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August 3, 2014

Administrator Gina McCarthy
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Environmental Radiation Protection Standards for Nuclear Power Operations – Advance Notice of Proposed Rulemaking Docket, Docket ID No. EPA-HQ-OAR-2013-0689

Dear Administrator McCarthy:

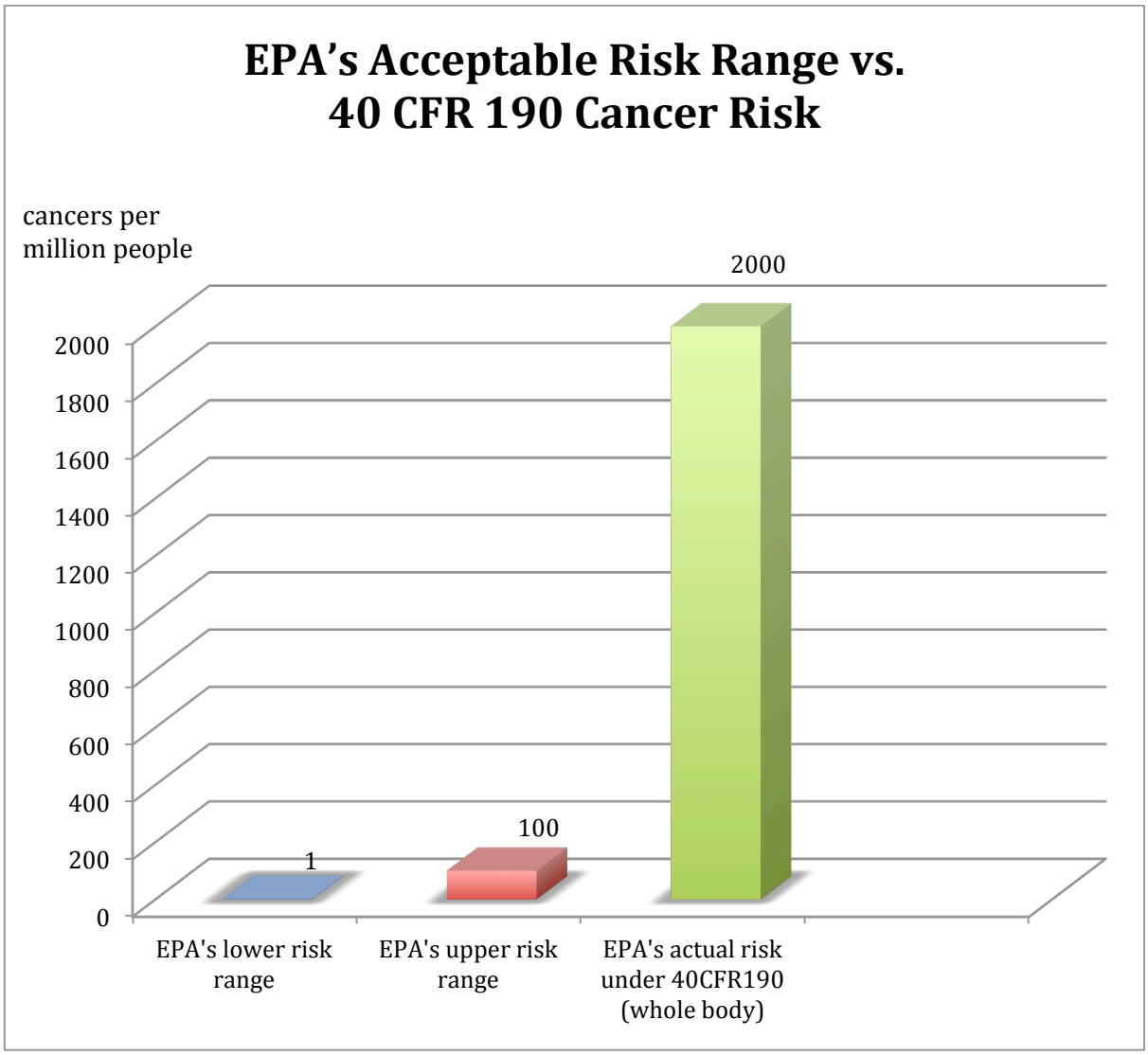
EPA has long opposed other agencies when they proposed radiation protection standards that EPA deemed "not protective of human health and the environment."[1] EPA has insisted that to be protective, exposure to carcinogens must be controlled so as to limit cancer risks within EPA's longstanding "acceptable risk range" of one-in-a million to one-in-ten thousand (10^{-6} to 10^{-4}), aiming to get as close as possible to the one-in-a-million level. It does not matter whether the carcinogen is a radionuclide or a hazardous chemical; the public must be protected from them equally. As EPA memorably said when it criticized proposed regulations by the Nuclear Regulatory Commission that would have allowed exposures outside that historic risk range:

