

POLICY ISSUE INFORMATION

June 9, 2011

SECY-11-0078

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: U. S. ENVIRONMENTAL PROTECTION AGENCY REVISIONS TO THE
PROTECTIVE ACTION GUIDANCE MANUAL

PURPOSE:

The purpose of this paper is to inform the Commission of the status of the ongoing revisions to the U.S. Environmental Protection Agency (EPA) Protective Action Guidance (PAG) Manual.

BACKGROUND:

Public officials, in discharging their responsibility to protect public health during a radiological emergency, may be faced with decisions that must be made quickly. Although a number of factors will influence their choice of protective actions, it is likely that not all of the information needed to make the optimum choice will be available immediately. In such situations, it is helpful to develop preplanned strategies to optimize the protection of public health and safety. It is within this context that EPA was charged to develop the PAG Manual and associated guidance.

The historical and legal basis of EPA's role starts with Reorganization Plan No. 3 of 1970, in which the EPA Administrator assumed all the functions of the Federal Radiation Council,

CONTACT: Patricia A. Milligan, NSIR/DPR
(301) 415-2223

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 States.”¹ Subsequently, the Federal Emergency Management Agency (FEMA) changed the radiological emergency planning and preparedness regulations in Title 44 of the *Code of Federal Regulations* (44 CFR) 351.22(a) to require that EPA “[e]stablish Protective Action Guides (PAGs) for all aspects of radiological emergency planning in coordination with appropriate Federal agencies.” FEMA also tasked EPA, in 44 CFR 351.22(b), 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” and presenting it in the PAG Manual.

Additionally, Section 274h of the AEA charges the EPA Administrator with performing “such other functions as the President may assign to him [or her] by Executive order.” Section 1601(2) of Executive Order 12656, “Assignment of Emergency Preparedness Responsibilities,” dated November 18, 1988, states that the Administrator shall “[d]evelop, for national security emergencies, guidance on acceptable emergency levels of nuclear radiation....” The *National Response Framework, Nuclear/Radiological Incident Annex*, issued June 2008, also recognized EPA’s role in the development of PAGs.

A series of recommendations issued in the 1960s introduced the concept of a PAG, which has since been developed over the years. A key concept² about PAGs is that the decision to implement protective actions should be based on the projected dose that would be received if the protective actions were not implemented. Developers of the EPA PAGs considered the following three principles in establishing exposure levels for the PAGs:³

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

These principles apply to the determination of any PAG. Principles 1 and 2 have been endorsed for use by the international community as essential bases for decisions to intervene during an incident and relied upon by EPA since the early 1990s:

PAGs should not be higher than justified on the basis of optimization of cost and the collective risk of effects on health. That is, any reduction of risk to public health achievable at acceptable cost should be carried out.⁴

¹ Reorganization Plan No. 3 of 1970, Section 2(a)(7) and 6(a)(2), 5 USC Appendix; Atomic Energy Act of 1954 as amended (AEA), 42 USC 2021(h).

² EPA, “Protective Action Guidance for Radiological Incidents, Draft for Interagency Review,” February 2011.

³ EPA, “Protective Action Guidance for Radiological Incidents, Draft for Interagency Review,” February 2011.

⁴ EPA 400-R-92-001, “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,” 1992.

The International Atomic Energy Agency (IAEA) has recognized principle 3 as an appropriate additional consideration.⁵

In 1975, EPA published the first edition of the “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents.” It established protective actions for whole body and thyroid exposure. The document recognized the need for, but did not establish, PAGs for exposure from radioactively contaminated food or water, and radioactive material deposited on property or equipment. It did, however, state that the lifting of controls for protective actions may be justified on the basis of cost savings when corresponding health risks have been adequately reduced.⁶ In 1980, EPA updated this manual to include methods for estimating population dose from plume exposure and to provide guidance for decisionmakers on comparing projected dose with PAGs. However, the protective action recommendations continued to apply only to emergency planning for nuclear power reactors. In 1992, EPA substantially revised the manual to include recommendations that featured lower dose values based on the adoption by the U.S. Government of the 1977 International Commission on Radiological Protection (ICRP) recommendations.⁷ It also broadened the range of radiological and nuclear incidents to include events at other than nuclear power plants (i.e., nuclear fuel cycle facilities, defense and research facilities, transportation accidents, radioisotope manufacturing facilities, and any other event except nuclear war).⁸ The agency developed this guidance cooperatively with the Federal Radiological Preparedness Coordination Committee (FRPCC), with representation from EPA, FEMA, the U.S. Department of Energy, the U.S. Department of Defense, the U.S. Nuclear Regulatory Commission (NRC), the U.S. Department of Health and Human Services, including the Centers for Disease Control and Prevention and the Food and Drug Administration, the U.S. Department of Agriculture, and the U.S. Department of Labor. However, the 1992 revision did not provide guidance for the late or recovery phase⁹ or drinking water PAGs.

DISCUSSION:

Almost immediately after the publication of the 1992 PAG Manual (EPA 400-R-92-001), a working group was formed to develop the late phase guidance and drinking water PAGs. The working group was staffed by interagency representatives and coordinated by the FRPCC. The revised document was finally published as a draft for public comment on the EPA Web site in early January 2009. This update provided drinking water PAGs and incorporated recovery guidance previously endorsed by the interagency working group as the U.S. Department of Homeland Security (DHS) PAGS for radiological dispersion devices (RDDs) and improvised nuclear devices (INDs). These PAGs provided the recovery strategy of “optimization,” meaning that all reasonable efforts would be made to reduce doses, considering a number of factors,

⁵ IAEA Safety Guide GS-G-2.1, “Arrangements for Preparedness for a Nuclear or Radiological Emergency,” 2007.

