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.

I hope this addresses your concerns.

Sincerely,

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

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Thanks, Dwan

OEDO, 3/6/00

ENCLOSURE 1

Federal Emergency Management Agency
Washington, D.C. 20472

APR 29 1999

Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Madam Chairman and Commissioners:

I read in the April 24, 1999 New York Times and in your press release that you voted to withdraw your commitment to fund the purchase of potassium iodide for States that elect to stockpile it for use by the general public in the event of a radiological release from a nuclear power plant. In addition to deciding that the NRC would not pay for State stockpiles, you announced that FEMA should pay for both regional and state stockpiles. I strongly oppose this unilateral decision that reverses your previous position and adversely affects the implementation of the policy proposed by the Federal Radiological Preparedness Coordinating Committee (FRPCC). The policy provides that if a State chooses to add potassium iodide as a supplement to its evacuation and sheltering protective actions, the State will inform FEMA and we will forward that request to the NRC to support the purchase.

Your abrupt retreat from repeated promises to the Federal community, states and the public is apparently based on a misapprehension of FEMA's authorizing legislation and a disregard of our view—and that of other FRPCC agencies—that regional potassium iodide stockpiles will not enhance local radiological emergency preparedness. On funding, we stand fast on our position that FEMA lacks authority and appropriations for acquisition of potassium iodide and thus, cannot and will not assume the NRC financial commitment to the States.

Based on concerns expressed by States, FEMA has always opposed the notion that Federal regional stockpiles of potassium iodide would be effective in the event of a release from a nuclear power plant. The complex logistics of storage and distribution far outweigh the usefulness of such a stockpile. Regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness.

NRC and FEMA must work together with the States to implement the FRPCC policy. As you may recall, this proposed policy would leave the option to the State on whether it would use potassium iodide as a supplemental protective measure for the general public. If a State opted to incorporate its use as a protective measure for the general public, and the NRC fulfills its commitment, funds will be provided for such a purchase.

In light of the significance of this issue, and the concerns being raised by the States, I would appreciate a response to this letter by May 28, 1999.

Sincerely,

James Lee Witt
Director

Attachments: NRC Potassium Iodide Funding Commitments
Federal Radiological Preparedness Coordinating Committee proposed policy and scheme for potassium iodide request & funding

cc: William Travers, EDO
FRPCC Agencies

ENCLOSURE 2

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

CHAIRMAN

June 15, 1999

The Honorable James Lee Witt, Director
Federal Emergency Management Agency
500 C Street, SW.
Washington, D.C. 20472

Dear Mr. Witt:

I am responding to your letter of April 29, 1999, to the U.S. Nuclear Regulatory Commission (NRC) in which you commented on the NRC's recent action concerning the possible use of potassium iodide (KI) as supplemental protection for the public in case of a severe accident at a nuclear power plant. As indicated in a staff requirements memorandum (SRM) (a copy is enclosed for your information) to the NRC staff on April 22, 1999, and in a press release on April 23, 1999, the NRC is proposing to revise its emergency preparedness regulations to add KI to the protective actions that must be considered, along with evacuation and sheltering, in nuclear power plant emergency plans. The Commission also has decided not to fund State stockpiles of KI. We regret that we did not inform the Federal Emergency Management Agency (FEMA) sooner of our KI decision.

A related issue that recurs in the debate on the use of KI as a protective action for nuclear power plant accidents has been the role of the Federal government, in particular the NRC, in funding the purchase of a stockpile of KI for those States that may wish to include KI in their emergency plans. As previously discussed by the Commission in the Federal Register notice on emergency planning (45 FR 55402, August 19, 1980) under the section on funding, the Commission stated that "any direct funding of State or local governments solely for emergency preparedness by the Federal Government would come through FEMA." Notwithstanding earlier draft positions indicating that "the Federal Government (most likely the NRC)" would fund the purchase of State stockpiles of KI, this previously established NRC policy precludes NRC from funding such purchases. In addition, the NRC budget has continued to decrease and offers little margin for the Commission to divert resources to new initiatives.

According to your letter, the NRC announced that it expects the FEMA to pay for both regional and State stockpiles. This is not the case. Actually, the Commission supports the position that the Federal government should fund the purchase of KI for Federal stockpiles at appropriately located regional centers, possibly collocated with some of the three national and 27 regional stockpiles being established by FEMA to respond to possible nuclear, biological, and chemical (NBC) terrorism, discussed in the draft Federal Radiological Preparedness Coordinating Committee Policy Statement on KI. The Commission supports NRC funding of the initial purchase and resupply of KI for such regional stockpiles to the extent there are no constraints on the FEMA receiving money from the NRC for this purpose. The Commission believes that funding for State stockpiles of KI for States that elect to use it should come from the traditional sources of funding for State and local emergency response planning rather than the Federal government. Your letter also states that FEMA has always been opposed to regional stockpiles Although our staffs meet frequently and your staff has made presentations directly to the Commission, we did not understand that FEMA opposes regional stockpiles.

The Commission has directed the NRC staff to work with the 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. In your letter, you indicate that FEMA opposes the concept of Federal regional stockpiles of KI and that the complex logistics of storage and distribution of KI from regional stockpiles far outweigh the usefulness of such stockpiles. We agree that the storage and distribution of KI are among the vexing problems associated with the use of KI in an emergency, but believe that under the current draft policy that provides for only extremely limited Federal regional stockpiles, it would be difficult, if not impossible, for the Federal government to respond to requests for KI in the event of a nuclear emergency. Irrespective of whether the Federal government offered to pay for KI stockpiles, because States are not required to stockpile, we believe it is reasonable to assume that many States will not have stockpiles of their own. Therefore, regional stockpiles seem appropriate.

The NRC and FEMA have worked together as partners in protecting the health and safety of the public since President Jimmy Carter directed the FEMA to assume the lead responsibility for State and local government emergency planning and preparedness for nuclear power reactors on December 7, 1979, eight months after the accident at the Three Mile Island facility. The role of the FEMA in the NRC regulatory process is recognized in both NRC and FEMA regulations and in a memorandum of understanding between the two agencies that became effective on January 14, 1980. Presently, the NRC, with the assistance of the FEMA, representatives from other Federal agencies, and several States and local governments, is developing a substantially revised version of a study related to KI and an associated information document to assist State and local emergency planning officials in making decisions relative to the use of KI for the general public. I am confident that our two staffs, working together in a spirit of cooperation and dedication similar to the ongoing FEMA strategic review of its radiological emergency preparedness program, will be successful in resolving the KI issue.

Sincerely,

Shirley Ann Jackson

Enclosure:
Staff Requirements Memorandum

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

OFFICE OF THE
SECRETARY

April 22, 1999

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette Vietti-Cook, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-98-264 - PROPOSED AMENDMENTS TO 10 CFR 50.47; GRANTING 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
and
COMJSM-98-002 - FUNDING FOR POTASSIUM IODIDE STOCKPILES

The Commission has approved issuance of the proposed rule for comments subject to the following comment and attached changes to the Federal Register Notice (FRN). The FRN should be revised and returned to SECY for signature and publication.

(EDO) (SECY Suspense: 5/31/99)

The staff should amend the draft Federal Register Notice on the federal KI policy provided to FEMA to conform to this SRM, particularly with respect to the Commission's decision not to fund State stockpiles.

(EDO) (SECY Suspense: 5/31/99)

The staff should work with FEMA to establish and maintain regional KI stockpiles to be used in the event of a severe nuclear power plant accident. The Commission supports the position that the federal government should fund the purchase of KI for federal stockpiles at appropriately located regional centers. The Commission supports NRC funding of the initial purchase and resupply of KI to the extent that this cannot be covered by FEMA under its initiatives, and to the extent that there is no Economy Act constraint on FEMA's receiving money from the NRC for this purpose.

If FEMA decides after working with the States to develop any formal funding request to Congress for a program of federally funded grants for State KI stockpiles, the NRC should assist FEMA in developing its funding request.

The section entitled "Analysis of Issues raised by Public Comments" represents technical responses to questions and statements and does not represent policy decisions by the Commission. Therefore, the statements that are currently attributed to the Commission in this section should be changed to indicate that the responses are those of the NRC staff.

On page 17, after the last sentence, insert 'The Commission has considered the KI policy question on numerous occasions since 1984. The voting history of the Commission 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 is agreed that its historical difficulty to reach 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. With that relevant background, following are the Commission's views on specific issues raised by the Petition.'

The FRN should include reference to the fact that the staff is developing a final version of the NUREG related to KI and the associated development of an information document for State and local decision makers. On page 4, at the end of the second full paragraph, add a new sentence: NRC staff is preparing a technical report and an information brochure to enable State and local decision makers to make an informed decision in this matter.

Attachment:
As stated

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CIO
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR
DCS

Changes to the Federal Register Notice

1. On page 1, paragraph 2, sentence 2 should be revised to read "The proposed rule would amend the current regulations to require ~~indicate~~ that consideration shall be given to including potassium iodide (KI)~~, along with sheltering and evacuation~~, as a ~~supplemental~~ protective measure for the general public that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant.

2. The FRN currently states incorrectly that the Commission granted two petitions (PRM 50-63 and 50-63A). PRM 50-63 was replaced by PRM 50-63A which the Commission has granted. Therefore, the FRN should be revised to clarify this fact. On page 2, paragraph 1 under Supplementary Information, revise to read "By undertaking this rulemaking, the Commission, while not adopting the exact language suggested by the petitioner, is proposing to grant a petition for rulemaking (PRM 50-63A) submitted by Mr. Peter Crane on November 11, 1997. That petition is a revision of a petition (PRM 50-63) that he submitted on September 9, 1995.

3. On page 3, line 5, insert a new sentence after 'conditions' as follows: When the Commission amended its emergency planning regulations on November 3, 1980, it stated that 'any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through FEMA.' Begin the next sentence with 'In its decision on June 30, 1997, the Commission ....' In lines 5 and 6, delete 'consistent with the Commission's decision on June 30, 1997,'.

4. On page 3, line 7 and 8, replace the sentence 'The NRC staff will ... KI is established.' with 'The Commission has determined that notwithstanding the June 30, 1997 intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, the NRC budget has continued to decrease and offers little margin for the Commission to divert resources to new initiatives. Historically, funding for State and local emergency response planning has been the responsibility of those governments usually working with licensees. The Commission notes that the Petitioner has not requested the Federal funding of stockpiles of KI.' Start the next sentence as follows: 'In the alternative, the NRC will ....' On page 3, line 9, delete 'also'. In lines 9 and 10, replace 'procedures to enable the national' with robust, pre-positioned regional' and add an 's' to 'stockpiles'. In line 10, delete 'for terrorist activities'. In line 11, replace 'national' with 'regional'.

5. On page 4, first full paragraph, sentence 1, insert 'NRC staff's' before 'proposed'.

6. On page 4, second full paragraph, line 1, insert 'portion of the' before 'petition'. In line 2, replace 'by directing' with 'regarding'.

7. On page 6, last line, replace 'in favor of' with 'which favored'.

8. On page 15, at end of second full paragraph insert: However, FEMA recently reported that the federal stockpiles of KI are few and stocked only for first responders to terrorist action. As things stand now, needs of members of the public for KI on an *ad hoc* basis would have to be supplied from other sources. As stated above, the Commission intends to work with FEMA to assure that stockpiles contain adequate supplies of KI.

9. On page 17, before the Analysis of Issues raised by Public Comments insert a new paragraph as follows: On November 5, 1997, the Commission held a public meeting with its staff, FEMA representatives, and the author of the 1995 rulemaking petition to consider the petition and proposed changes to the Federal policy on the use of KI. In part as a result of the meeting, the petitioner amended his petition to ask for a rule that would require that consideration would be given in the formulation of emergency plans to the use of KI as a supplement to evacuation or sheltering, and on June 26, 1998, the Commission granted the amended petition, and directed the NRC staff to initiate the requested rulemaking. The Commissioners also decided that the FRPCC Federal Register notice on Federal KI policy should include a statement to the effect that the State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. On September 30, 1998, the Commission approved a draft Federal Register notice and directed that it be sent to the FRPCC.

10. On page 21, first full paragraph, line 1, insert 'thyroid' after 'excess'.

11. On page 22, second full paragraph, line 1, correct spelling of 'measures'.

12. On page 23, paragraph 2, add a footnote at end of second sentence, to read 'A "medically significant" reaction was one for which the person suffering the reaction consulted a physician more than once. Nauman and Wolff, "Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks," The American Journal of Medicine, Vol. 94, May 1993, p.530. About .02% of the population that received KI had "medically significant" adverse reactions to KI. Id. However, "[i]t should be pointed out that control values for these side effects in a population not receiving KI are not available." Id.' That is, it is not known what the incidence of such reactions would be in a population under similar stress, but not receiving KI, and thus it is not known to what extent these adverse reactions were the result of KI.

13. On page 24, under Conclusions from Polish Experience, line 1, insert 'In Poland' before '(1)'. In line 2, delete 'in Poland'.

14. On page 25, first full paragraph, line 1, insert 'In contrast to the Chernobyl experience,' before 'in the event'. In lines 2 and 3, remove the parentheses. In line 3 replace 'that would' with 'all of which'. In line 3, replace 'risk to' with 'risk of exposure of'. Also in line 3, insert 'to all radionuclides' after 'public'. In line 4, add 'or especially sheltering' after 'evacuation', and replace 'further' with 'resulting from exposure to one important group of radionuclides, the radioiodines.' That is why current NRC guidance discusses KI for plant personnel, emergency workers, and institutionalized persons unlikely to be evacuated promptly.

15. On page 25, delete the start of the second full paragraph (One public commenter ....) to the start of Issue 3 on the next page. Replace it with 'In this light, the Commission agrees that the use of KI may be determined by State and local emergency response planners to be a useful supplementary protective measure.'

16. On page 26, line 7 from the bottom, correct spelling of "nodules".

17. On page 27, under Commission Response, line 4, insert 'such as by making it available' after 'available'. In line 9, replace 'Other approaches' with 'Another approach' and replace 'could' with 'is to'.

18. On page 28, paragraph 1, replace with "The commenter is correct, in that it was difficult to obtain KI after the Three Mile Island accident. That is one reason why the Commission believes that planners should consider stockpiling KI, and why the Commission supports Federal stockpiles, so that States that have chosen not to stockpile KI could have access, albeit *ad hoc* and delayed, to an adequate supply in a radiological emergency at a nuclear power plant. As noted elsewhere in this notice, the Commission will work with other agencies to assure that there are Federal regional stockpiles that contain adequate supplies of KI. ~~However, with the limited Federal stockpile of KI for terrorist events and the willingness of the Federal Government to provide a stockpile of KI for any State that decides to use it as a supplemental protective measure for the general public,~~ Moreover, the general availability of KI is greater now than at the time of the TMI accident, partly because of the FDA's approval of KI as an over the counter drug. Some States have elected to incorporate KI into the emergency response plans and have obtained adequate supplies for this purpose. The Commission is not aware of any factors that would constrain the availability of KI for stockpiling purposes. The Commission believes that an adequate supply of KI could be obtained.

19. On page 32, line 7, replace the 'of' after 'State' with 'or'.

20. On page 32, line 2 from the bottom, replace' NRC staff' with 'Commission'.

21. On page 33, line 1, replace 'considers' with 'believes'. Delete the second full paragraph under the Commission Response.

22. On page 33, replace the Commission Decision with the following: 'KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. Therefore, 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 a 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 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 the achieve greater assurance that KI will receive due attention by planners, it seems reasonable to take a small further step and, continuing to recognize the authority of the States in matters of emergency planning, explicitly require that planners consider the use of KI.

The proposed rule change 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 accident.

The use of potassium iodide is intended to supplement, not to replace, other protective measures. This rule change thus represents no alteration in 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, whenever that is feasible. (Evacuation protects the whole body, whereas potassium iodide 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.

The NRC recognizes that the decision to stockpile KI presents issues of how best to position and distribute the medicine, to ensure, *e.g.*, that optimal distribution takes place in an emergency, with first priority given to protecting children; that persons with known allergies to iodine not take it; that members of the public understand that KI is not a substitute for measures that protect the whole body; etc. To date, these issues have been addressed in different ways in the numerous countries that currently stockpile KI. The NRC is working with States and localities to develop guidance on these and other points 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.

It is expected that States will inform FEMA and the NRC of the results of their consideration of whether to opt for stockpiling. This will enable the Federal government to engage in better contingency planning for States that decide against stockpiling KI.'

23. On page 34, first full paragraph, line 3, insert 'in part and denied in part' after 'granted'.

24. On page 34, under Commission Conclusions ..., line 1, replace 'agrees with many of' with ', having reviewed'. In line 2, replace the period with a comma and delete 'The Commission'. In item A., line 1, insert 'when determined by State and local emergency response planners and' after 'KI,'.

25. On page 34, line 7, replace 'noted' with 'finds' and replace 'consistent with the Commission's' with 'notwithstanding its'. In line 7, delete '(most likely the NRC)'. In line 8, replace 'will' with 'is not prepared to'. In line 9, replace 'The' with 'In the alternative, the' and replace 'also directed' with 'is directing'. In line 10, replace 'procedures to enable the national' with 'robust, prepositioned regional'. In line 12, replace 'the national' with 'regional'.

26. On page 36, in item E., line1, insert 'Although the cost of KI tablets has doubled,' before 'the Commission' and insert ', and other nations' experience,' after 'estimate'. In line 2, insert 'relatively' after 'is'. At the end of item E., add the following new sentence: 'However, the overall cost is minimal when placed in the context of emergency planning and should not be a deterrent to stockpiling KI for use by the general public should State and local decision makers determine that the prophylactic use of KI as a supplement to evacuation and sheltering is appropriate.' In item F., line 1, replace 'NBC medicinal' with 'robust, regional' and replace 'provide' with 'be established'. Replace lines 2 and 3 with 'to enable use by States that have not established local stockpiles and wish to make use

of KI in the event of a severe nuclear power plant accident.

27. On page 36, revise paragraph F to read "The Commission ~~believes~~ will work to assure that ~~medicinal~~ regional Federal stockpiles ~~should~~ will provide ~~assurance to States and local governments that a limited Federal stockpile of KI is available, if needed~~. enough KI to enable use by States that have not established local stockpiles and wish to make use of KI in the event of a severe nuclear power plant accident.

28. On page 36, replace 'Commission approval to fund KI' with 'Commission decision to fund KI'

29. On page 36, in the last paragraph, replace the last 2 sentences with: 'At that time it was believed that the NRC was the likely Federal agency to fund the stockpiling. Historically, funding for State and local; emergency response planning has been the responsibility of those governments usually working with licensees and, absent Congressional funding specifically for this purpose, NRC is not prepared to fund stockpiling of KI.

30. On page 38, paragraph 2 from the bottom, line 1, replace 'directed' with disagreed with' and replace 'in SRM 98-061 to grant' with 'recommendation to deny'.

31. On page 39, item II., line 2, replace 'SRM 98-06' with 'SRM 98-061'. In item IV., line 1, add an 's' to 'petitions' and replace 'require' with 'take'.

32. On page 41, paragraph 2 from the bottom, lines 1 and 2, replace 'grant the petition for rulemaking PRM-50-63A by revising' with 'revise'.

33. On page 42, second full paragraph, line 1, insert "that" after 'Given'.

34. On page 42, prior to the last paragraph, insert a new paragraph as follows: 'The Commission notes that when it amended its emergency planning regulations on November 3, 1980, the regulatory standards for emergency planning were a restatement of basic joint NRC-FEMA guidance to licensees and to State and local governments incorporated in NUREG-0654; FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for Interim Use and Comment." This guidance was cited in the regulation and speaks to radioprotective drugs including their use by the general public including quantities, storage and means of distribution and State and local plans for decision making with respect to their use. The Commission removed the citations of the guidance from the regulation in 1987 but the guidance has continued in use for planning purposes and by the Federal agencies for evaluating emergency plans. As a result, it is believed that all of the affected States have at some point considered the use of KI. Some States have made the decision to stockpile KI. Thus, in practical terms, the projected costs will occur only in those States that have not elected to stockpile KI and choose stockpiling in light of the Chernobyl accident, recent international practice, and the NRC requirement to consider the use of KI.

35. On page 48, line 1, replace 'have' with 'has'.

ENCLOSURE 3

STATE OF CALIFORNIA PETE WILSON, GOVERNOR

GOVERNOR'S OFFICE OF EMERGENCY SERVICES
P.O. Box 419047
Rancho Cordova, CA 95741-9047
Phone: (916) 464-3200

OES CALIFORNIA
Governor's Office of Emergency Services

October 13, 1998

Mr. David Meyer
Chairman, Rules, Review, and Directives Branch
MS T6D69
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Meyer:

Enclosed per your request are the comments on NUREG 1633, "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Reactor Accidents" from the Governor's Office of Emergency Services (OES), Radiological Preparedness Unit, and compiled comments from local jurisdictions.

If you have any questions, please call Paul Skiermont of my staff at (916) 464-3268.

Sincerely,

BEN TONG, Manager
Radiological Preparedness Unit

Enclosures

c: Aby Mohseni, Federal Coordinator
U.S. Nuclear Regulatory Commission (MS T4A43)
Pam Handley, Supervisor
Southern California Edison
Ed Waage, Supervisor
Pacific Gas and Electric
Vince Morici, Emergency Services Coordinator
San Luis Obispo County OES
George Brown, Emergency Services Coordinator
San Luis Obispo County OES
Mark Johnson, IPC Chair
City of Dana Point
Stephen Woods, Senior Health Physicist
Department of Health Services

COUNTY OF SAN LUIS OBISPO

HEALTH AGENCY

2191 Johnson Avenue • P.O. Box 1489
San Luis Obispo, California 93406
(805) 781-5500 • Fax: (805) 781-1048

Susan G. Zepeda, Ph.D.
Director

Gregory Thomas, M.D., M.P.H.
Health Officer

DATE: March 27, 1998

TO: Susan Zepeda, Ph.D., Health Agency Director

FROM: Greg Thomas, M.D., M.P.H., Health Officer

RE: POTASSIUM IODIDE STOCKPILING

The current nuclear power plant disaster response plan includes provision of potassium iodide (KI) to Emergency Response workers who remain in Emergency Planning Zones under limited conditions after evacuation orders as well as radiation monitoring teams. A supply of bottles of KI tablets are stored at certain emergency response sites around the County. In addition, the disaster plan provides an update annually of the number of additional doses of KI that are present at hospitals and laboratories around San Luis Obispo County.

In July 1997 the Nuclear Regulatory Commission changed its policy to allow states to stockpile and/or plan delivery of KI to the general population after a nuclear release. The State (DHS) is currently reviewing options regarding this new national policy.

It is my opinion that a statewide policy is imperative. Policies by individual counties would create potential confusion and havoc. For example, the reception center planned for a part of our Emergency Planning Zone is in Santa Barbara County. Leaving the decision to distribute KI to the general public up to the local government, will result in decisions that are confusing and contradictory.

If KI is to be offered in a nuclear accident scenario, it should be done at an evacuation reception center. Having multiple field sites within the potentially affected zones would lead to the potential of long lines awaiting KI in an area that is supposed to be in the process of evacuation.

Adequate screening for the persons requesting KI in a radiation release scenario would be required to prevent provision of KI to a person who has allergies to it.

Please see the letter to Mr. Woods of the Department of Health Services Radiation Branch regarding our proposed position on this subject.

c: Health Commission Members
Vince Morici, County EOS

COUNTY OF SAN LUIS OBISPO

HEALTH AGENCY

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Susan G. Zepeda, Ph.D.
Director

Gregory Thomas, M.D., M.P.H.
Health Officer

March 27, 1998

Mr. Steve Woods
State of California Department of Health Services
P.O. Box 942732
Sacramento, CA 94234-7320

RE: Potassium Iodide stockpilling and distribute to the general public

Dear Mr. Woods:

It is our understanding that the State Department of Health Services is considering revising the State policy regarding the use of Potassium Iodide (KI) for nuclear power plant emergencies. While it is early in the process, we want you to consider our perspective and position regarding the pre-distribution and/or stockpilling of KI for use by the general public.

Pre-distribution of KI to multiple field locations is not an acceptable option. Pre-distribution for use by other than emergency workers is contrary to our planned public protective actions of sheltering or evacuation. If the State decides that KI should be made available to the general public, then all aspects of planning, storage and distribution should be a state responsibility. KI use will likely extend over more than one county. For example, the Reception Center planned for a part of our Emergency Planning Zone is in Santa Barbara County. Leaving the decision to distribute KI to the general public up to local governments will result in a variety of decisions that will be confusing and contradictory. A consistent State policy, combined with consistent State placement, maintenance and management of stockpiles and a consistent State procedure for providing KI to the public is the only reasonable alternative for implementing this concept.

It is probable that if KI is distributed to the general public during a nuclear power plant emergency, people many miles and several county lines away from the incident will ask or demand to have KI. The State policy must clearly describe the boundaries for persons who will and who will not be eligible for KI. Local governments should not be burdened with the costs of the provision and ongoing maintenance of KI stockpiles. Lastly, the same entities who reviewed and approved the State's original KI policy must be involved in the review and approval of the revised State KI policy.

This issue clearly extends over multiple local jurisdictional boundaries and has statewide policy implications. The State must develop a coherent and consistent policy and strategy if stockpiling of KI for general public use is implemented. Local governments should not be the focal point for State KI stockpilling and use by the general public.

Thank you for considering our position. We anticipate that the policy will be sent to us for review and comment in a draft form. Please feel free to contact me if you have questions.

Sincerely,

Greg Thomas, M.D., M.P.H.
San Luis Obispo County Health Officer

c: Clark Channing, San Luis Obispo County Administrator
Ben Tong, State Office of Emergency Servcies
Mark Johnson, IPC Chair, City of Dana Point

Comments on the NRC Document
"Assessment of the Use of Potassium Iodide (KI)
As a Public Protective Action During Severe Reactor Accidents"

After reviewing this document it appears that it would be better not to stockpile and use KI as a supplemental protective measure for the general public within the plume pathway. The following are some examples of the areas covered in the document that lead us to that conclusion.

For protective action considerations in the ten mile EPZ, the report states that "use of KI is not an alternative to evacuation", "the use of KI in conjunction with evacuation could potentially delay evacuation". The objective of protective actions for the public is to minimize early health effects (injuries or death) in the event of a severe reactor accident. Based on the fact that the preferred protective action is early evacuation, it would not appear to be prudent to take any course of action that would delay that action. If the effort to distribute the KI slowed the evacuation the public could be exposed when they might otherwise have been out of harms way. When considering protective actions outside of ten miles (ingestion pathway) the report says "KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs". If, as planned, the public is evacuated before a release occurs it is obvious that administering KI would have no positive effect.

From the consideration of potential health effects of KI, the report states "use of KI with other medications (such as anti-thyroid agents, diuretics (potassium sparing), and lithium) could lead to problems of major clinical significance. A high degree of caution would have to be exercised before recommending its administration on a mass basis, including pregnant women and children." Further the report states "the recommendation by the WHO is to administer KI to pregnant women and children, whereas U.S. references specifically warn against administering KI to the same group". Administering a drug to the general public, including pregnant women and children, during an emergency without direct medical supervision is a significant departure from the norm in emergency response.

This raises the question of liability. For example, local school districts may not have the authority to administer a drug to school children even if the local health officer recommends it. The implementation of such a protective action may entail litigation. In context of this issue the report states, "One can expect that administration of KI on a mass basis would certainly entail litigation in this country."

The data presented in this report shows the benefit of taking KI in close proximity to exposure to radioactive iodine, is a potential reduction in thyroid dose of about a factor of ten. That reduction would seem to make the use of KI by the general public a very good idea. However, this reduction is possible only if the KI is administered just before

or very shortly after exposure to inhalation of radioactive Iodine. There are significant logistical reasons to believe that it is impractical to assume that the KI could be administered within these time constraints, thus reducing the benefit of KI's use. The whole body exposure resulting from a severe reactor accident is the most significant public health concern. However, KI will only provide some level of protection to one nuclide from one exposure pathway and will have no effect on the whole body exposure of the noble gases.

Mc Kenna's comments on Draft NUREG-1633
September 27, 1998

1. Page iii, Para. 4. Add. Protective actions for the public beyond 3 miles would be determined based on dose projection and field monitoring data. (Ref NUREG-0654, supp. 3, page. 3). Thus, the decision to expand protective action beyond 3 miles most likely will occur after the start of a release.

2. Page iv, Para 2. Add after the first sentence: These dose estimates are for the centerline of the plume and assume a constant wind direction. The average off-site dose resulting from these scenarios would be much lower especially if the wind direction varies as would be expected.

3. Page iv, Para 3 last two sentences revise to read something to the effect: For the two most serious accident scenarios persons at the centerline of the plume could receive doses resulting in early deaths out to about 5 miles and doses sufficient to result in other early health effects vomiting or hypothyroidism beyond 10 miles. Reductions in a thyroid dose would not reduce the risk of early deaths or other non-thyroid heath effects. The only effective protective action for reducing the risk of early deaths is prompt evacuation of the area out to 5 miles. However, reduction in a thyroid dose within 10 miles could substantially reduce the number of early heath effects involving the thyroid. Thyroid blocking reduces the distance to which the center line dose exceed the threshold for deterministic thyroid effects (5×10^2 rem) to less than 10 miles in one case. In both cases the number of persons with doses above the threshold for deterministic thyroid effects will be reduced significantly by thyroid blocking. Reduction in a dose to thyroids within 10 miles would also reduce an individual's risk of thyroid cancer. However, to affect a substantial reduction in number of excess thyroid cancers would require reduction in thyroid doses to people well beyond 10 miles << may need to discuss collective dose>>.

4. Page iv, Para 4 last sentence: Revise to something to the effect: For the third accident scenario the whole body doses at the centerline of the plume can result in early, but not fatal, heath effects, within one or two miles and thyroid dose sufficient to result in early health effects beyond 10 miles. Reduction in thyroid doses could substantially reduce the number of early health effects involving the thyroid. It could also reduce the individual's risk of cancer within 10 miles especially among children. However, as discussed above, in order to reduce substantially the number of excess thyroid cancers will require reduction in thyroid doses well beyond 10 miles. Only prompt evacuation will be effective in reducing the risk of the more serious non-thyroid cancers such as leukemia.

5. Page iv, Last para, last sentence, revise to read something to the effect: The ideal time to recommend KI for the public close to the plant is before a release. This is best assured by recommending KI upon detection of actual or projected core damage. However, this could result in the public taking KI without a release warranting such action. Notwithstanding, accidents of this severity should be very rare and are expected at most only once or twice during the next 50 years. In addition, if KI was recommended upon confirmation of a release the risk of unwarranted administration would be greatly reduced. This latter approach may be appropriate

for the areas beyond 3 miles and is consistent with the approach for this area where additional protective actions are taken based on environmental monitoring results.

6. Page v, Para 2 last sentence, revise something to the effect: Consequently, because the potentials exist for early deaths close to the plant any time core damage occurs, prompt evacuation of the area within 2-3 miles is used to protect the public. The public beyond 3 miles is instructed to go inside and listen for further instructions in order to be prepared to act promptly. Further protective actions for the public beyond 3 miles would be determined based on dose projections and field monitoring data. (Ref NUREG-0654, supp 3, page. 3) Thus the decision to expand protective action beyond 3 miles most likely will occur after a release. Thus, the people beyond 3 miles most likely will be exposed to the plume in the event of a large release.

7. Page v, Para 3 add the following points under "Chernobyl Experience"

- It is generally accepted among the international scientific community that the excess thyroid cancers in Belarus, Ukraine and Russia are the result of the intake of radioiodine.

- It is generally accepted among the international scientific community that KI is safe when given to the appropriate cohort, in the appropriate dose and with the appropriate instructions.

8. Page v, Para 5, and page vi Para 2. True KI is not a substitution for evacuation when attempting to substantially reduce the risk of early deaths. However, there are situations where KI could be beneficial. Accidents are possible where thyroid EPA PAGs are exceeded in an area 2-5 times larger than the area where the evacuation PAG is exceeded (See NUREG-0396 fig I-16). Also, discuss the short comings of evacuation such as: slowest of options, not always possible, not appropriate for all situations (Evac PAG not exceeded but KI PAG is exceeded). There are accidents where the release will be too fast to allow an evacuation of the areas near the plant to be completed in time to avoid the plume (see NUREG-1150, page 11-2). In addition, evacuation beyond 3 miles will most likely start after the release is detected and therefore this area cannot be evacuated before the arrival of the plume. KI could be very beneficial for this area. Revise to discuss the benefits and challenges for the use of KI for the reasonable range of accident scenarios and areas. See the table below for suggestions.

Benefits and Challenges of KI for a Severe Reactor Accident

Area Miles	KI beneficial for:	Challenges	Comment
0-2/3	Reducing the number of deterministic thyroid effects for: - Release before evacuation is completed - Special populations - Entrapment - bad weather - During evacuation if over taken by plume Reducing individual risk of thyroid cancer but no significant reduction in total number of excess thyroid cancer	Provision to give KI so it will not delay evacuation.	Protective action recommended based on plant conditions - a primary goal is to take action before a release to reduce risk of early deaths
2/3-10	Reducing the number of deterministic thyroid effects for: - During decisions making process (before evacuation is recommended) - Entrapment - bad weather - During evacuation Reducing individual risk of thyroid cancer but no significant reduction in total excess thyroid cancers for: - Those listed above and lesser releases not warranting evacuation	Provision to promptly detect environmental levels warranting taking KI and to administer KI without delaying evacuations.	Protective actions recommended after a release based on environmental data.
> 10	Reducing in the in total excess thyroid cancers for large release resulting in high thyroid doses over a large area (out to 20-50 miles) - Timely evacuation would be impossible or impractical. - Reception centers in the event of a large release - Special populations	Timely distribution to large population	Protective actions recommended after a release based on environmental data. EPA PAG for KI may be exceeded over a very large and complex area.

9. Page vi. Para 3. Revise to indicate that the size and availability of the national stockpiles are uncertain. << I do not think that there are more than a few thousand doses>>

10. Page vii, Para 3, Change ".. Buglova M.D." to "..Buglova M.D. Ph.D."

11. Page 2 Para 6 (last), Sentence 3 and 4, are incorrect. It is true that the risk of early deaths is virtually "0" for late containment failures (see NUREG-1150, Fig 13.6). However, core melt accidents with a late containment failure or leakage can result in very high thyroid doses and dose exceed the EPA PAG for evacuation. I ran a late containment failure on RASCAL (I-131 release fraction of 1.2 e-2, which is consistent with NUREG-1150 late failure cases, e.g., fig 5.7 p.5-14) and got the following:

	1 mile	10 miles
TEDE	160 rem	16 rem
Thyroid	3000 rem	300 rem

Clearly late containment failures can result in high thyroid doses and whole body doses warranting protective actions (evacuation and thyroid blocking). Revise sentence 3 and 4 to read something to the effect: A core melt with early containment failure is required for early deaths offsite. However, cores melt with late failure or leakage can result in doses warranting evacuations and thyroid doses resulting in deterministic thyroid effects. Thus, to be considered severe in the present context, an accident must involve core damage. Without core damage there is not needed for any protective action including evacuation or administration of KI.

13. (No comment)

14. Page 4, Para 5, Add that deterministic health effects are possible at thyroid doses above 500 rad (5 Gy - IAEA SS-109). Revise the last sentence to read something to the effect: Deterministic health effects require relatively large doses and the first objective of emergency planning is to take actions to prevent or avoid these effects (EPA 400-R-92-001,IAEA-BSS, ICRP-60). The second objective of emergency planning is to reasonably reduce the risk of stochastic health effects. That is the protective action should do more good than harm.

15. Page 5, Para 1, last sentence. Revise to read something to the effect: It is during the plume phase that large doses to the whole body and thyroid can occur. For most accidents, the largest doses are projected to occur in the plume EPZ (10 mile radius) but high thyroid doses, sufficient to result in deterministic health effects or that exceeds the EPA PAGs, may occur well beyond 10 miles. Add a new paragraph to te effect: EPA is responsible for developing the protective action guides (PAGs) for the non-ingestion pathways (EPA 400-R-92-001). The EPA PAGs indicate evacuation if 1-5 rem is projected to the whole body and administration of stable iodine if 25 rem is projected to the thyroid from radio-iodine.

16. Page 5, Para 6, This paragraph is not very clear or helpful. I think that something similar to that in NUREG-0396, Appendix I-Section E (Fig I-11, I-13) would be more useful.

17. Page 5, Para 7, This paragraph is not clear. It is possible to have offsite releases where the thyroid deterministic threshold (500 rad) is exceeded and the whole body deterministic threshold (50 rem) is not. This is demonstrated by Table 5 of the document. Therefore, the adverse heath effects of the thyroid doses may not be much less than those of the whole body doses.

18. Page 6 Para 5, IAEA (BSS and SS-109) indicates that the threshold for deterministic thyroid effects is 5 Gy (not 1000 rad). Also revise to indicate that it is possible to have offsite releases resulting in doses exceeding the thyroid deterministic threshold (500 rad) and yet the whole body deterministic threshold (50 rem) is not exceeded as shown in Table 5. It is also possible to have a release resulting in doses exceeding the EPA PAG for KI administration and yet the whole body dose is less than the EPA PAG for evacuation.

19. Page 8, Para 1, Delete last sentence, stable iodine will block all isotopes of radio-iodine equally well.

20. Page 8, Para 2, Add: Since Chernobyl, Belarus studies could not find a correlation between iodine deficiency in the diet and incidents of excess thyroid cancers (Dr Buglova's talk at EPA Conference).

21. Page 10, Para 3, Revise to clarify, as discussed earlier that there is a range of deterministic health effects including some affecting the thyroid. So clearly thyroid blocking could prevent some (thyroid) deterministic health effects.

22. Page 11, para 2, revise to remove the questions concerning the Polish experience. Their results have received extensive international peer review and are internationally accepted (IAEA, WHO, US-NIH, numerous governments ..). In addition, clarify that except for two cases the side effects from the administration of stable iodine in Poland were "mild and transient" (Potassium Iodine Prophylaxis in Case of Nuclear Accident: Polish Experience, Dr J. Nauman, EPA International Radiological Post-Emergency Response Issues Conference, Meeting Proceedings, Sept 9-11, 1998) such as skin rashes, headaches, vomiting (ref 23). Also make it clear that based on the Polish experience that Poland, Belarus, WHO et al found KI to be safe for use by the general public.

23. Page 12/13, IV Emergency Preparedness, Add a discussion of te EPA PAGs and guidance for evacuation, shelter and administration of stable iodine. Also, address comment 8.

24. Page 16, add comment 20.

25. Page 18, last para. Revise as indicted in comment 22.

26. Page 25, Table 4. The elevation for RUSR-1 and 4 cases are most likely "0 m" and not "1010 m" (1010 m gives a 0 rem thyroid dose within 10 miles). Are you sure the release time for the cases are correct?

27. Page 27/28 revise to be consistent with other comments on pages iii, iv, v and vi.

28. Page 30, remove reference 19 (personnel communications with Dr Bloglova) and replace with the appropriated reference provided by her).

James A. Martin, Jr.
22 Harvard Court
Rockville, MD 20850
301-340-1676

September 22, 1998

U.S. Nuclear Regulatory Commission
Attn: Aby S. Mohseni
Office for Analysis and Evaluation of Operational Data (T 4A43)
11545 Rockville Pike
Rockville, MD 20852

Ladies and Gentlemen:

RE: NUREG-1633, Draft dated July 1998

Technical comments are appended. From a policy standpoint:

1. A license to operate a nuclear power plant should not be conditioned on Mary Jones having a pill (KI, or any other kind). Third party control may be unconstitutional.

2. Long ago the Food and Drug Administration was assigned as the lead Federal agency on the KI matter. Long ago, the FDA authorized the non-prescription sale of KI.

3. This being so, the NRC should not be concerned with the matter. The Commission should direct its staff to direct all inquiries to the FDA. (NRC could 'not object' to an FDA (or FEMA) position.)

It's been almost twenty years now since I first made these and other relevant comments to NRC staff. (Meeting long ago with Commission staff (Ed Podolak), and Mat Taylor, Jocelyn Mitchell, and Peter Crane.) Yet the staff persists in pursuing this matter. Engineers, health physicists, and lawyers are not qualified to dispense medical and pharmaceutical advice. If this were a hearing on the matter, the authors of the draft would not be qualified to testify regarding potential efficacy. (Most are good friends of mine, but this would not be sufficient.)

So as not to dilute this message, my further comments are attached.

Sincerely,

James A. Martin, Jr.

cc: Dave Aldrich
Roger Blond

James A. Martin, Jr.
22 Harvard Court
Rockville, MD 20850
301-340-1676

September 22, 1998

U.S. Nuclear Regulatory Commission
Attn: Aby S. Mohseni
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So as not to dilute this message, my further comments are attached.

Sincerely,

/S/

James A. Martin, Jr.

cc: Dave Aldrich
Roger Blond

September 22, 1998

COMMENTS ON DRAFT NUREG-1633
DATED JULY 1998

Jim Martin

This draft is fairly well done, but there are some major lapses, most of which can be cleaned up rather easily.

The history of this issue is not established in this draft; this matter is not of recent vintage. I note with some chagrin that the draft fails to reference the Aldrich/Blond NUREG/SANDIA report that the Commission relied upon for its original positions regarding KI. Especially bad is the failure to acknowledge Professor Il'in's original report from which Figure 1 in the draft is taken. Figure 1 is a reproduction of a figure in either the Aldrich/Blond paper, or my own Health Physics Note - I don't recall which, but both, perhaps. I revised the original Il'in figure to remove confusing details; later, McKenna revised it further, as I recall. But its genesis should be referenced properly. Also, this figure should be repeated in the Executive Summary - it succinctly and clearly sets forth both the promise and the problem regarding preparedness for possible KI distribution during a radiological emergency.

(Professor Il'in played a major role in directing the USSR emergency response to the Chernobyl accident. He was head of the Soviet Academy of Sciences, as I recall. His KI report is a textbook example of the scientific method of investigation. But he exposed only a few subjects, so the figure is only indicative of the potential efficacy in a population. It does illustrate that for KI to be potentially efficacious it must be right handy.)

Now, even 'tho for a long, long time I've been against the NRC being involved with the KI issue (it's been a real drag - I'm getting too old for this!), some perspectives bear repeating (over and over ...):

- The draft fails to acknowledge the FDA role, and the fact that FDA has authorized the non-prescription sale of KI.

- The draft fails to properly reference the pertinent history, some of which was listed in my HP Jr. note, enclosed. (Is the current staff even aware of the public meeting the NRC held to hear various views on the matter. Nobel laureate Roz Yalo was flat against it, but Richard Wilson argued for it. There was a NUREG published summarizing the meeting.)

- As Aldrich and Blond showed, KI can eliminate the individual's risk of thyroid ablation in the near field in the event of a large atmospheric release. As they, and McKenna and Martin, showed (over and over, in many ways), early evacuation from nearby areas can do the same. (Early warning provisions are in the NPP EALs, which the NRC still hasn't done correctly.)

- Thus, in the event of a large release, early ingestion of KI can achieve the first (and foremost) emergency phase objective of keeping individual doses below the threshold of serious and adverse deterministic/non-stochastic health effects (re: ICRP # 63). For core melt/failed containment source terms, PAGs and projected doses would be beside the point during the early emergency response phase.

- In contrast, for atmospheric releases, total calculated thyroid **cancers arise** predominantly in populations located **beyond 35 to 50 miles from a release point**, and **in non-interdicted areas**, to boot. This is where the person-rems accumulate. (This applies to all calculated cancers, and most atmospheric source terms, by the way. For large NPP accident source terms, stationary persons nearby die early, so they don't get cancer later.)

- Thus, whatever is done within 35-50 miles cannot have more than a factor of two effect on total calculated cancers. This is one reason why a national KI predistribution program was considered long ago.

- The draft NUREG makes no distinction between risks of early and seriously adverse health effects (large individual rems, early fatalities) and much later cancer risks (small individual rems, large person-rems), and the distances within which the separate problems could arise. And the different protective action objectives for large releases (save lives, prevent threshold health effects) and small releases (PAGs apply). (Shame on the HPs in the bunch.)

- And don't get fooled by the plume rise issue. Western NPP containments would most likely fail at the sides, not at the tops, if at all. So you should not expect much of a plume rise in any event. And one should not plan for there to be a significant plume rise unless you assure this with ESFs - which we don't. (Plume rise models wouldn't help here, either - you wouldn't know the heat term.)

- A factor of 40 is not "orders of magnitude". The point is that one's early fatality risk highly escalates upon incidence of core melt, from ten to minus six, or so, to 1/40, or so (on average, in some cases the containment would fail before, or simultaneously with core melt). Core melt should be considered a clear and imminent threat. It would be foolish to plan to wait for clear and present danger before initiating protective actions, especially when the conditional risks are so well known.

- Further, just how often does the staff expect core melts to occur? (Especially at one site, re: last sentence, p. ix of the draft).

- Predistribution of KI to and within emergency centers would be easy, not difficult. Natural predistribution systems exist within the normal internal mail systems in government, schools, hospitals, fire and police stations, and other centers where KI could be stored and controlled.

- KI is so cheap that PTAs could pay for bottles of the stuff in schools using proceeds from car washes! If I lived near a nuclear power plant, I'd have had KI in my kids' schools long ago - it's so cheap!!! And the school principals would know which parents had preauthorized the distribution to their kids if needed or desirable. (But I'd still be against a government requiring this as a condition of a license to operate.)

- KI is so cheap that it should not be a Federal matter. (The law should not concern itself with trivia.)

- In small amounts (100 mg, adults) KI is about as dangerous as aspirin! Note the Polish Chernobyl experience in this NUREG.

- Concentration on predistribution of KI within the 10 mile EPZ is misplaced. Attention should be on areas outside EPZs where evacuees and others could go in a timely manner to pick up a pill - if distribution is to be planned. If carte blanche is to be the posture, why not plan to have volunteers placed at major intersections to hand out pills to passersby? Outside the EPZ, of course. But such preparedness should not be a license condition, of course.

- Concentration on evacuation road networks within the EPZ is similarly misplaced, by the way. If you want to empty a bucket, you must keep the spickets open, and remove impediments outside the bucket! The water will mill around, but out it comes - if there are places for it to go! With people, all you have to do is tell them - and do them a big favor by providing for **early** warnings, information, and

instructions. People are very good at protecting themselves once they are warned - see EPA and DCPA reports.

- The draft uses the word 'prompt' when either early, or fast is meant, in different contexts. [EALs have to do with time (**early**), sirens with speed (quick), and EPZs with distance (for preparedness and possibly immediate protective actions when warranted).]

- Evacuate is an active verb meaning 'to leave', which we do very often and very well. To say that "The Sheriff will evacuate the area." means that the Sheriff leaves!!! This gets the planners attention on the Sheriff rather than on the people, and attention is thus misplaced.

- Getting a PF of ten for every organ by early evacuation is easy! For a large source term, puff release, leaving even fifteen minutes after the beginning of the release eliminates the calculated fataities using CRAC2 or MAACS. For a five hour release, the PF can be ten if one leaves a half hour after the release begins. (Slow, radial evacuation speeds were assumed (5-10 mph, as I recall).

- The pre-TMI EP rule required provisions in emergency plans for the early warning of offsite agencies for protective actions when necessary or desireable, but this requirement was dropped in the post-TMI rule. It's now in the EAL guidance, but not done well, unfortunately. It was better done in the old Reg. Guide 1.101. Maybe I should ask for a rule change!!??

- The report should illustrate these perspectives. On the other hand, a nuclear power plant isn't safe because of how fast one can run away from it!

- Returning to KI, the staff would benefit from a trip to a Pharmacy to look at the warnings and admonitions on a bottle of prescription strength KI.

