June 29, 2001

COMMISSION VOTING RECORD

DECISION ITEM: SECY-01-0069

TITLE: STATUS OF POTASSIUM IODIDE ACTIVITIES

The Commission (with Chairman Meserve and Commissioners Diaz and Merrifield agreeing and Commissioners Dicus and McGaffigan agreeing in part and disagreeing in part) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of June 29, 2001.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

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Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO

VOTING SUMMARY - SECY-01-0069

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	6/27/01
COMR. DICUS	X	X			X	6/25/01
COMR. DIAZ	X				X	5/14/01
COMR. McGAFFIGAN	X	X			X	6/19/01
COMR. MERRIFIELD	X				X	6/21/01

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners Diaz and Merrifield approved the staff's recommendation and provided some additional comments. Commissioners Dicus and McGaffigan approved in part and disapproved in part the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on June 29, 2001.

Commissioner Comments on SECY-01-0069

Chairman Meserve

I approve the staff's proposal to publish Draft NUREG-1633 for public comment, subject to the following suggestions.

First, I concur with the suggestion that the publication of Draft NUREG-1633 should await the publication of the final FDA guidance so that the final version can be included in the NUREG. It is my understanding that this guidance should not be unduly delayed. The staff should also continue their interactions with FEMA so that the NUREG can reflect, as appropriate, the understandings that have been reached as to how the program will operate.

Second, I agree with my colleagues that the NUREG should be consistent with the statements of consideration in the final rule and should include the most up-to-date information available concerning the experience of States and foreign governments in the distribution of KI. Because the FDA guidance should provide the foundation for the NUREG, I do not believe it is necessary to include WHO or IAEA documents within the NUREG. Of course, these other documents should be referenced appropriately.

Finally, I agree with Commissioner McGaffigan that the staff should urge FDA to address the issue of KI prophylaxis for those over 40 years of age under the postulated circumstances of a reactor accident.

Commissioner Dicus

I approve the staff recommendation to publish draft NUREG-1633 for a 60-day public comment period but only after the FDA guidance is issued in final form, which should be sometime in the very near future. This will allow the staff to fully incorporate the FDA guidance as final (rather than proposed) and will prevent the NUREG from going out twice for public comment (once now with draft FDA guidance, and then once later when the FDA document is made final). The is a much more efficient process saving staff resources with minimal delay in publication of the NUREG.

Before NUREG-1633 is published for public comment, I would strongly recommend that this NUREG continue to be an options guidance document for the States, that presents both the pros and cons of stockpiling KI as a compliment to other emergency protective actions such as sheltering and evacuation. It is important that those States willing to share their experiences with KI be included in this NUREG, which will provide its readers with the experience of States and those in the international Communities who have chosen to stockpile or not to stockpile KI. This is in keeping with the intent of the Staff Requirements Memorandum, dated December 22, 2000, which stated that the final rule amending 10 CFR 50.47(b)(10) "... require that consideration be given to including the prophylactic use of KI as a protective measure..."

In addition, I would recommend that the only document to be inserted in its entirety in NUREG-1633 be the final FDA guidance (when published), and that only references be made to other international recommendations of the WHO and IAEA.

Finally, I believe it would be advisable to have the EDO contact appropriate senior management

at FEMA to discuss our plans regarding KI with FEMA before NUREG-1633 is finalized, as well as to obtain input as to what the new Administration's views and FEMA roles are on this important issue. One of the outcomes of this meeting could be that the NRC would be able to obtain a more accurate timeline of when the Commission could expect to see a Federal KI Policy (from the FRPCC) as well as to ensure that FEMA continues to maintain a leadership role in the distribution and implementation of KI for those States that decide to stockpile KI.

Additional, specific comments for recommended changes to NUREG-1633 are attached to this vote sheet.

