HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

November 5, 2015

U.S. Nuclear Regulatory Commission
Docket ID NRC-2015-0057

Nancy Kirner, CHP, President
nancy.kirner@gmail.com

Subject: Comments in Response to Petitions regarding the Linear No-Threshold Model and Standards for Protection Against Radiation

The Health Physics Society[1] (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety. The HPS appreciates the opportunity to provide comments in response to the Petitions for Rulemaking published June 23, 2015 relating to the use of the linear no-threshold model in the regulation of radiation exposure.

Where the HPS has a formal position, it is noted; where it does not, we have provided information that the NRC may want to consider.

The HPS appreciates this opportunity to provide comments. If you have any questions regarding these comments, please feel free to contact me at 509-996-3422 or nancy.kirner@gmail.com.

Sincerely,

Nancy Kirner, CHP
President, Health Physics Society

c: Brett Burk, HPS Executive Director
Craig Little, PhD, HPS Government Agency Liaison
Robert Cherry, Jr, CHP, HPS President-Elect
Barbara Hamrick, CHP, HPS Past President

[1] The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 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.

Health Physics Society (HPS) Comments
NRC 2015-0057
Submitted November 5, 2015
On behalf of Nancy Kirner, President, HPS

NRC-2015-0057

On June 23, 2015 the NRC published a request for comments on three petitions for rulemaking submitted in early 2015, and all relating to the use of the linear no-threshold (LNT) model used as the basis for the regulation of radiation in the United States.

The Health Physics Society has two position statements, which strongly support the petitioners' requests for a re-evaluation of the basis for US radiation protection standards, and one position that affirms that the current dose limits are adequate:

Position Statement PS010-2, "Radiation Risk in Perspective" advises:

"Doses from natural background radiation in the United States average about 3 mSv per year. A dose of 50 mSv will be accumulated in the first 17 years of life and 0.25 Sv in a lifetime of 80 years. Estimation of health risk associated with radiation doses that are of similar magnitude as those received from natural sources should be strictly qualitative and encompass a range of hypothetical health outcomes, including the possibility of no adverse health effects at such low levels."

The reasoning underlying this position specifically relates to the use of the LNT model:

"…there is substantial evidence that this [the LNT] model is an oversimplification. It can be rejected for a number of specific cancers, such as bone cancer and chronic lymphocytic leukemia, and heritable genetic damage has not been observed in human studies…the effect of biological mechanisms such as DNA repair, bystander effect, and adaptive response on the induction of cancers and genetic mutations are not well understood and are not accounted for by the linear, no-threshold model."

A recent evaluation of the Life Span Study data (considered the gold standard for examining stochastic radiation risk), found that for the solid cancer data there was a previously identified upward curvature in the low-dose range (0-2 Gy), which with the evaluation of the additional data in this study reached significance. The authors state, "The apparent upward curvature appears to be related to relatively lower than expected risks in the dose range 0.3-0.7 Gy, a finding without a current explanation."[1]

Of course, one explanation may be that the curvature results from a hormetic effect. While HPS does not take a position on the specific shape of the risk vs. dose curve in the low dose region, a significant part of the HPS mission is to encourage research in radiation science. All reasonable hypotheses should be open to consideration.

As recommended in **Position Statement PS 008-2**, "Uncertainty in Risk Assessment":

---

[1] Osaza, et al., "Studies of the Mortality of Atomic Bomb Survivors, Report 14, 1950-2003: An Overview of Cancer and Noncancer Diseases." Radiation Research, 177(3):229-243. 2012.

"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."

The statement goes on to say:

"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."

Position Statement PS013-1, "Occupational Radiation Safety Standards and Regulations are Sound" states:

"…occupational radiation safety standards and regulations have been sound, and protective of radiation workers, since the mid-1950s."

It goes on to say that "Since the mid-1950s…standards have included provisions for incorporating the philosophy of…ALARA", but cautions that the "rigor of an ALARA program" is not "necessarily [a measure] of worker safety." That is, the application of ALARA "is founded in the professional judgment of radiation safety managers…and is not…able to be used as a measure of whether or not a particular radiation safety program is adequate…" Taken together these statements may be interpreted as an acknowledgement that ALARA is a philosophy, somewhat subjective in application, and an ALARA program provides a qualitative rather than quantitative indication of safety.

Based on the above, HPS reaffirms that the current standards are sound, and the concept of ALARA may be useful. In an area with great uncertainty, such as present in the low-dose, or low-dose rate, all reasonable hypotheses should be explored. For the same reason, regulation should be based on the best available knowledge, and consider the costs and benefits of the use of a variety of models, and their associated uncertainties.

