POLICY ISSUE
NOTATION VOTE

May 11, 2007 SECY-07-0078

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: OPTIONS AND RECOMMENDATIONS FOR THE RESPONSIBILITY OF FUTURE REPLENISHMENT OF POTASSIUM IODIDE

PURPOSE:

To provide options and recommendations as directed by the Commission in Staff Requirements Memorandum (SRM) - COMSECY 07-0002, "Potassium Iodide Replacement," dated February 28, 2007, and SRM - SECY-06-0142 – "Options and Recommendations for Replenishing Expired Potassium Iodide (KI)," dated September 6, 2006, regarding future KI replenishment provided by the Nuclear Regulatory Commission (NRC) to States with populations in the 10-mile emergency planning zone (EPZ) of a commercial nuclear power plant.

SUMMARY:

Based on discussions with stakeholders and the uncertainty with the potential implementation of Public Law 107-188 Section 127, Expanded Distribution of Potassium Iodide to 20 miles, as well as the recent transfer of the Radiological Emergency Preparedness Program from Department of Homeland Security (DHS) back to the Federal Emergency Management Agency (FEMA), the staff recommends, at this time, the NRC maintain responsibility for the KI public distribution program. This will provide stability to the KI program, allow for budget predictability, and maintain stakeholder confidence.

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BACKGROUND:

In 2001, the NRC revised a section of its emergency preparedness regulations (Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.47(b)(10)) to require that States and Tribal Governments with a population within the 10-mile EPZ of commercial nuclear power plants consider including KI as a protective measure for the general public as a supplement to 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 reduces the risk of development of thyroid disease including cancer. On January 19, 2001, the NRC published the rule change in the *Federal Register* (Volume 66, Number 13, page 5427).

Along with this rule change, the NRC provided funding for a supply of KI for a State or Tribe that chose to incorporate KI for the general public into their emergency plans. Initially, the Commission made no commitments to replenish the initial supply upon expiration. In the Statements of Consideration published in the *Federal Register* on January 19, 2001, it was stated that, "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." The Final Rule became effective on April 19, 2001. Since the final rule became effective, the NRC has had a number of interactions with the States regarding the KI program:

1) On December 20, 2001, the NRC sent letters to the 34 States that have populations within a 10-mile EPZ of a commercial nuclear power plant to inform them of the funding for the NRC program. At present, 21 of 34 States and Tribal governments have requested KI (130 and/or 65 mg tablets) from the NRC program.

2) On January 23, 2004, the NRC sent letters to the 34 States that have populations within a 10-mile EPZ of a commercial nuclear power plant to inform them of the availability of Food and Drug Administration (FDA) approved 65 mg KI tablets. Fourteen states have requested the 65 mg tablets.

3) On January 12, 2005, the FDA approved an oral solution of 65mg/ml dose for children. On November 10, 2005, in cooperation with the Department of Health and Human Services (HHS), the NRC sent letters to the States, announcing the availability of liquid pediatric KI for States with populations within the 10-mile EPZ. The NRC paid the shipping costs of the liquid KI and HHS provided the drug product. This distribution of liquid KI is separate from the NRC KI tablet program and is not included in NRC replenishment plans.

4) On October 26, 2006, the NRC sent a letter to each of the 21 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. This letter was supplemented with a letter from the NRC on March 14, 2007, which informed the States of the availability of additional liquid KI from HHS, as well as information from the FDA on shelf-life extension of current State stockpiles of KI.

During this time period, the Commission has provided the staff additional direction regarding the KI program:

1) Staff Requirements Memorandum - SECY-06-0142 dated September 6, 2006, directed the staff to work with appropriate stakeholders and provide options to the Commission by May 15, 2007, for future KI supply and replenishment within the 10-mile EPZs of commercial nuclear power plants. The Commission directed that one of the options included should be direct-funding by licensees.

