



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

December 22, 2000

OFFICE OF THE
SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-00-0040

TITLE: FINAL AMENDMENTS TO 10 CFR 50.47;
THEREBY GRANTING IN PART TWO
PETITIONS FOR RULEMAKING (50-63 AND
50-63A); RELATING TO A REEVALUATION OF
POLICY ON THE USE OF POTASSIUM IODIDE
(KI) FOR THE GENERAL PUBLIC AFTER A
SEVERE ACCIDENT AT A NUCLEAR POWER
PLANT

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

Annette 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
PDR

VOTING SUMMARY - SECY-00-0040

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE	X				X	11/22/00
COMR. DICUS	X				X	3/10/00
COMR. DIAZ	X	X			X	4/4/00
COMR. McGAFFIGAN	X	X			X	10/17/00
COMR. MERRIFIELD	X				X	11/28/00

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners Dicus and Merrifield approved the staff's recommendation and provided some additional comments. Chairman Meserve supported the initial acquisition of State stockpiles of potassium iodide (KI). Commissioners Diaz and McGaffigan approved in part and disapproved in part. They agreed to offer funding for State stockpiles of KI. All Commissioners approved the final rule which amends 10 CFR §50.47(b)(10) to require that consideration be given to including the prophylactic use of KI as a protective measure for the general public in the plume exposure pathway Emergency Planning Zone (EPZ) that would serve as a supplement to evacuation and sheltering. The Commission, with Chairman Meserve and Commissioners Diaz and McGaffigan agreeing, voted to approve the publication and implementation of this final rule granting one petition in part and granting the amended petition. As a matter of policy, the Commission agreed to offer initial funding for State stockpiles of potassium iodide. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard. The Commission approved State funding because it concluded that local stockpiles would be more likely to be effective than Federal regional stockpiles. Commissioners Dicus and Merrifield approved the final rule, except they disagreed with the Commission funding State stockpiles instead of funding regional stockpiles. They believed that Federal funding for regional stockpiles would better serve the public because States could fund their own stockpiles and regional stockpiles would serve as a prudent back-up measure for States whose stockpiles prove insufficient, or where a State has elected not to stockpile KI. Accordingly, they believed that funding regional stockpiles would be a more effective use of Federal funds and would be more consistent with the allocation of responsibility between the Federal government and the States for all other emergency matters.

The Commission approved the final rule in an Affirmation Session as reflected in the Affirmation Session SRM issued on December 22, 2000.

A F F I R M A T I O N V O T E

R E S P O N S E S H E E T

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN MESERVE

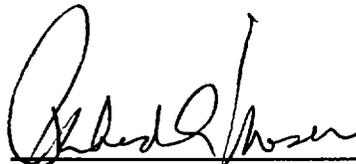
SUBJECT: **SECY-00-0040 - FINAL AMENDMENTS TO 10 CFR 50.47;
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ACCIDENT AT A NUCLEAR POWER PLANT**

Approved ^{w/comments} X Disapproved Abstain

Not Participating

COMMENTS:

SEE ATTACHED COMMENTS



SIGNATURE

November 22, 2000

DATE

Entered on "STARS" Yes X No

COMMENTS OF CHAIRMAN MESERVE ON SECY-00-0040

I approve the modification of 10 CFR 50.47(b)(10) so as to require the consideration of potassium iodide (KI) among the range of protective actions for the general public in the plume exposure pathway for the Emergency Planning Zone (EPZ). I also approve the publication of the Federal Register notice, subject to the following comments.

General Policy. Unlike most other countries that produce electricity using nuclear power, the United States does not, as a general policy, plan for the distribution of KI to the general public as an element of the response to a nuclear accident.¹ KI, of course, serves solely to limit the uptake of radioactive isotopes of iodine by the thyroid and thus does not offer protection to other organs and from other fission products. Thus, the primary emergency response to a nuclear accident is, and should remain, the evacuation of affected populations.

Nonetheless, KI deserves to be considered among the arsenal of possible responses. The Report of the President's Commission on the Accident at Three Mile Island (the report of the Kemeny Commission) recommended that an adequate supply of KI should be available for public distribution² and the validity of this recommendation was demonstrated by the apparent effectiveness of KI in limiting thyroid uptake of radioiodine among children in the aftermath of the Chernobyl accident.³ I conclude that it is appropriate to require planning authorities to consider the use of KI as a supplement to other emergency response activities.

¹ Evaluation criteria for the plans of offsite response organizations specify that protective measures for the plume exposure pathway shall include provisions for the use of radioprotective drugs within the plume exposure EPZ when immediate evacuation may be infeasible or very difficult, but this requirement is focused on emergency workers and institutionalized persons. NRC, Criteria for Preparation and Evaluation of Radiological Emergency Response Plans in Support of Nuclear Power Plants 18 (Sept. 1988) (NUREG-0654, FEMA-REP-1, Revision 1, Supplement 1)

² Report of The President's Commission on the Accident at Three Mile Island: The Need For Change: The Legacy of TMI 75 (1979).

³ R.F. Mould, Chernobyl Record 79 (2000); J. Nauman & J. Wolff, "Iodine Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks," 94 Am. J. of Med. 524 (1993).

I would not go so far, however, as to require the utilization of KI. States, under the supervision of the Federal Emergency Management Agency (FEMA), have the primary responsibility for planning and executing the offsite portion of emergency response.⁴ Some states may conclude that efforts to distribute KI would serve to complicate or disrupt evacuation, and hence may choose not to include the distribution of KI to the general public in their planning. It is not appropriate for the NRC to override this decision in light of the primary responsibility of FEMA and the states for emergency offsite response and of the fact that they, more than the NRC, are aware of the logistical complications that KI distribution could present in particular local circumstances. Nonetheless, it is appropriate for the NRC to require that consideration be given to the use of KI and to provide guidance to the States and FEMA on issues related to its distribution.

My vote today also does not reflect a conclusion that nuclear plants are unsafe or that extraordinary additional emergency-response measures beyond those previously contemplated are necessary. Quite the contrary, the objective data show that the overall safety performance of nuclear plants has been steadily improving. I support the consideration of the distribution of KI as a prudent step to assure that the Nation is prepared to respond appropriately to even unlikely events.

Funding. Perhaps the most contentious aspect of this matter has not turned on the substance of the rule itself, but rather on an issue relating to the funding of the purchase of KI by those states that choose to stockpile it. The Commission publicly announced its willingness to provide such funding, but then subsequently announced that it would not do so.⁵ The Commission changed its position on the basis of several considerations, including in particular that regional stockpiles might better serve the public because some states might elect not to stockpile KI and because the funding of regional stockpiles might prove a more efficient and effective use of limited NRC resources and would better reflect the allocation of responsibility on such matters between the states and the federal government. The Commission's decision

⁴ Exec. Order 12,148, 44 Fed. Reg. 43,239 (1979).

⁵ The Commission announced its intention to provide funding of state stockpiles of KI in the SRM associated with SECY-97-124 (June 30, 1997). It subsequently announced its support of federal funding of regional stockpiles in lieu of state stockpiles in the SRM for SECY-98-264 and COMJSM-98-002 (Apr. 22, 1999).

precipitated adverse comments from the Director of FEMA, who expressed concern following the Commission's "abrupt retreat from repeated promises to the Federal community, states and the public."⁶ It also prompted responses from those who advocate the stockpiling of KI based on the premise that the Commission's change of position reflected a failure to recognize the significance and importance of KI in emergency circumstances.

I was not serving on the Commission at the time of the decision to decline to fund state stockpiles. It is my view, however, that the criticisms of my predecessor and colleagues are distinctly unfair. The fact of the matter is that the entirety of the Commission supported the consideration of KI in emergency planning -- the fundamental issue. Moreover, the decision to decline to fund state stockpiles did not reflect a withdrawal of financial support -- rather, it reflected a conclusion by a divided Commission that our limited assets might be more effective if allocated differently (namely, to regional stockpiles) and that such an allocation was consistent with appropriate federal/state relations in this area. In short, the Commission's sole purpose was the advancement of the availability of KI.

Nonetheless, I conclude that the Commission should offer funding for state stockpiles. I reach this conclusion for several reasons.

