May 15, 2017

Nancy P. Kirner, CHP
Scientific and Public Issues Committee, Chair
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Office of Administration
U.S. Environmental Protection Agency
Mail Stop:
Washington, DC 20555–0001.

Docket ID No.  EPA–HQ-OA-2017–0190

Subject:  EPA Request for Regulatory Reform Task Force

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 values the opportunity to provide input to the Regulatory Reform Task Force in the attached document.

If you have any questions regarding these comments, please contact the HPS Agency Liaison, Craig Little, at 970-260-2810 or by email to agencyliaison@hps.org.

Sincerely,

Nancy P. Kirner, CHP

cc:  Robert Cherry, Jr, CHP, HPS President
     Eric Abelquist, PhD, CHP, HPS President- Elect
     Craig Little, PhD, HPS Agency Liaison
     Brett Burk, HPS Executive Director

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.
Background

President Trump issued Executive Order 13777 that established the “policy of the United States to alleviate unnecessary regulatory burdens placed on the American people.” It requires each agency to create a Regulatory Reform Task Force to evaluate existing regulations and to identify regulations that should be repealed, replaced or modified. The US Environmental Protection Agency (EPA) Administrator advised the Office of Air and Radiation (OAR), and others, to provide the Task Force recommendations on specific rules that could be repealed, replaced or modified to make them less burdensome by May 15, 2017. As part of the process, OAR hosted a public meeting on April 24, 2017, to solicit proposals for consideration.

The Health Physics Society (HPS) gave verbal comments during the April 24 teleconference urging EPA to reconsider their adherence to the linear non-threshold (LNT) model and to improve several documents by better addressing uncertainties in low-dose, low dose-rate (LDDR) environments. The HPS also stated that reliance on the LNT model “…tends to foment the public’s fear of all types of radiation.” This document provides background for our verbal remarks and emphasizes the continuing need for scientifically defensible federal guidance on matters relating to radiation protection.

Position Details

As a scientific organization of professionals who specialize in radiation safety, the HPS believes the EPA’s reliance on the LNT model, especially at very low doses and dose rates, is inappropriate and can exaggerate the risk. Of most concern to the HPS is the EPA’s extrapolation of the LNT model to calculate collective dose and the use of collective dose as a metric for risk.

The LNT model and/or collective dose appear to be key elements in EPA’s development of the following documents:

- Radon in Homes EPA 402-R-03-003;
- Federal Guidance Report (FGR) 13, Cancer Risk Coefficients for Exposure to Radionuclides, EPA 402-R-99-001;
- FGR 12, EXTERNAL EXPOSURE TO RADIONUCLIDES IN AIR, WATER, AND SOIL, EPA 402-R-93-081;
- Federal Guidance Report No. 11: Limiting Values Of Radionuclide Intake And Air Concentration And Dose Conversion Factors For Inhalation, Submersion, And Ingestion, EPA-520/1-88-020;
- EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population (the “Blue Book”);
- Health Effects Assessment Summary Tables, Radionuclide Table: Radionuclide Carcinogenicity Slope Factors.
- OSWER Memorandum 9200.4-18, August 22, 1997 “Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination” (Jointly signed by Director, Office of Emergency and Remedial Response and Acting Director, Office of Radiation and Indoor Air)

The EPA has also applied the LNT model to the regulations in 40 CFR 190, “Environmental Radiation Protection Standards for Nuclear Power Operations,” and 40 CFR 192, “Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings.” Without consideration of the uncertainties in the estimated health effects, a linear extrapolation of effects at high doses and high dose rates to
LDDR situations and potentially exposed populations is simplistic at best and may cause needless expense.

The HPS often looks to international standard-setting organizations for guidance that is based on the preponderance of scientific knowledge and a prudent measure of safety. In its most recent report to the United Nations General Assembly, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) wrote the following about the concept of collective dose:

"A collective dose is the product of the mean dose to a specified population from a particular source, and the number of people in that population, integrated over a defined period of time. In other words, a collective dose is the dose received by all members of a particular population combined, over a defined period of time. However, the calculated doses are metrics to be used only for the comparison of different sources of exposure, not to estimate implications for health." (UNSCEAR 2016).

Some of the aforementioned EPA documents use collective dose or encourage its use in subsidiary documents. The EPA should follow the guidance of UNSCEAR and not use collective dose “to estimate implications for health” or, as the EPA usually phrases it, cancer risk. This methodology is particularly egregious when the calculation is the multiplication of minuscule individual doses by multiple millions of people and deriving large numbers of theoretical cancer deaths. This calculation is then used to drive unnecessarily costly cleanup or limitation of emissions of radionuclides. The HPS requests that the EPA uses and applies collective dose calculations in ways that follow the guidance in the UNSCEAR report.