- For balance, the potential efficacy of shelter and ad hoc respiratory protection should be discussed, also. As shown in vol. VI of the Reactor Safety Study, one can expect a respiratory protection factor of ten or so for a puff release, just by going inside and closing openings. By going into an internal room (e.g., a closet), one could get an additional factor of ten inhalation PF. No credit was taken for this in the RSS because "...it would be too difficult..." for people to do!!!

- As Dave Kocher (ORNL) has shown, if one assumes a deposition velocity of 1 cm/sec the inhalation PF inside a typical building could be 100 or more, without hiding in a closet.

(At a PA course one time I noted this, and added that a waterfall is used to remove paint particles in a paint shop, at which point Maggie Reilly wagged: "Aha! Take a shower with a friend!")

- The potential benefits of ad hoc respiratory protection is also noted in the RSS, where attention is called to a table in the Respiratory Protection Devices Manual which illustrates that inhalation PFs of ten or so can be achieved by breathing through sheets or towels. We investigated this further and showed that leakage around a typical dust mask was 25 %, or so, but if the mask is held in place using panty hose a PF of 100 was achieved for 1 micron particles. See NUREG/CRs 2272, 2958, and 3537. (I illustrated the panty hose tactic once, for the PA group, and three people fell on the floor laughing - literally!. I never did that again.)

- So, there are many ways to get the factor of ten PF promised by KI. The KI report should at least note these, although it would be better to illustrate the balances. KI is not the be all and end all!

- Although I doubt that you would use this, I note that one study indicated that one good nose blow can remove 1/5 to 1/3 of the activity of solid particles deposited in the nose, but subsequent blows don't add much. (Another use for the ad hoc handkerchief?!) (HP Jr. Note, April 1983, pp 418-421.)

- Finally, the use of the present tense when discussing accidents and emergency response should be avoided. There is no NPP accident in progress now, and none is expected. We deal now with emergency preparedness, not with emergency response. Our intent is to keep it that way. It would be best that forty years from now people look back at this time and say: "What a waste of resources! Nothing ever happened."

Enclosed is a marked up copy of the draft and a copy of my HP Jr. Note that has the Il'in and earlier Sec'y references. Unfortunately, as luck will have it, I recently threw out most of my KI file, including the Il'yn report (DOE translation series). Peter Crane probably still has a copy of the Aldrich/Blond report. Good luck!

Jim Martin

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NOTES

Potassium Iodide: Predistribution or Not? The Real Emergency Preparedness Issue

(*Received* 26 *July* 1984; *accepted* 13 *February* 1985)

A RECENT review article provided a broad sample of literature regarding the administration of potassium iodide (KI) to reduce thyroid dose upon inhalation of radioiodine (Cr84). Unfortunately, the article failed to address a fundamental point, to wit: for emergency preparedness, the KI issue reduces to the question: Should KI be predistributed or not? This note will shed some light on this narrow, yet fundamental question.

The potential efficacy of KI is illustrated in Fig. 1 (Il72). Ingestion of 130 mg of stable KI either some hours before intake of radioiodine, or within 2–3 h afterward, provides an effective block to the uptake of the radioiodine by the thyroid. A thyroid dose reduction factor of about 20 is possible if the KI is taken at the time of a slug (short, rapid) intake of radioiodine. Beyond 3 or 4 h after a slug intake, the benefit of the KI would be markedly reduced for many people, although one subject in the study benefitted to the extent of about 10% after such a delay. Only a few subjects were involved in this study, so the spread in individual responses would be expected to be greater in the public at large.

Two other significant observations by Il'in *et al.* (as translated from the original Russian) are:

(i) with regard to a slug intake of ^{131}I:

> "It is important to emphasize that the acceleration of the elimination of radioiodine which enters the body on a one-time basis cannot be achieved more by increasing the frequency of administration of large amounts of iodide than by a single administration of a large dose of iodides." (Il72, p. 234)

and (ii) with respect to the chronic intake case:

> "Thus, the result of studies involving repeated administration of ^{131}I convincingly show that quite a high value of protective effect can be reached only by administering to the body relatively large amounts of iodides (100 mg or more per administration) simultaneously with or several hours before the administration of ^{131}I. In our studies the protective effect . . . was reliably at a maximum upon daily administration of 200 mg of stable iodide . . . ." (Il72, p. 229)

Equal amounts of ^{131}I were administered daily in the latter experiments.

Thus, in either the slug or chronic intake case the initial dose of KI is most important, but for the slug exposure case the initial dose of KI is the *only* important one and it must be taken within 2–3 h to be of substantive benefit after a slug intake of ^{131}I. For the chronic intake (of ^{131}I) case, daily administration of KI would be necessary to maintain thyroid blockage. At any rate, the initial dose of KI must be immediately available to be of potential benefit, i.e. with or near a person or in numerous local distribution centers.

A decision against predistribution or local stockpiling would be tantamount to a decision to be unprepared for the administration of KI at a time when it would be most beneficial. This could well be a defensible position based on the low probability of an accidental release for which administration of KI would be warranted, the costs of a 40-y preparedness program and the limited benefits the drug would provide (US80a; US80b). On the other hand, the drug is quite inexpensive (about 10¢ each, capital cost). As an alternative, the preparedness matter could be left to the individual where the drug is available for purchase.

The number of persons selected to be involved in a preparedness program would depend on the radiation protection objectives of the authorities. A point often missed is that for an atmosphere release, a significant reduction in collective dose (and total numbers of adverse health effects) can be achieved only by reducing doses over long ranges, i.e. 50–200 km for most nuclear power plant sites in the United States (US83). Thus, a preparedness program would have to be broadcast to be potentially beneficial in this regard. By the same token, during an emergency response, the numbers of people who would have to respond to achieve this benefit would be quite large. This would raise the possibility of a small number of the low probability adverse reactions to KI described by Crocker (Cr84).

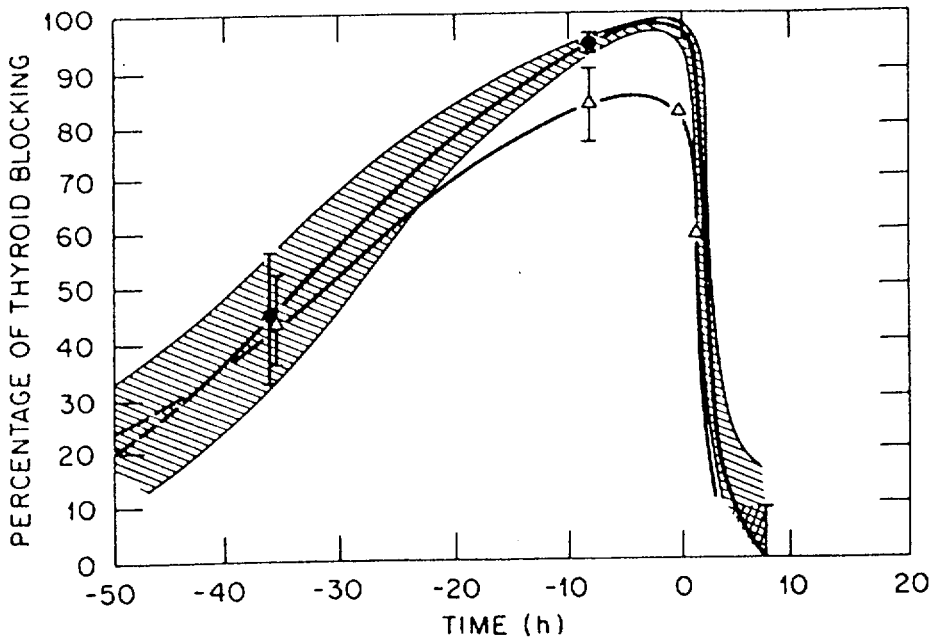

FIG. 1. Percent of thyroid blocking afforded by 100 mg of stable I as a function of time of administration before or after a 1 μCi slug intake of ^{131}I. Data points are for different subjects, of which only a few (3–5) were involved (Il72).

In contrast to collective dose, which would increase with distance, individual risks of thyroid ablation and latent cancer decrease monitonically with distance (Il72; US80a; US80b). Thus, a preparedness program which has the objective of reducing individual risks could be limited to a short range, e.g. 5 km, and fewer people, with a lower potential for adverse reactions to KI.

In the United States, the Nuclear Regulatory Commission and the Federal Emergency Management Agency recommend that KI be stockpiled in or near nuclear power plants for the use of plant personnel, emergency workers and inhabitants of certain local institutions during a radiological emergency (US80c). The U.S. Food and Drug Administration has determined that ingestion of KI would be warranted at a projected thyroid dose of 25 rem and has authorized the non-prescription sale of the drug (US82).

The remaining issue in the United States is whether or not KI should be predistributed to the public for immediate use in the event of the release of significant quantities of radioiodines to the atmosphere. The KI issue has been debated for many years in the United States but only recently has the focus been on the predistribution issue (US83; US84). The matter is unresolved at this time in the United States.

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References

Cr84 Crocker D. G., 1984, "Nuclear reactor accidents—the use of KI as a blocking agent against radioiodine uptake in the thyroid—a review," *Health Phys.* **46**, 1265–1279.

Il72 Il'in L. A., Arkhangel'skaya G. V., Konstantinov Y. O. and Likhtarev I. A., 1972, *Radioactive Iodine in the Problem of Radiation Safety*, Atomizdat, Moscow, U.S.S.R. (English translation available from National Technical Information Services, U.S. Department of Commerce, Springfield, VA 22151, as AEC-tr-7536, June 1974.)

US80a U.S. Nuclear Regulatory Commission, 20 May 1980, *Radiation Protection-Thyroid Blocking*, Memorandum for the Commissioners, U.S. Nuclear

Earlier in '85 NRC & FEMA opted against a national predistribution plan/requirement. They didn't say if they meant a licensing requirement.

Regulatory Commission, Washington, DC 20555, SECY-80-257.

US80b U.S. Nuclear Regulatory Commission, 18 September 1980, *Radiation Protection-Thyroid Blocking,* Memorandum for the Commissioners, U.S. Nuclear Regulatory Commission, Washington, DC 20555, SECY-80-257A.

US80c U.S. Nuclear Regulatory Commission and U.S. Federal Emergency Management Agency, 1 November 1980, *Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,* U.S. Nuclear Regulatory Commission, Washington, DC 20555, Rev. 1, NUREG-0654/FEMA-REP-1.

US82 U.S. Food and Drug Administration, 1982, "Potassium Iodide as a Thyroid Blocking Agent in a Radiation Emergency—Final Recommendations on Use," *Federal Register* **47**(125), 28158.

US83 U.S. Nuclear Regulatory Commission, 30 August 1983, *Emergency Planning-Predistribution/Stockpiling of Potassium Iodide for the General Public,* Memorandum for the Commissioners, U.S. Nuclear Regulatory Commission, Washington, DC 20555, SECY-83-362.

US84 U.S. Nuclear Regulatory Commission, 20 January 1984, *Use of Potassium Iodide for Thyroid Blocking,* Memorandum for the Commissioners, U.S. Nuclear Regulatory Commission, Washington, DC 20555, SECY-83-362A.

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301-340-1676

September 22, 1998

U.S. Nuclear Regulatory Commission
Attn: Aby S. Mohseni
Office for Analysis and Evaluation of Operational Data (T 4A43)
11545 Rockville Pike
Rockville, MD 20852

Ladies and Gentlemen:

RE: NUREG-1633, Draft dated July 1998

Technical comments are appended. From a policy standpoint:

1. A license to operate a nuclear power plant should not be conditioned on Mary Jones having a pill (KI, or any other kind). Third party control may be unconstitutional.

2. Long ago the Food and Drug Administration was assigned as the lead Federal agency on the KI matter. Long ago, the FDA authorized the non-prescription sale of KI.

3. This being so, the NRC should not be concerned with the matter. The Commission should direct its staff to direct all inquiries to the FDA. (NRC could 'not object' to an FDA (or FEMA) position.)

It's been almost twenty years now since I first made these and other relevant comments to NRC staff. (Meeting long ago with Commission staff (Ed Podolak), and Mat Taylor, Jocelyn Mitchell, and Peter Crane.) Yet the staff persists in pursuing this matter. Engineers, health physicists, and lawyers are not qualified to dispense medical and pharmaceutical advice. If this were a hearing on the matter, the authors of the draft would not be qualified to testify regarding potential efficacy. (Most are good friends of mine, but this would not be sufficient.)

So as not to dilute this message, my further comments are attached.

Sincerely,

James A. Martin, Jr.

cc: Dave Aldrich
Roger Blond

Aby —
Please send copies of all but the marked up draft to each co-author and Peter Crane.
— J A M

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MARTIN Comments

NUREG-1633

Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Reactor Accidents

Draft Report for Comment

U.S. Nuclear Regulatory Commission

Office for Analysis and Evaluation of Operational Data

Office of Nuclear Reactor Regulation

EXECUTIVE SUMMARY

Each nuclear power plant (NPP) in the United States has two emergency planning zones (EPZ): the plume EPZ and the ingestion EPZ. The plume EPZ is that area requiring immediate action to reduce risk to the public and is approximately 10 miles in radius. The zone is sufficiently large that protective actions within it provide for substantial reduction in early health effects (injuries or deaths) in the event of a worst-case core melt accident. The ingestion EPZ is the area in which plans exist for protecting the public from the consumption of contaminated food and for which there is considerable time for action to reduce risk. The ingestion EPZ is approximately 50 miles in radius, which also includes the 10 mile radius plume EPZ.

In NPP licensing, the U.S. Nuclear Regulatory Commission (NRC) subscribes to the defense-in-depth safety strategy. The elements of that strategy include: accident prevention, redundant safety systems, containment, accident management, siting, and emergency planning. Following the Three Mile Island Unit 2 (TMI) accident, emergency response capabilities were expanded with improved emergency plans, equipment, and facilities. Emergency response personnel from industry, State and local organizations, and Federal agencies receive extensive training and are evaluated by periodic drills.

The NRC and the Federal Emergency Management Agency (FEMA) are the two Federal agencies tasked to evaluate emergency preparedness at and around NPPs. The NRC will not issue an operating license for a nuclear power reactor unless a finding is made by the NRC that there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The NRC bases its finding on a review of the FEMA findings and determinations as to whether State and local emergency plans are adequate and whether there is reasonable assurance that they can be implemented and on the NRC assessment as to whether the utility's onsite emergency plans are adequate and whether there is reasonable assurance that they can be implemented.

One of the emergency planning elements that FEMA evaluates is the adequacy of public protective actions. In general, evacuation, sheltering, and access control are the principal protective actions considered for the early phase of an accident. Evacuation is the preferred protective action for projected severe accidents with **prompt** evacuation clearly the most effective. To ensure that evacuations are prompt, protective actions are recommended as soon as core damage is projected, which for most reactor accidents is well before a major release begins. In general, when core damage is projected, persons within 2-3 miles around the plant are evacuated and persons in the remainder of the plume EPZ are directed to remain indoors and await further instructions.

The use of potassium iodide (KI) as a supplemental protective action for the general public is the subject of this technical paper. Specifically, this technical assessment documents the basis that the NRC staff used to evaluate options related to the use of KI by the general public within the 10-mile EPZ. To ensure an informed decision, this assessment begins with a brief history of reactor accidents, leading to an overview of severe reactor accident source terms. Next, thyroid and whole body dosimetry, their associated risk assessments, and their relationship to severe reactor accident source terms are discussed. In addition, this assessment summarizes the medical aspects of KI use, and includes a glossary of medical terms, as well as a comprehensive list of references.

Early (time) from EALs.
Fast (speed) from sirens.
Distance from LPZ and EPZ.
time, distance, speed.

To assess the effectiveness of KI in reducing the radiological impact on populations close to NPPs, the staff estimated offsite doses for several accident scenarios, with and without the timely distribution of KI. The staff then related these findings and insights to the Chernobyl accident and the resulting emergency responses of the Ukraine, Belarus, and Poland. To complete the picture, the staff then summarized the KI guidance and policies of the United Kingdom, Sweden, Switzerland, Finland, France, the World Health Organization (WHO), and the International Atomic Energy Agency (IAEA).

The staff's approach to assessing the effectiveness of KI involved calculating whole body and internal organ doses, including thyroid, to populations within the 10-mile EPZ. The staff performed these calculations for several severe reactor accident scenarios using the source terms for the Surry NPP, as specified by NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," dated 1990. For each accident scenario, the staff performed two identical calculations, except that one calculation assumed that KI was administered to every person within the 10-mile EPZ just before any exposure to radioactive releases.

Examination of the resulting data indicates that timely administration of KI reduces thyroid doses by about a factor of 10 for all scenarios and distances. If the doses are in the stochastic range (up to several thousand rads), thyroid blocking could reduce the risk of thyroid cancer by about a factor of about 5. Other cancer risks are not affected by the use of KI, and this reduction in the risk of thyroid cancer obviously does not apply if the thyroid is ablated (dose greater than about 25,000 rads). The effects of whole body doses greater than 25 rem can be seen as changes in blood chemistry, and doses above about 100 rad cause serious physiological damage. About 50 percent of individuals receiving acute doses greater than about 400 rad die within about 90 days. For the two most severe accident scenarios considered, reductions in thyroid doses are dwarfed by the physiological effects of the accompanying acute whole body doses. Early death or very serious effects would occur to all individuals exposed out to nearly 10 miles. The third accident yields whole body doses that are substantial, but probably not fatal. Timely administration of KI offers some thyroid dose saving, but the major population impact (e.g., leukemia, lymphoma, and other radiogenic cancers) results from stochastic effects associated with the large whole body doses. The fourth accident scenario which yields the least impacting source term would cause insignificant doses for both the thyroid and the whole body.

Early KI can prevent thyroid ablation, which is to be avoided if possible.

This technical assessment yielded the following insights and conclusions:

Reactor Accident Frequencies and Protective Actions

- Although there have been no evacuations in the United States from NPP emergencies since the TMI-2 accident, in theory, there could be numerous evacuations without an associated release of radioactive material. The calculated frequency of core damage is generally decades higher (e.g., about 40 times higher for Surry) than the calculated frequency of core damage accompanied by a significant release. Current practice, as described in references published by the NRC and the U.S. Environmental Protection Agency (EPA), requires protective actions (i.e., evacuation, when possible) when core damage is deemed probable. The intent is to move people away from potential harm well in advance of any possible radionuclide release. Similarly, if KI were used as a routine protective measure, theoretically, it could be administered to a general public numerous times without any associated exposure to radioiodines.

- Evacuation of the public during non-nuclear emergencies or disasters is relatively common in the United States. A study ("Identification and Analysis of Factors Affecting Emergency Evacuation," NUMARC, 1989) indicated that there are on the average about 31 major evacuations a year in the US involving more than a 1000 people. By contrast, the administration of a drug to the general public, including pregnant women and children, during an emergency in the United States without direct medical supervision is a significant departure from the norm in emergency response.[1]

- After the onset of core damage, the probability of a relatively insignificant release of the key radioisotopes is about the same as the probability of a major release. Consequently, because the potential exists that severe health effects may result any time core damage occurs, evacuation is the principal effective action used to protect the general public.

Chernobyl Experience

- Following the Chernobyl accident, excess thyroid cancer among the children in Belarus, the Ukraine, and Russia has been detected. Essentially all the affected children lived more than 10 miles from the reactor and are believed to have been irradiated as a result of consuming contaminated foodstuffs. Above all, this experience underscores the importance of early action to prevent ingestion of contaminated foodstuffs by the general public, especially children. The United States provisions for the interdiction of contaminated food and water would have prevented this unfortunate occurrence. Thus, given the significant alternative food supplies in the United States, KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs.

KI Benefits and Challenges

- KI is relatively safe for short-term use if administered in proper dosage with proper medical advice to those patients who are not under certain medication or do not have certain medical conditions. The U.S. Pharmacopeia (USP) Drug Information monograph states that KI is contraindicated in several situations. For example, use of KI with other medications (such as anti-thyroid agents, diuretics (potassium sparing), and lithium) could lead to problems of major clinical significance. A high degree of caution would have to be exercised before recommending its administration on a mass basis, including to pregnant women and children. Logistics and liability are significant issues probably best handled by the States.

- Use of KI for the general public is not an alternative to evacuation. The benefits of KI can be fully realized only if it is administered just before the inhalation of radioiodines[1]. The use of KI in conjunction with evacuation could potentially delay evacuation. The States and local officials are responsible for implementing protective actions. KI distribution could present considerable logistical concerns. The officials must make sure that the public self-administers the correct amount of medication and is cognizant of potential contraindications when used with other medication. Realistically, the State and local officials are in the best

[1] KI protects the thyroid from interal exposure to radioiodines. KI does not protect against internal exposure to other radioisotopes and does not protect against external irradiation.

position to deal with these issues, and determine how best to allocate State's resources following a severe accident.

- The existing emergency ~~response~~ preparedness capability for each NPP site is principally based on ~~moving~~ people rapidly out of potential harm's way. Introducing a process that requires critical timing in distribution/administration of a drug could slow evacuation and thereby reduce effectiveness of a process that protects ~~the population~~ people from all radionuclides and pathways.

National stockpiles of KI have been recommended along with chemical antidotes, serin vaccines and antibiotics for response to nuclear, biological, and chemical weapons. As an added assurance, these stockpiles are available to State officials, should there be a need for KI on an ad-hoc basis.

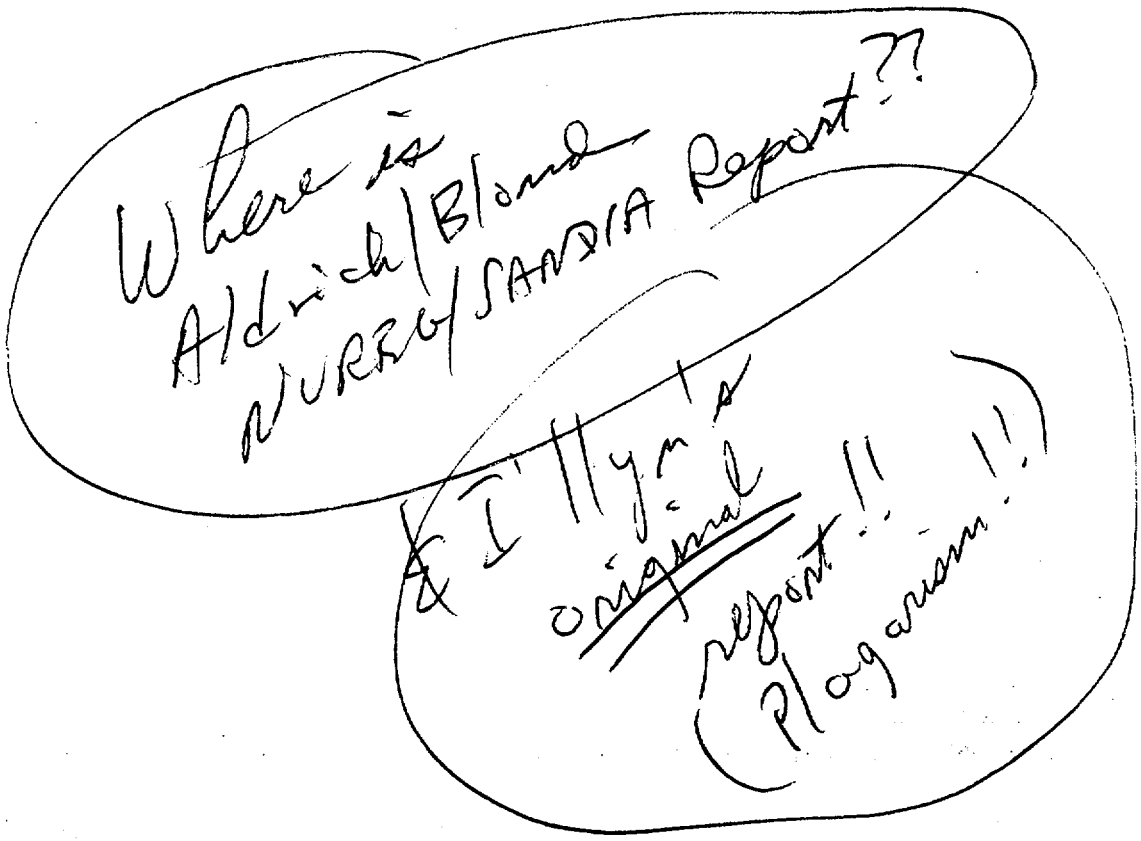
International Practices

- Other countries and major international organizations, including the IAEA and WHO, endorse the use of KI. The international policies, in some cases, are significantly different from the U.S. policies. The principal example is the recommendation by the WHO to administer KI to pregnant women and children, whereas U.S. references specifically warn against administering KI to that same group. Cultural and legal differences between the U.S. and other countries may be the basis for differing perspectives on general drug use.

Show the promise/problem figure here in the executive summary.

31. "Emergency Planning in the NHS: Medical Services Arrangements for Dealing with Major Incidents," Vol. 2, Accidents Involving Radioactivity Source, UK.

32. Thomas, Clayton L., Ed., *Taber's Cyclopedic Medical Dictionary*, 16th Ed., Philadelphia: F. A. Davis Co., 1989.



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NRC Commissioners - Chairperson Shirley Jackson, FAX 301-415-1757
Commissioners Nils Diaz and Edward McGaffigan, FAX 301-415-1672

From: Connie Kline 38531 Dodds Landing Dr., Willoughy Hills, OH 44094
Phone & Fax 440-946-9012, Dedicated Fax 216-663-4177

Date: 9/21/998

Re: Comments On NUREG-1633, "Assessment of the Use of Potassium Iodide as a Public Protective Action During a Severe Reactor Accident" (4 pages)

Thank you for allowing me extra time to submit these comments. I have been inundated at my teaching job implementing changes to the recently reauthorized Individuals With Disabilities Education Act.

The Nuclear Regulatory Commission should immediately withdraw NUREG-1633. It is one of the most biased, contradictory documents I have ever read. It seems to intentionally discourage the use of KI and is misleading and in some instances inaccurate. My criticisms, which are not all inclusive, include the following points:

1. The document fails to mention the U.S. NRC July 1, 1998 decision to grant Amended Petition for Rulemaking PRM-50-63A which requires states to consider the use of KI for the general public in the of a nuclear power plant accident.

2. NUREG-1633 does not refer to the NRC June 30, 1997 decision to provide federal funding for states to stockpile KI for public use.

3. NUREG-1633 fails to mention that the Food and Drug Administration has approved KI as a "safe and effective", nonprescription, over-the counter drug.

4. On p. 11 and elsewhere, NUREG-1663 refers to unreferenced "reports (that) consistently state that the products are contraindicated for various groups of people (principally pregnant women, nursing mothers...)." This statement is contradicted by the 1997 Physician's Desk Reference and the package insert for Thyro-Block which state:

> The only people who should NOT take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or antithyroid drug). Pregnant and nursing women and babies and children may also take this drug. (emphasis added)

It is not until page 19 that NUREG-1633 mentions the WHO Guidelines which "recommend predistribution of stable iodine close to the site...(and) distribution to pregnant women, neonates, infants, and children if the predicted dose is likely to exceed reference levels."

Every drug has contraindications and the potential for allergic reactions. In an emergency as dire as a reactor accident, where people risk illness and death, they should have the choice of making an informed decision and assuming possible risk, particularly given KI's proven safety and effectiveness.

5. The document emphasizes evacuation and sheltering while minimizing the role of KI. On p. 1 and elsewhere, NUREG-1633 states "...prompt evacuation is the most effective protection for the general public in close proximity to a NPP during a severe reactor accident...Sheltering is also worth

considering under certain circumstances..." The document does acknowledge the limitations of sheltering "(which) is of little value in a single-family home and fallout shelters (or large buildings with ventilation control) are rare."

NUREG-1633 promotes evacuation as if it were an easy panacea under the unique circumstances of a reactor accident. "Evacuation is relatively commonplace in the U.S." (p. 1) The evacuations cited in the document are usually temporary in nature and of relatively short duration, involving situations where people can return to their homes to salvage belongings. Evacuation in the event of a NPP accident may be permanent with no access to restricted areas.

Contrary to the document's assertion that "travel routes are generally well suited to the movement of large numbers of people" (p. 13), due to their proximity to water and their rural locations, many reactor sites have inadequate escape routes. In the case of the Perry NPP, there is a two-lane east-west route that has been the site of many accidents. The winding, two-lane southern evacuation roads are unlit and full of dangerous curves. Due to Lake Erie, there are no northern evacuation roads.

Page 13 of the document contains a dubious statement regarding weather-related impediments to evacuation, "...however attendant unstable meteorology and high winds would more effectively disperse radioactive materials and thereby reduce the overall radiological hazard." High winds could just as easily cause more widespread dispersion and deposition of radioactive materials as happened during the Chernobyl accident. Change in wind direction can make evacuation more dangerous than sheltering. As the document admits, inclement weather can prevent evacuation altogether. Without readily available KI, the only alternative is admittedly inadequate sheltering at home.

Furthermore, in the case of the Perry plant and probably elsewhere, some evacuation receiving centers are less than a mile outside the EPZ in buildings without adequate ventilation or other sheltering controls.

) arguments that availability of KI would lull the public into a false sense of security or reduce the ...elihood of people evacuating or adhering to reentry or food restrictions during recovery are fatuous. The public is capable of understanding a wide array of current public health information; they will be able to comprehend the radioiodine specificity of KI. Just because there are other radionuclides to which people may be exposed, they should not be denied KI which can counteract the deadly effects of radioactive iodine. Furthermore, human nature dictates that people will avail themselves of multiple barriers of protection.

Evacuation, sheltering and the availability of KI are not mutually exclusive; KI reinforces the other two emergency preparedness options. Evacuation is a far more daunting, monumental undertaking than providing for the availability of KI. As NUREG-1633 says, "Emergency preparedness must accommodate considerable uncertainty." Better to be fully prepared for any contingency, which would include readily available KI for the general public.

6. NUREG-1633 acknowledges the efficacy of KI when administered on a timely basis, but discourages its use by consistently characterizing public accessibility as difficult and nearly insurmountable. "The logistical exigencies of such access to KI by the general public during severe reactor accidents are difficult to meet." (p. 7). "Distribution of KI is especially challenging under these circumstances (hazardous travel conditions, seismic events or traffic accidents)." (p. 13) Evacuation is especially challenging, if not impossible, under such conditions!

"KI distribution could present considerable logistical concerns...Introducing a process that requires critical timing in distribution/administration of a drug could slow evacuation and thereby reduce effectiveness..." (p. xi).

, Ohio Department of Health's June 1998 draft policy "Use of Potassium Iodide for the 10-Mile Emergency Planning Zone Population" solves these concerns through **public education, informed consent, and provisions for both predistribution (which is absolutely essential given the timing criticality of KI) and accident distribution of KI**:

KI will be provided to the general public without cost; however, recipients will be required to sign a "KI Receipt Form" for themselves and for minor children or wards in their care. The KI Receipt Form provides general information and instructions on taking the tablets, including dosage for adults, children and infants, as well as possible side effects and possible allergic reactions to KI...If they do not sign the form, then they will not be given the KI tablets. Information will also be provided to KI recipients on the limits of protection provided by the KI. It is effective only if taken several hours before, during and immediately after exposure. The benefit of KI applies only to radiolodine ...therefore, it is supplementary to evacuation, which remains the most effective method of protection...County emergency plans will...make provisions for the pre-accident distribution of KI to adults who want to voluntarily pick it up from their local health department for themselves and for their children or wards...Evacuees arriving at a designated facility for evacuee reception or other KI distribution point who want to take KI will be required to sign a KI Receipt Form...County emergency plans will need to be revised to allow parents and guardians for minor children and wards to register their consent beforehand.

7. On page 2, NUREG-1633 says, "This paper does not address the...legal factors associated with use (or non-use) of KI." Yet throughout NUREG-1633, the document mentions the threat of litigation to discourage the use of KI. "The principal questions raised by the decision-makers concern distribution and procedures and legal liabilities." (p. 13). "In the US (sic), the implementation of a protective action may entail litigation and liability for long after the accident. The TMI accident is a case in point. One can expect that administration of KI on a mass basis would certainly entail litigation in this country..." (p. 22)

the first place, any litigation following TMI was NOT the result of protective action, which involved a delayed, limited, selective recommendation to evacuate. (Despite desperate efforts to locate KI, none was available). Subsequent litigation involved delaying the recommendation to evacuate, faulty or nonfunctioning radiation monitors, and radiation exposure issues. In other words, litigation involved the accident, itself, and subsequent negligence and radiation dangers, not the protective actions that were undertaken.

Furthermore, so-called **liability issues can be easily resolved by thoroughly educating and informing the public about KI and by having recipients sign a waiver of liability as the State of Ohio is proposing. Lastly, given the safety and efficacy of KI, states and localities should be much more concerned about liability if they FAIL TO HAVE KI READILY AVAILABLE.**

8. As another discouragement to the use of KI, NUREG-1633 warns throughout that something like administration of KI to the public is unprecedented in the United States. "A high degree of caution would have to be exercised before recommending its administration on a mass basis..." (p. x). A high degree of caution must also be exercised before recommending mass childhood immunization or flu shots. Mass administration of the Salk and Sabin polio vaccines were undertaken in the 1950's and 1960's. Workers in certain occupations must be vaccinated against hepatitis as a condition of employment. Some school districts require verification of immunizations before enrollment. After certain natural disasters such as serious floods, people are strongly advised to get tetanus shots. While these examples are not identical to the KI situation, they are very similar and demonstrate precedence. The U.S. makes mass health recommendations or requirements because the individual ar ...cietal benefits far outweigh the risks.

"...administration of a drug like KI to the general public has no precedence in the United States. Thus it is not known how the public (or public officials) would react to a recommendation to administer KI..." (p. 2). The same could be said for mass evacuation following a reactor accident. Since this has no precedence in the U.S., it is unknown how the public (or public officials) would react

9. To further discourage the use of KI, NUREG-1633 contains xenophobic, ethnocentric language, implying U.S. cultural and political superiority. "The United States provisions for the interdiction of contaminated food and water would have prevented this unfortunate occurrence." (p. x) There is no way of knowing the degree of food and water contamination or the adequacy of food and water supplies following a catastrophic reactor accident in the U.S.

"Cultural...differences between the U.S. and other countries may be the basis for differing perspectives on general drug use." (p. xi) When it comes to protecting its citizens with KI, the U.S. is the worldwide exception.

"The differences between practices in the United states (sic) and Europe might be attributed to...history, geography, and cultural/political conditions...There are certain cultural and political differences between Europe and the US (sic) that might account for the difference in response during a major crisis. The public's trust of their elected officials...influences how and to whom they turn (during) a major disaster. The U.S. political structure differs from that of most European countries. Public involvement...is more accepted in the U.S. than in many European countries." (pp.22-23) There is widespread public distrust of government and governmental agencies in the United States that could erode public confidence in an emergency. With policies like one-step licensing; expedited license renewal hearings; on-site, dry cask HLRW storage without benefit of a site specific hearing or operating license amendment etc. etc., the NRC has decimated public participation and involvement.

10. And last, but not least, NUREG-1633 implies that states will have sufficient access to national stockpiles of KI that have been created by the Federal Government as part of readiness for acts of "NBC" (nuclear, biological, and chemical) terrorism. "National stockpiles of KI have been recommended along with chemical antidotes, serin, vaccines, and antibiotics for response to nuclear, biological, and chemical weapons. As an added assurance, these stockpiles are available to State officials, should there be a need for KI on an ad-hoc basis." (pp. xi, 28) These national KI stockpiles are inadequate and insufficient in the event of a nuclear power plant accident. For example, the only Ohio city included in the present NBC plan is Columbus which is 200 miles from Ohio's two reactors. According to the NRC, Cleveland will probably be one of the cities eventually included in the NBC program, but Cleveland is 30 miles from the Perry reactor and 90 miles from the Davis Besse reactor. In the event of a reactor radiological emergency, KI must be readily accessible in the immediate vicinity of Ohio's two reactors. Furthermore, FEMA says no consideration has been given to moving KI from terrorism stockpiles to nuclear power plant sites in the event of a reactor accident.

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

September 3, 1998

MEMORANDUM TO: L. Joseph Callan
Executive Director for Operations

FROM: Myron Pollycove M. P.
Visiting Medical Fellow

SUBJECT: DISTRIBUTION OF POTASSIUM IODIDE TO BLOCK THYROID UPTAKE OF IODINE-131 ACCIDENTAL RELEASE

In June 1998 the NRC endorsed a proposal that encourages states to make potassium iodide available to the public and that provides Federal funding for supplies of the drug. Statistically significant data cited by ICRP, NCRP, National Cancer Institute, and UNSCEAR 1994 demonstrate that neither low nor high doses if I-131 have been shown to be carcinogenic (attached). The radiation - induced thyroid cancer in children after the Chernobyl accident probably resulted from exposure to gamma-emitting short-lived radioiodines (attached). Since the administration of low diagnostic doses to a cohort of 35 thousand patients, including 2,000 under the age of 20, and high therapeutic doses to another cohort of 12 thousand patients demonstrate no carcinogenic effect, the stockpiling of potassium iodide for mass distribution to block thyroid uptake of I-131 is unwarranted.

Furthermore, the occasional occurrence of adverse, even fatal effects of potassium iodide medication (attached) and lack of effectiveness to block I-131 uptake when administered more than six hours after exposure (attached) contradict widespread distribution of potassium iodide for oral administration. In 1977, when I-131 was thought to be carcinogenic, NCRP 55 (attached) stated, "the blocking agent should be administered within a few hours after an accident. Since reliable radiation monitoring data may not be available that quickly, the decision to administer stable iodide should be based on a pre-planned estimate of the probable degree of contamination from the accident."

"The short-and long-term consequences of inhalation of radioactive iodine are far less than the possible injury that might result from individual or mass panic arising from efforts to obtain the blocking agent, and this modicum of common sense should be remembered by each person."

Attachments: As stated

Carcinogenicity of ^{131}I and Use of Potassium Iodide

Myron Pollycove, M.D.

ICRP 1990 (enclosed) agrees with UNSCEAR 1988 and BEIR V that the most current estimates of risk to the thyroid are presented in the enclosed NCRP Report 80 (NCRP, 1985). ICRP 1990 states that the carcinogenicity of external radiation is estimated for the high dose range and extrapolated to low doses "....because of the presumed linear nature of the thyroid response to external radiation. ^{131}I was estimated to be about one-fourth to one-third as effective as external radiation (NCRP, 1985; UNSCEAR 1988b)."

The genesis of this estimation of ^{131}I carcinogenic effectiveness is presented in the enclosed thyroid cancer section of my discussion of the UNSCEAR 1994 Report. The enclosed part of the UNSCEAR report states that for "A combined analysis of nearly 47,000 Swedish patients given ^{131}I for thyroid cancer, for hyperthyroidism or for diagnostic purposes [Holm 1989, 1991]....no clear association of cancer induction by radiation was evident in this analysis." The NCRP 1985 report analyses the earlier studies by Holm (1980, 1981, 1984) of 14,690 ^{131}I administrations, including 10,133 patients (494 under age 20) with diagnostic doses and 4,557 patients with therapeutic doses for hyperthyroidism and concludes,".... ^{131}I has not been shown to be carcinogenic in people...." This 'problem' was circumvented by assuming the largest number of thyroid cancer cases compatible with the data at the upperbound of the 95% confidence level. This assumption was used to determine that an upper limit value of one-third is the relative effectiveness of ^{131}I compared to external radiation for the induction of thyroid carcinoma. A decade later the above mentioned reports by Holm continue to demonstrate no excess cancer or leukemia. These reports include a cohort of 35,074 patients given diagnostic doses, including 2000 under the age of 20, and another 12,000 patients given therapeutic doses of ^{131}I. This much larger number of patients has reduced the upper limit value of relative effective carcinogenicity of ^{131}I compared to external radiation from 1/3 to 1/17. To reach zero in this manner an infinite number of patients is required.

Since the administration of low or high doses of ^{131}I to almost 50,000 patients has demonstrated that ^{131}I is not carcinogenic, the stockpiling of potassium iodide for mass distribution to block ^{131}I uptake by the thyroid is needless. Furthermore, potassium iodide has numerous harmful side effects and should not be administered indiscriminately. Even in 1977, when ^{131}I was still thought to be carcinogenic, enclosed NCRP 55(NCRP, 1977) stated, "the short-and long-term consequences of inhalation of radioactive iodine are far less than the possible injury that might result from individual or mass panic arising from efforts to obtain the blocking agent, and this modicum of common sense should be remembered by each person."

Enclosures: As stated

Adopted Nov 1990

imply that relative risks agree quite well not only in the above three groups but also in the Canadian fluoroscopy series. BEIR V (NAS, 1990) finds in the two mortality series (the life span study in Japan and the Canadian cohort without the Nova Scotia patients) that absolute risks agree while in the three incidence series, relative risks agree better and they preferred a relative risk model. Apparently the information is insufficient, when separated out according to age, to provide definitive answers even in the case of cancer of the breast.

B.5.11. *Expected years of life lost from fatal cancer in organs vs. sex, age and population*

(B106) Calculations can be made of expected years of life lost (e.g. see UNSCEAR, 1988b, Table 70) for different sexes, ages, populations, etc. for site specific and total cancers. A set of tables parallel to those for cancer deaths are obtained. A summary table of ratios based on expected years of life lost, average for males and females, five national populations, two models, age 0–90 y is given in Table B-16. The ratios are broadly similar to those in Table B-15 except that leukaemia is higher, reflecting the shorter latency for leukaemia.

Table B-16. Relative values of expected life lost due to induced cancer among organs averaged for sex, five national populations and two models (multiplicative and NIH), age 0–90 y

Organ	Relative life lost
Oesophagus	0.048
Stomach	0.190
Colon	0.148
Lung	0.154
Breast	0.049
Ovary	0.025
Bladder	0.039
Bone marrow	0.197
Remainder	0.150
All cancer	1.000

B.5.12. *Fatal cancer in other selected organs*

(B107) Not accounted for in the list of organs for which fatal risks are derived from the Japanese data are some organs which are often selectively irradiated and therefore specific information on probability of induced cancer is available and for which relative fatal probabilities are especially useful. Included among these are the thyroid, bone, skin and liver. Each of these tissues shows elevated but nonsignificant relative risks in the Japanese data but additional risk information is available from other sources.

Thyroid

(B108) UNSCEAR (1988b, Annex F, p. 493) and BEIR V (NAS, 1990, p. 294) agree that the most current estimates of risk to the thyroid are those presented in *NCRP Report 80* (NCRP, 1985). These estimates give a lifetime risk estimate for fatal cancer of 0.075×10^{-2} Gy^{-1}. The fatality rate is stated to be 0.1, thus the incidence is 0.75×10^{-2} Gy^{-1}. The value for total cancer is estimated for the high dose range but will be included in Table B-17 as it is because of the presumed linear nature of the thyroid response for external radiation. ^{131}I was estimated to be about one-fourth to one-third as effective as external radiation (NCRP, 1985; UNSCEAR 1988b).

4. Human Experience after Exposure to Iodine-131

4.1 Therapeutic ^{131}I for Thyrotoxicosis

4.1.1 *Adults*

Dobyns *et al.* (1974) found that 86 of 16,042 patients with Graves' disease without palpable nodules at the time of radioiodine therapy were subsequently operated on and found to have nodules after ^{131}I therapy. Approximately 98 percent of the 16,042 patients were over the age of 20 years at the time of treatment. The mean followup time was only 8 years. Two of these 86 patients were operated on because of recurrent thyrotoxicosis, but in both of these a palpable mass was specifically described in the thyroid. In the other 84, surgery was presumably indicated because of some palpable abnormality (Tompkins, 1976). Nine of the 86 (10.5 percent) had cancer and 77 (89.5 percent) had benign lesions. In an additional 494 of 16,042 patients, palpable nodules were found to have developed after ^{131}I therapy, but the 494 had not undergone surgery and have not been systematically followed since the end of the study. Based on the 9 documented cases of thyroid cancer, the prevalence of thyroid cancer would be about 0.06 percent in radioiodine treated patients, compared to a spontaneous prevalence in Graves' disease of about 0.1 percent. On the assumption that the prevalence of cancer would be the same in 494 unoperated patients as in the 86 patients subjected to surgery, 52 additional cases of thyroid cancer could be postulated. These assumptions would suggest a maximum prevalence of thyroid cancer of about 0.4 percent in ^{131}I treated patients. The radiation dose in these patients was always more than 2000 rads, with a mean of approximately 8755 rads to the thyroid, based on an assumption of a 6-day effective half-life (Maxon *et al.*, 1977; O'Connor *et al.*, 1979).

Holm and associates reported on 4557 people with hyperthyroidism who were treated with ^{131}I in Sweden (Holm *et al.*, 1980b; Holm, 1984). The mean follow-up period was 9.5 years and the mean age of the subjects was 56 years at the time of exposure. The mean administered

activity of ^{131}I was 13 mCi, calculated to deliver between 6000 and 10,000 rads in most cases. The subjects were about equally divided between those who had toxic diffuse goiters and those who had toxic nodular goiters. A total of 4 thyroid cancers was found, and all were in women with previous toxic nodular goiters treated with a mean total activity of 27.5 mCi ^{131}I. Based on Swedish tumor registry data from non-irradiated women with nodular goiters, 2 cases were predicted. The difference between 2 expected and 4 observed cancers was not considered significant. In a separate population, Sokal (1954) estimated the prevalence of thyroid cancer in toxic nodular goiter to be 0.94 percent. Application of this figure to the approximately 1900 women with toxic nodular goiter in the Holm study (Holm, 1984) results in a prediction of about 18 spontaneous cancers.

In the two populations discussed above (Dobyns *et al.*, 1974; Holm, 1984) with a total of 20,599 adult subjects followed for means of 8 and 9.5 years, there is no evidence of ^{131}I-induced thyroid carcinogenesis at high dose levels (greater than 2000 rads) in adults. This apparent absence of carcinomas may be due in large part to the effects of cell-killing and/or sterilization at such high dose levels and/or to the short follow-up times in relatively (compared to children) radioresistant adults.

4.1.2 *Children*

Safa *et al.* (1975) have reported on 273 patients treated between the ages of 1 and 20 years with ^{131}I for Graves' disease. There were 31 additional children aged 16 years or less who were treated with ^{131}I in the Cooperative Thyrotoxicosis Follow-up Study (Tompkins, 1976). Pooling of these observations reveals 2 cases of thyroid cancer in the combined population of 304 people followed after ^{131}I therapy. Estimates of mean thyroid dose and follow-up period, available from 271 of 304 subjects, are about 9,000 rads and about 11 years. The 2 observed cancer cases are more than might be expected spontaneously in Graves' disease (0.3 case), although the difference between the observed and expected cases is not considered significant.

4.2 Non-therapeutic Exposures to ^{131}I

Holm *et al* (1980a, 1981) reported a retrospective analysis of outcome in 10,133 subjects exposed to diagnostic administration of ^{131}I (total

less than 1 mCi) for suspected thyroid disease. The population included 8047 females (79 percent) and 2086 males (21 percent) with a mean age of 44 years for both sexes. Of the 10,133 subjects, 9639 were over the age of 20 years at exposure and 494 were less than 20 years of age. For the 9639 adults, the mean calculated thyroidal dose was 58 rads, whereas, in the 494 younger subjects, the mean dose was 159 rads. Patients were followed for a mean time (after adjustment for drop-out due to death), of 17 years after exposure to ^{131}I. No patients were included who had received external radiation therapy above the diaphragm or who had been treated previously with other internal emitters. Any cancers diagnosed less than 5 years after the ^{131}I exposure were excluded as not being related to the exposure. The study had insufficient data to take into account possible effects of intervening thyroid hormonal or surgical therapy after the radioiodine exposure on the subsequent development of thyroid cancer. In 8 patients, a thyroid cancer was confirmed as being present. All 8 of the cancers were in the 9639 adults; none was found in the children. Six of the 8 cancers (75 percent) occurred in women and 2 (25 percent) in men, reflecting the sex ratio of the study population as a whole. This did not represent any significant increase in cancer in the irradiated population. The expected number of thyroid malignancies, computed from age- and sex-specific cancer incidences in the Swedish Cancer Registry, was 8.3 cases over the period at risk (follow-up time minus 5 years).

