RISK ASSESSMENT

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

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

Risk assessment is the process of describing and characterizing the nature and magnitude of a particular risk and includes gathering, assembling, and analyzing information on the risk. Risk assessment is a foundation of risk management and risk communication. In order to effectively manage risks and to communicate risks to the public, a clear understanding of the nature and magnitude of the risk at relevant exposure levels is necessary. The Health Physics Society has become increasingly concerned with the erratic application of risk assessment in the establishment of radiation protection regulations. These regulations are inconsistent, poorly coordinated among federal agencies, and inadequately communicated to the public. Examples of problem areas include (1) 100- to 1,000-fold discrepancies in permissible exposure levels among various regulations, all allegedly based on the same scientific risk-assessment data, and (2) proposed expenditures of billions of federal and private dollars to clean up radioactively contaminated federal and commercial sites without careful consideration of the actual public health benefits to be achieved.

The Health Physics Society recognizes that there are many questions and uncertainties associated with the risk-assessment process and that data may be incomplete or missing. Accordingly, limitations in risk assessment must be fully recognized and made explicit in establishing regulations for the protection of the public health. The Health Physics Society supports risk assessments that are consistent, of high technical quality, unbiased, and based on sound, objective science.

Only credible science should be used in risk assessment

Risk assessment should employ the best available scientific and/or technical data. 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 data collection and interpretation, (2) appropriate consideration of underlying assumptions and limitations of 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. Calculations based on the 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. Some data support a linear no-threshold model, whereas other data support models that would predict lower estimates of risk and perhaps even a threshold below which no radiation health risk may exist.

Risk assessment should include consideration of uncertainties

The establishment and use of risk coefficients to estimate public health determinants from individual or population exposures must be considered in the context of uncertainties in the estimates. It is essential that all uncertainties, assumptions, and inferences used in this assessment process be explicitly stated and that any biases incorporated into the assessments for the purpose of ensuring prudent public health protection (such as "margin of safety") be clearly noted, including consideration of dose and species extrapolations and statistical uncertainties. In addition to "best guess" or central estimates of risk, ranges of risk should be provided. Any conservative assumptions, safety margins, and uncertainty factors should be clearly delineated.

Limitations of extrapolation of risk to low dose

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 levels established by regulators for protection of the public.

Radiological risk assessment, particularly for radiogenic cancer, currently is only able to demonstrate a consistently elevated risk in those groups of the study populations that have been exposed to radiation at high doses (>1 Sv). In order to estimate radiation risk in the low-dose region, typical of most occupational and environmental exposures, health effects in the high-dose region are extrapolated to the low-dose region using a variety of mathematical models, including the linear, no-threshold model. Cancer and other health effects have not been observed consistently at low doses (<100 mSv) because the existence of a risk is so low as to not be detectable by current epidemiological data and methods.

In the absence of direct observations, estimation of radiogenic health risks at low doses must be viewed with caution. In most instances, to estimate risks (e.g., cancer) of small doses of radiation, a linear extrapolation from large doses to zero is used. Extrapolation assumes that the pathway of radiogenic effects is identical at any dose, which may not be valid. At high doses (>1 Sv), cell killing and cell replacement occurs, creating an environment favorable for tumor growth. At low doses (<100 mSv), cell killing and proliferation of surviving cells (which may be mutated or otherwise damaged) is much less probable. In discussing the question of the limitations of extrapolation to estimate radiogenic risk in the 10 microsievert range, the National Academy of Sciences, in its 1990 BEIR V report noted, " . . . the possibility that there may be no risks from exposures comparable to external natural background radiation cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero" (NRC 1990). The Health Physics Society recommends that assessments of radiogenic health risks be limited to dose estimates near and above 100 mSv. Below this level, only dose is credible and statements of associated risks are more speculative than credible. Thus, compliance with regulations to achieve very low levels of exposure result in enormous expenditures of money with no demonstrable public health benefits.

Reference

National Research Council. Report of the Committee on the Biological Effects of Ionizing Radiations: health effects of exposure to low levels of ionizing radiation. BEIR V. Washington, DC: The National Academies Press; 175; 1990.

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*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 grown to nearly 5,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, 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.