Commissioner Diaz

I approve staff's recommendation to publish draft NUREG-1633 for a 60-day public comment period, subject to my comments below. Publication of this document to solicit comments is important to ensuring that the document contains complete and clear information to assist the States in making their decision on whether the prophylactic use of potassium iodide (KI) for their population is appropriate in the unlikely event that a severe reactor event occurs.

Before the NUREG is published for public comment, I believe that it should be further modified to ensure that it follows the Commission policy in the Statement of Considerations for the final rule, "Consideration of Potassium Iodide in Emergency Plans" (66 FR 5427). The NUREG should not read as an options paper; it should support the Commission's policy requiring States to consider including KI as a protective measure for the general public and committing to providing funding. Therefore, wherever possible, the Commission-approved statements and responses to public comments on the final rule should be reiterated in the NUREG. For example, Section 4.2 (Consideration of the Use of KI) and Section 4.3 (Funding of KI) of the NUREG should more closely reflect the responses to Issue E (Requiring versus Considering Use of KI) and Issue F (Funding), respectively. Likewise, the recommendations of health organizations on using KI to reduce the risk of thyroid cancer should be reiterated clearly to help the States with their decision making.

I agree with including the Food and Drug Administration's (FDA), Department of Health and Human Services (HHS), guidance document, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," in its entirety in the NUREG. This document also includes guidance for the State and local government, developed under 44 CFR 351, and I believe it would be helpful to have it readily available with the NRC's guidance. Because the FDA guidance includes a section on the World Health Organization (WHO) recommendations, I do not believe that we also need to include the entire WHO document, "Guidelines for Iodine Prophylaxis Following Nuclear Accidents; Update 1999."

As Commissioner McGaffigan noted at the May 9, 2001 briefing by the staff, information needs to be presented in a manner that is useful to the States and includes our knowledge of how States have approached deciding the KI issue, e.g., Ohio. It is important for the States to have the benefit of up-to-date information on experiences associated with the use of KI in States and other countries.

I continue to strongly believe that we have a responsibility to clearly aid the States by providing them with information and with funding. The NRC can then trust the States to make the right decision, knowing that we have done our best to protect public health and safety.

Commissioner McGaffigan

I would like to preface my comments by recognizing the staff's efforts to conform NUREG-1633 with the Commission's position in the final rule amending 10 CFR 50.47(b)(10). This draft is much improved over prior drafts, but in my view, still falls short in several areas in carrying out prior Commission guidance, and requires further work before publication for comment.

Background

In 1998, the Commission decided that a previous version of this draft NUREG should be withdrawn and substantially revised. The September 30, 1998 SRM stated:

> The reissued document should include an improved discussion of how the practical problems in KI stockpiling, distribution and use are handled in states which already use KI as a supplement and in the numerous nations who use KI as a supplement. A discussion, in some detail, of the various guidance documents of the World Health Organization and International Atomic Energy Agency, as well as the U.S. Food and Drug Administration, would be very useful to state and local decisionmakers. The guidance should be consistent with the policy adopted by the Commission in response to the petition for rulemaking and should fairly discuss the factors that need to be weighed in state and local decisions.

In the Statement of Considerations on the final KI rule the Commission also set some expectations with regard to the draft NUREG. The Commission stated:

> The NRC recognizes that any decision to use KI as a supplemental protective measure for the general public presents issues of how best to position and distribute the medicine, to ensure: (1) that optimal distribution takes place in an emergency, with first priority given to protecting children; (2) that persons with known allergies to iodine not take it; and (3) that members of the public understand that KI is not a substitute for measures that protect the whole body. To date, these issues have been addressed in different ways in the numerous countries that currently use KI as a protective measure for their citizens. The NRC is working with States and other Federal agencies to develop guidance on these and other issues relating to the use of KI. The NRC believes that these implementation issues can be solved, given the level of expertise in the relevant Federal and State agencies, and the experience of numerous nations that have built KI into their emergency plans.

