POLICY ISSUE
(Notation Vote)

March 3, 2009 SECY-09-0041

FOR: The Commissioners

FROM: R. W. Borchardt
Executive Director for Operations

SUBJECT: RECOMMENDATION FOR FUTURE REPLENISHMENT OF POTASSIUM IODIDE

PURPOSE:

The staff requests Commission approval of its recommendation regarding potassium iodide (KI). The staff recommends that the U. S. Nuclear Regulatory Commission (NRC) continue to replenish expired potassium iodide (KI) to requesting States with populations in the 10-mile emergency planning zone (EPZ) of a commercial nuclear power plant. In response to the Commission's Staff Requirements Memorandum (SRM)-SECY-06-0142, "Options and Recommendations for Replenishing Expired Potassium Iodide (KI)," dated September 6, 2006, the staff has determined with stakeholder input that NRC's continued replenishment of expired KI, upon request, is the only viable option.

BACKGROUND:

In 2001, the NRC revised a section of its emergency preparedness regulations to require that States and Tribal Governments (henceforth called States) with a population within the 10-mile EPZ of commercial nuclear power plants consider including KI as a protective measure for the general public to supplement sheltering and evacuation in the unlikely event of a severe nuclear power plant accident. KI, if taken properly, helps reduce the dose of radiation to the thyroid gland from radioactive iodine and, therefore, helps reduce the risk of thyroid cancer. The final rule amended Title 10, Section 50.47(b) (10), of the *Code of Federal Regulations*. The NRC published the rule change in the *Federal Register* on January 19, 2001 (66 FR 5427), and the change became effective on April 19, 2001.

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Along with this rule change, the NRC provides funding for an initial supply of KI for a State with a population within the 10-mile EPZ that chooses to incorporate KI for the general public into its emergency plans. On December 20, 2001, the NRC sent letters to the 34 States with populations within the 10-mile EPZ of commercial nuclear power plants to inform them of the NRC program to provide KI supplies to States. Over the past 7 years, 22 of those States have thus far requested KI supplies from the NRC.

By requiring consideration of the use of KI, the Commission recognized the important role of States and local governments in matters of emergency planning. Initially, the Commission made no commitments to replenish the initial supply of KI upon expiration. The Statements of Consideration accompanying the final rule state: "The Commission expects that those States who decide to use KI for the general public will make suitable arrangements to fund costs other than the initial purchase of a supply of KI. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard."

On January 12, 2005, the Food and Drug Administration (FDA) approved a 65-milligram per milliliter dose of oral solution for children. On November 10, 2005, the NRC, in cooperation with the Department of Health and Human Services (HHS), sent letters to the States announcing the availability of liquid pediatric KI for States with populations within the 10-mile EPZ. The NRC paid to ship the liquid KI for those states requesting it and HHS provided the drug product. The distribution of liquid KI is in addition to the NRC KI program and is not included in replenishment plans.

As a result of Commission direction in SRM-SECY-06-0142 authorizing a one-time replenishment of KI tablets, the NRC sent letters to States participating in the NRC KI program to inform them that the NRC will provide a one-time replenishment of currently-existing stockpiles of KI held by the States.

In SRM-SECY-06-0142, the Commission directed the staff to work with appropriate stakeholders to identify options by May 15, 2007, for future KI supplies and replenishment within the 10-mile EPZ of commercial nuclear power plants. The Commission directed that the options should include direct funding by licensees. The staff sent an options paper to the Commission but the staff later withdrew the paper because there was uncertainty whether distribution of KI might be required out to 20 miles from every nuclear power plant as a result of Section 127 of Public Law 107-188 (the BioShield Act). The BioShield Act required the President to implement such distribution, unless the President determined that there are more effective measures for protecting the thyroid. The President had not yet made his determination and so the staff felt it was prudent to withdraw the paper with a commitment to resubmit it when the issue was resolved.

On March 14, 2007, the NRC sent letters to all States with populations within the 10-mile EPZ to inform them of the additional availability of liquid KI from HHS and sent information from the FDA on the shelf-life extension of current State stockpiles of KI. All participating KI States responded with replenishment decisions by the deadline of April 30, 2007. Several States requested immediate replenishment and many others decided to take advantage of the 2-year shelf-life extension and accept replenishment in 2009.

Uncertainty surrounding the NRC's future role in the distribution of KI was increased when, in a July 3, 2007, memorandum, President Bush assigned to the NRC his responsibility for implementing Section 127, except the subsection which assigns to the President the responsibility for determining whether there are more effective measures for protecting the thyroid. The President's July 3, 2007, memorandum assigned that responsibility to the President's Office of Science and Technology Policy (OSTP).