Another source of international guidance are reports of the International Commission on Radiation Protection (ICRP). The Executive Summary of ICRP Report 103, “The 2007 Recommendations of the International Commission on Radiological Protection,” states:

“(k) The collective effective dose quantity is an instrument for optimisation, for comparing radiological technologies and protection procedures, predominantly in the context of occupational exposure. Collective effective dose is not intended as a tool for epidemiological risk assessment, and it is inappropriate to use it in risk projections. The aggregation of very low individual doses over extended time periods is inappropriate, and in particular, the calculation of the number of cancer deaths based on collective effective doses from trivial individual doses should be avoided.”

The Health Physics Society reflects these sentiments and more recent epidemiological studies in its 2016 update of “Radiation Risk in Perspective,” PS010-03, available on the HPS.org website under Position Statements of the Health Physics Society. The central message of that statement is:

“The Health Physics Society advises against estimating health risks to people from exposures to ionizing radiation that are near or less than natural background levels because statistical uncertainties at these low levels are great,” and “… below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero...”

In addition, the Position Paper states that use of LNT model near background levels cannot provide reliable risk projections:

“For radiation protection purposes and for setting radiation exposure limits, current standards and practices are based on the questionable premise that any radiation dose, no matter how small, could
result in detrimental health effects such as cancer or heritable genetic damage. Implicit in this linear no-threshold (LNT) hypothesis is the core assumption that detrimental effects occur proportionately with radiation dose received (NAS/NRC 2006). However, because of statistical uncertainties in biological response at or near background levels, the LNT hypothesis cannot provide reliable projections of future cancer incidence from low-level radiation exposures (NCRP 2001).”

The HPS is also concerned with the inconsistent application of risk assessment in radiation protection regulations. These regulations are not well coordinated between federal agencies as discussed in HPS Position Statement on Uncertainty in Risk Assessment (PS008-2):

“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.”

“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 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).”

The EPA has an unusual role in the U.S. radiation regulatory scheme, as it serves as the federal guidance authority providing advice to federal agencies about radiation matters directly or indirectly affecting public health. In this role, EPA’s Federal Guidance Reports (FGR) and policy recommendations, Presidential Guidance Documents, establish the basis for federal and state regulations. It is imperative that our regulatory structure has a strong foundation in current scientific principles and recommendations of international organizations, while reflecting the unique statutory and cultural milieu of the United States.

Therefore, it appears that at least some of the EPA documents that apply the LNT model and collective-dose calculations are inconsistent with guidance issued by international expert groups. It also appears that such documents have not been exposed to the public comment rule making process, but rather have been formulated by internal EPA work groups. HPS recommends that all internal documents that have such significant economic and scientific impact on the country not only be reviewed by internal EPA review groups, such as EPA’s Science Advisory Board, but also be given public exposure through formal notice and comment processes similar to this docket, EPA-HQ-OA-2017-0190.
To address the uncertainties in the current scientific understanding of the risks of low dose and low dose rate radiation exposure, the HPS requests that the EPA continue to support the “Million Worker Study,” currently being conducted under the auspices of the National Council on Radiation Protection and Measurement. The results of this study should provide current and statistically valid quantification of the risks associated with low dose rate and low dose radiation exposure.

The HPS also requests that the EPA consider revision of the above-mentioned documents to address the current scientific understanding of risk and to coordinate radiation regulations with other federal agencies to more closely follow the scientific recommendations of international bodies such as the International Commission on Radiological Protection (ICRP). The ICRP has established the International System of Radiological Protection that is the world-wide basis for radiological protection standards, legislation, guidelines, programs, and practice.

In addition, the HPS urges the EPA to identify statutes that drive and direct the use of the LNT model in EPA implementing regulations. The HPS is not aware of any statutes that preclude the use of other scientific methods of determining the risk of low dose and low dose rate radiation exposure of people.

The HPS appreciates the efforts of the EPA in protecting public health and the environment, and we look forward to working with our colleagues at EPA to improve the existing regulations and to seek additional epidemiological research on low levels of radiation.

References:


The Health Physics Society advises against estimating health risks to people from exposures to ionizing radiation that are near or less than natural background levels because statistical uncertainties at these low levels are great.

The average annual equivalent dose\(^1\) from natural background radiation in the United States is about 3 mSv. A person might accumulate an equivalent dose from natural background radiation of about 50 mSv in the first 17 years of life and about 250 mSv during an average 80-year lifetime.

Substantial and convincing scientific data show evidence of health effects following high-dose exposures (many multiples of natural background). However, below levels of about 100 mSv above background from all sources combined, the observed radiation effects in people are not statistically different from zero.

Scientists evaluate and estimate radiation risk using several assumptions that, taken together, may lead to a range of hypothetical health risk estimates for any given exposure scenario.

