



OFFICE OF THE
SECRETARY

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

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.

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.

NOTATION VOTE

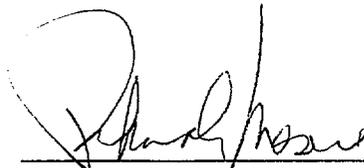
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: CHAIRMAN MESERVE
SUBJECT: **SECY-01-0069 - STATUS OF POTASSIUM IODIDE
ACTIVITIES**

Approved ^{w/comments} X Disapproved _____ Abstain _____
Not Participating _____

COMMENTS:

SEE ATTACHED COMMENTS.



SIGNATURE

June 27, 2001

DATE

Entered on "STARS" Yes X No _____

CHAIRMAN MESERVE'S COMMENTS ON SECY-01-0069

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.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER DICUS
SUBJECT: **SECY-01-0069 - STATUS OF POTASSIUM IODIDE
ACTIVITIES**

Approved x ^{Inpart} Disapproved x ^{Inpart} Abstain _____
Not Participating _____

COMMENTS:

See attached comments.

Greta Jay Dicus
SIGNATURE

June 25, 2001
DATE

Entered on "STARS" Yes x No _____

Commissioner Dicus' comments on SECY -01-0069:

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). This 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 complement 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.

gjd
6-25-01

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6-25-01

PREFACE

This document presents information to assist State officials in determining whether the prophylactic use of KI for their population is appropriate in the unlikely event that a severe reactor accident occurs within their state. The Commission finds that the use of KI is a reasonable, prudent, and an inexpensive supplement to evacuation and sheltering. The Commission also finds that KI would help prevent thyroid cancers in the unlikely event of a major release of radioactive iodine. Therefore, the Commission has amended its emergency planning regulations to require that off-site authorities consider KI as a protective measure for the general public that would supplement evacuation and sheltering.

In order to assist emergency management officials to make fully-informed decisions about the use of KI, the staff has presented information on accident scenarios and offsite consequences, source terms, exposure pathways, the role of emergency preparedness, and appropriate protective action measures, including the benefits and risks of using KI. This document also contains ~~final draft~~ guidance from the Food and Drug Administration on the use of KI as a thyroid blocking agent, ~~as well as World Health Organization recommendations~~. In addition, information on stockpiling KI for the general public, logistics, amounts of KI, and public information needs from the experience of State and foreign governments that have made KI available to the public are included.

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6-25-01

EXECUTIVE SUMMARY

In response to petitions for rulemaking, the Commission directed the NRC staff in June 1998 to proceed with rulemaking to require that in developing the range of protective actions, consideration should be given to evacuation and sheltering, and, as a supplement to these, the prophylactic use of KI, as appropriate. In a final rule published in the *Federal Register* on January 19, 2001, the Nuclear Regulatory Commission amended its emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule requires that consideration be given to including potassium iodide (KI) as a protective measure for the general public that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactive iodine from a nuclear power plant. The Commission found that KI is a reasonable, prudent, and an inexpensive supplement to evacuation and sheltering.

The use of KI is intended to supplement, not replace, other protective measures, such as evacuation and sheltering, which the Commission continues to view as the most effective measures in the event of a radiological emergency. The Commission recognizes the supplemental value of KI and the prerogative of the State to decide on the appropriateness of the use of KI by its citizens. The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's initial supply 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' role in such matters. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave this decision to State and local emergency response planners, who may find that KI should be a supplementary protective measure, rather than to mandate its use. To assist the State and local officials, the Commission directed the staff to develop this guidance document to help State and local planners in reaching an informed decision concerning use of KI as an appropriate protective supplement.

Following the Chernobyl accident, excess thyroid cancer has been detected among children in Belarus, the Ukraine, and Russia. Most of the affected children lived more than 16 km (10 miles) from the reactor and ingestion of contaminated foodstuffs contributed the majority of their thyroid doses. This experience indicates the importance of early action to prevent ingestion of contaminated foodstuffs by the general public, especially children. Conversely, Poland has not detected excess cancers resulting from the intake of radioiodines. In Poland, a 40-45% reduction in thyroid burden due to thyroid blocking by KI and milk restrictions demonstrates the value of implementing a range of protective measures. The Polish experience supports the use of KI as a safe and effective prophylaxis for the thyroid gland across a large population.