Since 1973, a national collaborative study of children exposed to diagnostic levels of ^{131}I between 1946 and 1967 has been in progress under the auspices of the Bureau of Radiological Health of the U.S. Department of Health and Human Services, with support from the National Cancer Institute and the Nuclear Regulatory Commission. The study was designed to include about 13,000 potential subjects, equally divided among controls, exposed persons, and siblings of irradiated people (Harris, 1980). No data have been made available since preliminary communications regarding 443 of the subjects in 1975 (Hamilton *et al.*, 1975). Those communications suggested that at mean doses of 94 rads to the thyroid, with a range of less than 10 to 1900 rads, 6 subjects of 443 who received diagnostic ^{131}I studies in childhood were found to have benign thyroid nodules, and none of the 443 was found to have thyroid cancer at least 16 years later. There was no significant correlation between estimated thyroidal radiation dose and the incidence of benign nodules.

In a survey of 5179 children, of whom 1378 had been exposed to ^{131}I in radioactive fallout in the western United States, Rallison *et al.* (1974) could find no significant differences between irradiated and non-irradiated subjects in the prevalence of thyroid nodules, benign and malignant, at an average follow-up time of 14 years. The dosimetry is uncertain and undergoing extensive review, but new dose calculations are not yet available. The lowest figure proposed has been a mean thyroidal dose of 18 rads (Rallison *et al.*, 1974) with some other estimates being an order of magnitude higher (BEIR, 1980). Because of the uncertain dosimetry these data have not been used for risk estimates in this report.

For children exposed to diagnostic ^{131}I, the combined studies represent a total of 937 subjects representing 1.4 million person-rad-years at risk. For adults, the Swedish study contains 9639 subjects representing about 6.7 million person-rad-years at risk. If the absolute risk estimates derived earlier from carcinogenesis following external radiation exposures in childhood in the United States were applicable to these populations exposed to ^{131}I, then an excess of about 3–4 thyroid cancers in children and of about 8 to 9 thyroid cancers in adults would be expected, assuming that adults are at about one-half the risk of children. However, these experiences, with mean thyroidal doses from ^{131}I which are well below 200 rads, contain no evidence for the presence of human thyroidal radiation carcinogenesis.

4.3 The Relative Carcinogenicity of ^{131}I and External Radiation

Because ^{131}I has not been shown to be carcinogenic in people, a comparison of the thyroid cancer risk from ^{131}I with that from x-ray exposure is difficult.

Hanley *et al.* (1983) have discussed the problem of interpreting zero numerators. To find the largest number of excess cases with which a finding of 0/n is still compatible with the data at the upper bound of the 95% confidence level, one may solve the equation:

$$\text{Largest Number of Excess Cases} = 1 - (0.05)^{1/n} \qquad (4\text{-}1)$$

In the case of 937 children exposed to relatively low doses from diagnostic ^{131}I, this calculation results in a value of 0.00319 or about 3.2 excess cases/1000 as the upper 95 percent limit of risk compatible with zero observed cases. If the observed risk of 2.5 excess cases/10^6 person-rad-years at risk following external irradiation in childhood

were applicable, then with 1.4 million person-rad-years at risk one would expect 3.5 cases/937 or about 3.7 cases/1000. For the 9639 adults exposed to diagnostic ^{131}I, similar calculations using a risk following external irradiation of 1.25 excess cases/10^6 person-rad-years at risk (i.e., adults = one-half the risk of children) lead one to expect 0.87 excess cases/1000. The largest number of excess cases compatible with the upper 95 percent limit of a zero numerator in the adults is 0.31 cases/1000. Therefore, since the risk estimate derived for external radiation predicts a larger number of excess cancer cases than the upper 95 percent limit for what was observed in the ^{131}I exposed patients, then the risk of human thyroidal carcinogenesis following exposure to ^{131}I would appear to be less than the risk following exposure to the same dose from external x radiation.

Another approach to the question of the relative carcinogenicity of ^{131}I and external radiation needs to be considered. Choi (1978) and Feinstein (1977) have discussed mathematical models for predicting the minimum number of subjects required in a study of adverse effects characterized by an increased incidence of a spontaneously occurring abnormality. The number of subjects may be given by the formula:

$$n = \frac{Z_\alpha^2 \cdot P_0 \cdot (1-P_0)}{(P-P_0)^2}, \qquad (4\text{-}2)$$

Where Z_α is the standard normal (Gaussian) variate at a specified level of significance, α, which is 1.645 for a single tailed test at $\alpha = 0.05$; P_0 is the proportion of cases in which thyroid cancer occurs naturally; and P is the proportion of cases in which thyroid cancer occurs after radiation, including spontaneous cases. Implicit in this formula is the assumption of a power of 50% (or $\beta = 0.5$ and $Z_\beta = 0$) in order to approximate a central estimate analogous to the risk estimate calculation for external radiation. $P-P_0$ can be defined by the risk estimate (in cases per million per rad per year) [see Eq. (2-1)] times the number of person-rad-years at risk times 10^{-6}, divided by the number of persons in the population. One may then modify the basic equation to give the risk level at which one would expect to find an excess number of radiation-associated thyroid cancers in a given exposed population at $\alpha = 0.05$ as follows:

$$\text{Risk} = \frac{n \cdot 10^6}{\text{person-rad-years at risk}} \sqrt{\frac{(1.645)^2 (P_0)(1 - P_0)}{n}}. \qquad (4\text{-}3)$$

In applying Eq. (4-3) to the human data following low dose ^{131}I exposures, it would appear that if external radiation and ^{131}I are equally harmful in terms of thyroid cancer induction on a rad-for-rad basis,

then for the population of 9639 people exposed in adult life in Sweden and representing 6.7 million person-rad-years at risk with a spontaneous thyroid cancer rate in the unexposed Swedish population of 8.3/10,133 or $8.19 \cdot 10^{-4}$, and for a population of 937 people exposed in childhood and representing 1.4 million person-rad-years with an estimated spontaneous rate of clinically detectable thyroid cancer of about $3 \cdot 10^{-4}$, at $\alpha = 0.05$, one should find an excess of radiation-associated thyroid cancers at risk levels of greater than 0.62 to 0.69 cases per million person per rad per year for children and adults respectively.

In other words, if the risk following ^{131}I exposure is equal to or greater than 0.6 to 0.7 cases per million persons per rad per year, then one should be able to detect the excess cancers at $\alpha = 0.05$. In fact, no excess cancers were determined to be present. The calculation in the case of children is less certain due to the small numbers and lack of precise information regarding their actual spontaneous rate of thyroid cancer as they reach adult life.

Thus, in summary, ^{131}I appears less carcinogenic in people on a rad-for-rad basis than external radiation. How much less is yet to be determined; in fact, available human data on low dose ^{131}I exposures have not shown ^{131}I to be carcinogenic in the human thyroid. A comparison for children of the risk coefficient for ^{131}I of 0.6 cases per million persons per rad per year to the risk of thyroid cancer of 2.5 cases per million persons per rad per year following external radiation suggests that ^{131}I is no more than about one-fourth as effective as external radiation. For adults, a similar calculation using 0.7 cases per million persons per rad per year for ^{131}I and a risk of 1.25 cases per million persons per rad per year following external radiation, suggests that ^{131}I is no more than one-half as carcinogenic as external radiation.

Based on human experience, the range of the relative effectiveness of ^{131}I compared to external radiation is between zero and one-half. Combining the calculated values in children (¼) and adults (½) for application to the general population, an upper limit value of one-third is recommended for application to the general population, until additional data become available.

populations available for study, such attempts are fraught with difficulties. These include uncertainties in the doses actually received by individuals, geographic variability in the accuracy of cancer diagnoses, and confounding with the numerous other environmental factors that may well have a much greater influence on cancer risk. Furthermore, when geographical areas are compared, exact matching of control groups is difficult. It is not surprising, therefore, that studies that have attempted to correlate exposure to background gamma-radiation with cancer mortality or incidence without carefully considering these other factors have at times produced erratic and implausible results."(p.57,240).

"Few of the above studies have attempted to relate the observed leukemia rates to realistic estimates of dose, taking into account migration and differences between indoor and outdoor exposure rates. One exception is a Chinese study, in which two neighboring regions having different levels of exposure to background radiation (owing to the high thorium content of the monazite sands in one of them) were selected for study [H35, W8, w15, W16]. In both regions the overwhelming majority of the inhabitants had lived in the area for their entire lives. Exposures were determined by measurements not only at fixed locations indoors and outdoors but also in a sample of individuals in each area who wore personal dosimeters for two months. The average annual dose in the red bone marrow was estimated to be 1.96 mSv in the high background area and 0.72 mSv in the control area. During 1970-1985 the age-adjusted mortality rates for leukemia in males were 3.32 and 3.82 10^{-5} PY^{-1} in the high background and control areas, respectively (16 and 17 deaths), while in females the rates were 2.21 and 3.56 10^{-5} PY^{-1} in the high background and control areas, respectively (10 and 16 deaths), and consequently not significant. This study thus provides no evidence for a radiation effect following low-dose protracted exposure throughout life, since leukemia rates were lower in the population with higher exposure living on radioactive monazite sands."(p.57,242).

Despite meeting all the criteria for a scientific study of the effects of high background radiation, "implausible results" may still occur and the data is omitted from part XII of Table 8. Also omitted are the low-level radiation effects on leukemia of the Atomic Bomb Life Span Study published by the Radiation Effects Research Foundation (RERF) in 1992. These are shown in Chapter 11 of BELLE, Part II. At the 87% confidence level the *decrement* in the risk of leukemia is -0.4 for radiation doses that average 0.075 Sv and is consistent with the risk decrements at 0.015 Sv and 0.035 Sv and the zero increment at 0.15 Sv (zero equivalent dose, i.e., threshold). These RERF Life Span Study results are consistent with the lower leukemia rates observed in the Chinese population with higher exposure living on radioactive monazite sands. Both studies "support the view that the adaptive response in cells reduce the natural incidence of malignant conditions... in humans after low doses."

Thyroid Cancer

Significant thyroid cancer risk increments are produced by high doses of x-ray or gamma radiation to the thyroid administered in thymic irradiation of children and thymus/tonsil/acne screening (Part XI, Table 8, Annex A). Dose estimates of low-level thyroid radiation are uncertain when derived from the penumbra and scatter of doses given to other organs directly in the x-ray beam. Dosimetry of the thyroid in the diagnostic and therapeutic use of ^{131}I is well established by thyroid uptake measurements. "The effects of the diagnostic use of ^{131}I have been evaluated by Holm *et al* [H12, H27, H41]. A

total of 35,074 patients examined for suspected thyroid disorders between 1951 and 1969 in Sweden were followed for an average of 20 years. The mean age at the time of examination was 44 years. The average amount of ^{131}I administered to the patients was 2 MBq, and the radiation dose to the thyroid gland was approximately 0.5 Gy, while for other organs the dose was <10 mGy. Record linkage with the Swedish Cancer Register identified 3,746 cancers occurring five or more years after the initial ^{131}I examination, and the standardized incidence ratio for all malignant neoplasms, based on general population rates, was 1.01 (95% CI: 0.98-1.04)."(p.62,264.).

Even in the combined analysis of nearly 47,000 Swedish patients given ^{131}I for therapy or diagnosis discussed in Leukemia above, "no clear association of cancer induction by radiation was evident in this analysis." (p.62,265.).

Nevertheless, ICRP 1990 recommendations state:

"UNSCEAR (1988b, Annex F, p.493) and BEIR V (NAS, 1990, p.294) agree that the most current estimates of risk to the thyroid are those presented in NCRP Report 80 (NCRP, 1985). These estimates give a lifetime risk estimate for fatal cancer of 0.075×10^{-2} Gy^{-1} [External Radiation]. The fatality rate is stated to be 0.1, thus the incidence is 0.75×10^{-2} Gy^{-1}. The value for total cancer is estimated for the high dose range but will be included in Table B-17 as it is because of the presumed linear nature of the thyroid response for external radiation. ^{131}I was estimated to be about one-fourth to one-third as effective as external radiation (NCRP, 1985; UNSCEAR 1988b)."

Based upon reports by Holm *et al* (1980, 1981) of 9,639 adults receiving diagnostic doses of ^{131}I, the relative carcinogenicity of ^{131}I and external radiation was calculated in NCRP 80, 1985:

"Because ^{131}I has not been shown to be carcinogenic in people, a comparison of the thyroid cancer risk from ^{131}I with that from x-ray exposure is difficult. Hanley et al. (1983) have discussed the problem of interpreting zero numerators. To find the largest number of excess cases with which a finding of 0/n is still compatible with the data at the upper bound of the 95% confidence level, one may solve the equation:

$$\text{Largest Number of Excess Cases} = 1 - (0.05)^{1/n}$$

For 9639 adults exposed to diagnostic ^{131}I... calculations using a risk following external irradiation of 1.25 excess cases/10^6 person-rad-years at risk...lead one to expect 0.87 excess cases/1000. The largest number of excess cases compatible with the upper 95 percent limit of a zero numerator in the adults is 0.31 cases/1000"
Combining this calculation with other mathematical models, NCRP 80, 1985 concludes, "Based on human experience,...the relative effectiveness of ^{131}I compared to external radiation,...an upper limit value of one third is recommended for application to the general population, until additional data become available."

A decade later more data has become available. Reports by Holm *et al* (1989, 1991) continue to demonstrate no excess cancer or leukemia in a much larger cohort of 35,074 patients given diagnostic doses, including 2000 under the age of 20, and 12,000 patients given therapeutic doses of ^{131}I. Application of the above calculations to these patients results in reductions

of the upper limit value of 33 percent of relative effectiveness of ^{131}I compared to external radiation to 7 percent for the 35,000 diagnostic patients and 6 percent for the 47,000 combined diagnostic and therapeutic cohorts.

Female Breast Cancer

"Elevated risk of breast cancer following exposure has been demonstrated in several studies, including the life span study [T2, T15], the Massachusetts tuberculosis fluoroscopy study [B31], tuberculosis fluoroscopy studies in Nova Scotia and other Canadian provinces [M19] and the acute post-partum mastitis study in New York [S9], as can be seen in Part VIII of Table 8 and of Figure II."... "A number of studies have considered radiation exposure and breast cancer but provide little or no convincing evidence of an association: the contralateral breast studies in Denmark [S60] and in the United States [B18]; the cervical cancer case-control study [B11, B20, B21]; the Israeli tinea capitis study [M20]; and for women in the Swedish skin hemangioma study [F12.]"(p.30,105.). "The failure to detect an increased breast cancer risk in the cervical cancer case-control study is somewhat surprising in view of the large number of cases and moderate doses (average 0.3 Gy)."(p.30,106.). "In general, constant relative risk models that have a linear dose response and that depend on age at exposure appear to describe the breast cancer data quite well within cohorts."(p.31,108.). "The second study of tuberculosis patients given fluoroscopies included 31,710 women treated at sanatoria in Canada between 1930 and 1952 [M19]. About a quarter of these women received doses of 0.10 Gy or more and their relative risk of death from breast cancer as compared with those exposed to less than 0.10 Gy was 1.36 (95% CI: 1.11-1.67). Women in Nova Scotia experienced excess relative risks per unit dose that were approximately three times higher than women in other provinces."... "Within the Canadian cohort, differences in the slopes of the dose-response curve for women treated Nova Scotia and in the other provisions is puzzling. Although the mean numbers of fluoroscopic exposures were similar, the dose rate was more than an order of magnitude greater in Nova Scotia than elsewhere [M19], and a possible explanation suggested by the authors is that this might be a dose-rate effect."(p.44,175.)... "The evidence for radiation-induced breast cancer is discussed in Annex A, "Epidemiological studies of radiation carcinogenesis". Although exposure to radiation at high doses and high dose rates is associated with excess breast cancer, the potential hazard from low-dose, fractionated exposures during early breast development has not been thoroughly evaluated. The failure to detect increased breast cancer in several large studies is surprising, and no satisfactory explanation is forthcoming." (p.221,257.). Indeed, if all the acknowledged adaptive responses and mechanisms presented in Annex B are rejected *a priori* as ineffective because there must be some "residual damage," then "no satisfactory explanation is forthcoming."

The most significant data of the repeatedly cited Canadian Fluoroscopy Study [M19] is in the 0.10-019 Gy and 0.20-0.29 Gy low dose ranges that demonstrate a highly significant ($p<0.02$) risk decrement of -0.34 for death from breast cancer. This low dose data is not presented in this report but is added to the high dose data to obtain a mean dose of 0.43 Gy (M19, Part VIII Table 8, Annex A). This article with its tabulated low dose data and an added graph of the data are included in Part I following Annex B and discussed in Part II, BELLE: Chapter 11. The authors reject the statistically significant low dose data of this study by linear extrapolation of higher dose data that do not differ significantly from the control 0-0.09 Gy breast cancer mortality. This linear extrapolation is then used to predict the lifetime

264. The effects of the diagnostic use of ^{131}I have been evaluated by Holm et al. [H12, H27, H41]. A total of 35,074 patients examined for suspected thyroid disorders between 1951 and 1969 in Sweden were followed for an average of 20 years. The mean age at the time of examination was 44 years. The average amount of ^{131}I administered to the patients was 2 MBq, and the radiation dose to the thyroid gland was approximately 0.5 Gy, while for other organs the dose was <10 mGy. Record linkage with the Swedish Cancer Register identified 3,746 cancers occurring five or more years after the initial ^{131}I examination, and the standardized incidence ratio for all malignant neoplasms, based on general population rates, was 1.01 (95% CI: 0.98-1.04). There were 50 cases of thyroid cancer, and the standardized incidence ratio was initially estimated as 1.27 (95% CI: 0.94-1.67) [H12], but this was reduced to 1.18 (95% CI: 0.88-1.56) after adjustment for region of residence [H27]. There was a significant excess of thyroid cancer 5-9 years following irradiation (SIR: 1.95, based on 23 cases; 95% CI: 1.24-2.92). However, women and those observed for 10 years or more showed no evidence of an excess or of a dose response, so it was concluded that the increase during years 5-9 was probably due to a high level of medical surveillance, which led to an increased level of detection of indolent tumours. Furthermore, a portion of this early excess may have been related to the underlying conditions being evaluated. Also, among 2,000 patients less than 20 years old, no increased risk of thyroid cancer was observed. For the other cancers, there were significant excesses of leukaemia (SIR: 1.34, based on 119 cases; 95% CI: 1.11-1.60), but only after 15 years, and both chronic lymphocytic leukaemia and non-chronic lymphocytic leukaemia showed similar significant excesses. Endocrine tumours other than the thyroid (SIR: 1.93, based on 130 cases; 95% CI: 1.62-2.29) and cancers of the nervous system (SIR: 1.19, based on 135 cases; 95% CI: 1.00-1.41) also showed significant risks. For breast cancer and cancers of the kidney and bladder there was no evidence of any increase (breast cancer SIR: 0.98, based on 739 cases; 95% CI: 0.91-1.06; kidney and bladder cancers SIR: 1.08, based on 259 cases; 95% CI: 0.95-1.22).

265. A combined analysis of the nearly 47,000 Swedish patients given ^{131}I for thyroid cancer, for hyperthyroidism or for diagnostic purposes and included in the studies above has also been reported. Interpretation of this analysis is complicated by differences in the demographic characteristics of the populations studied and the non-overlapping dose ranges. Bone marrow doses were estimated for individual patients based on total administered ^{131}I activity, 24-hour thyroid uptake and ICRP tables [H26]. Standardized incidence ratios for all leukaemias, all leukaemias excluding chronic lymphocytic leukaemia, and chronic lymphocytic leukaemia are shown by sex, absorbed dose in bone marrow, age at exposure and years after exposure in Table 46. The administration of ^{131}I did not appear to influence the subsequent risk of leukaemia in either males or females. Nor was there evidence for a higher risk among those exposed at age <40 years or in years 2-9 after exposure. The risk of chronic lymphocytic leukaemia, which has not been associated with ionizing radiation, was similar to that of other types of leukaemia. For the whole population (mean absorbed bone marrow dose: 14 mGy), the standardized incidence ratio of all leukaemia, excluding chronic lymphocytic leukaemia, was 1.09 (95% CI: 0.91-1.29); for those in the <100 mGy dose group (mean marrow dose: 48 mGy) it was 1.09 (95% CI: 0.91-1.30) and for those in the >100 mGy dose group (mean absorbed bone marrow dose: 221 mGy) it was 1.04 (95% CI: 0.28-2.67). Thus, although the combination of these three cohorts is not without difficulties, no clear association of cancer induction by radiation was evident in this analysis.

266. Several studies have been carried out of the effects of radioiodine in fallout. Over 200 inhabitants of the Marshall Islands were exposed to a mixture of radioiodines (^{131}I, ^{132}I, ^{133}I, ^{134}I and ^{135}I), tellurium and gamma-radiation in fallout from the 1954 Bravo thermonuclear test [C28, R21]. The whole-body gamma-ray dose was estimated to be 0.11-1.9 Gy to the Marshallese on three atolls. The mean thyroid dose from gamma rays and radioiodines was estimated to be 3-52 Gy in children and 1.6-12 Gy in adults. Many of these individuals subsequently received anti-thyroid drugs or had thyroid surgery. Thyroid cancer appeared in 7 of 130 women and in 2 of 113 men over a follow-up period of 32 years. The earliest thyroid lesion appeared 9 years after exposure in a girl who was 3 years of age at the time of the exposure. The calculated risk coefficient for thyroid cancer was $1.4\ 10^{-4}\ Gy^{-1}$, but this estimate is uncertain for several reasons. The high thyroid doses may have resulted in cell-killing and decreased the number of cells at risk for cancer development. Frequent thyroid surgery may have reduced the tissue at risk, and prophylactic thyroid hormone medication might have influenced the risk. Furthermore, the effects of gamma-ray exposures could not be distinguished from those of internal radioiodines. The dose to the thyroid from the short-lived and more energetic radioiodines was 2-3 times greater than that from ^{131}I, and thus the contribution of ^{131}I to the development of thyroid cancer could not be determined.

267. The possibility of thyroid effects in people exposed to radioiodine releases during and after the Chernobyl accident has received much attention. In the international Chernobyl project [I3], nearly 600 children aged 5 and 10 years from contaminated and control areas were examined in 1990. The children had been between 1 and 6 years old at the time of the accident. The proportion of children having thyroid nodules was the same in the exposed and unexposed children [M21]. More recently, however, an increase of thyroid cancer in children living in areas contaminated by radionuclide deposition from the accident, where doses from short-lived

radioiodines may have been substantial, has been reported from the Ukraine [P34] and Belarus [K22] but not from the Russian Federation. In Belarus an increase was observed in children only four years after the accident. In all other studies of thyroid cancer an increased risk has never been seen until more than five years after radiation exposure [S61]. No information on the individual thyroid doses received by these children is available. It is not yet possible to determine whether the reported increases are truly associated with radiation exposure or whether they are a result of increased surveillance for thyroid disease, which is known to result in apparent increases [B15, B42, C5, R11, S63, S70].

268. A survey of thyroid disease among children in Utah and Nevada exposed to fallout radiation from weapons testing in the 1950s and control groups living in Utah and Arizona has found no significant differences the incidence of any type of thyroid disease [R12]. No cases of thyroid carcinoma were found in 1,378 children thought to have been exposed, while two cases occurred among 3,443 children who were not living in the primary fallout area during infancy. In a recent paper, Kerber et al. [K1] report an association between ^{131}I exposure and thyroid neoplasms among a cohort of about 2,500 children exposed to fallout from nuclear weapons tests in Utah. A total of 19 cases were observed and about 13 expected during 20 years of follow-up (1965-1986). The average thyroid dose, based on individual dose estimates, was 0.17 Gy. The estimated excess relative risk per gray was about 7. When the analysis was limited to the eight thyroid cancers included in this series, the point estimate of the excess relative risk per gray was slightly greater than that for all neoplasms but was not statistically significant ($p = 0.10$). As indicated by the authors, factors related to the study design might have led to biases in this estimate. These included issues related to selection and dietary recall used in the dose reconstruction. The authors concluded that such effects were unlikely to have had a large impact on their finding. While this estimate is not out of line with risks seen in children exposed to external low-LET radiation, it is substantially higher than risks seen in other studies of populations exposed to ^{131}I. In particular, the risks derived in the Kerber study [K1] are much larger than those seen in the Swedish study [H12] of patients, primarily adults, who had received an average dose of 0.5 Gy for whom the (non-significant) estimated excess relative risk per gray was 0.4. Based on only two cases among children in the Swedish study, the non-significant estimated excess relative risk per gray was 1.4.

269. The incidence of thyroid cancer has also been studied in Cumbria, United Kingdom, near the Sellafield nuclear site, which has discharged both ^{129}I and ^{131}I into the sea and atmosphere since the early 1960s [B25]. Measurements of ^{129}I were made on 130 thyroid glands taken opportunistically at necropsy from adults who died of various causes in Cumbria between November 1984 and September 1987. Levels of activity decreased with the distance of the patients' homes from Sellafield ($p < 0.001$). In contrast, age-standardized thyroid cancer registration rates for the 288 parishes in Cumbria in 1969-1986 showed a positive correlation with distance from Sellafield ($p < 0.001$), with the higher incidence at greater distances. It was estimated that most of the sample population received less than 0.67 μSv a^{-1} from ^{129}I, and none were likely to have received more than an additional 1.5 μSv a^{-1}. Because of its short half-life, ^{131}I could not be measured in the sampled thyroid glands, but the authors estimated that total cumulative doses from the two radionuclides were probably about equal. Such small exposures would not be expected to result in detectable effects of any kind, and indeed none were found.

270. Comparisons between the carcinogenic potential in the thyroid of external radiation and radioiodines such as ^{131}I have frequently been attempted. In view of the scant and uncertain data on increases in cancer risk following exposure to ^{131}I outlined above, such comparisons are difficult [C12]. The National Council for Radiation Protection and Measurements [N5] found that, based on human experience, the relative effectiveness of ^{131}I compared with external radiation is between zero and one half; data from animals suggest a value between one tenth and one. A value of one third was recommended in the NCRP report. Shore [S61], in a more comprehensive and recent review of the human data, found only 8.3 observed excess cancer cases from all ^{131}I studies combined compared with 37.0 cases expected based on risk estimates for external exposure. The ratio, 0.224, is about one quarter. Evidently the protracted dose to the thyroid that results from ^{131}I exposure is one reason for this difference, but the distribution of ^{131}I in the thyroid gland and the resulting non-uniformity of dose may be another [S68].

2. Other radionuclides

271. Phosphorus-32 is a high-energy beta emitter that tends to concentrate in the skeleton. Repeated injections of ^{32}P have commonly been used to treat polycythemia vera, a disease characterized principally by the overproduction of red blood cells. In a study of patients with polycythemia vera diagnosed in 1937-1953 in the United States and followed to the end of 1961, the cumulative incidence of leukaemia by 15 years after diagnosis was 20% in the ^{32}P-treated group but only 2% in the non-irradiated polycythemia vera patients who had been treated with phlebotomy, sometimes in combination with chemotherapy [M34]. Detailed dosimetry calculations have not been performed, but crude dosimetry suggests that the average skeletal dose to these patients was about 3 Gy, which appears to have resulted in an excess cumulative incidence of leukaemia of 18%. This risk is high compared to that seen in patients exposed to external

G15 Gunz, F.W. and H.R. Atkinson. Medical radiations and leukaemia: a retrospective survey. Br. Med. J. 1: 389-393 (1964).

G16 Gilbert, E.S., E. Omohundro, J.A. Buchanan et al. Mortality of workers at the Hanford site: 1945-1986. Health Phys. 64: 577-590 (1993).

G17 Gilbert, E.S., S.A. Fry, L.D. Wiggs et al. Analyses of combined mortality data on workers at the Hanford site, Oak Ridge National Laboratory and Rocky Flats nuclear weapons plant. Radiat. Res. 120: 19-35 (1989).

G18 Gibson, R., S. Graham, A. Lilienfeld et al. Irradiation in the epidemiology of leukemia among adults. J. Natl. Cancer Inst. 48: 301-311 (1972).

G19 Gilbert, E.S., D.L. Cragle and L.D. Wiggs. Updated analysis of combined mortality data on workers at the Hanford site Oak Ridge National Laboratory and Rocky Flats Weapons Plant. Radiat. Res. 136: 408-421 (1993).

G20 Gilbert, E.S., G.R. Petersen and J.A. Buchanan. Mortality of workers at the Hanford site: 1945-1981. Health Phys. 56: 11-25 (1989).

G21 Gardner, M.J., M.P. Snee, A.J. Hall et al. Results of case-control study of leukaemia and lymphoma among young people near Sellafield nuclear plant in West Cumbria. Br. Med. J. 300: 423-429 (1990).

G22 Gardner, M.J. Communication to the UNSCEAR Secretariat (1990).

G23 Gjørup, H.L. and H.J.M. Hansen. Lifetime loss through lung cancer in Denmark and Sweden in relation to radon levels. p. 165-169 in: Health Effects of Low Dose Ionising Radiation - Recent Advances and Their Implications. British Nuclear Energy Society, 1987.

G24 Goss, S.G. Sizes of population needed to detect an increase in disease risk when the levels of risk in the exposed and controls are specified: examples from cancer induced by ionizing radiation. Health Phys. 29: 715-721 (1975).

H1 Hanford, J.M., E. Quimby and V. Frantz. Cancer arising many years after radiation therapy. J. Am. Med. Assoc. 181: 132-138 (1962).

H2 Hancock, S.L., M.A. Tucker and R.T. Hoppe. Breast cancer after treatment of Hodgkin's disease. J. Natl. Cancer Inst. 85: 25-31 (1993).

H3 Harvey, E.B., J.D. Boice, M. Honeyman et al. Prenatal x-ray exposure and childhood cancer in twins. N. Engl. J. Med. 312: 541-545 (1985).

H4 Heasman, M.A., I.W. Kemp, J.D. Urquhart et al. Childhood leukaemia in northern Scotland. Lancet I: 266 and 385 (1986).

H5 Hess, C.T., C.V. Weiffenbach and S.A. Norton. Environmental radon and cancer correlations in Maine. Health Phys. 45: 339-348 (1983).

H6 Hancock, S.L., R.S. Cox and R. McDougall. Thyroid diseases after treatment of Hodgkin's disease. N. Engl. J. Med. 325: 599-605 (1991).

H7 Hoffman, D.A. Late effects of I-131 therapy in the United States. p. 273-280 in: Radiation Carcino-genesis: Epidemiology and Biological Significance. (J.D. Boice Jr. and J.F. Fraumeni Jr. eds.) Raven Press, New York, 1984.

H8 Hoffman, D.A., W.M. McConahey, E.L. Diamond et al. Mortality in women treated for hyperthyroidism. Am. J. Epidemiol. 115: 243-254 (1982).

H9 Hoffman, D.A., W.M. McConahey, J.F. Fraumeni Jr. et al. Cancer incidence following treatment of hyper-thyroidism. Int. J. Epidemiol. 11: 218-224 (1982).

H10 Hofmann, W., R. Katz and C. Zhang. Lung cancer incidence in a Chinese high background area - epidemiological results and theoretical interpretation. Sci. Total Environ. 45: 527-534 (1985).

H11 Holm, L.E. Malignant disease following iodine-131 therapy in Sweden. p. 263-271 in: Radiation Carcinogenesis: Epidemiology and Biological Significance. (J.D. Boice Jr. and J.F. Fraumeni Jr., eds.) Raven Press, New York, 1984.

H12 Holm, L.E., K.E. Wiklund, G.E. Lundell et al. Thyroid cancer after diagnostic doses of iodine-131: a retrospective cohort study. J. Natl. Cancer Inst. 80: 1132-1138 (1988).

H13 Horta, J. da Silva, M.E. da Silva Horta, L. Cayolla da Motta et al. Malignancies in Portuguese thorotrast patients. Health Phys. 35: 137-151 (1978).

H14 Hill, C.K., A. Han and M.M. Elkind. Fission spectrum neutrons at a low dose rate enhance neoplastic transformation in the linear dose region (0-10 cGy). Int. J. Radiat. Biol. 46: 11-15 (1984).

H15 Howe, G.R., R.C. Nair, H.B. Newcombe et al. Lung cancer mortality (1950-80) in relation to radon daughter exposure in a cohort of workers at the Eldorado Beaverlodge uranium mine. J. Natl. Cancer Inst. 77: 357-362 (1986).

H16 Howe, G.R., R.C. Nair, H.B. Newcombe et al. Lung cancer mortality (1950-80) in relation to radon daughter exposure in a cohort of workers at the Eldorado Port radium uranium mine: possible modification of risk by exposure rate. J. Natl. Cancer Inst. 79: 1255-1260 (1987).

H17 Hohryakov, V.F. and S.A. Romanov. Lung cancer in radiochemical industry workers. Sci. Total Environ. 142: 25-28 (1994).

H18 Homung, R.W. and T.J. Meinhardt. Quantitative risk assessment of lung cancer in U.S. uranium miners. Health Phys. 52: 417-430 (1987).

H19 Haynes, R.M. The distribution of domestic radon concentrations and lung cancer mortality in England and Wales. Radiat. Prot. Dosim. 25: 93-96 (1988).

H20 Hofmann, W., R. Katz and C. Zhang. Lung cancer risk at low doses of α particles. Health Phys. 51: 457-468 (1986).

H21 Hempelmann, L.H., W.J. Hall, M. Phillips et al. Neoplasms in persons treated with x-rays in infancy: fourth survey in 20 years. J. Natl. Cancer Inst. 55: 519-530 (1975).

H22 Hildreth, N.G., R.E. Shore and P.M. Dvoretsky. The risk of breast cancer after irradiation of the thymus in infancy. N. Engl. J. Med. 321: 1281-1284 (1989).

H23 Howe, G. Communication to UNSCEAR Secretariat (1992).

H24 Hoffman, D.A., J.E. Lonstein, M.M. Morin et al. Breast cancer in women with scoliosis exposed to multiple diagnostic X rays. J. Natl. Cancer Inst. 81: 1307-1312 (1989).

H25 Hagstrom, R.H., S.R. Glasser, A.B. Brill et al. Long term effects of radioactive iron administered during human pregnancy. Am. J. Epidemiol. 90: 1-10 (1969).

H26 Hall, P., J.D. Boice Jr., G. Berg et al. Leukaemia incidence after iodine-131 exposure. Lancet 340: 1-4 (1992).

H27 Holm, L.E., K.E. Wiklund, G.E. Lundell et al. Cancer risk in population examined with diagnostic doses of ^{131}I. J. Natl. Cancer Inst. 81: 302-306 (1989).

H28 Hamilton, T.E., G. van Belle and J.P. LoGerfo. Thyroid neoplasia in Marshall Islanders exposed to nuclear fallout. J. Am. Med. Assoc. 258: 629-636 (1987).

H29 Hoel, D.G. and G.E. Dinse. Using mortality data to estimate radiation effects on breast cancer incidence. Environ. Health Perspect. 87: 123-129 (1990).

H30 Hakulinen, T., M. Kenward, T. Luostarinen et al. Cancer in Finland in 1954-2008. Incidence, Mortality and Prevalence by Region. Finnish Foundation for Cancer Research, Helsinki, 1989.

H31 Hall, P., L.E. Holm, G. Lundell et al. Cancer risk in thyroid cancer patients. Br. J. Cancer 64: 159-163 (1991).

H32 Hadjimichael, O.C., A.M. Ostfeld, D.A. D'Atri et al. Mortality and cancer incidence experience of employees in a nuclear fuels fabrication plant. J. Occup. Med. 25: 48-61 (1983).

H33 Hatch, M.C., J. Beyea, J.W. Nieves et al. Cancer near the Three Mile Island nuclear plant: radiation emissions. Am. J. Epidemiol. 132: 397-412 (1990).

H34 Hatch, M. and M. Susser. Background gamma radiation and childhood cancers within ten miles of a US nuclear plant. Int. J. Epidemiol. 19: 546-552 (1990).

H35 High Background Radiation Research Group. Health survey in high background radiation areas in China. Science 209: 877-880 (1980).

H36 Hempelmann, L.H., C.C. Lushbaugh and G.L. Voelz. What happened to the survivors of the early Los Alamos nuclear accidents? p. 17-32 in: The Medical Basis for Radiation Accident Preparedness. (K.F. Hübner and S.A. Fry, eds.) Elsevier North Holland, Inc., 1980.

H37 Hodgson, J.T. and R.D. Jones. Mortality of a cohort of tin miners 1941-86. Br. J. Ind. Med. 47: 665-676 (1990).

H38 Henshaw, D.L., J.P. Eatough and R.B. Richardson. Radon as a causative factor in induction of myeloid leukaemia and other cancers. Lancet 335: 1008-1012 (1990).

H39 Hill, C. and A. Laplanche. Overall mortality and cancer mortality around French nuclear sites. A letter. Nature 347: 755-757 (1990).

H40 Holm, L.E., P. Hall, K.E. Wiklund et al. Cancer risk after iodine-131 therapy for hyperthyroidism. J. Natl. Cancer Inst. 83: 1072-1077 (1991).

H41 Holm, L.E. Cancer risks after diagnostic doses of ^{131}I with special reference to thyroid cancer. Cancer Detect. Prev. 15(1): 27-30 (1991).

H42 Hatch, M.C., S. Wallenstein, J. Beyea et al. Cancer rates after the Three Mile Island nuclear accident and proximity of residence to the plant. Am. J. Public Health 81: 719-724 (1991).

H43 Howe, G.R. Effects of dose, dose-rate and fraction on radiation-induced breast and lung cancers: the Canadian fluoroscopy study. p. 108-113 in: Proceedings of the International Conference on Radiation Effects and Protection, Mito, 1992. Japan Atomic Energy Research Institute, Tokyo, 1992.

H44 Howe, G.R., A.M. Chiarelli and J.P. Lindsay. Components and modifiers of the healthy worker effect: evidence from three occupational cohorts and implications for industrial compensation. Am J. Epidemiol. 128: 1364-1374 (1988).

H45 Howe, G.R., J.L. Weeks, A.M. Miller et al. A study of the health of the employees of Atomic Energy of Canada Limited. IV. Analysis of mortality during the period 1950-1981. AECL-9442 (1987).

H46 Harley, N.H., A.B. Kolber, R.E. Shore et al. The skin dose and response for the head and neck in patients irradiated with x-ray for tinea capitis: implications for environmental radioactivity. p. 125-142 in: Epidemiology Applied to Health Physics. CONF-830101 (1983).

H47 Harley, N.H. and E.S. Robbins. ^{222}Rn alpha dose to organs other than lung. Radiat. Prot. Dosim. 45: 619-622 (1992).

H48 Hopton, P.A., P.A. McKinney, R.A. Cartwright et al. X-rays in pregnancy and the risk of childhood cancer. Lancet ii(8458): 773 only (1985).

I1 Ishikawa, Y., T. Mori, Y. Kato et al. Lung cancers associated with Thorotrast exposure. High incidence of small cell carcinoma and implications for estimation of radon risk. Int. J. Cancer 52: 570-574 (1992).

I2 Iwasaki, T., M. Minowa, S. Hashimoto et al. Non-cancer mortality and life expectancy in different natural background radiation levels of Japan. p. 107-112 in: Low Dose Irradiation and Biological Defense Mechanisms. (T. Sugahara et al., eds.) Elsevier Science Publishers, Amsterdam, 1992.

I3 International Chernobyl Project. Assessment of radiological consequences and evaluation of protective measures. Technical Report. IAEA, Vienna (1991).

I4 International Commission on Radiation Units and Measurements. The quality factor in radiation protection. ICRU Report 40 (1986).

I5 Ichimaru, M. and T. Ishimaru. Atomic bomb radiation and adult T-cell leukemia. Acta Med. Nagasaki. 36(1): 170-175 (1991).

I6 International Agency for Research on Cancer. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man: Some Miscellaneous Pharmaceutical Substances. Volume 13. IARC Lyon, 1976.

I7 Inskip, P.D., R.R. Monson, J.K. Wagoner et al. Leukemia following radiotherapy for uterine bleeding. Radiat. Res. 122: 107-119 (1990).

I8 Inskip, P.D., R.R. Monson, J.K. Wagoner et al. Cancer mortality following radium treatment for uterine bleeding. Radiat. Res. 123: 331-344 (1990).

I9 International Agency for Research on Cancer. IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Tobacco Smoking. Volume 38. IARC, Lyon, 1985.

I10 International Commission on Radiological Protection. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Pergamon Press, Oxford, 1990.

I11 Iwasaki, T., M. Minowa, S. Hashimoto et al. Cancer mortality rates by geographic distribution and levels of natural radiation dose in Japan. p. 503-514 in: Proceedings of the International Conference on High Levels of Natural Radiation, Ramsar, Iran, 1990. IAEA, Vienna, 1993.

I12 Inskip, P.D., R.A. Kleinerman, M. Stovall et al. Leukemia, lymphoma and multiple myeloma following pelvic radiotherapy for benign disease. Radiat. Res. 135: 108-125 (1993).

6. Summary and Recommendations

6.1 General Principles

A major protective action to be considered after a serious accident at a nuclear power facility involving the release of radioiodine is the use of stable iodide as a thyroid blocking agent to prevent thyroid uptake of radioiodines.

For greatest effectiveness, the blocking agent should be administered within a few hours after an accident. Since reliable radiation monitoring data may not be available that quickly, the decision to administer stable iodide should be based on a pre-planned estimate of the probable degree of contamination from the accident.

If the initial estimate at the facility indicates that thyroid total absorbed doses[2] of 10–30 rad or more are projected, the blocking agent should be administered immediately to employees at the facility and to other support personnel coming to or working near the facility.

If the estimate of thyroid total absorbed dose is less than 10 rad, it may be preferable to consider instructing people to remain indoors and to await further instructions, before deciding to administer blocking agents. If the estimates of the total thyroid absorbed dose exceed 10 rad, blocking agents should be considered.

Based on information supplied by the facility operator as to the magnitude of the accident, either the responsible physician for the facility or state and local officials should consider prompt administration of the blocking agent (without making absorbed dose estimates) to emergency personnel who respond to the accident. This group includes police officers, firemen, physicians, health physicists, nurses, ambulance drivers and paramedical personnel. These people would be considered a "high-risk" group.

For people beyond the immediate vicinity of the reactor, the decision to administer stable iodide, to instruct them to remain indoors,

[2] Total absorbed dose is the cumulated absorbed dose resulting, in this case, from the inhalation of radioiodines during a particular exposure period. The quantity dose commitment does not apply to this situation.

or to evacuate them would depend on the type of accident, on pre planned estimates of release, on wind direction and, later, on monitoring data as they become available (USNRC, 1975).

6.2 The Use of Potassium Iodide

Potassium iodide can and may be stocked at the nuclear facility firehouses, police stations, hospitals, clinics, factories, office buildings, municipal buildings, physicians' and dentists' offices, pharmacies, and other locations where normal emergency medical service are usually available.

A daily dose of 130 mg of potassium iodide (1 tablet) will provide adequate blocking for each person. A half tablet may be given to children under one year of age. One tablet should be taken each day until the public is advised that the emergency is ended. Only on 130-mg tablet daily is needed and more will not be helpful. The first dose should be taken as soon after the warning as possible. Instructions for the cessation of iodide administration is the responsibility of public health authorities. The need for blocking agents is estimate as being required for 3–7 days and probably no longer than 10 day for a total dose of about 1 gram.

Potassium iodide need be taken only by individuals who are in the area of contamination. Instructions of public health officials should be followed carefully.

The short- and long-term consequences of inhalation of radioactive iodine are far less than the possible injury that might result from individual or mass panic arising from efforts to obtain the blocking agent, and this modicum of common sense should be remembered by each person.

6.3 Evacuation

An extensive review of mass evacuation has been carried out b the Environmental Protection Agency (Haus and Sell, 1974). Thi study shows clearly that masses of up to 150,000 persons have bee evacuated safely in natural or potential man-made disasters. Thes evacuations have been carried out within hours without loss of life panic or looting. Based on these experiences, urban as well as rura populations can be evacuated promptly and safely.

VOLUME I

Drug Information for the Health Care Professional

USP DI®

1998

18TH EDITION

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By authority of the United States Pharmacopeial Convention, Inc.

POTASSIUM BICARBONATE—See *Potassium Supplements (Systemic)*

POTASSIUM BICARBONATE AND POTASSIUM CHLORIDE—See *Potassium Supplements (Systemic)*

POTASSIUM BICARBONATE AND POTASSIUM CITRATE—See *Potassium Supplements (Systemic)*

POTASSIUM BITARTRATE AND SODIUM BICARBONATE—See *Laxatives (Local)*

POTASSIUM CHLORIDE—See *Potassium Supplements (Systemic)*

POTASSIUM CITRATE—See *Citrates (Systemic)*

POTASSIUM CITRATE AND CITRIC ACID—See *Citrates (Systemic)*

POTASSIUM CITRATE AND SODIUM CITRATE—See *Citrates (Systemic)*

POTASSIUM GLUCONATE—See *Potassium Supplements (Systemic)*

POTASSIUM GLUCONATE AND POTASSIUM CHLORIDE—See *Potassium Supplements (Systemic)*

POTASSIUM GLUCONATE AND POTASSIUM CITRATE—See *Potassium Supplements (Systemic)*

POTASSIUM GUAIACOLSULFONATE-CONTAINING COMBINATIONS—

Bromodiphenhydramine, Diphenhydramine, Codeine, Ammonium Chloride, and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic)*

Brompheniramine, Phenylephrine, Phenylpropanolamine, Dextromethorphan, Potassium Guaiacolsulfonate, and Ipecac (Systemic)—See *Cough/Cold Combinations (Systemic)*

Chlorpheniramine, Phenylephrine, Phenylpropanolamine, Carbetapentane, and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic), XR, 1780*

Chlorpheniramine, Phenylephrine, Phenylpropanolamine, Dextromethorphan, Potassium Guaiacolsulfonate, and Ipecac (Systemic)—See *Cough/Cold Combinations (Systemic), XR, 1780*

Hydrocodone and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic)*

Phenylephrine, Phenylpropanolamine, Carbetapentane, and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic)*

Promethazine, Codeine, and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic), XR, 1780*

Promethazine, Phenylephrine, Codeine, and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic)*

Promethazine, Phenylephrine, and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic)*

Promethazine and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic)*

Pseudoephedrine, Hydrocodone, and Potassium Guaiacolsulfonate (Systemic)—See *Cough/Cold Combinations (Systemic)*

POTASSIUM IODIDE Systemic

VA CLASSIFICATION (Primary/Secondary): HS852/AD900; AM700; TN499

Commonly used brand name(s): *Pima; Thyro-Block.*

Other commonly used names are KI and SSKI.

Note: For a listing of dosage forms and brand names by country availability, see *Dosage Forms* section(s).

Category

Antihyperthyroid agent; radiation protectant (thyroid gland); thyroid inhibitor; antifungal (systemic); iodine replenisher.

Indications

Note: Bracketed information in the *Indications* section refers to uses that are not included in U.S. product labeling.

Accepted

Hyperthyroidism (treatment)[1]—Potassium iodide is indicated in the treatment of hyperthyroidism.

Radiation protection, thyroid gland—Potassium iodide is indicated as a radiation protectant (thyroid gland) prior to and following oral administration or inhalation of radioactive isotopes of iodine or in radiation emergencies.