⁶ EPA-520/1-75-001, “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,” 1975, Section 1.6.3.9 A.

⁷ ICRP 26, “Recommendations of the International Commission on Radiological Protection,” 1977; and ICRP 30, “Limits for Intakes of Radionuclides by Workers,” 1979.

⁸ EPA 400-R-92-001, “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,” 1992, Section 1-1.

⁹ The late or recovery phase is the period beginning when cleanup and recovery actions designed to reduce radiation levels in the environment to acceptable levels are commenced and ending when all recovery actions have been completed.

including social and economic issues.¹⁰ Both ICRP¹¹ and IAEA¹² have endorsed the optimization strategy in recently published guidance.

In late January 2009, EPA withdrew the draft PAG Manual from its Web site for review by the incoming EPA Administrator. In January 2011, EPA distributed a significantly revised version to the interagency working group for review. This draft was revised entirely within EPA and deleted the consensus content on long-term recovery strategies as well as the water PAGs. Instead, it directs decisionmakers to the radiological standards associated with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Safe Drinking Water Act (SDWA). In response to EPA's request for comment on this draft, the NRC staff provided substantive comments. Some of the staffs' comments were incorporated; a great many were not. In particular, and of great importance, EPA did not address the NRC staff's underlying concern about the application of the CERCLA and SDWA standards following a nuclear power plant accident or a malevolent attack with an RDD or IND. Based on participation in several working group meetings conducted in January and February 2011, the staff has the following concerns relative to the anticipated request for NRC concurrence on the revised PAG guidance:

- EPA has backed away from its commitment, published in the *Federal Register* (73 FR 45030, August 1, 2008), to incorporate the DHS RDD/IND PAGs into the revised PAG Manual. Specifically, the RDD/IND PAGs adopted optimization decisionmaking for cleanup and recovery rather than a single value(s) such as the CERCLA risk range of 10E-4 to 10E-6 (which translates to a range of about 0.1 millirem to 15 millirem per year).
- EPA deleted its proposed chapter on drinking water PAGs in favor of deferring to the SDWA standard of 4 millirem per year. The proposed drinking water PAGs in the withdrawn guidance document were to be consistent with the Food and Drug Administration food PAG limit of 500 millirem per year.

In the recent 2011 working group meetings, the EPA staff has stated that it will not consider any comments on drinking water PAGs and that it considers this issue to be closed. The NRC staff has a number of concerns about the use of the SDWA standards, which were developed for normal operations, in an emergency and immediate post-emergency situation. The application of these standards could result in forcing communities to supply bottled water or relocate populations to avoid doses of 4 millirem per year. Adopting a 4-millirem per year standard for water PAGs introduces significant inconsistency with the PAG values for food (0.5 rem per year), shelter (1–5 rem), evacuation (1–5 rem), and relocation (doses in excess of 2 rem in the first year, not to exceed 500 millirem per year in any subsequent year or 5 rem over 50 years). Endorsing CERCLA goals for long-term recovery is inconsistent with the EPA PAGs for relocation in the intermediate phase, stated to be “applicable to the most critical or sensitive

¹⁰ ICRP Safety Reports Series No. 1, “Optimization of Radiation Protection in the Control of Occupational Exposure,” 2002.

¹¹ ICRP 103, “The 2007 Recommendations of the International Committee on Radiation Protection,” 2007; ICRP 109, “Application of the Commission’s Recommendations for Protection of People in Emergency Exposure Situations,” 2008; and ICRP 111, “Application of the Commission’s Recommendations for the Protection of People Living in Long-Term Contaminated Areas After An Accident or Radiological Emergency,” 2008.

¹² IAEA General Safety Guidelines 2, “Criteria for Use in Preparedness and Response for a Nuclear or Radiological Emergency,” 2011.

segment of the population”¹³ (2 rem for the first year, not to exceed 500 millirem per year in any subsequent year or 5 rem over 50 years), as well as with the guidelines in the 1992 PAG Manual, which states that “PAGs should not be higher than justified on the basis of optimization of cost and the collective risk of effects on health. That is, any reduction of risk to public health achievable at acceptable cost should be carried out.”¹⁴

The staff does not believe that adopting SDWA limits and CERCLA goals meets EPA’s own stated objectives to “balance protection with other important factors and ensure that actions result in more benefit than harm”; therefore, the staff intends to continue to support the inclusion of the DHS RDD/IND PAGs in the EPA PAG Manual.

The staff and other stakeholders have engaged EPA management regarding their plans for completion of the PAG Manual. However, the staff is not confident that the feedback and comments submitted to EPA will be in the draft intended to be submitted to the Office of Management and Budget (OMB). EPA intends to submit the draft manual to OMB within the next few weeks which will initiate a process for Federal departments and agencies, including NRC, to provide formal comments. After resolving the interagency comments, EPA plans to publish the draft manual in the *Federal Register* for public comment. In particular, EPA management expressed interest in receiving input from State and local government stakeholders. The staff will provide any updates through Commission Assistant Notes.

COORDINATION:

The Office of the General Counsel reviewed this package and has no legal objection.

/RA by Martin J. Virgilio for/

R. W. Borchardt
Executive Director
for Operations

¹³ EPA 400-R-92-001 “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,” 1992, chapter 6, pp. 8, section 2.1.1.

¹⁴ EPA 400-R-92-001, “Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,” 1992, pp. 1–5.