POLICY ISSUE
(Notation Vote)

June 21, 2006 SECY-06-0142

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations ***/RA/***

SUBJECT: OPTIONS AND RECOMMENDATIONS FOR REPLENISHING EXPIRED POTASSIUM IODIDE (KI)

PURPOSE:

To obtain Commission approval of the staff's recommendation regarding the replenishment of the expired potassium iodide (KI) provided by the U.S. Nuclear Regulatory Commission (NRC) to States, with populations in the 10-mile emergency planning zone (EPZ) of a commercial nuclear power plant.

SUMMARY:

The staff recommends extending the shelf life of stockpiled KI and replacing those tablets that have been previously distributed. Although certain resources have already been budgeted in FY 2007 for KI purchase and replenishment, the staff will address any additional unbudgeted resources resulting from the Commission's guidance in the Planning, Budgeting, and Performance Management (PBPM) process.

CONTACT: Kathryn M. Brock, DPR/NSIR
(301) 415-2015

BACKGROUND:

In 2001, NRC revised a section of its emergency preparedness regulations and amended 10 CFR 50.47(b)(10). NRC now requires States and Tribal Governments (henceforth called States) with a population within the 10-mile EPZ of commercial nuclear power plants to 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. If taken properly, KI reduces the risk of thyroid cancer by saturating the thyroid gland with non-radioactive iodine, thus inhibiting the uptake and potential for internal exposure to radioactive iodine. On January 19, 2001, NRC finalized and published the change in the *Federal Register* (Volume 66, No. 13, page 5427), and the rule change became effective April 19, 2001.

Along with this rule change, NRC funded an initial supply of KI for States with a population within the 10-mile EPZ that chose to incorporate KI for the general public into their emergency plans. In a letter dated December 20, 2001, NRC informed all 34 States with populations within the 10-mile EPZ of commercial nuclear reactors that upon request by the State, NRC would provide KI to these States, and 21 of these States have requested KI from NRC. The staff believes the final rule with the Commission's decision to fund the States' initial supplies of KI strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' roles in such matters.

The Commission has recognized the important role of State and local governments in emergency planning and thus far has made no commitment to replenish the initial supply. According to the Statements of Consideration published in the *Federal Register* on January 19, 2001, "The Commission expects that those States that 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 130-mg KI tablets originally issued in 2002 have a shelf life of 5 years, and these initial supplies will expire in 2007; therefore, the staff requests that the Commission give direction on the future of the KI tablet program.

On January 12, 2005, the Food and Drug Administration (FDA) approved the use of an oral solution of 65 mg/mL KI for children (i.e., liquid pediatric KI). In a letter dated November 10, 2005, NRC announced the availability of liquid pediatric KI for States with populations within the 10-mile EPZ. According to the NRC agreement with the Department of Health and Human Services (DHHS), NRC will fund the shipping costs of the liquid KI, and DHHS will provide the drug. The liquid KI program is separate from the tablet KI program and has no effect on the question of whether to replenish tablets.

DISCUSSION:

Twenty-one of the 33 eligible States and 1 Tribal Government requested that NRC furnish their initial supplies of KI as a supplemental protective measure for public health and safety. The use of KI has been integrated into these States' emergency plans. These States have made individual decisions regarding the issuance of KI to the public; some chose to stockpile the tablets, and others pre-distributed the tablets to the public. Based on discussions with several states, the staff estimates that for those states that stockpiled the tablets, each state may have pre-distributed approximately 10% of their supplies to the public. In either case, some States have informed staff that the expiration of the KI supply could be a financial burden. On several occasions, States have asked the Office of Nuclear Security and Incident Response (NSIR) staff about the Commission's intentions with regard to replenishment of the KI supply.

NRC's initial supplies included 130-mg KI tablets with a 5-year shelf life and 65-mg KI tablets with a 2-year shelf life. Although existing FDA regulations still require a shelf life for all drug products, the FDA recognized that KI in tablet form is very stable and can remain a viable product, when stored correctly (i.e., within temperature limits and not exposed to excessive humidity), long after the stamped date of expiration has passed. Therefore, FDA has issued guidance to the States recommending a process for a 2-year shelf life extension for the KI tablets. In addition, the FDA required a 2-year shelf life for the 65-mg tablet because this is the first product FDA approved for this manufacturer, the Swedish-owned Recip AB. FDA will increase the "base" shelf life as the FDA acquires additional information on the manufacturer.

NRC currently provides KI in 65-mg and 130-mg tablets for a State's initial supply. Anbex, Inc., holds NRC's current contract to supply KI and has supplied approximately 12 million tablets (65 mg and 130 mg) at a cost of approximately $2.2 million to NRC. The base contract expired in February 2006; however, the contract has three 1-year option periods, the first of which was exercised in March 2006.

There are two outside actions that may impact the NRC KI distribution program and replenishment decisions:

1. The Consumer Product Safety Council is considering requirements that all KI tablets be packaged in childproof packaging. This is consistent with the requirements for the pediatric formulation of KI and is due to the potential toxicity if a small child ingests an entire package of KI tablets. Such changes would include not only the packaging but also the labeling and possible dosage instructions. Childproof packaging will add a yet unknown cost to the tablets. The current negotiated price for the tablets does not include childproof packaging.

2. The decision regarding implementation of Public Law 107-188, Section 127 Expanded distribution of KI to 20 miles around nuclear power plants, is presently under consideration. If the decision is made to go forward with Section 127 implementation, it may be prudent for the Department of Health and Human Services to be responsible for all distribution of potassium iodide. There would be only one point of contact within the Federal government for States requesting KI. However, if Section 127 is implemented, the NRC decision on whether to replenish or extend KI stockpiles may have to be revisited.

