HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

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U.S. Environmental Protection Agency
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Subject: Comments in Response to Advance Notice of Proposed Rulemaking (40 CFR 190) Environmental Radiation Protection Standards for Nuclear Power Operations

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 Advance Notice of Proposed Rulemaking (ANPR) published February 4, 2014 relating to potential changes to 40 CFR 190.

The HPS is responding to the first two issues addressed in the ANPR, as official HPS positions directly address these topics. The remaining four issues are still very significant, and would impact the practice of radiation safety depending upon how they are resolved. We will continue to follow them as the rulemaking evolves.

The HPS appreciates this opportunity to provide comments on this white paper. If you have any questions regarding these comments, please feel free to contact me at 714-456-5607 or bhamrick@uci.edu.

Sincerely,

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c: Brett Burk
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[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.

ISSUE 1. Consideration of a Risk Limit to Protect Individuals.

a. Should the Agency express its limit for the purpose of this regulation in terms of radiation risk or radiation dose?

The Environmental Protection Agency (EPA) should continue to express limits in terms of dose.

Although 40 CFR 190 applies to dose to the public and general environment from the nuclear fuel cycle (NFC), a move to a risk-based limit in this arena would likely ignite discussion in other arenas, such as non-NFC licensees of the Nuclear Regulatory Commission and Agreement States, as well as the entire medical radiology community; therefore, the Health Physics Society's (the Society's) response to this question and those that follow carry a tacit assumption that a move from dose to risk will ultimately impact all areas of radiation protection and not simply those areas related to the off-site consequences of NFC operations.

The Society has a position statement, which directly goes to the topic of calculating risk:

"*In accordance with current knowledge of radiation health risks, the Health Physics Society recommends against quantitative estimation of health risks below an individual dose 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."[2]

The Society has a second position statement that also directly addresses this issue. The text supporting this position statement notes:

"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 (<

[2] Position Statement of the Health Physics Society, PS010-2, "Radiation Risk in Perspective," (Rev. July 2010).

0.01 Gy) typical of most occupational and environmental exposures."[3]

The current annual limit on dose equivalent in 40 CFR 190 is more than two orders of magnitude less than the level at which the Health Physics Society recommends making a quantitative estimation of health risk; therefore, the limits should continue to be expressed in terms of dose.

Other factual matters that are relevant:

1. The international community continues to use dose as the metric of choice.[4]
2. Dose and concentrations of radioactive material in the environment are directly measurable quantities, whereas risk is not.
3. Measurements of dose and concentrations of radioactive material in the environment already carry uncertainties; these uncertainties increase as the dose or concentrations draw close to naturally occurring levels. The translation of dose to risk will increase the type and number of uncertainties associated with a demonstration of compliance with the limits.
4. Today, in the United States, there is not a universally-accepted methodology for translating dose to risk.

One of EPA's stated reasons for considering a move from dose-based to risk-based limits is as follows:

"The primary technical difference between a risk standard and a dose standard is that the relationship between risk and dose has varied over time. Should this trend continue, there is a potential for a dose standard to diverge over time from its original underlying risk level. In contrast, a risk standard represents a constant level of risk, regardless of the type of facility, mix of radionuclides or changes in the underlying science involved in estimating the risk."

From a practical standpoint this transfers the problem of the changing relationship between dose and risk from the entities charged with setting standards to those that use them. As noted above, there is not a universally-accepted translation from dose to risk, leaving two possibilities: 1) each regulated entity may devise its own translation (within some broad boundaries), or 2) a single (or limited) number of acceptable methodologies are codified or otherwise required. The former case will result in inconsistent protection, varying from one regulated entity to another, and the latter results in the same concern that EPA is attempting to resolve (i.e., the changing relationship between dose and risk will require the same regulatory revisions currently necessary, but instead of revising a dose limit, revisions will be made to the translation methodologies).

[3] Position Statement of the Health Physics Society, PS008-2, "Uncertainty in Risk Assessment," (Rev. February 2013).
[4] See also, item 3 in Position Statement of the Health Physics Society, PS004-1, "*Compatibility in Radiation Safety Regulations,"* (Reaffirmed July 2007).

b. Should the Agency base any risk standard on cancer morbidity or cancer mortality? What would be the advantages or disadvantages of each?

