HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

July 25, 2016

U.S. Environmental Protection Agency
Docket ID No. EPA-HQ-OAR-2007-0268-0210

Eric Abelquist, PhD, CHP
President Elect
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Subject: Comments in Response to Draft Protective Action Guide for Drinking Water after a Radiological Incident

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 subject draft guide published June 10, 2016, and relating to proposed drinking water protective action guides.

The HPS is responding with comments in the attached document. The first pages are devoted to general comments with respect to the establishment of protective action guides and basic health physics concepts, followed by comments specific to the information provided in the Federal Register notice.

The HPS appreciates this opportunity to provide comments on this draft guide. If you have any questions regarding these comments, please feel free to contact the HPS Agency Liaison, Craig Little, at 970-260-2810 or by email at agencyliaison@hps.org.

Sincerely,

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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.

GENERAL COMMENTS:

1. The Health Physics Society (HPS) has a position statement, "Compatibility in Radiation Safety Regulations," which recommends that radiation standards be consistent with recommendations of the International Commission on Radiological Protection (ICRP), the National Council of Radiation Protection and Measurements, and scientific consensus standards [1] . While the position expressly does not apply to "accidental releases of radioactive material," those basic radiation safety concepts that may guide actions in those circumstances are the same as those common to everyday radiation safety practices as follows:

   A. ALARA (As Low as Reasonably Achievable) is as acronym that conveys the principle that:

      "In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring [radiation] exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account" [2].

      The above definition is consistent with current usage in the United States, while the definition provided in the document for comment calls for dose to be "as low as possible," which is inconsistent with international and national consensus standards.

   B. The current ICRP guidance on protection of human health in emergencies provides guidance to limit dose in the range of 20-100 millisievert (mSv) as the situation may warrant [3]. Given the wide range of scenarios to which the proposed drinking water protective action guides may apply, it may be prudent to offer a broader range of protective action guides than the EPA proposes, which could then be tailored to the scope and extent of the event, in light of the competing risks associated with evacuation, relocation, and the adequacy and availability of alternate water supplies.

2. While the linear no-threshold hypothesis (LNTH) is routinely used in the United States to establish standards for normal operations, the justification for the use of the conservative assumptions and modeling underpinning the LNTH (and its application, including the calculation of collective dose) may not be appropriate for emergency planning purposes, as highlighted by the Japanese experience following the 2011 Tōhoku earthquake and tsunami [4].

3. From a purely practical standpoint, EPA may want to consider the establishment of protective action guides for drinking water in the form of concentrations of radionuclides in water, rather than in the form of effective dose. Effective dose is not directly measurable, while concentrations of radionuclides in water can be more readily quantified, within the bounds of the sampling and analyses uncertainties.

SPECIFIC COMMENTS

Comment 1:

The Federal Register Notice (FRN) states:

"The PAGs are based on the following essential principles, which also apply to the selection of any protective action during an incident:

- Prevent acute effects.
- Balance protection with other important factors and ensure that actions result in more benefit than harm.
- Reduce risk of chronic effects."

RESPONSE:

ACUTE EFFECTS: The proposed primary drinking water PAG, 5 millisievert (mSv), is certainly so low that prevention of acute effects is assured.

BALANCE: EPA has provided no information on how they achieved the balance called for in the second principle above. This is especially important in light of the experience following the Fukushima Daiichi accident, where the public was adversely impacted by overly restrictive radiation protection guidelines [4]. As seen in the 1986 Chernobyl accident, the largest public health problem anticipated from the Fukushima Daiichi accident were mental health effects, including depression, anxiety and post-traumatic symptoms [4].

RISK OF CHRONIC EFFECTS: The Health Physics Society (HPS) Position Statement PS010-3 advises that "radiogenic health effects have not been consistently demonstrated below 100 mSv," and that, "considerable uncertainties remain for stochastic effects…between 100 mSv and 1,000 mSv" [5]. The proposed primary PAG, 5 mSv, is 20 times lower than the threshold at which there is some (inconsistent) evidence of risk, and three times lower than the average 5-year-old child in the U.S. will have already accrued in his or her life due to natural background radiation. There is currently no sound evidence demonstrating that any increased risk exists related to exposures below 5 mSv, thus imposing a limit below this level cannot produce any quantifiable benefit, which should be taken into consideration during the application of the balancing principle.

