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OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Notice of Decision Under Section 127(f) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Office of Science and Technology Policy, Executive Office of the President.

ACTION: Notice of Decision to Waive Requirements of Sections 127(a) and (d) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Notice of Availability of Associated OSTP Director's Decision Memorandum and Interagency Technical Evaluation Report.

SUMMARY: Notice is hereby given of the determination, under Section 127(f) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act), to waive the requirements of Section 127(a) and (d) of the Act. Notice is also given that the Associated Decision Memorandum and an interagency technical analysis report are available on the Office of Science and Technology Policy (OSTP) Web site at http://www.ostp.gov/KI.

Section 127(a) of the Act directed the President to establish a Potassium Iodide (KI) distribution program, under which State and local governments could receive KI tablets for distribution to the population in the 20 mile radius surrounding nuclear power plants (NPPs). The Nuclear Regulatory Commission (NRC) already has such a program for the 10 mile emergency planning zones surrounding NPPs, so Section 127(a) effectively extended that program to the 10-20 mile range.

Through Section 127(f), Congress authorized the President to waive this distribution requirement if there exists ``an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.''

On July 3, 2007, the President delegated the Section 127(f) waiver authority to the Director of the Office of Science and Technology Policy.

On July 30, 2007, to help inform his decision, the OSTP Director requested the Federal Radiological Policy Coordinating Committee (FRPCC) to provide a technical evaluation of the issues surrounding Section 127. The FRPCC is an interagency organization, with membership from 17 Federal agencies, established to coordinate Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime nuclear emergencies. The FRPCC transmitted its final technical evaluation paper to the OSTP Director on October 23, 2007.

On January 22, 2008, the OSTP Director executed his final decision pursuant to the Section 127(f) delegation. The complete Decision Memorandum, as well as the FRPCC technical information paper, is available on the OSTP Web site at http://www.ostp.gov/KI.

The OSTP Director's determination waived Section 127(f) because a more effective preventive measure does exist for the extended zone covered by the Act, namely avoidance of exposure altogether through evacuation of the potentially affected population and interdiction of

contaminated food. Analysis of radiological release events that could lead to adverse thyroid conditions beyond the current 10 mile zone shows that limiting or avoiding exposure to radiation through these mechanisms is practical and much more effective than the administration of KI in the proposed extended zone.

DATES: The Decision Memorandum was executed on January 22, 2008. Associated documents will be available on the OSTP Web site on January 31, 2008.

ADDRESSES: Questions concerning this Notice should be sent to OSTP by e-mail at comments@ostp.eop.gov or by Fax at 202-456-6027.

Background

Section 127(a) of the Act directs the President to establish a KI distribution program as discussed above. Section 127(b) of the Act calls for State and local authorities to submit their KI stockpile plans to the President. Section 127(c) requires the President to issue guidelines for the stockpiling of KI tablets. Section 127(d) requires the Federal government to undertake efforts to make states and localities aware of the availability of KI under 127 (a). Section 127(e) requires the President to

submit a progress report to Congress no later than 6 months after the guidelines under (c) are issued, and requires the President to request the National Academies of Science to conduct a study to determine the most effective and safe way to distribute and administer KI on a mass scale.

In Section 127(f), Congress authorized the President to waive the requirements of Sections 127(a) and (d) if there exists ``an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.''

On July 3, 2007, the President delegated the authority to make a determination whether to invoke Section 127(f) to the Director of the Office of Science and Technology Policy, and the authority to implement the remaining subsections of Section 127 to the Nuclear Regulatory Commission (NRC), which established and implements the existing 10 mile KI distribution program.

On July 30, 2007, the OSTP Director requested the FRPCC to provide a technical evaluation of the issues surrounding Section 127(f). The FRPCC is an interagency organization, with membership from 17 Federal

agencies, established to coordinate Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime nuclear emergencies. Member agencies include the NRC, the Federal Emergency Response Agency (FEMA), the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the Environmental Protection Agency, and others. The OSTP Director asked the FRPCC to provide him with technical background information only; the FRPCC was not asked to provide any findings or recommendations concerning the invocation of Section 127(f). The FRPCC asked their Potassium Iodide Working Group to conduct the work of drafting this document.

