REQUEST REPLY BY: 2/12

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

COMSECY-07-0002

January 26, 2006

Approved, subject to attached comments.

Dale E. Klein 2/9/07

MEMORANDUM TO: Chairman Klein
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: POTASSIUM IODIDE REPLENISHMENT

The purpose of this memorandum is to inform the Commission of the status of staff efforts to replenish Potassium Iodide (KI) tablets for those States currently providing it for populations within the 10-mile Emergency Planning Zone (EPZ) as directed by the Staff Requirements Memorandum on SECY-06-0142, "Options and Recommendations for Replenishing Expired Potassium Iodide (KI)". In SECY-06-0142, the staff provided an estimate of $1.7 million in FY 2007 and $500K in FY 2008 for replenishment of existing KI stockpiles. At the time SECY-06-0142 was submitted to the Commission, the staff expected that the States would request the same number and dose of tablets as they did with their original order. The staff also estimated that the bulk of the replenishment orders would be filled during the first quarter of FY 2007 before the price increase in the second quarter of FY 2007 when option year 3 of the contract would take effect (approximately $100K cost increase for 13 million tablets). In addition, due to the shelf life of the tablets, the staff estimated that the replenishment request would come 5 years after the original order for the Anbex, Inc. (Anbex)130 mg tablets and 2 years after the original order for the Recip Stockholm AB (Recip) 65 mg tablets.

Due to the impacts of the Continuing Resolution, the staff contacted the States in December 2006 to verify the resources needed to implement the Commission's direction. At that time, the staff identified that all States indicated interest in replenishment of KI stockpiles in FY 2007 and, thus, the $2.3M projected for KI will be needed in FY 2007. During these discussions, some States indicated interest in extending the shelf life of stockpiles rather than full replenishment.

As a result of these and subsequent discussions with States, the staff is pursuing shelf-life extension options with the Food and Drug Administration (FDA). The FDA considers extending the new expiration dating to the previously manufactured lots scientifically sound if there were no significant differences in the formulation, manufacturing process, or packaging materials for

CONTACT: P.A. Milligan, NSIR/DPR
301-415-2223

Chairman Klein's Comments on COMSECY-07-0002,
Potassium Iodide Replenishment

I approve the staff's current course of action in engaging the States in the effort to resolve the issue of the pending expiration of the shelf life of potassium iodide (KI) that has been provided to States by the NRC. As with the agency's interactions with States in other areas of common interest, the staff's experiences thus far show that each State's needs and perspectives differ, and the NRC and States can, and should, collaborate to develop solutions that work best for the affected people. The staff should continue to engage the States to obtain their views on this matter, and should factor State insights into the options paper that will be provided to the Commission in May 2007.

DK
2/9/07

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UNITED STATES
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COMSECY-07-0002

January 26, 2007

Approved subject to the attached comments.
/RA/ 2/8/07

MEMORANDUM TO: Chairman Klein
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Commissioner Merrifield
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Commissioner Lyons

FROM: Luis A. Reyes
Executive Director for Operations

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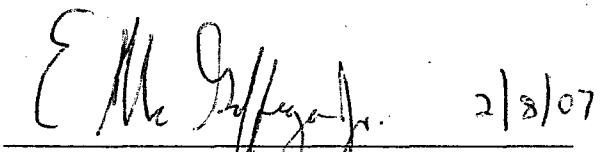
Commissioner McGaffigan's Comments on COMSECY-07-0002

I approve of the Staff's efforts to pursue shelf-life extension options with the Food and Drug Administration, assisting States providing Potassium Iodide (KI) tablets for populations within the 10-mile Emergency Planning Zone. Consistent with the Commission's direction in the Staff Requirements Memorandum on SECY-06-0142, the Staff should also continue its efforts to replenish KI for those States that have expressed a need for either complete or partial replenishment. In the SRM, the Commission instructed that the staff "should make it clear that this replenishment is a one-time action and will not be renewed in the future." I do not believe that the partial replenishment requested by New York, and possibly Connecticut, Delaware, Arizona, Maryland, New Jersey and Pennsylvania, should count as the "one-time action" contemplated by the Commission.

The Commission should be kept informed of any changes in the budget implications resulting from continued funding of the KI program, any additional responses from the States regarding shelf-life extension or replenishment, and any other significant developments affecting the program.



2/8/07

Edward McGaffigan, Jr. (Date)

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
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COMSECY-07-0002

January 26, 2006

Approved, subject to the attached comments.