Discussion of revised draft NUREG 1633

As I said above, I believe the staff has attempted to conform the paper with the Commission's position in the final KI rule. However, I believe that the paper still does not fully implement the objectives outlined in the September 30, 1998 SRM and in the SOC on the final KI rule. Therefore, I do not approve the publication of the draft NUREG for comment at this time. After the passage of time, and the development of other national and international policy and guidance documents, I believe that it would be helpful for the staff to take the time to review the overall objectives of NUREG-1633. In light of the FDA guidance, the FEMA policy statement, the Commission's SOC on the final KI rule, and the revised EPA protective action guidelines, what role can this NUREG fulfill? In addition, through many iterations, this document has lost some coherence and internal consistency. Therefore, I would urge the staff to undertake a global

review of the scope and contents of this NUREG to make it a more useful document. The time taken to carry out this review will have the added benefit of ensuring that the final FDA guidance can be incorporated into this draft. In lieu of a detailed mark-up of my comments on this draft, I will note broad areas for focused staff attention:

Chapters 5 and 6, which discuss respectively U.S. and International experience with KI as a supplemental public protective action, have until recently been appendices. They still seem an after-thought with little coherence, in part because of the methodology adopted by staff of basically repeating the input received. In Chapter 5, I would have included the states of Ohio and Maine, both of which have moved toward inclusion of KI in their emergency plans (although in Maine's case the closure of Maine Yankee meant the policy was never implemented). I don't know why Pennsylvania is included. They have not completed their process and the discussion doesn't help on how the practical problems of KI distribution are handled. I would also note that current emergency plans have long provided for KI prophylaxis for plant workers, emergency workers (such as law enforcement personnel), and certain members of the public at institutions within emergency planning zones, such as hospitals and prisons, whose evacuation would be delayed. Perhaps there is something to be learned from how States, such as Connecticut, have planned to carry out this limited effort of KI prophylaxis.

Given the vast international experience in planning for KI use, Chapter 6 clearly should be expanded. The information on France is particularly out of date. It is my understanding (from periodicals and conversation with French officials) that the French have moved to predistribution to homes. I would note that there is an excellent discussion (in French) on the DSIN home page (www.asn.gouv.fr/temp/faq/sommaire.html) on what to do in case of a radiological emergency, including the potential use of iodine prophylaxis. It is written in "Plain French" in a question and answer format and could serve as a model for an emergency planning section on the NRC web page someday. I do not expect the staff to discuss in detail every nation which has included KI prophylaxis in its emergency plans, but a fuller and more up-to-date discussion of a representative sample, perhaps together with a table listing the nations who have adopted KI prophylaxis pursuant to WHO and IAEA recommendations, should be achievable.

In 1998, the Commission also called for a discussion of WHO, IAEA, and FDA documents. Chapter 3 now consists of the draft FDA guidance while Appendix A provides the 1999 WHO guidance. No IAEA guidance is mentioned, apparently because it is currently under review. But this results in the peculiar situation that the FEMA draft KI policy (see December 22, 2000 SRM on the final KI rule) references three IAEA documents while NRC's NUREG references none. The fundamental point that the State and local decisionmakers need to understand is that WHO and IAEA have for some time recommended KI prophylaxis be part of emergency plans. There have been differences between the agencies over time as to the appropriate intervention level (1 vs. 5 vs. 10 rem) and KI dose for various age cohorts. In this country FDA's final guidance will resolve those issues and will be incorporated in our guidance, FEMA's guidance, and EPA's updated protective action guidelines (PAGs). A discussion of the history of international KI guidance, including IAEA guidance, should be included in the main body of the report. I am wary of including the 1999 WHO guidance as an appendix because it was not fully endorsed by the American Thyroid Association (because of the 1 rem intervention level recommended) or by the FDA and is already adequately discussed in FDA's guidance (Chapter 3).

I would also suggest restoring a discussion of the pros and cons of various KI distribution logistics, in a chapter informed by, and located after, the expanded and updated discussions of the U.S. and international experiences.