First, I have serious doubt about the effectiveness of regional stockpiles of KI for the purpose of emergency response at nuclear power plants. KI provides protection for the thyroid because the non-radioactive iodide in KI saturates the iodide transport system and thereby prevents the uptake of radioactive iodine. It serves its purpose only if it is taken before or shortly after exposure. In fact, the effectiveness of KI as a blocking agent drops to about 50 percent if administered 3-4 hours after exposure.⁷

⁶ Letter from J.L.Witt, Dir., FEMA to S.J. Jackson, Chairman, NRC (Apr. 29, 1999). See also Letter from K.C. Goss, Ass. Dir., FEMA, to A.Viitti-Cook, Sec., NRC (Jan. 12, 2000).

⁷ See World Health Organization, Guidelines for Iodine Prophylaxis following Nuclear Accidents 19-20 (1999) (50 percent effectiveness if KI is administered 8 hours after the onset of a 4-hour intake of radioactive iodine); H. Behling et al., An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident 2-15 to -17 (Feb. 1995) (NUREG/CR-6310) (50 percent effectiveness 3-4 hours after a single pulse intake); National Council on Radiation Protection and Measurements, Protection of the Thyroid Gland in the Event of Releases of Radioiodine 19-21 (Report No. 55) (1977) (same).

In light of the need for prompt administration, the logistical problems associated with the transport and distribution of regional stockpiles of KI make their use problematic for emergency response at reactor sites. For example, the regional stockpiles that are suggested by the staff, the National Pharmaceutical Stockpile that is being established by the Center for Disease Control and Prevention (CDC), relies on contract shippers (e.g., Federal Express, UPS) to deliver materials from a regional stockpile to a specific location within 12 hours of the decision to deploy.⁸ Of course, once the KI is delivered, there would then be additional delay associated in the distribution of KI to intended recipients. There thus is reason to doubt whether regional stockpiles could be deployed quickly enough in accident circumstances to allow distribution in advance of or even shortly after a radioactive release. And if there were adequate time to distribute KI from regional stockpiles, there should also be adequate time to complete the evacuation of the public (which is the preferred alternative in any event), thereby alleviating the need for KI distribution. State stockpiles, in contrast to regional stockpiles, could be distributed more quickly by reason of the opportunity to pre-position KI in the vicinity of the plant (at schools, hospitals, etc.) or KI might even be pre-distributed to affected populations.

I recognize that it is likely to be the case that some states will choose not to stockpile KI and the absence of a regional stockpile might mean that KI is not available for an accident in such a state. But, given the relatively short time frame within which KI must be administered if it is to be effective, it is unlikely a program that is developed at the time of an event to distribute KI will prove effective, particularly since the response organizations no doubt will be severely taxed in fulfilling the other tasks that are part of their emergency response obligations. Moreover, even if a state has planned to use a regional KI stockpile, the delays incident to the delivery and distribution of KI from regional stockpiles would no doubt greatly reduce the effectiveness of the program as compared with distribution from a locally available stockpile. In this regard, it does not seem wise to encourage the states to rely on regional stockpiles.

Second, I am mindful of the importance of NRC coordination with FEMA on this issue. Pursuant to Executive Order 12,148 and the Memorandum of Understanding between the NRC

⁸ Combatting Terrorism: Management of Medical Stockpiles, Before the House Subcomm. on Nat'l Security, Veterans Affairs, and Int'l Relations of the House Comm. On Gov't Reform, 106th Cong. (Mar. 8, 2000) (statement of Stephen M. Ostroff, M.D., Associate Director for Epidemiologic Science National Center for Infectious Diseases, Centers for Disease Control and Prevention Department of Health and Human Services).

and FEMA,⁹ FEMA has primary responsibility for the offsite portion of emergency response at nuclear facilities. Any implementation of a program to provide KI is therefore subject to review and approval by FEMA. As noted above, however, FEMA has noted its strenuous objection to reliance on regional stockpiles of KI.¹⁰ Thus, an NRC decision to favor regional stockpiles could and likely would be thwarted by FEMA. In any event, the NRC should give particular consideration to the views of FEMA, particularly in light of our need to coordinate with a sister agency that has primacy in the area of offsite emergency planning.¹¹

Third, I am aware of the fact that the NRC's acceptance of the cost of state stockpiling is contrary to past practice whereby the Commission has not ordinarily provided funding for the costs of offsite protective actions.¹² The Commission's acceptance of this cost, however, is a one-time departure from the general rule that is justified by a need to assure that the states undertake a serious look at the benefits (and problems) associated with KI distribution in a

⁹ Memorandum of Understanding Between Federal Emergency Management Agency and Nuclear Regulatory Commission, 44 C.F.R. part 53, app. A (2000).

¹⁰ To the extent that this objection is based on concerns about the timeliness of distribution from a regional stockpile, the FEMA objections are understandable and, in my view, justified. The FEMA letters (see note 6, supra) suggest, however, that at least part of FEMA's objection is based on the fact that the NRC had indicated an intention to fund state stockpiles and that, as a result, the NRC could not subsequently choose a different course. This foundation for FEMA's objection does not bear much weight in my view in light of the responsibility that each agency must play in the stewardship of its funds. The NRC had not made any contractual or other legally binding commitment to expend its funds in a particular way and, so far as I am aware, there was no detrimental reliance by others on the NRC decision. Under these circumstances, the NRC, like other agencies, must reserve the right to modify its decisions if the modification would better serve the public. It is clear to me that the change in Commission position in 1999 was based on exactly such a conclusion -- albeit a conclusion with which I disagree.

¹¹ I reach this conclusion even though the Commission's decision in this matter has been delayed as a result of the difficulty in arranging a meeting with the upper management of FEMA to discuss the KI issue.

¹² See SECY-00-040, Att. 6, at 33 (Feb. 14, 2000). In the mid-1970s the Federal government did provide one-time grants to states for preparing basic emergency response plans. Although this money could be used for emergency planning for nuclear facilities, it appears that few states did so. R.T. Styles, "Nuclear Power Plants and Emergency Planning: An Intergovernmental Nightmare," 5 Pub. Admin. Rev. 393, 395 (1984). Nonetheless, the provision of funding for state emergency preparations is clearly not unprecedented.

fashion that is not unduly constrained by the cost of stockpiling. I am mindful in this connection, moreover, that the ultimate burden, regardless of our decision, is likely to be our licensees. If the NRC agrees to subsidize the stockpiles then our licensees will ultimately bear the burden because the NRC budget is primarily derived from licensee fees. And, similarly, if the states were asked to fund the creation of the KI stockpiles, then it is likely that ultimately the licensees will be relied upon to pay the associated costs, even if such payments are not directly compelled.¹³ This suggests that the vehicle for payment of the costs -- through licensee payment of NRC fees or through licensee direct payments for KI -- does not deserve extended attention.

Finally, I give consideration to the impact of our decision on the NRC budget. Part of the justification for reconsideration of the funding issue in 1999 was concern for the largely uncontrollable costs that might arise from an unqualified promise to fund state demands for KI. But that concern can be addressed through appropriate limitations on funding. For example, in light of the constraints on the NRC budget, any funding of KI should appropriately be limited in several ways:

- NRC funding should support only the initial acquisition of a state stockpiles. Replenishment of the stockpiles and the ancillary costs (e.g., warehousing, education, training) should remain a state responsibility.
- Funding might be limited in aggregate amount to the funds defined in the NRC budget (\$400,000 in FY2001 and an additional amount in FY2002). To allow the fair distribution of funds, we might request that any request for funding be submitted by a date certain and inform the applicants that they might have to share pro rata if the demands exceed the allocated funds. Alternatively, the NRC might establish a cap on the amount it will pay per dose (e.g., \$0.20 per tablet).
- Any funding should be limited to assure that the size of the federally supported stockpile is reasonable in light of the potentially exposed population.

¹³ NRC regulations require that there be reasonable assurance that adequate protective measures can and will be taken in the event of an emergency. 10 C.F.R. § 50.47. If a state plan were to contemplate distribution of KI as a part of the plan, but if the states were to refuse to purchase it, licensees might then be compelled to purchase KI.

In addition, the NRC might consider a centralized purchase of KI in order to facilitate a volume acquisition at low cost. In short, the NRC can place appropriate constraints on the funding of KI so that the costs do not place too great a burden on the agency.

* * *

The approach urged in these comments will require revision of the Federal Register notice.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-00-0040 - FINAL AMENDMENTS TO 10 CFR 50.47;
THEREBY GRANTING IN PART TWO PETITIONS FOR
RULEMAKING (50-63 AND 50-63A); RELATING TO A
REEVALUATION OF POLICY ON THE USE OF POTASSIUM
IODIDE (KI) FOR THE GENERAL PUBLIC AFTER A SEVERE
ACCIDENT AT A NUCLEAR POWER PLANT**

Approved ^{w/comments} x Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

See attached comments and edits.