On January 22, 2008, Dr. John Marburger, Director of OSTP, released his determination that more effective measures did in fact exist. Dr. Marburger rejected expanding the distribution of KI to 20 miles around nuclear power plants, stating that the scientific evidence did not support such expansion of the current program. That decision resolved much of the uncertainty about the future distribution of KI. But in framing his decision, Dr. Marburger took it as given that Federal resources, through the NRC, were already committed to the distribution of KI supplies to the general public in the 10-mile EPZ. (See, page 2 of Dr. Marburger's decision memorandum, enclosed.) Additionally, Dr. Marburger recommended the NRC work in concert with other Federal, State, and local health authorities to develop a "best practices" guideline for KI distribution. The NRC has been actively engaged with these stakeholders in a series of virtual meetings to address this matter.

DISCUSSION:

Twenty-two of the 34 eligible States have responded to the NRC program to furnish an initial supply of KI as a supplemental measure for protection of public health and safety. States have integrated the use of KI into their emergency plans and have made individual decisions regarding the issuance of KI to the public. Some States chose stockpiling and others predistributed the drug to the public. All 22 States have indicated interest in, and are expecting, continued replenishment of KI stockpiles by the NRC in the future.

The Statements of Consideration accompanying the final rule state that funding for KI is for the initial purchase of these supplies, and that the Commission may consider "extending the program to fund stockpile replenishment, but has made no commitments in this regard." Later, the Commission directed that one round of replenishment be provided but was very specific in SRM-SECY-06-0142 that "this replenishment is a one-time action and will not be renewed in the future."

However, in SRM-SECY-06-0142, the Commission also directed the staff to meet with stakeholders to further determine how KI replenishment could be handled in the future. The staff met with representatives from the Nuclear Energy Institute (NEI) to discuss industry funding directly to the States. The industry was unwilling to collectively agree and suggested that the best approach was for NRC to meet with each nuclear power plant licensee to discuss the issues. The staff did not pursue such individual meetings. The two major Federal entities the staff met with were the Federal Emergency Management Agency (FEMA) of the U.S. Department of Homeland Security and HHS. Officials from FEMA were not willing to consider taking over the NRC KI distribution program as they felt they did not have the expertise to be in charge of drug product (KI) distribution. As a result of the decision by Dr. Marburger, HHS no longer stockpiles KI for distribution to the public around nuclear power plants and NRC has assisted HHS in distribution of its existing stockpiles to participating States. HHS is no longer in a position to distribute KI. In light of what has transpired since SRM-SECY-06-0142

was issued most of the options the staff had previously considered no longer exist. Of particular importance is the assumption by Dr. Marburger in rendering his decision on the BioShield Act relative to NRC's continued involvement in KI distribution.

RECOMMENDATION:

The staff recommends that the Commission modify its KI distribution policy from a one-time replenishment action to one providing KI tablets to affected States that request them and replenishing KI tablet stockpiles upon States' requests consistent with the tablet shelf life. This recommendation is consistent with the July 3, 2007, memorandum from the President and with the determination made by OSTP Director Dr. Marburger on January 22, 2008, regarding Subsection 127(f) of Public Law 107-188.

RESOURCES:

Absent new States requesting KI, the staff estimates the NRC's cost to maintain the long-term replenishment of KI tablets to be approximately 4–5 million dollars every 6 years starting with Fiscal Year (FY) 2013. Resources are not required pertaining to this proposal until FY 2013. Resource needs to support this in FY 2013 and beyond will be addressed through that FY's Planning, Budgeting, and Performance Management Process.

The staff has recently provided the Chairman a memorandum requesting a new contract to expend the 2.8 million dollars that has been allocated for FY2009 to finalize the one time replenishment for States that chose to extend their stockpiles by 2 years.

COORDINATION:

The Office of the General Counsel has no legal objection to future replenishments of KI tablets to requesting, eligible States. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA Bruce S. Mallett for/

R. W. Borchardt
Executive Director
for Operations

Enclosure:
As stated

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20502

January 22, 2008

Decision Memorandum

From: John H. Marburger, III
Director, Office of Science and Technology Policy

Re: Decision on Delegation of Section 127(f) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

I. 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.

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

[1] P.L. 107-188, 42 U.S.C. Sec. 300hh-12 (Notes)

