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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OAR-2007-0268; FRL -]

Revision to the PAG Manual: Protective Action Guide (PAG) for Drinking Water after a Radiological Incident

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: As part of its mission to protect human health and the environment, the U.S. Environmental Protection Agency publishes protective action guides (PAGs) 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, recently updated its guidance manual on this topic, titled "Protective Action Guides and Planning Guidance for Radiological Incidents" (referred to herein as the PAG Manual). On December 8, 2016, EPA announced availability of the updated 2016 PAG Manual in the Federal Register. In this notice, EPA is announcing that it has amended Chapter 4 of the 2016 PAG Manual to incorporate guidance for radiation protection decisions concerning drinking water. The drinking water PAG is not binding and does not in any way affect regulatory requirements or enforcement of the Safe Drinking Water Act (SDWA), including maximum contaminant limits (MCLs) for radionuclides established by regulation under the SDWA. The drinking water PAG is guidance only and is intended for use by federal, state and local emergency management officials in the unlikely event of significant radiological contamination incidents, such as a disaster at a nuclear power plant, a radiological dispersal

device or an improvised nuclear device, and for a duration which may last for weeks to months but not longer than one year. The dose levels reflected in the drinking water PAG provide a level of protection against cancer risks for a short-term (weeks to months but not longer than a year), similar to that provided by EPA's MCLs for radionuclides (which are calculated based on 70 years of exposure).

DATES: The revised drinking water PAG is available for use upon publication of this notice in the Federal Register, at www.regulations.gov, under ID No. EPA-HQ-OAR-2007-0268.

FOR FURTHER INFORMATION CONTACT: Samuel Hernandez, 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) 564-1735; email: hernandez.samuel@epa.gov.

SUPPLEMENTARY INFORMATION:

A. How can I get copies of the PAG Manual and supporting information?

Docket: EPA has established a docket for this action under Docket ID No. EPA-HQ-OAR-2007-0268. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the Air and Radiation Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20004. The Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Docket's Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket is (202) 566-1742. In accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged for photocopying.

Electronic access: The PAG Manual in electronic form suitable for printing, as well as

related guidelines and further information, can be found on the PAGs' website at http://www.epa.gov/radiation/protective-action-guides-pags.

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

The historical and legal basis of EPA's role in the PAG Manual begins with the 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 recognized 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?

The PAG Manual provides federal, state and local emergency management officials with guidance for responding to radiological emergencies. A protective action guide 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, but are not limited to, evacuation, shelter-in-place, temporary relocation and food restrictions.

Development of the PAGs was 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. This guidance does not address or impact site cleanups occurring under other statutory authorities such as the EPA's Superfund program, the Nuclear Regulatory Commission's (NRC) decommissioning program, or other federal or state cleanup programs. As indicated by the use of non-mandatory language such as "may," "should" and "can," the PAG 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 other federal agency. Rather, the PAG Manual recommends projected radiation doses at which specific actions may be warranted in order to reduce or avoid that dose. The 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. How did EPA respond to public comments on the proposed Draft Protective Action Guide for Drinking Water?

PAGs do not represent "acceptable" routine exposure in the way that regulatory standards such as maximum contaminant levels do. PAGs are guidance levels to support emergency decision making by response authorities to avoid unnecessary radiation exposure. Development and implementation of PAGs is always guided by three basic 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.

On June 10, 2016, EPA published a Federal Register notice requesting public comments on the proposed drinking water PAG and the guidance for advance planning (81 FR 37589). EPA sought specific comments and feedback on the appropriateness of the drinking water PAG and possible implementation challenges associated with the two-tiered approach. In addition, EPA asked whether a single-tier drinking water PAG should be considered rather than using the tiered approach.

In response, EPA received over 60,000 comment letters from members of the public, state and local emergency response and health organizations, environmental advocates, industry associations and other stakeholders. Most of the comment letters expressed concerns with the proposed guidance. Commenters wrote that the proposed guidance could weaken the regulatory

requirements of the Safe Drinking Water Act. In addition, environmental advocacy organizations indicated that the drinking water PAG dose levels were too high and insufficient to be protective of human health, and asked EPA to withdraw the proposed guidance and, in its place, use the National Primary Drinking Water Regulations for Radionuclides as the basis for any emergency response measures regarding drinking water.

Commenters also asserted that the proposed drinking water PAG did not conform to the National Environmental Policy Act (NEPA) as well as other regulations dealing with cleanup and waste management of radioactive contaminants. Commenters expressed doubts regarding the duration that the drinking water PAG would be implemented after an incident, claiming that the drinking water PAG could be in place for timeframes exceeding one year.

