



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

March 3, 2000

Mr. Peter G. Crane
4809 Drummond Avenue
Chevy Chase, MD 20815

Dear Mr. Crane:

This is in response to your letter dated October 15, 1999, in which you raised issues regarding the interactions between the Federal Emergency Management Agency (FEMA) and the U.S. Nuclear Regulatory Commission (NRC). In addition, you asked several questions concerning the NRC's efforts in dealing with potassium iodide (KI) policy making.

First, I do not agree that the NRC misrepresented FEMA's position on regional KI stockpiles. In a letter from FEMA Director James L. Witt, dated April 29, 1999 (Enclosure 1), to former NRC Chairman Shirley Jackson, Commissioner Dicus, Commissioner Diaz, Commissioner McGaffigan, and Commissioner Merrifield, Director Witt stated, among other concerns, that FEMA did not support establishment of regional KI stockpiles. Chairman Jackson's reply (Enclosure 2), dated June 15, 1999, included a statement that she was confident that the NRC and FEMA staffs will be successful in resolving the KI issue. The NRC's responses to the post-hearing questions reflected that NRC and FEMA were undertaking this effort and NRC's belief that the agencies would reach a successful outcome. The NRC never stated nor intended to imply that FEMA had indicated any change in its position. As a result of Chairman Jackson's letter to Mr. Witt and Commission direction to the staff, the NRC and FEMA staffs have been meeting to identify options for stockpiling KI, consistent with the views of each agency.

On January 12, 2000, the NRC received a letter from FEMA, signed by Ms. Kay Goss, Associate Director for Preparedness, Training, and Exercises. The letter reiterates the concerns expressed by Mr. Witt in his letter of April 29, 1999. The letter also provided comments on a predecisional final rulemaking package not available to the public, and we cannot be more specific regarding its contents until these documents become publicly available. We will place a copy of the FEMA letter and NRC response on the NRC website after they are publicly available.

You also stated that the Commission withdrew draft "NUREG-1633, in the face of withering criticism from the health departments of New York State and Ohio, and from me." In the staff requirements memorandum (SRM) dated June 26, 1998, the Commission stated, in part, "To assist the State and local decision makers, the staff should submit its paper, 'Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents,' for public comment. Staff is encouraged to submit the assessment in whole, or in part, to peer reviewed journals for publication. Following receipt and evaluation of the public comments, the staff should revise the paper, as appropriate subject to Commission review." In conformance with this directive (COMSECY 98-016, dated July 13, 1998), the staff announced the availability of NUREG-1633 in the Federal Register and solicited public comments.

By the end of September 1998, the staff received about 80 comment letters from individuals, organizations and States. All comments received on draft NUREG-1633 are attached for your information and review (Enclosure 3). In an SRM dated September 30, 1998, the Commission directed the staff to withdraw draft NUREG-1633, and "in light of the many useful public comments on draft NUREG-1633, a substantially revised document that takes those comments into account will be issued in its place, and that the draft NUREG is therefore being withdrawn." The staff is currently developing an updated NUREG-1633 that conforms to the direction of the SRM.

You also raise the issue of a staff apology at the Commission meeting held on November 5, 1997, regarding the accuracy of the information upon which the Commission's policies on KI are based. The meeting transcript pages addressing this issue (Enclosure 4) show that, in response to a specific question, the staff requested that the record reflect correction of an error in one statement in a Commission paper, dated June 16, 1997 -- SECY-97-124, "Proposed Federal Policy Regarding the Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant" (Enclosure 5). The statement mistakenly implied that FEMA [where correctly it was the NRC] was the primary Federal regulatory agency [on KI] that did not support the purchase and stockpiling of KI by the Federal government.

Another issue you raised concerned the cost of KI. The basis for the cost figures presented in our Congressional response is described in Attachment 2 to SECY-97-124 (see Enclosure 5) and updated in SECY-98-264, dated November 10, 1998 (Enclosure 5a). At this time, the U.S. Food and Drug Administration (FDA) is reevaluating its 1978/1982 KI guidance. If FDA proposes KI dosages other than the current ones (130 mg per day for adults and children over 1 year old), the cost for KI could change. It is not practical or possible at this time to provide an exact total cost of KI. You also raised a question regarding the staff's representation of these costs. All costs presented refer to the annual costs for purchasing KI. In the situation where it was assumed that all of the potential purchases of KI occurred in one year, that total cost was attributed to one year, consistent with budget implementation. Even if the cost did not recur for 10 years, the cost per year is still the total amount for the first year, zero cost for the next nine years, with the total cost occurring again in the tenth year.