This guidance document ~~presents information and~~ discusses the various factors that need to be weighed in State and local decisions on the use of KI. ~~This document presents information from which State and local officials can draw conclusions pertinent to their specific conditions related to the use of KI by the general public. This guidance begins with a brief discussion of~~ The basis for emergency planning, reactor accidents and associated consequences, and an overview of severe reactor accident source terms are ~~briefly discussed~~. Next, thyroid and whole body doses, their associated risk assessments, and their relationship to severe reactor accident source terms are discussed. In addition, ~~This guidance document contains a~~

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discussion of how the practical problems in KI stockpiling, distribution, and use are handled in the States which already use KI as a supplement and in the several nations which use KI as a supplement. The staff has also included guidance documents of the World Health Organization (WHO) and the final guidance document from U.S. Food and Drug Administration (FDA), which should be useful to State decision makers, as well as references to other international documents, such as those of the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) to assist the States in their decision-making process.

JFD
by
PJD
6-25-01

1.3.1 The Accident at Three Mile Island

In the United States, the worst commercial nuclear power plant accident occurred at the Three Mile Island Unit 2 (TMI-2) reactor. The two nuclear power reactors at TMI are light water-cooled and moderated.

The accident was caused by a series of errors in operation and maintenance. As a consequence of these errors, the reactor core was not continuously covered with water, so a major fraction of the core melted and released much of its fission product inventory. The initial release was through pipes (that should have been blocked), which allowed the containment to be bypassed. This release consisted almost entirely of noble gases and it was eventually limited by operator action.

The TMI accident did not cause deaths, injuries or over-exposures to radiation. The maximum dose to a member of the public was about 0.85 mSv (85 mrem), the equivalent of the dose the average person receives from natural sources every 3 months. The TMI accident had a major impact on the US nuclear power program, including a major increase in regulatory requirements. TMI also showed the need for improved emergency preparedness, both on-site as well as off-site. Additionally, this accident also cast serious doubt on the emphasis that had been placed on the importance of the radioiodines in a U.S. nuclear accident. At TMI-2, a major core melt occurred, millions of curies of noble gases were released to the environment but the iodine release was limited to approximately 15 curies. These doubts led to the development of a revised source term.

1.3.2 The Chernobyl Reactor Design vs. the Light-Water Reactor Design

The accident at Chernobyl provided more information on reactor accidents and source terms. This accident, which involved an explosion and fire in the graphite-moderated core, rapidly carried fission products, including noble gases, and large quantities of iodines into the environment. There are many important lessons that were learned from the Chernobyl accident: the function of containment, operating within the safety envelope, human performance in safety, emergency planning, early public notifications, and the importance of administration of KI to large population groups at risk of exposure to significant quantities of radioiodine and the importance of evacuation, sheltering and embargoing of food stuffs. The Chernobyl experience validated the value and effectiveness of the emergency planning process.

The reactor designs in the U.S. are different from the Chernobyl design:

- the choice of moderators is different, in the U.S., water is used, whereas the Chernobyl type reactors (RBMK-1000) use graphite;
- because of the core characteristics, the RBMK is less stable and more difficult to control, unlike U.S. designs, and power excursions present a greater risk;
- a graphite moderator, unlike water, is flammable;
- "defense-in-depth" barriers provided to ensure that nuclear fuel and fission products cannot escape from the core. Both the RBMK-1000 and U.S. LWRs use uranium oxide (UO₂) fuel pellets surrounded by zirconium cladding, however,

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CHAPTER 2. BASIS FOR IODINE PROPHYLAXIS

2.1 Physiology of the Thyroid Gland

To understand the basis for the use of KI, also known in this report as iodine prophylaxis, it is important to understand how the thyroid works and the importance of iodine to the thyroid gland. This chapter discusses the potential for adverse reactions to stable iodide, the risks for thyroid cancer, and the evaluation of specific modifying factors relating to internal thyroid dose.

The thyroid gland is the ~~largest~~ ~~biggest~~ largest gland in the neck (Surks 1999). It is situated in the front of the neck attached to the lower part of the voicebox (or larynx) and the upper part of the windpipe (or trachea). The thyroid gland has the shape of a butterfly: the two wings being the right and left lobes which wrap around the trachea. Each lobe is about 4 cm (1.5 in) long and 1 to 2 cm (0.65 to 0.78 in) wide (Surks 1999). The sole function of the thyroid gland is to produce thyroid hormones. These hormones affect nearly all tissues of the body by increasing metabolism or cellular activity. Thyroid hormones contain iodine and iodine is important in the function of the thyroid gland. In addition to being the important component of thyroid hormones, iodine is important in producing them.