> **To put it bluntly, radiation should not be treated as a privileged pollutant.** You and I should not be exposed to higher risks from radiation sites than we should be from sites which had contained any other environmental pollutant.
>
> Ramona Trovato, Director, EPA Office of Radiation and Indoor Air, April 21, 1997 (emphasis added) [2]

[1] See e.g., letter from Robert Perciasepe, Assistant Administrator for Air and Radiation, and Timothy Fields, Assistant Administrator for Solid Waste and Emergency Response, to Charles , Hardin, Executive Director, Conference of Radiation Control Protection Directors, July 7, 2000, http://www.epa.gov/superfund/health/contaminants/radiation/pdfs/EPA2000f.pdf, p.1-2; and OSWER Memorandum No. 9200.4-18, *Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination*, from Stephen D. Luftig, Director, Office of Emergency and Remedial Response, and Larry Weinstock, Acting Director, Office of Radiation and Indoor Air, August 22, 1997, "Dose Limits in NRC Rule are not Protective," http://www.epa.gov/superfund/health/contaminants/radiation/pdfs/radguide.pdf

[2] *Statement on the Nuclear Regulatory Commission's Rule on Radiological Criteria for License Termination.*

What has long been kept secret, however, is that EPA's own radiation protection standards fall far outside the acceptable risk EPA insists on for all other carcinogens. For example, 40 CFR 190, Environmental Radiation Protection Standards for Nuclear Power Operations, the regulation being addressed by the current Advanced Notice of Proposed Rulemaking (ANPR), allows whole body exposures, that, according to EPA's own official risk figures, **produce cancer risks twenty to two thousand times higher than EPA's own acceptable risk range**.[3]



[3] EPA's current official radiation cancer risk figure, gender- and age-averaged, is 1.16 x 10^{-3} excess cancers per person-rem of exposure. *EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population,* "Blue Book," EPA 402-R-11-001, April 2011, pp. iv, 2. http://epa.gov/rpdweb00/docs/bluebook/bbfinalversion.pdf For lifetime exposure of 25 millirem/year, EPA's own risk estimate would be 0.025 rem/year x 70 years x 1.16 x 10^{-3} = 2 x 10^{-3} (1 cancer per 500 people exposed), twenty times the 10^{-4} upper end of the risk range and two thousand times the 10^{-6} lower end of the range. For females, the EPA Blue Book gives the age-averaged risk figure as 1.35 x 10^{-3} cancers per person-rem, so EPA's risk estimate for 25 millirem per year over a lifetime would be even higher, 2.3 x 10^{-3}, twenty-three times the upper end of the EPA acceptable risk range.

Use of Dose Rather Than Risk Obscures the Hazard

In other words, EPA has itself allowed radiation to be treated as a "privileged pollutant," permitted to expose people to risks far in excess of those allowed for any other environmental pollutant. This troubling fact, however, has been obscured by the practice of also treating the method of regulation for radiation differently than for all other carcinogens. Whereas all other standards are risk-based, radiation regulations have generally been allowed to be based on opaque units of radiation dose such as rems and sieverts. This exemption from normal EPA practice has made it difficult if not impossible for the public and policymakers, including senior EPA officials, to even be on notice that the radiation regulations are so much less protective than what EPA requires for all other threats to the environment and public health.