Notwithstanding these limitations, the cost of KI tablets when purchased in large quantities (greater than about 500,000 tablets) was estimated. As you stated, a Swedish firm offers KI in bulk at 6 cents per pill, with a stated 10 year shelf life. The Swedish company, RECIP AB, provided costs that ranged from 11.5 cents per tablet for 1,000,000 tablets to 6 cents per tablet for 50,000,000 tablets. It should be noted that these costs are for 65 mg tablets whereas the current recommended FDA KI dosage for adults and children over 1-year old is 130 mg KI per day. The cost per 130 mg dose is twice the cost per tablet stated above and would therefore range from 23 cents to 12 cents per 130 mg dose. Additionally, this cost does not include shipping nor any costs associated with RECIP AB obtaining FDA approval of this KI product. In the United States, we have located two companies advertising KI tablets on the internet for purchase by the general public that have received FDA approval. ANBEX charges \$10 per package of 14 KI tablets (130 mg dose) plus \$4.00 for shipping up to 10 packages. The shelf-life is stated by ANBEX to be "indefinite." Based on the staff's informal inquiry to the company, it was indicated that the cost could be reduced to about \$2.50 - \$2.60 per package of 14 tablets in quantities of about 1,000,000 tablets, resulting in a cost of about 18 cents to 19 cents per tablet. Carter-Wallace Laboratories sells Thyro-Block Tablets, a 130 mg KI tablet. The tablets

are sold in a 98-day supply (98 130 mg tablets) for individuals at a cost of \$42.95 or in a case of 100 bottles of 14 130 mg KI tablets per bottle for \$560. This is about 40 cents to 43 cents per tablet. It is estimated that purchasing a million or more tablets at a time could get the price down to about 20 cents per tablet.

You also requested that NRC provide an accurate account of the actual expended costs of studying the KI issue. In our answer to the hearing question, we estimated that our spending to study the KI issue exceeded \$2.6 million in period from October 1989 to August 11, 1999. The precise sum for the individual items listed came to \$2.64 million. The response to the hearing question 16(B) represents the staff's best estimate of costs associated with the KI issue over the last 10 years (1989 - 1999). On the basis of the records available from our internal work tracking system, the staff was able to determine the cost of preparing the cost-benefit study entitled, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident" (NUREG/CR-6310) and the number of NRC full-time equivalent (FTE) positions associated with its publication. In addition, the cost associated with the KI rulemaking was determined with the aid of the internal tracking system. The cost to the NRC for providing travel funds to State members of the group preparing and reviewing the document, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents", draft NUREG-1633, in December, 1998, and March, 1999, totaled about \$9,100. Other KI activities involving offices and regions were not captured here because they did not necessarily have a specific tracking number referencing KI efforts over the 10-year period being evaluated. Furthermore, all Commissioner and management involvement is considered "overhead" with no specific reference to projects. Therefore, on the basis of a review of the records to the extent possible and discussions with principal staff members, the staff estimated that approximately 5 FTEs of lead technical staff time (through 1999) and 3 FTEs of lead coordinator time were expended. The other 12 FTEs represent the sum of the following estimates: (1) the management overhead cost at 0.2 FTE per year, subtotal — 2 FTE; (2) direct staff (other than lead staff), for example, development of the staff's technical reports on KI (for example, various versions of draft NUREG-1633), and Commission correspondence, at 0.8 FTE per year, subtotal — 8 FTEs; (3) technical staff assistance with reviews of reports, meetings with the Federal Radiological Preparedness Coordinating Committee and FEMA, and correspondence review at 0.2 FTE per year, subtotal — 2 FTE. These estimates result in the total of approximately 20 FTEs, which was provided in the response to question 16(B). It should be noted that the management overhead cost estimate is somewhat uncertain and could be higher than 0.2 FTE per year but the staff does not have a basis to make a better estimate.

In addition to NRC staff and its contractors, it is important to note that other Federal agencies have also expended FTEs and incurred other costs associated with KI, together with the efforts expended by States and local governments. None of these costs for work on the KI issue by government entities outside the NRC have been included in the staff's estimates noted above (with the exception of the state travel cost reimbursement stated above).

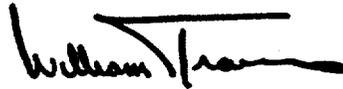
You also asked, "Who must consider KI under the proposed rule?" The proposed rule is directed principally to States and local governments, the entities with the important role to determine the appropriateness of the use of KI for their citizens, calling on these governments to 'consider' KI as one of the elements of their offsite emergency planning.

Mr. Peter G. Crane

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I hope this addresses your concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "William D. Travers". The signature is written in a cursive style with a long horizontal stroke extending to the right.

William D. Travers
Executive Director
for Operations

Enclosures:

1. Letter to NRC Commission fm J. L. Witt, FEMA
dtd April 29, 1999
2. Letter to J. L. Witt, FEMA fm Chairman S. Jackson, NRC
dtd June 15, 1999
3. Comments on draft NUREG-1633
4. November 5, 1997 Meeting Transcript Pages
5. NRC SECY-97-124, dtd June 16, 1997 - Proposed Federal
Policy Use of Potassium Iodide after a Severe
Accident at a Nuclear Power Plant
- 5a. NRC SECY 98-264, dtd November 10, 1998 - Proposed Amendments
to 10 Cfr 50.47; Granting of Petitions for Rulemaking (Prm 50-63 and
50-63a) Relating to a Reevaluation of Policy on the Use Of Potassium
Iodide (Ki) after a Severe Accident at a Nuclear Power Plant