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

March 9, 2000

CHAIRMAN

The Honorable Edward J. Markey
United States House of Representatives
Washington, D.C. 20515-2107

Dear Congressman Markey:

I am responding to your letter of November 10, 1999, expressing concerns about the U.S. Nuclear Regulatory Commission's (NRC's) responses to your questions on potassium iodide (KI) stockpiles associated with the hearing on July 21, 1999, on the Fiscal Year 2000 NRC Authorization Act before the Subcommittee on Energy and Power. In particular, you refer to a letter from Mr. Peter Crane, dated October 15, 1999, concerning alleged misrepresentations by the NRC of the Federal Emergency Management Agency (FEMA) position on regional KI stockpiles, alleged intentionally inaccurate testimony on the cost of buying KI, and an alleged misleading representation of the money NRC has spent studying KI.

I do not believe 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 the Commission, Director Witt stated, among other concerns, that FEMA did not support establishment of regional KI stockpiles. Former Chairman Jackson's reply (Enclosure 2), dated June 15, 1999, included a statement that she was confident that the NRC and FEMA staffs would 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 former Chairman Jackson's letter to Mr. Witt and Commission direction to the NRC staff, the NRC and FEMA staffs have been meeting to identify options for stockpiling KI.

On January 12, 2000, the NRC received a letter from FEMA, signed by Ms. Kay Goss, Associate Director for Preparedness, Training, and Exercises (Enclosure 3). The letter reiterates the concerns expressed by Mr. Witt in his letter of April 29, 1999, including the statement that FEMA does not support regional stockpiles. (We note that this letter addresses predecisional issues and therefore has not been released to the public.) We will provide you a copy of the NRC response. We have no communications from FEMA to the effect that it has changed its position on regional stockpiles and, as noted above, NRC did not mean to imply that FEMA had modified its position.

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You also requested "updated and accurate figures detailing the cost of buying potassium iodide," including "the cost per pill and the expected shelf-life for KI tablets." The basis for the cost figures presented in our response to the referenced Congressional correspondence is described in Attachment 2 to NRC SECY-97-124, dated June 16, 1997, (Enclosure 4) and updated in SECY-98-264, dated November 10, 1998 (Enclosure 4a). The estimate provided in post-hearing question 16a was based on the distribution of two pills, costing 25 cents each, to 80,000 people in the vicinity of each site. The total cost for 70 sites was estimated in the response at $3.25 million. However, we note that there was an error in the calculation, and the correct estimate should have been $2.8 million. Obviously, the overall cost for funding the purchase of KI depends, among other factors, on both the current market price of KI tablets and the number of States that would establish stockpiles.

The U.S. Food and Drug Administration (FDA) is currently reevaluating its 1978/1982 KI guidance. If FDA proposes KI dosages other than the current ones, the cost for KI could change. Nonetheless, in response to your request, we can estimate the cost of KI tablets when purchased in large quantities (greater than about 500,000 tablets). Mr. Crane references correspondence from a Swedish firm that offers KI in bulk at 6 cents per pill, with a stated 10-year shelf-life (Enclosure 5). 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. These cost estimates are for 65 mg tablets, whereas the current recommended FDA KI dosage for adults and children over the age of 1-year is 130 mg of KI per day. The cost per 130 mg dose is twice the cost per tablet and would therefore range from 23 cents to 12 cents per 130 mg dose. This stated cost does not include shipping nor any costs associated with RECIP AB obtaining FDA approval of this KI product for use in the United States.

In the United States, two companies advertise KI tablets that have received FDA approval for sale to the general public. 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, the company 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 KI tablets (130 mg) per bottle for $560. This is about 40 cents to 43 cents per tablet. The company estimated that purchasing a million or more tablets at a time could reduce the price to about 20 cents per tablet. In sum, we believe that the cost estimate used in our response -- 25 cents per tablet -- is an appropriate (albeit perhaps slightly conservative) estimate.

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 over the period from October 1989 to August 11, 1999. The sum for the individual items listed came to $2.64 million. This estimate is based on information available in the internal work tracking system and estimates of staff and management overhead costs. The specific costs are detailed in the enclosed response to Mr. Crane (Enclosure 6).

If you would like additional information, please do not hesitate to contact me.

Sincerely,

Richard A. Meserve

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. Letter from Ms. Kay Goss, FEMA, dtd January 12, 2000
4. NRC SECY-97-124, dtd June 16, 1997 - Proposed Federal Policy Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant

4a. 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

5. E-mail fm Swedish firm, dtd December 17, 1998 re KI SUPPLIER
6. Letter to P. Crane fm W. Travers, NRC

ENCLOSURE 1