EPA's Official Risk Estimates for Radiation Have Markedly Increased, But the Standards Have Not Been Tightened Accordingly

Furthermore, because the limits are expressed in terms of dose rather than risk, when EPA's own scientific information determines, as it has repeatedly, that radiation is far more dangerous per unit dose than previously believed, the permissible exposures have not been tightened accordingly. Indeed, 40 CFR 190 was adopted in the mid-1970s, and despite marked increases in EPA's own official risk estimates for radiation and those of the National Academy of Sciences (NAS), the permissible radiation exposures have not been lowered accordingly. EPA has relied upon the NAS reports on the Biological Effects of Ionizing Radiation (BEIR) for determining the risks from radiation. BEIR V found cancer risks to be 3-4 times larger per unit dose than the previous BEIR report, and BEIR VII found cancer incidence risks 35% higher than in BEIR V. EPA has adopted these increased values in its official "Blue Book" on radiogenic risk.[4] Yet, despite a three-, four- or five-fold increase in risk, the 40 CFR 190 standards have not been tightened since promulgation in the mid-1970s. At that time, EPA promised to review the regulations for adequacy every five years and revise them as necessary, but it has not done, until now, any such review. One would thus think that the ANPR would focus on significantly strengthening the protections, given the large increase in official risk estimates, but that unfortunately has not been the case.

Instead of Reducing Permissible Radiation Exposures to Reflect Increased Risk, EPA Proposes Weakening Protections

Rather than lower permissible exposures due to the increased risk acknowledged from radiation, EPA's Office of Radiation and Indoor Air (ORIA) has proposed changes that would dramatically weaken the regulations and increase allowable public exposures. In the ANPR, ORIA has floated the idea of eliminating the organ dose limits in the current rule, which are the primary existing protections. ORIA proposes using a fictional "effective dose equivalent" (EDE) rather than actual organ doses, a change that would result in relaxing current protections and allowing increased exposures to many key radionuclides by as much as *twenty-five-fold*,

[4] Using other comparisons, the official EPA risk factors have increased at least three-fold since 40 CFR 190 was promulgated.

according to studies done for EPA.[5] For all but a handful of radionuclides, permissible exposures would increase if the 25 millirem per year organ dose limits in 40 CFR 190 were deleted and a 25 millirem EDE incorporated instead. For radionuclides of particular concern in contaminated sites, on average the standards would be weakened by a factor of about three and a half (i.e., exposures 3.5 times higher would be allowed.)[6]

"Effective Dose Equivalent" is Flawed and Should be Replaced with Effective Risk

EDE is a flawed concept that should be replaced, according to Dr. D. J. Brenner of the Center for Radiological Research at Columbia University Medical Center.[7] EDE represents "questionable science," according to Dr. Brenner, being based instead based on "subjective committee-defined numbers" (e.g., as inputs for "organ weighting factors"). These "adjustments" discount certain cancers by subjective values placed on, for example, the presumed degree of pain and suffering from treatment for cancers that are survived. Dr. Brenner proposes replacing effective dose with effective risk, tissue-specific lifetime cancer risks. "The resulting quantity," he writes, "would perform the same comparative role as effective dose; it would have the potential to be age- and, if desired, gender-specific, just as easy to estimate, less prone to misuse, more directly interpretable, and based on more defensible science."

Eliminating Organ Dose Limits and Replacing with EDE Would Markedly Increase Permissible Radiation Exposures to the Public

Eliminating the 25 millirem/year dose limits for organs (and eliminating the 75 millirem thyroid limit) and shifting instead to a 25 millirem/year EDE, as suggested by ORIA, by definition would significantly increase permitted exposures, as discussed below. This would occur at the very time EPA's own data, derived largely from the National Academy of Sciences, indicate that radiation is more dangerous than assumed earlier and standards need to be tightened.

