



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2007-0268; FRL-9947-55-OW]

Notice of Availability: Draft Protective Action Guide (PAG) for Drinking Water after a Radiological Incident

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Document Availability; Request for Public Comment.

SUMMARY: As part of its mission to protect human health and the environment, the Environmental Protection Agency (EPA) publishes protective action guides to help federal, state, local and tribal emergency response officials make radiation protection decisions during emergencies. EPA, in coordination with a multi-agency working group within the Federal Radiological Preparedness Coordinating Committee, is proposing an addition to the 2013 revised interim Protective Action Guides and Planning Guidance for Radiological Incidents (“2013 revised PAG Manual” hereafter) to provide guidance on drinking water. The Draft Protective Action Guide for Drinking Water is now available in the EPA Docket, under ID No. **EPA-HQ-OAR-2007-0268**, and EPA is requesting comment on the draft guide.

DATES: Comments must be received on or before [insert date], 45 days after date of publication in the Federal Register.

ADDRESSES: Submit your comments, identified by Docket ID No. **EPA-HQ-OAR-2007-0268**, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or

other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Lisa M. Christ, Standards and Risk Management Division, Office of Ground Water and Drinking Water , Mail Code 4607M, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: (202) 564-8354; fax number: (202) 564-3758; E-mail: christ.lisa@epa.gov.

SUPPLEMENTARY INFORMATION:

1. General Information

A. Does this Action Apply to me?

This action does not impose any requirements on anyone. It notifies interested parties of EPA's proposed, draft drinking water protective action guide (PAG) and requests public comment. The drinking water PAG will help federal, state, local, tribal officials and public water systems make decisions about use of water during radiological emergencies. The drinking water PAG is non-regulatory guidance.

B. What authority does EPA have to provide Protective Action Guidance?

The historical and legal basis of EPA's role in the 2013 PAG Manual begins with Reorganization Plan No. 3 of 1970, in which the Administrator of the EPA assumed all the

functions of the Federal Radiation Council (FRC), including the charge to "...advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with [s]tates." (Reorg. Plan No. 3 of 1970, sec. 2(a) (7), 6(a) (2); § 274.h of the Atomic Energy Act of 1954, as amended (AEA), codified at 42 U.S.C. § 2021(h)). Recognizing this role, the Federal Emergency Management Agency (FEMA) directed EPA, in its Radiological Emergency Planning and Preparedness Regulations, to "establish Protective Action Guides (PAGs) for all aspects of radiological emergency planning in coordination with appropriate federal agencies." (44 CFR 351.22(a)). FEMA also tasked EPA with preparing "guidance for state and local governments on implementing PAGs, including recommendations on protective actions which can be taken to mitigate the potential radiation dose to the population." (44 CFR 351.22(b)). All of this information was to "be presented in the Environmental Protection Agency (EPA) 'Manual of Protective Action Guides and Protective Actions for Nuclear Incidents.'" (44 CFR 351.22(b)).

Additionally, section 2021(h) charged the Administrator with performing "such other functions as the President may assign to him [or her] by Executive Order." Executive Order 12656 states that the Administrator shall "[d]evelop, for national security emergencies, guidance on acceptable emergency levels of nuclear radiation...." (Executive Order No. 12656, sec. 1601(2)). EPA's role in PAGs development was reaffirmed by the National Response Framework, Nuclear/Radiological Incident Annex of June 2008.

C. What is the PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents?

In 2013, EPA revised the PAG Manual to provide federal, state and local emergency management officials with guidance for responding to radiological emergencies (78 FR 22257, April 15, 2013). See the 2013 PAG Manual at <https://www.epa.gov/radiation/protective-action-guides-pags>. A protective action guide (PAG) is the projected dose to an individual from a release of radioactive material at which a specific protective action to reduce or avoid that dose is recommended. Emergency management officials use PAGs for making decisions regarding actions to protect the public from exposure to radiation during an emergency. Such actions include evacuation, shelter-in-place, temporary relocation, water and food restrictions.

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.

The PAG Manual is not a legally binding regulation or standard and does not supersede any environmental laws; PAGs are not intended to define “safe” or “unsafe” levels of exposure or contamination. As indicated by the use of non-mandatory language such as “may,” “should” and “can,” the Manual only provides recommendations and does not confer any legal rights or impose any legally binding requirements upon any member of the public, states or any federal agency. Rather, the PAG Manual provides projected radiation dose levels at which specific actions are recommended in order to reduce or avoid that dose. The 2013 revised interim PAG Manual is designed to provide flexibility to be more or less restrictive as deemed appropriate by decision makers based on the unique characteristics of the incident and the local situation.

D. What additional guidance is being proposed for the PAG Manual?

The draft drinking water protective action guidance was developed by a multi-agency PAG Subcommittee of the Federal Radiological Preparedness Coordinating Committee and is published by the EPA with concurrence from the Department of Energy, the Department of Defense, the Department of Homeland Security (DHS), including the Federal Emergency Management Agency, the Nuclear Regulatory Commission, the Department of Health and Human Services, including both the Centers for Disease Control and Prevention and the Food and Drug Administration (FDA), the U.S. Department of Agriculture and the Department of Labor.

A large scale radiation contamination incident could impact the United States, driving the need for a pre-established drinking water PAG. EPA is proposing a two-tiered intermediate phase drinking water PAG of 100 mrem projected dose in the first year for infants, children and pregnant or nursing women and 500 mrem 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 PAG for ingestion of food) and provides an additional level of protection for the most sensitive life stages. Authorities have flexibility on how to apply the PAG. In some cases they may find it prudent to use a single PAG (e.g., 100 mrem) as a target for the whole population, while in other circumstances, authorities may find that it makes sense to use both targets simultaneously. For example, emergency managers can use a two-tiered approach to focus on protecting the most sensitive population with limited, alternate water resources. Because the water and food PAGs are designed to be used in concert, the appropriate protective actions will be influenced by the exposure scenario and factors that influence the

viability of alternative approaches to reducing that dose.