As part of this process, OSTP specifically requested that agencies with expertise in topical subjects in the technical evaluation take the lead on the subjects of their particular expertise--to be responsible for carefully reviewing and approving the information presented. For example, FDA was asked to take the lead on the sections dealing with the effects of Potassium Iodide, HHS was asked to take the lead on the sections dealing with the health effects of radiation including radioiodine, and FEMA was asked to take the lead on the sections

dealing with evacuations, etc. In addition, each agency had the opportunity to review and approve the entire document, both at the working group and full FRPCC levels. If irreconcilable disputes existed between the various Federal agencies while drafting the document, OSTP requested that this information, along with the reasons why, be presented to the OSTP Director as well.

The FRPCC transmitted its final technical evaluation paper to the OSTP Director on October 23, 2007.

On January 22, 2008, the OSTP Director executed his decision on the 127(f) delegation. The analysis underlying the decision to invoke the Section 127(f) waiver is presented in a Decision Memorandum. The complete Decision Memorandum, as well as the supporting interagency FRPCC technical information paper, is available on the OSTP Web site at http://www.ostp.gov/KI.

To provide additional background on the basis for the decision in this Notice, the ``Decision Summary'' section of the Decision Memorandum is presented in full below:

Decision Summary

On July 3, 2007, the President delegated to me his authority to invoke, if appropriate, the waiver provision in the Potassium Iodide

(KI) distribution program enacted through Section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act).\1\ In that Section of the Act, Congress authorized the President to waive the program if he determines that there exists ``an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.'' Under the Act, the Federal government would provide KI to be distributed by state and local governments to populations living in a zone extending an additional 10 miles beyond the existing 10 mile emergency planning zone near nuclear power plants (NPPs), in which a KI distribution program already exists. The Background section below describes the process I used to make the necessary determination.

\1\ Pub. L. 107-188, 42 U.S.C. 300hh-12 (Notes).

After a thorough review of the technical issues, and as explained in detail below, I have decided to invoke the Section 127(f) waiver. I have determined that a more effective preventive measure does exist for

the extended zone covered by the Act, namely avoidance of exposure
altogether through evacuation of the potentially affected population
and interdiction of contaminated food. Analysis of radiological release
events that could lead to adverse thyroid conditions beyond the current
10 mile zone shows that such limiting or avoiding exposure to radiation
through these mechanisms is practical and much more effective than the
administration of KI in the proposed extended zone.

Key facts leading to this conclusion are the existence of Federal
support for KI distribution programs within 10 miles of an NPP, the
long advance warning available to potentially affected populations
given the type of event that could possibly lead to actionable
radionuclide concentrations beyond 10 miles, and the existence of
tested operational plans for effectively interdicting contaminated
agricultural products in this extended zone.

For the types of nuclear reactors in use within the United States,
there are very few accident scenarios that produce such effects. These
very severe events have been well-analyzed, and none lead to the rapid
appearance of thyroid-threatening radioiodines beyond 10 miles.
Experience with major evacuations (approximately one every three weeks
in the U.S.), and detailed analysis for a typical nuclear power plant

(NPP), show that populations in the extended zone likely to be affected by such an event can be evacuated in time to avoid adverse thyroid conditions. Moreover, KI is only effective in decreasing thyroid exposure to radioactive isotopes of iodine, and the events in question would produce health effects from radionuclides other than the isotopes of iodine. Evacuation and interdiction of contaminated food products are the preferred actions to prevent exposures to these other radionuclides, and will have to be taken in response to such an event in any case.

While the Section 127(f) authority delegated to me primarily concerns distribution of KI beyond the current 10 mile Nuclear Regulatory Commission (NRC) program, the review brought to my attention weaknesses in the implementation of existing programs within 10 miles that deserve attention. States distribute KI currently provided by the NRC in diverse programs with disparate characteristics, suggesting that many are not based on best practices for prevention of adverse thyroid conditions. Accordingly, while not a pre-condition of my decision to invoke the Section 127(f) waiver, I strongly recommend that the NRC, in conjunction with the Federal Emergency Management Agency (FEMA), the Department of Health and Human

Services (HHS), State and local health authorities and relevant public and private sector stakeholders develop and promulgate ``best practice'' guidelines for the existing state-level KI distribution programs within the 10 mile emergency planning zones.

Stanley S. Sokul,
Chief of Staff and General Counsel, Office of Science and Technology Policy.

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