The function of the thyroid gland is to take iodine found in the foods we eat and the water we drink, and convert it into thyroid hormones, thyroxine (T4) and triiodothyronine (T3). Thyroid cells are the only cells in the body that can absorb iodine. These cells combine iodine and an amino acid to make T3 and T4, which are then released into the blood stream where they control metabolism. Every cell in the body depends upon thyroid hormones for regulation of its metabolism. The average adult body contains between 20 and 50 mg of iodine and more than 60 percent of this is concentrated in the thyroid gland.

As early as 1824, it was recognized that: (1) iodine is an essential element for humans, and (2) the lack of stable iodine in the diet leads to a condition called colloid goiter (Brucer 1990).

Subsequently, when stable iodine was added to most table salt (about half of a teaspoonful of salt provides the minimum daily requirement of 150 μg of iodine), colloid goiter essentially disappeared from the U.S. In recent decades, stable iodine has also become an important additive to bread and fast foods. It is estimated that the average American takes in over 600 micrograms of stable iodine daily (Combs 1998). The fast food diet in the United States contributes approximately 30 times the minimum daily requirement of iodine. As a result, thyroid glands in the United States are already partially saturated (Brucer 1990). The primary significance of dietary iodide levels is that for a common exposure to radioiodide (inhalation or ingestion), individuals with a lower dietary intake of stable iodide will have a higher thyroid uptake of radioiodide, resulting in a proportionately higher thyroid exposure. Daily intake levels of stable iodide may also influence adverse reactions to stable iodide when administered in doses that greatly exceed dietary levels. However, daily dietary intake of iodine is not a factor in the consideration of the use of iodine prophylaxis.

CHAPTER 3 POTASSIUM IODIDE AS A THYROID BLOCKING AGENT

3.1 What is KI?

KI is potassium iodide. It is a salt, similar to table salt and, in fact, KI is the ingredient that is routinely added to table salt to make it "iodized". KI will be taken up by the thyroid gland and, if taken in large enough quantities, will effectively saturate the thyroid gland. This saturation of the thyroid gland can prevent the uptake of radioactive iodine that may be released in the unlikely event of a severe nuclear reactor accident. KI offers additional protection for one radiation-sensitive organ, the thyroid, under conditions of inhalation or ingestion of radioactive iodine.

3.2 FDA Guidance

The FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of KI. Existing FDA guidance related to the use of KI on dosage intervention levels is contained in a June 29, 1982 notice (47 FR 28158). As stated therein, "FDA concludes in the final recommendations that risk from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem". That notice also provides recommended dosages for adults and children. New FDA guidance was published in the Federal Register for public comment on January 4, 2001 (66 FR 801). ~~In this draft guidance, (Change references to final FDA guidance throughout NUREG-1633.)~~ The FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland under certain specified conditions for use, and thus to obviate the risk of thyroid cancer in the event of a radiation emergency where there is a release of radioactive iodine. The new FDA guidance is presented in this chapter in its entirety.

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4.3 Funding of KI

~~The Commission has decided to fund State stockpiles of KI.~~

The Commission intends to fund initial supplies for one to two doses per individual for those within the 10-mile EPZ provided in NRC and FEMA regulations. The Commission has determined that for a State that has decided to stockpile KI, NRC funding for purchases of KI for use by that State during a radiological emergency would make a direct contribution to fulfilling NRC's regulatory mission.

The Commission also only intends to fund purchases consistent with the anticipated revision of the FDA recommendations on KI doses. The funding available for KI is not intended to fund any ancillary costs, including costs associated with storing stockpiles or distributing KI in the event of an emergency. States are encouraged to begin their process for considering KI as early as possible, recognizing that the NRC's resources for this purpose are limited.

4.4 The Role of Evacuation and Sheltering in Emergency Preparedness

Early evacuation is the most effective protective action for NPP accidents. Plant operators are expected to recommend prompt evacuation to offsite authorities without waiting for a release of radioactive materials. They base their recommendations on current and expected plant conditions.

In some cases, sheltering may be the appropriate protective measure. If travel conditions present an extreme hazard, public officials may initially decide to shelter (rather than evacuate) the nearby population until conditions improve. Sheltering may also be the appropriate initial action for people requiring assistance with transportation. In addition, sheltering may be the appropriate protective action for controlled releases of radioactive material from the containment if there is assurance that the release will be of short duration and if the area near the plant cannot be evacuated before the plume arrives.