The Society does not have a formal position addressing this issue, but offers the following information for consideration:

1. In the simplest formulation, mortality refers to death, while morbidity refers to disease incidence. While there are uncertainties related to assessing cancer-related mortalities (e.g., if a death actually caused by a cancer occurs prior to diagnosis, or a death is attributed to the acute cause of death – such as pneumonia – rather than the cancer itself), the uncertainties related to morbidity are much greater. Uncertainties related to morbidity include a) improper accounting of false positives, b) the gray area in differentiating among diagnoses of dysplasia, carcinoma in situ, or indolent cancers and c) the ever-improving early screening and detection tools that may increase detection (and therefore morbidity), but will also include detection of disease states that may cause no harm to the patient.[5,6]

2. The relationship between mortality and morbidity varies dramatically depending upon the cancer site; e.g., for lung cancer almost 84% of the diagnoses result in mortality; while for thyroid cancers only 6% result in mortality.[7] A move to use morbidity rather than mortality could result in very significant changes to the dose surrogates (e.g., effluent concentrations) currently used to demonstrate compliance with the standards.

c. How might implementation of a risk limit be carried out? How might a risk standard affect other federal regulations and guidance?

As noted in our response to the first question, in order to use a risk limit, there must be an accepted methodology (or some limited number of them) for translating dose to risk. In addition, and as a practical matter, if multiple risk limits (e.g., based on age, gender, or other individual factors) are established, only the most restrictive limit will likely be implemented with respect to public dose, since regulated entities do not have control over which members of the public may be exposed in an unrestricted and uncontrolled area.

If risk limits are established in 40 CFR 190, it is likely that other regulations would be evaluated for the feasibility of making a similar change. These include Nuclear Regulatory Commission regulations, the comparable Agreement State regulations, and Agreement State and non-Agreement State regulations relating to the use of machine-produced radiation, and naturally-occurring radioactive material, including radon. Interestingly, if radon is to be included as contributing to off-site risk from the uranium fuel cycle,

[5] Esserman, L, MD, *"Rethinking Screening for Breast Cancer and Prostate Cancer,"* JAMA. 2009;302(15):1685-1692. Doi:10.1001/jama.2009.1498.
[6] Esserman, L, MD, *"Overdiagnosis and Overtreatment in Cancer, An Opportunity for Improvement,"* JAMA. 2013;310(8):797-798. Soi:10.1001/jama.2013.108415.
[7] Lifetime Risk, SEER Cancer Statistics Review 1975-2010, National Cancer Institute.

and assuming the risk limit would be at least as restrictive as the current 100 millirem limit on dose to the public, the radon concentrations would have to be up to two orders of magnitude lower than the current guidance allows for homes, schools and commercial structures.

Other federal agency regulations that could ultimately be impacted are those promulgated by the Occupational Safety and Health Administration (OSHA) and the OSHA State Plan states, state and local air and water protection agencies, the Department of Energy, the Department of Defense, the National Aeronautic and Space Administration, the Food and Drug Administration, and others.

ISSUE 2 Updated Dose Methodology (Dosimetry).

a. If a dose standard is desired, how should the Agency take account of updated scientific information and methods related to radiation dose – such as the concept of committed effective dose?

b. In updating the dose standard, should the methodology in ICRP 60 or ICRP 103 be adopted, or should implementation allow some flexibility? What are the relative advantages or disadvantages of not specifying which ICRP method be used for the dose assessment?

The Society's mission is "excellence in the science and practice of radiation safety." Implicit in this mission is support for using the best available science; however, as a practical matter, it takes time for new results to be confirmed, and longer for them to infiltrate to the level of implementation. It could be disruptive and cost-prohibitive to make a rigid commitment to revising standards with each new piece of information; thus, one might consider developing a threshold for change (i.e., a trigger level below which a change in the relationship between dose and risk would not require a specific action).

In addition, "updated scientific information" may lead to an understanding that certain levels or types of exposures (e.g., nuclide-dependent internal exposures) carry less risk than previously thought, and EPA may want to consider how that type of "updated scientific information" would be addressed.

The Society also has a position statement that applies to this topic:

"Radiation safety standards shall be consistent with the recommendations of the International Commission on Radiological Protection (ICRP), the National Council of Radiation Protection and Measurements (NCRP), and scientific consensus standards."[8]

Nevertheless, while consistency is an admirable goal, there may be multiple methodologies that provide approximately the same result overall. Given that EPA is charged with setting these standards, but not enforcing them, it may be appropriate to allow the enforcement agencies (e.g., US NRC, OSHA, etc.) to develop the guidance with respect to the demonstration of compliance with the dose standards.

[8] Position Statement of the Health Physics Society, PS004-1, "Compatibility in Radiation Safety Regulations,"in Risk Assessment," (Reaffirmed July 2007).