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/

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Executive Director
for Operations

Enclosure:
As stated

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