

NOTATION VOTE

RESPONSE SHEET

TO: John C. Hoyle, Secretary

FROM: COMMISSIONER MCGAFFIGAN

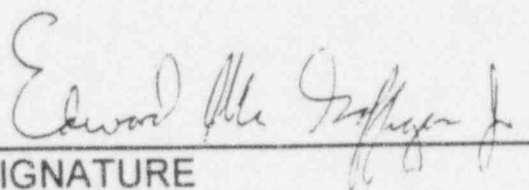
SUBJECT: **SECY-97-124 - PROPOSED FEDERAL POLICY REGARDING
USE OF POTASSIUM IODIDE AFTER A SEVERE ACCIDENT
AT A NUCLEAR POWER PLANT**

Approved _____ Disapproved x Abstain _____

Not Participating _____ Request Discussion _____

COMMENTS:

I disapprove the staff's recommended options and, instead, approve Option 3c -- proceed with rulemaking that will require KI to be included as part of the protective actions for the general public. My comments and bases for this position are attached.



SIGNATURE

Release Vote x

 6/25/97

DATE

Withhold Vote

Entered on "AS" Yes x No _____

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PDR COMMS NRCC
CORRESPONDENCE PDR

Commissioner McGaffigan's Comments on SECY-97-124:

I disapprove the staff's recommended options on the treatment of potassium iodide (KI) in the radiological event context, and, instead, support option 3c. I would urge that we proceed with rulemaking to modify 10 CFR 50.47(b)(10) to specifically include the predistribution of KI to the level of individual households¹ as a measure to supplement the range of protective actions currently required by that regulation. I take this position not because KI constitutes an effective protective action in and of itself,² but because I believe that the extensive predistribution of KI can and will enhance the effectiveness of other protective actions, such as sheltering and evacuation, for those persons within the plume EPZ.³

Without more localized predistribution, the value of KI stockpiling, at least in the context of commercial nuclear power plant accidents, is somewhat reduced.⁴ As the staff's proposed draft Federal Policy on Potassium Iodide clearly indicates, to be useful, KI must be "[t]aken in time." To be "taken in time" to be of optimal value for either evacuation or sheltering, KI should be predistributed to the household level (where it can be administered promptly upon the protective action decisionmakers' direction), rather than

¹ Under the modified rule, we could specifically direct licensees to predistribute prepackaged KI tablets to the general public within the plume exposure pathway emergency planning zone (plume EPZ). Such predistribution could be made to individual households, businesses, factories, hotels, hospitals, retirement communities and schools as part of the annual emergency preparedness brochure distribution process that most utilities undertake to comply with 10 CFR 50.47(b)(7).

² I acknowledge that KI effectively reduces radiation exposure for only the thyroid gland from ingested or inhaled radioiodines. I also acknowledge that, in view of NRC requirements with regard to containments and containment spray systems that would contain and/or remove most radioiodines, KI might be needed only in certain limited circumstances. Nevertheless, it is my view that KI does provide additional special protection that would be of substantial benefit to both protective action decisionmakers and, more importantly, the general public within the plume EPZ, and I believe that it is time we took advantage of these benefits. The Government of France apparently agrees as it has recently decided to require the predistribution of KI in the vicinity of all of its nuclear power plants.

³ Predistribution of KI pursuant to modified NRC rules would also augment the Federal government's new policy regarding preparedness for terrorism, recognizing the "new national impetus for expanding the Federal preparedness to include medicinal supplies for [nuclear, biological and chemical] events" by effectuating substantial predistribution of KI in those limited areas of the country where there are commercial nuclear power plants.

⁴ The need for basic preplanning was shown by the TMI-2 accident which resulted, among other things, in new requirements for radiological emergency planning in order to avoid the ad hoc approaches that proved to be so inadequate in the past.

stockpiled at a few central locations around the country or in a single State repository at a substantial distance from the location of the radiological incident where it might be needed.⁵ Short of the household level of predistribution, the benefit of KI in a radiological emergency at a commercial nuclear power plant is reduced.

I strongly disagree with the staff's assertion (at page 16 of SECY-97-124) that this approach might "undo the web of emergency planning." At the same time, I recognize that this approach arguably introduces issues with regard to (1) the States' prerogatives, (2) side effects from the use of KI, (3) the current protective action scheme, (4) the need to amend emergency plans and increased costs to licensees, and (5) backfit considerations. I do not view these potential issues as significant for the following reasons --

- (1) I do not believe that further rulemaking in this area would be contrary to the States' views on the use of KI or usurp the States' authority and responsibility with regard to protecting the health of their citizens. The States' logistical concerns that timely distribution of KI to the general public would be difficult could be addressed by placing the responsibility for predistribution on NRC licensees, most of whom have a reasonable method for household level predistribution already established through their annual emergency preparedness information distribution mechanisms (e.g., emergency preparedness calendars/brochures sent to all member of the public in the plume EPZ). The States' concerns about liability associated with the misuse of KI should be minimized by the fact that the FDA has made KI an "over the counter" commodity and the licensees/States likely will provide "warning labels" on the proper use of the drug. Concerns about usurping the States' prerogatives are really "red herrings" -- under the revised rules and emergency plans, State and local governments would retain their authorities as final protective action decisionmakers; the State and local governments would retain the authority to decide whether to direct actual administration of KI, just as they are the current protective action decisionmakers for ordering evacuation or sheltering.⁶

⁵ I believe that Option 2 of SECY-97-124, which could entail the establishment of KI stockpiles in only three widely dispersed locations in the United States, may result in such limited predistribution of KI that it will be of little value in a radiological emergency at a nuclear power plant. Option 3b is a substantial improvement over Option 2 and could result in much greater and more effective predistribution of KI for potential use in a nuclear power plant emergency. However, I prefer Option 3c because it will optimize the value, benefits and effectiveness of KI in a radiological emergency.

