

December 22, 2000

COMMISSION VOTING RECORD

DECISION SECY-00-0040

ITEM:

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.

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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

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VOTING SUMMARY - SECY-00-0040

RECORDED VOTES

	<b>APRVD</b>	<b>DISAPRVD</b>	<b>ABSTAIN</b>	<b>NOT PARTICIP</b>	<b>COMMENTS</b>	<b>DATE</b>
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.

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## Commissioner Comments on SECY-00-0040

### Chairman Meserve

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.<sup>(1)</sup> 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 distribution<sup>(2)</sup> 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.<sup>(3)</sup> I conclude that it is appropriate to require planning authorities to consider the use of KI as a supplement to other emergency response activities.

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.<sup>(4)</sup> 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.<sup>(5)</sup> 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 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."<sup>(6)</sup> 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.<sup>(7)</sup>

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.<sup>(8)</sup> 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 and FEMA,<sup>(9)</sup> 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.<sup>(10)</sup> 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.<sup>(11)</sup>

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.<sup>(12)</sup> 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 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.<sup>(13)</sup> 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.

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.

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

## Commissioner Dicus

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.

## Commissioner Diaz

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,<sup>(14)</sup> I believe we have a responsibility to clearly aid the States by providing them with information and funding.<sup>(15)</sup> 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.

## Commissioner McGaffigan

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.

## **Commissioner Merrifield**

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]" redistribution 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.

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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).

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).

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.Vietti-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).

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, 106<sup>th</sup> 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).

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.

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.

14. 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.

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