I question the need for much of Chapter 2 which strikes me as duplicative of the FDA guidance in Chapter 3. If Chapter 2 is retained, it will need work. In particular, I would note that UNSCEAR 2000 Appendix J (page 504) stated: "There can be no doubt about the relationship between radioactive material released from the Chernobyl accident and the unusually high number of thyroid cancers observed in the contaminated areas during the past 14 years." I read the UNSCEAR 2000 report as consistent with and supportive of both WHO's and FDA's guidance.

Finally, the discussion of the alternative source terms in Chapter 1 appears to me to be stated more categorically than other source term documents that have been presented to the Commission. NUREG 1465, for example, states that "it is important to emphasize that the release fractions for the source terms presented in this report are intended to be representative or typical, rather than conservative or bounding values, of those associated with a low pressure core-melt accident." Similarly, Regulatory Guide 1.183 states: "Although the AST provided in this guide was based on a limited spectrum of severe accidents, the particular characteristics have been tailored specifically for DBA analysis use. The AST is not representative of the wide spectrum of possible events that make up the planning basis of emergency preparedness." Reg. Guide 1.183 also includes scenarios (e.g., PWR steam generator tube ruptures, PWR rod ejection accidents) in which iodine releases from steam generators to the environment are elemental iodine, not cesium iodide.

However, rather than expanding or correcting the source term discussion, I would encourage the staff to reconsider whether this section is necessary or relevant. The thrust of the current discussion seems to be that the risk of a significant radioactive iodine release in U.S. reactors is small to nonexistent. However, the use of KI, like the use of other emergency preparedness measures, is not based squarely on probabilistic considerations. Rather, it is predicated on the Commission's original finding that emergency preparedness is an essential aspect of the protection of public health and safety, in conjunction with the Commission's recently issued decision that "KI is a reasonable, prudent, inexpensive supplement to evacuation and sheltering for specific local conditions." If the staff wishes to rebut the implication that consideration of KI use is being required because there was some newly recognized increased risk, I would suggest that the staff set the correct context in the NUREG from the outset with a restatement of Commission's policy decision, perhaps using text quoted from the Federal Register notice on the recent final rule on KI (56 FR 5427; January 19, 2001), and that the source term discussion be eliminated.

<u>Development and Implementation of a KI program</u>

I agree that the options that the staff identified for the application process and for distribution of KI purchased for the States by the NRC are appropriate for further discussion with FEMA.

One important issue that will require further clarification for the development and implementation of a KI program is definitive guidance on KI prophylaxis for individuals over 40. Both WHO and FDA set the intervention level for iodine prophylaxis for those over 40 at 5 gray (500 rem) to the thyroid. WHO states:

> The risk of radiation induced thyroid cancer in this group (adults over 40 years) is probably extremely low and may even be zero. The risk of side effects from stable iodine increases with increasing age as the incidence of thyroid diseases is higher. Stable iodine prophylaxis is not indicated for this group unless doses to the thyroid from inhalation rise to levels threatening thyroid function, that is of the order of about 5 Gy.

Such radiation doses will not occur far away from an accident site.

Since we do not expect, even in the worst circumstances, any member of the public to receive 500 rem to the thyroid, it would be useful for FDA to clarify whether we should plan for KI prophylaxis for those over 40. It is my understanding that the staff has already received an inquiry on this issue from the Conference of Radiation Control Program Directors (CRCPD). At interagency meetings, the staff should urge FDA to address this issue in its final guidance document. To document this concern, the staff may want to refer the CRCPD letter to FDA for resolution.

The Commission should be informed promptly of any issues requiring Commission resolution.

Commissioner Merrifield

I approve the paper and issuing the attached NUREG-1633 subject to following comments.