In response to comments, EPA has amended the drinking water guidance to emphasize, with regards to the scope of the drinking water PAG recommendations, that they are only intended to apply to nationally significant radiological contamination incidents, such as a disaster at a nuclear power plant, a radiological dispersal device or an improvised nuclear device, and for a duration that may last for weeks to months but not longer than one year.

Some commenters expressed concerns that PAGs would weaken drinking water standards and regulations. Environmental regulations or standards are legal limits designed to minimize health effects from everyday exposure to low levels of radiation over long periods. 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. The PAG levels trigger public safety measures to minimize radiation exposures during an emergency.

To develop guidance on drinking water considerations, EPA based its assessment on assumptions limiting exposures to a one-year timeframe. EPA expects that the responsible party for 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.

The National Primary Drinking Water Regulations establish regulatory limits designed to minimize health effects from everyday exposure to low levels of radiation over long periods; those limits are not changing with this action. Emergency guides are temporary measures to minimize risk while enabling distribution of limited resources during an emergency response.

Estimated risk of excess cancer cases for lifetime exposure (70 years) to beta emitting radioactive contaminants in drinking water at 4 mrem/yr (the MCL) generally falls in a range of risks deemed acceptable by EPA. Estimated risks associated for a shorter (one-year) exposure to radioactivity in drinking water at the proposed PAG levels fall within a similar risk range.

The drinking water PAG meets NEPA policy goals because it is based on analyses, documentation and review procedures that are functionally equivalent to NEPA. "Activities for the development of federal radiation regulations and guidance in accordance with the Atomic Energy Act of 1954 are functionally equivalent to NEPA" (63 Fed. Reg. 58045, October 29, 1998).

Commenters questioned whether the EPA considered cumulative effects in developing the drinking water PAG. In developing the PAG Manual, EPA considered the potential for cumulative exposure from multiple exposure pathways including: plume inhalation, immersion, ground shine, drinking water ingestions and food, among others. However, EPA has determined that for implementation purposes, it is impractical to compartmentalize joint protective actions, since allocations of dose to different segments of the population based on individual exposure

routes will depend on site-specific circumstances and are impossible to quantify. While the PAGs for the various pathways are separate, emergency management officials should consider all relevant exposure routes when making protective action decisions in an emergency. In addition, incident-specific factors like geographical location, ongoing weather, the isotopes released and population affected should be considered after a contamination event, and specific exposure routes should be identified to allow different types of protective actions to be aimed at the specific risks to be avoided.

Several commenters from state emergency management agencies and radiation control programs expressed support for EPA's proposal, stating that the guidance was well developed and technically sound; and that the incorporation of the drinking water PAG into the PAG Manual is a critical aspect of a coordinated emergency response after a radiation contamination incident.

Some commenters suggested that while they support the incorporation of the drinking water PAG, they believe the proposed PAG was too conservative and that EPA should consider establishing the PAG in the 2,000 to 10,000 mrem range.

EPA believes that the drinking water PAG should be consistent with and within the range of currently available guidance for other exposure pathways during the intermediate phase. Also, when possible, the drinking water PAG recommendations should be based on an additional level of protection to sensitive life-stages. For short-term incidents, as explained in the PAG Manual, it is appropriate to have a 500 mrem PAG level for drinking water for the general population and a lower-tier PAG level of 100 mrem for persons at sensitive life-stages, including pregnant women, nursing women, and children 15 years old and 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 abundance of caution built into the derivation of the drinking water PAG through a variety of assumptions, including conservative dose-response modeling; selection of the most sensitive life stages to derive the PAG for children through age 15 years; and, the assumption of no decay of isotopes over the calculated one-year exposure period, which may be appropriate in some situations. This action ensures that the protective measures it recommends are appropriate for all members of the public, including sensitive subpopulations.

E. What is the timeframe for implementation of this PAG Manual?

Emergency management and radiation protection organizations that use the PAGs in their emergency plans are encouraged to incorporate this updated guidance as soon as possible. This may entail training, as well as the update of plans and procedures. Outreach and technical training will be conducted by EPA, the Federal Radiological Monitoring and Assessment Center and interagency partners of the PAG Subcommittee. FEMA expects certain organizations associated with nuclear power plant operations to use the PAG Manual in developing their emergency management plans. FEMA plans to begin using the new PAG Manual during their evaluation of offsite response organizations around nuclear power facilities 12 months after the publication of this notice in the Federal Register.

For further information and related guidelines, see the EPA website: http://www.epa.gov/radiation/protective-action-guides-pags. Keywords include: drinking water, radiation, radiological incident, emergency and protective action guide.

Dated: January 10, 2017.

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