Greta Jay Dicus
SIGNATURE

March 10, 2000
DATE

Entered on "STARS" Yes x No _____

COMMISSIONER DICUS' COMMENTS ON SECY-00-0040:

I approve the staff's proposed final rule which would amend 10 CFR 50.47(b)(10) to require that consideration be given to including the prophylactic use of potassium iodide (KI) as a protective measure for the general public that would serve as a supplement to sheltering and evacuation.

After a review of all the literature to date, along with the arguments raised by the petitioner and other stakeholders, I believe that the Commission now has enough evidence to fairly and reasonably make an informed decision to grant in part the petitions received over the years and finally amend the regulations to provide a resolution on this issue.

Minor editorial corrections to the Federal Register Notice are attached.

X
Action During Severe Reactor Accidents", Rev. 2 is expected to be issued for comment in mid-2000, following receipt of the FDA's draft revised position on exposure action levels and proper dosage of KI, expected to be issued for public comment ~~early~~ in 2000.

In addition, the NRC plans to develop a public information brochure concerning the use of KI by the general public following completion of the final NUREG.

Public Comment Evaluation

On November 27, 1995 (60 FR 58256), the NRC announced the receipt of the original petition for rulemaking (PRM 50-63), and requested public comment on the suggested rule amendment. A total of 65² comment letters were received. Letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association. Letters opposed to the petition came from 20 utilities, 9 State governmental agencies, 2 utility interest organizations, a letter signed by 12 health physicists, 2 State university medical centers and 1 member of the public.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition (PRM 50-63A) in the Federal Register. In response to several requests, the comment period was extended until February 17, 1998, by a Federal Register notice published on January 21, 1998 (63 FR 3052). A total of 86 comment letters were received. The letters in favor of granting the petition came from 8 public interest groups, 48 members of the public (including 3 from the petitioner), 3 physicians, 2 U.S. Senators, 1 State Representative, FEMA, the American Thyroid Association, a KI manufacturer, and the US Pharmacopeia Convention. Fourteen utilities, 3 State government agencies, 1 utility interest association, and 2 members of the public opposed the petition for rulemaking. A detailed

²Two letters that were received in response to the notice did not address the issues in the petition and are not discussed further.

Issue I: FDA Input on KI

A few commenters thought that the dosage and intervention levels should be lowered from the values in the existing FDA guidance. For instance, they conclude that NRC should require using KI prophylaxis at one rem projected dose exposure not at the current 25 rem. It was noted that Poland uses a 5 rem intervention level. The concern of these commenters is that continued use of the old guidance subjects children to greater risk than necessary.

Response. The Food and Drug Administration 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 risks 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 is scheduled for publication in the Federal Register for public comment ^{later this year} ~~by early 2000 with final publication scheduled for late 2000~~. Once this new information is available, the Commission will incorporate it into its guidance documents.

Issue J: Original Petition versus Revised Petition

A few commenters state that in the proposed rule, the Commission claims to have granted the alternative submitted in the amended petition, but did not actually do so. In their view, the amended petition contained the combination of three elements-- the requirement to consider KI stockpiling, the unequivocal recommendation that States establish stockpiles, and

Three Mile Island accident: "The Commission's final rules are based on the significance of adequate emergency planning and preparedness to ensure adequate protection of the public health and safety. It is clear...that onsite and offsite emergency preparedness as well as proper siting and engineered design features are needed to protect the health and safety of the public. As the Commission reacted to the accident at Three Mile Island, it became clear that the protection provided by siting and engineered design features must be bolstered by the ability to take protective measures during the course of an accident."

The Commission did not rely upon probabilistic risk assessments in developing this final regulation on consideration of the use of KI.

The Commission interprets the third comment to relate to factors that the commenter believes could increase the likelihood of an accident and which, in the commenter's view, heighten the importance of emergency planning. The Commission's regulations recognize the importance of emergency planning by requiring development of a range of protective actions, which include sheltering and evacuation and, by this rulemaking, consideration of the use of KI for the general public.

X
N
Issue ϕ : Cost of KI and Shelf-Life

One commenter feels that the NRC has exaggerated the estimated cost of KI, ignoring comments that point to the availability of inexpensive and long-lasting KI. This commenter thinks that market forces are likely to bring down the cost of KI and that savings in the NRC budget could be effected without diminishing the safety of America's children.

The U.S. Pharmacopeia wrote in its comment letter that the long-term viability of the drug was tested and it was found that 11 years after manufacture and eight years after the expiration date, the tablets were assayed at 99.1% of the labeled content of KI. The petitioner

expressed the view that since the U.S. is currently engaged in a \$15 million study of radiation-caused thyroid disease in the Ukraine, it was hard to understand why the government was not willing to spend a fraction of that amount to prevent radiation caused thyroid disease at home.

Response. Cost estimates used in past documents were based upon information available at those times. NRC presently estimates the cost of KI to be about 18 to 20 cents per tablet if purchased in bulk, with a shelf life of 7 to 10 years. As a result, the Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for the general public for specific local conditions.

The information gained to date from Chernobyl relating to the usefulness of KI in preventing thyroid cancer was considered by the Commission. However, just as NRC has not funded other offsite protective actions (e.g. State and local government planning for evacuation and sheltering, KI for response personnel/emergency workers and institutionalized persons), the Commission has decided not to fund State supplies of KI for the general public.

X
0
Issue ~~X~~: Safety of KI

Commenters believe that there is new information available from Poland and Belarus regarding use of KI following a radioactive release. They state that there were no reported serious adverse reactions. Specifically, 18 million individuals received prophylactic potassium iodide with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects. Commenters state that this experience has been recognized by other countries who are stockpiling KI for use by the general public. This data has led some commenters to say that just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine. Every drug has contraindications and the potential for allergic reactions. In an emergency as

Rationale for the Commission Decision

The Commission has considered the KI policy question on numerous occasions since 1984. The history of the Commission deliberations shows that reaching consensus on this policy question has been an elusive goal. An important reason for this historical lack of consensus is that this policy question is not a clear-cut one. Individual Commissioners, past and present, have differed in their views with respect to the relative importance to be given to factors bearing on the KI issue. These honest differences have led to divided Commission views on how to resolve the policy question. The Commission agrees that its historical difficulty in reaching consensus on the KI policy question underscores the reality that this policy question is not a simple one, is not one that is easily resolved and, as a result, has been the subject of protracted deliberation.

After considering all public comments received, the information available in the literature, 20 years of experience gained in evaluating licensee emergency preparedness plans, and the arguments presented by the petitioner, the Commission has decided to amend 10 CFR 50.47(b)(10), by adding a sentence similar to the one suggested in the revised petition. Specifically the following sentence is inserted in §50.47(b)(10), after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate."

X
The Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG-0654/FEMA-REP-1, Rev. 1, p. 63, items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during ^{an international} radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes remarkably few threatening side effects.

Moreover, many nations in Europe and elsewhere, nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan, have stockpiled KI for its use. So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it is reasonable to take a further small step and, continuing to recognize the important role of the States and local governments in matters of offsite emergency planning, explicitly require that planners consider the use of KI.

The amendment should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has ^{significantly} improved since the current emergency planning requirements were put in place after the Three Mile Island-2 accident in 1979. ✕

The use of KI is intended to supplement, not to replace, other protective measures. This amendment does not change the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs (evacuation protects the whole body, whereas KI protects only a single gland, the thyroid). Depending on the circumstances, KI may offer additional protection if used in conjunction with evacuation and/or sheltering. In developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public. In appropriate circumstances, KI can provide additional protection. 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 such decisions to State and local emergency response planners, who may find that KI should be a supplementary protective measure.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-00-0040 - FINAL AMENDMENTS TO 10 CFR 50.47;
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Approved *ld* Disapproved *ld* Abstain _____
Not Participating _____

COMMENTS:

See attached comments.

