biomarkers* of relevant human health impacts that are validated in appropriate animal models and human cohorts to accelerate translational research investigating long-term health outcomes, as well as longitudinally monitoring exposed populations to better estimate, personalize, and reduce risk of long-term health consequences of exposure.
    - Development of *advanced translational biological systems* to assess relevant biological pathways associated with health impacts following radiation exposure.
- Definition of the role of individual susceptibility (including sex differences).
    - Identification or development of sensitive and specific *biomarkers of radiation sensitivity* to assess individual radiation susceptibility to understand the uncertainties in risk estimates based on epidemiology.
    - Identification of biological models to assess the role of genetic background, tissue sensitivity, and sex in radiation-associated health impacts and to refine risk assessment.

Integral elements to each of these objectives are *accurate dosimetry*, robust *statistical analysis* and *bioinformatics*, and *data-driven modeling*. To improve transparency and provide a more comprehensive picture of the risks and benefits of radiation exposure, underlying uncertainties and assumptions associated with risk estimates need to be well-documented. Communicating uncertainty and variability in radiation risk estimates to the public is a major challenge and should therefore be a focus of risk communication strategies.

A coordinated and tactical approach is necessary to maximize effectiveness and efficiency of research efforts and resources. This coordination should occur across domestic agencies as well as with international partners. To achieve effective multiagency coordination, the two most impactful resources that need to be established are (1) a shared data repository and (2) an advisory committee. One such effort is the work of the Nuclear Energy Agency High-Level Group on Low-Dose Research. A data repository will allow research groups to leverage results from other laboratories for more robust analyses. Most radiation research is funded through public funding agencies, and thus, the data generated through this research should be made freely available to promote data sharing and pooling. Further, knowledge of available data may serve to limit redundancies, improve standardization between research groups, and possibly lead to successful collaborations. An advisory committee will act to focus and guide research priorities by identifying knowledge gaps, as well as appropriate methods to fill those gaps; ensure redundancies are avoided to improve efficiency; and synthesize results on a more global level. In addition to coordinated technical research initiatives, an integrated, formalized education and training program would be beneficial to ensure retention of institutional knowledge and provide the field of radiation research with the scientists necessary to continue future work.

Radiation Risk Communication Research and Outreach

Risk communication is generally defined as “an interactive process of exchange of information and opinion among individuals, groups, and institutions. It involves multiple messages about the nature of risk and other messages, not strictly about risk, that express concerns, opinions, or reactions to risk messages or to legal and institutional arrangements for risk management.”[17]

Radiation risk communication is a subset of risk communication. Building on this definition, it is useful to think of radiation risk communication as the exchange of information, opinions, and ideas about the benefits and risks of radiation in terms of health, economics, and social well-being. The goal of radiation risk communication is to enable individuals, communities, governments, and other key groups, collectively known as “stakeholders,” to make informed decisions about how to protect themselves against radiological hazards while taking into consideration a range of other factors, including the benefits of nuclear and radiological technology.

Radiation risk communication is rooted in both science and practice. Learning the general principles of communication is important; putting those principles into action is often challenging. In Position Statement #41, ANS acknowledges that the ability to communicate about radiation—its sources, uses, benefits, and risks—is of critical importance for the Society and for the public at large. Radiation sources and uses are ubiquitous, and discussions about radiation too often generate more confusion than clarity. People generally discount the impacts of naturally occurring radiation yet dread the same type and amount of radiation if it comes from anthropogenic sources or a disposal site.[18] On the other hand, experts rank radiation risks based on science and technical knowledge. This difference in perception about radiation leads to challenges in understanding[19] and is an obstacle to the beneficial utilization of new technologies and the sustainable use of nuclear power.[20]

In addition, the practice of radiation risk communication has often been unsuccessful because radiation experts wrongly assume that the purpose of radiation communication is to “educate (dictate to) the public” about technical issues rather than engage in a conversation. It is imperative to avoid the idea that the goal of radiation risk communication is to fill gaps that might exist about radiation in others’ knowledge. This deficit reduction model, based on the idea that public skepticism and lack of support are due to inadequate understanding of science, has been shown to be counterproductive. Radiation risk communication thus demands both learning how to approach non-experts and interact with them, as well as how to convey expertise about the hazards of radiation and how to manage them.[21]

Effective radiation risk communication is founded on trust.[22] A relationship of trust is an absolute prerequisite for effective communication with the public and stakeholder groups. In fact, trust building should be the first goal of any communication dialogue. Trust is something that is earned over time.[22,23] Using dated techniques for outreach about radiation can hinder efforts to engage communities and the public in a discussion about the risks and benefits of technologies that employ ionizing radiation. Communication requires active listening first. Active listening shows compassion and concern, and it is one of the keys to establishing a trust relationship with stakeholders.[24] Discussing the benefits as well as the risks of radiation, and how they should be weighed, is a conversation that can take place after a relationship of trust is established.

One of the key points made in ANS Position Statement #41 is that "a robust social science program should be prioritized to help promote science-informed perspectives regarding the risks and benefits of nuclear and radiological technologies in all industries." Such a research program is needed so that experts can learn how to communicate, build trust, and assist stakeholders in making radiation protection–related decisions. Using social science techniques such as focus groups and interviews with thought leaders, this research program should collect both qualitative and quantitative data about what members of the public (1) want to know about radiation risks, (2) perceive about different radiation sources, and (3) understand about the benefits associated with radiation technologies.[25,26] Taking advantage of social media and modern communication methods is imperative. These methods are evolving rapidly, and their societal impact is increasing. It is also important to learn who the public trusts to deliver information about radiation and how to best establish a relationship of trust with stakeholders.[23,24,27] This research program will create a strong basis on which to build a communications and outreach effort—a blueprint for action—that will assist individuals and communities in making informed and evidence-based decisions about radiation risks.