RADIATION RISK IN PERSPECTIVE

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

Adopted: January 1996
Revised: July 2010

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

In accordance with current knowledge of radiation health risks, the Health Physics Society recommends against quantitative estimation of health risks below an individual dose[1] of 50 millisievert (mSv) in one year or a lifetime dose of 100 mSv above that received from natural sources. Doses from natural background radiation in the United States average about 3 mSv per year. A dose of 50 mSv will be accumulated in the first 17 years of life and 0.25 Sv in a lifetime of 80 years. Estimation of health risk associated with radiation doses that are of similar magnitude as those received from natural sources should be strictly qualitative and encompass a range of hypothetical health outcomes, including the possibility of no adverse health effects at such low levels.

There is substantial and convincing scientific evidence for health risks following high-dose exposures. However, below 50–100 mSv (which includes occupational and environmental exposures), risks of health effects are either too small to be observed or are nonexistent.

In part because of the insurmountable intrinsic and methodological difficulties in determining if the health effects that are demonstrated at high radiation doses are also present at low doses, current radiation protection standards and practices are based on the premise that any radiation dose, no matter how small, may result in detrimental health effects, such as cancer and hereditary genetic damage. Further, it is assumed that these effects are produced in direct proportion to the dose received, that is, doubling the radiation dose results in a doubling of the effect. These two assumptions lead to a dose-response relationship, often referred to as the linear, no-threshold model, for estimating health effects at radiation dose levels of interest. There is, however, substantial scientific evidence that this model is an oversimplification. It can be rejected for a number of specific cancers, such as bone cancer and chronic lymphocytic leukemia, and heritable genetic damage has not

[1] Dose is a general term used to express (quantify) how much radiation exposure something (a person or other material) has received. The exposure can subsequently be expressed in terms of the absorbed, equivalent, committed, and/or effective dose based on the amount of energy absorbed and in what tissues.

been observed in human studies. However, the effect of biological mechanisms such as DNA repair, bystander effect, and adaptive response on the induction of cancers and genetic mutations are not well understood and are not accounted for by the linear, no-threshold model.

Radiogenic health effects have not been consistently demonstrated below 100 mSv

Radiogenic health effects (primarily cancer) have been demonstrated in humans through epidemiological studies only at doses exceeding 50–100 mSv delivered at high dose rates. Below this dose, estimation of adverse health effect remains speculative. Risk estimates that are used to predict health effects in exposed individuals or populations are based on epidemiological studies of well-defined populations (for example, the Japanese survivors of the atomic bombings in 1945 and medical patients) exposed to relatively high doses delivered at high dose rates. Epidemiological studies have not demonstrated adverse health effects in individuals exposed to small doses (less than 100 mSv) delivered in a period of many years.

Limit quantitative risk assessment to doses at or above 50 mSv per year or 100 mSv lifetime

In view of the above, the Society has concluded that estimates of risk should be limited to individuals receiving a dose of 50 mSv in one year or a lifetime dose of 100 mSv in addition to natural background. In making risk estimates, specific organ doses and age-adjusted and gender-adjusted organ risk factors should be used. Below these doses, risk estimates should not be used. Expressions of risk should only be qualitative, that is, a range based on the uncertainties in estimating risk (NCRP 1997) emphasizing the inability to detect any increased health detriment (that is, zero health effects is a probable outcome).

Impact on radiation protection

Limiting the use of quantitative risk assessment, as described above, has the following implications for radiation protection:

1. The possibility that health effects might occur at small doses should not be entirely discounted. The Health Physics Society also recognizes the practical advantages of the linear, no-threshold hypothesis to the practice of radiation protection. Nonetheless, risk assessment at low doses should focus on establishing a range of health outcomes in the dose range of interest and acknowledge the possibility of zero health effects. These assessments can be used to inform decision making with respect to cleanup of sites contaminated with radioactive material, disposition of slightly radioactive material, transport of radioactive material, etc.

2. Collective dose (the sum of individual doses in a defined exposed population expressed as person-sievert) has been a useful index for quantifying dose in large populations and in comparing the magnitude of exposures from different radiation sources. However, collective dose may aggregate information excessively; for example, a large dose to a small number of people is not equivalent to a small dose to many people, even if the collective doses are the same. Thus, for populations in which almost all individuals are estimated to receive a lifetime dose of less than 100 mSv above background, collective dose is a highly speculative and uncertain measure of risk and should not be used for the purpose of estimating population health risks.

Reference

National Council on Radiation Protection and Measurements. Uncertainties in fatal cancer risk estimates used in radiation protection. Bethesda, MD: NCRP; NCRP Report No. 126; 1997.

---

*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.

HEALTH PHYSICS SOCIETY

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.