I agree with Commissioner Diaz that the NUREG should be further modified to ensure that it follows the policy of the Statement of Consideration (SOC) for the final rule. In addition to the sections that Commissioner Diaz mentions, the staff should modify the discussion of Commission's findings with respect to use of KI. The SOC states, "[t]he Commission finds that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions." Final Rule: Consideration of Potassium Iodide in Emergency Plans, 66 Fed. Reg. 5427, 5430 (Jan. 19, 2001)(underline added). The draft NUREG repeats a portion of this finding in numerous places, but in every instance leaves off the language that I have underlined. The staff should modify the draft NUREG to include the entire quote each time it is repeated. The quote should also always be put in context. For example, in the SOC the quote is directly followed by the following discussion in responding to a commenter:

> Through its decision to require that the use of KI be 'considered' (rather than being required), the Commission is acknowledging that the efficacy of any protective measure will depend upon a number of factors, including those noted by the commenter, that can vary not only between countries but in individual States. Thus, the Commission concluded that decisions on the use of KI need to be resolved on a case-by-case basis. As part of this consideration, State and local governments can weigh **all** relevant factors. 66 Fed. Reg. at 5430 (emphasis added).

This discussion, or a slightly modified version, should be added to the various places in the NUREG that repeat the quote. Further, an informed decision by the state on "all" relevant factors requires a balanced NUREG-1633. To me, if this means that the NUREG looks like an options paper, that is appropriate, in light of the Commission's expressed decision to require consideration of use of KI, not to require use of KI. An unbalanced, factually deficient NUREG would clearly undermine that important distinction.

The staff should continue its efforts to ensure that future modifications to the NUREG and KI policy do not undermine other NRC regulations and policies concerning emergency planning. Similarly, the staff should continue its efforts to remain neutral on FDA's proposed guidance. A federal decision to not recommend KI for persons over 40 could be highly controversial at the State level and is clearly within the medical expertise of the FDA. Therefore, any staff discussions with FDA on the age cut-off issue should strive to remain neutral on the matter. To ensure that the NUREG is as thorough as possible, the staff should await finalizing the NUREG

until it receives FDA's final guidance.

It is troublesome to me that the resource implications of the various options for the Application Process and Distribution Process are not well understood at this time. As with any new endeavor, when considering options, the staff should consider how to most efficiently and effectively use our resources. In this context, the most important effort by the staff should be to ensure that to the maximum extent possible, Commission funds allocated for stockpiles go toward purchasing actual KI tablets, rather than toward administrative costs.

As the SRM associated with the final rule indicates, the Commission is fully supportive of the staff working with the Federal Emergency Management Agency (FEMA), in FEMA's role to carry out the KI policy. It was my expectation that FEMA would be the agency carrying out the bulk of the implementing functions for stockpiling. Congress has given FEMA, not the NRC, the primary responsibility for off-site emergency planning. For its part, and at FEMA's urging, the Commission has committed significant resources to finalize a rule requiring consideration of KI, to provide a draft Federal KI Policy, to provide NUREG-1633, and finally, to provide funding for KI stockpiles. I am concerned about FEMA's comment on the draft KI policy, dated May 4, 2001, stating that "there is still a great deal of uncertainty regarding what role, if any, FEMA will have in either the purchasing or distribution of KI to the States. This role will need to be clearly defined and concurred in by Director Allbaugh before we can feel comfortable endorsing the NRC's proposed KI policy." The staff should make it clear to its FEMA counterparts that the success of the Federal KI policy depends on FEMA asserting a leadership role by agreeing to carry out necessary implementing functions and finalizing a Federal KI policy.

The staff should explore the option of the federal government negotiating a contract with a pharmaceutical company to supply all stockpiles of KI, for any state that requests it, at a certain price that will include distribution. Under such a contract the federal government would not be responsible for physically storing KI, in anticipation of State requests, or distributing KI, but would be able to benefit from bulk purchase pricing. This may eliminate or reduce some of FEMA's concerns about purchasing and distribution.