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.*

II. Background

A. Statute

Section 127 of the Act provides for the distribution of KI to populations in the vicinity of NPPs. Section 127(a) requires the Federal government to make KI tablets available to states and localities for stockpiling and distribution "in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant." Because the federal government already makes KI available to states for distribution within 10 miles of a nuclear power plant, Section 127 would effectively expand the KI distribution zone to the 10-20 mile range. Section 127 (b) calls for State and Local authorities to submit their KI stockpile plans to the President.[2] 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 (NAS) to conduct a study to determine the most effective and safe way to distribute and administer KI on a mass scale. Section 127(f) allows for Sections 127(a) and (d) to be waived, however, if there exists "an alternative and more effective

[2]Section 127(b)(2) provides a mechanism for a local government to implement a KI distribution program when its state government chooses not to do so regardless of the radius of the distribution zone. The scope of the waiver provision, Section 127(f), does not cover Section 127(b). Any provisions of paragraphs (b), (c), and (e) not affected by this waiver will continue in force under the Act.

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 me, and the authority to implement the remaining subsections of Section 127 to the Nuclear Regulatory Commission, which established and implements the existing 10 mile KI distribution program.

B. History of Related Administration Efforts

The Administration has been actively examining this issue since the President signed the Act into law on June 12, 2002. In addition to the development of guidelines for Potassium Iodide (KI) distribution, HHS has used the Special Reserve Fund authorized under the Project BioShield Act of 2004 to procure enough liquid pediatric KI to protect children, the population most vulnerable to the effects of radioactive iodine, within 20 miles of a NPP.[3] This acquisition was based on a recommendation from the National Science and Technology Council's Weapons of Mass Destruction Medical Countermeasures Subcommittee, and approved by Secretaries Thompson and Ridge of the Departments of Health and Human Services and Homeland Security respectively, and by the Director of the Office of Management and Budget. Prior to the Food and Drug Administration's (FDA) approval of this product on January 12, 2005, there was no dosage form available for children who could not swallow pills. The NRC, in cooperation with HHS, is working to make liquid KI available to states for children within the 10-mile Emergency Preparedness Zone (EPZ) around NPPs. In addition, the NRC is also working to replace the previously distributed but expiring stockpiles of KI for the populations within the 10 mile EPZ.

In the Fall of 2004 HHS sent draft guidelines for distribution of KI in the 10-20 mile zone to State and Local stakeholders, and Congress, for comment. On August 29, 2005, HHS published the revised guidelines for the distribution of KI to those within the 10-20 mile range of NPPs under Sections 127(a) and 127(d) of the Act. Many comments received in response to these notices expressed concern with the HHS plan, including comments from states that would have to develop new stockpiling and distribution procedures. In these comments, no State or Local agency supported expanded distribution. Many comments suggested that the waiver provision of Section 127(f) should be invoked. In response to the issues raised in comments received during this period, the Administration began considering whether a process was needed to assess whether the Section 127(f) waiver provision should be invoked.

C. The OSTP Technical Evaluation Process

Upon receiving the Section 127(f) waiver delegation in July 2007, I established an evaluation process to provide a sound technical foundation to inform my decision. The National Research Council of the National Academies report, developed in response to the Act

[3] Note: Section 127 of the Act authorized the distribution of KI tablets, not the liquid KI most suitable for children.

(Section 127(e)), was an important source of information.[4] I also requested a technical analysis of issues related to the decision from the Federal Radiological Preparedness Coordinating Committee (FRPCC).[5] The FRPCC is a national level forum for development and coordination of radiological prevention and preparedness policies and procedures. It is composed of representatives from multiple agencies and chaired by DHS-FEMA. The FRPCC has established various subcommittees with specific subject matter expertise to consider issues of concern for the federal government. One such subcommittee is the Potassium Iodide Subcommittee established in August of 2001 (prior to the Act) to expedite review and revision of the Federal Policy on Use of Potassium Iodide (KI) and to coordinate KI implementation issues. Key subcommittee membership includes staff from FEMA, NRC, FDA, and the Environmental Protection Agency (EPA). The NRC and FEMA co-chair the Subcommittee as they are responsible for oversight of emergency preparedness at and around nuclear power plants. The FDA is responsible for decisions about appropriate thresholds and dosages for use of potassium iodide, and EPA publishes protective action guides for nuclear incidents. The Chair of the FRPCC asked the Potassium Iodide Subcommittee to draft the technical analysis report I requested.

Technical staff in the Office of Science and Technology Policy reviewed and analyzed relevant scientific and policy issues and examined positions developed by organizations such as the American Academy of Pediatrics and the American Thyroid Association. I also met with representatives of the latter organizations to make sure I understood the basis for their positions and recommendations. I also requested input on these issues from the Science and Technology Policy Institute (STPI). STPI is a federally funded research and development center run by the Institute for Defense Analyses that provides technical and analytical support to my office and other Executive Branch organizations. My staff and I have also thoroughly reviewed all correspondence received on this matter and I have considered the technical issues raised therein in arriving at my decision.