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[5] See, e.g., *Comparison of Critical Organ and EDE Radiation Dose Rate Limits for Situations Involving Contaminated Land,* prepared for EPA by S. I. Cohen & Associates, April 18, 1997; summarized in OSWER Memorandum No. 9200.4-18, *op cit*., p.5 and Appendix 4. The study identifies a number of radionuclides, including critical ones such as most of the plutonium isotopes, for which the current 25/75/25 40 CFR 190 rules would be equivalent to 1 millirem/year EDE. Thus, if the organ dose limits in 40 CFR 190 were jettisoned and replaced with a 25 millirem EDE, twenty-five times higher exposures to the public would be allowed than is now permitted under the current 40 CFR 190.

[6] *Comparison of Critical Organ and EDE Radiation dose Rate Limits, ibid.* The study concludes that the averaged over all radionuclides analyzed, the current 40 CFR 190 rule of 25 millirem whole body, 75 thyroid, and 25 all other organs is equivalent to 10 millirem/year EDE. (The ANPR inexplicably says that a 25 millirem whole body, 75 millirem organ dose limit is on average the equivalent of 15 millirem EDE, but 40 CFR 190's limits for all organs except thyroid is three times lower, so this comparison is irrelevant and inflated.) For key radionuclides, the average figure is 7 EDE. But comparison of the "average" radionuclide to EDE is misleading; one shouldn't average the different radionuclides. As discussed in the prior footnote, for many radionuclides, such as most of the plutonium isotopes, shifting to EDE would weaken public protections by 25-fold. The limit for each radionuclide needs to be protective, not for the "average" radionuclide. The public exposed to any radionuclide needs to be assured it will not face a cancer risk outside the acceptable risk range.

[7] *Effective Dose: A Flawed Concept that Could and Should be Replaced,* The British Journal of Radiology, 81 (2008), 521–523, http://www.columbia.edu/~djb3/papers/bjr3.pdf

Take a radionuclide that concentrates in primarily one organ, say the bone surface. Under current 40 CFR 190, permissible exposures would be limited to those producing 25 millirem actual dose to that organ or tissue. But under a 25 millirem EDE limit, the permissible dose to that organ is increased by a factor of thirty three. By multiplying the actual organ dose by an organ weighting factor of 0.03, or 1/33 and eliminating the organ dose limits, under an EDE regime, a dose to that same organ of 825 millirem per year would be allowed compared to the 25 millirem limit in current regulation. A 25 millirem EDE regulation would thus allow people to be exposed to thirty-three times higher levels of that radionuclide than one can at present under 40 CFR 190. Protections for a few radionuclides would stay the same, but for the vast majority, the multiplying of actual organ doses by the organ weighting factors for EDE results in markedly increasing permissible exposures, significantly decreasing protections.

"Reference Man" Needs to be Abandoned; Age and Gender Must Be Taken Into Account

Additionally, 40 CFR 190, like many of EPA's radiation regulations, was based in some measure on "Reference Man," a male young adult. It is well known that women are more susceptible to radiation-induced cancer than males, and the child more susceptible than young adults. The ANPR concedes that EPA generally takes into account age and gender in establishing its standards for all other carcinogens, but doesn't do so for radiation, once again treating it in a less protective fashion. We urge the standards be targeted so as to assure that the most radiation-sensitive groups in our lifecycle are protected to the risk goal which must be well within the accepted risk range.

EPA's acceptable risk range, as indicated above, is 1×10^{-6} to 1×10^{-4}, with a requirement to aim as close to the 10^{-6} as feasible. We therefore stress that 40 CFR 190 should be tightened to set standards that meet those requirements. We note that EPA will, under very exceptional site specific circumstances, allow risks as high as 3×10^{-4}, but no such exceptional circumstances apply to general radiation regulations, and thus risks should be kept to below 1×10^{-4} for any radionuclide. We also note that the ANPR conceded that the standards should be based on lifetime exposure, which is appropriate, since they cover the entire nuclear fuel cycle. EPA generally sets standards based on keeping the risks within the accepted range assuming lifetime exposure.[8]