2) Staff Requirements Memo to COMSECY 07-0002, dated February 28, 2007, directed the staff to continue working with the States to best determine the means by which existing KI stockpiles are maintained or replaced, including pursuing shelf-life extension with the FDA. The staff was also encouraged to investigate transfer of the implementation of the KI program to another Federal agency.

DISCUSSION:

The staff identified the States, industry, DHS, and HHS as the appropriate stakeholders to engage in discussions regarding future KI replenishment options.

Discussion with States:

In order to better understand the concerns of States and Tribal government stakeholders, the staff conducted a series of teleconferences with the States in January 2007, to solicit their input on future replenishment options. All impacted States participated in at least one phone call, and several States participated in more than one of the teleconferences. Many States included local county emergency management and public health officials in the discussions. There were a number of issues raised by the States, including:

- Several States expressed concern that the NRC would withdraw from the KI program. States expressed that their involvement with KI distribution was a direct result of the NRC's free offer and the resultant public interest to participate in this program. Most of the States prefer NRC to be the distribution point for KI, but seek greater long-term stability in the process.

- Some States indicated an interest in extending current stockpiles and replenishing the stockpiles at a future date. Some States have extended the shelf-life of the stockpiled KI tablets and requested NRC to provide the one-time replenishment option in 2009 or 2010 when the initial shelf life for their current stockpile would be expired.

- Many States expressed concerns that there may be a conflict of interest for DHS to have responsibility for the voluntary KI distribution program and then evaluate the implementation of that same program at the State level. States also questioned whether DHS has the needed expertise with drug products.

- Many States were reluctant to embrace transfer of the program to HHS, although it was acknowledged that this may be the most logical place for such a program. The State Health Departments were concerned that HHS would reallocate funds from existing

programs to pay for the KI tablets.

- Some States suggested that NRC change the rule to require licensees to pay for the KI program as many licensees have not been willing to voluntarily shoulder the increased costs to the States as a result of participation in the NRC KI program.

- Some States proposed that NRC change 10 CFR 50.47(b)(10) to delete any reference to KI as the cost to the States for the program far exceeds any measurable benefit from maintaining a KI program. Some States have followed up with the populations that have received tablets and found some evidence that:

  - Many people didn't remember:
    – if they received KI
    – where they had stored it in their home
    – what it is to be used for and when they should take their tablets

  - Some members of the public stated that if they were ordered to evacuate, they would delay evacuation to look for their KI tablets

  - Some would consider going to a local pharmacy to obtain KI, even though most local pharmacies are not the distribution source and do not have sufficient stockpiles

  - There was lack of interest by the public in obtaining predistributed KI tablets[1]

- Other States raised objections stating that changing the rule or discontinuing the program would be a difficult decision for them and may cause confusion among the general public.

- One State suggested that the NRC maintain responsibility for the KI program but partner with the private sector for distribution. For example, one State has worked with a large retail outlet to distribute KI to the EPZ populations. In this partnership, the retail operation maintains the stockpiles and distribution records. The State provides fact sheets for the public to be given during distribution and education to retail outlet pharmacy staff.

All 21 States, who have previously requested KI, have indicated interest in replenishment of current KI stockpiles; however, due to the differences in States implementation plans, no single option discussed emerged as a satisfactory solution for all the States.

[1] "Assessment of Potassium Iodide (KI) Distribution Program Among Communities Within the Emergency Planning Zones of Two Nuclear Power Plants", James Blando et al, The Radiation Safety Journal Vol 92, suppl 1 February 2007, Operational Radiation Safety

Discussion with Industry:

NRC staff discussed KI distribution with industry representatives and the Nuclear Energy Institute. There was considerable reluctance to assume responsibility from NRC for this program as the KI program is an optional one that has limited benefits in relation to the potential high cost. Industry representatives noted that the most current information regarding thyroid cancers in the pediatric population around the Chernobyl nuclear power plant confirms that the pathway responsible for most, if not all, the thyroid cancers was ingestion and extensive plans for prevention of contaminated foods are an integral part of current emergency plans.