III. Rationale for Decision

A. *Criteria:* Following the President's July 3, 2007 delegation of authority, I outlined the criteria I would use to arrive at a decision in a July 5, 2007 memo to the FRPCC agencies "Interagency Technical Evaluation Process for Section 127(f) of the Bioterrorism Act of 2002."[6] The language of the Act itself sets forth three basic criteria. For Section 127(f) to be invoked there must exist: (1) alternative prophylaxis or preventive measures; for (2) adverse thyroid conditions that may result from the release of radionuclides from NPPs; that are (3) more effective.

(1) *Alternative prophylaxis or preventive measures.* Section 127(f) does not provide a reference point for "alternative." Because Section 127(f) is a waiver provision,

[4] Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident, National Research Council of the National Academies, National Academies Press, 2005. Cited in the text as "the NAS report."
[5] "Interagency Technical Evaluation Paper for Section 127(f) of the Bioterrorism Act of 2002." Prepared by the Federal Radiological Preparedness Coordinating Committee. (Members include DHS/FEMA, NRC, DHS, DOE, USDA, FDA, NIH, DOL, DOE/NNSA, DOD/Naval Reactors/AFFRI) This Paper is cited as Reference 1 in the text.
[6] Congressman Edward Markey, who had written the President concerning the status of Section 127 implementation, was also copied on this correspondence.

however, "alternative" must be considered to refer to what would be waived, namely Sections 127(a) and (d) which would provide KI out to 20 miles from nuclear power plants. Therefore, "alternative prophylaxis or preventive measures" were considered to be any countermeasure other than making KI available to states for distribution to those in the 10-20 mile radius of a NPP per Sections 127(a) and (d). The countermeasures considered were both medical and non-medical.

(2) *Adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.* This criterion defines how the other criteria must be judged. It specifies that the relevant public health issue is adverse thyroid conditions resulting from exposure to radionuclides. This is consistent with the fact that Section 127 is otherwise a KI distribution program. Moreover, while Section 127 as a whole is viewed as affecting the 10-20 mile radius as discussed above, Section 127(f) itself does not include that distance limitation. This is consistent with Congress' attempt to achieve the maximum benefit to public health. The evaluation process considered averted thyroid dose to represent the ability of a countermeasure to prevent adverse thyroid conditions.

(3) *More Effective.* The third criterion requires an alternative to be *more* effective in order to waive the program Congress specified (Sections 127(a) and (d)). An alternative prophylactic or preventive measure was judged more effective (than making KI available to states for distribution to those within the 10-20 mile zone for the prevention of adverse thyroid conditions that may result from the release of radionuclides from a NPP), if one or more of the following conditions were met:

(a) An alternative prophylactic or preventive measure, or combination of alternative measures, is expected to result in an averted thyroid dose of radioiodine (among the population surrounding a NPP following the release of radionuclides from the NPP) *greater* than that obtained by making potassium iodide available per subsections 127(a) and (d), within the 10-20 mile zone; *or*

(b) An alternative prophylactic or preventive measure, or combination of alternative measures, is expected to result in an averted thyroid dose of radioiodine (among the populations surrounding a NPP following the release of radionuclides from the NPP) *equal* to that obtained by making potassium iodide available per subsections 127(a) and (d), within the 10-20 mile zone, *and* are more likely to be effectively utilized by that population; *or*

(c) An alternative prophylactic or preventive measure, or combination of alternative measures, is expected to result in an averted thyroid dose of radioiodine (among the populations surrounding a NPP following the release of radionuclides from the NPP) *equal* to that obtained by making potassium iodide available per subsections 127(a) and (d), within the 10-20 mile zone, *and* is likely to cause less harm.

B. *Decision:* After a thorough review of the technical issues implicated by Section 127 of the Act, and as explained below, I decided to invoke the Section 127(f) waiver.

This decision follows from my determination that a more effective preventive measure does exist. Evacuation and interdiction of contaminated food will result in a much greater averted thyroid dose of radioiodine and a much lower potential risk for adverse thyroid conditions, compared with administration of KI through State and Local distribution programs.

The following discussion is informed by the "Interagency Technical Evaluation Paper" prepared at my request by the FRPCC, which should be consulted for more detail (hereafter cited as Reference 1; see footnote 5).