After performing the initial early evacuation near the plant, licensee and offsite officials could modify the protective action recommendations, as appropriate, on the basis of (1) dose projections indicating that the EPA PAG doses may be exceeded in areas beyond those that have been evacuated, and (2) field monitoring results that have located areas with high levels of contamination. On the basis of this information, plant and offsite officials may expand the evacuations to encompass other areas in the plume EPZ and, for worst-case accident scenarios, protective actions may be required beyond the plume EPZ

4.5 The Role of KI in Emergency Preparedness

The Commission has found that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The use of KI for public protection is a special kind of protective measure in that it offers very specialized protection. KI can provide protection against internal doses to the thyroid from radioiodines. Depending on the specific circumstances around an NPP and the type of accident, a State may find the availability of KI to be an added benefit.

JS
by
BUD
6-25-01

**APPENDIX A
WORLD HEALTH ORGANIZATION RECOMMENDATIONS**

*Delete all.
Only reference in NUREG-1633.*

*gpc
6-25-01*

NOTATION VOTE

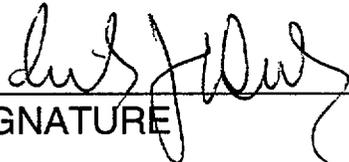
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER DIAZ
SUBJECT: **SECY-01-0069 - STATUS OF POTASSIUM IODIDE
ACTIVITIES**

Approved Disapproved _____ Abstain _____
Not Participating _____

COMMENTS:

See attached comments.



SIGNATURE
5.14.01

DATE

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COMMENTS OF COMMISSIONER DIAZ ON SECY-01-0069, STATUS OF
POTASSIUM IODIDE ACTIVITIES

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.

NOTATION VOTE

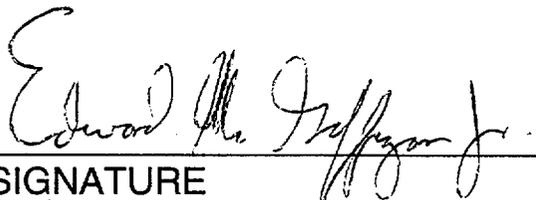
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MCGAFFIGAN
SUBJECT: **SECY-01-0069 - STATUS OF POTASSIUM IODIDE
ACTIVITIES**

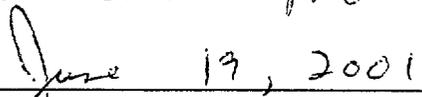
Approved ^{in part} Disapproved ^{in part} Abstain _____

Not Participating _____

COMMENTS:



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DATE

Entered on "STARS" Yes No _____

Commissioner McGaffigan's comments on SECY-01-0069

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.

Development and Implementation of a KI program

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.

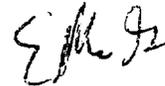
One important issue that will require further clarification for the development and implementation of a KI program is definitive guidance on KI prophylaxis for individuals over 40. Both WHO and

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.

A handwritten signature in black ink, appearing to be 'E. M. G.', located in the lower right quadrant of the page.

NOTATION VOTE

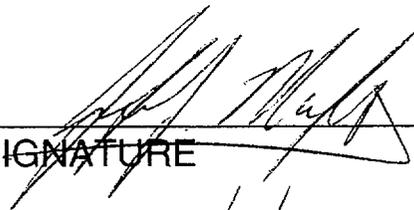
RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MERRIFIELD
SUBJECT: **SECY-01-0069 - STATUS OF POTASSIUM IODIDE
ACTIVITIES**

Approved Disapproved Abstain
Not Participating

COMMENTS:

See attached comments.



SIGNATURE

6/21/01

DATE

Entered on "STARS" Yes No

COMMENTS OF COMMISSIONER MERRIFIELD ON SECY-01-0069

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.

A handwritten signature in black ink, appearing to be "A. J. Allbaugh", written in a cursive style.

6/21/01



OFFICE OF THE
SECRETARY

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

June 29, 2001

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary *Annette Vietti-Cook*

SUBJECT: STAFF REQUIREMENTS - SECY-01-0069 - STATUS OF
POTASSIUM IODIDE ACTIVITIES

The Commission has directed the staff to revise Draft NUREG-1633 subject to the changes provided in the attachment and the following comments. The revised draft NUREG should be provided to the Commission prior to publication for comment.

