



STATE OF NEW YORK  
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN  
ATTORNEY GENERAL

DIVISION OF SOCIAL JUSTICE  
ENVIRONMENTAL PROTECTION BUREAU

November 21, 2016

**By Overnight & Electronic Mail**

Howard Shelanski, Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17<sup>th</sup> Street NW  
Washington, D.C. 20503  
OIRA\_submission@omb.eop.gov

Re: RIN 2060-ZA19; EPA Protective Action Guidance for Radiological Incidents

Dear Administrator Shelanski:

On October 21 of this year, the United States Environmental Protection Agency (EPA) submitted the above-referenced draft guidance to the Office of Management and Budget for Office of Information and Regulatory Affairs (OIRA) review. The guidance, entitled “Draft Protective Action Guide (PAG) for Drinking Water,” purports to establish acceptable levels of radiation in public drinking water supplies in the wake of a radiological incident. However, the draft guidance advances a much less protective standard for drinking water interdiction than is set forth in existing EPA guidance and in EPA regulations promulgated under the Safe Drinking Water Act. Because it would substantially, indefinitely, and unjustifiably increase New Yorkers’ exposure to radioactive contamination in drinking water in the aftermath of a potential radiological incident, the State of New York Office of the Attorney General strongly urges that OIRA either disapprove the draft guidance now under review or, in the alternative, return the guidance to the EPA for further consideration.<sup>1</sup>

---

<sup>1</sup> The Office of the Attorney General expressed its concerns regarding the draft guidance to the EPA by letter dated July 25, 2016. See Letter from State of New York Office of the Attorney General to Joel Beauvais, Deputy Assistant Administrator for the Office of Water, EPA (July 25, 2016) (incorporated herein by reference). The EPA has not responded to these concerns.

By statute, the EPA must advise the President on radiation matters and must formulate radiation standards. See 42 U.S.C. § 2021 (h). The Federal Emergency Management Agency has promulgated regulations directing the EPA to develop protective action guides – PAGs – “for all aspects of radiological emergency planning” and to “[p]repare guidance for State and local governments on implementing PAGs, including recommendations on protective actions which can be taken to mitigate . . . potential radiation dose[s] to the population.” 44 C.F.R. § 351.22 (a), (b) (1982). In 1992, EPA issued a PAG manual to “assist [public] officials in establishing emergency response plans and in making decisions during a nuclear incident.” 1992 EPA Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, at iii (hereinafter “1992 manual”). The 1992 manual noted that the EPA was “work[ing] to develop PAGs for drinking water.” Id. Some 20 years later, in its 2013 update of the 1992 manual, the EPA declined to propose a “specific drinking water PAG”; instead, the agency indicated that response planners should, “to the extent practicable,” base drinking water-related protective action decisions on the radiological contamination standards promulgated by the EPA under the authority of the Safe Drinking Water Act. 2013 EPA Protective Action Guides and Planning Guidance for Radiological Incidents, at 42 (hereinafter “2013 manual”). As relevant here, under the Safe Drinking Water Act, the EPA previously established a maximum contaminant level (MCL) of 4 millirem “annual dose equivalent to the total body or any internal organ” for beta- and photon-emitting radionuclides. See 40 C.F.R. § 141.66 (d).

In a significant departure from the position taken in the 2013 manual, the EPA now proposes to “protect the public” in the event of a radiological incident by abandoning its Safe Drinking Water Act-derived standard in favor of a substantially higher, less protective threshold for drinking water interdiction. 2016 EPA Draft Protective Action Guide (PAG) for Drinking Water, at 4 (hereinafter “2016 draft manual”). In the 2016 draft manual, the EPA “propos[es] a two-tiered drinking water PAG” to be “used during the intermediate phase following a radiation incident.” Id. According to the manual, drinking water interdiction would occur only when radiological contamination levels exceed 500 millirem per year “committed effective dose” for the general population or 100 millirem per year “committed effective dose” for pregnant or nursing women and children aged 15 or younger. Id. at 4-5. These protective action thresholds are orders of magnitude less protective of public health than either the Safe Drinking Water Act-derived MCLs for radionuclides or the drinking water remediation standards applicable to radioactive contamination at Superfund sites. See 40 C.F.R. § 300.430 (e). Further, because they are intended for use during the “intermediate phase” of radiological incident response – that is, during the period after the acute release has been controlled but before large-scale remediation has begun – the draft PAGs effectively create a variance of indeterminate duration from Safe Drinking Water Act standards. In other words, application of the draft PAGs could allow federal and local emergency officials to permit citizens to be exposed to levels of radiation far above Safe Drinking Water Act limits for “many months” or even “years” following an accident. 1992 manual, at 1-3; see also 2016 draft manual, at 4.

As a procedural matter, OIRA should reevaluate its apparent determination that the EPA’s 2016 draft guidance is not a “significant regulatory action” within the meaning of Executive Order 12,866. This executive order defines the term “significant regulatory action” to include “any regulatory action that is likely to result in a rule that may,” *inter alia*, “adversely affect . . . the environment, public health[,] or [public] safety.” Exec. Order 12,866, 58 Fed. Reg.