[8] An exception not relevant here is the CERCLA program, which for radioactive contamination presumes a 40 year exposure for the agricultural scenario and a 30 year exposure for the suburban residential scenario, based on the assumption that most people move within that period and would not be likely to move from living atop a Superfund site to living atop another Superfund site. Such an assumption would be nonsensical for 40 CFR 190, which covers the entire nuclear fuel cycle. People may move from one home in Chicago, say, to another neighborhood in Chicago, but they would still be close to one of the numerous nuclear facilities in the area and still subject to exposure. But even were one to—improperly in our view—not consider lifetime exposure but only on the order of 30 years as used for Superfund residences, one would have to then use a higher risk coefficient to reflect the increased risk at earlier ages (CERCLA assumes it is the first 30 or 40 years of life in which one is exposed). The EPA Blue Book shows average cancer risk of approximately 2×10^{-3} per rem for the first thirty years of life, gender-averaged, ~70% higher than the risk coefficient per rem given for risk at average age. 25 mrem per year for just 30 years is thus a risk of 0.025 rem/year x 30 years x 2×10^{-3} cancers/rem = 1.5×10^{-3}, or 15 to 1500 times the EPA risk range. Taking into account gender, which according to the EPA Blue Book shows a 65% increased risk for females compared to males and a 25% increased risk compared to the gender-averaged figure, results in even 30 years exposure at 25 millirem/year being 1.9×10^{-3}, or 19-1900 times the risk range. But we stress, lifetime exposure should be assumed, as indicated in the ANPR, because lifetime exposure is permitted by the standard.

Radiation Risk Needs to be Based on Cancer Incidence

The ANPR concedes that EPA generally measures risk for chemical carcinogens in terms of morbidity (cancer incidence) instead of mortality (deaths) but says that ORIA occasionally uses mortality and asks which measure of risk should be applied to any revision of 40 CFR 190. This is one more arena in which radioactivity should not be treated as a privileged carcinogen. Radiation risk should be measured in the same terms as all other carcinogens—based on cancer incidence. Counting only those deaths from cancer would inappropriately ignore the roughly equal number of cancers that cause great impact on people from the treatments, whether surgery, radiation and/or chemotherapy, but from which they survive. Doing so would also inappropriately allow a doubling of permissible exposure, because there are roughly as many non-fatal cancers as fatal ones.[9] This would be an unacceptable outcome. (We note that CERCLA uses incidence for both chemicals and radioactivity.)

All Water Must be Protected to the Maximum Concentration Limits for Water

As to protection of surface water and groundwater, EPA has long pushed for protective standards for water — EPA's Maximum Contaminant Limits (MCLs) — to be included in other agencies' radiation standards. Efforts to relax MCLs have been resisted by EPA as violating no-backsliding requirements. We therefore urge that 40 CFR 190 include a requirement that releases at the point of entry of radioactivity into surface waters and groundwater be prohibited at levels above the MCLs. Because of the importance of protecting water sources, this should include all waters, not just those currently used as drinking sources.

40 CFR 190 Must Be Rigorously Enforced

Lastly, we note that 40 CFR 190 is virtually never enforced. Although legally it is supposed to apply to the entire nuclear fuel cycle, in practice NRC ignores it and requires its nuclear licensees to meet the far less protective standards in 10 CFR 20, far, far outside the risk range, levels EPA has long opposed. NRC allows public exposure to radionuclide concentrations that produce whole body doses four times those allowed by 40 CFR 190 and many times higher than that for most internal emitters. NRC does have a brief reference in 10 CFR 20.1301(d) that in passing says that in addition to meeting the specified NRC regulations (based on 100 millirem per year EDE), those licensees "subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190 shall comply with those standards." Yet, while NRC provides a detailed table in 10 CFR 20 Appendix B of concentrations to meet NRC's far weaker regulations, no such requirements are specified to meet the more protective 40 CFR 190 requirements, and the NRC rarely if ever inspects against and enforces the EPA's more protective standards. EPA itself has not issued concentration limits for complying with 40 CFR 190. For all practical purposes, 40 CFR 190 is simply ignored.[10] (We note that whether

[9] EPA Blue Book, *op. cit.,* pp. iv, 2

[10] The ANPR asserts that Appendix I of 10 CFR 50 is generally consistent with 40 CFR 190. But 10 CFR 50 Appendix I represents merely design objectives while a reactor is being designed; it does not constitute enforceable limits for operation and NRC does not enforce those objectives once a plant is operating.

regulations are based on dose or risk, they all generally end up coming down to permissible concentrations of radionuclides to which one may be exposed to meet those limits.)