[Erythema nodosum (treatment)][1]—Potassium iodide is used in the treatment of erythema nodosum.

[Iodine deficiency (treatment)][1]—Potassium iodide is used in the treatment of iodine deficiency.

[Sporotrichosis, cutaneous lymphatic (treatment)][1]—Potassium iodide is used in the treatment of cutaneous lymphatic sporotrichosis.

[Thyroid involution, preoperative][1]—Potassium iodide is used concurrently with an antithyroid agent to induce thyroid involution prior to thyroidectomy.

Unaccepted

Potassium iodide has not been shown to have a clinically significant expectorant action.

[1]Not included in Canadian product labeling.

Pharmacology/Pharmacokinetics

Physicochemical characteristics

Molecular weight—166.00.

Mechanism of action/Effect

Antihyperthyroid agent—

In hyperthyroid patients, potassium iodide produces rapid remission of symptoms by inhibiting the release of thyroid hormone into the circulation. The effects of potassium iodide on the thyroid gland include reduction of vascularity, a firming of the glandular tissue, shrinkage of the size of individual cells, reaccumulation of colloid in the follicles, and increases in bound iodine. These actions may facilitate thyroidectomy when the medication is given prior to surgery.

Radiation protectant—

When administered prior to and following administration of radioactive isotopes and in radiation emergencies involving the release of radioactive iodine, potassium iodide protects the thyroid gland by blocking the thyroidal uptake of radioactive isotopes of iodine.

When potassium iodide is administered simultaneously with radiation exposure, the protectant effect is approximately 97%. Potassium iodide given 12 and 24 hours before exposure yields a 90% and 70% protectant effect, respectively. However, potassium iodide administered 1 and 3 hours after exposure results in an 85% and 50% protectant effect, respectively. Potassium iodide administered more than 6 hours after exposure is thought to have a negligible protectant effect.

Precautions to Consider

Pregnancy/Reproduction

Potassium iodide crosses the placenta; use during pregnancy may result in abnormal thyroid function and/or goiter in the infant.

Breast-feeding

Potassium iodide is distributed into breast milk; use by nursing mothers may cause skin rash and thyroid suppression in the infant.

Pediatrics

Potassium iodide may cause skin rash and thyroid suppression in infants. Appropriate studies have not been performed for use as a systemic antifungal.

Geriatrics

Appropriate studies on the relationship of age to the effects of potassium iodide have not been performed in the geriatric population. However, geriatrics-specific problems that would limit the usefulness of this medication in the elderly are not expected.

Dental

Potassium iodide may cause salivary gland swelling or tenderness, burning of mouth or throat, metallic taste, soreness of teeth and gums, and unusual increase in salivation.

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

» Antithyroid agents
(concurrent use of these medications with potassium iodide may potentiate the hypothyroid and goitrogenic effects of antithyroid agents or potassium iodide; baseline thyroid status should be determined at periodic intervals to detect changes in the thyroid-pituitary response)

Captopril or
Enalapril or
Lisinopril
(concurrent use of captopril, enalapril, or lisinopril with potassium iodide may result in hyperkalemia; serum potassium concentrations should be monitored)

» Diuretics, potassium-sparing
(concurrent use with potassium iodide may increase the effects of potassium, possibly resulting in hyperkalemia and cardiac arrhythmias or cardiac arrest; serum potassium concentrations should be monitored)

» Lithium
(concurrent use with potassium iodide may potentiate the hypothyroid and goitrogenic effects of either medication; baseline thyroid status should be determined at periodic intervals to detect changes in the thyroid-pituitary response)

Sodium iodide I 131, therapeutic
(potassium iodide may decrease thyroidal uptake of I 131)

Laboratory value alterations

The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

With diagnostic test results
Thyroid function studies
Thyroid imaging, radionuclide and
Thyroid uptake tests
(potassium iodide may decrease thyroidal uptake of I 131, I 123, and sodium pertechnetate Tc 99m)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance).

Risk-benefit should be considered when the following medical problems exist:

» Hyperkalemia
(condition may be exacerbated)

Hyperthyroidism (for use other than thyroid inhibitor)
(prolonged use of iodine may cause thyroid gland hyperplasia, thyroid adenoma, goiter, or hypothyroidism)

Myotonia congenita
(condition may be exacerbated by potassium)

» Renal function impairment
(may cause excessive serum potassium concentrations)

Sensitivity to potassium iodide

Tuberculosis
(may cause irritation and increase secretions)

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; » = major clinical significance):

Serum potassium concentrations
(recommended at periodic intervals during therapy in patients with renal function impairment)

Side/Adverse Effects

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)—not necessarily inclusive:

Those indicating need for medical attention

Incidence less frequent
Allergic reactions, specifically angioedema (swelling of the arms, face, legs, lips, tongue, and/or throat); ***arthralgia*** (joint pain); ***eosinophilia; swelling of lymph nodes; urticaria*** (hives)

With prolonged use
Iodism (burning of mouth or throat; gastric irritation; increased watering of mouth; metallic taste; severe headache; skin lesions; soreness of teeth and gums; symptoms of head cold); ***potassium toxicity*** (confusion; irregular heartbeat; numbness, tingling, pain, or weakness in hands or feet; unusual tiredness; weakness or heaviness of legs)

Those indicating need for medical attention only if they continue or are bothersome

Incidence less frequent
Diarrhea; nausea or vomiting; stomach pain

Patient Consultation

As an aid to patient consultation, refer to *Advice for the Patient, Potassium Iodide (Systemic).*

In providing consultation, consider emphasizing the following selected information (» = major clinical significance):

Before using this medication

» Conditions affecting use, especially:
Sensitivity to iodine or potassium iodide
Pregnancy—May cause thyroid problems or goiter in the newborn infant
Breast-feeding—May cause skin rash and thyroid problems in nursing babies
Use in children—May cause skin rash and thyroid problems in nursing infants
Dental—May cause swelling of salivary glands, burning of mouth or throat, metallic taste, soreness of teeth and gums, or increase in salivation
Other medications, especially antithyroid agents, diuretics (potassium sparing), or lithium
Other medical problems, especially hyperkalemia or renal function impairment

Proper use of this medication

» Taking after meals or with food or milk to minimize gastrointestinal irritation

Proper administration technique for oral liquids:
Taking medication by mouth even if dispensed in a dropper bottle
Not using if solution turns brownish yellow
Taking medication in a full glass (240 mL) of water or in fruit juice, milk, or broth to improve taste and lessen gastric upset; drinking full dose
If crystals form in solution, warming closed container in warm water and gently shaking container

Proper administration technique for uncoated tablets:
Dissolving each tablet in ½ glass (120 mL) of water or milk before taking; drinking full dose

» Compliance with full course of therapy (fungal infections)

» Proper dosing
Missed dose: Taking as soon as possible; not taking if almost time for next dose; not doubling doses

» Proper storage

For use as a radiation protectant (thyroid gland)

Taking medication only upon instructions from state or local health authorities

» Taking medication daily for 10 days, unless otherwise instructed; not taking more medication or more often than instructed

Precautions while using this medication

Regular visits to physician to check progress during therapy

» Caution in patients on potassium-restricted diet

Side/adverse effects

Signs of potential side effects, especially allergic reactions, iodism, or potassium toxicity

General Dosing Information

The potassium content is 6 mEq (234 mg) per gram of potassium iodide.

To minimize stomach upset, the medication may be administered after meals and at bedtime with food or milk.

To protect against possible gastrointestinal injury, which has been associated with the oral ingestion of concentrated potassium salt preparations, it is recommended that the oral solution be administered in a full glass (240 mL) of water, or in fruit juice, milk, or broth. It is also recommended that each regular tablet be dissolved in ½ glass (120 mL) of water or milk before ingestion.

Prolonged use may result in hypothyroidism, parotitis, iodism, and, particularly in postpubescent patients, acneiform skin lesions.

Oral Dosage Forms

Note: Bracketed uses in the *Dosage Forms* section refer to categories of use and/or indications that are not included in U.S. product labeling.

POTASSIUM IODIDE ORAL SOLUTION USP

Usual adult and adolescent dose

Antihyperthyroid agent[f]—

Oral, 250 mg three times a day.

Radiation protectant (thyroid gland)—

Oral, 100 to 150 mg twenty-four hours prior to and once a day for three to ten days following administration of, or exposure to, radioactive isotopes of iodine.

[Antifungal (systemic)][1]—

Oral, 600 mg three times a day, the dosage being increased by 60 mg at each dose until the maximum tolerated dose is reached.

[Iodine replenisher][1]—

Oral, 5 to 10 mg per day.

[Thyroid inhibitor—Thyroid involution, preoperative][1]: Prior to thyroidectomy—

Oral, 5 drops of a 1-gram-per-mL solution (approximately 250 mg) three times a day for ten days before surgery, usually administered concurrently with an antithyroid agent.

Usual adult prescribing limits

Up to 12 grams daily.

Usual pediatric dose

Radiation protectant (thyroid gland)—

Infants up to 1 year of age: Oral, 65 mg once a day for ten days following administration of, or exposure to, radioactive isotopes of iodine.

Infants and children 1 year of age and older: Oral, 130 mg once a day for ten days following administration of, or exposure to, radioactive isotopes of iodine.

[Antifungal (systemic)][1]—

Dosage has not been established.

[Iodine replenisher][1]—

Oral, 1 mg per day.

[Thyroid inhibitor—Thyroid involution, preoperative][1]—

See *Usual adult and adolescent dose*.

Strength(s) usually available

U.S.—

1 gram per mL (Rx) [GENERIC].

Packaging and storage

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container. Protect from freezing.

Stability

Crystallization may occur under normal conditions of storage, especially if refrigerated; however, on warming and shaking, the crystals will redissolve.

Free iodine may be liberated by oxidation of the potassium iodide, causing the solution to turn brownish yellow in color. If this occurs, the solution should be discarded.

Auxiliary labeling

- For oral use only.
- Do not refrigerate.
- Continue medicine for full time of treatment (antifungal).

POTASSIUM IODIDE SYRUP

Usual adult and adolescent dose

Radiation protectant (thyroid gland)—

Oral, 100 to 150 mg twenty-four hours prior to and once a day for three to ten days following administration of, or exposure to, radioactive isotopes of iodine.

[Antifungal (systemic)][1]—

Oral, 600 mg three times a day, the dosage being increased by 60 mg at each dose until the maximum tolerated dose is reached.

[Iodine replenisher][1]—

Oral, 5 to 10 mg per day.

[Thyroid inhibitor—Thyroid involution, preoperative][1]: Prior to thyroidectomy—

Oral, 4 mL (approximately 260 mg) three times a day for ten days before surgery, usually administered concurrently with an antithyroid agent.

Usual adult prescribing limits

Up to 12 grams daily.

Usual pediatric dose

Radiation protectant (thyroid gland)—

Infants up to 1 year of age: Oral, 65 mg once a day for ten days following administration of, or exposure to, radioactive isotopes of iodine.

Infants and children 1 year of age and older: Oral, 130 mg once a day for ten days following administration of, or exposure to, radioactive isotopes of iodine.

[Antifungal (systemic)][1]—

Dosage has not been established.

[Iodine replenisher][1]—

Oral, 1 mg per day.

[Thyroid inhibitor—Thyroid involution, preoperative][1]—

See *Usual adult and adolescent dose*.

Strength(s) usually available

U.S.—

325 mg per 5 mL (Rx) [*Pima*].

Packaging and storage

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), in a well-closed container, unless otherwise specified by manufacturer. Protect from freezing.

Auxiliary labeling

- For oral use only.
- Continue medicine for full time of treatment (for 3-day uncinariasis treatment).

Note: When dispensing, include a calibrated liquid-measuring device.

POTASSIUM IODIDE TABLETS USP

Usual adult and adolescent dose

Radiation protectant (thyroid gland)—

Oral, 100 to 150 mg twenty-four hours prior to and once a day for three to ten days following administration of, or exposure to, radioactive isotopes of iodine.

[Antifungal (systemic)][1]—

Oral, 600 mg three times a day, the dosage being increased by 60 mg at each dose until the maximum tolerated dose is reached.

[Iodine replenisher][1]—

Oral, 5 to 10 mg per day.

[Thyroid inhibitor—Thyroid involution, preoperative][1]: Prior to thyroidectomy—

Oral, Dissolve 2 tablets (approximately 260 mg) in 1 glassful of water, three times a day for ten days before surgery, usually administered concurrently with an antithyroid agent.

Usual adult prescribing limits

Up to 12 grams daily.

Usual pediatric dose

Radiation protectant (thyroid gland)—

Infants up to 1 year of age: Oral, 65 mg once a day for ten days following administration of, or exposure to, radioactive isotopes of iodine.

Infants and children 1 year of age and older: Oral, 130 mg once a day for ten days following administration of, or exposure to, radioactive isotopes of iodine.

[Antifungal (systemic)][1]—

Dosage has not been established.

[Iodine replenisher][1]—
Oral, 1 mg per day.
[Thyroid inhibitor—Thyroid involution, preoperative][1]—
See *Usual adult and adolescent dose*.

Strength(s) usually available
U.S.—
Not commercially available; however, potassium iodide tablets are available to government and public health organizations for use in radiation emergencies.
Canada—
130 mg (Rx) [*Thyro-Block*].

Packaging and storage
Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight container.

Auxiliary labeling
- Dissolve in liquid before taking.
- Continue medicine for full time of treatment (for 3-day uncinariasis treatment).

POTASSIUM IODIDE TABLETS (ENTERIC-COATED) USP

Note: Enteric-coated potassium iodide tablets are not recommended since the administration of this dosage form has been associated with small bowel lesions, which can cause obstruction, hemorrhage, perforation, and possibly death.

Strength(s) usually available
U.S.—
300 mg (Rx) [GENERIC].

[1]Not included in Canadian product labeling.

Revised: 04/14/92
Interim revision: 08/26/94

POTASSIUM AND SODIUM PHOSPHATES—See *Phosphates (Systemic)*

POTASSIUM PHOSPHATES—See *Phosphates (Systemic)*

POTASSIUM SUPPLEMENTS Systemic

This monograph includes information on the following: 1) Potassium Acetate†; 2) Potassium Bicarbonate; 3) Potassium Bicarbonate and Potassium Chloride; 4) Potassium Bicarbonate and Potassium Citrate†; 5) Potassium Chloride; 6) Potassium Gluconate; 7) Potassium Gluconate and Potassium Chloride†; 8) Potassium Gluconate and Potassium Citrate†; 9) Trikates†.

VA CLASSIFICATION (Primary): TN403

Commonly used brand name(s): *Apo-K*[3]*; Cena-K*[5]*; Effer-K*[4]*; Gen-K*[5]*; Glu-K*[6]*; K+ 10*[5]*; K+ Care*[5]*; K+ Care ET*[2]*; K-10*[5]*; K-8*[5]*; K-Dur*[5]*; K-Electrolyte*[2]*; K-G Elixir*[6]*; K-Ide*[2]*; K-Lease*[5]*; K-Long*[5]*; K-Lor*[5]*; K-Lyte*[2]*; K-Lyte DS*[4]*; K-Lyte/Cl*[3]*; K-Lyte/Cl 50*[3]*; K-Lyte/Cl Powder*[5]*; K-Med 900*[5]*; K-Norm*[5]*; K-Sol*[5]*; K-Tab*[5]*; K-Vescent*[2]*; KCL 5%*[3]*; Kalium Durules*[5]*; Kaochlor 10%*[3]*; Kaochlor S-F 10%*[5]*; Kaochlor-10*[5]*; Kaochlor-20*[5]*; Kaon*[6]*; Kaon-Cl*[5]*; Kaon-Cl 20% Liquid*[5]*; Kaon-Cl-10*[5]*; Kato*[5]*; Kay Ciel*[5]*; Kaylixir*[6]*; Klor-Con 10*[5]*; Klor-Con 8*[5]*; Klor-Con Powder*[5]*; Klor-Con/25 Powder*[5]*; Klor-Con/EF*[2]*; Klorvess*[3]*; Klorvess 10% Liquid*[5]*; Klorvess Effervescent Granules*[3]*; Klotrix*[5]*; Kolyum*[7]*; Micro-K*[5]*; Micro-K 10*[5]*; Micro-K LS*[5]*; Neo-K*[3]*; Potasalan*[5]*; Potassium-Rougier*[6]*; Potassium-Sandoz*[3]*; Roychlor-10%*[5]*; Rum-K*[5]*; Slow-K*[5]*; Ten-K*[5]*; Tri-K*[9]*; Twin-K*[8].

Another commonly used name in the U.S. for trikates is potassium triplex.

Note: For a listing of dosage forms and brand names by country availability, see *Dosage Forms* section(s).

†Not commercially available in Canada.

Category

Antihypokalemic; electrolyte replenisher.

Indications

Accepted

Hypokalemia (treatment)—Potassium supplements are indicated in patients with hypokalemia, with or without metabolic alkalosis; in chronic digitalis intoxication; and in patients with hypokalemic familial periodic paralysis. Potassium supplementation is indicated in severe hypokalemia in patients receiving potassium-wasting diuretics for uncomplicated essential hypertension, when dosage adjustment of the diuretic is ineffective or unwarranted. Potassium supplementation may be needed in patients receiving antibiotics that cause potassium depletion, either by drug-induced nephrotoxicity (e.g., amphotericin B, polymyxin B, or gentamicin) or by a nonreabsorbable anion effect (e.g., azlocillin, carbenicillin, mezlocillin, penicillin, piperacillin, or ticarcillin). Potassium chloride is usually the salt of choice in the treatment of hypokalemia, since it is better absorbed from the gastrointestinal tract than the nonchloride potassium salts, and the chloride ion may be required to correct hypochloremia, which often occurs with hypokalemia. In rare circumstances (e.g., patients with renal tubular acidosis), potassium depletion may be associated with metabolic acidosis and hyperchloremia. In such patients, potassium replacement should be accomplished with potassium salts other than chloride, such as potassium acetate, potassium bicarbonate, potassium citrate, or potassium gluconate.

Hypokalemia (prophylaxis)—Potassium supplements are indicated to prevent hypokalemia in patients who would be at particular risk if hypokalemia were to develop (e.g., digitalized patients with significant cardiac arrhythmias). Potassium depletion will occur when the rate of loss through renal excretion and/or loss from the gastrointestinal tract exceeds the rate of potassium intake. Potassium supplements may also be indicated in patients who suffer from hepatic cirrhosis with ascites; states of aldosterone excess with normal renal function; certain diarrheal states, including those induced by chronic laxative use; prolonged vomiting; Bartter's syndrome; potassium-losing nephropathy; and in patients, including children, on long-term corticosteroid therapy.

Deficiency of potassium may lead to muscle weakness, irregular heartbeat, mood or mental changes, or nausea or vomiting.

Acceptance not established

There are insufficient data to show that potassium supplementation lowers *blood pressure* in hypertensive patients.

Unaccepted

Enteric-coated tablets of potassium chloride are no longer recommended for use because of the high incidence of severe injury to adjacent gastrointestinal tissues during tablet dissolution.

Pharmacology/Pharmacokinetics

Physicochemical characteristics

Molecular weight—
Potassium acetate: 98.14.
Potassium bicarbonate: 100.12.
Potassium chloride: 74.55.
Potassium citrate: 324.41.
Potassium gluconate: 234.25.

Mechanism of action/Effect

Potassium is the predominant cation (approximately 150 to 160 mEq per liter) within cells. Intracellular sodium content is relatively low. In extracellular fluid, sodium predominates and the potassium content is low (3.5 to 5 mEq per liter). A membrane-bound enzyme, sodium-potassium–activated adenosinetriphosphatase (Na^+K^+ ATPase), actively transports or pumps sodium out and potassium into cells to maintain these concentration gradients. The intracellular to extracellular potassium gradients are necessary for the conduction of nerve impulses in such specialized tissues as the heart, brain, and skeletal muscle, and for the maintenance of normal renal function and acid-base balance. High intracellular potassium concentrations are necessary for numerous cellular metabolic processes.

Elimination

Renal—90%.
Fecal—10%.

Precautions to Consider

Carcinogenicity

No data are available on long-term potential for carcinogenicity in animals or humans. Potassium is a normal dietary constituent.

mg suppositories (white wrapper/green type), NDC 0245-0161-12, 12 per carton. 20 mg suppositories (white wrapper/red type), NDC 0245-0162-12, 12 per carton. 30 mg suppositories (white wrapper/gold type), NDC 0245-0163-12, 12 per carton.

DEA ORDER FORM REQUIRED—

Caution: Federal law prohibits dispensing without prescription.

SSKI® ℞

Potassium Iodide Oral Solution, USP (Saturated) 1 g/ml

DESCRIPTION

SSKI® (potassium iodide oral solution, USP) is a saturated solution of potassium iodide containing 1 g of potassium iodide per ml.

CLINICAL PHARMACOLOGY

Potassium iodide is thought to act as an expectorant by increasing respiratory tract secretions and thereby decreasing the viscosity of mucus.

INDICATIONS AND USAGE

For use as an expectorant in the symptomatic treatment of chronic pulmonary diseases where tenacious mucus complicates the problem, including bronchial asthma, bronchitis and pulmonary emphysema.

CONTRAINDICATIONS

Contraindicated in patients with a known sensitivity to iodides.

WARNINGS

Potassium iodide can cause fetal harm, abnormal thyroid function, and goiter when administered to a pregnant woman. Because of the possible development of fetal goiter, if the drug is used during pregnancy or if the patient becomes pregnant during therapy, apprise the patient of the potential hazard.

PRECAUTIONS

General: In some patients, prolonged use of iodides can lead to hypothyroidism. Iodides should be used with caution in patients having Addison's disease, cardiac disease, hyperthyroidism, myotonia congenita, tuberculosis, acute bronchitis, or renal function impairment.

Interactions: Concurrent use with lithium and other thyroid drugs may potentiate the hypothyroid and goitrogenic effects of these medications. Concurrent use with potassium-containing medications, potassium-sparing diuretics and angiotensin-converting enzyme inhibitors (ACE inhibitors) may result in hyperkalemia and cardiac arrhythmias or cardiac arrest.

Drug/Laboratory Test Interactions: Thyroid function tests may be altered by iodide.

Pregnancy: Category D—see "Warnings" section.

Nursing Mothers: Potassium iodide is excreted in breast milk. Use by nursing mothers may cause skin rash and thyroid suppression in the infant.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The most frequent adverse reactions to potassium iodide are stomach upset, diarrhea, nausea, vomiting, stomach pain, skin rash, and salivary gland swelling or tenderness. Less frequent adverse reactions include gastrointestinal bleeding, confusion, irregular heartbeat, numbness, tingling, pain or weakness in hands or feet, unusual tiredness, weakness or heaviness of legs, fever, and swelling of neck or throat. Thyroid adenoma, goiter, and myxedema are possible side effects.

Iodism or chronic iodine poisoning may occur during prolonged treatment or with the use of high doses. The symptoms of iodism include burning of mouth or throat, severe headache, metallic taste, soreness of teeth and gums, symptoms of head cold, irritation of the eyes with swelling of the eyelids, unusual increase in salivation, acneform skin lesions in the seborrheic areas, and rarely, severe skin eruptions. If symptoms of iodism appear, the drug should be withdrawn and the patient given appropriate supportive therapy.

Hypersensitivity to iodides may occur and may be manifested by angioedema, cutaneous and mucosal hemorrhage, and signs and symptoms resembling serum sickness, such as fever, arthralgia, lymph node enlargement, and eosinophilia.

OVERDOSAGE

Toxicity from potassium iodide is relatively rare. An occasional individual may show marked sensitivity and the onset of acute poisoning can occur immediately or hours after administration. Angioedema, laryngeal edema and cutaneous hemorrhages may occur.

Iodism or chronic iodine poisoning may occur during prolonged treatment or with the use of high doses. Symptoms of iodism typically disappear soon after discontinuation of the drug. Abundant fluid and salt intake aids in iodide elimination.

GOODMAN and GILMAN's

The Pharmacological Basis of Therapeutics

SIXTH EDITION

Untoward Reactions. Occasional individuals show marked sensitivity to iodide or to organic preparations that contain iodine when they are administered intravenously. The onset of an *acute reaction* may occur immediately or several hours after administration. Angioedema is the outstanding symptom, and swelling of the larynx may lead to suffocation. Multiple cutaneous hemorrhages may be present. Also, manifestations of the serum-sickness type of hypersensitivity, such as fever, arthralgia, lymph node enlargement, and eosinophilia, may appear. Thrombotic thrombocytopenic purpura and fatal periarteritis nodosa attributed to hypersensitivity to iodide have also been described.

The severity of symptoms of *chronic intoxication* with iodide (*iodism*) is related to the dose. The symptoms start with an unpleasant brassy taste and burning in the mouth and throat, as well as soreness of the teeth and gums. Increased salivation is noted. Coryza, sneezing, and irritation of the eyes with swelling of the eyelids are commonly observed. Mild iodism simulates a "head cold." The patient often complains of a severe headache that originates in the frontal sinuses. Irritation of the mucous glands of the respiratory tract causes a productive cough. Excess transudation into the bronchial tree may lead to pulmonary edema. In addition, the parotid and submaxillary glands may become enlarged and tender, and the syndrome may be mistaken for mumps parotitis. There also may be inflammation of the pharynx, larynx, and tonsils. Skin lesions are common, and vary in type and intensity. They usually are mildly acneform and distributed in the seborrheic areas. Rarely, severe and sometimes fatal eruptions (ioderma) may occur after the prolonged use of iodides. The lesions are bizarre, resemble those caused by bromide, and, as a rule, involute quickly when iodide is withdrawn. Symptoms of gastric irritation are common; and diarrhea, which is sometimes bloody, may occur. Fever is occasionally observed, and anorexia and depression may be present. The mechanisms involved in the production of these derangements remain unknown.

WARNINGS

No-Niacin® Tablets should not be used by persons with a known sensitivity or allergy to niacin. Persons with heart disease, particularly those who have recurrent chest pain (angina) or who recently suffered a heart attack, should take niacin only under the supervision of a physician. Persons taking high blood pressure or cholesterol-lowering drugs should contact a physician before taking niacin because of possible interactions. Do not take niacin unless recommended by and taken under the supervision of a physician if you have any of the following conditions; gallbladder disease, gout, arterial bleeding, glaucoma, diabetes, impaired liver function, peptic ulcer, pregnancy or lactating women. Increased uric acid and glucose levels and abnormal liver function tests have been reported in persons taking daily doses of 500 mg or more of niacin.

Discontinue use and consult a physician immediately if any of the following symptoms occur: persistent flu-like symptoms, nausea, vomiting, a general "not well" feeling; loss of appetite; a decrease in urine output associated with dark-colored urine; muscle discomfort such as tender, swollen muscles or muscle weakness; irregular heartbeat; or cloudy or blurry vision.

Keep out of the reach of children.

INGREDIENTS

250 mg niacin (nicotinic acid), supplying 1,250% of the Reference Daily Intake (RDI) for niacin.
500 mg niacin (nicotinic acid), supplying 2,500% of the Reference Daily Intake (RDI) for niacin.
750 mg niacin (nicotinic acid), supplying 3,750% of the Reference Daily Intake (RDI) for niacin.
Each tablet also contains: cellulose polymer derivative, vegetable stearine, magnesium stearate, silicon dioxide, glyceryl behenate, and FD&C Red # 40.

HOW SUPPLIED

250 mg tablets in bottles of 100: List No. 0245–0062–11
500 mg tablets in bottles of 100: List No. 0245–0063–11
750 mg tablets in bottles of 100: List No. 0245–0064–11
U.S. Patent No. 5,126,145 and other patents pending.
Shown in Product Identification Guide, page 340

Vitaline Corporation
385 WILLIAMSON WAY
ASHLAND, OR 97520

Direct Inquiries to:
Jed D. Meese, Technical Director
(800) 648-4755
(541) 482-9231
FAX: (541) 482-9112
E-Mail: jmeese@vitaline.com

L-CARNITINE USP OTC

250mg Tablets, 500mg Scored Caplets and 500mg Chewable Wafers
Renal Patient L-Carnitine
Dietary Supplement

DESCRIPTION

Carnitine is a naturally occurring substance, and is essential for fatty acid oxidation and energy production. Without it, long-chain fatty acids cannot cross from cellular cytoplasm into the mitochondria and out again, resulting in loss of energy and toxic accumulations of free fatty acids. Ninety-five percent of the body's carnitine is found in cardiac and skeletal tissue; these muscles rely upon fatty acid oxidation for most of their energy.

INDICATIONS

Dietary supplementation of L-Carnitine for individuals who may benefit from supplementation of this essential nutrient. Renal dialysis patients have a special need for L-Carnitine supplementation because of dietary restrictions and other factors.

WARNINGS

None reported.

SUGGESTED USE

As a dietary supplement: Adults, one gram 2 to 3 times daily or as directed by physician, registered dietitian or nutritionist. Children, as directed by physician.

HOW SUPPLIED

250mg tablets in bottles of 90 NDC 54022-2100-1
500mg scored caplets in bottles of 30 NDC 54022-2120-1
500mg chewable wafers in bottles of 30 NDC 54022-2700-1

REFERENCES

1. Effect of Oral L-Carnitine on Serum Myoglobin in Hemodialysis Patients. *Renal Failure. 18(1):91-96, 1996.*
2. Effects of Nutritional Status and Oral Essential Amino Acid Replacement on Serum L-Carnitine Levels of Chronically Hemodialyzed Patients. *Nephron. 72(2):341-342, February 1996.*
3. A Randomised, Double-Blind, Placebo-Controlled Trial of L-Carnitine in Suspected Acute Myocardial Infarction. *Postgraduate Medical Journal. 72(843):45-50, January 1996.*

COENZYME Q_{10} OTC

(Ubiquinone)
200mg, 100mg & 60mg Chewable Wafers, and 200mg, 60mg & 25mg Tablets

DESCRIPTION

Coenzyme Q_{10} (CoQ_{10}) is an essential nutrient that is a cofactor in the mitochondrial electron transport chain, the bio-

Continued on next page

Perspective: National Cancer Institute Summary Report About Estimated Exposures and Thyroid Doses Received from Iodine 131 in Fallout After Nevada Atmospheric Nuclear Bomb Tests

Scott A. Hundahl, MD

Background

The intersection of politics and science sometimes engenders puzzling projects. A 15-year governmental initiative to calculate iodine 131 exposures attributable to atmospheric nuclear testing in the United States is a fine example.

Recognizing that this project represents the principal federally mandated study of national health risks from atmospheric nuclear testing, clinicians might well ask, Why focus on the distribution of this isotope, which has a short half-life and is associated with thyroid cancer—an almost negligible cause of cancer mortality—while ignoring more worrisome isotopes? Why focus on an individual isotope at all, when most existing epidemiologic risk studies focus on total tissue dose from all sources? Why dwell on ^{131}I-induced thyroid cancer and ignore leukemias?

Appreciating the medico-legal-scientific-politico-strategic polka surrounding any study addressing the health risks of atmospheric nuclear testing, one recognizes both the barriers to such an attempt and possible reasons why the questions listed earlier have remained unanswered.

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This article is also available online at http://www.ca-journal.org.

Enacted on January 4, 1983, Public Law 97-414, section 7(a), directs the Secretary of Health and Human Services to, among other things, "develop . . . assessments of the risks of thyroid cancer that are associated with thyroid doses of iodine-131" and "estimate the thyroid doses of iodine-131 that are received by individuals from nuclear bomb fallout . . . and develop assessments of the exposure to iodine-131 that the American people received from the Nevada atmospheric nuclear bomb tests."[1]

The Secretary delegated this task to the National Cancer Institute (NCI) in 1983. On August 1, 1997, 15 years after the legislative request, the NCI issued a news release summarizing the findings. The actual NCI summary report, titled "Estimated Exposures and Thyroid Doses Received by the American People from Iodine-131 in Fallout Following Nevada Atmospheric Nuclear Bomb Tests," weighing in at 1,000 pages, was released in October 1997.[2]

The report deals only with ^{131}I exposure and does not contain estimates of attributable thyroid cancers. The Institute of Medicine, a part of the National Academy of Sciences, has been contracted by NCI to generate estimates of thyroid cancer risk. The Institute of Medicine's report, unfortunately delayed, is due to be released in September 1998. Meanwhile, according to the NCI, "persons concerned about fallout exposure should consult a health professional."

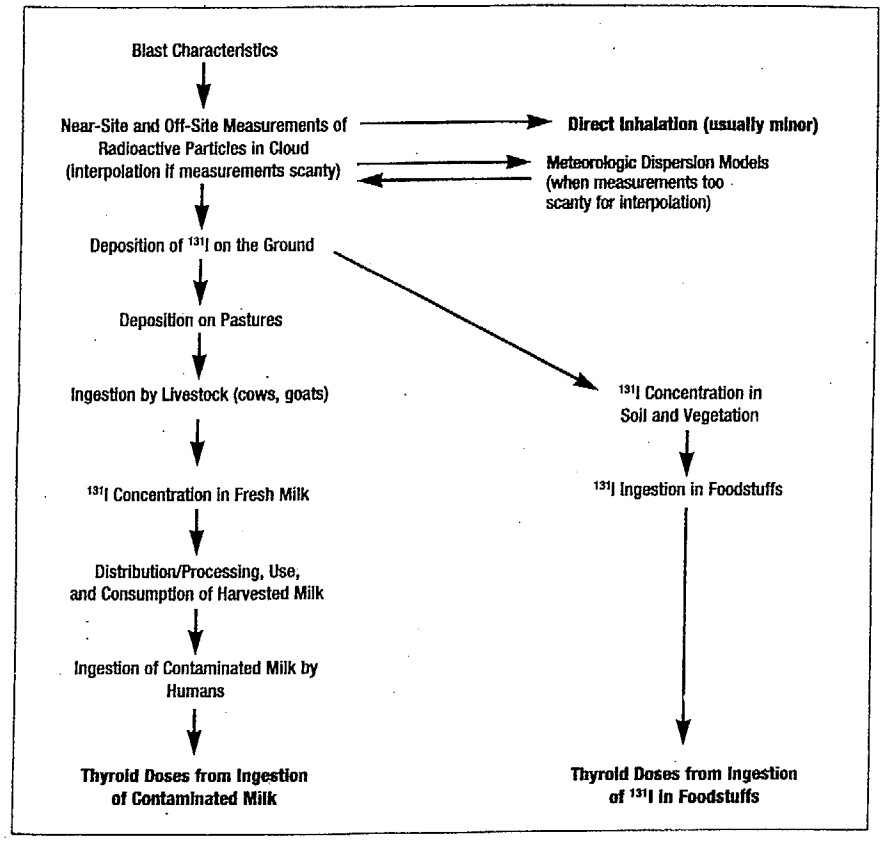

Fig. 1. Method used to calculate total thyroid dose attributable to iodine 131 (^{131}I).

This review summarizes the NCI report and offers some information to help health professionals deal with the NCI report's potential "fallout."

Methodology

Figure 1 illustrates the steps involved in generating estimates of thyroid dose attributable to ^{131}I from Nevada test site nuclear explosions. For each step, significant uncertainty about sampling error, assumptions, and so forth propagates down the chain. Compounding this uncertainty, variables relating to individual characteristics (such as age, dietary habits, source of milk and foodstuffs, and so forth) can dramatically alter thyroid dose estimates for particular individuals. Stepwise review of methodology facilitates appropriate interpretation of the dose estimates reported. Unless otherwise noted, all factual statements derive from the report itself.

History of Nuclear Testing at the Nevada Test Site

Located only 65 miles northwest of Las

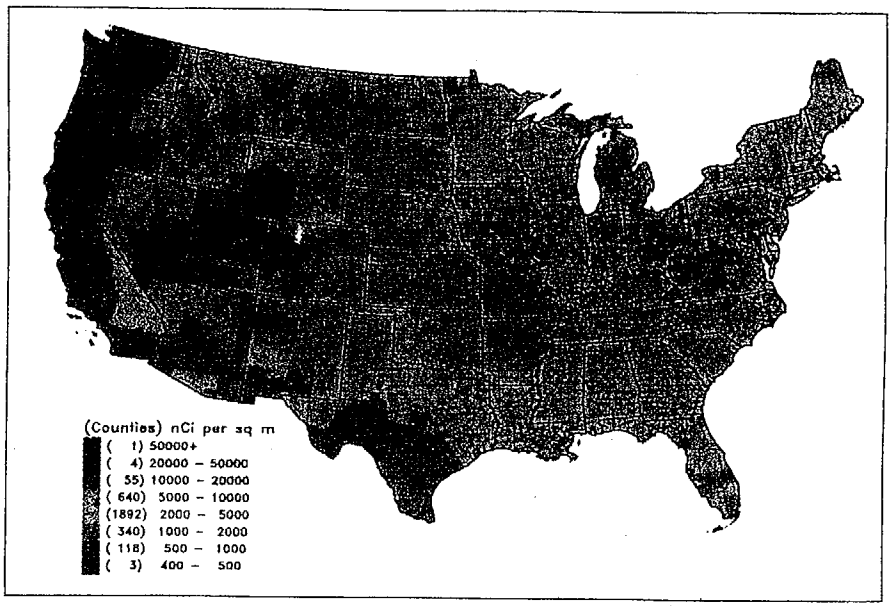

Fig. 2. Total iodine 131 ground deposition for all tests combined. Reprinted from National Cancer Institute.[2]

Vegas, Nevada, the Nevada Test Site (NTS) encompasses 1,350 square miles and measures at its widest points 35 miles in east-west width and 55 miles in north-south length. An additional zone of 4,120 square miles of restricted federally owned land buffers the NTS on three sides, effectively creating a 5,470-square-mile desert reserve of unpopulated land, the largest such area in the continental United States.

To decrease the lead time and expense associated with weapons development, nuclear testing in the United States shifted from the distant Pacific atolls of Bikini and Eniwetak to the NTS in 1951. Between January 1951 and October 1958, the United States conducted 119 nuclear tests, including 97 atmospheric tests, 2 shallow cratering tests, and 20 deep underground tests. A voluntary nuclear-test moratorium began in October 1958 and lasted until the Soviet Union exploded a 57-megaton bomb—the largest ever—on September 1, 1961. Fortunately, with the signing of the Limited Test Ban Treaty on August 5, 1963, further atmospheric testing ceased.

From 1961 through 1992, however, more than 800 underground tests were conducted. On October 2, 1992, President Bush announced a unilateral moratorium on all nuclear testing, and this remains in effect.

As documented by near-site measurements at the NTS, radioactive debris from nuclear explosions remains largely contained when such tests are conducted underground. Significant release of ^{131}I appears to be almost exclusively restricted to ground-level and above-ground nuclear explosions.

Volatile elements such as ^{131}I collect in the particulate matter swept up in the

Table 1
Dates Associated with Largest Release of Iodine 131 from Nuclear Testing at Nevada Test Site

Date	Test Series	Total Release of ^{131}I (kCi)	Release Rate/ Month (kCi)
October–November 1951	Buster-Jangle	10,540	5,270
April–June 1952	Tumbler-Snapper	15,480	5,160
March–June 1953	Upshot-Knothole	36,756	9,189
February–May 1955	Teapot	24,480	6,120
February–October 1957	Plumbbob	57,628	6,403

radioactive mushroom cloud generated by such blasts. Such radioactive mushroom clouds frequently extend more than 10 kilometers into the sky and are subsequently distributed by upper-atmosphere winds over vast distances. Particulate debris associated with such clouds can take several months, and perhaps years, to fall back to earth. Precipitation ("wet deposition") substantially increases the return of such particulate debris. Because ^{131}I has a half-life of 8.04 days and usually decays to xenon 131, a stable isotope, the early (within days) deposition of fallout particles appears most significant with respect to health effects from ^{131}I.

Ninety-nine percent of the ^{131}I activity released into the atmosphere because of nuclear testing at the NTS, an estimated total of 150 MCi, resulted from 90 tests conducted mostly from 1951 to 1958.[2] Table 1 lists the periods associated with the release of most of the detectable ^{131}I.

Estimating the Deposition of ^{131}I on the Ground

In the 1950s, measurement of radioactive contamination generally consisted of assessment of gross β activity. Specific measurement of ^{131}I in the environment appeared impractical before 1960 and was rarely done. Fortunately, however, "close-in measurements," "aerial sampling" by aircraft, and "specific radiochemical data" relating to the radioactive cloud generated by the explosions yielded sufficiently detailed compositional information to permit reasonable estimates of ^{131}I in relation to total β activity. Because the half-life of ^{131}I is only 8.04 days, the activity of ^{131}I present in the 30-year-old samples has disappeared. Such measurements cannot be confirmed today using modern equipment.

During the period of interest, environmental monitoring programs in place both near the NTS and throughout the United States did capture systematic measurements of total β activity in the air and deposited on (sticky) gummed film. One project collected samples from approximately 95 sites throughout the United States. Such measurements of β activity do permit reasonable estimates of ^{131}I deposition at distant sites throughout the United States.

Three procedures were used to estimate the ^{131}I deposition in counties of the United States for which no direct monitoring data are available. First, if measurements of gross β activity in neighboring counties are sufficient, these, together with precipitation data, can be converted to direct estimates of ^{131}I deposition. By interpolation (refined using special statistical techniques), estimates for all counties in the United States can be generated.

Second, when β measurements are too sparse for reasonable interpolation, estimates from the nearest county are combined with county precipitation data to yield an approximation.

Third, in situations in which surface deposition values still cannot be estimated reliably, wet deposition (i.e., that associated with precipitation, usually the major source of deposition) can be calculated based on a meteorologic model that simulates the transport of radioactive cloud debris (and ^{131}I) according to observed wind patterns.

Figure 2 depicts the total activity of ^{131}I deposited per unit area of ground for all tests combined.

Transfer of ^{131}I from Ground Deposition to Fresh Cows' Milk and Other Routes of ^{131}I Exposure

Dairy cows consume pasture grasses, water, and other feed contaminated with fallout containing ^{131}I, then secrete ^{131}I in their milk. Bovine exposure routes other than pasture consumption constitute only 2% to 4% of total time-integrated concentration in milk when cows graze on land distant from the NTS; however, such routes can be important for sites close to the NTS.

The NCI report includes the calculation of doses to both cows and people attributable to routes other than the pasture-cow-milk chain, but doses from such routes are generally less significant. The methods used for calculating thyroid dose attributable to such routes parallel the methods used for the pasture-cow-milk chain. For humans, such alternative routes include ^{131}I absorbed from air, foodstuffs, goats' milk, cottage cheese, eggs, leafy vegetables, and mothers' milk.

Pasture grazing of dairy cows varies considerably with locale and season. Important factors with respect to ^{131}I transfer include the mass interception factor by vegetation, the mean time of retention of ^{131}I on vegetation (about 1 week), the amount of contaminated pasture ingested by cows, and the transfer coefficient from feed to milk for cows.

For average grazing and feeding practices on representative farms, time-integrated ^{131}I concentrations in fresh cows' milk were estimated for each county for every test. The average time-integrated concentrations for all tests combined, by county, varied from a low of 10 to 20 nCi per liter for California to a high of 5,000 nCi per liter for parts of Idaho. The report contains specific county-by-county information.

Although contaminated cows' milk is the principal route by which ^{131}I enters the human food chain, goats' milk contains approximately 10 times the concentration of radioiodine found in cows' milk. Fortunately, few individuals routinely consumed goats' milk during the period in question, but this factor can be significant in individual cases.

Milk Distribution, Processing, and Consumption

Because ^{131}I has a half-life of only 8.04 days, even short delays caused by the processing and transport of milk can decrease the ^{131}I eventually ingested by humans. During the 1950s, approximately 50% of the milk produced in the United States was consumed as fresh fluid milk, and most of the rest was used in the manufacturing of dairy products such as cheese.

During the early 1950s, milk was usually produced close to where it was consumed (within 300 km). Later, with refrigerated tank cars and reduced transportation costs, bulk processing methods

resulted in a greater delay between production and consumption. Because radioactive decay is not sensitive to changes in temperature, such practices decreased the ^{131}I activity in ingested milk, particularly in urban centers. Delays between production and consumption averaged 1, 2, 3, and 4 days for areas the report characterized as farm, rural non-farm, urban—same milk region, and urban—different milk region, respectively.[2]

Milk consumption varies surprisingly as a function of geography (higher in midwestern and northern states), age (highest for those 5 to 15 years old), and gender (females less than males during this period). Based on US Department of Agriculture surveys and using 1954 as the most representative year, the report gives milk consumption estimates for each state and for each age group.

Thyroid Dose Calculations

The product of milk consumption rate times time-integrated ^{131}I in cows' milk times the thyroid dose conversion factor appropriate to the individual considered equals the thyroid dose received as a result of a given test. The report contains specific data for each test.

Because of the small size of an infant's thyroid and the avidity with which radioiodine is concentrated in the thyroid, the thyroid dose conversion factor is highest for infants 0 to 2 months old (15 mrad per nCi) and gradually decreases with age until it plateaus beyond age 20 (1.3 mrad per nCi for men and 1.8 mrad per nCi for women). This means that for a given time-integrated concentration of ^{131}I in fresh milk, infants are affected to a far greater degree than are adults.

Thus, age at time of exposure represents a key variable in estimating an individual's thyroid dose from a particular test. For this reason and because of the geographic variation in ^{131}I ground deposition, cumulative individual doses must be calculated on a test-by-test basis and then summ

For calculation of total thyroid dose for a given individual, dose contributions from other routes are also summed. Because all routes of ^{131}I exposure for all tests must be considered, calculation of the dose to specific individuals requires considerable discipline and patience. The report cites detailed examples of how to do this, however, and the necessary tables are contained in the report's voluminous appendices.[2]

The report offers a convenient shortcut for assessing dose for particular individuals based on a series of computer-generated, color-coded maps of the continental United States. The report offers maps illustrating total thyroid dosage for individuals born in 1930, in 1945, and for each year from 1950 through 1960 as well as for 1962.[2] For each birth year, maps corresponding to "milk from backyard cow," "no milk consumption," "average milk consumption," and "high milk consumption" are offered.

In this and other sections of the report, the important issue of uncertainty is addressed on two levels. First, assumptions made to quantify estimates (and, indeed, to quantify the uncertainty) may not always apply. This can generate difficult-to-quantify systematic errors. Second, although cumulative uncertainties for average dose calculations can be reasonably approximated, those for individual dose can be much larger and probably are not precisely quantifiable.

Summary of Cumulative Thyroid Dose Estimates

Nuclear explosions at the NTS resulted in delivery of an average thyroid dose of 2 rad per person for the approximately 160 million people residing in the United States during the 1950s. Uncertainties attributable to the quality of the data, interpolative techniques employed, assumptions made, models used, and so forth combine to make the estimated uncertainty of this average thyroid dose a factor of 2 (i.e., the average dose could be as low as 1 rad or as high as 4 rad).