Basis for determination that "a more effective preventive measure exists": It has been clearly established by multiple sources that if consumed within an appropriate time period and at the appropriate dosage, KI can be extremely successful in inhibiting thyroid uptake of radioiodine following an inhalation or ingestion exposure. The decision on whether to provide KI in the extended range of 10-20 miles from an NPP hinges on whether a "more effective prophylaxis or preventive" measure exists to protect the public from adverse thyroid conditions in the event of an accident or terrorist incident that causes elevated levels of radioactive iodine in the extended range. Such a measure must be evaluated relative to the benefit of KI administration to the population in this range. The probability of occurrence of such a release is not an issue here, only the response to its consequences.[7]

A nuclear power plant accident that creates public health risks beyond the 10 mile range would be a highly unusual catastrophic event. In the 10-20 mile range, where ample notice to evacuate exists for scenarios leading to such events, evacuation from beneath an approaching plume must remain the top public protection priority. Radioactive iodine is not the only radionuclide that would be released in such an event, and other species are also potentially threatening to public health. The focus on evacuation should not be diverted or confused by attempts to distribute KI from stockpiled locations, as directed by Section 127.

In the extended zone beyond 10 miles, ingestion of food contaminated with radioisotopes poses a much greater threat to the thyroid than inhalation of plume material. All U.S. NPPs are required to maintain and regularly exercise plans for interdiction of contaminated foods in this zone. Current emergency preparedness plans that include contaminated food interdiction sufficiently protect populations in the region beyond 10 miles from NPPs. Federal distribution of KI beyond the 10 mile emergency planning zone (EPZ) is not warranted, and the mandate for KI availability places an unnecessary burden on State and Local emergency preparedness coordinators already struggling with the establishment and maintenance of programs within the 10 mile EPZ.

[7] The risk of a severe release of radioactive iodide between 10 - 20 miles from an NPP is very low - on the order of one in a million to one in ten million. My decision is grounded in the assumption that such an event can occur, and what must happen if one does occur, not that such an event is highly unlikely.

C. *Discussion*

More details regarding the topics discussed here may be found in Reference 1; see footnote 5.

1. U.S. nuclear power plant accidents and emergency planning zones

Relevant Federal documents (10 CFR 50.47(a)(1) and 10 CFR 50, Appendix E) define two emergency planning zones (EPZs) around NPPs. The plume exposure (inhalation) pathway EPZ (10-mile EPZ) has a radius of approximately 10 miles from the reactor;[8] this radius may vary given individual considerations at each location. Predetermined protective action plans are in place for this EPZ and are designed to avoid or reduce dose from potential exposure to radioactive materials. These actions include sheltering, evacuation, and the supplemental use of KI where appropriate. Analyses of severe accident scenarios (including terrorist attacks) at U.S. nuclear power plants indicate that risk from the inhalation pathway is very low beyond 10 miles.

The ingestion exposure pathway EPZ (50-mile EPZ) has a radius of about 50 miles from the reactor. Predetermined protective action plans are in place for this EPZ and are designed to avoid or reduce dose from potential ingestion of radioactive materials. These actions include the interdiction of potentially contaminated food and water, the prevention of further contamination (*e.g.*, placing dairy cattle in the area on stored feed) and public communication to prevent the consumption of other contaminated food and water (*e.g.*, from home gardens).

Severe accident scenarios have been studied in great detail for the types of reactors licensed to operate in the U.S., and sequences of events identified and analyzed that might lead to large releases of reactor core materials. U.S. NPPs are designed with multiple layers of containment that prevent instantaneous release of radioactive material in the event of damage to the reactor core. The subsequent physical development of the accident is relatively insensitive to the triggering event for the most severe accident scenarios. Leak rates from an NPP that would be impacted by a severe accident or terrorist attack are found to be low (0.1% to 0.5% of total radioactive material contents per day) and released materials must travel through multiple layers of containment and building structures to whose surfaces aerosols of radioactive iodine and other radionuclides adhere, further diminishing concentration levels.

Acts of terrorism do not lead to release scenarios more threatening to distant populations than the most severe accident scenarios considered in establishing existing off-site emergency planning zones. Taking them into account could possibly increase the probability of such events, but not their severity or offsite characteristics affecting thyroid exposure.

[8] The principal sources of exposure in this pathway would be from: (a) whole body exposure to gamma radiation from the plume and from deposited material, and (b) inhalation exposure from the passing plume. The duration of potential exposure could range in length from one-half hour to days.