⁶ Although it might be argued that putting KI in the hands of individual citizens by requiring household level predistribution usurps the States' authority to decide the issue as to whether and when the administration of KI would be appropriate, KI is currently an over-the-counter commodity (like aspirin) which an individual citizen can self-administer. NRC rulemaking in this area would only make KI more readily available to individuals.

- (2) I believe that the potential for side effects from the proper use of KI in a radiological emergency is inconsequential. KI does have the potential for side effects but the FDA has removed the requirement for prescriptions for the use of KI and thus put KI in the same category as aspirin. There are no restrictions on the use of iodized table salt (note that the iodizing ingredient of common iodized table salt is potassium iodide, though obviously in much lower concentrations than would be used in a radiological emergency). In any event, absent a demonstration that the side effects are both widespread and significant, it is my view that the radiological protective benefits from the proper use of KI far outweigh the apparently limited side effects.⁷
- (3) I believe that rulemaking to require the predistribution of KI to the general public would, in fact, enhance the current protection afforded by sheltering and evacuation, rather than undermine the current protective action scheme. If the additional option of KI were available, the effectiveness of sheltering would certainly be increased since individuals ordered to shelter would have the additional protection from radioiodines. The evacuation option would be made more effective because the early ingestion of KI would provide protection to evacuating individuals from radioiodines in the plume that they may encounter in the course of their evacuation. KI is not a stand-alone protective action that would be used as an alternative to, and thereby undermine the traditional protective actions of, evacuation or sheltering. Rather, KI will serve only to enhance the effectiveness of both of these traditional protective actions.
- (4) Rulemaking to require the household level predistribution of KI would require the amendment of emergency plans in the protective action area and would result in some costs to utilities (basically the costs of procuring KI, distributing KI to the general public in the plume EPZ, revising emergency plans, and providing training or instructions on the revised plans and the proper use of KI in a radiological emergency). From the staff's assessment in Attachment 2 to SECY-97-124, it appears that the costs of procurement of KI will not be unreasonable. In view of the already-established mechanisms for distributing emergency preparedness materials and information to the general public in the

⁷ As stated in the staff's proposed draft Federal Policy on Potassium Iodide,

[t]he FDA has evaluated the medical and radiological risks of administering KI for emergency conditions and has concluded that it is safe and effective and has approved over-the-counter sale of the drug for this purpose. FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiological emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem or greater.

plume EPZ. I believe that the cost of distributing KI, revising emergency plans and providing information and training on the use of KI will not be unreasonable. At bottom, I believe that this approach will enhance protective actions at fairly low cost and it would demonstrate to the public that all reasonable efforts are being undertaken to enhance their protection.

- (5) Finally, as to potential backfit issues, in view of the fact that KI predistribution to the household level would make both evacuation and sheltering more protective and, thus, would broaden the range of practical protective actions (from evacuation alone to evacuation and sheltering), I believe that a case can be made that this rulemaking is, in essence, a compliance backfit that is needed to better comply with the current provisions of 50.47(b)(10).

For all of these reasons, I urge that we direct the staff to initiate rulemaking to require the predistribution of KI to the household level and thereby effectively extend the enhanced protection afforded by KI to members of public in the vicinity of NRC-licensed nuclear power plants. The Government of France has taken this step and I have a hard time accepting a lower level of protection for the general public in a radiological emergency in this country.



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

June 30, 1997

OFFICE OF THE
SECRETARY

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: John C. Hoyle, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-97-124 - PROPOSED
FEDERAL POLICY REGARDING USE OF POTASSIUM
IODIDE AFTER A SEVERE ACCIDENT AT A NUCLEAR
POWER PLANT

The Commission has approved Option 2 - endorsing the Federal Radiological Preparedness Coordinating Committee (FRPCC) recommendations. As such, the Commission has endorsed the Federal offer to fund the purchase of potassium iodide (KI) for States at their request and endorsed the FRPCC recognition of the availability to State and local governments of the Federal stockpiling of KI for purposes of mitigating the consequences of terrorist use of nuclear, biological, or chemical (NBC) weapons. Under this option, the Federal government would provide funding for the purchase of KI and State and local governments would be responsible for maintenance, distribution, and subsequent costs. NRC licensees should, as part of the emergency response planning, discuss this matter with State and local governments who make decisions on protective measures as part of their planning for responses to emergencies. The staff should inform the Commission as to how it will inform NRC licensees of the need to discuss KI with State and local governments.

(EDO)

(SECY Suspense: 8/29/97)

KI stockpiles should be available to NRC employees who are expected to perform first responder responsibilities.

The Commission's approval of Option 2 should not be viewed as a denial of, or Commission action on, the petition for rulemaking (PRM) of Peter Crane. The staff should prepare an assessment of Mr. Crane's petition and of the comments on that petition and submit the assessment to the Commission for its consideration in

SECY NOTE: THIS SRM, SECY-97-124, AND THE COMMISSION VOTING
RECORD CONTAINING THE VOTE SHEETS OF ALL
COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5
WORKING DAYS FROM THE DATE OF THIS SRM.

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accordance with 10 CFR 2.802 and 2.803.
(EDO)

(SECY Suspense:

8/29/97)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
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