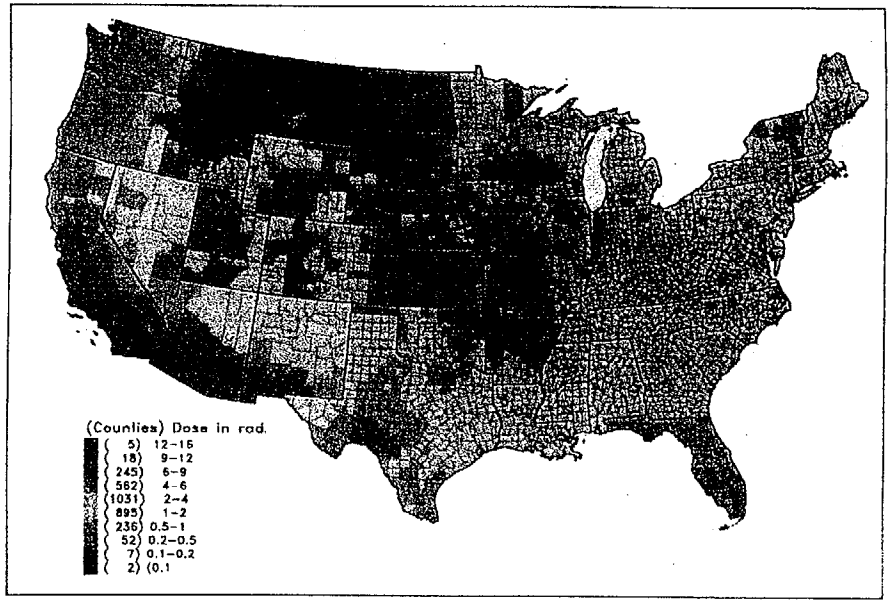

Fig. 3. Total average per capita cumulative thyroid dose attributable to iodine 131 contamination from all tests and all sources. Reprinted from National Cancer Institute.[2]

Individuals residing in certain counties experienced a higher-than-average total thyroid dose. The highest average total doses (12 to 16 rad) were seen in Meagher County, Montana, and Custer, Gem, Blaine, and Lemhi counties, Idaho, near the Continental Divide.[2] Total average thyroid doses of 9 to 12 rad were seen in many other western counties, mostly in Montana. For those living in such areas and born between 1945 and 1958, the dose can be significantly higher than the per capita average.

Figure 3 depicts average per capita thyroid dose from ^{131}I from all routes and for all tests combined. For milk drinkers born 1945 to 1958, the total thyroid dose can be much higher than that depicted in Figure 3. For individuals drinking fresh goats' milk during this period, cumulative dose may be more than 10 times higher. The report's color-coded dose maps describing dose by birth year and milk consumption category (described earlier) are helpful in assessing individual dose more accurately.

Table 2, which is taken directly from the NCI report, summarizes total thyroid dose for representative individuals residing at the indicated locations and consuming average amounts of milk. The table reveals that date of birth and place of residence can alter an individual's dose estimate considerably.

Putting the dose estimates in perspective, average thyroid dose per year from cosmic rays, natural background, and other sources has been estimated at 0.1 rad per year. Summing this annual "natural" dose over a 10-year period (a method similar to that used for calculating cumulative ^{131}I dos[illegible] NCI re-

Table 2
Sample Calculations of Total Thyroid Dose (All Tests Combined) According to City of Residence and Age

Place of Residence	Thyroid Dose Estimates (Rads)				
	Father born 9/15/27	Mother born 10/10/29	Child born 10/1/51	Child born 9/15/52	Child born 11/28/56
Los Angeles	0.03	0.03	0.3	0.06	0.02
Salt Lake City	1.3	1.4	10.0	8.9	5.5
Denver	1.1	1.1	10.0	8.9	5.5
Chicago	0.7	0.7	6.6	5.8	2.9
New York	0.5	0.6	5.0	3.8	2.2
Tampa	0.3	0.3	1.7	0.8	2.2

Reprinted from National Cancer Institute.[2]

port), the cumulative dose is 1.0 rad. Persons receiving diagnostic radioiodine for thyroid scanning receive a total thyroid dose of approximately 1.1 Gy, or 110 rad per scan. Persons receiving therapeutic radioiodine for ablation of the thyroid (such as in treatment of thyrotoxicosis) receive total thyroid tissue doses of 10 to 100 Gy, or 1,000 to 10,000 rad.

^{131}I and Thyroid Cancer

As mentioned earlier, the Institute of Medicine report relating ^{131}I exposure to thyroid cancer should be completed by September 1998. The difficulty of assessing dose-response relationships for the generally low-dose exposures identified represents a challenge. Radioepidemiologic data for the dose range of interest appear to be scant.

Although a high rate of thyroid cancer was among the first abnormalities detected in studies of those surviving the Hiroshima and Nagasaki explosions, the exposures in these instances were mixed external and internal, with the former predominating.[3] The relative biologic effectiveness (RBE) differs significantly for different types of radiation (e.g., neutron radiation has a much higher RBE than does gamma radiation). Also, type of dose (i.e., continuous versus intermittent), frequency of exposure, and dose per exposure can alter the RBE of a given total dose dramatically.[4]

What do we know about the radiobiologic effect of ^{131}I, especially with respect to thyroid cancer? In Sweden, 35,074 patients receiving diagnostic ^{131}I (estimated total thyroid dose, 110 rad per scan) have been studied carefully, and based on experience with external x-ray radiation, a substantially higher rate of thyroid cancers was anticipated. No increase in thyroid cancers was detected, however.[4-6] A German study of almost 14,000 patients similarly treated also failed to detect any carcinogenic effect associated with such a dose.[7]

Iodine 131 radiation to the thyroid appears, at worst, far less carcinogenic to the thyroid than external x-rays or

gamma rays. Whether this is because of the relatively slow dose rate attributable to the 8.04 day half-life or the distribution of absorbed ^{131}I within the gland (i.e., within colloid follicles) remains speculative.

Treatment of specific conditions such as thyrotoxicosis with ^{131}I requires higher doses, usually 10 to 100 Gy (1,000 to 10,000 rad). Thyroid cancer has never been linked to treatment with such doses, probably because of the loss of cellular function associated with such relatively high doses.[8]

The studies mentioned earlier fail to link increased cancer risk with ^{131}I thyroid doses higher than 110 rad. The impact of lower doses, particularly their effect on children, remains undetermined. Age at exposure may significantly modify the carcinogenic effect of ^{131}I.[4]

In 1986, fallout (including ^{131}I) related to the Chernobyl nuclear disaster in the Ukraine fell most heavily in the Gomel region of Belarus. From 1989 to 1991, pediatric thyroid cancer, which was previously rare (one or two cases a year), increased dramatically (an apparent rate of more than 100 cases per year).[9-11] Although hampered by registry problems, imprecise dosimetry, and other difficulties, studies of thyroid cancer in areas affected by Chernobyl fallout certainly suggest significant radiocarcinogenesis in pediatric age groups. Presumably, this is caused by iodine isotopes, of which ^{131}I is the most significant, but other isotopes and compounds may also contribute to this apparent carcinogenesis.

Evaluation of Patients with Thyroid Nodules

Fine-needle aspiration techniques and improvements in cytologic analysis have largely replaced other modalities in the evaluation of thyroid nodules.[12-16] For nodules that are small or difficult to palpate, ultrasound-guided fine-needle aspiration works well. Ultrasound is also useful in screening the rest of the gland for occult nodules.

For patients presenting with a thyroid nodule, with or without a history of thyroid radiation, evaluation begins with history, which should note especially documented growth, voice change, and other symptoms.

Ninety-nine percent of the ^{131}I activity released into the atmosphere because of nuclear testing at the Nevada test site, an estimated total of 150 MCi, resulted from 90 tests conducted mostly from 1951 to 1958.

Physical examination should include not only detailed palpation of the thyroid but also detailed examination of the neck for adenopathy. Palpation of the thyroid and cervical nodes is best conducted with the examiner standing behind the patient, reaching around to the front of the neck and gently compressing the soft tissues. Papillary thyroid cancers are usually firm to palpation. Follicular neoplasms tend to be softer and can sometimes mimic benign colloid nodules. Cervical adenopathy caused by thyroid cancer is usually found in the middle and lower jugular nodes and also in the posterior triangle. This is sometimes the first sign of a thyroid malignancy.

The physical examination also should include detailed examination of the oropharynx and, if possible, indirect laryngoscopy. A thyroid nodule or firm neck node in a patient who does not have oropharyngeal pathology, particularly if the patient is a nonsmoker, sug-

gests the possibility of thyroid malignancy. Ipsilateral impairment of vocal chord motion is particularly worrisome.

Tests useful in evaluating thyroid function include levels of thyroid-stimulating hormone (TSH) and free thyroxine (FT4). Although such tests are useful for identifying the hypersecretion associated with a "hot" nodule (almost always benign), such functional tests alone fail to identify thyroid cancer.

In situations of equivocal examination, difficult to localize abnormalities, or suspicion of contralateral disease, neck ultrasonography offers a sensitive means of cancer detection.[17]

Nuclear explosions at the Nevada test site resulted in delivery of an average thyroid dose of 2 rad per person for the approximately 160 million people residing in the United States during the 1950s.

Currently, fine-needle aspiration is the main diagnostic procedure in a patient with a thyroid nodule.[14-18] Malignant or equivocal aspirates should prompt surgical intervention. Benign nodules sometimes can be managed with hormonal suppression (i.e., enough thyroid hormone to suppress TSH to subnormal levels), with surgery reserved for refractory or growing nodules. When follow-up examination documents growth of a nodule, surgical treatment is indicated regardless of results of initial cytologic studies. In a patient with a history of neck irradiation, the threshold for surgical treatment should be low. A worrisome, firm nodule, particularly in the context of previous pediatric cervical irradiation, usually merits surgical tr t.

The extent of thyroidectomy for thyroid cancer remains controversial. For patients with a history of neck irradiation, however, most experts recommend total thyroidectomy.[18] In patients without such a history and with no risk factors for aggressive disease (such as age older than 45 years, extrathyroidal extension, large size, and metastases), studies with 20-year follow-up document that unilateral lobectomy-isthmusectomy generates excellent survival (99%) with less morbidity than is seen with total thyroidectomy.[19]

Adjuvant treatment of thyroid carcinoma includes routine hormonal suppression sufficient to depress TSH to subnormal levels. Patients with risk factors for more aggressive disease (who should be treated with total thyroidectomy, as mentioned earlier) also should be treated with radioiodine.[18,20]

Survival Rates for Patients with Thyroid Cancer

Figure 4 depicts 10-year survival rates for 53,856 patients in the United States with the indicated thyroid malignancies accessioned to the National Cancer Data Base (NCDB) between 1985 and 1995. Detailed information concerning patterns of care and stage-stratified survival is available for this cohort, the largest reported to date.[20a]

Based on experience with radiation-associated thyroid malignancies after the Chernobyl nuclear accident and after the explosions at Hiroshima and Nagasaki, most such radiation-associated malignancies appear to be of papillary or follicular histology. In the Hiroshima and Nagasaki studies, occult tumors less than 1.5 cm in size frequently were discovered at autopsy. Higher rates of medullary or anaplastic cancers were not observed.[21]

Based on the experience after the Chernobyl accident, the pediatric population appears to be at greatest risk of

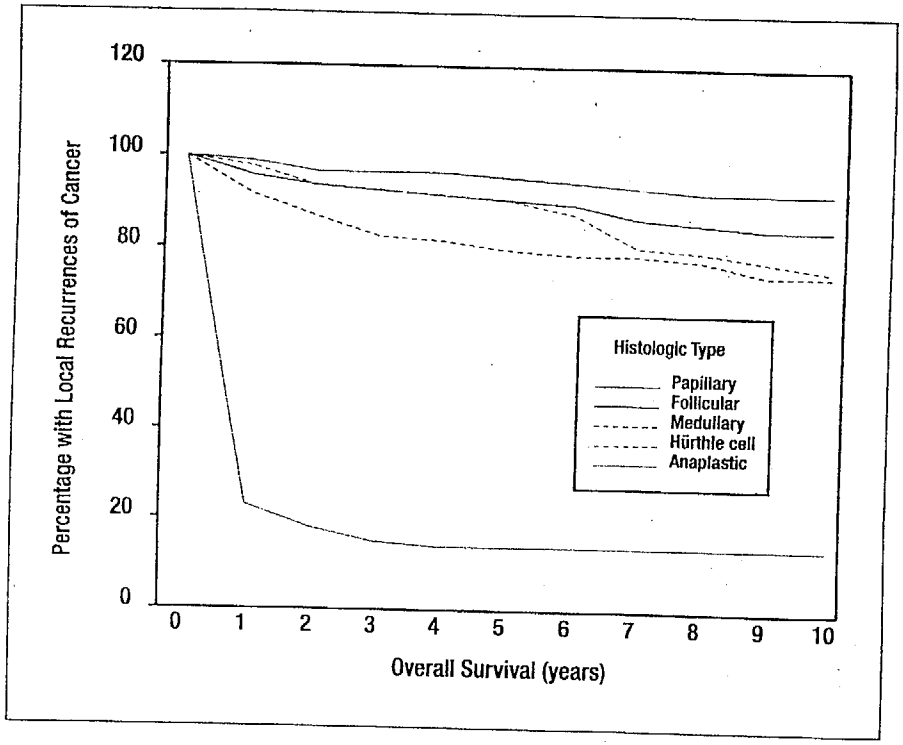

Fig. 4. Ten-year overall relative survival based on histologic type for 53,856 cases of thyroid cancer diagnosed between 1985 and 1995 and reported to the National Cancer Data Base.

fallout-induced thyroid malignancy. Survival rates for young patients with thyroid cancer are of interest. According to unpublished data from the aforementioned NCDB cohort, overall 5-year relative survival rates for patients less than 20 years old at time of diagnosis are 99% for papillary cancers (N = 631) and 100% for follicular cancers (N=73).

Comprehensive assessment of survival for papillary and follicular thyroid neoplasms probably requires two to three decades of follow-up, however. In a retrospective survey of papillary or follicular cancer in 106 patients younger than 20 years who had a longer (16-year median) follow-up, cumulative cancer mortality was 2%.[20] Thus, mortality for pediatric patients with papillary and follicular cancer does seem low. However, the prognosis of radiation-induced neoplasms may differ from that of similar, non–radiation-induced neoplasms.

Conclusion and Critique

The nationwide distribution of fallout containing ^{131}I from United States atmospheric testing at the NTS appears to have resulted in abnormal thyroid radiation exposure for most persons born between 1945 and 1958, with contamination of the human food chain representing the major source. The average

cumulative thyroid dose per capita is in the range of 1 to 4 rad, but the average dose for some regions is as high as 16 rad. Persons born between 1945 and 1958 who resided in high-deposition areas and consumed milk received much higher doses. Fortunately, the cumulative thyroid dose attributable to ^{131}I received by most persons in the United States appears to be relatively low.

In contrast to external neck irradiation, which is associated with thyroid carcinogenesis, thyroid radiation from ^{131}I has yet to be specifically linked to increased rates of thyroid cancer. Pediatric patients are underrepresented in existing radioepidemiologic incidence studies, however. High rates of pediatric thyroid cancers have been observed in regions affected by the Chernobyl nuclear disaster, and this is presumably because of exposure to ^{131}I, but other isotopes, carcinogenic compounds, and other factors might also contribute.

Neither the true extent of environmental contamination of the continental United States nor the health effect attributable to fallout from atmospheric nuclear testing has been satisfactorily reported.

Overall, thyroid cancer has an excellent prognosis, and this also appears true for younger patients.

Given the relatively low number of expected cases of thyroid cancer attributable to the identified ^{131}I contamination and the remarkably good prognosis of papillary and follicular thyroid cancer, the ^{131}I contamination associated with atmospheric nuclear bomb tests conducted from 1951 to 1958 cannot be viewed as a significant national health problem.

The NCI report largely ignores contamination attributable to other isotopes associated with atmospheric nuclear testing and completely ignores the potential adverse health effects of these isotopes.[2] In fairness, however, section 7(a) of Public Law 97-414 specifically targets ^{131}I and thyroid cancer. At the intersection of politics and science, some paths may indeed be blocked. The report does seem to invite exploration of the "blocked paths," however, as does section 7(b) of the same law. By highlighting sources of information and analytic techniques, the report illuminates despite its omissions.

Legitimate difficulties in assessing radiocarcinogenesis include the challenge of accurate dosimetry and the differing RBE attributable to various types of radiation, various isotopes, various dose rates, and other factors. Health effects from radiation are usually expressed in terms appropriate to mixed-source dosage (e.g., the sievert, which represents the absorbed tissue dose in grays multiplied by a weighting factor appropriate to the RBE of the radiation).[22] The report focuses on rad to the thyroid from ^{131}I alone.

The forthcoming Institute of Medicine report concerning health risks from the reported ^{131}I contamination must consider all the factors mentioned earlier, generating, it is hoped, more than a large question mark in the process.

As of this writing, no satisfactory report has been made of the true extent of environmental contamination of the continental United States or of the health effects attributable to fallout from atmospheric nuclear testing. Given social, legal, scientific, and political realities, such a report may never emerge.

Summary

Environmental ^{131}I contamination from atmospheric nuclear bomb tests conducted at the NTS from 1951 to 1958 exposed Americans nationwide to a cumulative average dose of 1 to 4 rad to the thyroid gland. By comparison, 10 years of exposure to natural background sources of thyroid radiation results in a cumulative dose of 1 rad.

Americans living in certain high-deposition areas received an average cumulative thyroid dose of as much as 16 rad. Individual dose rates vary considerably as a function of age at the time of exposure, site of residence, and dietary habits with respect to milk consumption. The individual cumulative thyroid dose for persons born between 1945 and 1958 may be significantly higher than the reported averages for their locale. The NCI report contains voluminous data tables permitting detailed calculations of individual dose. Additionally, color-coded dose maps allow one to approximate individual dose conveniently.

Translation of cumulative thyroid dose attributable to ^{131}I to predictions of increased rates of thyroid cancer appears problematic and is the subject of further study. In contrast to studies of patients receiving external thyroid irradiation, existing studies of patients treated with ^{131}I for diagnostic and therapeutic medical purposes do not document increased rates of thyroid cancer. An Institute of Medicine task force is expected to issue a report on this subject in September 1998.

This review also briefly summarizes the evaluation, diagnosis, and treatment of patients with papillary and follicular thyroid cancers. **Data from 53,856 patients with thyroid cancer accessioned to the NCDB from 1985 to 1995 document extremely high survival rates for patients in the United States with papillary and follicular thyroid cancer.**[20a] CA

References

1. Pub L No. 97-414 (HR 5238 Orphan Drug Act) §7a and §7b, amending §301 of the Public Health Service Act, 42 USC 241 (1983).
2. National Cancer Institute: Estimated Exposures and Thyroid Doses Received by the American People from Iodine-131 in Fallout Following Nevada Atmospheric Nuclear Bomb Tests. NIH Publication No. 97-4264. Available at: http://rex.nci.gov/massmedia/Fallout/index.html.
3. Thompson DE, Mabuchi K, Ron E, et al: Cancer incidence in atomic bomb survivors. Part II: Solid tumors, 1958-1987. Radiat Res 1994;137(Suppl 2):S17-S67.
4. Holm LE, Wiklund KE, Lundell GE, et al: Cancer risk in populations examined with diagnostic doses of 131-I. J Natl Cancer Inst 1989;81:302-306.
5. Holm LE, Wiklund KE, Lundell GE, et al: Thyroid cancer after diagnostic doses of iodine-131: A retrospective cohort study. J Natl Cancer Inst 1988;80:1132-1138.
6. Hall P, Mattsson A, Bioce JD Jr: Thyroid cancer after diagnostic administration of iodine-131. Radiat Res 1996;145:86-92.
7. Globel B, Globel H, Oberhausen E: Epidemiologic studies on patients with iodine-131 diagnostic and therapeutic exposure, in Kaul A, Neider R, Pensko J, et al (eds): Radiation Risk Protection, Vol. II, ed 5. Koln, Verlag TUV Rheinland, 1984, pp 565-568.
8. Holm LE, Hall P, Wiklund K, et al: Cancer risk after iodine-131 therapy for hyperthyroidism. J Natl Cancer Inst 1991;83:1072-1077.
9. Baverstock K, Egloff B, Pinchera A, et al: Thyroid cancer after Chernobyl. Nature 1992;359:21-22. Letter.
10. Malone J, Unger J, Delange F, et al: Thyroid consequences of Chernobyl accident in the countries of the European Community. J Endocrinol Invest 1991;14:701-717.
11. Furmanchuk AW, Averkin JI, Egloff B, et al: Pathomorphological findings in thyroid cancers of children from the Republic of Belarus: A study of 86 cases occurring between 1986 ('post-Chernobyl') and 1991. Histopathology 1992;21:401-408.
12. Grantt CS, Hay ID, Gough IR, et al: Long-term follow-up of patients with benign thyroid fine-needle aspiration cytologic diagnoses. Surgery 1989;106:980-985.
13. Hamburger JI: Consistency of sequential needle biopsy findings for thyroid nodules: Management implications. Arch Intern Med 1987;147:97-99.
14. Piromalli D, Martelli G, Del Prat al: The

role of fine needle aspiration in the diagnosis of thyroid nodules: Analysis of 795 consecutive cases. J Surg Oncol 1992;50:247-250.
15. Hamburger JI, Husain M: Semiquantitative criteria for fine-needle biopsy diagnoses: Reduced false-negative diagnosis. Diagn Cytopathol 1988;4:14-17.
16. Walfish PG, Hazani E, Strawbridge HT, et al: Combined ultrasound and needle aspiration cytology in the assessment and management of hypofunctioning thyroid nodule. Ann Intern Med 1977;87:270-274.
17. Jones AJ, Aitman TJ, Edmonds CJ, et al: Comparison of fine needle aspiration cytology, radiosotopic and ultrasound scanning in the management of thyroid nodules. Postgrad Med J 1990;66:914-917.
18. Gagel RF, Goepfert H, Callender DL: Changing concepts in the pathogenesis and management of thyroid carcinoma. CA Cancer J Clin 1996;46:261-283.
19. Shaha AR, Shah JP, Loree TR: Low-risk differentiated thyroid cancer: The need for selective management. Ann Surg Oncol 1997;4:328-333.
20. Mazzaferri EL, Jhiang SM: Long-term impact of initial surgical and medical therapy on papillary and follicular thyroid cancer. Am J Med 1994;97:418-428.
20a. Hundahl SA, Fleming I, Fremgen A, et al: 53,856 cases of thyroid cancer treated in the United States 85-95: A National Cancer Data Base report. Cancer, in press.
21. Ezaki H, Ishimaru T, Hayashi Y, et al: Cancer of the thyroid and salivary glands, in Shigematsu I, Kagan A (eds): Cancer in Atomic Bomb Survivors. New York, Plenum Press, 1986.
22. International Commission on Radiological Protection: 1990 Recommendations of the International Commission on Radiological Protection. Oxford, Pergamon Press, 1991.

American Cancer Society Great American Smokeout November 19, 1998

November 19, 1998, marks the 22nd year of the American Cancer Society's Great American Smokeout. This nationwide event is designed to help smokers quit and to call attention to tobacco control issues year round.

The Smokeout now also targets smokeless tobacco, second-hand smoke, and cigar smoking.

Nearly 70% of smokers report they want to quit smoking but cannot. Over the years, the Smokeout has provided an important impetus to help smokers quit the habit for good. Last year, 24% of smokers (about 11,280,000 people) reported they participated in the Smokeout, and of those, 19% reported they were smoking less or not at all up to 5 days later.

Further information, for both health professionals and patients, is available from your local American Cancer Society.

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Radiation-Induced Thyroid Cancer in Children After the Chernobyl Accident

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Editor's Summary: *In the aftermath of the tragic Chernobyl Nuclear Power Station accident, important new information has been gathered regarding the mechanisms of radiation-induced thyroid cancer. Careful statistical analyses have shown that the high incidence of thyroid cancer in children can be directly related to the geographic distribution of the fallout and is not simply a function of more careful screening procedures instituted following the accident. A set of distinguishing features characterized the tumors. Over 95% of the neoplasms were papillary in structure. An unexpectedly high prevalence of solid variant papillary tumors was found. Although several children have died as a result of the thyroid cancer, the overall prognosis of the remainder remains uncertain. The authors discuss current concepts of thyroid tumorigenesis at the molecular level. Radiation may lead directly to oncogenic mutations; alternatively, radiation-induced genomic instability may predispose to transforming mutations. Radiation-induced* ret *gene rearrangements also may play an important role in post-Chernobyl cancers, particularly the* ret/PTC3 *variety.*

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The Chernobyl accident took place in the former USSR on April 26, 1986, when an explosion and a subsequent fire at the 4th unit of the Chernobyl Nuclear Power Station destroyed the nuclear reactor core and released millions of curies of radioactive materials into the atmosphere.[1] **During the initial period after the accident, the most biologically significant isotopes released in the fallout were radioiodines, including about 40 million curies of ^{131}I and about 100 million curies of short-lived iodines (^{133}I and tellurium 132, a precursor of ^{132}I).[2]** The high temperatures generated by the reactor fire, and the volatility of the radioiodines, resulted in rapid dispersion of the isotopes into the atmosphere. **The areas adjacent to Chernobyl were probably exposed to greater levels of short-lived radioiodine isotopes, believed to have carcinogenic effects on the thyroid similar to those of instantaneous x-rays.[3]**

The significant delays in informing the public about the accident hampered attempts to administer potassium iodide (KI) prophylaxis within the affected communities. These efforts were largely initiated too late, and the distribution of KI reached only a minority of the population. Other efforts to shelter the population, to protect the food supply, and to evacuate the most contaminated areas were not implemented in a timely fashion. As a result, the absorption of radioiodines from ingestion of contaminated food and water and through

inhalation led to internal exposure to the thyroid gland, which was estimated to be 3 to 10 times higher in children than in adults. About 10% of the thyroid dose came from external irradiation.

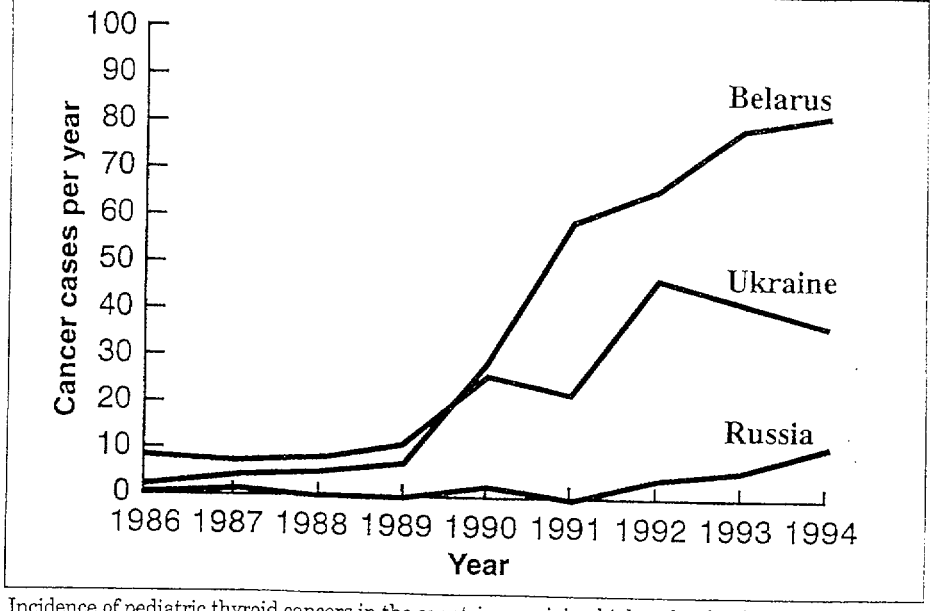
As a consequence of weather conditions immediately after the accident, most contaminated areas were located in the territory of the Republic of Belarus, especially in the Southern provinces, which lie immediately to the north of the Chernobyl plant. Current estimates suggest that thyroid doses in children younger than 7 years living in these areas were among the highest, and ranged between 15 and 100 cGy (1 Gy = 100 rads); about 10% of children received more than 500 cGy.[3] Other areas of significant contamination included regions of Northern Ukraine and Western Russia.

Plant workers were the first victims of the accident, and a number of them died of acute radiation sickness. So far, the expected increase in leukemia among the individuals exposed to the highest doses, such as those involved in the cleanup operations, has not materialized. The most significant health consequences relate to an increase in thyroid disease, which is the major focus of this review.

First Reports of Pediatric Thyroid Cancer

During the 4 years following the accident, substantial changes in thyroid function occurred in the exposed children, especially those less than 7 years of age.[4] Beginning in 1990, a dramatic increase in the frequency of pediatric thyroid cancer took place in Belarus,[5] with 424 new cases diagnosed between 1986 and 1995[6,7] (Figure 1). In other affected areas an increased rate of thyroid cancer was noted after a somewhat longer latency (between 1986 and 1994), with 118 cases diagnosed in five Northern regions of Ukraine and 23 cases in two Western regions of Russia.[7]

■ Figure 1



Incidence of pediatric thyroid cancers in the countries receiving highest levels of radiation contamination after the Chernobyl nuclear accident in 1986. Note the major increase beginning in 1990. The southernmost region of Belarus, immediately north of Chernobyl, was the most affected. Modified from Balter M.[5]

The initial reports of an increased incidence of thyroid carcinoma in children from the affected areas were greeted with considerable skepticism by the international community. This was in part due to the unprecedented short time after exposure, the sharp and progressive increase in thyroid cancer cases reported, and the absence of information about individual thyroid doses in the affected children. Skeptics attributed the supposedly greater incidence of thyroid cancer to heightened awareness, more careful surveillance by health agencies after the nuclear accident, or underestimation of the true incidence before the accident. From the perspective of a decade later, it is clear that the increased rate of pediatric thyroid cancer is real and that this phenomenon is due to the 1986 Chernobyl accident. The evidence in support of these statements follows:

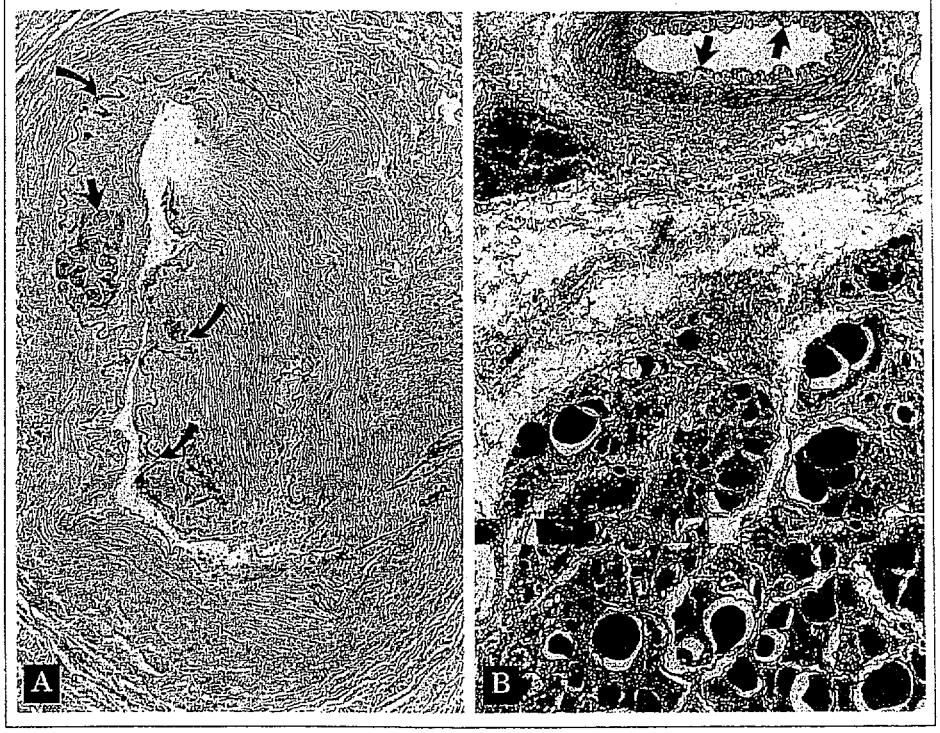
1. Sporadic thyroid carcinoma is a rare disease in children. The estimated annual incidence is 0.19 per million in children less than 15 years of age in England and Wales,[8] and 1 case per million in Norway.[9] In the United States, for the period from 1973 to 1982, there were 1.8 cases per million per year.[10] These data are similar to the incidence of pediatric thyroid carcinoma in Belarus before the accident, which was 0.4 cases per million children per year between 1976 and 1985.[11] By contrast, in 1991-1992, the total number of morphologically verified pediatric thyroid cancers was 116, with an incidence of 24.7 cases per million children per year; this represents a 62-fold increase in rate in 1991-1992 as compared to 1976-1985.[12] The numbers calculated for the Gomel region, the most highly contaminated by the fallout, are even more dramatic: 0.5 cases per million children per year in 1981-1985 and 96.4 in 1991-1994, representing a 193-fold increase.[7]

2. If intense screening were to have accounted for such high incidence, it should have resulted in the finding of a large number of early or occult tumors. To the contrary, post-Chernobyl thyroid cancers were mostly diagnosed at advanced stages of disease. Thus, in a consecutive series of 84 tumor operations in 1991 and 1992, 88% of patients had tumor nodules greater than 1 cm in diameter, and an identical proportion of the tumors presented with lymph node metastases.[12] About 42% of tumors removed between 1986 and 1992 showed extrathyroidal extension.[5]

3. The incidence of pediatric thyroid carcinomas was proportional to the levels of radioiodine contamination of particular areas. Thus, the incidence of thyroid carcinoma in Belarus was 19 per million children in areas of ^{131}I contamination levels of 5-10 Ci/km^2, 159 in areas with 40 to 50 Ci/km^2, 311 in areas with 50 to 100Ci/km^2, and 976 in areas with >100Ci/km^2.[13] Among 333 children with thyroid carcinoma operated in Belarus in 1986-1994, 54% resided at the time of the accident in the Gomel region, which is nearest to Chernobyl, whereas only 2% were from the Vitebsk region, which has a comparable population but did not experience significant radiation fallout.[13]

4. The thyroid doses reconstructed for 11 children with thyroid carcinoma ranged between 30 and 1000 cGy, mean 208±82 cGy.[13] Morphological examination of thyroid tissues adjacent to the tumor nodule revealed a high frequency of changes usually associated with radiation exposure, including interstitial perifollicular fibrosis, vascular injury, and follicular atrophy[12,14] (Figure 2). Although no single lesion is pathognomonic of radiation damage, the arterial wall fibrosis and calcification seen in the glands of many of these children is unusual in any other setting and is highly likely to be radiation-related. In addition, cytogenetic analysis of lymphocytes from children with thyroid carcinoma showed an increased incidence of other markers of radiation exposure, such as dicentric and ring chromosomes.[13]

■ Figure 2

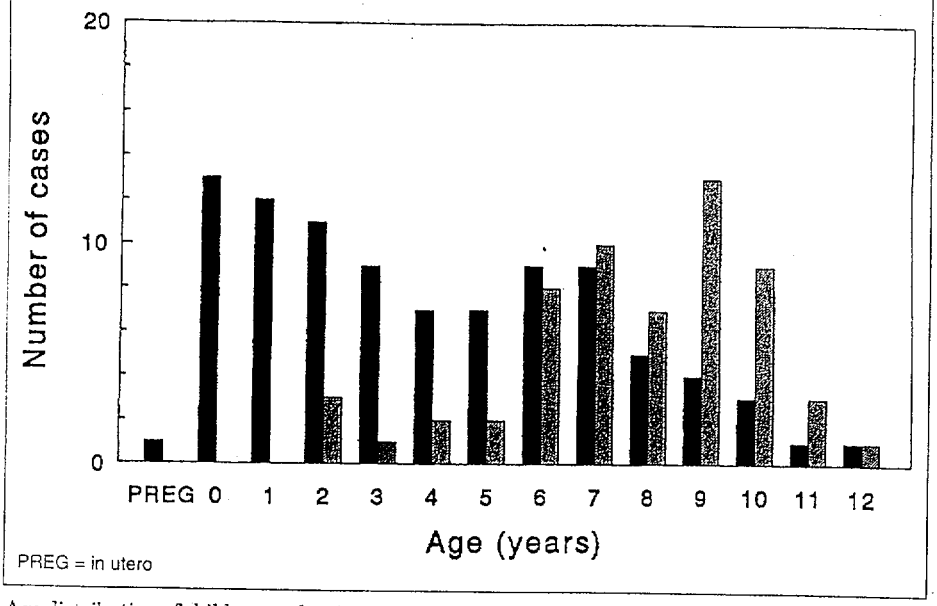


Non-neoplastic thyroid tissue in children with post-Chernobyl thyroid carcinomas showing extensive vascular injury and interstitial fibrosis, the changes most commonly seen after irradiation. **A**, Hematoxylin-eosin stain of perithyroidal muscular artery in an 11-year-old boy shows focal calcification of the vascular wall (straight arrow) and extensive calcification and disruption of the internal elastic membrane (curved arrows). **B**, Trichrome stain of thyroid gland from a 7-year-old girl shows thick fibrotic bands (green) surrounding thyroid follicles, and subintimal fibrosis (green, indicated by arrows) in a perithyroidal artery.

5. There was a characteristic age distribution of the children affected (Figure 3). Almost all thyroid cancers occurred in children already born or in a late stage of fetal development at the time of the accident. Thus, among 333 patients with thyroid carcinoma diagnosed in Belarussian children in 1986-1994, only 7 were born after the Chernobyl disaster.[7] The average age of patients at clinical presentation has tended to increase with time: it was 8.3±2.9 years in 1990, 9.0±2.9 years in 1991, and 10.4±2.7 years in 1992.

Based on this information, it is safe to conclude that the occurrence of pediatric thyroid carcinomas amid this population is directly associated with radiation exposure in April 1986. Other factors, including iodine deficiency in some areas in Southern Belarus, may have contributed to the promotion of thyroid tumorigenesis but are not likely to be primarily responsible for this phenomenon. This tragic accident has had devastating consequences for the surrounding population. It has also resulted in a unique group of patients with radiation-induced thyroid tumors, which will contribute significantly to the understanding of the mechanisms of radiation carcinogenesis.

■ Figure 3



Age distribution of children at the time of the Chernobyl accident in whom malignant and benign thyroid lesions subsequently developed. Black bars represent those subsequently affected by thyroid carcinomas; hatched bars represent patients subsequently affected by benign lesions as primary diagnosis. From Nikiforov et al[15] with permission.

Epidemiology

The prevalence of thyroid cancer in children from the affected areas was inversely associated with the distance from the Chernobyl nuclear plant and with levels of radioiodine contamination after the accident. In addition, the age of the children at the time of exposure was an important modulating factor. Thus, in a series of tumors operated on in 1991-1992, one patient may have been exposed in utero, whereas others were between 1 month and 12 years of age at the time of the accident.[15] The greatest number of patients who subsequently developed thyroid carcinomas were less than 1 year of age at the time of exposure, and the number decreased progressively through age 12 (Figure 3). Conversely, none of the children with benign thyroid lesion who underwent surgery during the same time period was less than 2 years of age at the time of exposure. Age 5 to 6 years at exposure was the threshold separating a statistically significant prevalence of malignant tumors in younger children from the more frequent benign lesions seen in older ones.

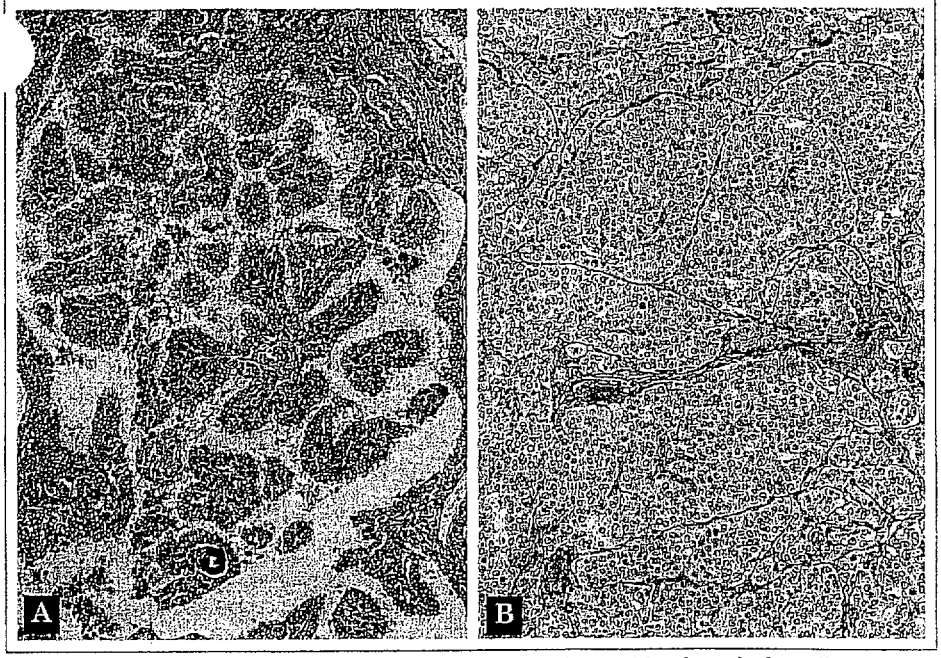
One possible explanation for the critical importance of the age at exposure may be differences in dose, since the thyroid dose was correlated inversely with age. It is not known whether older children may be more likely to develop cancers later in life, in a manner analogous to that seen in children exposed to therapeutic external radiation.[16] Sex distribution of post-Chernobyl thyroid tumors differed from that of spontaneous carcinomas. The female-male ratio was 1.6:1 among 427 children and adolescents from Belarus, in contrast with 2.5:1 among 346 unexposed patients of the same age from Italy and France.[17]

Pathological Features and Prognosis

Histologically, more than 95% of post-Chernobyl thyroid cancers were papillary carcinomas.[7,12] A distinguishing feature of these tumors is the high prevalence of solid pattern growth in the tumor nodule, which appears as sheets of malignant epithelial cells surrounded by varying amounts of fibrotic stroma (Figure 4). This contrasts with the characteristic papillary growth of sporadic tumors. Among 84 unselected cases operated on in Belarus between 1991 and 1992, solid variant papillary carcinomas (containing exclusively or predominantly solid areas of growth) were the most frequently observed, composing 34% of all tumors.[12] Another 12% contained some solid areas mixed with follicular and/or typical papillary components. Thus, a solid growth pattern was seen in almost half of all Chernobyl cancers. By contrast, this type of growth is rare in spontaneous papillary carcinomas in adults and children. For example, the solid variant was seen in only 4% of papillary carcinomas in children with no history of radiation exposure from two different regions in the United States.[18] Similar data were observed in post-Chernobyl tumors from Ukrainian patients when compared with sporadic tumors in patients from the United Kingdom.[19]

The particular phenotypic features of post-Chernobyl tumors raise concerns about the prognosis for these young patients. A solid or insular growth pattern is part of the diagnostic criteria of poorly differentiated thyroid carcinoma, a tumor with less favorable prognosis. However, other morphological features of poorly differentiated carcinoma, including

Figure 4



A, Microscopic appearance of typical papillary thyroid carcinoma. Note branched papillae with central fibrovascular cores covered by neoplastic epithelium. This pattern is the most prevalent among sporadic tumors in children and adults. B, Solid variant of papillary carcinoma composed of solid sheets of tumor cells separated by delicate fibrous layers. This growth pattern is predominant in post-Chernobyl thyroid cancers in children.

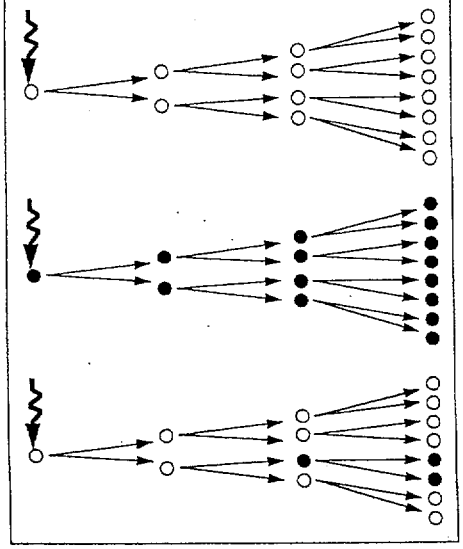
high mitotic activity, tumor necrosis, d distant metastasis, were absent in the post-Chernobyl tumors. In general, sporadic thyroid papillary carcinomas in children, but not in adults, are characterized by more aggressive growth characteristics and an advanced stage at the time of diagnosis. Nevertheless, the prognosis is extremely good.[20] In addition, the survival rate of thyroid carcinoma in patients with a history of external irradiation during childhood is not different from that of persons with sporadic tumors.[21] So far, several children with post-Chernobyl thyroid carcinomas have died of the disease,[2] but the overall prognosis is unclear.

Molecular Mechanisms of Radiation Tumorigenesis

biological effects of ionizing iation, including cell killing, mutagenesis, and transformation, are generally considered to originate from radiation-induced damage to DNA. Ionizing radiation results in single-strand and double-strand DNA breaks, as well as a wide range of base substitutions, insertions, and deletions.[22,23] The initial damage apparently occurs randomly throughout the genome, as demonstrated by tracking selected chromosomes from irradiated cells.[24] Complex enzymatic mechanisms restore normal DNA structure. Misrepair of double-strand DNA breaks probably is the major basis of mutation formation. In contrast, single-strand breaks and base pair changes are repaired rapidly and accurately by mechanisms that use the complementary undamaged strand as a template. However, discrete DNA abnormalities, such as point mutations and small deletions, do occur as sequelae of radiation exposure.

After a cell has been exposed to radiation, several outcomes are possible. In most cases, the mutations will be discrete enough to allow full repair, and thus fail to affect the genome at a critical site (Figure 5). Another possibility is that the damage may be overwhelming and that the cell will undergo apoptotic (programmed) cell death. For those cells destined to initiate a tumorigenic clone, two possible general mechanisms of radiation carcinogenesis have been proposed[25]: (1) Radiation may lead directly to oncogenic mutations by activating an oncogene or inactivating a tumor suppressor. All progeny of this cell will carry the same abnormality and thus initiate the path to malignancy. (2) Alternatively, it is possible that radiation does not directly target a cancer gene, but instead induces a state of genomic instability that is transmitted through subsequent cell

Figure 5



Hypothetical events leading to tumor formation after exposure to ionizing radiation. Top: Cell successfully repairs its DNA, with no consequences to its progeny. Middle: Radiation directly causes an oncogenic mutation, and the affected cell initiates the neoplastic clone. Bottom: Radiation destabilizes the cellular genome causing tumor formation. The cell is not immediately transformed but develops late tumorigenic mutations after a number of cell divisions, with consequent clonal expansion. Adapted from Little.[25]

divisions. This instability predisposes to multiple errors during DNA replication and/or mitosis, thus increasing the probability of later occurrence of transforming mutations. This sequence of events is designated as the delayed or "indirect" mechanism of radiation tumorigenesis. In this regard, Chernobyl-related cancers do not appear to exhibit microsatellite instability, a particular class of genomic destabilization characterized by DNA mismatch repair deficiency.[26] Our thinking in this area is largely based on in vitro experiments and has not been tested in vivo. Post-Chernobyl radiation-induced thyroid tumors offer a unique opportunity for validation or disproval of these hypotheses.

The *ras* Oncogene in Radiation-Induced Follicular Neoplasms

Some of the initial studies of the Chernobyl tumors have focused on the genes known to be mutated in the sporadic (ie, non–radiation induced) forms of the disease. One of the first to be explored was the proto-oncogene *ras*. A proto-oncogene is the normal counterpart of the cancer-producing oncogene carried by some retroviruses. *Ras* is a membrane-associated protein that transmits signals arising after ligand binding to tyrosine kinase receptors. These ligands include insulin, epidermal growth factor, and platelet-derived growth factor. In its inactive state, *ras* is bound to guanosine diphosphate (GDP). After activation, *ras* releases GDP and binds GTP, and it becomes the bridge to a series of serine-threonine kinases that further transmit and distribute the signal.