For radiation protection purposes and for setting radiation exposure limits, current standards and practices are based on the questionable premise that any radiation dose, no matter how small, could result in detrimental

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\(^1\) Dose is a term used to express or quantify the amount of radiation a person or object has received. Equivalent dose to an organ or tissue is a quantity derived from the absorbed dose. Equivalent dose is used in radiation protection to relate absorbed dose to the probability of a stochastic radiation effect (cancer induction and hereditary changes) in that organ or tissue. The equivalent dose represents the sum of all of the contributions from radiations of different types multiplied by their respective radiation qualities.
health effects such as cancer or heritable genetic damage. Implicit in this linear no-threshold (LNT) hypothesis is the core assumption that detrimental effects occur proportionately with radiation dose received (NAS/NRC 2006). However, because of statistical uncertainties in biological response at or near background levels, the LNT hypothesis cannot provide reliable projections of future cancer incidence from low-level radiation exposures (NCRP 2001).

**Molecular-level radiation effects are nonlinear**

Studies show that dose-response relationships are typically nonlinear (Tubiana and Aurengo 2006; Tubiana et al. 2006). Substantial scientific data indicate that the LNT model of radiation effects oversimplifies the relationship between dose and response. Linearity at low dose may be rejected for a number of specific cancers, such as bone cancer, lymphoma, and chronic lymphocytic leukemia. Heritable genetic damage has not been observed in human studies.

Recent low-dose research indicates that biological response mechanisms such as DNA repair, bystander effects, and adaptive response modulate radiation-induced changes at the molecular level. Cellular transformation leading to carcinogenesis by mutation of genetic material appears to be a complicated, multistep process that is not reflected in the LNT model.

**Radiogenic health effects have not been consistently demonstrated below 100 mSv**

Due to large statistical uncertainties, epidemiological studies have not provided consistent estimates of radiation risk for whole-body equivalent doses less than 100 mSv. Underlying dose-response relationships at molecular levels appear mainly nonlinear. The low incidence of biological effects from exposure to radiation compared to the natural background incidence of the same effects limits the applicability of radiation risk coefficients at organ equivalent doses less than 100 mSv (NCRP 2012).

The references to 100 mSv in this position statement should not be construed as implying that health effects are well established for doses exceeding 100 mSv. Considerable uncertainties remain for stochastic effects of radiation exposure between 100 mSv and 1,000 mSv, depending upon the population exposed, the rate of exposure, the organs and tissues affected, and other variables. In addition, it is worth noting that epidemiological studies generally do not take into account the dose that occupationally or medically exposed persons incur as natural background; thus, the references to 100 mSv in this position statement should generally be interpreted as 100 mSv above natural background dose.

**Dose-rate issues**

Risk estimates commonly used to predict health effects in exposed individuals or populations are based primarily on epidemiological studies of Japanese atomic bomb survivors and other populations exposed to relatively high doses delivered at high dose rates. Animal, cellular, and molecular studies all demonstrate that at any level of biological organization, the responses following low-dose-rate exposure are less than observed after the same dose delivered at a high dose rate (Dauer et al. 2010). Epidemiological studies have not consistently demonstrated adverse health effects in persons exposed to small (less than 100 mSv) doses protracted over a period of many years.
**Collective dose and radiation protection planning**

A common approach in many circles, not recommended here, involves extrapolating the calculated risk derived at high doses to low-dose levels. Extrapolation may be convenient for setting radiation protection guidelines. However, when used prospectively to predict future risk to an exposed population, the multiplication of small risk coefficients by large population numbers leads inevitably to unsupportable claims of cancer risk from ionizing radiation (NCRP 1997, 2012).

Significant dosimetry uncertainties for individual subjects characterize most epidemiological studies. Actual doses and individual responses to radiation may be highly variable. It follows, therefore, that the collective population dose (the sum of individual whole-body equivalent doses expressed in units of person-sievert) is a highly uncertain number. Since the risk coefficient at low dose is uncertain, and the individual contributors to collective population dose are also uncertain, the resultant uncertainty is greater than each of the individual contributions—and should not be used with confidence to predict cancer incidence in an exposed population.

**Equivalent dose is not defined for short-term deterministic effects**

The concept of equivalent dose applies only to population group averages (reference models) for radiation protection purposes and not to biological risk for individual subjects. Since the radiation-weighting factors used to derive equivalent dose were developed only for stochastic effects, the equivalent dose is not applicable to deterministic biological effects. Therefore, equivalent dose should not be used for evaluating organ or tissue toxicity from radiation.

**References**


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UNCERTAINTY IN RISK ASSESSMENT

POSITION STATEMENT OF THE HEALTH PHYSICS SOCIETY*

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


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