UNCERTAINTY IN RISK ASSESSMENT

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: July 1993
Revised: April 1995, February 2013

Contact: Brett Burk
Executive Director
Health Physics Society
Telephone: 703-790-1745
Fax: 703-790-2672
Email: HPS@BurkInc.com
http://www.hps.org

The Health Physics Society supports risk assessments that are consistent, of high technical quality, unbiased, and based on sound, objective science. Risk assessments should employ the best available scientific and/or technical data and should include consideration of uncertainties.

Risk assessment is the process of describing and analyzing the nature of a particular risk and includes gathering, assembling, and analyzing information on the risk and, wherever possible, quantifying the magnitude of the risk and its accompanying uncertainty. The Health Physics Society believes that once risks are quantified, then the expenditure of public and private funds to mitigate these risks should be commensurate with the public health benefits expected to be achieved. Consequently, risk assessment forms the foundation of risk management, risk communication, and risk mitigation.

The Health Physics Society remains concerned with the inconsistent application of risk assessment in the establishment of radiation protection regulations. These regulations are not well coordinated among federal agencies and, therefore, create public confusion and concern. 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.

The Health Physics Society recognizes that there are many questions and uncertainties associated with the risk-assessment process and that not all needed or desired data may be available. Accordingly, the limitations of any risk assessment must be fully addressed and made explicit in establishing regulations for the protection of public health. The Health Physics Society supports risk assessments that are of high technical quality, unbiased, and based on sound, objective science and include detailed uncertainty analyses.

Only Credible Science Should Be Used in Risk Assessment

Risk assessment should employ the best scientific and/or technical data available. Credible science is characterized by (1) objective analysis of data, including suitability of experimental design, appropriate uses of statistical tests, and careful attention to the uncertainties in the data themselves, as well as in their interpretation, (2) identification and appropriate consideration of the limitations of underlying assumptions, theories, and models used in the analysis and interpretation of data, and (3) peer review and publication in reputable scientific journals. However, it should also be recognized that credible scientific studies may lead to honest differences in data interpretation and support of competing theories and that calculations based on different theories may lead to risk estimates that are significantly different. For instance, the radiation protection literature is filled with differing views as to the shape of the radiation dose-response curve at low doses and dose rates. Some data support a linear no-threshold model, whereas other data support models that predict lower estimates of risk and perhaps even a threshold below which no detectable radiation health risk exists.

Risk Assessment Should Include Consideration of Uncertainties

The establishment and use of risk coefficients to estimate public health detriments from individual or population exposures must be considered in the context of all the uncertainties in the estimates. It is essential that all uncertainties, assumptions, and inferences used in the assessment process be explicitly stated and quantified wherever possible. Any biases incorporated into the assessments for the purpose of ensuring public health protection (such as "margin of safety") should be clearly noted and quantified if possible. Examples of such uncertainties include, but are not limited to, statistical uncertainties in the data and uncertainties arising from extrapolation of data to different dose levels, dose rates, species, and human populations. The credible ranges of risk estimates should always be provided in addition to their central, or most likely, values.

Limitations of Extrapolation of Risk to Low Dose and Dose Rate

Health risks of radiation exposure can only be estimated with a reasonable degree of scientific certainty at radiation levels that are orders of magnitude greater than limits established by regulation for protection of the public. In its recent report, the National Research Council Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation (BEIR VII Phase 2) divided radiation doses into the following categories: low dose, < 0.1 Gy; intermediate dose, 0.1–1.0 Gy; and high dose, > 1 Gy (NRC 2006). Radiological risk assessment, particularly for radiogenic cancer, currently is only able to demonstrate a consistently elevated risk in the intermediate- and high-dose groups of the studied populations. 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. Consequently, in order to estimate radiation risk in the low-dose region, observed health effects in the higher-dose regions are extrapolated to the low-dose region by using a variety of mathematical models, including the linear, no-threshold model (with a correction for dose and dose rate).

The BEIR VII report stated that ". . . current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose-response relationship between exposure to ionizing radiation and the development of cancer in humans" (NRC 2006). The report provides estimates of the number of excess cancers predicted to occur in a population of 100,000 persons of the same age distribution as the U.S. population, each of whom receives a dose of 0.1 Gy; typically the lower bound of the estimate is a factor of 2–3 lower than the central estimate, while the upper bound is a factor of 2–3 higher, indicating the uncertainty in these estimates. As radiation levels decrease below 0.1 Gy, the relative uncertainty in risk estimates necessarily increases even more.

National Council on Radiation Protection and Measurements Report No. 171 addresses uncertainties in epidemiological methods, dosimetry, selected radioepidemiological cohorts, and risk assessment for radiation protection, and concludes that "epidemiology will not be able to convincingly detect [or rule out] excess cancer risks at 100 mSv above the background of naturally occurring cancers, yet these are the levels of current scientific and societal interest" (NCRP 2012).

The 2012 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) states that radiation-inducible malignancies cannot be unequivocally attributed to radiation exposure because radiation is not the only possible cause and there are no generally available biomarkers that are specific to radiation exposure. The UNSCEAR report does not advocate multiplying very low doses by large numbers of individuals to estimate radiation-induced health effects at doses equivalent to or lower than natural background levels (UNSCEAR 2012). The Health Physics Society has previously adopted this position in PS-010, "Radiation Risk in Perspective" (HPS 2010).

However, despite the uncertainty, we can bound the range of the risk, with an upper bound being approximately twice that extrapolated from the intermediate- and high-dose ranges and the lower bound including zero. Consequently, the Health Physics Society recommends 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 (Brumfield 2013).

References

Brumfield J. Fukushima: Fallout of fear. Nature 493:290–293; 2013. Available at: http://www.nature.com/news/fukushima-fallout-of-fear-1.12194. Accessed 15 February 2013.

Health Physics Society. Radiation risk in perspective. Health Physics Society Position Statement. 2010. Available at: http://hps.org/documents/risk_ps010-2.pdf. Accessed 15 February 2013.

National Research Council. Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation. Health risks from exposure to low levels of ionizing radiation: BEIR VII Phase 2. Washington, DC: The National Academies Press; 2006.

National Council on Radiation Protection and Measurements. Uncertainties in the estimation of radiation risks and probability of disease causation. Bethesda, MD: NCRP; Report No. 171; 2012.

United Nations Scientific Committee on the Effects of Atomic Radiation. Report of the United Nations Scientific Committee on the Effects of Atomic Radiation: Fifty-ninth session (21-25 May 2012). New York: United Nations; 2012. Available at: http://www.un.org/ga/search/view_doc.asp?symbol=A/67/46. Accessed 15 February 2013.

*The Health Physics Society 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. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society. The Society may be contacted at 1313 Dolley Madison Blvd., Suite 402, McLean, VA 22101; phone: 703-790-1745; fax: 703-790-2672; email: HPS@BurkInc.com.