Point mutations in discrete domains within the oncogene *ras* that increase its affinity for GTP, or inactivate the autocatalytic GTPase function of the protein, permanently switch the protein to the "on" position. *Ras* mutations are common in many types of benign and malignant neoplasms, including those of the thyroid, colon, bladder, and pancreas. Point mutations of the three *ras* genes are reported in 18% to 62% of papillary thyroid carcinoma and with even greater prevalence in follicular thyroid tumors (reviewed in reference 27). Even more important, several investigators have proposed a role for *ras* mutations, with a predilection for the subtype K-*ras*, in radiation-induced thyroid tumors.[28-30]

The prevalence of *ras* mutations in post-Chernobyl tumors was studied in a series of 33 papillary carcinomas, 1 follicular carcinoma, and 22 benign nodular lesions from Belarussian children.[31] In contrast with previous reports, post-Chernobyl papillary carcinomas in children did not exhibit mutations of N-, H-, or K-*ras*. Therefore, *ras* oncogenes do not appear to be mediators of radiation-induced papillary thyroid cancer formation. However, *ras* point mutations were detected in 1/1 case of follicular carcinoma (N-*ras* codon 61 $CAA^{gln} \rightarrow AAA^{lys}$), and in 3/7 follicular adenomas (N-*ras* codon 61 $CAA^{gln} \rightarrow CGA^{arg}$ - two, $CAA^{gln} \rightarrow AAA^{lys}$); presence of the mutation suggests a possible role of this genetic event in the origin of follicular thyroid tumors. Indeed, although the number of tumors studied was small, it is conceivable that radiation may induce at least two distinct pathways of tumor initiation, and that *ras* activation through point mutations may predispose to formation of follicular-type thyroid neoplasms.

Absence of p53 Mutations in Post-Chernobyl Thyroid Cancers

The most commonly mutated gene in human cancer is p53. The p53 protein is involved with the cell cycle machinery, largely by its ability to transactivate expression of genes coding for proteins such as p21/WAF1, which induce G1 arrest by inhibiting cyclin-dependent kinase complexes. In addition, p53 can help trigger a program of apoptosis. The ability to arrest the cell cycle and, under certain conditions, to activate a program of cell death places p53 at a major crossroads in the determination of cell survival.

Levels of p53 increase after exposure to agents that induce DNA damage, such as ionizing radiation, and certain drugs used in cancer therapy. Presumably, p53 acts to allow DNA repair to proceed under more favorable conditions. However, if the damage is severe, p53 can initiate apoptosis so as to prevent perpetuation of the flawed cell. Inactivating point mutations of the p53 tumor suppressor gene are highly prevalent in anaplastic and poorly differentiated thyroid tumors, but not in well-differentiated papillary or follicular carcinomas (reviewed in reference 27). However, as was discussed, papillary carcinomas in children after Chernobyl are characterized by a high prevalence of solid growth and other features of advanced disease. In addition, p53 mutations have been reported with a high frequency in radon-associated lung cancers in uranium miners.[32,33]

Somatic point mutations of p53 were found in only 1/33 Chernobyl-related papillary carcinomas: a missense mutation in exon 5 (codon 160

ATG^{met}→GTG^{val}).[31] One tumor had a ...nt mutation of unknown signifi...ice (codon 182, TGC^{cys}→TGT^{cys}). More recently, absence of p53 mutations was also reported in another series of 34 tumors from Belarus and Ukraine.[34] These data indicate that inactivation of the p53 tumor suppressor gene is not involved in radiation-induced papillary thyroid tumor formation. It should be said that, by and large, these cancers were removed relatively early in their progression. We cannot exclude the possibility that in the future, cancers removed at a more advanced stage may acquire p53 mutations as part of their microevolution.

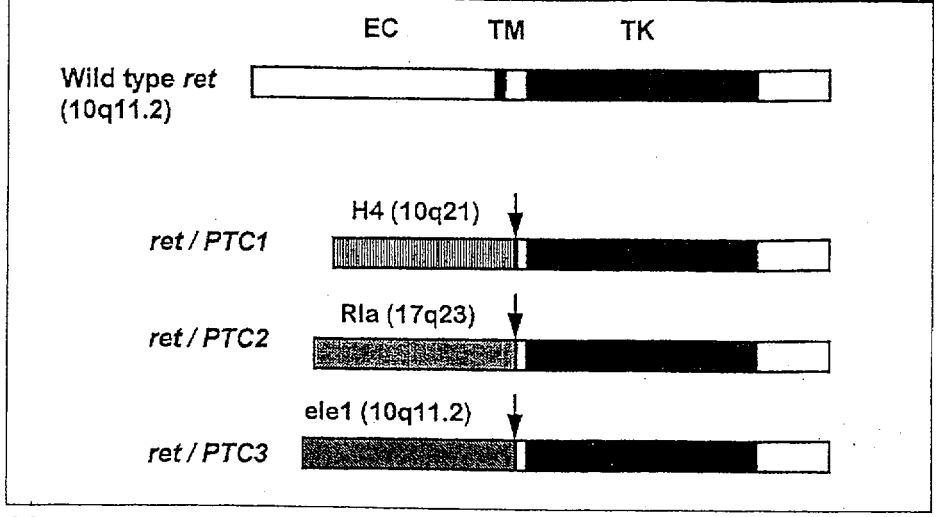
Activation of *ret* in Post-Chernobyl Thyroid Cancers

Ret is an important membrane recep...n cells of neuroendocrine lineage, ...as the parafollicular C cells. This gene is not normally expressed in thyroid follicular cells. A chromosomal rearrangement linking the promoters of unrelated genes to the C-terminal fragment of *ret* results in the aberrant production of a truncated form of the receptor in thyroid cells. This chimeric protein contains the region involved in the transmission of the growth signal, but it lacks the sites allowing signal reception (ligand binding) and anchorage to the plasma membrane. The mutant *ret* is then able to activate downstream effectors in an unregulated fashion.

At least three types of *ret* rearrangements are found in human thyroid papillary carcinomas. These are formed by the fusion of the intracellular tyrosine kinase domain of the gene with different 5′ gene fragments. (Figure 6) *Ret/PTC1* is formed by a para...c inversion of the long arm of ...omosome 10 leading to fusion with a gene named *H4/D10S170*.[35] *Ret/PTC3* is also a result of an intrachromosomal rearrangement and is formed by fusion with the *RFG/ELE1* gene.[36,37] *Ret/PTC2* is formed by a reciprocal translocation between chromosomes 10 and 17, resulting in the juxtaposition of the tyrosine kinase (TK) domain of c-*ret* with a portion of the regulatory subunit of *RIα* cAMP-dependent protein kinase A.[38] In all cases, the truncated fragment of *ret* lacks the transmembrane domain, and the aberrant protein is located within the cytosol.[39] The expression of this chimeric product is driven by the respective promoters of the genes upstream of the rearrangement. Rearrangements of *ret* are found in less than half of papillary carcinomas in the adult population (reviewed in reference 40).

By contrast, a high prevalence of *ret* rearrangements has been reported in post-Chernobyl papillary carcinomas[18,41,42] (Table 1). Three separate

■ Figure 6



Schematic representation of the wild-type *ret* gene and activated forms of *ret/PTC* rearrangements (*ret/PTC1*, *ret/PTC2*, and *ret/PTC3*) in human papillary thyroid carcinomas. (EC, extracellular domain; TM, transemembrane domain; TK, tyrosine kinase domain of *ret*). Hatched and crossed hatched boxes indicate regions contributed by the chimeric partners of *ret*. Arrows indicate the breakpoints.

■ Table 1

Prevalence of *ret* Rearrangements in Radiation-Induced and Sporadic Pediatric Thyroid Papillary Carcinomas

Occurrence	Number of cases studied	*ret/PTC1*	*ret/PTC2*	*ret/PTC3*
Radiation-induced				
Fugazzola et al[41]	6	0	1(17%)	3(50%)
Klugbauer et al[42]	12	2(17%)	0	6(50%)
Nikiforov et al[18]	38	6(16%)	1(3%)	22(58%)
Sporadic				
Nikiforov et al[18]	17	8(47%)	0	3(18%)
Bongarzone et al[40]	9	3(33%)	2(22%)	1(11%)

■ Table 2

Prevalence of ret Rearrangements in Morphological Variants of Pediatric Papillary Carcinomas*

Morphological Variant	Number of cases	*ret/PTC1*	*ret/PTC2*	*ret/PTC3*
Typical papillary	21	8 (38%)	1 (5%)	4 (19%)
Solid and mixed	17	1 (6%)	0	14 (82%)

* Modified from Nikiforov et al[18]

studies analyzed a total of 56 cases, 73% of which were positive for one of the three types of *ret/PTC*. Prevalence of *ret/PTC* may be even higher amid this population, since some tumors appeared to have *ret/PTC3* variants that were not resolved with the initial screening strategies.[18,43,44]

How do the findings in the pediatric thyroid carcinomas consequent to Chernobyl compare to papillary cancers from unexposed children? The ideal "nonexposed" control population should be matched for age, sex, and ethnicity and geographical area. Such comparison was not feasible because of the very low prevalence of pediatric thyroid cancer in Belarus before 1986, and because of the difficulty in accessing suitable samples. We therefore examined thyroid carcinomas arising in age-matched children from Cincinnati and Los Angeles.[18] Interestingly, the prevalence of *ret* rearrangements was very high in both radiation-exposed and sporadic cases, but the frequency of specific types of rearrangement was significantly different (see Table 1). The dominant chimeric gene in the radiation-induced tumors was *ret/PTC3*, whereas *ret/PTC1* was more common in the sporadic cancers. Similar data on predominance of *ret/PTC1* over *ret/PTC3* in sporadic pediatric thyroid carcinomas has been reported in Italian children and adolescents younger than 19 years,[45] indicating that regional variations are not a likely explanation for the predilection for *ret/PTC1* in cancers arising in the absence of documented radiation exposure.

These data indicate that radiation exposure may favor formation of a particular fusion gene (ie, *ret/PTC3* over *ret/PTC1*), and they raise the question of whether this predilection has any phenotypic consequences. Interestingly, morphological variants of papillary carcinoma showed differences in prevalence of the specific types of *ret* rearrangement (Table 2).[18] Solid variant tumors had a striking preponderance of *ret/PTC3*, whereas *ret/PTC1* was associated more commonly with typical papillary carcinomas both in radiation-induced and sporadic groups. Although both the *ret/PTC1* and *ret/PTC3* gene products result in overexpression of the tyrosine kinase domain of the *ret* receptor, they differ in the structure of the N-terminus (donated by the respective partner in the chimera) and, presumably, in the activities of the promoters of the H4 and ele1 genes that drive expression of the fusion protein (see Figure 6). Further support for the concept that the different *ret* fusion genes may have distinct functional properties is provided by preliminary evidence that *ret/PTC3*-positive tumors may have more aggressive growth characteristics.[46]

It remains unclear whether *ret* rearrangements are a direct result of radiation-induced DNA damage or if they occur later in the evolution of the neoplastic clone. Occurrence of *ret/PTC1* rearrangements has been demonstrated in cultured human undifferentiated thyroid carcinoma and fibrosarcoma cells harvested 48 hours after x-irradiation with 50 and 100 Gy.[47] However, these data were obtained in vitro on clonal carcinoma cell lines that presumably have a fairly unstable genome, after exposure to very high levels of radiation, and it is premature to extrapolate these findings to the in vivo setting.

Cancer Susceptibility and Radiation Exposure

Although exposure of children in the affected territories was widespread, only a minority was affected with thyroid cancer with the unusually short latency described here. The explanations for this are likely to be complex and may include differences in individual susceptibility to carcinogenic effects of radiation. Several cases were reported in siblings, reflecting either higher levels of exposure or a familial predisposition to neoplasia.[48] Well-recognized human genetic disorders, such as ataxia-telangiectasia, xeroderma pigmentosum, and trichothiodystrophy, are characterized by defective DNA repair and increased sensitivity to ionizing and/or ultraviolet (UV) radiation.[49]

As mechanisms controlling mammalian DNA repair become better understood, perhaps other, subtler defects conferring genetic predisposition to radiation-induced neoplasia will be discovered. If so, the experience of the Chernobyl population may prove to be particularly informative in this regard.

Lessons From the Chernobyl Experience

Recent disclosures indicate that a significant segment of the US population was exposed to radioiodines by the series of nuclear bomb explosions at the Nevada test site in the 1950s.[50] Predictions of excess relative risk of thyroid cancer vary but may prove to be significant. However, at present it is not possible to determine whether individual tumors arose as a result of radiation or as sporadic events.

By contrast, the accident at Chernobyl has resulted in the most clearly defined epidemiological connection between radiation exposure and solid tumor formation in humans; all but a few cases of cancer in this population are likely to have been directly caused by the nuclear catastrophe. It will be interesting to determine whether some of the characteristics of the post-Chernobyl tumors (high prevalence of solid variant papillary carcinomas, predilection for *ret/PTC3* rearrangements) are truly signature events of radiation-induced tumors and whether they apply to thyroid cancers arising in other radiation-exposed populations.

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References

1. Ilyin LA, Balonov MI, Buldakov LA, Bur'yak VN, Gordeev KI, Dement'ev SI, Zhakov IG, Zubovsky GA, Kondrusev AI, Konstantinov YO, Linge II, Likhtarev IA, Lyaginskaya AM, Matyuhin VA, Pavlovsky OA, Potapov AI, Prysyazhnyuk AE, Ramsaev PV, Romanenko AE, Savkin MN, Starkova NT, Tron'ko ND, Tsyb AF: Radiocontamination patterns and possible health consequences of the accident at the Chernobyl nuclear power station. *J Radiol Prot* 1990;10:13-29.

2. Robbins J: Lessons from Chernobyl: the event, the aftermath fallout: radioactive, political, social. *Thyroid* 1997; 7: 189-192.

3. Becker DV, Robbins J, Beebe GW, Bouville AC, Wachholz BW: Childhood thyroid cancer following the Chernobyl accident. A status report. *Endocrinol Metab Clin North Am* 1996;25:197-211.

4. Astakhova LN, Demidchuk EP, Davydova EV, Arinchin AN, Gres' NA, Zelenko SM: Health status of Byelorussian children and adolescents exposed to radiation as consequence of the Chernobyl AES accident (in Russian). *Vestn Akad Meditsinskikh Nauk SSSR* 1991;11:25-27.

5. Kazakov VS, Demidchik EP, Astakhova LN: Thyroid cancer after Chernobyl. *Nature* 1992;359:21.

6. Balter M. Chernobyl's thyroid cancer toll. *Science* 1995;270:1758-1759.

7. Stsjazhko VA, Tsyb AF, Tronko ND, Souchkevitch G, Baverstock KF: Childhood thyroid cancer since accident at Chernobyl. *BMJ* 1995;310:801.

8. De Keyser LFM, Van Herle AJ: Differentiated thyroid cancer in children. *Head Neck Surg* 1985;8:100-114.

9. Akslen LA, Haldorsen T, Thoresen SO, Glattre E: Incidence of thyroid cancer in Norway 1970-1985. Population review of time trend, sex, age, histological type and tumor stage in 2625 cases. *APMIS* 1990;98:549-558.

10. Young JL, Ries LG, Silverberg E, Horm JW, Miller RW: Cancer incidence, survival, and mortality for children younger than 15 years. *Cancer* 1986;58:598-602.

11. Okeanov AE, Averkin YI: In: Matyukhin VA, Astakhova LN, Konigsberg YE, Nalivko SN, eds. *Catastrophe at the Chernobyl AES and Estimation of Health State of Population of the Republic of Belarus.* Minsk: Research Institute of Radiation Medicine, 1991;25-33.

12. Nikiforov Y, Gnepp DR: Pediatric thyroid cancer after the Chernobyl disaster. Pathomorphologic study of 84 cases (1991-1992) from the Republic of Belarus. *Cancer* 1994;74:748-766.

13. Medical consequences of the catastrophe at the Chernobyl AES in Belarus. In: Konoplia EF, Rolevitch IB, eds. *Ecological, Medical-Biological and Social-Economical Consequences of the Catastrophe at the Chernobyl AES in Belarus.* Minsk: Ministry for Emergency Situations and Protection of Population from the Consequences of the Catastrophe at the Chernobyl AES of the Republic of Belarus & Institute of Radiobiology of Academy of Science of Belarus; 1996;103-214.

14. Nikiforov Y, Heffess CS, Korzenko AV, Fagin JA, Gnepp DR: Characteristics of follicular tumors and non-neoplastic thyroid lesions in children and adolescents exposed to radiation after the Chernobyl disaster. *Cancer* 1995;76:900-909.

15. Nikiforov Y, Gnepp DR, Fagin JA: Thyroid lesions in children and adolescents after the Chernobyl disaster: implications for the study of radiation carcinogenesis. *J Clin Endocrinol Metab* 1996;81:9-14.

16. Schneider AB, Ron E, Lubin J, Stovall M, Gierlowski TC: Dose-response relationships for radiation-induced thyroid cancer and thyroid nodules: evidence for the prolonged effects of radiation on the thyroid. *J Clin Endocrinol Metab* 1993;77:362-369.

17. Pacini F, Vorontsova T, Demidchik E, Molinaro E, Agate L, Romei C, Shavrova E, Cherstvoy E, Ivashkevitch Y, Kuchinskaya E, Schlumberger M, Rouga G, Felesi M, Pinchera A: Post-Chernobyl thyroid carcinoma in Belarus children and adolescents: comparison with naturally occurring thyroid carcinoma in Italy and France. *J Clin Endocrinol Metab* 1997;82:3563-3569.

18. Nikiforov YE, Rowland JM, Bove K, Monforte-Munoz H, Fagin JA: Distinct

pattern of *ret* oncogene rearrangements in morphologic variants of radiation-induced and sporadic thyroid papillary carcinomas in children. *Cancer Res* 1997;57:1690-1694.

19. Bogdanova T, Bragarnik M, Tronko ND, Harach HR, Thomas GA, Williams ED: Thyroid cancer in the Ukraine post Chernobyl. *Thyroid* 1995; 5(suppl 1):S-28. Abstract.

20. Zimmerman D, Hay ID, Gough IR, Goellner JR, Ryan JJ, Grant CS, McCoughey WM: Papillary thyroid carcinoma in children and adults: long-term follow-up of 1039 patients conservatively treated at one institution during three decades. *Surgery* 1988;104:1157-1166.

21. Schneider AB, Pinsky S, Bekerman C, Ryo UY: Characteristics of 108 thyroid cancers detected by screening in a population with a history of head and neck irradiation. *Cancer* 1980;46:1218-1227.

22. Ward JF: DNA damage produced by ionizing radiation in mammalian cells: identities, mechanisms of formation and repairability. *Progr Nucleic Acids Mol Biol* 1988;35:95-125.

23. Goodhead DT: The initial physical damage produced by ionizing radiation. *Int J Radiat Biol* 1989;56:623-634.

24. Kovacs MS, Evans JW, Johnstone IM, Brown JM: Radiation-induced damage, repair and exchange formation in different chromosomes of human fibroblasts determined by fluorescence in situ hybridization. *Radiat Res* 1994;137:34-43.

25. Little JB: Failla Memorial Lecture: Changing views of cellular radiosensitivity. *Radiat Res* 1994;140:299-311.

26. Nikiforov YE, Brenta G, Fagin JA: Genomic instability in radiation-induced and sporadic thyroid tumors: thyroid cancers exhibit large-scale genomic abnormalities but not microsatellite instability. The Endocrine Society, 78th Annual Meeting (Abstract), 1996;P3-824.

27. Fagin JA: In: Braverman LE, Utiger RD, eds. *Werner and Ingbar's. The Thyroid. A Fundamental and Clinical Text*. Philadelphia: Lippincott-Raven, 1996;909-915.

28. Lemoine NR, Mayall ES, Williams [illegible], Thurston V, Wynford-Thomas D: Agent-specific *ras* oncogene activation in rat thyroid tumours. *Oncogene* 1988;3 541-544.

29. Wright PA, Williams ED, Lemoine NR, Wynford-Thomas D: Radiation-associated and 'spontaneous' human thyroid carcinomas show a different pattern of *ras* oncogene mutation. *Oncogene* 1991;6:471-473.

30. Challeton C, Bounacer A, Du Villard JA, Caillou B, De Vathaire F, Mouier R, Schlumberger M, Suarez HG: Pattern of *ras* and *gsp* oncogene mutations in radiation-induced human thyroid tumors. *Oncogene* 1995;11:601-603.

31. Nikiforov YE, Nikiforova M, Gnepp DR, Fagin JA: Prevalence of mutations of *ras* and *p53* in thyroid tumors from children exposed to radiation after Chernobyl. *Oncogene* 1996;13:687-693.

32. Vahakangas KH, Samet JM, Metcalf RA, Welch JA, Bennett WP, Lane DP, Harris CC: Mutations of *p53* and *ras* genes in radon-associated lung cancer from uranium miners. *Lancet* 1992;339:576-580.

33. Taylor JA, Watson MA, Devereux TR, Michels RY, Saccomanno G, Anderson M: Mutational hotspot in the *p53* gene in radon-associated lung tumors from uranium miners. *Lancet* 1993;343:86-87.

34. Williams ED: Pathology and molecular biology of post-Chernobyl thyroid carcinoma. *J Endocrinol Invest* 1996;6(suppl):4. Abstract.

35. Grieco M, Santoro M, Berlingieri MT, Melillo RM, Donghi R, Bongarzone I, Pierotti MA, Della Porta G, Fusco A, Vecchio G: PTC is a novel rearranged form of the *ret* proto-oncogene and is frequently detected in-vivo in human thyroid papillary carcinomas. *Cell* 1990;60:557-563.

36. Santoro M, Dathan NA, Berlingieri MT, Bongarzone I, Paulin C, Grieco M, Pierotti MA, Vecchio G, Fusco A: Molecular characterization of *RET/PTC3*: a novel rearranged version of the RET proto-oncogene in a human thyroid papillary carcinoma. *Oncogene* 1994;9: 509-516.

37. Minoletti F, Butti MG, Coronelli S, Miozzo M, Sozzi G, Pilotti S, Tunnacliffe A, Pierotti MA, Bongarzone I: The two genes generating *RET/PTC3* are localized in chromosomal band 10q11.2. *Genes Chromosomes Cancer* 1994;11:51-57.

38. Bongarzone I, Monzini N, Borello G, Carcano C, Ferraresi G, Alrighi E, Mondellino P, Della Porta G, Pierotti MA: Molecular characterization of a thyroid tumor-specific transforming sequence formed by the fusion of *ret* tyrosine kinase and the regulatory subunit Rlα of cyclic AMP-dependent protein kinase A. *Mol Cell Biol* 1996;13:358-366.

39. Lanzi C, Borrello MG, Bongarzone I, Migliazza A, Fusco A, Grieco M, Santoro M, Gambetta RA, Zunino F, Della Porta G, Pierotti MA: Identification of the product of two oncogenic rearranged forms of the *RET* proto-oncogene in papillary thyroid carcinomas. *Oncogene* 1992;7:2189-2194.

40. Sugg SL, Zheng L, Rosen IB, Freeman JL, Ezzat S, Asa SL: *Ret/PTC-1, -2*, and *-3* oncogene rearrangements in human thyroid carcinomas: implications for metastatic potential? *J Clin Endocrinol Metab* 1996;81:3360-3365.

41. Fugazzola L, Pilotti S, Pinchera A, Vorontsova TV, Mondellini P, Bongarzone I, Greco A, Astakhova L, Butti MG, Demidchik EP, Pacini F, Pierotti MA: Oncogenic rearrangements of the RET proto-oncogene in papillary thyroid carcinomas from children exposed to the Chernobyl nuclear accident. *Cancer Res* 1995;55:5617-5620.

42. Klugbauer S, Lengfelder E, Demidchik EP, Rabes HM: High prevalence of *RET* rearrangement in thyroid tumors of children from Belarus after the Chernobyl reactor accident. *Oncogene* 1995;11:2459-2461.

43. Fugazzola L, Pierotti MA, Vigano E, Pacini F, Vorontsova TV, Bongarzone I: Molecular and biochemical analysis of *RET/PTC4*, a novel oncogenic rearrangement between *RET* and ELE1 genes, in a post-Chernobyl papillary thyroid cancer. *Oncogene* 1996;13:1093-1097.

44. Klugbauer S, Lengfelder E, Demidchik EP, Rabes HM: A new form of *RET* rearrangement in thyroid carcinomas of children after the Chernobyl reactor accident. *Oncogene* 1996;13:1099-1102.

45. Bongarzone I, Fugazzola L, Vigneri P, Mariani L, Mondellini P, Pacini F, Basolo F, Pinchera A, Pilotti S, Pierotti MA: Age-related activation of the tyrosine kinase receptor protooncogenes *RET* and NTRK1

in papillary thyroid carcinoma. *J Clin Endocrinol Metab* 1996;81:2006-2009.

46. Nikiforov YE, Fagin JA, Biddinger P: sociation of different *ret/PTC* arrangements with behavior and morphology of pediatric papillary thyroid carcinomas. (Abstract). *Mod Pathol* 1998;11:58A.

47. Ito T, Seyama T, Iwamoto KS, Hayashi T, Mizuno T, Tsuyama N, Dohi K, Nakamura N, Akiyama M: *In vitro* irradiation is able to cause *RET* oncogene rearrangement. *Cancer Res* 1993;53:2940-2943.

48. Nikiforov YE, Fagin JA: Prevalence, significance, and biologic behavior of *ret/PTC*-associated papillary thyroid carcinoma—Author's response. *J Clin Endocrinol Metab* 1997;82:2016-2017. Letter.

49. Murnane JP, Kapp LN: A critical look at the association of human genetic syndromes with sensitivity to ionizing radiation. *Semin Cancer Biol* 1993;4:93-104.

50. Estimated Exposures and Thyroid Doses Received by the American People from Iodine-131 in Fallout Following Nevada Atmospheric Nuclear Bomb Tests. tional Cancer Institute Report, 1997.

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DELAWARE STATE BOARD OF PHARMACY
JESSE S. COOPER BUILDING, ROOM 205
FEDERAL AND WATER STREETS
DOVER, DELAWARE 19901

TELEPHONE: (302) 739 - 4708
FAX: 739 - 3071

September 23, 1998

Mr. Aby Moseini, Division of Incident Response
Office for Analysis and Evaluation of Operative Data
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Comments on NUREG- 1633 Assessment of the Use of Potassium Iodide

Dear Mr. Moseini:

This correspondence is pursuant to the request for comments made by the Nuclear Regulatory Commission (NRC) regarding the use and distribution of KI. The Delaware Board reviewed this issue at their regularly scheduled meeting of September 9, 1998. As Executive Secretary, and at the Board members' request, I forward their comments and concerns.

- It is admirable that the NRC takes active steps in this area. However, the Board feels that the highest priority should be given to evacuation not to administration and distribution of KI. KI should be utilized after evacuation, when exposure is an issue, under proper guidance of medically related personnel.

- There are a number of pharmacologically related issues which are raised with NRC's plans. The Board has concerns with issues centering around:
  - KI side effects
  - KI contraindications
  - Patient compliance and proper labeling
  - Non-medical distribution and administration
  - Patients education relating to factors of KI protection and false assurities

Should you wish to contact us further in the above regards, please do not hesitate.

Sincerely,

David W. Dryden, R.Ph., J.D.
Executive Secretary

DWD:ks moseini.ltr

cc: Mary Lou Hurd, Board President
David Hake, DEMA
File (Board)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 28, 1998

Frank J. Congel, Director
Incident Response Division
Office for Analysis and Evaluation of Operational Data
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Dr. Congel:

I am writing in response to your letter of August 4, 1998, in which you shared the Nuclear Regulatory Commission's draft report of July 1998 entitled, "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents (NUREG-1633). Thank you for sharing this draft with the Food and Drug Administration (FDA). I have consulted the officials most directly involved with KI products in the Center for Drug Evaluation and Research, and they have reviewed the draft NUREG-1633 in relation to the FDA's 1978 notice regarding KI as a thyroid-blocking agent in radiation emergencies (43 FR 58798-58000, December 15, 1978).

We acknowledge the excellent questions you raised in your report and your letter, in particular, your request for updated recommendations. At the present time, however, we have no new information and therefore can make no new recommendations regarding the use of KI in potential radiation emergencies. Your draft report and our review highlight several questions that should be addressed in order to complete the development and implementation of any public protective policy involving KI, questions which were not been addressed in our earlier 1978 notice but would likely need to be updated now in any case. These questions include, but are certainly not limited to, the implications of any recommendations for patients with contraindicating conditions and especially for young children. The FDA would also have to consider any regulatory action that might be required of us in support of any policy adopted in final form.

We are at present unable to answer these questions and would welcome further collaboration with you and your office in order to address them. Please feel free to contact me at CDER (HFD-001), 1451 Rockville Pike, Rockville, MD, 20857 or telephone 301/594-5400.

Sincerely,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

OHIO DEPARTMENT OF HEALTH

246 N. High Street
Post Office Box 118
Columbus, Ohio 43266-0118
Telephone 614 466-3543

GEORGE V. VOINOVICH
Governor

A. LEE FISHER
Director of Health

September 16, 1998

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTENTION: Docketing and Services Branch

Dear Mr. Hoyle:

Subject: **Comments by Dr. Ernest L. Mazzafferri, M.D. to Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Core Accidents."**

The attached set of comments are being forwarded to you on behalf of Dr. Ernest L. Mazzaferri, M.D. These are being forwarded in response to the USNRC request for comments, published in the Federal Register, Notice 63FR38865, dated July 20, 1998.

Dr. Mazzaferri is Professor of Internal Medicine and Physiology, Chairman of Internal Medicine, The Ohio State University, Department of Medicine. He is a leading expert on thyroid disease and serves on the National Academy of Science committee that reviews data on thyroid effects from U.S. atomic bomb fallout and effluents from federal high-level waste and spent fuel reprocessing facilities. In our view, Dr. Mazzaferri is highly qualified to give expert opinion on this matter; and therefore, we solicited his comments to the draft NUREG-1633 by our letter to him, which is also attached, and which asks him to respond to certain questions that we posed to him. Both letters are being forwarded, in order that you may have a complete understanding of the questions posed and Dr. Mazzaferri's response.

Sincerely,

Roger L. Suppes

Roger L. Suppes, Chief
Bureau of Radiation Protection

RLS/HBB/hb
File: ki\mazza-com.trn

Attachment

pc: Ernest L. Mazzaferri, OSU
Deborah L. Arms, ODH, Prevention
Harvey B. Brugger, ODH-BRP
Frank J. Congel/Aby S. Mosheni, NRC-AEOD

OHIO STATE
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September 14, 1998

Roger L. Suppes
Chief, Bureau of Radiation Protection
Ohio Department of Health
246 N. High Street
P O Box 118
Columbus, OH 43266-0118

Re: Use of Potassium Iodide by the Public in the Event of a Nuclear Power Plant Accident

Dear Mr. Suppes:

I have reviewed the documents that you sent me concerning an analysis of potassium iodide (KI) prophylaxis for the general public in the event of a nuclear accident. I will try to answer the questions that you posed to me in your letter of August 24, 1998.

The first question you asked me to comment upon was the proposed projected dose level for taking potassium iodide. The Chernobyl accident clearly indicates that the risk of thyroid cancer only occurs in children, mainly those under age 10. After age 15, there was no increase in the incidence of thyroid cancer in adults. The levels of radiation, namely 5 REM in children and 25 REM in adults, is a very conservative estimate that is likely to be below the dose necessary to induce cancer. The data for children, the main population for which preventive therapy should be targeted, probably is around 10 REM and higher.

2. I do not think that it is necessary for the entire exposed population to take potassium iodide. The risk is mainly in children under the age of 15 and in pregnant women. I think the risk of ingesting potassium iodide to the remainder of the population would, on balance, equal or exceed that posed by a risk of radiation-induced thyroid cancer caused by I-131.

3. The major risk in taking potassium iodide is in pregnant women or those who are lactating or breastfeeding. Prolonged use of potassium iodide will cause a goiter for children in either situation. However, the acute use of potassium iodide over one or two days is not normally associated with this problem and would not pose an unduly large risk to pregnant women or those who are lactating. The doses that you mentioned in your memorandum, one-half tablet to babies under one year of age and one 130 mg tablet to children over this age, should not pose a serious risk of thyroid disease in these children. This is exactly the group who will develop thyroid cancer should they be exposed to large doses of radioiodine in the order of 10 RADS or greater to the thyroid gland.

4. There has been some uncertainty in the past as to whether I-131 will induce thyroid cancer. The Chernobyl accident, however, has clearly documented the excess number of thyroid cancers in children following exposure to I-131. The thyroid cancer that has occurred in these children seems to be more aggressive than usual, associated with a large number of pulmonary metastases. This is a serious disease that requires therapy, often for a person's entire life. Accordingly, distribution of potassium iodide to be given to the target population (children and young adults under age 15) clearly outweighs the risks posed to this target group.

5. If the government could prevent the ingestion of radioiodines that people were nonetheless exposed to gamma radiation from an explosion, thyroid cancer could still occur in the exposed population. Again, this appears to be greatest in children and young adults.

6. Potassium iodide ordinarily inhibits uptake of radioiodines for longer than eight hours, as noted in the figure. It's difficult to project precisely; however, I believe that the potassium iodide dose posed is likely to be beneficial for longer than 24 hours, since it would expand the iodide pool sufficiently to dilute the dose of radioiodine captured by the thyroid gland.

7. It probably would be more effective to take two potassium iodide tablets, one each on consecutive days. Given the situation that you describe, I agree that it's unlikely that people under such stressed conditions would be likely to remember to take the drug.

8. The side effects of potassium iodide are not likely to occur immediately when the tablets are given. Instead, these are generally long-term effects that occur days to a week after the drug is ingested. I don't think it would be a problem to have someone distributing the drug who is not a trained medical person.

9. I do not know the answer to the question that you pose concerning the storage conditions of potassium iodide. I do, however, know that it must be protected from light and stored at reasonable room temperatures. From a practical standpoint, I doubt that most people would remember where their potassium iodide was stored after a several year period.

10. I would not recommend that the population at large be given a supply of potassium iodide. Instead, I think that a system should be devised to distribute it to the population should the need arise.

I hope these comments are of some use to you.

Sincerely,

Ernest L. Mazzaferri

Ernest L. Mazzaferri, MD, MACP
Professor of Internal Medicine
and Physiology
Chairman of Internal Medicine

ELM/rd

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A. Mohseni

OHIO DEPARTMENT OF HEALTH

63FR38865
July 20 1998
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246 N. HIGH STREET
Post Office Box 118
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Telephone: (614) 466-3543

GEORGE V. VOINOVICH
Governor

WILLIAM RYAN
Director of Health

August 24, 1998

Dr. Ernest L. Mazzaferri, M.D.
Department of Internal Medicine
213 Means Hall
The Ohio State University
1654 Upham Drive
Columbus, Ohio 43210-1228

Dear Dr. Mazzaferri:

Subject: **USE OF POTASSIUM IODIDE BY THE PUBLIC IN THE EVENT OF A NUCLEAR POWER PLANT ACCIDENT**

It was a pleasure to meet with you on August 20, 1998, in order to discuss the issue of public distribution of potassium iodide (KI) for nuclear power plant accident use. We were glad to learn of your interest in reviewing the Ohio Department of Health draft policy on KI public distribution, as well as your interest in responding to the request by the NRC for comments to their draft report, NUREG-1633. A copy of both are enclosed.

During our meeting we mentioned the wording of the package insert for THYRO-BLOCK, the stable KI tablet that we currently distribute for use by emergency workers and institutionalized populations in the 10-mile emergency planning zones around nuclear power plants. We also mentioned that the NRC recently sent a letter to the FDA requesting their assistance in considering mass distribution of KI to the public, (Frank J. Congel to Michael A Friedman, M.D., Acting FDA Commissioner, July 29, 1998.) A copy of both documents are enclosed.

In consideration of the information provided and your own expert knowledge, research and experience, we would appreciate your response to the questions that the NRC posed to Dr. Friedman and your consideration of other aspects listed in the attachment. The NRC has requested comments on NUREG-1633 by September 15, 1998. We would appreciate getting your comments, so that we may forward them to the NRC. If you have any questions, please contact me or Harvey Brugger at (614)644-2727.

Sincerely,

Roger L. Suppes

Roger L. Suppes, Chief
Bureau of Radiation Protection

RLS/HBB/hb
File: ki\mazzafer.trn

Attachments

pc: Harvey B. Brugger

QUESTIONS FOR YOUR RESPONSE

1. The Ohio Department of Health (ODH) currently recommends evacuation, if the total effective dose equivalent (TEDE) is projected to exceed one Rem, or if it is projected that the committed dose equivalent (CDE) to a child's thyroid is expected to exceed 5 Rem. Using the draft ODH policy, when this dose projection is made, a recommendation would also be made to all those people in the areas to be evacuated to take the first 130 mg KI tablet. Previously, the take your KI recommendation was only made to emergency workers and institutionalized populations, and that recommendation would be based on a projection of 25 Rem to the thyroid or greater, per FDA guidance. Would you comment on the proposed projected dose level for taking KI?

2. In the ODH draft policy, those who do not have KI when it is recommended to be taken, would need to go to a reception center or elsewhere out of the evacuated area to get it. They would be urged not to delay their evacuation in order to get it in the affected area. If they successfully evacuate before the plume's arrival, of course taking KI would be unnecessary. Also, since evacuation would be based on a projection that may not come to pass, many people might be taking KI who would not be exposed or would be minimally exposed. Nor would we expect anyone to be exposed from ingesting radioiodine, since the food supply would be interrupted and people would be urged not to eat locally grown food. In consideration of this situation, would the benefit of mass use of KI outweigh the health risks?

3. The U.S. Pharmacopeia and the Physician's Desk Reference make statements concerning contraindications and side effects, as discussed in NUREG-1633. The World Health Organization recommendations also contain some serious warnings on taking it. In light of these cautions, and the ODH recommended use of 130 mg tablets to adults (including pregnant and/or lactating women) and children one year of age and older; and 1/2 of a tablet to babies under 1 year of age (including neonates), for upwards of ten days, what do you think about the benefits versus the risks of taking KI?

4. Some opponents to mass distribution of KI do not believe thyroid cancer is serious enough to warrant the mass distribution of KI. Would you comment on this in light of your research on metastasized cancer found in children having radiation induced thyroid cancer from the Chernobyl accident in Belarus and other areas?

5. If the emergency response of the Federal, State and local authorities could indeed prevent ingestion of radioiodines, and since taking KI in the 10-mile emergency planning zone (EPZ) cannot protect the thyroid from direct dose from the

QUESTIONS FOR YOUR RESPONSE

cloud or ground shine, would mass distribution of KI still be warranted?

6. Figure 1, Page 8 in NUREG-1633 presents time before and after exposure versus percentage blocking of the thyroid with stable iodine. (This figure is taken from NUREG-6310, An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the event of a Nuclear Accident, USNRC, February 1995. Copy enclosed.) The figure appears to indicate that stable iodine would be capable of up to 95% blocking of the thyroid for perhaps two hours after exposure, but that the blocking diminishes rapidly to 50% in about 4 hours, and zero in about 8 hours. Would you comment on the time frame for which KI would be effective?

7. Would you comment on the aspects of taking KI at the recommended dosage, versus taking more than one tablet at one time, at a time when the person may be stressed by the situation, and therefore not capable of understanding the risks of their action - the potential and effect of over-dosing?

8. Would you comment on the situation that the person who is distributing KI will in all likelihood not be a trained medical person or even capable of observing for side effects and understanding what to do about them if they appeared?

9. Would you comment on the probability that the mass public could safely store a personal supply of KI over a five year period and still have it effective when needed? (The Thyro-Block package insert states "Store at controlled room temperature between 15° and 30°C (59° and 86°F). Keep container tightly closed and protect from light."

10. Would you comment on whether a personal supply of KI can be safely stored by the mass public, in light of the possibility of mistakes that could happen; i.e.,including someone very young accidentally taking the entire 10 tablet contents of the bottle?

Nuclear Regulatory Commission

Office of Public Affairs

Washington DC 20555

Telephone: 301/415-8200 – E-mail: opa@nrc.gov

No. 97-102

July, 1, 1997

NRC REVISES POSITION ON USE OF POTASSIUM IODIDE IN CASE OF ACCIDENT AT NUCLEAR POWER PLANT

The Nuclear Regulatory Commission has decided to modify its position regarding the use of potassium iodide as a protective measure for the general public in case of a severe nuclear reactor accident. The agency has decided to endorse the Federal Radiological Preparedness Coordinating Committee's (FRPCC) recommended policy to federally fund the purchase of potassium iodide for states at their request, and the NRC will provide the funding.

The Commission noted that the federal government recently began stockpiling potassium iodide near major metropolitan areas for use in mitigating the consequences of potential terrorist use of nuclear, biological or chemical weapons. The potassium iodide would be available to any state for any type of radiological emergency at any time.

If a state wishes to have its source of potassium iodide close at hand for use in a possible nuclear reactor accident, the federal government would fund the purchase, under the Commission's revised position.

Potassium iodide, if taken in time, blocks the thyroid gland's uptake of radioactive iodine and thus could help reduce thyroid diseases that might otherwise be caused by exposure to airborne radioactive iodine that could be dispersed in a nuclear accident.

Under the NRC's revised position, the federal government would purchase potassium iodide, but interested state and local governments would be responsible for maintenance, distribution and subsequent costs. NRC licensees would, as part of their 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 potential emergencies.

If finalized by the FRPCC, the proposed new policy will be published in the Federal Register. NRC will work with the Federal Emergency Management Agency to prepare the final policy statement and to develop implementation details, including criteria for evaluating a state's request for funding for potassium iodide.

The current federal policy was published in the Federal Register in 1985. It recommends that potassium iodide be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies, but does not recommend requiring pre-distribution or stockpiling for the general public.

The best technical information indicates that prompt evacuation and in-place sheltering are the preferred protective actions for the general public. However, the state (or in some cases, the local government) bears ultimately responsibility for the protection of its citizens. Therefore, the decision for local stockpiling and use of potassium iodide as a protective measure for the general public is left

to the discretion of the state or local government.

Currently two states (Tennessee and Alabama) include in their emergency planning the use of potassium iodide as a protective measure for the general public.

In 1995 the White House issued Presidential Decision Directive 39 on "U.S. Policy on Counterterrorism." It directed federal agencies to take a number of measures to reduce vulnerability to the potential use by terrorists of nuclear, biological and chemical weapons.

A report was prepared by a group chaired by the Federal Emergency Management Agency, with representatives from the NRC and other federal agencies. The report recommended that the federal government purchase and stockpile chemical nerve gas antidotes, vaccines for anthrax, antibiotics, potassium iodide and other medicines for use by the general public in the event of a terrorist attack. Currently there are three national stockpiles of medical supplies that include potassium iodide. Additionally, there will be 26 Metropolitan Medical Strike Teams, each with a full set of medical supplies, including potassium iodide. Two of the teams have been established, and the remaining 24 are in the process of being established. Thus the size and number of locations of federal stockpiles of potassium iodide are expected to increase. Potassium iodide from these resources could be used as a protective measure for the general public in the event of a severe nuclear accident.

This report was presented to the President and approved for distribution in May. Thus potassium iodide is already available nationally as part of emergency response preparedness for terrorism involving nuclear, biological and chemical agents.

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OHIO DEPARTMENT OF HEALTH

September 16, 1998

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTENTION: Docketing and Services Branch

Dear Mr. Hoyle:

Subject: **Comments by Bureau of Radiation Protection, Ohio Department of Health to Draft for Public Comment, NUREG-1633, entitled: "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Core Accidents."**

Attached are the subject comments. These have been prepared in response to the USNRC request for comments, published in the Federal Register, Notice 63FR38865, dated July 20, 1998.

Sincerely,

Roger L. Suppes

Roger L. Suppes, Chief
Bureau of Radiation Protection

RLS/HBB/hb
File: ki\n1633com.trn

Attachment

pc: Deborah L. Arms, ODH, Prevention
Harvey B. Brugger, ODH-BRP
Frank J. Congel/Aby S. Mosheni, NRC-AEOD

September 16, 1998

For transmittal to Internet address: asm@nrc.gov

To: Frank J. Congel and Aby S. Mosheni, Division of Incident Response,
Office for Analysis and Evaluation of Operational Data,
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

Subject: Comments by Bureau of Radiation Protection, Ohio Department of Health to Draft for Public Comment, NUREG-1633, entitled: "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Core Accidents."

1.0 OVERALL IMPRESSION

The NRC report needs to be more neutral in presenting the benefits and detriments of adoption of KI as a supplement to evacuation. Whatever the original intent of this report, it will make objective consideration of the use of KI more difficult for State and local officials. This is despite the NRC Commissioners approval of this course of action as a valid supplementary protective measure for the public. This is a very strange situation, when considering the fact that this issue was brought to the fore by the NRC's offer to pay for purchase of KI for the public in a news release, No. 97-102, July 1, 1997. This situation is also strange in that using KI was a consideration that was previously rejected by most states for very good reasons.

The apparent bias of draft NUREG-1633, is also contrary to the positions taken in support of public distribution by many prestigious national and international organizations, such as the American Thyroid Association, the World Health Organization, the International Atomic Energy Agency, the U.S. National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection. They all favor KI use for the public as a protective measure for reactor core accidents. Other nations producing nuclear-electric power, such as Germany, France, the United Kingdom, Finland, Sweden and Switzerland all make great efforts to ensure their accident affected populations will have KI immediately on hand to take. As an example of draft NUREG-1633 bias, it contains a discussion of why Americans are different than Europeans, because our thyroids are already partially blocked by eating salty fast food. (See draft NUREG-1633, Page 14.) This situation is not true for all Americans, for example, it is obviously not true for neonates. Aside from the fast food statement, we are told that differences in our cultural, legal and political organizations would make the logistics of distribution and administration much more difficult than in Europe. We believe this is a very valid point and that the NRC should reconsider their funding offer in light of it. That is, the NRC should bear more of the burden of costs, since apparently the NRC Commissioners' intent was to eliminate economics in the local consideration of whether to adopt us of KI. (Reference: SECY 97-124, June 16, 997, Page 11, Option 2 highlights, second bullet.)

State and local officials in Ohio have been approached by citizens to take up consideration of the NRC funding offer. However, we find ourselves confronted with draft NUREG-1633, which argues against distribution, using principally the idea that KI is a dangerous drug. If one reads the package insert for THYRO-BLOCK that was prepared by its manufacturer, Wallace Laboratories, it is obvious that the manufacturer doesn't consider KI a dangerous drug when used in the doses prescribed for radiation protection. (THYRO-BLOCK is provided for emergency workers and institutionalized populations by the Ohio Department of Health(ODH) in the 10-mile EPZ.) Further, the Ohio Board of Pharmacy has advised ODH that KI is not a prescription drug, if used for radiation protection.

If the NRC continues to believe that the severe core accident scenario is valid for use of KI as a supplementary measure to evacuation, then the NRC should be prepared to both fund and distribute KI to people in places like Toledo, Cleveland, Akron and Columbus, and all the places in between, because local and State officials would be totally overwhelmed by the logistics of that task. Further, the entire concept currently used throughout the Nation for evacuation planning is that of a 10-mile EPZ. This would be negated by the severe reactor accident scenario, with the consequence that all State and local emergency planning would have to be redone. Certainly, the NRC doesn't require nuclear power plants to be (re)designed to accommodate a severe reactor accident scenario. Why then should the NRC suggest that the Nation's nuclear power plant emergency response efforts consider this accident scenerio? The lack of consistency is troubling. If this accident isn't a design basis accident, then why is the NRC seeking to expend federal, state and local emergency response resources to deal with it? Is this not ratcheting up the emergency response requirements?