--REC'D BY HJD--

Bill G. Diaz

SIGNATURE

16 FEB 00 2:16

April 4, 2000

DATE

Entered on "STARS" Yes No _____

ORIGINAL

COMMISSIONER DIAZ'S COMMENTS ON SECY-00-0040

I approve the publication of a final rule that will grant in part two petitions for rulemaking relating to consideration and use of potassium iodide (KI) in offsite emergency planning, contingent on the Commission clearly stating that it believes stockpiling of KI is a prudent measure and on NRC funding of KI for those States choosing to maintain a stockpile. This is consistent with my belief in "Federalism," the NRC's mission and my own fiscal conservatism. The Supreme Court's *Pacific Gas & Electric* decision in 1983 reaffirms the NRC's solitary role in regulating the safety of nuclear power and the Federal Government's preemption of the entire field of nuclear power safety concerns except when expressly ceded to the States. With our mission of protecting public health and safety thus buttressed, as a prudent measure (as demonstrated by the availability of KI for nuclear power workers) and given the accumulation of data on thyroid cancers,¹ I believe we have a responsibility to clearly aid the States by providing them with information and funding.² The NRC can then trust the States to make the right decision for them, knowing that we have done our best to protect public health and safety.



¹ Please compare the experience of Poland, on the one hand, and Russia, Belarus, and Ukraine on the other, in KI preparedness and distribution and in subsequent rates of childhood thyroid cancer. See also the March 15, 2000, Reuters dispatch, reporting on an article in "Cancer", published by the American Cancer Society, documenting Chernobyl-related thyroid cancer in children under two. For the views of physicians expert in this field, see the statements of the American Thyroid Association on that organization's website.

² The NRC's FY 2001 budget which was recently submitted to Congress includes a \$400K planning wedge for the possible purchase of KI.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

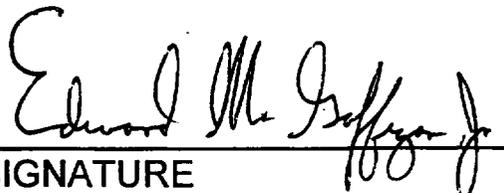
SUBJECT: **SECY-00-0040 - FINAL AMENDMENTS TO 10 CFR 50.47;
THEREBY GRANTING IN PART TWO PETITIONS FOR
RULEMAKING (50-63 AND 50-63A); RELATING TO A
REEVALUATION OF POLICY ON THE USE OF POTASSIUM
IODIDE (KI) FOR THE GENERAL PUBLIC AFTER A SEVERE
ACCIDENT AT A NUCLEAR POWER PLANT**

Approved X ^{in part} Disapproved X ^{in part} Abstain
(with comments)

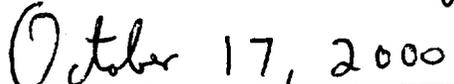
Not Participating

COMMENTS:

See attached comments, and edits to draft Federal Register notice.



SIGNATURE



DATE

Entered on "STARS" Yes X No

Comr. McGaffigan's Comments on SECY-00-0040

I have waited several months to cast my vote on this paper. There was a desire for interaction with the Federal Emergency Management Agency (FEMA) at a high level. Since this has still not occurred, I feel it is time to vote.

In brief, I am voting to approve this final rule, but also to return to the Commission's 1997 and 1998 policy to fund the purchase of a stockpile of KI for the States upon request.

I believe, as I have since first confronting this issue in the spring of 1997, that the lack of stockpiling and/or predistribution of KI for local populations in the emergency planning zones of nuclear power plants in most of the United States is one of the most pronounced deviations from world practice in NRC nuclear safety regulation. Literally every other country, including many countries with far fewer resources than the United States, provides for use of KI as a supplemental protective measure for local populations. Both the IAEA and World Health Organization have long endorsed use of stable iodine prophylaxis. We ourselves have long required that KI be available for emergency personnel and persons in nearby institutions, such as hospitals or prisons, who for logistics reasons will likely need to be sheltered before evacuation.

The resistance to following international practice by many in this country is difficult for me to understand. I firmly believe in the role of nuclear energy as part of our nation's energy supply. I do not believe nuclear accidents are becoming more likely. Quite the opposite. By almost every measure the nation's 103 operating reactors are significantly safer today than at any time since the U.S. first started operating nuclear power plants.

However, we can not rule out an accident. That is why we have a robust emergency planning system which we routinely exercise. Prompt evacuation is, and deserves to be, the first option in emergency plans. But prompt evacuation will not always be possible. Sheltering may well be necessary. If people need to shelter prior to evacuation, they should be taking KI if they are under 40 years of age. If I lived in the emergency planning zone of a nuclear power plant, I would have KI in my medicine cabinet and be sure my children understood how to use it.

Early this year the World Health Organization (WHO) published "Guidelines for Iodine Prophylaxis Following Nuclear Accidents." These guidelines are endorsed by the European Thyroid Association, the Asia and Oceania Thyroid Association, and the Latin American Thyroid Society. I have spoken to Dr. David Becker of the American Thyroid Association (ATA) on why the ATA, which strongly supports this final rule, did not endorse the WHO document. He told me that the main difference was over the 10 milligray (mGy) exposure action level advocated in the document for neonates, infants, children, adolescents to 18 years, and pregnant and lactating women. The ATA believes that a 50 mGy exposure action level is appropriate for these groups. Such a level is consistent with current EPA protective action guidelines. Dr. Becker said that there were also minor differences over recommended doses for certain age groups. Dr. Becker strongly supported the overall thrust of the WHO document and was hopeful a future edition would resolve ATA's concerns.

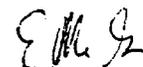
The Food and Drug Administration (FDA) is in the process of updating the guidance on KI doses and exposure action levels. It is my understanding that FDA will propose guidelines similar to WHO's, but with changes which the ATA supports, in particular the 50 mGy exposure action level for those up to 18 years of age and pregnant and lactating women. Obviously, the States and local communities will need this updated FDA guidance to make informed decisions on the stockpiling and/or pre-distribution of KI.

The draft Federal Register notice for the final rule (Attachment 6 of the paper) correctly states that by this rule and the language in the Statement of Considerations, the Commission is granting in part Peter Crane's amended petition for rulemaking. Consistent with the Commission's 1999 change of position, the draft notice also denies his request that we support NRC funding of State KI stockpiles.

I would urge my colleagues to go back to our 1997 and 1998 position and fund State KI stockpiles. The Commission's 1999 policy change (by a 3 - 2 vote) has clearly had very unfortunate repercussions for our relationship with FEMA. Mr. Witt, the FEMA Director, has repeatedly asked us to reconsider our decision, most recently on June 22, 2000. The Commission's original unanimous June 30, 1997 decision to endorse the Federal Radiological Preparedness Coordinating Committee (FRPCC) recommendation on federal funding of State KI stockpiles was based on a staff recommendation to do so. On June 26, 1998, the Commission unanimously reiterated that policy. After two decades of wavering on the use of KI as a supplemental measure in emergency planning, that was the right decision to make. The cost was expected to be minimal. The \$400,000 included in the FY 2001 budget for potential regional KI stockpiles is enough to buy approximately 2 million 130 mg tablets at \$.20/tablet if bought in bulk. Given the WHO and likely FDA guidance that adults over 40 do not need to take KI, and that 65 mg or less is needed by children, this is enough KI for a very substantial population. It would certainly accommodate any conceivable requests we would receive from States in FY 2001, if we were to go back to our 1997 and 1998 policy.

I join Mr. Witt and Commissioner Diaz in believing that these funds would be far better invested in State and local stockpiling/predistribution efforts than in distant regional or national stockpiles. KI needs to be taken before, or during the first few hours after, exposure to radioactive iodine to be effective in protecting the thyroid. It is hard to imagine the logistics working out such that non-local KI stockpiles would be relevant in an actual emergency. The Commission previously had the misimpression that those involved in emergency planning against nuclear terrorism were planning on storing KI in large numbers (high 20's) of regional stockpiles. Some of those stockpiles undoubtedly would have been proximate to nuclear power plants and might have provided a back-up in an emergency. But our current understanding is that any anti-terrorism stocks of KI will be in a handful of locations with up to a 12 hour delivery time from a request being made. Rather than using our scarce resources to place KI where it will likely not be useful for our purposes, we should fund the States who decide to use KI in their emergency plans.

I am attaching edits to the Federal Register notice. These are factual and not meant to effect the policy change discussed above. More fundamental editing would be required if a majority of the Commission decides to return to a policy of funding State KI stockpiles and thereby grant Mr. Crane's amended petition in toto.



Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

In the September 9, 1995, petition (PRM 50-63), the petitioner stated that he believes that if his proposed rule change is adopted, the plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission to stockpile KI will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

On November 11, 1997, the petitioner submitted a revision to his original petition (PRM 50-63A). In the revised petition, the petitioner requested that 10 CFR 50.47(b) be amended to read: (10) "A range of protective actions have been developed for the plume exposure EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed."