Comment 2:

The FRN states:

"PAGs are not intended to define "safe" or "unsafe" levels of exposure or contamination."

RESPONSE:

The EPA effort to establish drinking water PAGs is intended to provide guidance; however, since it is not

appropriate to estimate collective or individual risk at these low levels of exposure [5,6], and since EPA has deemed these levels neither safe nor unsafe, the value of the guidance is unclear.

In addition, it is probably worthwhile to note that public advocacy groups are mischaracterizing this proposed PAG as allowing an *unsafe* increase in the level of radionuclides allowed in drinking water, calling it "shocking" and "immoral" [7]. A part of EPA's mission is to ensure that "all parts of society – communities, individuals, businesses, and state, local and tribal governments – have access to accurate information sufficient to effectively participate in managing human health and environmental risks" [8].

In the absence of definitive information from the EPA on the lack of identifiable risk at the level of exposure from the proposed PAGs, it is likely society will be left with wide-ranging, conflicting interpretations as to the significance of the PAGs, including a great deal of inaccurate information, and an inability to effectively participate in managing the risks.

Comment 3:

The FRN states:

"EPA proposes a two-tiered intermediate phase drinking water PAG of 100 millirem (mrem) [1 mSv] projected dose in the first year for infants, children and pregnant or nursing women and 500 mrem [5 mSv] projected dose in the first year for the general population. The proposed PAG is designed to work in concert with the other Protective Action Guides currently in place for other media in the intermediate phase (*i.e.,* the Food and Drug Administration's 500 mrem [5 mSv] PAG for ingestion of food) and provides an additional level of protection for the most sensitive life stages."

RESPONSE:

HPS offers the following for your consideration:

- The use of age- and sex-averaged tissue weighting factors, as recommended by the International Commission on Radiological Protection can be applied to calculate a single, protective effective dose to a population of both sexes and all ages [3].
- The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) has concluded that children are more sensitive than adults for only 25% of cancer types [9]. For 15% of cancer types, children have the same sensitivity as adults, for 10% they are less sensitive than adults, for 20% no conclusion can be drawn because the evidence is too weak, and for 30% of cancer types there is only a weak or no relationship between that cancer and radiation exposure. Thus, for 75% of cancer types, the conclusions of UNSCEAR do not support EPA's assertion that children are more radio-sensitive than adults.
- The difference between the EPA proposed PAG for pregnant women and children and that for non-pregnant adults (1 mSv vs. 5 mSv, respectively) is 4 mSv. These values and the difference between

them are all typical of natural background levels around the United States (average is about 3.1 mSv yr^{-1}) [10]. UNSCEAR has explicitly advised, "In general, increases in the incidence of health effects in populations cannot be attributed reliably to chronic exposure to radiation at levels that are typical of the global average background levels of radiation… the Scientific Committee does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels" [6]. In addition, HPS Position Statement PS010-3 reiterates UNSCEAR's position and specifically advises against estimating health risks to people from exposures…near or less than natural background levels [5]. The non-pregnant adult PAG is near (or less than in certain areas of the country) natural background levels and the individual and collective health effects are indeterminate or non-existent at this level. EPA may want to consider (and justify for the purpose of applying the balancing principle) why a secondary more restrictive PAG has any value when the risks of exposure at the primary PAG level cannot be educed.

Comment 4:

The FRN states:

"The two-tier approach seeks to balance the goal of keeping radiation doses as low as possible with the practical and logistical challenges of providing alternative drinking water during the response to a disaster."

RESPONSE:

HPS is unaware of any commonly accepted goal of "keeping radiation doses as low as *possible*" (emphasis added). Rather, the nationally and internationally accepted goal is keeping doses *as low as* ***reasonably*** *achievable (ALARA), economic and social factors being taken into account*. In keeping with EPA's stated balancing principle, the costs and risks of exposure must be balanced against the costs and risks of preventing exposure, including the social costs (*e.g*. evacuations, relocations, and, mental health effects) [4,11]. It does not appear that EPA has undertaken this balancing effort.