In conclusion, we would request that you withdraw draft NUREG-1633 and instead, possibly prepare another report that objectively addresses the real issues of logistics of distribution, and if at all possible, proffers workable solutions in the way of making KI use effective as a supplement to evacuation. We would further request that NUREG-1633, if not withdrawn, address a more realistic accident scenario than the severe core accident, an accident at least 20 times less probable than those for which current nuclear power plants in the U.S.A. are designed. You can not address local emergency response measures for an extremely unrealistic scenario, the severe core accident, and at the same time limit those measures to a 10-mile EPZ. We believe that organizing effective emergency response protective measures for severe reactor core accidents may be impossible, given the societal resources that would need to be deployed for a severe core accident that would negatively impact the health of the population out to several hundred miles from the plant. This is in comparison to the FEMA planning distance for evacuation of 10 miles around a nuclear power plant. This disparity between the evacuation emergency planning zone (10-mile EPZ) and the expected distance of radioactive plume affect is a fact borne out by reading a scholarly study prepared for the NRC by Sanford Cohen & Associates, and published by the NRC as NUREG-6310, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident", February 1995.

2.0 DETAILED COMMENTS

2.1 Limiting consideration of use of KI to the 10 mile emergency planning zone (EPZ) is an artificiality, in that given the title of the NUREG, "Assessment ...Severe Reactor Accidents", for this highly unlikely scenario, the pathway where KI intervention would be effective is several hundred miles. Consider changing the title and/or be prepared to provide enormous funding to both pay for KI and distribute it in the severe accident pathway, since the resources required would overwhelm State and local governments and would be a lot more than any nuclear-electric utility would be willing to fund. According to NUREG-6310, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident", 1995, "thyroid risks are based on external exposures ranging from about 5 to 1500 Rads" (page 2-10) and "...in the downwind sector, the child thyroid dose of at least 50 rem has a probability of nearly 100% for distances out to about 50 miles. Between 50 and 175 miles, the probability of exceeding 50 rem declines steadily..."(Page 4-16).

2.2 The artificiality of considering KI for just the 10-Mile EPZ is borne out by NUREG-1633 itself in the statement "For the two most severe accident scenarios considered, reductions in thyroid doses are dwarfed by the physiological effects of the accompanying acute whole body doses. Early death or very serious effects would occur to all individuals exposed out to nearly 10 miles. (See the report Executive Summary, bottom of Page 3.)

2.3 The artificiality of the 10-Mile EPZ is further borne out by the report (Page 21) statement that the vast majority of thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the (Chernobyl) site. The current emergency planning and projections for purposes of recommending protective actions are based upon a straight line downwind trajectory being followed by the radioactive plume. Nature doesn't behave this way very often. Wind dispersion and meteorological conditions can be erratic, as evidenced in the Chernobyl accident, where the plume rose about 1000 feet and then dispersed, thus sparing the close-in population from bearing the brunt of the thyroid cancer incidence. Hence planning for just the 10-mile EPZ for KI or any other protective measure, including evacuation, is oversimplification. In NUREG-1633 (the authors' own words), (Page 28) "meteorological parameters do not lend themselves to simple extrapolation to distances beyond the EPZ. For example, the Chernobyl release produced a pattern that was extremely difficult, if not impossible, to project."

2.4 The report (Page 28) goes on to state two dangerous fallacies: (1) that "...the potential for large doses is limited to the 10-mile EPZ..." and (2) "The preparations made in the 10-mile EPZ allow public officials to expand their protective action beyond 10 miles if needed on a case-by-case basis." In fact, most states, with FEMA approval, have emergency plans, procedures and preparations that deal specifically with evacuation of populations in the 10-mile EPZ only. There is no established alert and notification system, nor planned evacuation routes, nor planned reception centers, nor even any effort

to bring officials from the downwind counties beyond the 10-mile EPZ into any semblance of emergency preparedness for the eventuality of having to respond to a telephone call requesting they evacuate their threatened populations.

2.5 In at least two places in NUREG-1633, reference is made to administration of KI to "women and children" as "requiring a high degree of caution", (Pages 5 and 32.) This contrasts with the package insert on the KI that the State of Ohio currently distributes to emergency workers and institutionalized populations, which states "Pregnant and nursing women and babies and children may also take this drug." (Reference: Wallace Laboratories, Patient Package Insert for Thyro-Block Tablets, Potassium Iodide Tablets, USP, IN-0472-03, Rev. 5/94). This contradiction detracts from the valid consideration of the real issue of distribution that needs to be addressed.

2.6 Page 32 of the report states that "The use of KI in conjunction with evacuation could potentially delay evacuations." This statement is prejudicial toward a dispassionate consideration of the issues for and against adopting KI as a supplement to evacuation. Is it not possible that if KI is pre-distributed to people within the plume pathway, or made available to them outside of the evacuated area, there would be no reason to delay evacuation in order to get it. Indeed, there may be every reason for the public to make speed in evacuation, so that they could get to the place outside the evacuated area where KI could be obtained.

2.7 NUREG-1633 fails to address the public education effort needed for people to understand why they should take KI and when they should take it. Public outreach is a resource consuming but necessary effort. There is no way for KI to be an effective supplement to evacuation without public education. It is difficult enough just to get permanent residents to understand what to do when they hear the sirens in the 10-mile EPZ, let alone the seasonal and transient populations. Educational outreach to prepare the public to take KI is also an effort that could easily have negative implications for communities that have nuclear plants and also have a substantial tourism element to their economies. How do you educate people in order to make KI usage effective without scaring away the tourists or making the populace fear nuclear power?

2.8 The original NRC news release wherein the NRC offered to fund KI for nuclear power plants also elaborated on the Federal Government plans for stockpiling of nuclear, biological and chemical antidotes around the country, (No. 97-102, July 1, 1997). Draft NUREG-1633 also holds out the availability of these anti-terrorism stockpiles for nuclear accidents. (Page 33). Although, we understand that the NRC needs to coordinate its emergency response efforts with other federal agencies, we believe that use of KI as a supplement to evacuation for a nuclear power plant accident should be a stand alone issue to be addressed by the NRC, out of the Federal Radiological Preparedness Coordinating Committee (FRPCC) context of anti-terrorist activity. Doing otherwise feeds a public misperception that nuclear devices and nuclear power plants are synonymous, which they are not.

RLS/HBB/hb
file: n1633com.r-3

D504
A. Nelson

63FR 38865
July 20 1998
(5)

J. Barnie Beasley, Jr., P.E.
Vice President
Vogtle Project

Southern Nuclear Operating Company, Inc.
40 Inverness Center Parkway
P.O. Box 1295
Birmingham, Alabama 35201

Tel 205.992.7110
Fax 205.992.0403

SOUTHERN COMPANY
Energy to Serve Your World℠

September 15, 1998

Docket Nos. 50-348 50-321 50-424 HL-5682
50-364 50-366 50-425 LCV-1250

Mr. David L. Meyer, Chief
Rules Review and Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D. C. 20555-0001

Comments on Draft Nureg-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents,"
(63 Fed. Reg. 38865, July 20, 1998)

Dear Sir:

Southern Nuclear Operating Company (Southern Nuclear) has reviewed NRC's Draft Nureg-1633, notice of which was published in the Federal Register on July 20, 1998. The Draft Nureg provides a synopsis of the historical use, the technical basis and industry experiences with KI as a supplemental protective action for the general public living in the area around a commercial nuclear power plant. In accordance with the request for comments, Southern Nuclear endorses comments submitted by the Nuclear Energy Institute (NEI) which accurately convey Southern Nuclear's position on the referenced NRC Draft Nureg-1633.

Southern Nuclear would like to emphasize that though KI stockpile and distribution are common practice in the European countries, consequences of the Chernobyl experience should not provide adequate grounds for changing the current U. S. policy. The Federal Radiological Preparedness Coordinating Committee (FRPCC) policy statement discussed in COMSECY 97-028, asserts that evacuation, and under certain conditions shelter, constitute the primary protective actions for public protection. At the emergency classifications where protective actions are performed, KI would not add any significant level of safety and could actually hinder and complicate the emergency response effort.

Should you have any questions, please advise.

Respectfully submitted,

J. Barnie Beasley, Jr.

JBB, Jr./NMM

cc: Southern Nuclear Operating Company
L. M. Stinson, General Manager - Plant Farley
P. H. Wells, General Manager - Plant Hatch
J. T. Gasser, General Manager - Vogtle Electric Generating Plant
D. N. Morey, Vice President - Plant Farley
H. L. Sumner, Vice President - Plant Hatch

U. S. Nuclear Regulatory Commission, Washington, DC
J. I. Zimmerman, Licensing Project Manager - Farley
L. N. Olshan, Licensing Project Manager - Hatch
D. H. Jaffe, Licensing Project Manager - Vogtle

U. S. Nuclear Regulatory Commission, Region II
L. A. Reyes, Regional Administrator
T. P Johnson, Senior Resident Inspector - Farley
J. T. Munday, Senior Resident Inspector - Hatch
J. Zeiler, Senior Resident Inspector - Vogtle

HL-5682
LCV-1250

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63 FR 38865
July 20, 1998
(12)

DS09
A. Nelson

SOUTHERN COMPANY
Energy to Serve Your World℠

September 15, 1998

Docket Nos.	50-348	50-321	50-424	HL-5682
	50-364	50-366	50-425	LCV-1250

Mr. David L. Meyer, Chief
Rules Review and Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D. C. 20555-0001

Comments on Draft Nureg-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998)

Dear Sir:

Southern Nuclear Operating Company (Southern Nuclear) has reviewed NRC's Draft Nureg-1633, notice of which was published in the Federal Register on July 20, 1998. The Draft Nureg provides a synopsis of the historical use, the technical basis and industry experiences with KI as a supplemental protective action for the general public living in the area around a commercial nuclear power plant. In accordance with the request for comments, Southern Nuclear endorses comments submitted by the Nuclear Energy Institute (NEI) which accurately convey Southern Nuclear's position on the referenced NRC Draft Nureg-1633.

Southern Nuclear would like to emphasize that though KI stockpile and distribution are common practice in the European countries, consequences of the Chernobyl experience should not provide adequate grounds for changing the current U. S. policy. The Federal Radiological Preparedness Coordinating Committee (FRPCC) policy statement discussed in COMSECY 97-028, asserts that evacuation, and under certain conditions shelter, constitute the primary protective actions for public protection. At the emergency classifications where protective actions are performed, KI would not add any significant level of safety and could actually hinder and complicate the emergency response effort.

Should you have any questions, please advise.

Respectfully submitted,

J. Barnie Beasley, Jr.

JBB, Jr./NMM

cc: Southern Nuclear Operating Company
L. M. Stinson, General Manager - Plant Farley
P. H. Wells, General Manager - Plant Hatch
J. T. Gasser, General Manager - Vogtle Electric Generating Plant
D. N. Morey, Vice President - Plant Farley
H. L. Sumner, Vice President - Plant Hatch

U. S. Nuclear Regulatory Commission, Washington, DC
J. I. Zimmerman, Licensing Project Manager - Farley
L. N. Olshan, Licensing Project Manager - Hatch
D. H. Jaffe, Licensing Project Manager - Vogtle

U. S. Nuclear Regulatory Commission, Region II
L. A. Reyes, Regional Administrator
T. P Johnson, Senior Resident Inspector - Farley
J. T. Munday, Senior Resident Inspector - Hatch
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PSEG

12507
A. Mahseni

63FR 38865
July 20, 1998

Public Service Electric and Gas Company P.O. Box 236 Hancocks Bridge, New Jersey 08038-0236

Nuclear Business Unit

(11)

1:47

SEP 15 1998

LR-N980448

Mr. David L. Meyer
Chief, Rules Review and Directives Branch,
U.S. Nuclear Regulatory Commission
Office of Administration
Washington, DC 20555

COMMENTS ON NRC DRAFT NUREG-1633
SALEM AND HOPE CREEK GENERATING STATIONS
DOCKET NOS. 50-272, 50-311 AND 50-354

Dear Mr. Meyer:

Public Service Electric & Gas Company (PSE&G) submits the following in response to the notice requesting comments on the draft of NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents".

The draft NUREG provides a technical assessment on the potential impact of the release of radioiodines during a severe reactor accident and the effect of the use of KI to reduce the effects of the radioiodines on the impacted population. As an assessment, we believe the NUREG should provide a balanced discussion on the benefits and risks of the use of KI.

We recommend reversing the sequence of the first two bullets in the "KI Benefits and Challenges" section to put more emphasis on evacuation as the most appropriate and effective protective action. The existing emergency plans at commercial nuclear power plants and the impacted states provide adequate protection for the public by implementing timely evacuation of the public and quarantine of contaminated food and drink.

The NUREG should provide additional discussion on the significant experience in the United States of successfully implementing public evacuations, as is regularly demonstrated in the response to the threat of hurricanes. Most of the examples cited in the draft NUREG are related to KI distribution in Europe where international boundaries can impact the implementation of protective actions requiring planned evacuation of members of the public. The United States does not have these boundary limitations.

SEP 15 1998

The benefits of the use of KI are discussed in the draft NUREG without a balanced discussion of the risks of the use of KI. KI has been shown to be effective in reducing thyroid dose when taken just prior to uptake of radioiodines. This protective action is appropriate for emergency workers entering areas of potential or actual airborne radioiodine contamination. Procedures issued by the states contain strict controls for issuing KI to emergency workers. These same controls would not be practical if KI is predistributed for public use. State plans require precautionary evacuation of schools at a Site Area Emergency. This precludes the need for issuing KI for children. Many states also prohibit issuing any medication to school children without parental permission. While these issues are presented in the draft NUREG, the negatives of predistribution of KI are not described as clearly as the potential benefits of use of KI.

Stockpiling and predistribution of KI would more likely lead to use when it is not needed or delays in implementation of other planned protective actions. As stated in the draft NUREG, KI is medically inadvisable for various groups of people. For these reasons the use of KI for public consumption can increase risks more than the potential benefits gained. PSE&G recommends the NRC reconsider the proposed rulemaking petition for stockpiling and use of KI for the general public.

In SECY-98-061, the NRC staff addressed their support of evacuation and sheltering as the primary protective actions. The discussion contained within SECY-98-061 should be included in the draft NUREG.

If you have any questions or require additional information, please contact Ms. Donna Miller at (609) 339-1757.

Sincerely,

D. R. Powell

D. R. Powell
Director -
Licensing/Regulation and Fuels

C Mr. H. J. Miller, Administrator - Region I
U. S. Nuclear Regulatory Commission
475 Allendale Road
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Mr. P. Milano, Licensing Project Manager - Salem
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USNRC Senior Resident Inspector - Salem

Mr. S. Pindale (X24)
USNRC Senior Resident Inspector - Hope Creek

Mr. K. Tosch, Manager IV,
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PO Box 415
Trenton, NJ 08625

DVH

BC	Sr. Vice President - Nuclear Operations	(X04)
	Sr. Vice President - Nuclear Engineering	(N19)
	General Manager - Salem Operations	(S05)
	General Manager - Hope Creek Operations	(H07)
	Director - QA/NT/EP	(X01)
	Program Manager - NRB	(N38)
	Manager - Financial Control & Co-Owners Affairs	(N18)
	Onsite Safety Review Engineer - Salem	(S12)
	Onsite Safety Review Engineer - Hope Creek	(H11)
	Salem Licensing Manager	(N21)
	Hope Creek Licensing Manager	(N21)
	Jeff Keenan, Esq.	(X09)
	Records Management	(N21)
	Microfilm Copy	
	File	

From: "Ernestine M. Kuhr" <tmkuhr@duke-energy.com>
To: TWFN_DO.twf2_po(ASM)
Date: Tue, Sep 15, 1998 9:31 AM
Subject: Duke Energy Comments on DRAFT NUREG-1633

A hard copy of the following comments from Duke Energy is being mailed today.

September 10, 1998

Mr. David L. Meyer
Chief, Rules Review and Directives Branch
Mail Stop T-6 D69
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Federal Register 38865, July 20, 1998)

Duke Energy offers the following comments on Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Federal Register 38865, July 20, 1998). The Draft NUREG provides an evaluation of the use of potassium iodide as a supplemental protective action within the plume exposure pathway.

The Draft NUREG-1633 provides a researched conclusion that the proposed rule change, requiring stockpiling and prophylactic issue of KI, will not effectively improve protective actions for the public. In some instances, KI may slow evacuations or even be administered unnecessarily as a result of the rule. Unnecessary administration of KI may have significant health consequences. Duke Energy urges the NRC to reconsider its approval of the Petition for Rulemaking filed by Mr. Peter G. Crane (60 Federal Register 58256, November 27, 1995).

Consequences of Chernobyl are often cited as a reason that the United States should distribute KI. This NUREG states that most of the thyroid dose at Chernobyl was from ingestion pathway. This emphasizes the importance of existing emergency planning for the ingestion pathway, rather than KI. For severe accidents with containment failure, the whole body doses are hazardous, not just the thyroid doses. Evacuation is more effective in reducing the dose to the whole body. Where evacuations are performed, KI would not add any measure of safety to the existing emergency response, and could actually hinder emergency response by decreasing the speed of evacuation.

Administration of a drug without medical supervision to a broad population is a significant departure from the norm in emergency response, which is evacuation. In addition, the population most sensitive to radioiodines is children. One impediment to KI distribution to children in day cares and schools is the logistics associated with obtaining parental approval and

having sufficient, qualified medical personnel available to administer the KI. Most offsite emergency plans call for precautionary evacuation of schools and day cares when a Site Area Emergency is declared. Under these conditions, offsite doses should not exceed a small fraction of the EPA protective action guideline levels of 5 Rem Thyroid CDE offsite, and should be much lower than the EPA's protective action guideline for the administration of stable iodine (25 Rem Thyroid CDE).

In order to achieve maximum thyroid blocking, KI has to be taken just prior to a release. The dose reduction is only a factor of 2 if KI is taken 3 to 4 hours after exposure, which would more typically be the case if KI were given outside the Emergency Planning Zone when people arrive at a reception center.

Severe accident studies have shown that even if there is serious damage to the core, there may not be a large release to the environment. The information included on the likelihood of a severe accident, and what (small) fraction of those result in a large early release, needs to be emphasized. In all four of the examples sited, the release occurred more than 11 hours after the initiating event, allowing time for evacuation to be completed prior to the release, eliminating the need for KI. The draft NUREG states, "If containment integrity can be maintained for 24 hours or more, the offsite risk is limited because of decay and in-containment removal processes." Duke Energy has implemented Severe Accident Management to help achieve that end in the unlikely event of a severe accident.

If there are any questions regarding the comments provided, please contact Tina Kuhr by telephone at (704) 382-3151.

Yours truly,

M. S. Tuckman

DSO
A. Mohseni

63 FR 38865
July 20, 1998

(4)

TU ELECTRIC

Log # TXX-98205
File # 10185

9:56

September 11, 1998

C. Lance Terry
Senior Vice President
& Principal Nuclear Officer

Mr. David L. Meyer
Chief, Rules Review and
Directives Branch,
Mail Stop T-6 D69
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Comments on Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Protective Action During Severe Reactor Accidents"

REF: (1) 63 FR 38865 - July 20, 1998

(2) TU Electric letter logged TXX-96047 to Mr. John C. Hoyle from C. L. Terry dated February 9, 1996

Dear Mr. Meyer:

In response to the referenced Federal Register Notice, TU Electric is submitting comments on Draft NUREG-1633 which reviews the historical use, technical basis, and industry experiences with KI as a supplemental protective action for the general public.

TU Electric endorses the Draft NUREG-1633 which concludes that careful consideration should be given to whether the use of KI for the public during an emergency is advantageous. Additionally, TU Electric is in agreement with comments being provided to this Notice by the Nuclear Energy Institute (NEI). The NEI comments include strongly urging the Commission to reconsider it's approval of the latest proposed rulemaking petition of Mr. Peter Crane. In previous comments to 60 FR 58256 via reference 2, TU Electric recommended that the NRC deny Mr. Crane's original petition for rulemaking which had requested the NRC amend its regulations concerning emergency planning to include a requirement that emergency planning protective actions for the general public include sheltering, evacuation and the prophylactic use of KI.

With respect to the latest "modified" petition filed by Mr. Crane, TU Electric agrees with the NRC staff's assessment in SECY 98-061 "Staff Options for Resolving a Petition for Rulemaking Relating to Reevaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant." TU Electric and the NEI endorse Option 2 which recommends denying the latest petition and supports the Federal Radiological Preparedness Coordinating Committee (FRPCC) policy statement discussed in COMSECY 97-028 which maintains that evacuation and sheltering are the primary protective actions.

The U. S. federal agencies, nuclear industry, state and local response organizations have developed the most effective and sophisticated emergency preparedness plans in the world. The U. S. Model recognizes that evacuating an area is the most effective response for protecting the public health and safety. Where evacuations are performed, KI would not add any measure of safety to this proven approach, and could actually complicate and hinder emergency response.

TU Electric believes that the current regulations and the proposed 1997 federal guidance (FRPCC policy statement discussed in COMSECY-97-028) adequately address the concern for protection of the public.

Sincerely,

C. L. Terry

C. L. Terry

By: Roger D. Walker
Roger D. Walker
Regulatory Affairs Manager

CLW/clw

c - Lynnette Hendricks, NEI
Richard Ratliff, Texas BRC

NRC-98-95

0509
A. Mohseni

Wisconsin Public Service Corporation
(a subsidiary of WPS Resources Corporation)
600 North Adams Street
P.O. Box 19002
Green Bay, WI 54307-9002
1-920-433-5544 fax

63 FR 38865
July 20, 1998

(1)

September 3, 1998

Mr. David L. Meyer
Chief, Rules Review and Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Meyer:

Docket 50-305
Operating License DPR-43
Kewaunee Nuclear Power Plant
Draft NUREG-1633, "Assessment of the use of Potassium Iodide (KI) as a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998)
Request for Comments

Wisconsin Public Service Corporation, operator of the Kewaunee Nuclear Power Plant, wishes to submit the following comments in response to the subject notice. After reviewing the draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998), we find no basis that stockpiling or predistribution of KI as a protective action adds any significant benefit to the public health and safety. Wisconsin Public Service agrees with the NRC staff's assessment in SECY-98-061, "Staff Options for Resolving a Petition for Rulemaking Relating to Reevaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant," and we endorse Option 2. This option recommends denying the petition and supports the FRPPC policy statement discussed in COMSECY 97-028 which maintains that evacuation and sheltering are the primary protective actions.

Wisconsin Public Service strongly urges the NRC to reconsider its approval of the proposed rulemaking petition.

Sincerely,

for

Mark L. Marchi
Site Vice President-Kewaunee Plant

RPP
cc - US NRC Document Control Desk
US NRC Region III
US NRC Senior Resident Inspector

PSEG

Public Service Electric and Gas Company P.O. Box 236 Hancocks Bridge, New Jersey 08038-0236

Nuclear Business Unit

LR-N980448

Mr. David L. Meyer
Chief, Rules Review and Directives Branch,
U.S. Nuclear Regulatory Commission
Office of Administration
Washington, DC 20555

COMMENTS ON NRC DRAFT NUREG-1633
SALEM AND HOPE CREEK GENERATING STATIONS
DOCKET NOS. 50-272, 50-311 AND 50-354

Dear Mr. Meyer:

Public Service Electric & Gas Company (PSE&G) submits the following in response to the notice requesting comments on the draft of NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents".

The draft NUREG provides a technical assessment on the potential impact of the release of radioiodines during a severe reactor accident and the effect of the use of KI to reduce the effects of the radioiodines on the impacted population. As an assessment, we believe the NUREG should provide a balanced discussion on the benefits and risks of the use of KI.

We recommend reversing the sequence of the first two bullets in the "KI Benefits and Challenges" section to put more emphasis on evacuation as the most appropriate and effective protective action. The existing emergency plans at commercial nuclear power plants and the impacted states provide adequate protection for the public by implementing timely evacuation of the public and quarantine of contaminated food and drink.

The NUREG should provide additional discussion on the significant experience in the United States of successfully implementing public evacuations, as is regularly demonstrated in the response to the threat of hurricanes. Most of the examples cited in the draft NUREG are related to KI distribution in Europe where international boundaries can impact the implementation of protective actions requiring planned evacuation of members of the public. The United States does not have these boundary limitations.

SEP 15 1998

The benefits of the use of KI are discussed in the draft NUREG without a balanced discussion of the risks of the use of KI. KI has been shown to be effective in reducing thyroid dose when taken just prior to uptake of radioiodines. This protective action is appropriate for emergency workers entering areas of potential or actual airborne radioiodine contamination. Procedures issued by the states contain strict controls for issuing KI to emergency workers. These same controls would not be practical if KI is predistributed for public use. State plans require precautionary evacuation of schools at a Site Area Emergency. This precludes the need for issuing KI for children. Many states also prohibit issuing any medication to school children without parental permission. While these issues are presented in the draft NUREG, the negatives of predistribution of KI are not described as clearly as the potential benefits of use of KI.

Stockpiling and predistribution of KI would more likely lead to use when it is not needed or delays in implementation of other planned protective actions. As stated in the draft NUREG, KI is medically inadvisable for various groups of people. For these reasons the use of KI for public consumption can increase risks more than the potential benefits gained. PSE&G recommends the NRC reconsider the proposed rulemaking petition for stockpiling and use of KI for the general public.

In SECY-98-061, the NRC staff addressed their support of evacuation and sheltering as the primary protective actions. The discussion contained within SECY-98-061 should be included in the draft NUREG.

If you have any questions or require additional information, please contact Ms. Donna Miller at (609) 339-1757.

Sincerely,

D. R. Powell

D. R. Powell
Director -
Licensing/Regulation and Fuels

C Mr. H. J. Miller, Administrator - Region I
U. S. Nuclear Regulatory Commission
475 Allendale Road
King of Prussia, PA 19406

Mr. P. Milano, Licensing Project Manager - Salem
U. S. Nuclear Regulatory Commission
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Mr. R. Ennis, Licensing Project Manager - Hope Creek
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Rockville, MD 20852

Mr. S. Morris (X24)
USNRC Senior Resident Inspector - Salem

Mr. S. Pindale (X24)
USNRC Senior Resident Inspector - Hope Creek

Mr. K. Tosch, Manager IV,
Bureau of Nuclear Engineering
PO Box 415
Trenton, NJ 08625

Lynnette Hendricks
DIRECTOR,
PLANT SUPPORT
NUCLEAR GENERATION DIVISION

September 11, 1998

Mr. David L. Meyer
Chief, Rules Review and
Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

SUBJECT: Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998)

Dear Sir:

The Nuclear Energy Institute (NEI)* submits these comments on behalf of the nuclear energy industry in response to the subject notice. We have reviewed draft NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998). The draft NUREG reviews the historical use, technical basis, and industry experiences with KI as a supplemental protective action for the general public.

Draft NUREG-1633 supports the industry position that "considering" stockpiling or predistribution of KI as a protective action will not add any significant public health and safety benefit to the adequate level of protection currently provided by existing emergency planning at and around commercial nuclear power plants. NEI strongly urges the NRC to reconsider it's approval of the proposed rulemaking petition.

The industry endorses those conclusions in the draft NUREG which indicate careful consideration should be given to whether the use of KI for the public during an emergency is advantageous. The industry agrees with the staff's assessment in
SECY 98-061 "Staff Options for Resolving a Petition for Rulemaking Relating to Re-evaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant." Accordingly, we endorse Option 2 which recommends denying the petition and supports the FRPPC policy statement discussed in COMSECY 97-028 which maintains that evacuation and sheltering are the primary protective actions.

Consequences of Chernobyl are often cited as a reason the United States (U.S.) should distribute potassium iodide. Studies have found that evacuation is more effective and will reduce the dose to all body organs. The study

*NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

concluded that a nationwide requirement for KI predistribution or stockpiling for use by the general public would not be worthwhile as an add-on to evacuation and sheltering.

The fact that KI distribution is a fairly common practice in Europe is not a valid reason for changing the current policy. There are significant differences in the level of U.S. and European emergency preparedness (e.g., organization, training facilities, equipment, and regulatory oversight). In the absence of detailed plans many countries distribute KI as the first line of defense. Review of these preparedness programs indicates distribution of KI would provide marginal or no benefit in the United States due to the protective defense-in-depth features contained in our preparedness programs.

This protective defense-in-depth philosophy is demonstrated by the fact that most emergency plans suggest precautionary evacuation of schools and day care facilities at declaration of a Site Area Emergency. Under these conditions, there is no imminent release of radioactive material that will exceed EPA Protective Action Guidelines beyond the site boundary. If children are evacuated, there is no opportunity to further reduce risk through distribution of potassium iodide.

A major impediment to KI distribution to school children is coordination and administration of the program, e.g., the actual decision-making process to administer KI or evacuate, parental approval and record keeping, identification and mitigation of allergic reactions, and the availability of a qualified medical professional to administer the potassium iodide.

The U.S. federal agencies, nuclear industry and state and local emergency response organizations have developed the most effective and sophisticated emergency preparedness plans in the world. The U.S. model recognizes that evacuating an area is the most effective response for protecting the public health and safety. Where evacuations are performed, potassium iodide would not add any measure of safety to this proven approach, and could actually complicate and hinder emergency response.

If there are any questions regarding the comments provided please contact me at (202) 739-8109 or by e-mail (lxh@nei.org), or Alan Nelson at (202) 739-8110 or
e-mail (apn@nei.org). NEI is available to meet with the NRC and discuss these issues further if desired.

Sincerely,

Lynnette Hendricks

APN/LH/tnb

c: Aby S. Mohseni, U.S. Nuclear Regulatory Commission

PECO NUCLEAR

A Unit of PECO Energy

PECO Energy Company
965 Chesterbrook Boulevard
Wayne, PA 19087-5691

September 17, 1998

Mr. Aby S. Mohseni
Division of Incident Response
Office for Analysis and Evaluation of
Operational Data
U. S. Nuclear Regulatory Commission
Washington, DC 20555-001

Subject: Comments Concerning Draft NUREG-1633,
"Assessment of the Use of Potassium Iodide (KI) as a
Public Protective Action During Severe Reactor Accidents"
(63FR38865, dated July 20, 1998)

Dear Mr. Mohseni:

This letter is being submitted in response to the NRC's request for comments published in the Federal Register (63FR38865, dated July 20, 1998) concerning draft NUREG-1633, *"Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents."* This draft NUREG provides information with regard to the historical use, technical basis, and industry experiences with KI as a supplemental protective action for the general public.

PECO Energy appreciates the opportunity to comment on this draft NUREG and offers the following comments for consideration by the NRC.

Comments

The draft NUREG-1633 supports the industry position that "considering" stockpiling or predistribution of KI as a protective action will not add any significant public health and safety benefit to the adequate level of protection currently provided by existing emergency planning at and around commercial nuclear power plants.

PECO Energy endorses the draft NUREG which concludes careful consideration should be given to whether the use of KI for the public during an emergency is advantageous. The industry agrees with the NRC's assessment in SECY-98-061, "Staff Options for Resolving a Petition for Rulemaking Relating to Re-evaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant." We endorse Option 2 which recommends denying the petition and supports the Federal Radiological Preparedness Coordinating Committee (FRPPC) policy statement discussed in COMSECY-97-028 which maintains that evacuation and sheltering are the primary protective actions.

Studies have found that evacuation is the most effective protective action and will reduce the dose to all body organs. The use of KI in conjunction with evacuation could potentially delay evacuation. Introducing a process that requires critical timing in distribution/administration of a drug could slow evacuation, and thereby, reduce the effectiveness of a process that protects the population from all radionuclides and pathways.

If administered promptly, KI can be effective in blocking the thyroid and preventing radioiodine uptakes. A high degree of caution would have to be exercised before recommending its administration on a mass basis, including to pregnant women and children.

Federal, state, local, and nuclear utility emergency response organizations in the United States (U.S.) have developed the most effective and sophisticated emergency preparedness plans in the world. The model used in the U.S. recognizes that evacuating an area is the most effective response for protecting the public health and safety. Where evacuations are performed, KI would not add any measure of safety to this proven approach, and could actually complicate and hinder emergency response.

If you have any questions or require additional information, please do not hesitate to contact us.

Very truly yours,

Garrett D. Edwards
Director - Licensing

Entergy

Entergy Operations, Inc.
P.O. Box 31995
Jackson, MS 39286-1995

September 16, 1998

Mr. David L. Meyer
Chief, Rules Review and Directives Branch
Office of Administration
Mail Stop T-6 D69
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Comments on Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998)

CNRO-98/00021

Dear Mr. Meyer:

Entergy Operations, Incorporated (Entergy) has reviewed draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998). The draft NUREG reviews the historical use, technical basis, and industry experiences with KI as a supplemental protective action for the general public.

Entergy has worked with the Nuclear Energy Institute (NEI) and supports NEI's comments regarding the proposed rulemaking petition that requires states to "consider" the stockpiling or predistribution of KI as a protective action during emergencies. Additionally, Entergy has discussed this issue with our affected states of Arkansas, Louisiana, and Mississippi.

As a result, Entergy continues to believe that evacuating an area is the most effective response for protecting the public health and safety. Where evacuations are performed, we believe KI would not add any measure of safety to this proven approach, and could actually complicate and hinder emergency response. Based on this understanding, Entergy continues to support the position that evacuating and sheltering the public are the primary protective actions to follow during an emergency.

In conclusion, Entergy fully endorses the comments submitted by NEI regarding draft NUREG-1633. Entergy also requests the NRC reconsider its approval of the proposed rulemaking petition.

Thank you for the opportunity to provide our comments.

Sincerely,

Gary H. Davant

for Stephen J. Bethay
Acting Vice President, Operations Support

SJB/DAR/baa

cc: Mr. C. M. Dugger (W-3)
Mr. W. A. Eaton (GGNS)
Mr. R. K. Edington (RBS)
Mr. C. R. Hutchinson (ANO)
Mr. J. R. McGaha (ECH)

Mr. Jack N. Donohew, NRR Project Manager, GGNS
Mr. Chandu P. Patel, NRR Project Manager, Waterford-3
Mr. William D. Reckley, NRR Project Manager, ANO-1 & 2
Mr. David L. Wigginton, NRR Project Manager, RBS

Duke Energy

M. S. Tuckman
Executive Vice President
Nuclear Generation

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PS09
A. Mohseni

63 FR 38865
July 20, 1998

(8)

September 10, 1998

Mr. David L. Meyer
Chief, Rules Review and Directives Branch
Mail Stop T-6 D69
Office of Administration
U. S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Federal Register 38865, July 20, 1998)

Duke Energy offers the following comments on Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Federal Register 38865, July 20, 1998). The Draft NUREG provides an evaluation of the use of potassium iodide as a supplemental protective action within the plume exposure pathway.

The Draft NUREG-1633 provides a researched conclusion that the proposed rule change, requiring stockpiling and prophylactic issue of KI, will not effectively improve protective actions for the public. In some instances, KI may slow evacuations or even be administered unnecessarily as a result of the rule. Unnecessary administration of KI may have significant health consequences. Duke Energy urges the NRC to reconsider its approval of the Petition for Rulemaking filed by Mr. Peter G. Crane (60 Federal Register 58256, November 27, 1995).

Consequences of Chernobyl are often cited as a reason that the United States should distribute KI. This NUREG states that most of the thyroid dose at Chernobyl was from ingestion pathway. This emphasizes the importance of existing emergency planning for the ingestion pathway, rather than KI. For severe accidents with containment failure, the whole body doses are hazardous, not just the thyroid doses. Evacuation is more effective in reducing the

dose to the whole body. Where evacuations are performed, KI would not add any measure of safety to the existing emergency response, and could actually hinder emergency response by decreasing the speed of evacuation.

Administration of a drug without medical supervision to a broad population is a significant departure from the norm in emergency response, which is evacuation. In addition, the population most sensitive to radioiodines is children. One impediment to KI distribution to children in day cares and schools is the logistics associated with obtaining parental approval and having sufficient, qualified medical personnel available to administer the KI. Most offsite emergency plans call for precautionary evacuation of schools and day cares when a Site Area Emergency is declared. Under these conditions, offsite doses should not exceed a small fraction of the EPA protective action guideline levels of 5 Rem Thyroid CDE offsite, and should be much lower than the EPA's protective action guideline for the administration of stable iodine (25 Rem Thyroid CDE).

In order to achieve maximum thyroid blocking, KI has to be taken just prior to a release. The dose reduction is only a factor of 2 if KI is taken 3 to 4 hours after exposure, which would more typically be the case if KI were given outside the Emergency Planning Zone when people arrive at a reception center.

Severe accident studies have shown that even if there is serious damage to the core, there may not be a large release to the environment. The information included on the likelihood of a severe accident, and what (small) fraction of those result in a large early release, needs to be emphasized. In all four of the examples sited, the release occurred more than 11 hours after the initiating event, allowing time for evacuation to be completed prior to the release, eliminating the need for KI. The draft NUREG states, "If containment integrity can be maintained for 24 hours or more, the offsite risk is limited because of decay and in-containment removal processes." Duke Energy has implemented Severe Accident Management to help achieve that end in the unlikely event of a severe accident.

If there are any questions regarding the comments provided, please contact Tina Kuhr by telephone at (704) 382-3151.

Yours truly,

M. S. Tuckman

SCE&G

South Carolina Electric & Gas Company
Virgil C. Summer Nuclear Station
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(803) 345-4344
(803) 345-5209

Gary J. Taylor
Vice President
Nuclear Operations

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A. Ronsini

63 FR 38865
July 20, 1998

(9)

September 14, 1998
RC-98-0165

Mr. David L. Meyer
Chief, Rules Review and Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Meyer:

Subject: VIRGIL C. SUMMER NUCLEAR STATION
DOCKET NO. 50/395
OPERATING LICENSE NO. NPF-12
DRAFT NUREG-1633 COMMENTS

South Carolina Electric and Gas submits these comments in response to the subject notice. We have a reviewed draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998). The draft NUREG reviews the historical use, technical basis, and industry experiences with KI as a supplemental protective action for the general public.

Draft NUREG-1633 supports the industry position that "considering" stockpiling or predistribution of KI as a protective action will not add any significant public health and safety benefit to the adequate level of protection currently provided by existing emergency planning at and around commercial nuclear power plants. SCE&G urges the NRC to reconsider its approval of the proposed rulemaking petition.

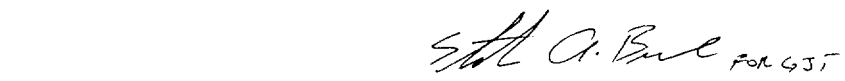
SCE&G endorses the draft NUREG which concludes careful consideration should be given to whether the use of KI for the public during an emergency is advantageous. SCE&G agrees with the staff's assessment in SECY 98-061, "Staff Options for Resolving a Petition for Rulemaking Relating to Reevaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant." We endorse Option 2. This option recommends denying the petition and supports the FRPPC policy statement discussed in COMSECY 97-028 which maintains that evacuation and sheltering are the primary protective actions.

If administered promptly, KI can be effective in blocking the thyroid and preventing radioiodine uptakes. The population most at risk in the situation are children through age 15. However, most emergency plans suggest precautionary evacuation of schools and day care facilities at declaration of a Site Area Emergency. Under these conditions, there is no imminent release of radioactive material that will exceed EPA Protective Action Guidelines beyond the site boundary. If children are evacuated, there is no opportunity to further reduce risk through distribution of potassium iodide.

A major impediment to KI distribution to school children is coordination and administration of the program, e.g., the actual decision-making process to administer KI or evacuate, parental approval and record keeping, identification and mitigation of allergic reactions, and the availability of a qualified medical professional to administer the potassium iodide.

The U.S. federal agencies, nuclear industry, state and local emergency response organizations have developed the most effective and sophisticated emergency preparedness plans in the world. The U.S. model recognizes that evacuating an area is the most effective response for protecting the public health and safety. Where evacuations are performed, potassium iodide would not add any measure of safety to this proven approach, and could actually complicate and hinder emergency response.

Very truly yours,



Gary J. Taylor

RAM/GJT/vjk

c: J. L. Skolds
W. F. Conway
R. R. Mahan
R. J. White
L. M. Padovan
M. K. Batavia
L. C. Hipp (505)
V. J. Kelley (507)
RTS (NRG 1633)
File (811.10)
DMS (RC-98-0165)

D509
A. Rahsen

63FR38865
July 20, 1998

North Atlantic

North Atlantic Energy Service Corporation
P.O. Box 300
Seabrook, NH 03874
(603) 474-9521

The Northeast Utilities System

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September 16, 1998

NYN-98108

Mr. David L. Meyer
Chief, Rules Review and
Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Seabrook Station
Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI)
As a Protective Action During Severe Reactor Accidents,"
(63 Fed. Reg. 38865, July 20, 1998)

North Atlantic Energy Service Corporation (North Atlantic), managing agent for the Joint Owners of Seabrook Station Nuclear Power Plant, endorses the Nuclear Energy Institute's (NEI) comments on the draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998).

North Atlantic believes that the use of KI as a protective action may be detrimental to the implementation of an effective emergency preparedness program that utilizes evacuation as a fundamental action. Therefore, we recommend that the NRC reverse its decision to revise emergency planning regulation to include consideration of KI as a protective measure for the general public.

North Atlantic appreciates the opportunity to comment on the draft NUREG. If you should have any questions on North Atlantic's comments, please contact Mr. Donald R. Tailleart, Emergency Preparedness Manager, at (603)773-7359.

Very truly yours,

NORTH ATLANTIC ENERGY SERVICE CORP.

Ted C. Feigenbaum
Executive Vice President and
Chief Nuclear Officer

Commonwealth Edison Company
1400 Opus Place
Downers Grove, IL 60515-5701

ComEd

September 18, 1998

Chief, Rules and Directives Branch
Division of Administrative Services
Office of Administration
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Subject: Comments on Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents"

Reference: Federal Register Volume 63, No. 138, Page 38865, July 20, 1998

This letter provides Commonwealth Edison (ComEd) Company comments on the subject Draft NUREG.

We have reviewed draft NUREG-1633,"Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (Federal Register Volume 63, No. 138, Page 38865, July 20, 1998). ComEd strongly supports the comments provided by the Nuclear Energy Institute and the State of Illinois in separate letters dated September 11, 1998.

Draft NUREG-1633 supports the position that "considering stockpiling or redistribution of KI as a protective action will not add any significant public health and safety benefit to the adequate level of protection currently provided by existing emergency planning at and around commercial nuclear power plants." ComEd concurs with this conclusion and recommends that the Nuclear Regulatory Commission review the current position and reconsider the adoption of Option 2 (i.e., the option to not have stockpiling or redistribution of KI as a protective action) of SECY 98-061, "Staff Options for Resolving a Petition for Rulemaking Relating to Re-evaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant."

Respectfully,

R. M. Krich
Vice President – Regulatory Services

CHARLES H. CRUSE
Vice President
Nuclear Energy

Baltimore Gas and Electric Company
Calvert Cliffs Nuclear Power Plant
1650 Calvert Cliffs Parkway
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410 495-4455

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A. Mohseni

63FR38865
July 20, 1998

(19)

September 22, 1998

U. S. Nuclear Regulatory Commission
Washington, DC 20555

ATTENTION: Mr. David L Meyer, Chief
Rules Review and Directives Branch

SUBJECT: Calvert Cliffs Nuclear Power Plant
Unit Nos. 1 & 2; Docket Nos. 50-317 & 50-318
Request for Comments; Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents" (63 FR 8865, July 20, 1998)

We have reviewed draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," concerning the historical use, technical basis, and industry experiences with KI as a supplemental protective action for the general public.

We endorse the draft NUREG's conclusion that careful consideration should be given to whether the use of KI for the public during an emergency is advantageous. The draft NUREG accurately states that "considering" stockpiling or predistribution of KI as a protective action will not add any significant public health and safety benefit beyond the existing emergency planning practices at commercial nuclear power plants.

Baltimore Gas and Electric Company also agrees with the staff's assessment in SECY 98-061 "Staff Options for Resolving a Petition for Rulemaking Relating to Re-evaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant." We endorse Option 2. This option recommends denying the petition and supports Federal Radiological Preparedness Coordinating Committee policy statement discussed in draft "Federal Register Notice on Potassium Iodine Policy," COMSECY 97-028, which maintains that evacuation and sheltering are the primary protective actions. We strongly urge the NRC to reconsider its approval of the proposed rulemaking petition.

Should you have questions regarding this matter, we will be pleased to discuss them with you.

Very truly yours,

CHC/JMO/dlm

cc: Document Control Desk, NRC
R. S. Fleishman, Esquire
J. E. Silberg, Esquire
S. S. Bajwa, NRC
A. W. Dromerick, NRC
H. J. Miller, NRC
Resident Inspector, NRC
R. I. McLean, DNR
J. H. Walter, PSC

From: Guy H Davant <gdavant@entergy.com>
To: TWFN_DO.twf2_po(ASM)
Date: Wed, Sep 16, 1998 4:30 PM
Subject: Comments on Draft NUREG-1633

September 16, 1998

Mr. David L. Meyer
Chief, Rules Review and Directives Branch
Office of Administration
Mail Stop T-6 D69
United States Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Comments on Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998)

CNRO-98/00021

Dear Mr. Meyer:

Entergy Operations, Incorporated (Entergy) has reviewed draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998). The draft NUREG reviews the historical use, technical basis, and industry experiences with KI as a supplemental protective action for the general public.

Entergy has worked with the Nuclear Energy Institute (NEI) and supports NEI*s comments regarding the proposed rulemaking petition that requires states to "consider" the stockpiling or predistribution of KI as a protective action during emergencies. Additionally, Entergy has discussed this issue with our affected states of Arkansas, Louisiana, and Mississippi.

As a result, Entergy continues to believe that evacuating an area is the most effective response for protecting the public health and safety. Where evacuations are performed, we believe KI would not add any measure of safety to this proven approach, and could actually complicate and hinder emergency response. Based on this understanding, Entergy continues to support the position that evacuating and sheltering the public are the primary protective actions to follow during an emergency.

In conclusion, Entergy fully endorses the comments submitted by NEI regarding draft NUREG-1633. Entergy also requests the NRC reconsider its approval of the proposed rulemaking petition.

Thank you for the opportunity to provide our comments.
Sincerely,

(Originally signed by Guy H. Davant for Stephen J. Bethay)

Stephen J. Bethay
Acting Vice President, Operations Support

From: "James D. Jones" <jonesjd@nimo.com>
To: TWFN_DO.twf2_po(ASM),GATED.nrcsmtp("jonesj1@nimo.c...
Date: Mon, Sep 14, 1998 8:50 AM
Subject: Comments on Draft NUREG-1633

Sirs:

I submit these comments on the Draft NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) as a Protective Action During Severe Reactor Accidents". I endorse the draft NUREG which concluded careful consideration should be given to whether the use of KI for the public during an emergency is advantageous. I agree with the staff's assessment in SECY 98-061 "Staff Options for Resolving a Petition for Rulemaking Relating to Re-evaluation of the Policy Regarding the Use of Potassium Iodide (KI) by the General Public After a Severe Accident at a Nuclear Power Plant". I endorse Option 2, which recommends denying the petition and supports the FRPCC policy statement discussed in COM SECY 97-028 which maintains that evacuation and sheltering are the primary protective actions. I believe that developing and maintaining an effective KI distribution and administration policy does not provide benefit to the public, and the current use of sheltering and evacuation sufficiently ensures the health and safety of the public during severe reactor accidents. Thank you for the opportunity to comment on this draft document.
James D. Jones, Director of Emergency Preparedness, Nine Mile Point Nuclear Station

0509
A. Nunsen

63FR 38865
July 29, 1998

(2)

September 8, 1998
2525 Votaw Road,
Apopka, FL 32703

Mr. David L. Meyer
Chief, Rules Review and Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Meyer:

I am writing to you in reference to draft NUREG-1633 which adresses the use of potassium iodide for the general public during a severe reactor accident. Although I work for the state of Florida in emergency response, I am writing to you as a member of the public.

The Nuclear Regulatory Agency has recently modified its policy with regard to the use of potassium iodide for the general public during a radiological accident. The new policy will require that states consider potassium iodide when developing emergency plans for dealing with radiological accidents, particularly nuclear power plant accidents.