2. Relevant characteristics of an event leading to consequences beyond the 10 mile EPZ

Once released into the environment, volatile reactor core components must be carried beyond the NPP by meteorological phenomena. In the absence of wind, the material would remain near the NPP and most of it would precipitate in its vicinity. Rain and snow would hasten the precipitation. Wind draws the aerosols and other volatile materials into a plume, which dissipates with distance like a plume of smoke from an industrial smokestack. Here too, rain or snow hastens precipitation and depletion of the plume within the 10 mile zone. Faster wind speeds are accompanied by turbulence which accelerates the dissipation. Winds that change direction during the plume at any speed substantially reduce concentrations in any offsite zone. Slow wind speeds with laminar flow in a constant direction therefore constitute the meteorological conditions necessary to carry significant concentrations of radionuclides from a severe NPP accident beyond the 10 mile EPZ.

These meteorological factors necessarily lead to scenarios in which the appearance of significant concentrations of radionuclides beyond 10 miles occurs with advance warning times adequate for effective evacuation of potentially affected sectors. Detailed modeling and calculations of realistic evacuation scenarios have been carried out specifically to assess the effectiveness of evacuation versus administration of KI to populations beyond the 10 mile EPZ, using a system of computer codes developed for such purposes.[9]

3. Comparison of evacuation with KI administration

The Interagency Technical Evaluation Paper (Reference 1) describes the conditions under which a detailed model was used to compare the estimated peak radiation doses to the thyroid within a sector in the extended zone beyond 10 miles from a typical U.S. NPP, the well-characterized Peach Bottom Nuclear Generating Station in Pennsylvania. The model postulates a severe release and meteorological conditions that would lead to radionuclide concentrations beyond 10 miles that would require protective response. Conservative assumptions were made to convert the estimated radionuclide concentrations in the plume to doses to the thyroid. Similarly conservative estimates were made regarding the time during the event at which a General Emergency would be declared, the delay between the alarm time and evacuation, the behavior of relocated individuals in response to the alarm, evacuation speed, and the efficiency and effectiveness of KI administration. The study assumed that the required plans for the interdiction of radiologically contaminated food were executed in the extended zone. Experience with such interdictions, discussed in Reference 1, reinforces confidence that these regularly exercised plans will be executed successfully.

The result of this detailed study is striking. Evacuation leads to a reduction of dosage to the thyroid 1,000 to 10,000 times greater than that of KI administration without evacuation. I emphasize that this result makes realistic assumptions about evacuation. It

[9] NUREG/CR-5691, Volume 2, "MELCOR Accident Consequence Code System (MACCS): Model Description," Sandia National Laboratories, Albuquerque, NM.

does not assume the population is suddenly removed from harm's way, but includes information gained from experience with actual evacuations. An example of a detailed analysis of an evacuation scenario is included as an Attachment to Reference 1.

4. Distribution of KI within the 10 mile EPZ

Our state of knowledge regarding severe NPP accidents decisively favors evacuation compared with the administration of KI in the extended zone beyond 10 miles from an NPP. Experience with the existing NRC program for distribution of KI within the 10 mile EPZ is, however, indirectly relevant to a discussion of KI distribution at greater distances. For optimum benefit, KI should be administered just before, concurrent with, or within 3 to 4 hours after exposure. The function of KI in this case is to prevent thyroid uptake of radioactive isotopes of iodine that might be inhaled as aerosols present in a plume originating from an NPP event. KI is not an "anti-radiation" drug, and does not diminish the effects of radiation emitted by any radionuclide. It only inhibits the uptake of iodine and its radioactive isotopes into the thyroid gland where they can linger and possibly cause DNA damage, and hence cancer, over a period of time. A dose of KI is effective for approximately 24 hours; repeat dosage is necessary for prolonged exposure to radioiodine[10]. The FDA has concluded that once the plume has passed, prevention of thyroid uptake of ingested iodine-131, the longest lived of the radioactive isotopes of iodine with a half-life of about 8 days, is best accomplished by food control measures and not by repeated administration of KI. Prevention of ingestion of radionuclides is already a primary element for planning within the 50 mile EPZ.

According to the NAS Study,[11] maximum protection is attained if KI is taken one hour before exposure to radioactive iodine. At 2 hours post-exposure, protection drops to 80%. Consequently KI distribution programs within the 10 mile EPZ must address a narrow window of administration times to be effective. Within this zone, the NRC provides KI for the potentially affected population if the states choose to include it in their emergency planning. Currently 21 of 33 states eligible for KI in the 10-mile EPZ are taking advantage of this NRC program (63%).[12]

Of the 21 states with programs to stockpile or distribute KI within the 10-mile EPZ none explicitly supported expanded distribution in response to the draft and revised HHS guidelines of 2004 and 2005, and comments from 9 states indicated they were opposed to expanded distribution.[13] Their responses reveal difficulties in implementing effective

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[10] Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies. U.S. Department of Health and Human Services, Food and Drug Administration. December 2001. http://www.fda.gov/cder/guidance/4825fnl.htm#KI%20Use%20in%20Radiation%20Emergencies:%20Treatment%20Recommendations

[11] Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident, National Research Council of the National Academies, National Academies Press, 2005. (Reference 1)

[12] Illinois did not participate in the NRC KI program, but procured its own supply of KI.