This proposed, additional draft guidance recommends protective actions when drinking water may be impacted by a radiological or nuclear incident. 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. EPA has included examples of estimated costs for selected drinking water protective actions in the Docket, ID No. **EPA-HQ-OAR-2007-0268**. In developing the drinking water PAG, the Agency considered potential cumulative exposure from a radiation incident. Ultimately, a PAG does not represent an “acceptable” routine exposure; a PAG is a dose at which protective action is advised in order to reduce or avoid that dose. 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. Emergency management officials should consider all exposure routes when making protective action decisions in an emergency.

Under the Safe Drinking Water Act (SDWA), the Agency has established maximum contaminant levels (MCLs) for radiological contaminants in drinking water. The National Primary Drinking Water Regulations (NPDWR) for radionuclides are based on lifetime exposure criteria and assume 70 years of continued exposure to contaminants in drinking water. While the SDWA framework is appropriate for day-to-day normal operations, it may not provide the necessary tools to assist emergency responders with determining the need for an immediate protective action. EPA expects that any drinking water system adversely impacted during a radiation contamination incident will take action to return to compliance with MCLs as soon as practicable.

E. How were comments received on the 2013 draft PAG Manual considered in developing this proposal?

On April 15, 2013, EPA published a Federal Register notice requesting public comments on the appropriateness of developing and incorporating a drinking water PAG in the revised PAG Manual (78 FR 22257).

Regarding the specific issue of drinking water, the Agency received about 50 comment letters from members of the public, state and local emergency response and health organizations, environmental advocates, industry associations, organizations opposed to nuclear power, and from national and international radiation protection organizations.

Several commenters from state emergency management agencies and radiation control programs expressed an urgent need for EPA to establish a drinking water PAG, pointing out that drinking water is the only media not currently addressed in the PAG Manual. Commenters stated that a drinking water PAG is a critical aspect of a coordinated emergency response after a radiation contamination incident.

Commenters representing states agencies from Ohio, Kansas, Pennsylvania, Illinois and Washington suggested that a drinking water PAG should be established at the 500 mrem level, to be consistent with the FDA food PAG and with the DHS guidance¹ 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 for sensitive life-stages including pregnant women, nursing women and children 15 years old and

¹ Guidance established by the Department of Homeland Security as an intermediate-level PAG for drinking water interdiction (73 FR 45029, April 1, 2008).

under. 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. Today's proposal ensures that protective measures are appropriate for all members of the public, including sensitive subpopulations.

In contrast, several commenters from environmental protection advocate organizations suggested that a drinking water PAG is not needed, and urged EPA to base any emergency response measures regarding drinking water solely on the NPDWR for Radionuclides MCLs. Some commenters expressed concerns that establishing a drinking water PAG would weaken existing environmental standards and regulations. However, the drinking water standards are legal limits designed to prevent health effects from everyday exposure to low levels of radiation over long periods and they are not changing with this proposal.

Estimated risk of excess cancer cases for lifetime exposure (70 years) to radioactive contaminants in drinking water at 4 mrem/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. Emergency guides are temporary measures to minimize risk while enabling prioritization of limited resources during an emergency response.

The PAG levels are guidance for emergency situations; they do not supplant any standards or regulations, nor do they affect the stringency or enforcement of any standards or regulations. The PAG levels are intended to be used only in an emergency when radiation levels have already

exceeded environmental standards. EPA expects that any drinking water system adversely impacted during a radiation incident will take action to return to compliance with Safe Drinking Water Act levels as soon as practicable.

F. When will the PAG Manual be finalized?

Once comments on this proposed, additional draft action have been addressed, EPA will add drinking water guidance to the full PAG Manual, which will then be issued in final form for incorporation into state, local, tribal and federal emergency response plans over a one-year implementation timeframe.

G. What Should I Consider as I Prepare My Comments for EPA?

When submitting comments, remember to:

- Identify the rulemaking by docket number, subject heading, Federal Register date and page number.
- Follow directions—the EPA may ask you to respond to specific questions or organize comments by referencing the chapter number of the draft action guide
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide technical information and data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow it to be reproduced.
- Illustrate your concerns with specific examples and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

H. What Specific Comments are Being Sought?

While all comments regarding any aspect of the draft drinking water PAG guidance will be considered, please comment on the following issues specifically:

- Please comment on the appropriateness of the drinking water PAG and the guidance for advance planning.
- Please comment on what implementation challenges might be associated with the two-tiered approach to the water PAG that EPA should consider, and suggest additional guidance that would be helpful.
- Please comment on whether (and if so why) EPA should reconsider using a single-tier drinking water PAG rather than tiered approach proposed in the draft action guide.
- Please suggest additional guidance that would aid pre-incident planning and implementation specific to your community's drinking water systems.
- Please comment on how this guidance should be implemented in emergency response and recovery plans at all levels of government, including considerations for public communications during an emergency.

In the future, calculations and derived response levels will be provided in the Federal Radiological Monitoring and Assessment Center (FRMAC) Assessment Manuals. Emergency planners are referred to FRMAC Monitoring and Sampling Methods to assess surface and drinking water impacts from a radiological emergency. See the Assessment and Monitoring &

Sampling folders at

<http://www.nv.doe.gov/nationalsecurity/homelandsecurity/frmac/manuals.aspx>. After considering public comments, EPA intends to issue a final PAG Manual, which will supersede the 1992 PAG Manual and the 2013 revised PAG Manual.

Dated: June 3, 2016.

Joel Beauvais,

Deputy Assistant Administrator, Office of Water.

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