The petitioner also provided a marked-up version of the NRC staff's proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) Federal Register document concerning a revision to the Federal policy relating to the use of KI by the general public. The NRC published a document announcing the receipt of the amended petition on December 17, 199⁷, (62 FR 66038) and requested public comment on the amended petition.

on June 14, 1999 (64 FR 31737). That notice provides greater detail concerning the basis for the petition and the NRC's rationale for the proposed rule language put forth for comment.

Other Activities Related to the Rulemaking on KI

In its decision on June 30, 1997, the Commission noted that the Federal government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request'. ^{However,} In its April 22, 1999, SRM, the Commission decided: (1) not to fund State stockpiles of KI; (2) to direct the NRC staff to work with FEMA to establish and maintain regional KI stockpiles; and (3) to support NRC funding of the initial purchase and resupply of the regional KI stockpiles to the extent that this cannot be covered by FEMA under its initiatives. The Commission determined that notwithstanding the June 30, 1997, intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, absent Congressional funding specifically for this purpose, NRC is not prepared to fund State stockpiles of KI.

in denied the federal offer to fund the purchase of KI for States at their request. On June 26, 1998, in an initial decision on this rulemaking petition, the Commission agreed

The Federal Radiological Preparedness Coordinating Committee (FRPCC) is responsible to coordinate all Federal responsibilities for assisting state and local governments in emergency planning and preparedness for peacetime radiological emergencies. Federal agencies which participate in the FRPCC include (among others): the Federal Emergency Management Agency (FEMA), NRC, the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS). The 1985 Federal Policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring pre-distribution or stockpiling for the general public.

¹ This was in contrast to previous Commission statements, such as those made when the Commission amended its emergency planning regulations (45 FR 55402) on November 3, 1980, wherein the Commission stated that any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through the Federal Emergency Management Agency (FEMA).

In parallel with petitioning the NRC for rulemaking, Mr. Crane requested that the FRPCC policy be reconsidered. In early 1996, the FRPCC convened a subcommittee on Potassium Iodide. The subcommittee recommended the following to the FRPCC regarding the Federal KI policy:

- (1) Without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC, or through FEMA), should fund the purchase of a stockpile for a State that decides to incorporate KI as a protective measure for the general public.
- (2) The language in the 1985 policy should be softened to be more flexible, as for instance, rewording it to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of a State, or in some cases local governments;" and
- (3) Local jurisdictions that wish to use KI should consult with the State to determine if the arrangements are appropriate.

On June 16, 1997, the NRC staff forwarded to the Commission the FRPCC- proposed Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant. In its SRM of June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for states. Subsequently, on April 22, 1999, the Commission directed the staff to amend the draft FRN on the Federal KI Policy to conform to the Commission decision on the petitions for rulemaking, and the decision not to fund State KI stockpiles.

On April 29, 1999, the Director of FEMA, Mr. James Lee Witt, forwarded a letter to the Commission commenting on the issue of funding of stockpiles of KI for States. The letter objected to the Commission's "unilateral" decision on funding, and also noted "FEMA has always opposed the notion that Federal regional stockpiles of KI would be effective [and believes that] regional stockpiles would complicate, not strengthen radiological emergency preparedness." FEMA believes that if a State opts to use KI as a supplemental protective measure, that the NRC should provide the funds for such a purchase.

On June 26, 1998, the Commission directed that the FRPCC proposed Policy be modified to -6- include a statement to the effect that State and local decision makers, provided with proper information, may find the use of KI as a protective supplement to be reasonable and prudent for specific local conditions. As noted above, the Commission also reiterated its endorsement of the Federal offer to fund KI stockpiles for states.

The NRC responded to Mr. Witt's letter on June 15, 1999. This letter noted the Commission's decision not to fund state stockpiles of KI as well as the reasons underlying that decision. The letter also referred to the Commission's direction to "the NRC staff to work with FEMA staff to establish and maintain regional KI stockpiles to be used in the event that local stockpiles prove to be insufficient, or when a state without a stockpile elects to use KI on an ad hoc basis in the case of a nuclear emergency". The letter expressed confidence that the staffs, working together will successfully resolve the KI supply issue. The status of the stockpile and funding issues are discussed later in this notice. NRC is working closely with the other Federal agencies to determine appropriate changes to the 1985 policy. A decision regarding policy changes ~~should be reached by mid-2000.~~ *will be reached after conclusion of this rule making.*

In accordance with a Memorandum of Understanding between NRC and FEMA, NRC sent draft versions of this Federal Register notice to FEMA for its review and comment. FEMA responded by letter dated January 12, 2000. That letter reiterated their previous comments opposing regional stockpiles and instead favoring NRC funding of state stockpiles. The letter also notes that the development of regional stockpiles of KI has not progressed. The substance of the specific comments attached to the FEMA letter are addressed by the issues in the public comment evaluation.

On September 30, 1998, *withdraw* *and substantially revise it*
The Commission also directed the staff to ~~revise~~ its guidance document, NUREG-1633, in a number of respects, including an improved discussion on how the practical problems in KI stockpiling, distribution and use are handled by States and other nations who use KI as a supplement. To accomplish this task, the NRC has formed a KI Core Group, consisting of representatives from those states that have KI as a supplemental protective action, the Conference of Radiation Control Program Directors, the National Emergency Management Agency, the U. S. Food and Drug Administration (FDA), EPA and FEMA. The revised draft guidance document, NUREG-1633, "Assessment of the Use of KI as a Supplemental Protective

Action During Severe Reactor Accidents", Rev. 2 is expected to be issued for comment in mid-~~2000~~, following receipt of the FDA's draft revised position on exposure action levels and proper dosage of KI, expected to be issued ^{shortly} ~~for public comment early in 2000~~.

In addition, the NRC plans to develop a public information brochure concerning the use of KI by the general public following completion of the final NUREG.

Public Comment Evaluation

On November 27, 1995 (60 FR 58256), the NRC announced the receipt of the original petition for rulemaking (PRM 50-63), and requested public comment on the suggested rule amendment. A total of 65² comment letters were received. Letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association. Letters opposed to the petition came from 20 utilities, 9 State governmental agencies, 2 utility interest organizations, a letter signed by 12 health physicists, 2 State university medical centers and 1 member of the public.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition (PRM 50-63A) in the Federal Register. In response to several requests, the comment period was extended until February 17, 1998, by a Federal Register notice published on January 21, 1998 (63 FR 3052). A total of 86 comment letters were received. The letters in favor of granting the petition came from 8 public interest groups, 48 members of the public (including 3 from the petitioner), 3 physicians, 2 U.S. Senators, 1 State Representative, FEMA, the American Thyroid Association, a KI manufacturer, and the US Pharmacopeia Convention. Fourteen utilities, 3 State government agencies, 1 utility interest association, and 2 members of the public opposed the petition for rulemaking. A detailed

²Two letters that were received in response to the notice did not address the issues in the petition and are not discussed further.

available to the public. As noted earlier, this information will be in a revised NUREG-1633, ^{after the FOA issues its draft guidance} which is scheduled for publication for comment ~~in mid-2000~~ and in an information brochure.

The Commission finds that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. 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 state-by-state basis. As part of the consideration, the State and local governments can weigh all relevant factors.

Issue C: The Importance of Information in the Decisionmaking Process Concerning the Public Use of KI

In the proposed rule, the Commission noted that NUREG-1633 was being revised to provide information about experience with distribution of KI, and that an information brochure was also being prepared. According to some commenters, distribution of information on the benefits and risks associated with the use of KI should not be limited to people living within nuclear power plant emergency planning zones. Further, commenters note that a comprehensive public information program outlining the potential range of benefits and risks of using KI and how to employ it most effectively in the event of a radiological emergency would be necessary to allow personal decisionmaking. Making the information and the KI itself available directly to members of the public provides them with the ability to decide for themselves how best to take advantage of the benefits associated with the use of KI as supplementary protection. One vehicle currently used for disseminating regular preparedness

needs. The Commission has formed a KI "Core Group" consisting of representatives of State, local, and Federal agencies whose responsibility is to develop clear guidance relating to the use of KI. This guidance (NUREG-1633, Rev. 2) should be published for comment ~~in mid-2000~~ ^{after FOIA issues its draft guidance for comment}.

The NRC is continuing to work with other Federal agencies through the FRPCC to coordinate government policies concerning radiation protection and emergency planning. Further, a public information brochure to be published later will assist States and individuals in making an informed decision on KI.