[13] Massachusetts is not included in this data, due to conflicting comments. The Massachusetts Emergency Management Agency (MEMA) provided comments against expanded distribution of KI based on lessons learned from the distribution of KI within the 10-mile EPZ. The Commonwealth of Massachusetts provided comments in

distribution programs of which examples are included in Reference 1 and the NAS Study. These comments suggest that such programs are regarded as burdensome by the states, and present public education and compliance challenges that have not been resolved. The NAS report devotes Appendices to an analysis of state KI distribution programs and recommendations for evaluation and implementation. It is clear that the execution of KI distribution programs within the 10 mile EPZ leaves much to be desired. The state of these programs does not give confidence that an expansion beyond the existing 10 mile limit would be implemented effectively, even if KI were superior in its protective function in this zone, which it clearly is not.

Reliance on KI could actually decrease effectiveness of other more protective actions. Iodine-131 is not the only radioactive material of concern associated with an NPP release. Evacuation preparedness is essential to protect citizens from radiation. KI is a crucial drug when the risk of radioactive iodide exposure is sufficient to warrant its use under a FEMA-approved plan, but it is not, as noted above, an "anti-radiation drug." Efforts by individuals to obtain KI at the last minute in a poorly administered distribution program have the potential to complicate other emergency preparedness planning elements and diminish response of the general population to emergency action notices. Also, it is possible that public misunderstanding of KI and its limits may lead to a dangerous sense of false confidence that KI provides inoculation against all forms of radiation.

The NAS Study also reports that European emergency planning zones for KI distribution are typically 10-20 km (6.2-12.4 miles), roughly consistent with the nominal 10 mile EPZ for the current U.S. KI program.

D. Analysis of Arguments in Support of Expanded Distribution

In arriving at a decision, I attempted to understand thoroughly the arguments made in comments, correspondence and various reports by proponents of expanded KI distribution. For various reasons none of these arguments suffice to overcome the huge advantage of evacuation relative to KI administration in the zone beyond 10 miles from a NPP, which is the basis for my decision to invoke Section 127(f) of the Act. The following discussion addresses arguments that were made most frequently by concerned respondents. Information relevant to other concerns may be found in Reference 1 and the various reports cited therein.

1. The 1986 accident at the Chernobyl nuclear power plant in the Ukraine, former USSR.

Commentators advocating KI distribution beyond 10 miles from a NPP frequently cite the Chernobyl accident as demonstrating the need for expanding the distribution zone. While the Chernobyl accident provided important information on the effects of radiation exposure, it is not a useful guide to preparation for NPP accidents in the U.S. No U.S. nuclear plant resembles, even remotely, the configuration and (absence of) safety features of the Chernobyl plant, a water-cooled graphite-moderated reactor with an inherently

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2004 stating no official position, indicating that MEMA does not create Policy for the Commonwealth of Massachusetts and citing obstacles to expanded distribution.

unstable design and stunningly inadequate containment structures. The characteristics of the Chernobyl accident, including its extremely long radiological plume, differ markedly from any possible accidental or terrorist-initiated events involving U.S. pressurized or boiling water reactors. The NAS Study gives details and many caveats regarding comparisons between Chernobyl and possible U.S. NPP accidents.

One feature of the Chernobyl accident, however, is characteristic of all severe NPP accidents: the greatest risk from the inhalation pathway for radioiodide exposure, for which KI prophylaxis is most appropriate, occurred close to the reactor. Only in the town of Pripyat, located 1.86 miles (3 km) from the accident, was the primary exposure pathway from inhalation. Drinking milk from cows that ate contaminated grass immediately after the accident was the primary contribution to high doses to thyroids of children at greater distances. In this connection, the Polish government ordered distribution and use of potassium iodide after the Chernobyl accident, an action sometimes cited in support of KI administration at large distances from the accident. The effectiveness of this action cannot be established, however, because the radiological exposures to the population were too low to have induced adverse thyroid effects. The use of KI in Poland should not be compared to the regions immediately surrounding the Chernobyl site where adverse thyroid effects were certainly caused by radioactive iodine. Reference 1 describes NRC and FEMA requirements for plans within the 50 mile ingestion pathway EPZ surrounding U.S. NPPs regarding interdiction of contaminated food products. These agencies require plans to be tested at least once every 6 years as part of a broader ingestion pathway exercise. Experience with similar interdictions of contaminated agricultural products, cited in Reference 1, gives assurance that these plans are likely to be effective.