Comment 5:

The FRN states:

"Every PAG is developed with the same three principles: prevent acute effects, balance protection with other important factors and ensure that actions result in more benefit than harm, and reduce risk of chronic effects."

RESPONSE:

See response to Comment 1.

Comment 6:

The FRN states:

"Commenters representing states agencies from Ohio, Kansas, Pennsylvania, Illinois and Washington suggested that a drinking water PAG should be established at the 500 mrem [5 mSv] level, to be consistent with the FDA food PAG and with the DHS guidance for water. While EPA agrees with the need of establishing a drinking water PAG, which is consistent with currently available guidance, it is also important to note that EPA believes that when possible, PAG recommendations should provide an additional level of protection to sensitive life-stages. For short-term incidents, it is appropriate to consider a lower tier PAG level of 100 mrem [1 mSv] for sensitive life-stages including pregnant women, nursing women and children 15 years old and under."

RESPONSE:

See response to Comment 3.

Comment 7:

The FRN states:

"This approach of setting a two-tier level of protection incorporates suggestions submitted by commenters regarding the adequate consideration of children and sensitive subpopulations. There is an abundant precaution built into the derivation of the drinking water PAG through a variety of assumptions, including amount of water consumed, exposure duration and dose-response modeling, using the dose-response for the most sensitive life stages to derive the PAG for children through age 15 years."

RESPONSE:

See response to Comment 3.

Comment 8:

The FRN states:

"Estimated risk of excess cancer cases for lifetime exposure (70 years) to radioactive contaminants in drinking water at 4 mrem/yr [0.04 mSv/yr] (the MCL) generally falls in a range of risks deemed acceptable by the Agency's regulations. Estimated risks associated with a shorter (one year) exposure to radioactivity in drinking water at the proposed PAG levels fall within a similar range."

RESPONSE:

Since there is no demonstrable difference in risk between the proposed PAG value and the MCL, EPA's conclusion that both values fall into a similar range is technically correct. However, EPA also seems to imply there is a positive value of risk associated with 4 mrem/yr [0.04 mSv/yr], and that such risk can be accurately

estimated. This is in direct contradiction to the advice of UNSCEAR [6], the International Commission on Radiation Protection [3], and the Health Physics Society [5]. EPA should explicitly acknowledge that there may be no risk at all associated with this radiation dose, which is ~100 times lower than natural background [10].

REFERENCES

[1] HPS (2007). Compatibility in Radiation Safety Regulations: position statement of the Health Physics Society. Retrieved 22 July 2016 from: http://hps.org/documents/compatibility_ps004-1.pdf.

[2] ICRP (1991). 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Annals of the ICRP 21 (Elsevier Science, New York).

[3] ICRP, 2007. Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann ICRP 37, 1-332.

[4] Gonzalez, A.J., M. Akashi, J.D. Boice, et al., 2013. Radiological protection issues arising during and after the Fukushima nuclear reactor accident. Journal of Radiological Protection 33, 497-571.

[5] HPS (2016). Radiation risk in perspective: position statement of the Health Physics Society. Retrieved 06 June 2016 from: http://hps.org/documents/risk_ps010-3.pdf.

[6] UNSCEAR, 2012. Report of the United Nations Scientific Committee on the Effects of Atomic Radiation Fifty-ninth Session (21-25 May 2012). A/67/46. U. Nations, New York, NY.

[7] EcoWatch (2016). EPA proposal allows radiation exposure in drinking water equivalent to 250 chest X-rays a year. Retrieved 28 June 2016 from: http://ecowatch.com/2016/06/08/epa-radiation-drinking-water/.

[8] EPA (2015). Our Mission and What We Do. Retrieved 07 July 2016 from: https://www.epa.gov/aboutepa/our-mission-and-what-we-do.

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[10] HPS (2012). Background radiation. Retrieved 22 July 2016 from: http://hps.org/documents/background_radiation_fact_sheet.pdf.

[11] Mossman, K.L., 2014. Cancer complexity and radiation protection. Health Phys 107, 73-79.