51,735, 51,738 (Oct. 4, 1993). Though the EPA styles the 2016 draft manual a nonbinding document, the agency clearly intends and expects that federal, state, and local emergency planners will incorporate the draft PAGs into their planning protocols for use in the event of a radiological emergency.<sup>2</sup> Further, since application of the draft drinking water PAGs would allow a significant increase in radiation contamination in both public and private drinking water supplies, it seems evident that the EPA's regulatory action could have significant adverse effects on the economy, agriculture, homeland security, health care, and public health and safety. For these reasons, OIRA should treat the EPA's 2016 draft manual as a significant regulatory action within the meaning of Executive Order 12,866 and should subject it to a level of review commensurate with that status. As a part of this review, OIRA should determine, among other things, whether the EPA has presented a transparent scientific justification for its assertion that its proposed drinking water PAGs come within the cancer risk range reflected in the Safe Drinking Water Act MCLs. See 81 Fed. Reg. 37,589, 37,591 (June 10, 2016).

Substantively, while the 2016 draft manual represents that the EPA set the proposed PAG thresholds with an eye toward "reducing risks associated with ingesting [radioactive] drinking water," the scientific ground for this statement is not clear on the face of the document. See 2016 draft manual, at 7. Indeed, certain studies apparently informing the EPA's analysis are not available publicly. See id. at 7 n 12, 9 n 19.<sup>3</sup> To the extent the EPA relies on non-public scientific data to reach its conclusions, it hampers the public's ability to participate intelligently in these administrative proceedings. The EPA's approach also lacks the level of transparency mandated both by order of the President and by the agency's own internal policy on scientific integrity in the decision-making process. See Memorandum on Scientific Integrity, 74 Fed. Reg. 10,671 (March 11, 2009); EPA Scientific Integrity Policy (2012), [http://www.epa.gov/sites/production/files/2014-02/documents/scientific\\_integrity\\_policy\\_2012.pdf](http://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf).

More troubling is the EPA's apparent abandonment of the organ dose-based radiation exposure measurement used in the Safe Drinking Water Act MCLs in favor of a measure of exposure expressed as "committed effective dose." 2016 draft manual at 5 n 3. The 2016 draft manual makes no attempt to explain the rationale for this critical change in the EPA's approach to radiation dose measurement. As a result of this methodological shift, however, the 2016 draft manual has the effect of substantially understating the increase in radionuclide concentrations allowable under the proposed PAGs over Safe Drinking Water Act levels. As discussed in the Office of the Attorney General's July 2016 comment letter to the EPA, the 2016 draft manual would allow, for example, a 3,450-fold increase in the maximum allowable concentration of iodine-131. Notably, the EPA has in the past rejected reliance on effective dose, recognizing that a shift from organ dose to effective dose understates cancer risk. See EPA Notice of Data Availability, 65 Fed. Reg. 21,576, 21,581-21,583 (April 21, 2000). Inexplicably, the EPA seems

---

<sup>2</sup> To wit, the EPA indicated in its Notice of Availability that its ultimate intention is to issue the 2016 draft manual in final form "for incorporation into state, local, tribal, and federal emergency response plans over a one-year implementation timeframe." 81 Fed. Reg. 37,589, 37,591 (June 10, 2016).

<sup>3</sup> While a short excerpt from the National Council on Radiation Protection and Measurements' Report No. 174 is present in the administrative docket, the full report – over 350 pages in length – is not publicly available without charge.

to have adopted PAGs that could expose the public to levels of cancer risk far in excess of what the agency itself considers the maximum acceptable risk threshold.

Also of note, the 2016 draft manual identifies “derived response levels” – concentrations for each radionuclide that will lead to a PAG exceedance – for only *three* of the 100 radionuclides the agency anticipates may be present in public drinking water systems in the wake of a radiological incident. Neither the State of New York nor members of the general public can plausibly evaluate the protectiveness of the EPA’s proposed PAGs without this additional data. Given the information available, however, it seems the EPA has proposed drinking water PAGs that would, when followed, expose the public to unprecedented and unacceptably high levels of radiation. If this is so, then the EPA must explain why it believes this new, divergent approach is justifiable both scientifically and as a matter of sound public policy.

The President has stressed that “[o]ur regulatory system must protect public health, welfare, safety, and our environment” and “allow for public participation and an open exchange of ideas.” Exec. Order No. 13563, 76 Fed. Reg. 3,821 (Jan. 21, 2011). To the extent the EPA’s proposed PAGs for drinking water would authorize public exposure to a much greater amount of ionizing radiation that would be legally permissible under the Safe Drinking Water Act, and to the extent the scientific bases for the proposed PAGs are either unavailable or simply unclear to members of the public and other interested governmental entities, the 2016 draft manual fails to satisfy the President’s threshold standards for benevolent regulatory activity. Accordingly, this Office respectfully requests that OIRA either disapprove the EPA’s 2016 draft manual or, in the alternative, return it to the EPA for further review.

Respectfully submitted,

*s/Joshua M. Tallent s/John J. Sipos*

Joshua M. Tallent  
John J. Sipos  
Assistant Attorneys General  
Office of the Attorney General  
of the State of New York  
The Capitol  
Albany, NY 12224-0341  
[e] joshua.tallent@ag.ny.gov  
[t] (518) 776-2456  
[e] john.sipos@ag.ny.gov  
[t] (518) 776-2380

copy to: James Laity, OMB/OIRA  
Margo Schwab, OMB/OIRA  
Vlad Dorjets, OMB/OIRA  
Joel Beauvais, EPA/OW