Discussion with DHS:

In its discussion with NRC staff, DHS REP officials noted that the program was originated by the NRC and the role assigned to the Radiological Preparedness Program Office was only to verify the population data submitted by the States and to review updated emergency plans during subsequent plan reviews. DHS did not feel that it was the appropriate agency to be responsible for administration of a drug product to the general public. DHS REP staff pointed to Section 319F-2(c)(2) of the project Bioshield Act of 2004 that assigns DHS the responsibility, in conjunction with HHS and other agencies, to assess current and emergent threats of natural or chemical or biological, radiological, and nuclear agents, and to 319F-2(c)(7)(C), which states that HHS is ultimately responsible for managing the countermeasure procurement process including the negotiation of terms and entering into contracts for research, development, acquisition, procurement, storage and distribution of countermeasures.

Discussion with HHS:

HHS was tasked under the BioShield Act of 2002 Section 127 to support expanded distribution of KI to requesting populations within a 20-mile radius of a commercial nuclear power plant. HHS developed guidelines for expanded distribution in accordance with the requirements of the Act. These guidelines have not been finalized, and are pending review and determination on the applicability of Section 127(f) by the Executive Office of the President.

A liquid pediatric KI formulation was developed to support implementation of Section 127. Shortly after the liquid formula became available, NRC staff was approached by HHS Office of Public Health Emergency Medical Countermeasures (OPHEMC) and asked to facilitate distribution of pediatric KI to States participating in the NRC KI public distribution program. Only a few States requested liquid KI. HHS, however, is preparing to expand the offer to the population out to 20 miles in accordance with PL 107-188, Section 127 requirements. As many States noted in comment letters on the HHS draft guidelines for distribution of KI to 20 miles, the implementation of expanded KI distribution could have significant impact on public confidence in the rigorously-tested elements of the well-established 10-mile plume exposure EPZs around commercial nuclear power plants. In a November 1, 2005, letter to HHS commenting on the guidelines, the NRC also noted these concerns.

The OPHEMC has expressed willingness to further explore with NRC details regarding any potential for transfer of responsibilities for KI distribution from NRC to HHS/OPHEMC. Two key issues were identified during these discussions:

- HHS/OPHEMC traditionally works with State health departments and not with emergency management officials. There is concern that the appropriate emergency management decision-makers on the State and local level may not be involved in KI distribution and implementation decisions.

- HHS may choose to distribute KI to an area greater than the 10-mile EPZ in accordance with their tasking under the BioShield Act and the *Project BioShield Annual Report to Congress 2005* dated July 2006. This could result in confusion for members of the public who are outside the 10-mile EPZ and receives KI, but are not included in the planning that occurs for the populations within the 10 mile EPZ.

HHS officials are key stakeholders in determining the appropriate path forward for the NRC's program for KI distribution for the public. Continuing efforts need to be focused on strengthening the working relationships between these two agencies to determine the most appropriate path forward for use of KI by the public.

OPTIONS:

OPTION 1 - NRC RULE CHANGE TO REQUIRE LICENSEES TO FUND KI FOR STATES

PRO: A rule to require licensees to fund KI for EPZ populations would ensure long-term stability for current State KI programs.

CON: Such a rule change would likely be challenged by industry as a backfit. In particular, 10 CFR 50.109(a)(3) states that in order to require licensees to fund such a program "there is a substantial increase in the overall protection of the public health and safety or the common defense and security to be derived from the backfit and that the direct and indirect costs of implementation for that facility are justified in view of this increased protection." The most recent science may not support the threshold of "substantial increase in the overall protection of public health and safety…" A consensus opinion now exists within the international scientific community that the thyroid cancers that occurred as a result of the Chernobyl accident were likely the result of ingestion of contaminated milk and food products, and not as a result of an inhalation or external radiation dose. Based on this up-to-date science, licensees could argue that the preventive value of KI is not as advantageous as previously thought and not worth the substantial additional cost in money and personnel needed to implement the distribution of KI tablets to the public.