Issue D: Making KI Available to the General Public

A range of comments were submitted concerning ways by which KI could be made available to the general public in the event of a radiological emergency. Many commenters simply asked NRC to "make KI available" without further detail. In the proposed rule, the NRC discussed federal stockpiles of KI as part of Federal response to terrorist acts. (See also discussion at end of the comment evaluation concerning NRC activities related to Federally-funded stockpiles or other supplies of KI). One commenter indicated that expanding this supply may be the best approach. Another commenter stated that the public is not interested in stockpiles, but instead wants information to make their own decisions. Of those comments related to specific methods of availability, these can be generally grouped into individual availability, state stockpiles in the vicinity of nuclear power plants, or regional stockpiles.

Individual Availability

One State submitted, as part of its comments, a report that discussed a plan they have developed that would allow citizens to gain access to KI in advance of an accident. The plan calls for the State to secure agreements with KI manufacturers to sell the medication directly to individuals or retail outlets, and to urge local pharmacies to stock KI as an over-the-counter

for themselves if they wanted to store and use KI. In fact, some KI manufacturers have indicated that they would make KI available to any person who requests it, at a fee. This approach would minimize the need for State stockpiles or predistribution and would put KI in the hands of the public before an accident occurs, rather than attempting to distribute the KI from stockpiles after an emergency is declared.

The concerns about the effectiveness of regional stockpiles for rapid deployment of KI to the public are also acknowledged. This is why the Commission has concluded that Federally-funded regional stockpiles or other supplies of KI are intended ^{only} as a backup, and that States should not rely upon the existence of such supplies in their consideration of the merits of use of KI as part of their emergency planning measures. FEMA has stated that in their view, regional stockpiles will not enhance local radiological emergency preparedness because of complex logistics. The Commission's decision on support for funding of regional stockpiles or other Federally-funded supplies as compared to funding of State supplies is discussed elsewhere in this notice. ✓

The Commission recognizes that regional stockpiles or other supplies of KI at the time of an accident may result in distribution difficulties that will reduce the effectiveness of the supplemental protective action. Nevertheless, the Commission notes that: (1) evacuation and in-place sheltering provide adequate protection for the general public and remain the primary protective actions; (2) those States that decide to use KI for the general public are also expected to prearrange for the KI supplies or stockpiles that they will need and not rely on Federally arranged supplies; and (3) Federal regional stockpiles or arrangements for supplies at the time of an accident are only intended as a contingent supply of last resort for those States who decide not to use KI for the general public but who change their minds at the time of an actual emergency and desire to distribute KI without preplanning (or in the event that State supplies are insufficient).

Issue I: FDA Input on KI

A few commenters thought that the dosage and intervention levels should be lowered from the values in the existing FDA guidance. For instance, they conclude that NRC should require using KI prophylaxis at one rem projected dose exposure not at the current 25 rem. It was noted that Poland uses a 5 rem intervention level. The concern of these commenters is that continued use of the old guidance subjects children to greater risk than necessary.

Response. The Food and Drug Administration 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 risks 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 is scheduled for publication in the Federal Register for public comment by ^{shortly} ~~early 2000~~ with final publication scheduled ^{in 2001} ~~for late 2000~~. Once this new information is available, the Commission will incorporate it into its guidance documents. ✓

Issue J: Original Petition versus Revised Petition

A few commenters state that in the proposed rule, the Commission claims to have granted the alternative submitted in the amended petition, but did not actually do so. In their view, the amended petition contained the combination of three elements-- the requirement to consider KI stockpiling, the unequivocal recommendation that States establish stockpiles, and

Three Mile Island accident: "The Commission's final rules are based on the significance of adequate emergency planning and preparedness to ensure adequate protection of the public health and safety. It is clear...that onsite and offsite emergency preparedness as well as proper siting and engineered design features are needed to protect the health and safety of the public. As the Commission reacted to the accident at Three Mile Island, it became clear that the protection provided by siting and engineered design features must be bolstered by the ability to take protective measures during the course of an accident."

The Commission did not rely upon probabilistic risk assessments in developing this final regulation on consideration of the use of KI.

The Commission interprets the third comment to relate to factors that the commenter believes could increase the likelihood of an accident and which, in the commenter's view, heighten the importance of emergency planning. The Commission's regulations recognize the importance of emergency planning by requiring development of a range of protective actions, which include sheltering and evacuation and, by this rulemaking, consideration of the use of KI for the general public.

✓ Issue N: Cost of KI and Shelf-Life

One commenter feels that the NRC has exaggerated the estimated cost of KI, ignoring comments that point to the availability of inexpensive and long-lasting KI. This commenter thinks that market forces are likely to bring down the cost of KI and that savings in the NRC budget could be effected without diminishing the safety of America's children.

The U.S. Pharmacopeia wrote in its comment letter that the long-term viability of the drug was tested and it was found that 11 years after manufacture and eight years after the expiration date, the tablets were assayed at 99.1% of the labeled content of KI. The petitioner

expressed the view that since the U.S. is currently engaged in a \$15 million study of radiation-caused thyroid disease in the Ukraine, it was hard to understand why the government was not willing to spend a fraction of that amount to prevent radiation caused thyroid disease at home.

Response. Cost estimates used in past documents were based upon information available at those times. NRC presently estimates the cost of KI to be about 18 to 20 cents per tablet if purchased in bulk, with a shelf life of 7 to 10 years. As a result, the Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for the general public for specific local conditions.

The information gained to date from Chernobyl relating to the usefulness of KI in preventing thyroid cancer was considered by the Commission. However, just as NRC has not funded other offsite protective actions (e.g. State and local government planning for evacuation and sheltering, KI for response personnel/emergency workers and institutionalized persons), the Commission has decided not to fund State supplies of KI for the general public.

✓ Issue D. Safety of KI ✓

Commenters believe that there is new information available from Poland and Belarus regarding use of KI following a radioactive release. They state that there were no reported serious adverse reactions. Specifically, 18 million individuals received prophylactic potassium iodide with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects. Commenters state that this experience has been recognized by other countries who are stockpiling KI for use by the general public. This data has led some commenters to say that just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine. Every drug has contraindications and the potential for allergic reactions. In an emergency as

Moreover, many nations in Europe and elsewhere, nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan, have stockpiled KI ^{and planned} for its use. ✓
So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it is reasonable to take a further small step and, continuing to recognize the important role of the States and local governments in matters of offsite emergency planning, explicitly require that planners consider the use of KI.

The amendment should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has improved since the current emergency planning requirements were put in place after the Three Mile Island-2 accident in 1979.

The use of KI is intended to supplement, not to replace, other protective measures. This amendment does not change the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs (evacuation protects the whole body, whereas KI protects only a single gland, the thyroid). Depending on the circumstances, KI may offer additional protection if used in conjunction with evacuation and/or sheltering. In developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public. In appropriate circumstances, KI can provide additional protection. 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 such decisions to State and local emergency response planners, who may find that KI should be a supplementary protective measure.

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.

Commission Decision on Funding of Regional Stockpiles or Supplies of KI

On June 30, 1997, the Commission voted to approve the NRC staff recommendation to endorse the FRPCC recommendations for the Federal government to fund the purchase of KI for States at their request. The Commission also endorsed the FRPCC recognition of the potential availability of the Federal stockpile of KI to State and local governments for purposes of mitigating the consequences of terrorist use of nuclear, biological, or chemical (NBC)

weapons. At that time it was believed that the NRC was the likely Federal agency to fund the state stockpiling. *On June 26, 1998, the Commission again noted that the Federal government (most likely NBC) is prepared to fund the purchase*

Historically, however, funding for State and local emergency response planning has been the responsibility of those governments often working with licensees. After further consideration of the matter of funding specific State stockpiles of KI (See Staff Requirements Memorandum on COMJSM 98-002 - Funding for Potassium Iodide Stockpiles, April 22, 1999), the Commission determined that absent Congressional funding specifically for this purpose, the

of a stockpile of KI for the States upon request.

NRC is not prepared to fund State stockpiling of KI. Nevertheless, the Commission supports the position that the Federal government should fund the purchase of KI for Federal stockpiles at appropriately located regional centers or other arrangements to expeditiously provide quantities of KI when needed in an actual emergency.