Based on EPA's Own Official Risk Figures, Concentrations, Risks, or Doses Must Be Limited to No More than that Associated with 10^{-6} to 10^{-4} Risk, or 0.01 to 1 Millirem Per Year

EPA's official age- and gender-averaged risk estimate is 1.16×10^{-3} cancers per person-rem; for females it is 1.35×10^{-3}. Given EPA's own official figures, then, lifetime exposure to 0.01 millirem per year yields a 10^{-6} risk, and 1 millirem per year yields a 10^{-4} risk.[11] The National Academy of Sciences BEIR report, performed at EPA's request and on which EPA relies, yields similar estimates.[12] To repeat, EPA's own official radiation cancer risk figures indicate that one must keep exposures to between 0.01 millirem per year and 1 millirem per year to be within EPA's longstanding acceptable risk range. Choosing instead to allow 25 or even 15 mrem EDE, for example, would be far, far outside EPA's acceptable risk range.

Recommendations and Conclusion

We recommend stop treating radiation as a "privileged pollutant." In particular, as is done for all other carcinogens:

- regulate radiation by risk, not dose; and
- require exposures to be limited so as to aim for a one in a million lifetime risk, but to not exceed in any case one in ten thousand with age and gender taken into account.

If EPA continues to refuse to regulate radiation as it does all other contaminants by risk and insists on keeping dose rather than use risk we urge that

- organ limits must be retained, as they are the primary protection in the 40 CFR 190 rule, and removing them would markedly weaken public protections; and
- the whole body dose limit and the thyroid and other organ limits must be tightened to bring them to and preferably well below the 10^{-4} upper end of EPA's acceptable risk range, reflecting EPA's significantly increased official risk figures since the rule was originally promulgated.

If EPA nonetheless refuses to both regulate by risk instead of dose and is intent, to eliminate organ dose limits entirely and use instead "effective dose equivalent" (EDE),

[11] 0.001 rem/year x 70 years x 1.35×10^{-3} cancers/person-rem (EPA Blue Book cancer risk figure for females)=9.45×10^{-5} (approximately 1×10^{-4}) risk. Gender-averaged EPA Blue Book risk figure is 1.16×10^{-3}, resulting in 1.3 millirem per year (0.0013 rem/year) producing a 1.06×10^{-4} risk. In round numbers, 1 millirem per year is a 10^{-4} lifetime risk; 0.01 millirem/year is a 10^{-6} risk.

[12] BEIR VII shows that lifetime exposure to 1 mGy/year (for these purposes, equivalent to 100 millirem/year) produces approximately a 10^{-2} risk; 1 millirem/year yields a 10^{-4} risk. See page 281.

- permissible EDE must be set so as to not exceed 1 millirem per year EDE, which produces a 1 x 10^{-4} risk of cancer according to EPA's own official risk estimates.

- The regulations should be set at between 0.01 millirem and 1 millirem per year, equivalent to 10^{-6} to 10^{-4} risk.

- One should aim for the lower risk, but in no case allow doses above 1 millirem per year. Anything higher than that would be outside EPA's own acceptable risk range, using EPA's own official risk figures for radiation.

Surface water and groundwater should be protected so that

- radionuclide concentrations above the Maximum Contaminant Limits are not allowed at the point of entry into those waters; and

- this should occur irrespective of whether they are now used for drinking purposes. Protection of water supplies over time is critical.

Finally:

- The regulations need to be strongly enforced. Right now they are essentially ignored.

Protection of the public and the environment from unnecessary radiation exposure is essential. EPA has rightly said radiation should not be treated as a privileged pollutant, allowed to expose the public to hazards greater than allowed for any other pollutant. It is time that EPA itself stop treating radiation as a privileged pollutant.

cc: Senator Barbara Boxer, EPW Chair
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Sincerely,[13]

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