Notes

1. National Council on Radiation Protection and Measurements. *Approaches for Integrating Information from Radiation Biology and Epidemiology to Enhance Low-Dose Health Risk Assessment*. NCRP Report No. 186. 2020.
2. Absorbed radiation dose is expressed in the SI unit of gray (Gy), where 1 Gy = 100 rad. The SI unit for both organ equivalent dose and effective dose is the sievert (Sv), where 1 Sv = 100 rem. For a whole-body, uniform exposure to X-rays or gamma radiation, 1 Gy = 1 Sv. For more information, refer to ICRP Publication 103 (see note 9).

3. National Research Council. *Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2* (Vol. 7). National Academies Press. 2006.
4. National Council on Radiation Protection and Measurements. *Implications of Recent Epidemiologic Studies for the Linear-Nonthreshold Model and Radiation Protection*. NCRP Commentary No. 27. 2018.
5. K. Leuraud et al. "Risk of Cancer Associated with Low-Dose Radiation Exposure: Comparison of Results Between the INWORKS Nuclear Workers Study and the A-Bomb Survivors Study." *Radiat. Env. Biophys.*, 60:23–39. 2021. https://doi.org/10.1007/s00411-020-00890-7.
6. A. M. Weinberg. "Science and Trans-Science." *Science*, 177(4045):211. 1972. https://doi.org/10.1126/science.177.4045.211.
7. For example, see Table 7-2 in: National Research Council. *Radiation Dose Reconstruction for Epidemiologic Uses.* Washington, D.C. The National Academies Press. 1995. For a mean whole-body dose of 5.0 mSv, to achieve statistical power of 80%, an exposed population of nearly 8 million people is required. For comparison, fewer than 100,000 people combined were present in Hiroshima and Nagasaki at the time of the atomic bombings.
8. United Nations Scientific Committee on the Effects of Atomic Radiation. *UNSCEAR 2006 Report to the General Assembly*. Annex A, "Epidemiological Studies of Radiation and Cancer." 2008.
9. International Commission on Radiological Protection. "The 2007 Recommendations of the International Commission on Radiological Protection." ICRP Publication 103. *Ann. ICRP*, 37(2–4). 2007. https://doi.org/10.1016/j.icrp.2007.10.003.
10. National Council on Radiation Protection and Measurements. *Management of Exposure to Ionizing Radiation: Radiation Protection Guidance for the United States (2018)*. NCRP Report No. 180. 2018.
11. *Code of Federal Regulations*. Title 10, "Energy." Part 20, "Standards for Protection Against Radiation."
12. *Code of Federal Regulations*. Title 10, "Energy." Part 835, "Occupational Radiation Protection."
13. *Code of Federal Regulations*. Title 49, "Transportation." Part 173, "Shippers—General Requirements for Shipments and Packagings."
14. For example: *Code of Federal Regulations*. Title 40, "Protection of Environment." Part 190, "Environmental Radiation Protection Standards for Nuclear Power Operations," and Part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Fuel, High-Level and Transuranic Wastes."
15. *Code of Federal Regulations*. Title 10, "Energy." Part 150, "Exemptions and Continued Regulatory Authority in Agreement States and in Offshore Waters Under Section 274."
16. Environmental Protection Agency. *Rules of Thumb for Superfund Remedy Selection*. EPA 540-R-97-013. August 1997.
17. National Academy of Sciences. *Improving Risk Communication*. Page 21. Washington, D.C. The National Academies Press. 1989.
18. P. Slovic. "The Perception Gap: Radiation and Risk." *Bull. At. Sci.*, 68(3):67–75. 2012. https://doi.org/10.1177/0096340212444870.
19. T. Perko. "Radiation Risk Perception: A Discrepancy Between the Experts and the General Public." *J. Environ. Radioact.*, 133:86–91. 2014. https://doi.org/10.1016/j.jenvrad.2013.04.005.
20. M. V. Ramana. "Nuclear Power and the Public." *Bull. At. Sci.*, 67(4):43–51. 2011. https://doi.org/10.1177/0096340211413358.
21. J. Wardman. "The Constitution of Risk Communication in Advanced Liberal Societies." *Risk Anal.*, 28(6):1619–1637. 2008. https://doi.org/10.1111/j.1539-6924.2008.01108.x.
22. R. Ando. "Trust—What Connects Science to Daily Life." *Health Phys.*, 115(5):581–589. 2018. https://doi.org/10.1097/HP.0000000000000945.

23. M. Crick. “The Importance of Trustworthy Sources of Scientific Information in Risk Communication with the Public.” *J. Radiat. Res.*, 62(S1):i1–i6. 2021. https://doi.org/10.1093/jrr/rraa143.

24. J. Weider. “Communicating Radiation Risk: The Power of Planned, Persuasive Messaging.” *Health Phys.*, 116(2):207–211. 2018. https://doi.org/10.1097/hp.0000000000000998.

25. Y. Kuroda. “Current State and Problems of Radiation Risk Communication: Based on the Results of a 2012 Whole Village Survey.” *PLoS Currents Disasters*. Edition 1. February 24, 2017.

26. J. Rayner and M. Hurlburt. *Low Dose Radiation Project: The Influence of Social Learning and Attitudes on the Perception of Risk from Low Dose Radiation*. Executive Summary. Report by the Centre for the Study of Science and Innovation Policy. 2020.

27. J. Lakey. “Informing the Public About Radiation: The Messenger and the Message.” *Health Phys.*, 75(4):367-374. 1998. https://doi.org/10.1097/00004032-199810000-00002.