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Comment on FR Doc # 2015-20722

Submitter Information

Name: Nancy Kirner

Submitter's Representative: Barbara Hamrick

Organization: Health Physics Society

General Comment

Please see attached document.

Attachments

NRC 2015-0057



HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

November 5, 2015

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

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

The Health Physics Society¹ (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.

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.

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

“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.