OPTION 2 - NRC RULE CHANGE TO DELETE USE OF KI FROM 10 CFR 50.47(b)(10)

PRO: States have always had the authority to include the use of KI in State radiological emergency plans. Many States felt substantial stakeholder pressure to include KI into State plans as a result of the NRC offer to fund KI tablets. Eliminating the requirement for States to consider use of KI from the rule would support States use of the most up-to-date science to make decisions that best provide for the health and safety of their populations.

CON: A change to the rule initiated by NRC staff could result in criticism by some members of the public.

OPTION 3 - NRC TO PURSUE TRANSFER OF KI PROGRAM TO HHS

PRO: HHS is the agency responsible for emergency stockpiling of pharmaceuticals. They have expertise in drug distribution and administration and have many programs available to assist States with emergency health care planning. Transfer of the program responsibilities to HHS would fit in with the HHS mission as the "U.S. Government's principal agency for protecting the health of all Americans..."

CON: The NRC could lose control over decisions on important aspects of KI distribution, such as the determination of which members of the population would receive KI and the recommendations for use of the product. HHS was tasked by the BioShield Act to make KI available to populations out to 20 miles around nuclear power plants. Expanded distribution of KI could negatively impact the current, well-tested and proven framework of the NRC and FEMA's long-standing, scientifically-based emergency preparedness regulations. Expanded distribution of KI could also undermine the public confidence in the NRC/FEMA 10-mile EPZ and result in a defacto expansion of the current 10-mile EPZ planning basis for all elements of emergency preparedness, not just for KI distribution. As a result, HHS (and not NRC and FEMA) may be perceived as the authority on protective actions for nuclear power plant events. This could result in guidance and/or actions from HHS that are at odds with established NRC/FEMA regulations/guidance.

OPTION 4 - NRC TO MAINTAIN RESPONSIBILITY FOR KI PROGRAM

PRO: The KI program has enabled the NRC to reach out to organizations and levels of State and local governments that are not typically involved in day-to-day radiological emergency planning, such as State and local health departments. Such outreach efforts with these groups have led to greater awareness of, and confidence in, the NRC.

Maintenance of the program by the NRC could ensure stability of the KI program and ensure KI distribution remains consistent with the NRC/FEMA established 10-mile EPZ until the Bioshield issue on KI distribution is resolved. KI tablets have a shelf life of at least 6 years; therefore, replenishment could become a predictable program that would operate on a 6 year cycle. For example, States would be notified that a "replacement window" of time will be available every 6 years to replenish KI stockpiles; all interested States would have the opportunity during that time to replenish existing stockpiles.

CON: Maintenance of the KI program will require financial and staff resources to continue to be dedicated to this program.

RECOMMENDATION:

At this time, the staff recommends Option 4. This option supports the NRC's current policy on use of KI for populations within the 10-mile EPZ. The staff also recommends that it be allowed to review the options for distribution of KI on a periodic basis as previously noted uncertainties are resolved, and report to the Commission the results of these reviews.

RESOURCES:

Absent new States requesting KI, the staff estimates the cost of Option 4 to be approximately $3 million dollars every 6 to 7 years, (starting in 2013), and an estimated average FTE of .1 annually. This resource estimate is a forward looking estimate and does not reflect the FY 07, FY 08, and FY 09 resources needed to complete the Commission's direction to support a one-time replenishment.

Options 1 and 2 could be included in emergency preparedness on-going rulemaking and there would be some incremental staff time; however, no additional resources would be needed.

Option 3 could be included as part of the regular staff outreach to stakeholders and, therefore, would require no additional resources.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Office of General Counsel has reviewed this paper and has no legal objection.

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