- 1) Publication of Draft NUREG-1633 should await the publication of the final FDA guidance, which should be included in the NUREG. While awaiting the publication of the final FDA guidance, the staff should undertake a global review of the scope and contents of the NUREG to make it a more consistent and useful document.
- 2) A discussion of the history of international KI guidance should be included in the main body of the report. The WHO document should not be included as an attachment but both WHO and IAEA documents should be appropriately referenced.
- 3) The NUREG should be consistent with the statements of consideration in the final rule. 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. Also, the staff should modify the discussion of the Commission's findings with respect to 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 underlined language. 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.

- 4) The discussion of the alternative source terms in Chapter 1 appears to be stated more categorically than other source term documents, and may not be necessary or relevant to this guidance document. The staff should consider deleting it. If retained, it should be expanded or revised to correct the deficiencies.
- 5) Chapter 2 duplicates much of the FDA guidance in Chapter 3 and should be simplified to remove the repetitious material or eliminated. If Chapter 2 is retained, it needs to be clarified that the UNSCEAR 2000 report is consistent with and supportive of both WHO's and FDA's guidance.
- 6) In Chapter 5, with the permission of the States, include the experience of 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). Remove the discussion of Pennsylvania since it has not completed its process and the discussion does not reveal how the practical problems of KI distribution are handled. If available, add additional information from States such as Connecticut where current emergency plans have long provided for KI prophylaxis for certain members of the public at institutions within emergency planning zones, such as hospitals and prisons, whose evacuation would be delayed.
- 7) In Chapter 6, correct the information on France, using, at a minimum, the information available on the DSIN web page.
- 8) The NUREG should include the most up-to-date information available concerning the experience, both pro and con, of States and foreign governments in the distribution of KI.
- 9) A discussion of the pros and cons of various KI distribution logistics should be included in the NUREG.
- 10) The staff should urge FDA to address in its final guidance document the issue of KI prophylaxis for those over 40 years of age under the postulated circumstances of a reactor accident. To document this concern, the staff may want to refer the CRCPD question to FDA for resolution.

The staff should ensure that to the maximum extent possible, Commission funds allocated for

stockpiles go toward purchasing actual KI tablets, rather than toward administrative costs.

The staff should convey to its FEMA counterparts the importance to Federal KI policy of FEMA's leadership role in finalizing and carrying out necessary implementing functions of 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.

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

Attachment: Changes to NUREG-1633 in SECY-01-0069

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR

Changes to NUREG-1633 in SECY-01-0069

1. On page iii, delete the line for Appendix A.
2. On page vi, paragraph 2, revise line 5 to read ' ... contains ~~final draft~~ guidance from' In line 6, insert a period after 'agent' and delete the remainder of the sentence.
3. On page vii, last paragraph, revise line 1 to read ' ... document ~~presents information and discusses the~~' Delete the second sentence (This document presents ... general public.) Revise line 4 to read '~~This guidance begins with a brief discussion of t~~ The basis for' Revise line 6 to read ' ... source terms ~~are briefly discussed.~~' Revise the last 2 lines to read ' ... terms are discussed. ~~In addition, t~~This guidance document contains a discussion of'
4. On page viii, revise lines 2 and 3 to read ' ... also included ~~guidance documents of the World Health Organization (WHO) and the final guidance document from U.S. Food~~' Revise the last line to read ' ... State decision makers, as well as references to other ~~international documents, such as those of the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) to assist the States in their decision-making process.~~'
5. On page 4, paragraph 1.3.2, in line 6 delete 'and'. Revise line 7 to read ' ... quantities of radioiodine ~~and the importance of evacuation, sheltering and embargoing of food stuffs.~~'
6. On page 9, paragraph 2, revise line 1 to read ' ... gland is the ~~largest biggest~~ gland in the neck'
7. On page 15, paragraph 3.2, in line 9, revise the reference to the FDA guidance document to reflect the final guidance. Do likewise throughout NUREG-1633.
8. On page 31, paragraph 4.3, delete the 1st sentence (The Commission ... of KI.) Add the following sentence in its place. 'The Commission intends to fund initial supplies for one or two doses per individual, consistent with FDA guidance, for those within the 10-mile EPZ provided in NRC and FEMA regulations.'
9. Delete Appendix A