2. Implications of NUREG/CR-1433 (Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents)

This study is also frequently cited in support of extended distribution of KI beyond the 10 mile EPZ. It was performed in 1980 following the NPP accident at Three Mile Island in order to provide a rational basis for the pre-event distribution of KI depending on the probability of accident occurrences, the impact on the public, and the costs and benefits of alternative protective measures. While the study concludes that a severe accident of the type considered here could lead to a dangerous dose to the thyroid beyond the 10 mile EPZ, it does not assess the efficacy of KI distribution relative to evacuation and interdiction of contaminated food, which would be necessary in an accident of this type to protect the public from radiation exposure from other radioisotopes in the plume. Thus NUREG-1433 does not provide technical arguments either for or against KI prophylaxis in the 10-20 mile zone.

3. Implications of NUREG CR-2239 (Technical Guidance for Siting Criteria Development)

This study, also cited by concerned citizens' groups in support of expanding KI distribution beyond the 10 mile EPZ, was not performed to assess realistic accident

scenarios. The study assumed an artificially high release of reactor core material so as to perform sensitivity analyses on accident consequences based on variables such as meteorology, population distribution, emergency response measures, reactor size, energy release rate, etc. The intent of such studies is to provide guidance to regulators on the most important safety factors when considering future power plant siting. The study was in no way intended to serve as guidance for emergency planning procedures and is not useful for that purpose. Consequently it is silent on the use of KI, and does not analyze its effectiveness relative to other protective measures in preventing thyroid damage as a function of distance from a NPP.

4. Weaknesses in NRC site-specific plume modeling capabilities

Some concerned citizens groups criticize meteorological analyses that assume a wind that blows constantly in a single direction, suggesting that variable trajectory models would better account for complex wind patterns, leading to accident consequences extending beyond current projections. In fact the opposite is true. The NRC and FEMA outline their strategies for emergency planning in the 2002 study *Assessment of the Use of Potassium Iodide (KI) as a Supplemental Public Protective Action during Severe Reactor Accidents* (NUREG 1633)[14], which addresses the effect of meteorology on accident consequences, specifically its effect on where the offsite release goes, and the concentration of radionuclides to which the public is exposed at some point downwind.

Under very stable atmospheric conditions (*i.e.*, like those modeled in a steady state plume), there is not much dispersion of the plume and the radionuclide concentration is much greater than under unstable atmospheric conditions. Stable meteorological conditions are considered the most unfavorable conditions in emergency planning because there is very little atmospheric dispersion or mixing of the plume, and the plume tends to stay concentrated and travel greater distances than in unstable meteorological conditions. Contrary to the criticisms, a more complex variable trajectory model would result in a more dispersed plume, a reduced radiation dose, and a reduced risk of thyroid damage.

5. Relevance of terrorism

The NRC acknowledges the threat of terrorism in its *Backgrounder on Emergency Preparedness at Nuclear Power Plants,* in which it finds that the consequences of a terrorist attack on a NPP will be the same as those postulated in their accident scenarios.[15] That is, the existence of a terrorist threat does not provide any additional rationale for expanding the KI distribution zone to 20 miles. Despite the low probability that a terrorist action would result in a significant concentration of radioiodine beyond the 10 mile EPZ (a conclusion reinforced in the NAS Study) the NRC has recently issued a Federal Register Notice applying to new license applicants that requires additional consideration of large

[14] http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0089/attachment1.pdf
[15] http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/emerg-plan-prep-nuc-power-bg.html

commercial aircraft impacts to NPPs.[16] The NRC is proposing to amend its regulations to require applicants for NPPs to include in their applications a description and evaluation of design features, functional capabilities, and strategies to avoid or mitigate the effects of an aircraft impact with reduced reliance on operator actions. The objective of the new rule would be to require NPP designers to perform a rigorous assessment of design features that could provide additional inherent protection to avoid or mitigate the effects of an aircraft impact. Whether such mitigation is achieved is not relevant to the decision to distribute KI beyond the 10 mile EPZ. As with my decision regarding Section 127(f), that decision must be made assuming a severe accident regardless of its probability of occurrence. What is important here is the technical assessment that the characteristics of severe terrorist-initiated releases of reactor core material are similar to severe accidents already included in safety analyses.

[16] FRN, Vol 72, No 191, Wednesday, October 3, 2007, page 56287; 10 CFR Part 52 - Consideration of Aircraft Impacts for New Nuclear Power Reactor Designs