The NRC intends to continue to work with other cognizant agencies in an attempt to establish regional stockpiles or other Federally supported supplies of KI. At this time, NRC and FEMA have been unable to reach an agreement relating to regional stockpiles, but the two agencies have explored a concept for those States who seek KI at the time of an actual emergency. Under this concept, a funding mechanism for multiple regional stockpiles of KI would not be required. Rather, this concept would rely on the Center for Disease Control "pipeline" approach, which is part of the evolving U.S. infrastructure to respond to terrorist efforts. It should be noted that this "pipeline" concept as it pertains to KI has not been approved by either NRC or FEMA. Resolution of the Commission's policy on funding of KI ^{^ regional} stockpiles is not needed to support the rule as written. ✓

The Federal Register notice for the proposed rule (64 FR 31737) sets forth in detail the basis for the Commission determination only to support funding of regional stockpiles or other supplies of KI as opposed to state stockpiling of KI. That notice also describes the petitioner's position on this and related issues.

The Commission recognizes that regional stockpiles or other supplies of KI at the time of an accident may result in distribution difficulties that will reduce the effectiveness of the supplemental protective action but the Commission notes that: (1) evacuation and in-place sheltering provide adequate protection for the general public and remain the primary protective actions; (2) those States that decide to use KI for the general public are also expected to prearrange for the KI supplies or stockpiles that they will need and not rely on Federally arranged supplies, and (3) Federal regional stockpiles or arrangements for supplies at the time

of an accident are only intended as a contingent supply of last resort for those States who decide not to use KI for the general public but who change their minds at the time of an actual emergency and desire to distribute KI without prior planning, or in the event that State stockpiles prove insufficient.

It should be noted that Federally supported supplies of KI (in regional stockpiles or otherwise) do not now exist (except for ^{extremely} limited supplies in stockpiles for Response to Nuclear, Biological, or Chemical Terrorism) and may never be established. State and local governments should not rely on the existence of Federal supplies when they consider their position on the use of KI for the general public.

Metric Policy

On October 7, 1992, the Commission published its final Policy Statement on Metrication. According to that policy, after January 7, 1993, all new regulations and major amendments to existing regulations were to be presented in dual units. The amendment to the regulations contains no units.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995, Pub. L 104-113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending its emergency planning regulations to require that consideration be given to including potassium iodide as a protective measure for the general public that would supplement sheltering and evacuation in the event of

incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this final rulemaking, is denying in part the original petition for rulemaking (PRM 50-63), which would require the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State by explicitly requiring that planners consider (PRM 50-63A) the use of KI for the general public.

II. Need for Action.

In SECY-97-245, the NRC staff proposed options for resolving the original petition for rulemaking. In an SRM on SECY-98-061, the Commission directed the NRC staff to proceed with the rulemaking. In so doing, the Commission found that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG-0654/FEMA-REP-1, Rev. 1, p. 63 items e and f). However, since the last revision of that guidance, there has been ~~some~~ experience with the mass distribution of KI during a radiological emergency. Although the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes ^{remarkably} few threatening side effects. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it seems reasonable, while continuing to recognize the important role of the States in matters of offsite emergency planning, to explicitly require that planners consider the use of KI. The rule is needed to ensure that the states are aware of and take into consideration the costs, risks, and benefits of KI in their decision making process in order to optimize emergency planning for the public health and safety.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

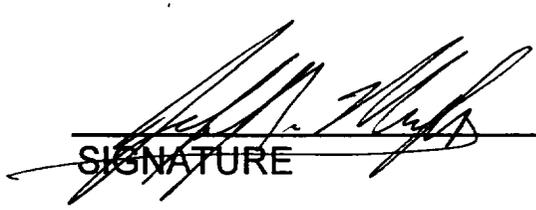
SUBJECT: **SECY-00-0040 - FINAL AMENDMENTS TO 10 CFR 50.47; THEREBY GRANTING IN PART TWO PETITIONS FOR RULEMAKING (50-63 AND 50-63A); RELATING TO A REEVALUATION OF POLICY ON THE USE OF POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT**

Approved Disapproved Abstain

Not Participating

COMMENTS:

See attached comments.



SIGNATURE

11/28/00

DATE

Entered on "STARS" Yes No

COMMENTS OF COMMISSIONER MERRIFIELD ON SECY-00-0040

I approve the draft final rule concerning the use of potassium iodide (KI) in the unlikely event of a nuclear emergency. To me, the draft final rule appropriately places responsibility on both the federal government and the states to address the use of KI. The draft final rule is consistent with the Commission's unanimous decision on SECY-98-264 (Nov. 10, 1998), to amend our regulations to ensure that state and local governments consider using KI in the event of a nuclear emergency. It is also consistent with a majority vote on that same paper to support the federal government establishing robust regional stockpiles of KI and to leave the decisions concerning local KI stockpiling, including matters of funding, entirely to the states.

Based on the votes of the other Commissioners on this paper, a majority of the Commission has decided to reverse the support for regional stockpiles, and to instead provide for state stockpiles. I respect their positions on this issue and will work with my colleagues to expedite a revised final rule carrying out their intentions. However, in light of the confusion following the Commission's decision on the proposed rule, I feel that I should outline my reasoning for supporting regional stockpiles and what I believe is the appropriate role of the states and the federal government with respect to KI. Ultimately, I do not agree with the majority that the Commission should fund state stockpiles and that regional stockpiles are not worthwhile to pursue. The majority's decision means that local communities that make KI available will have supplies of KI in the event of a nuclear emergency, but the rest of the country will be left entirely without any supplies on hand or any plan to access KI in the event of a nuclear emergency. To me, the draft final rule provided a simple solution; keep in place the existing policy with respect to the role of the states, and give the federal government a role in promoting a national KI policy that would ensure all states have access to regional KI stockpiles. That, however, is not the decision the Commission has chosen to make.

The Role of the States

Not interfering with the role of the States is a responsible approach to emergency planning because it empowers the states and local communities, who are most familiar with the geographic areas in question and the citizens of communities that may have a stake in these matters, to establish effective emergency plans. Further, not funding state stockpiles is consistent with long-standing federal policy on emergency planning, which leaves essentially all other details of specific emergency planning measures to the states.

I am aware that if not required, some states will elect to not stockpile KI. This is because stockpiling raises logistical issues about how to adequately distribute the stockpiles to the general public in an emergency and how to assure proper doses are administered for children and adults. For these reasons, states have taken different approaches to making KI available at the local level. For example, the State of New Hampshire established a working group of state and public interest group representatives to examine the use of KI in the event of an emergency and in a thoughtful and comprehensive report, concluded that making KI available at the local pharmacies for the public to purchase, rather than maintaining large stockpiles of KI at government facilities, was the most prudent and effective emergency planning measure for those communities. Citizens of those communities can purchase KI from these local pharmacies and keep it on hand, rather than relying on a mass distribution in the case of an emergency. After a public hearing, the Governor's Advisory Council on Radiation Protection for the Commonwealth of Massachusetts has recommended a similar policy. Opponents of this position argue that mass stockpiling would be far better for these communities. Putting aside whether the opponents are correct, certainly to resolve that issue, one must consider the specific emergency planning issues associated with those local communities and consequently any decision about such a local planning measure, properly rests with the states, not the Commission.

The States have demonstrated that they are well equipped to address these issues. That is why I believe it would be more appropriate for the NRC to spend its limited resources on its federal responsibilities for emergency planning. It may be true that a Commission decision to fund state stockpiles may make it difficult for a state to choose not to stockpile. However, pressuring states in this way is not an appropriate basis for providing such funds, as it would clearly be incongruous with the Commission's commitment to leave the decision whether to stockpile entirely to the states. Indeed, if it is true, as the proponents of KI suggest, that the costs to fund KI stockpiles at the local level will be minimal, then it is equally reasonable to conclude that there is no basis for providing federal funding when a state should have no difficulty funding a local KI stockpile on its own.

For these reasons, I do not support federal funding for state KI stockpiling. As I said in my original vote on SECY-98-264, "ultimately, I am convinced that the decision regarding whether a state should stockpile KI, including the details of how to fund it, should be left to the states." In my view, the Commission would need to identify a compelling reason to fund such an initiative and no such reason has been presented with respect to funding state stockpiles of KI.

The Role of the Federal Government

To me, it seems imprudent for the federal government to abandon all efforts to establish robust strategically placed regional KI stockpiles. Regional stockpiles are necessary to ensure that there is an adequate supply of KI available at the national level for communities that for any number of reasons would not otherwise have access to KI. For example, a regional KI stockpile may be accessed when a state stockpile proves to be inadequate, a state does not have a stockpile or has not otherwise made KI available. Not every state will have an adequate source of KI on hand. Comments responding to the proposed rule clearly indicate that some states would not stockpile, even if the federal government were to pay for stockpiling. As for those states that do stockpile, there is always the possibility that supplies close-in will be inadequate or difficult to access during a mass evacuation.