NRC communicates updates to the KI tablet program through letters with the States. This has been an effective means of communication and has provided an efficient method for distributing KI to the States. This is the recommended approach to update States on the NRC's decision regarding replenishment or shelf life extension.

OPTIONS:

The staff has identified four options relating to the replenishment of KI for the Commission's consideration.

Option 1: *Do not replenish the existing KI supply.*

PRO: This option would require no action by the staff and would require no funds to be allocated by NRC. The States would be notified by letter of NRC's decision.

CON: This option could cause a financial burden to the States that previously accepted the Commission offer of KI and may not have the means to replenish the supply without NRC assistance.

Failure to continue the KI program begun in 2001 could raise public concern about the NRC's commitment to public health and safety.

Option 2: *Replenish the existing KI supply.*

PRO: This option would address the concerns of the States that have incorporated KI into their scheme of protective actions for the public but do not have the resources to replenish the supply.

CON: This option imposes the burden on the States of changing out stockpiles and disposing of thousands of KI tablets. Large quantities of KI may be considered as a hazardous material and require specialized and possibly expensive disposal by the States.

Because of the different shelf lives of the 130-mg and 65-mg tablets, the replenishment cycle will continue over the next several fiscal years.

The cost to NRC will be approximately $1.7 million for FY 2007 and approximately $500,000 for FY 2008.

Option 3: *Extend the shelf life of stockpiled KI and replace those tablets that have been pre-distributed.*

NRC would follow FDA's guidance for extending the shelf life of KI that was kept under controlled conditions such as in State stockpiles. Option 3 requires laboratory testing of samples from State stockpiles by either FDA or a private laboratory. Shelf-life extension using FDA guidelines would result in assurances of good product quality for an additional 2 years.

PRO: This option would address the concerns of the States that requested the initial supply of KI from NRC by enabling them to extend the shelf life of their KI stockpiles and would provide additional KI to replace previously distributed tablets.

This option would eliminate the concerns regarding disposal of large quantities of KI and the burden of changing out the stockpiles held at various reception and emergency centers. States would have confidence in their current KI stockpiles .

This option is less expensive for NRC to implement and still assures the integrity of the KI tablets in the various State stockpiles.

CON: This option is more complex than Options 1 and 2. NRC will need to contract with a laboratory capable of shelf life extension testing and develop a process for States to send KI samples for testing.

All tablets that were initially distributed must be replaced. At least one State pre-distributed all of its tablets; therefore, NRC will need to replace this State's entire supply. Other States pre-distributed only some of its tablets and kept the remainder in storage.

The shelf life can be extended for 2-years at a time. An extension would be requested every 2 years for as long as the tablets are held. Additionally, there is the possibility that part of a State's stockpile will fail the shelf life extension and result in the need to partially replenish a State's supply.

There is concern by the States that the public will be reluctant to take a drug product with an outdated expiration date marked on the packaging.

The estimated cost to NRC to perform shelf life extension testing for all tablets in State control, make initial purchases, and to replenish approximately 10% of the pre-distributed tablets is approximately $400,000 for FY 2007 and $400,000 for FY 2008.

Option 4: Extend the shelf life of stockpiled KI and do not replenish pre-distributed supplies

PRO: This option would address the concerns of the States that requested the initial supply of KI from NRC by enabling them to extend the shelf life of their KI stockpiles.

This option would reduce the concerns regarding disposal of large quantities of KI from States would have confidence in their current KI stockpiles and not have to exchange their supplies.

This option is less expensive for NRC to implement and still assures the integrity of the KI tablets in the various State stockpiles.

This option would remove the NRC from the business of restocking KI supplies, which in the future may require additional oversight or expensive child-proof packaging.

CON: Similar to Option 3, this option may be complex. NRC will need to contract with a laboratory capable of shelf-life extension testing and develop a process for States to send KI samples for testing.

The shelf-life can be extended for 2 years at a time, and an extension must be requested every 2 years for as long as the tablets are held. Additionally, there is the possibility that a part of a State's stockpile will fail the shelf-life extension, so that the State has to replenish its own supply.

The estimated cost to NRC to perform shelf life extension testing for all tablets in State control and make initial purchases would be approximately $300,000 for FY 2007 and $350,000 for FY 2008.

RECOMMENDATION:

Although Option 1 is the least expensive option, it may cause some members of the public to question the NRC's commitment to public health and safety. Option 2 would be the largest resource burden for both NRC and the States for such a low probability event requiring the need for KI used by members of the public. Selecting either Option 3 or 4 will result in a continuous cycle of shelf life extensions for the pills, thereby requiring annual dedicated funds for KI. The staff recommends Option 3. This option supports the NRC's current policy that KI is a reasonable and prudent supplement to evacuation and sheltering for populations within the 10-mile EPZ, reduces costs for NRC and the States, and ensures the integrity of the KI product currently in States' stockpiles. The NRC will need to replace only those KI tablets that have been pre-distributed.

The staff recommends that NRC send a letter to the States within the 10-mile EPZ of a commercial nuclear power plant informing them of NRC's decision and provide additional guidance on the specific option selected.

RESOURCES:

The staff estimates the cost of Option 3: to extend the shelf life of all tablets in State control, to replenish approximately 10% for the pre-distributed tablets and fund initial KI purchases, is $400,000 in FY 2007 and $400,000 in FY 2008. These resources are included in the proposed FY 2008 budget. At this point, the staff does not anticipate any additional requests from the 12 states and 1 tribal nation that have not yet ordered any KI. However, if additional requests for initial purchase or replacement are received from the States, the staff may need to reallocate additional funds to support these requests.

COORDINATION:

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

/RA/

Luis A. Reyes
Executive Director
for Operations