MEMORANDUM TO: Chairman Klein
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons

FROM: Luis A. Reyes
Executive Director for Operations

2/12/07

SUBJECT: POTASSIUM IODIDE REPLENISHMENT

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Commissioner Merrifield's Comments on COMSECY-07-0002
Potassium Iodide Replacement

While I continue to support the use of potassium iodide as a prudent measure in implementing offsite protective strategies in the event of a severe nuclear power plant accident, I find the specific actions of Anbex to require more money to relabel its product to reflect a longer shelf-life unconscionable. It is bad enough that companies such as Anbex profit from the fear of radiation releases from nuclear plants held by the general public, but the letter from Anbex appears to border on sheer greed to profit from the American government. In January 2004, Anbex received FDA approval for a shelf life of seven years for the same potassium iodide product that is the subject of the NRC contract. In my opinion, the Anbex letter that states that they are willing to extend the expiration date for "...a mutually agreeable price..." appears to be a blatant attempt to defraud the American people and government by requesting payment for something that the pharmaceutical company has already received. In my opinion, the Commission should request that Congress investigate what appear to be actions by Anbex to engage in profiteering at the expense of the American people.

As for the specific staff activities, I support the recent staff activities to work with States to best determine the means by which existing potassium iodide stockpiles are maintained or replaced. As reflected in the staff's memorandum, some States prefer the option of shelf-life extension to replenishment and have actively pursued documentation that would support 2 year extensions to the expiration dates for stockpiled supplies. The Food and Drug Administration has recently issued guidelines for manufacturers to use to justify extensions of shelf-life for existing products manufactured in accordance with the FDA Good Manufacturing Processes. In addition, the American Thyroid Association acknowledges that the shelf-life of potassium iodide in tablet form is at least 5 years and could last as long as 11 years without any decrease in its effectiveness.

Consistent with the previous Commission position, I also continue to support the implementation of Option 2 of SECY-06-0142 for those States that wish to pursue replenishment of their existing potassium iodide stockpiles at the end of the manufacturer's published shelf-life.

The Commission has stated that potassium iodide can be considered as a protective measure for the general public to supplement the sheltering or evacuation strategies employed by the States in the event of a severe nuclear power plant accident. Consistent with my previous votes on the distribution and use of potassium iodide, I continue to believe that it is appropriate at this time for the staff to work with the Department of Homeland Security (DHS) and other cognizant Federal agencies responsible for consumer products to align funding, distribution and product management of this drug with the appropriate State authorities. DHS has been given the primary responsibility for off-site contingency planning and the staff should work to return the potassium iodide program to DHS.

I note that in the SRM on SECY-06-0142 the staff was directed to provide options to the Commission for future potassium iodide supply and replenishment by May 15, 2007. I would expect the staff to include discussions about its interactions with DHS or other federal agencies and any plans to transfer the potassium iodide program to a more appropriate lead agency, as well as the replenishment cost estimates for FY '07 and '08.

2/12/07

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UNITED STATES
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COMSECY-07-0002

January 26, 2006

Approved with attached comments.

Gregory B. Jaczko 2/9/07 Date

MEMORANDUM TO: Chairman Klein
Commissioner McGaffigan
Commissioner Merrifield
Commissioner Jaczko
Commissioner Lyons

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: POTASSIUM IODIDE REPLENISHMENT

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301-415-2223

Commissioner Jaczko's Comments on COMSECY-07-0002
Potassium Iodide Replenishment

I approve the staff efforts to comply with the requirements of SECY-06-0142. As I indicated in my vote on that paper, I continue to believe the staff should work with the states, as they have done in this case, to replenish tablets or to extend the shelf-life of tablets consistent with the Food and Drug Administration determinations.

2/9/07

Gregory B. Jaczko Date

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
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COMSECY-07-0002

January 26, 2007

Approve, with comment.

Peter B. Lyons 2/5/07
Peter B. Lyons Date

MEMORANDUM TO: Chairman Klein
Commissioner McGaffigan
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Commissioner Lyons

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: POTASSIUM IODIDE REPLENISHMENT

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Commissioner Lyons' Comments on COMSECY-07-0002

I appreciate the staff's efforts to better define the order and magnitude of the States' need for potassium iodide (KI) replenishment. I continue to support staff efforts to replenish KI for States with KI tablet expiration dates in 2007. I look forward to options and staff recommendations in the May 2007 paper to better inform the future of NRC's KI program. While I support the staff's role of facilitator between the States and the Food and Drug Administration regarding shelf life extensions, development of the basis to support a final decision to extend the self life must remain with the States.

Peter B. Lyons 2/5/07

Peter B. Lyons Date