I want to emphasize that I do not suggest that regional stockpiles should substitute for local response measures. Though it is without question that the United States Government has sophisticated equipment at its disposal to expeditiously deliver KI to communities in need, including a wide range of military assets, there of course will be some lag time between a request and delivery. The length of time will depend on the location of the stockpile in relation to the community in need. But, I strongly disagree with the theory that only state stockpiles that can be distributed within a short time after an event begins will be necessary or effective. The KI distributed in Poland, which has been credited with preventing thyroid cancer in children, was distributed days after the Chernobyl disaster first began. I find equally unconvincing the arguments that regional stockpiles should not be established because even if needed, will be too difficult to distribute or may hamper local emergency response measures. These are the exact same arguments levied against state stockpiling and which advocates of KI have urged the Commission to overcome. Evacuation, if possible, is the single most effective response measure in the event of a significant nuclear emergency and use of KI, whether stored locally or regionally, must not interfere with the efficient dispatch of any evacuation plan. To ensure that federal regional stockpiles do not interfere with state emergency response activities, the federal government would need to have an adequate federal supply on hand, and let the states determine whether and how to use them in the context of all other emergency planning measures.

Not only would the decision to abandon regional stockpiling be imprudent because it would eliminate any access to KI for states without a stockpile, but it would also be inconsistent with federal policy, Commission policy and recommendations of the international community.

The federal government years ago recognized the need to create regional stockpiles of pharmaceuticals to respond to significant disasters, such as an act of terrorism using biological or chemical weapons. In June 1997, a federal interagency committee, the Federal Radiological Preparedness Coordinating Committee (FRPCC), chaired by Federal Emergency Management Agency (FEMA), proposed using these same national medicinal stockpiles, to respond to significant nuclear emergencies, by including KI in the stockpiles. See SECY-97-124 (June 16, 1997), Attachment 1, Proposed Federal Policy on KI (April 16, 1997). These regional stockpiles of KI were to be used in addition to any state stockpiles to be funded by the federal government. However, the proposed policy noted that the supplies would be limited and stationed in only three regional centers. This number was later reported to have been revised to include another 26 regional centers. See SECY-97-124A (June 26, 1997). Based on the FRPCC's recommendation, the Commission recommended including the following revised language in the draft KI policy:

In addition [to funding state stockpiles], the Federal government is also required to prepare for a wider range of radiological emergencies. To that end, and as an added assurance for radiological emergencies in which the location and timing of an emergency are unpredictable and for which, unlike licensed nuclear power plants, there is little planning possible, limited stockpiles of KI are being established by the Federal government at a number of sites around the U.S. These Federal stockpiles will be available on an *ad hoc* basis to any State for any type of radiological emergency, at any time. However, the stockpiles are extremely limited and are not likely to provide enough KI for use by the general public in a major radiological emergency. (Emphasis added). *Staff Requirements Memorandum dated September 30, 1998, Attached Draft Policy, page 7.*

After recommending these revisions to the proposed policy, however, the Commission was informed that almost no KI was going into the medicinal stockpiles. Therefore, the Commission felt it was necessary to reassert its support for regional stockpiles and to commit to working with FEMA to make sure that any regional stockpiles would have a substantial supply of KI and would be strategically located. Importantly, the Commission committed to fund the regional stockpiles if funding could not be covered by FEMA under its initiatives and to the extent that there would be no Economy Act constraint on FEMA receiving money from the NRC. See Staff Requirements Memorandum (Apr. 22, 1999). At the same time the Commission decided to leave funding for state stockpiles to the states.

The only change in the Commission's policy was to withdraw its support for federal funding for state stockpiles. The Commission did not change its position on any substantive issue related to state stockpiling (e.g., the Commission never recommended eliminating or replacing state stockpiles with regional stockpiles). Subsequently, the Commission was urged to abandon federal regional stockpiling altogether. To me this was a far more substantive change to this same Commission policy. It results in the abandonment of any effort to create a national supply of KI and taking less precaution for nuclear emergencies than other types of natural disasters for which regional stockpiles of pharmaceuticals would still remain. Federal funding for state stockpiles cannot take the place of pre-positioned regional stockpiles because we know that even with funding for state stockpiles, some states will not have them and such a plan would guarantee that those states would have absolutely no access to KI. In contrast, only regional stockpiles would guarantee that KI would be available for all states to respond to specific local conditions where access to a regional stockpile could be useful.

A policy shift to have no regional stockpiles could also be viewed as inconsistent with international guidelines. The World Health Organization recommends for communities near the reactor "seriously consider[ing]" predistribution to households and "provisions for stockpiles in places controlled by authorities close in and at further distances." *Guidelines for Iodine*

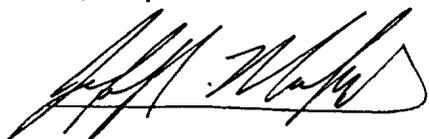
Prophylaxis Following Nuclear Accidents, 1999 update, at 18. I would leave such response measures in the capable hands of state and local communities to consider. In contrast, the WHO's recommendation that "widespread storage may be warranted at considerable distances from the potential accident site ..." and "[p]lanning should consider the use of redundant distribution areas to minimize delays in implementing stable iodine prophylaxis," are to me consistent with regional stockpiling, which should be the federal government's responsibility.

Although my recommendation to support regional stockpiles would have been consistent with previous Commission policy, I was very concerned that it would be inconsistent with the more recent views of the Federal Emergency Management Agency (FEMA), which has the lead federal role for offsite radiological emergency activities pertaining to U.S. commercial nuclear power plants. However, I would have preferred that before supporting a policy that would abandon regional stockpiling altogether, the Commission would have had further interactions with FEMA to ensure that FEMA had fully understood the bases for the Commission's decisions to support regional stockpiles. It would have been especially appropriate in this situation because when the Commission originally changed its position to not fund state stockpiles there was much confusion over the bases for the Commission's decision.

For example, there was some confusion among our stakeholders that the Commission might be suggesting that regional stockpiles should be a substitute for local measures, which is not the Commission's position. As a result, it is not clear that FEMA has had an opportunity to review the actual recommendation, which is that regional stockpiles continue to be offered even though some states may have local stockpiles. Also, some stakeholders mistakenly believed that the Commission had unilaterally decided that FEMA should fund state stockpiles, rather than the Commission. This is also incorrect. The Commission's recommendation was for the states to fund any state stockpile. It is also unclear whether some stakeholders are aware that the Commission had offered to pay for regional stockpiles. In light of this potential confusion, I believe that rather than changing our policy on regional stockpiles at this time, it would have been more prudent to continue to work with FEMA on this issue.

In sum, I believe that a federal policy which leaves the states to consider KI at the local level and which commits the federal government to take an active role at the federal level would have provided the most comprehensive and responsible approach to a national KI policy. Accordingly, I believe the final rule on KI should have continued to include an NRC recommendation for regional stockpiles, rather than funding for state stockpiles.

That having been said, recognizing that the decision will now stand that the NRC will pay for state stockpiles, the Commission needs to clearly address some of the practical and logistical concerns associated with such a proposal. For example, what requirements or disclaimers should accompany the funding for KI stockpiles? Is this a one-time supply, or would the Commission re-supply KI as populations change and the shelf life of the initial KI supply expires? How will the Commission reply to any requests to fund supplies at local pharmacies to be handed out on a routine basis to those requesting it? Is that considered a "stockpile?" If a majority of the Commission were willing to pay for supplies at local pharmacies, how would the Commission ensure that those supplies would go to individuals living within the 10 mile Emergency Planning Zone (EPZ)? How will the Commission effectively ensure that it will only be responsible for funding state stockpiles within the 10 mile EPZ if legislation like that proposed by Representative Phil English (R-PA) earlier this year (H.R. 4969), requiring a plan for stockpiling in areas within a 50-mile radius of a nuclear power plant, is reintroduced? How will the Commission prioritize funding for state stockpiles in relation to all other funding responsibilities of the agency and any budget restraints? These and other concerns associated with the Commission's decision to fund state stockpiles will require significant effort on the part of the Commission and the staff. While I respect the will of the majority in this matter, I hope there is a clear understanding that these will be difficult issues to resolve.



11/28/00⁴