The Nuclear Regulatory Agency requires that state and local emergency agencies have adequate plans in place to protect people during an emergency at a nuclear power plant prior to issuing an operating license to the utility. Florida has had these plans in place since before 1972 when Turkey Point Unit 3 began commercial operation. The counties around the four nuclear plant sites, Crystal River, St. Lucie, Turkey Point and Farley, along with the state exercise these plans on an annual basis, actually exceeding the Federal Emergency Management Agency's evaluation criteria. I believe the plans, personnel and equipment are among the best in the nation.

As Florida's nuclear power plant emergency plans evolved over the years, they considered the use of potassium iodide as a thyroid dose blocking agent. They have stockpiles for radiation workers and institutionalized persons, and the State Health Officer has preapproved its use during an emergency. For the general public, however, Florida's approach to dose avoidance is to evacuate the people prior to any release. The Nuclear Regulatory Agency, the Environmental Protection Agency and the Federal Emergency Management Agency all have agreed that evacuation is a superior method of avoiding dose when compared to others.

Potassium iodide is an effective way to limit thyroid dose to inhaled or ingested radioactive iodine, and I do not consider the medical side effects to be significant. If the only radionuclide involved in an accident were radioiodine, then perhaps issuing potassium iodide would be a viable plan. In a nuclear power plant accident many different radionuclides might be released, but never radioiodine by itself. The primary

goal of Florida's radiation emergency plans is to avoid deterministic health effects during a radioactive plume passage. Essentially this means avoiding exposure to the whole body from external radiation. The National Council on Radiation Protection and Measurements has evaluated the effect of external and internal radiation dose to the thyroid. They advise that external radiation is at least three times more detrimental to the thyroid than radioiodine per rad of absorbed dose, so it appears that using potassium iodide is not sufficient to protect the thyroid during a major release from a nuclear power plant.

I have spoken to the Florida Division of Emergency Management and the risk counties, all of whom are opposed to stockpiling potassium iodide. In addition, they are reluctant to attempt to distribute any drug during an ongoing emergency. They believe that such actions might impede evacuation. In addition, the means of distribution are a formidable problem. Some federal agencies have suggested firehouses, police stations, factories, hospitals, and doctor's offices as distribution centers, but I fear that fire and police will have their hands full with other evacuation requirements, while private offices and business places will be closed. As for schools and school children, no plans have been discussed that I am aware of, but the legal challenges of schools administering drugs to students are significant.

To summarize my opinions, I believe the current emergency plans offer the best means of protecting the general public during a reactor emergency and that distribution of potassium iodide would consume time better spent in evacuation and dilute resources while offering little or no additional protection. Thank you for considering my concerns about potassium iodide.

Sincerely,

Jearold C. Eakins

Peter G. Crane 4809 Drummond Avenue Chevy Chase, MD 20815 301-656-3998 pgcrane@erols.com

August 20, 1998

MEMORANDUM FOR: John C. Hoyle, Secretary, USNRC

FROM: Peter Crane

SUBJECT: SUPPLEMENTAL COMMENTS ON NRC STAFF TECHNICAL ASSESSMENT OF POTASSIUM IODIDE (DRAFT NUREG-1633)

I. **Introduction**

The NRC staff has published for comment the draft of NUREG-1633, which purports to be a technical assessment of potassium iodide. (The comment period expires September 15, 1998.) In announcing the availability of this document in the July 20, 1998, Federal Register, the staff omitted to mention that the Commission had granted my petition for rulemaking on KI a few weeks earlier. Can the actions of the Commission be of so little import to the NRC staff -- more precisely, to certain elements within the NRC staff -- that they can be ignored or disregarded altogether?[1]

I sincerely regret the need to submit these supplementary comments on NUREG-1633.[2] I am sure that the Commissioners are tired of reading my submissions on KI, but they cannot be half as tired of reading them as I am of having to write them. I had hoped that the KI issue was behind me. I had also hoped, for the NRC's sake, that the contention over KI was largely behind the agency (notwithstanding that a rulemaking would still have to be conducted), and that it would cease to be a distraction from the agency's other pressing responsibilities. It is high time that the NRC moved on to other matters. If all the money that the agency has spent studying and debating the KI issue during this period, including the salaries of all the people in different parts of the organization who have had to devote time to it, had been applied instead to buying KI, this country would probably have an abundance of KI for many years to come.

Nevertheless, I am submitting these comments, principally because, on closer review, I believe that NUREG-1633 has the potential to cause actual harm to the public in the event of an accident, through its discussion of tincture of iodine, as I shall explain below. At the same time, I will also offer some comments on other aspects of the document. As will be seen, my criticisms of NUREG-1633 focus on

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[1] I have already pointed out one remarkable omission from NUREG-1633 in a letter to the docket, dated August 5, 1998, that attached my recent talk on KI in Cambridge, England. The Food and Drug Administration's 1978 approval of KI as "safe and effective" goes unmentioned, as though it never happened, though this should be the starting point of any evaluation of KI's safety by a federal agency. (In other staff documents on KI, we have seen the omission of such other key events as the Kemeny Commission's recommendation in favor of KI stockpiling; the Chernobyl accident and the use of KI by the Poles; the upsurge of thyroid cancer in the former Soviet Union; and so on.) Contrary to the impression that readers of the August 17 issue of *Inside NRC* may have formed, my criticism was not that the NUREG failed to "explicitly acknowledge" the FDA position, it was that the NUREG contained not the slightest hint, explicit or implicit, that the FDA had made a finding on the safety and effectiveness of KI.

[2] As always, these are submitted in my private capacity, and are written at home on my own time.

the way that it represents the facts. You cannot expect a productive public debate on the merits of a policy issue if the public is denied the accurate and complete factual information that is necessary for an informed decision.

I would like to make clear to readers of what follows that I do not regard NUREG-1633 as representative of the NRC as a whole or of its most senior management. If NUREG-1633 were typical of the NRC's overall approach to factual issues relating to public health and safety, there would be reason for the gravest concern, but there is no reason to think that is the case. On the contrary, I believe that NUREG-1633, and the handling of the KI issue by the NRC staff, at levels below that of the staff's most senior management, are an aberration. (To be sure, the NRC's most senior managers bear some responsibility for the fact that the deficiencies in their subordinates' product were not noticed and corrected before NUREG-1633 was allowed to see the light of day, but that is a separate issue.) At the most senior level, the NRC staff is led, I believe, by people of integrity and good will, who do not and would not misrepresent or withhold facts that affect the health and safety of the American people, nor disregard the decisions of the Commission that they work for.

II. **Tincture of Iodine**

Drs. Janusz Nauman and Jan Wolff, in their May 1993 article in the American Journal of Medicine ("Iodine Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks", Vol. 94, p. 524), reported that "a surprising 6.14% [of Polish children] were given diluted tincture of iodine by their parents before the start of the [KI] program and then took a single dose of KI," adding, "This was confirmed by the brisk increase in sales of tincture of iodine in pharmacies." (At p. 528.) In their discussion of side effects, they report that "those children receiving diluted tincture of iodine had about twice the incidence of vomiting as the remainder of the group." (At p. 530.)

Dr. Nauman, at the Cambridge symposium, made the point that the fact that parents were willing to administer tincture of iodine to their children from bottles clearly labeled as containing poison suggested that people will not always behave rationally in a radiological accident, and that planners need to take that into account. In a private conversation with me, he said, "We said to these people, 'How could you do this, when it says 'POISON' on the bottle?", and they would say, 'Well, we thought it was a matter of life and death.'"

One moral to be drawn from this is that if you do not have KI available in an accident, some people will medicate their children and themselves with what is at hand, i.e., tincture of iodine.

NUREG-1633, in an apparent effort to discount the value of the Poles' use of KI, has this to say at p. 18: "In addition, about 6 percent of the prophylaxis resulted from self-administered tincture of iodine before the KI program was initiated." At page 37, in the "Glossary" section, it says this of "iodine tincture": "Disinfectant and germicide; 50 percent alcohol, 2 percent iodine, about 45 percent water; 3 drops in a quart of water kills amebas and bacteria in 30 minutes; ***a 4 oz. bottle contains enough iodine to block 22 thyroids.***" [Emphasis added.] There is not the slightest suggestion that there is anything inadvisable about giving tincture of iodine in lieu of KI in an emergency; on the contrary, one reasonable reading of these two passages is that KI stockpiling is unnecessary, because in a pinch, tincture of iodine can be used instead.

I recently telephoned the Georgetown University Hospital Poison Control Center and spoke to Ms. Jane Elshami. She told me that tincture of iodine, if taken by mouth, is rarely fatal. It is more likely to have caustic effects than systemic. The usual scenario for iodine tincture poisoning, she said, is an accidental pediatric ingestion, resulting in corrosive gastroenteritis, followed by vomiting. There can be

cardiac effects and renal toxicity. There is data, she said, on how much is a fatal dose. For adults, the probable mean lethal dose is 2-4 grams of free iodine or 1-2 ounces of a strong tincture. Reported lethal doses vary from a few tenths of a gram to more than 20 grams. She suggested that I could speak to one of their toxicologists if I wanted more detailed information, but it seemed to me that her information was sufficient for present purposes.

If ever there were a serious nuclear accident — unlikely as that is — and a state or local health official, in the excitement of the moment, were to come upon NUREG-1633 and decide, because of the absence of stockpiled KI, to advise parents to give their children tincture of iodine, the NRC would have much to answer for. I do not believe that the agency should take the chance of allowing the document to remain in circulation.

I plan to suggest to the Georgetown University Poison Control Center that it submit its comments on the draft, assuming that it has not already been withdrawn. Maybe if the staff hears directly from the toxicologists, it will pay attention.

III. **The Physician's Desk Reference and the Safety of KI**

With my concerns raised by the iodine tincture issue, it occurred to me to question some of the other factual representations in the document. At page 11, NUREG-1633 says:

> The staff's review of the *Physician's Desk Reference* (45th Edition, published by E.R. Barnhart, 1991) suggested that the safety of KI is far from absolute, especially if the drug is taken without medical supervision. The various reports concerning the medications containing KI are as diverse as the companies that produce the medications; however, these reports ***consistently state that the products are contraindicated for various groups of people (principally pregnant women; nursing mothers***; and people with hyperthyroidism, enlarged thyroids, or sensitivity to iodine."
>
> In addition to the ***consistent contraindications***, the reports include a variety of other warnings:
>
> - "Potassium iodide can cause fetal harm, abnormal thyroid function and goiter when administered to a pregnant woman. Because of the possible development of fetal goiter, if the drug is used during pregnancy or if the patient becomes pregnant during therapy, apprise the patient of the potential hazard." ....
>
> [Emphasis added.]

I recently consulted the 1997 Physician's Desk Reference and copied the only listing I found for potassium iodide tablets: Thyro-Block, manufactured by Carter-Wallace.[3] The section entitled "Who Should Not Take Potassium Iodide" reads as follows, in its entirety:

> The only people who should not take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or antithyroid drug). ***Pregnant and***

[3] A copy of this listing, which says that it was last revised in May 1994, is attached.

nursing women and babies and children may also take this drug. [Emphasis added.]

Later on in NUREG-1633, the NRC staff acknowledges (in a commendably full statement of the WHO position) that the World Health Organization and international practice call for administering KI to children and pregnant women in emergencies, but it reiterates the claim that U.S. sources recommend the opposite. The very last paragraph of the document, at p. 28, reads as follows:

International Practices

- Other countries and major international organizations, including the IAEA and WHO, endorse the use of KI. The international policies, in some cases, are significantly different from the U.S. policies. The principal example is the recommendation by the WHO to administer KI to pregnant women and children, ***whereas U.S. references specifically warn against administering KI to that same group.*** Cultural and legal differences between the U.S. and other countries may be the basis for differing perspectives on general drug use. [Emphasis added.]

I have not researched everything that may have been said about KI in every edition of the Physician's Desk Reference, but the quoted excerpt should suffice to refute the proposition that U.S. sources "consistently" advise against giving KI to children and pregnant women.

IV. **Miscellaneous Other Comments**

The following comments I will make only very briefly. Many of them deal with points that I have made at length, often repeatedly, in earlier submissions, and that have been repeatedly been ignored by the NRC staff. I am making them not because I think that at this late date, the same staff members who are responsible for the draft of NUREG-1633 will start responding to them, but for the Commissioners, NRC staff management at the highest levels, the public, and the record.

A. **When must KI be given to be beneficial?** [p. 2]

According to p. 2 of NUREG-1633, "the potential benefits can be realized *only* if the compound is administered just before the inhalation of ingestion of radioiodines." [Emphasis added.]

Let us compare this with what the Food and Drug Administration said in its final recommendations on KI, published in the Federal Register on June 29, 1982 (47 FR 28158):

> FDA concludes in the final recommendations that risks from the short-term use 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. FDA recommends that potassium iodide in doses of 130 milligrams (mg) be considered for thyroid blocking in radiation emergencies in those persons who are likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment. To have the greatest effect in decreasing the accumulation of radioiodine in the thyroid gland, these doses of potassium iodide should be administered immediately before or after exposure. If a person is exposed to

radioiodine when circumstances do not permit the immediate administration of potassium iodide, *the initial administration will still have substantial benefit even if it is taken 3 or 4 hours after acute exposure.* [Emphasis added.][4]

Readers can decide for themselves whom they believe: the federal agency with the responsibility for making judgments on the safety and effectiveness or drugs, or the authors of NUREG-1633, who for some reason did not think it appropriate to inform them that the FDA had spoken to the KI issue.

B. **How widespread is the use of KI internationally?** [pp. ix, 19-20]

The NUREG says that "to complete the picture," it includes advice as to the KI policies of the United Kingdom, Sweden, Switzerland, Finland, France, the WHO, and the IAEA. (In fact, it also deals with Germany.) The casual reader might understand this to be a complete list of the countries that stockpile KI, since there is no reference to the fact that many other countries also maintain supplies of the drug. Reference should therefore be made to Norway, Austria, the Czech Republic, Slovakia, Poland, Japan, Russia, Belarus, Ukraine, Armenia, Canada, etc. The reader should be made aware that U.S. policy is the exception rather than the rule.

I would draw particular attention to the case of Canada. (As long ago as April 1994, in a letter to the Commission that was brushed aside at the time, Senators Joseph Lieberman and Alan Simpson pointed out that Canadian provinces with nuclear power plants are among the governmental authorities that stockpile KI.) In view of all the staff's efforts in the NUREG to explain away the use of KI in other countries by pointing to the cultural, legal, and dietary differences between Europe and America, perhaps the staff should address what the differences are between, say, Ontario and Connecticut.

C. **What is the discussion of "ablation" about?** [p. ix]

The NUREG suggests that the "reduction in the risk of thyroid cancer obviously does not apply if the thyroid is ablated (dose greater than about 25,000 rads)." This is an argument that surfaced back in the 1980's: that if the thyroid dose is high enough, the thyroid is ablated (burned out), and thus all the risk of cancer disappears. The NUREG should make clear that even if you were to get an ablating thyroid dose without simultaneously getting enough whole-body dose to kill you, the consequences of being deprived of a functioning thyroid are not insignificant. For this and other medical questions, I suggest that the NRC staff should consult professional thyroidologists. When we have a Public Health Service whose expertise is presumably available to a federal agency, and NIH (which has been studying thyroid cancer for decades) is literally just down the street from NRC, why not call on their expertise?

D. **Evacuation vs. sheltering** [pp. ix, 1]

I have on numerous occasions cited the EPA "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents," EPA 400-R-92-001 (May 1992) for its discussion of sheltering, thyroid dose, etc. It is, I think, a thoughtful and balanced discussion of the pros and cons of evacuation and sheltering. (Rather than characterize what the EPA Manual says, I will attach the relevant pages.) I have tried to persuade the NRC staff to respond to what the Manual has to say; so far it hasn't.

Even if the NRC staff does not like what it says, the EPA Manual should be listed among the

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[4] A copy of the FDA Federal Register Notice is attached.

references. It isn't. As with the FDA "safe and effective" notice, the NRC staff has chosen to ignore what a sister agency has had to say on the very issue now under discussion.

Just to make my position crystal clear, the question as I see it is not whether KI is better than evacuation — it isn't, if complete evacuation is feasible -- but rather, given that emergencies often develop unpredictably, whether you want your emergency authorities to have three arrows in their quiver or only two. I feel strongly that it is better to have three, for greater flexibility in dealing with whatever may arise. If the third arrow were extremely expensive, it might be a harder question, but this one is so cheap that the issue is, or should be, a no-brainer.

E. **How easy is evacuation?** [p. i, 1-2]

The NUREG advises that "evacuation is relatively commonplace" in the U.S., since "people *largely* have their own means of transportation, travel routes are *generally* well suited to the movement of large numbers of people, and people have places to go." [Emphasis added]. The staff contrasts this with administration of a medicine to the general public, which "has no precedence [*sic*] in the United States."

I do not think that this kind of generalization, seemingly plucked out of the air, is a substitute for addressing issues. What does it mean that people "largely" have their own means of transportation? What does it mean that travel routes are "generally" well suited to moving large numbers of people? It would be considerably more useful if the staff addressed actual conditions in the vicinity of U.S. nuclear power plants, rather than offering Pollyannaish observations on the general state of life in the U.S.

F. **Carcinogenicity of I-131** (pp. 7, 9)

The authors of NUREG-1633 twice quote the following 1985 (*i.e.*, pre-Chernobyl) statement in NCRP-80: "Because I-131 has not been shown to be carcinogenic in people, a comparison of the thyroid cancer risk from I-131 with that from x-ray exposure is difficult." (The first time they quote it, they note, however, that the Chernobyl studies "indicate that internal and external dose may be equally effective in producing thyroid cancer.")

The world's leading expert on the long-term effect of I-131 used in medical treatment is Dr. L.E. Holm of Sweden. As he has reported in journal articles, and as he described at the recent conference in England, he has not found any increase in thyroid cancer in persons who received I-131 treatments in a medical setting. In the question period that followed his talk, I asked the following question: "In the United States, iodine prophylaxis with potassium iodide is a contentious issue, and some people are citing your work for the proposition that I-131 is not carcinogenic and that there is therefore no point in stockpiling KI. Would you care to comment?" His response was that his study did not establish whether or not I-131 was carcinogenic, but dealt only with this type of medical exposure to I-131. He added that he himself favored stockpiling of KI.

The crucial fact here is the one that the staff alludes to in the footnote: that in light of the disease appearing since Chernobyl, few experts now doubt the capacity of I-131 to cause cancer, especially in children aged 0-4 at the time of exposure.

G. **"Tendency of papillary cancer to recur in a more aplastic form some 10-20 years later."** [p. 9]

If the same thyroid cancers whose gravity the authors of NUREG-1633 are downplaying, because they "respond favorably to early treatment" [p. 17], tend to "recur in a more aplastic form some 10-20 years later," this puts radiation-caused papillary carcinoma in a new and more ominous light. Again, this is a question for medical experts, and NIH is down the street.

H. **Just two or three deaths**? [p. 17]

The reader could get the impression from this that the radiation-caused thyroid disease in the former Soviet Union is not all that significant. Sadly, that is not the case. Fatality figures alone give a very partial measure of the real significance. You need also to address such issues as the following: How many of the patients are likely to die of the disease at some point in the future? What is the quality of life like for those who have the disease but do not die of it? What is the frequency of metastasis? (At the Cambridge conference, a team from the Thyroid Cancer Center in Minsk, Belarus, reported metastases in more than 70% of cases, with distant metastases (*i.e.*, more extensive) in 14.7% of the patients.) What kinds of treatment are required? What are the health effects and quality of life impacts of those treatments?

If all you are willing to talk about is fatalities, you are giving an incomplete picture of the real significance of the disease, and thereby misleading the reader. One of these years, the NRC must finally begin to address, in a meaningful way, what non-fatal thyroid cancer entails, because this is an essential part of the factual basis for deciding whether it is sensible policy to have KI. Since 1989, I have been trying to explain to the staff that there is more to disease than whether you die of it, and that as a society, we regularly protect our children not only against diseases that are commonly fatal, but also against illnesses that normally are non-fatal, because we are concerned not just with saving life but also with preventing needless suffering. The staff has yet to address that point.

But fatalities are what NUREG-1633 wants to focus on. It says, at p. 9, of the risk of radiogenic thyroid cancer: "Even with external sources, however, the risk is difficult to assess for several reasons. *First, the less-reliable incidence data must be used because thyroid cancer is only infrequently fatal.*" [Emphasis added.] From a scientific agency, this is truly an extraordinary statement. The authors of NUREG-1633 are telling us that the data on radiogenic thyroid cancer is more reliable if it ends in a fatality than if it doesn't. How can such a claim be made with a straight face?

The crux of the policy question is not how many people will ultimately have "thyroid cancer" on their death certificates if there is an accident or act of terrorism and no KI is available, but whether it is worth seven cents to protect American children, especially those four years old and younger, from a disagreeable disease that will mean suffering for all of them and death for a few.[5] I'm sure I'll be accused of emotionalism for saying this, but I've shared a lot of hospital waiting rooms with children who have various types of cancer, and with their parents. I also once had a long telephone conversation with a distraught woman who called me and described the four-year battle of her daughter, then in her early teens, with thyroid cancer: initial surgery, radiation treatment, further surgery to clean out the cancerous lymph nodes from the length of her torso, followed by further radiation treatments. (This young woman will probably survive, but that doesn't mean that she and her mother have not suffered terribly already.) These experiences have helped inform my understanding of what cancer entails for young patients and

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[5] Perhaps the difference in viewpoint was summed up best by an exchange that took place in October, 1997, at the meeting in Painesville, Ohio. I made the point that the cancers in the Belarussian children have tended to be aggressive, with spread to the lymph nodes that leaves the children with surgical scars going from ear to ear. The NRC representative observed that this was in part a result of the limitations of surgical expertise in Belarus, and that in the U.S., the scars would be smaller. But the real issue is not whether American children will have long scars or short scars on their necks, it is whether at minimal cost we can take a step that will help ensure that they ne. : have *no* scars.

their families.[6] The American Thyroid Association's support of KI stockpiling also has a lot to do with the fact that its members are thyroidologists; they see the patients and their families, and they know what thyroid cancer involves. I can't help thinking that if the staff members responsible for NUREG-1633 had had similar experiences, they might be less impressed with the low fatality rates for childhood thyroid cancer and more inclined to agree with the Europeans, Canadians, Japanese, WHO, American Thyroid Association, Senator Lieberman, Senator Harkin, former Senator Simpson, and me that childhood thyroid cancer is a disease well worth preventing.

I. **Seismic events?** [p. 13]

The NUREG says of evacuations, "In addition, seismic events or traffic accidents could block some evacuation routes." Years ago, when intervenors in a California reactor licensing case tried to raise the issue of the complicating effects of earthquakes on emergency planning, the NRC dismissed this possibility, and was upheld in court. This NUREG may prove to be a boon to would-be filers of 2.206 petitions.

J. **"U.S. officials conducted a study"** [p. 21]

The NUREG discusses the TMI accident but fails to mention the President's Commission on the Accident at Three Mile Island (Kemeny Commission) and its recommendation in favor of KI stockpiling — a recommendation that the NRC initially endorsed enthusiastically. However, the NUREG does mention that after Chernobyl, "U.S. officials conducted a study" that determined that no changes in emergency planning were necessary. There is no citation to that study. In fact, it was a staff paper prepared by the NRC staff. (This is a matter of public record, because I criticized that staff paper in my Differing Professional Opinion, which is now a public document.) Here again we see the authors of the NUREG picking and choosing their data, inflating the significance of an ordinary NRC staff paper until it sounds like an authoritative U.S. Government position, while silently tiptoeing around the extensive, detailed, authoritative report of the Presidential Commission.

K. **Fast Food** [p. 8]

NUREG-1633 makes the point that Americans' thyroids are already partially blocked because of the high intake of iodine in the typical American diet. It says: "In recent decades, stable iodine has also become an important additive to bread and fast foods (especially hamburgers)."

In fact, most Americans *do* have a high intake of iodine, certainly as compared with the iodine-poor areas of Eastern Europe. The higher the individual's dietary intake of iodine, the less critical is the need for administration of KI in an emergency. So far, so good. Where I disagree with the authors of the NUREG is their apparent assumption that because millions of Americans have partially blocked thyroids, we can afford to ignore those who don't. Not everyone eats mass-produced bread or fast-food hamburgers.

L. **National Stockpiles** [p. 28]

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[6] I also saw many thyroid cancer patients professionally when I was an administrative judge on the Nuclear Claims Tribunal in the Republic of the Marshall Islands. Many of them had had their lives blighted by radiation-caused thyroid disease.

NUREG-1633 says: "National stockpiles of KI have been recommended along with chemical antidotes, serin vaccines and antibiotics for response to nuclear, biological, and chemical weapons. As an added assurance, these stockpiles are available to State officials, should there be a need for KI on an ad-hoc basis."

The reader should be informed that these stockpiles are supposed to amount to at most 4,000 pills in at most 27 sites. This minuscule amount is not enough to be of significant value to the general public in the event of a nuclear power plant accident or act of terrorism. Moreover, at the November 5, 1997, meeting at the NRC, FEMA officials said that no plans had been made for transferring KI from these stockpiles to the vicinity of nuclear power plants in an emergency.

M. **Legal Aspects** (p. 2)

NUREG-1633 says that it "does not address the ... legal factors associated with the use (or non-use) of KI," but then proceeds to do just that. It informs us, at p. 22, that "[t]he tort system in the U.S. is also quite unique," that in the U.S., "the implementation of a protective action may entail litigation and liability for long after the accident," and that "administration of KI on a mass basis would certainly entail litigation in this country...." It would be helpful to know whether these legal judgments represent the considered view of the NRC's Office of the General Counsel or of the authors of NUREG-1633. If the latter view themselves as better qualified than the FDA to judge drug safety, perhaps they also see themselves as better qualified than the NRC's lawyers to offer legal advice.

V. **Conclusion**

NUREG-1633, as I suggested in my comments filed on August 5, 1998, is a seriously defective document. It is, I submit, an advocacy piece, seemingly written to justify a particular policy position (one that the Commission has since rejected), rather than what was needed, which was a dispassionate analysis of the facts relating to KI. In its discussion of tincture of iodine, NUREG-1633 has sufficient potential to result in harm to the public that the printed copies of the document should be recalled and sent to the recycler. (Electronic versions should be taken off the NRC's website.) But the discussion of iodine tincture is just one of many, many problems with the document.

What the authors of NUREG-1633 may not understand is that a document as slanted as this one — if they recognize it to be slanted, which they may well not — is a reflection not only on them but also on the entire NRC and all the work that the agency does. It is far easier for individuals and organizations to lose their credibility than to regain it once it is lost. Persons intimately familiar with the NRC's work may have (and rightly so) high confidence that the agency would not suppress or manipulate safety data to keep an unsafe plant running; but what is the public at large to think, when it reads a document like this one? One can imagine members of the public asking themselves, "Why should we trust the NRC staff's evaluation of the safety of Millstone if we can't trust its evaluation of KI?" NUREG-1633 is a bad apple, and it should be removed from the barrel quickly.

The next question is whether the document should be rewritten or held in abeyance for now. I believe that the defects in NUREG-1633 are too pervasive to be patched up with an edit here and an edit there. I respectfully suggest to the Commission that the best course of action would be for the staff to proceed expeditiously with the rulemaking that the Commission has directed, and not be distracted from that effort by having simultaneously to try to make a silk purse out of the sow's ear that is NUREG-1633. When the rulemaking is complete, then and only then the staff should prepare a document that explains the basis of the final rule (in whatever form that final rule may take) and provides clear, honest, balanced

understandable, concise, and user-friendly guidance to help state and local authorities make informed choices regarding KI. Such a document does not need to be anywhere near 40 pages long, as is NUREG-1633. On the contrary, so long as the information in it is sound, a much shorter document would probably be far more helpful to state and local officials, because they are much more likely to read it through. (For the same reason, it is also more likely to get careful review within the NRC.)

In sum, I recommend that NUREG-1633 be shelved. If the information that was developed for it can be useful sometime in the future, when a new guidance document is prepared, well and good; if not, the whole episode nevertheless should have value to the NRC as a learning experience.

Attachments:
1. FDA Federal Register Notice (June 29, 1982)
2. Excerpt from 1997 Physician's Desk Reference
3. Excerpt from EPA Manual of Protective Action Guides and Protective Actions for Nuclear Incidents

cc:
Chairman Jackson
Commissioner Diaz
Commissioner McGaffigan
Senator Joseph Lieberman
Senator Tom Harkin
Georgetown University Poison Control Center
L. Joseph Callan, EDO
Hugh Thompson, Deputy EDO
Karen D. Cyr, General Counsel

18. ANDA 86-025; Isosorbide Dinitrate (sublingual) Tablets containing 10 mg of drug per tablet; Par.

ANDA 86-044; Dipyridamole Tablets containing 25 mg of the drug per tablet; Cord Laboratories, Inc., 2555 West Midway Blvd., Broomfield, CO 80020.

20. ANDA 86-081; Dipyridamole Tablets containing 25 mg of the drug per tablet; Bolar.

21. ANDA 87-006; Dipyridamole Tablets containing 25 mg of the drug per tablet; Zenith.

22. ANDA 87-039; Dipyridamole Tablets containing 25 mg of the drug per tablet; Chelsea.

23. ANDA 87-094; Dipyridamole Tablets containing 25 mg of the drug per tablet; Par.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-1053, as amended (21 U.S.C. 355)), and under authority delegated to the Director of the National Center for Drugs and Biologics (see 21 CFR 5.82 and 47 FR 26913 published in the Federal Register of June 22, 1982).

Dated: June 23, 1982.

Harry M. Meyer, Jr.,

Director, Bureau of Drugs and Biologics.

[FR Doc. 82-17473 Filed 6-28-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 81N-0087]

Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations On Use

AGENCY: Food and Drug Administration.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) announces the availability of final recommendations about administering potassium iodide to the general public in a radiation emergency. The final recommendations prepared by FDA's Bureau of Radiological Health and the Bureau of Drugs are being made available to assist State and local authorities in developing emergency-response plans for preventing adverse effects from exposure to radiation in the event that radioactivity is accidentally released into the environment.

ADDRESS: The final recommendations are on display in, and comments may be submitted to, the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and copies may be obtained from Bernard Shleien at the address below.

FOR FURTHER INFORMATION CONTACT: Bernard Shleien, Bureau of Radiological Health (HFX-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6220 or Edwin V. Dutra, Jr., Bureau of Drugs (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 22, 1980 (45 FR 69904), the Federal Emergency Management Agency (FEMA) outlined the responsibilities of several Federal agencies concerning emergency-response planning guidance that the agencies should provide to State and local authorities. The October 22, 1980 notice updated an earlier notice on the subject that the General Services Administration (GSA) published in the Federal Register of December 24, 1975 (40 FR 59494). (GSA responsibility for emergency management was transferred to FEMA by Executive Order 12148.)

The Department of Health and Human Services' (HHS) responsibilities for emergency-response planning include assisting State and local authorities in developing plans for preventing adverse effects from exposure to radiation in the event that radioactivity is released into the environment. These plans include the prophylactic use of drugs that would reduce the radiation dose to specific organs from the sudden release into the environment of large quantities of radioactivity that might include several radioactive isotopes of iodine.

As one step toward meeting the Department's responsibilities, FDA issued a notice in the Federal Register of December 15, 1978 (43 FR 58798) announcing its conclusion that potassium iodide is safe and effective for use as a thyroid-blocking agent in a radiation emergency under certain specified conditions of use. The notice also announced, however, that potassium iodide has not been used to such an extent or for such a period of time under radiation emergency conditions to permit the conclusion that the drug may be marketed without an approved new drug application (NDA). Thus, in the interest of public safety, the notice encouraged interested persons to submit to the agency NDA's for potassium iodide in oral dosage forms for use as a thyroid-blocking agent. In the issue for February 22, 1980 (45 FR 11912), FDA announced that potassium iodide as a thyroid-blocking agent is available commercially in both tablet and solution form. (Since that time, FDA has approved an additional NDA for potassium iodide in solution form for use as a thyroid-blocking agent.)

In the Federal Register of June 5, 1981 (46 FR 30199), FDA issued a notice announcing the availability of draft recommendations about administering potassium iodide to the general public in a radiation emergency. The draft recommendations were made available for public comment to provide FDA with views to be considered as it developed its final recommendations on this use of potassium iodide. The comment period closed on October 5, 1981 (see the Federal Register of September 18, 1981; 46 FR 46402).

FDA received comments from individual citizens, professional and consumer advocate groups, State and local health agencies, and other Federal agencies. The issues they raised are discussed in the "Background" section of the final recommendations.

One purpose of FDA's final recommendations is to facilitate a national consensus on the use of potassium iodide during a radiation emergency. Another is to provide information and guidance to Sate and local public health agencies and other persons responsible for formulating emergency-response plans for radiation accidents.

Uncertainties still exist about the dose-response for radioiodine-induced thyroid cancers and the incidence and severity of side effects from potassium iodide. These uncertainties, which are discussed in the final recommendations, are unlikely to be resolved soon.

Based on its consideration of comments received and its analysis of available information, 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. FDA recommends that potassium iodide in doses of 130 milligrams (mg) per day for adults and children above 1 year and 65 mg per day for children below 1 year of age be considered for thyroid blocking in radiation emergencies in those persons who are likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released into the environment. To have the greatest effect in decreasing the accumulation of radioiodine in the thyroid gland, these doses of potassium iodide should be administered immediately before or after exposure. If a person is exposed to radioiodine when circumstances do not permit the immediate administration of potassium iodide, the initial administration will still have substantial benefit even if it is taken 3 or 4 hours after acute exposure.

Taken together, the comments received during the public comment period and the actions of national and foreign radiation protection groups make these recommendations prudent because, although slightly above the range presented in draft recommendations (10 to 20 rem), a 25-rem projected dose to the thyroid is equal numerically to the Environmental Protection Agency's (EPA) upper Protective Action Guidance level for the general public and the United Kingdom's National Radiation Protection Board's upper level proposed for potassium iodide use. (EPA Protective Action Guides call for sheltering, evacuation, and controlled access as protective actions when the total accumulated thyroid doses are projected at 5 to 25 rem for the general population. The EPA guides do not specifically note the use of potassium iodide as a protective action for the general population.) These agencies would expect some protective action to be taken at 25 rem projected dose to the thyroid. Use of a single recommended value also eliminates questioned by State and local public health agencies about whether to use the upper or the lower part of a range of values.

FDA further recommends that officials responsible for radiation emergency response planning include in the emergency response planning a system of public information on the use of potassium iodide and a system of medical contact, reporting, and assistance.

Each State is responsible for formulating guidance on when, if at all, the public should be supplied with potassium iodide along with instructions on how to use it. In preparing guidance and making rules, State and local agencies should inform citizens of the nature of the radiation hazard and of the potential benefits and adverse effects of potassium iodide.

These final recommendations on potassium iodide use must be seen in the context of radiation emergency planning as a whole. The use of potassium iodide in the radiation emergency is not a panacea. It does not reduce the uptake by the body of other radioactive materials or provide protection against external radiation. The cost and effectiveness of other protective measures such as seeking shelter, evacuation, or respiratory protection also need to be considered.

Although FDA received written comments on the draft recommendations and considered them in formulation of these final recommendations, under 21 CFR 10.90 interested persons may submit further written comments on these final recommendations to the Dockets Management Branch (address above).

Dated: June 22, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-17466 Filed 6-28-82; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82F-0161]

Union Carbide Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Union Carbide Corp. has filed a petition proposing that the food additive regulations be amended to provide for specification changes in polysulfone resins as articles or components of articles intended for repeated use in contact with food.

FOR FURTHER INFORMATION CONTACT: Julia L. Ho, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B3629) has been filed by Union Carbide Corp., River Road, Bound Brook, NJ 08805, proposing that Part 177 (21 CFR Part 177) of the food additive regulations be amended to provide for a change in the molecular weight specifications and testing requirements for polysulfone resins as articles or components of articles intended for repeated use in contact with food.

The agency has carefully considered the potential environmental effects of this proposed action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 18, 1982

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 82-17471 Filed 6-28-82; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

Cancer Center Support Review Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Cancer Center Support Review Committee, National Cancer Institute, July 15-16, 1982, Building 31C, Conference Room 8, National Institutes of Health, Bethesda, Maryland 20205. This meeting will be open to the public on July 15 from 8:30 a.m. to 10:00 a.m. to review administrative details, and to present reports by the Division Director and the Branch Chief. Attendance by the public will be limited to space available.

In accordance with provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on July 15, from 10:00 a.m. to adjournment, and on July 16, from 8:30 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentale material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winifred Lumsden, the Committee Management Officer, National Cancer Institute, Building 31, Room 10A06, National Institutes of Health, Bethesda, Maryland 20205 (301/496-5708) will provide summaries of the meeting and rosters of committee members, upon request.

Dr. Robert L. Manning, Executive Secretary, Cancer Center Support Review Committee, National Cancer Institute, Westwood Building, Room 803 National Institutes of Health, Bethesda Maryland 20205 (301/496-7721) will furnish substantive program information.

Dated: June 17, 1982.

Betty J. Beveridge,

Committee Management Officer, National Institutes of Health.

(Catalog of Federal Domestic Assistance Number 13.397, project grants in cancer center support, National Institutes of Health

(NIH programs are not covered by OMB Circular A-95 because they fit the descripti of "programs not considered appropriate" i section 8(b) (4) and (5) of the Circular)

[FR Doc. 82-17484 Filed 6-28-82; 8:45 am]

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Wallace Laboratories—Cont.

Possible side effects include skin rashes, swelling of the salivary glands, and "iodism" (metallic taste, burning mouth and throat, sore teeth and gums, symptoms of a head cold, and sometimes stomach upset and diarrhea).
A few people have an allergic reaction with more serious symptoms. These could be fever and joint pains, or swelling of parts of the face and body and at times severe shortness of breath requiring immediate medical attention.
Taking iodide may rarely cause overactivity of the thyroid gland, underactivity of the thyroid gland, or enlargement of the thyroid gland (goiter).

WHAT TO DO IF SIDE EFFECTS OCCUR
If the side effects are severe or if you have an allergic reaction, stop taking potassium iodide. Then, if possible, call a doctor or public health authority for instructions.

HOW SUPPLIED
THYRO-BLOCK® Tablets (Potassium Iodide Tablets, USP) are white, round tablets, one side scored, other side debossed 472 WALLACE, each containing 130 mg potassium iodide. Available in bottles of 14 tablets (NDC 0037-0472-20).

WALLACE LABORATORIES
Division of
CARTER-WALLACE, INC.
Cranbury, New Jersey 08512
IN-0472-03 Rev. 5/94

TUSSI-ORGANIDIN® DM NR* ℞
(*Newly Reformulated) Liquid .

TUSSI-ORGANIDIN® DM-S† NR*
(*Newly Reformulated) Liquid
(guaifenesin, dextromethorphan hydrobromide)

Professional Labeling Information and Directions for Use
This product labeled for sale on prescription only.

DESCRIPTION
TUSSI-ORGANIDIN® DM NR* (*Newly Reformulated) Liquid is a clear yellow liquid with a raspberry flavor.
Each 5 mL (1 teaspoon) contains: .... 100 mg
Guaifenesin, USP .... 10 mg
Dextromethorphan Hydrobromide, USP
Other ingredients: Citric acid, D&C Yellow No. 10, FD&C Red No. 40, flavor (artificial), glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol.
Guaifenesin (glyceryl guaiacolate) has the chemical name 3-(2-methoxyphenoxy)-1,2-propanediol. Its molecular formula is $C_{10}H_{14}O_4$, with a molecular weight of 198.21. It is a white, colorless crystalline substance with a slightly bitter aromatic taste. One gram dissolves in 20 mL water at 25°C; freely soluble in ethanol. Guaifenesin is readily absorbed from the GI tract and is rapidly metabolized and excreted in the urine. Guaifenesin has a plasma half-life of one hour. The major urinary metabolite is beta-(2-methoxyphenoxy) lactic acid.

CLINICAL PHARMACOLOGY
TUSSI-ORGANIDIN® DM NR* (*Newly Reformulated) combines the expectorant, guaifenesin and the cough suppressant, dextromethorphan hydrobromide. Guaifenesin is an expectorant the action of which promotes or facilitates the removal of secretions from the respiratory tract. By increasing sputum volume and making sputum less viscous, guaifenesin facilitates expectoration of retained secretions. Dextromethorphan is a synthetic nonopioid cough suppressant, the dextro isomer of the codeine analogue of levorphanol. Dextromethorphan acts centrally to elevate the threshold for coughing, but does not have addictive, analgesic or sedative actions and does not produce respiratory depression with usual doses.

INDICATIONS AND USAGE
Temporarily relieves cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants. Calms the cough control center and relieves coughing. Helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes, and make coughs more productive.

CONTRAINDICATIONS
Hypersensitivity to any of the ingredients. The use of dextromethorphan-containing products is contraindicated in patients receiving monoamine oxidase inhibitors (MAOIs).

has not been established relative to possible adverse effects on fetal development. Therefore, this product should not be used in pregnant patients, unless in the judgment of the physician, the potential benefits outweigh possible hazards.
Nursing Mothers: It is not known whether guaifenesin or dextromethorphan is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when these products are administered to a nursing woman and a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
Laboratory Test Interactions: Guaifenesin or its metabolites may cause color interference with the VMA (vanillylmandelic acid) test for catechols. It may also falsely elevate the level of urinary 5-HIAA (5-hydroxyindoleacetic acid) in certain serotonin metabolite chemical tests because of color interference.
Drug Interactions: Serious toxicity may result if dextromethorphan is coadministered with monoamine oxidase inhibitors (MAOIs). The use of dextromethorphan hydrobromide may result in additive CNS depressant effects when coadministered with alcohol, antihistamines, psychotropics or other drugs which produce CNS depression.
Information for Patients: Patients should be warned not to use this product if they are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If patients are uncertain whether a prescription drug contains an MAOI, they should be instructed to consult a health professional before taking such a product.

ADVERSE REACTIONS
Guaifenesin is well tolerated and has a wide margin of safety. Nausea and vomiting are the side effects that occur most commonly. Other reported adverse reactions have included dizziness, headache and rash (including urticaria). Rare drowsiness or mild gastrointestinal disturbances are the only side effects associated with dextromethorphan in clinical use. (see also Drug Interactions)

OVERDOSAGE
Overdosage with guaifenesin is unlikely to produce toxic effects since its toxicity is low. Guaifenesin, when administered by stomach tube to test animals in doses up to 5 grams/kg, produced no signs of toxicity. In severe cases of overdosage, treatment should be aimed at reducing further absorption of the drug. Gastric emptying (emesis and/or gastric lavage) is recommended as soon as possible after ingestion. Overdosage with dextromethorphan may produce excitement and mental confusion. Very high doses may produce respiratory depression. One case of toxic psychosis (hyperactivity, marked visual and auditory hallucinations) after ingestion of a single 300 mg dose of dextromethorphan has been reported.

DOSAGE AND ADMINISTRATION
Adults and children 12 years of age and older: 2 teaspoonfuls (10 mL) every four hours not to exceed 12 teaspoonfuls (60 mL) in 24 hours.
Children 6 years to under 12 years of age: 1 teaspoonful (5 mL) every four hours not to exceed 6 teaspoonfuls (30 mL) in 24 hours.
Children 2 to under 6 years of age: ½ teaspoonful (2.5 mL) every four hours not to exceed 3 teaspoonfuls (15 mL) in 24 hours.
Children 6 mo. to under 2 years of age: A common dosage is ⅛ teaspoonful to ¼ teaspoonful (0.6 mL to 1.25 mL) every 4 hours or ½ teaspoonful (2.5 mL) every 6–8 hours, not to exceed 1.5 teaspoonfuls (7.5 mL) in 24 hours. Individualized dosage should be determined by evaluation of patient.

HOW SUPPLIED
Guaifenesin 100 mg and dextromethorphan hydrobromide 10 mg per 5 mL of clear yellow liquid in bottles of one pint (NDC 0037-4714-10) and one gallon (NDC 0037-4714-20), and 4 fl oz (NDC 0037-4714-01) labeled TUSSI-ORGANIDIN® DM-S† NR.*
Storage—Store at controlled room temperature—15°–30°C (59°–86°F). Protect from light. Keep bottle tightly closed.
†TUSSI-ORGANIDIN® DM-S NR* is TUSSI-ORGANIDIN® DM NR* Liquid either in a 4 fl oz unit of use container with a 10 mL graduated oral syringe and fitment or in a 30 mL sample container.
TUSSI-ORGANIDIN® DM NR* (*Newly Reformulated) Liquid is distributed by:
WALLACE LABORATORIES

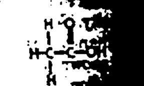
VASCOR®
brand of bepridil hydrochloride
Tablets

Marketed jointly by McNeil Pha[illegible] Laboratories. See McNeil Pharma[illegible] mation.

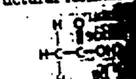
VōSoL®
OTIC SOLUTION
(acetic acid otic solution, USP)

VōSoL® HC
OTIC SOLUTION
(hydrocortisone and acetic acid

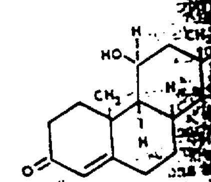
DESCRIPTION
VōSoL (acetic acid otic solution, USP) [illegible] acid (2%), in a propylene glycol vehic[illegible] glycol diacetate (3%), benzethonium [illegible] sodium acetate (0.015%). The empiri[illegible] acid is CH_3COOH, with a molecul[illegible] structural formula is:



VōSoL is available as a nonaqueous [illegible] pH 3 for use in the external ear [illegible]
VōSoL HC (hydrocortisone and [illegible] USP) is a solution containing hydroco[illegible] acid (2%), in a propylene glycol vehicl[illegible] glycol diacetate (3%), benzethonium [illegible] dium acetate (0.015%) and citric acid [illegible] formulas for acetic acid and hydroco[illegible] and $C_{21}H_{30}O_5$, with a molecular weig[illegible] respectively. The structural formula[illegible]



Acetic Acid



Chemically, hydroco[illegible]
Pregn-4-ene-3,20-di[illegible]
11,17,21-trihydroxy-[illegible]

VōSoL HC is available as a nonaqueo[illegible] at pH 3 for use in the external ear [illegible]

CLINICAL PHARMACOLOGY
VōSoL—Acetic acid is antibacterial [illegible] ene glycol is hydrophilic and provide[illegible] benzethonium chloride is a surface [illegible] motes contact of the solution with [illegible]
VōSoL HC—Acetic acid is antibacter[illegible] drocortisone is anti-inflammatory, [illegible] ritic; propylene glycol is hydrophilic [illegible] face tension; benzethonium chloride i[illegible] that promotes contact of the solution [illegible]

INDICATIONS AND USAGE
VōSoL—For the treatment of super[illegible] external auditory canal caused by [illegible] the action of the antimicrobial. [illegible]
VōSoL HC—For the treatment [illegible] of the external auditory canal cause[illegible] tible to the action of the antimi[illegible] inflammation.

...pyrazone —large doses of aspirin ...ffect of both drugs. Renal excretion ...be red...ed.
...s – ...ment of hypoglycemia ...
...nt th... ...s raise urinary pH, ant... ...ly decrease plasma salicylate con... ...y, their withdrawal can result in a ...
...–this and other drugs that acidify a ...ine can elevate plasma salicylate ...
...ced aspirin-induced fecal blood loss ...
...ylate plasma levels may be de... ...corticosteroids are given, and may ...ially when they are discontinued.
...nesis, Impairment of Fertility: No ...been done with 'Soma' Compound ...
...Effects: Pregnancy Category C. ...duction studies have not been con... ...pound with Codeine. It is also not ...Compound with Codeine can cause ...istered to a pregnant woman or can ...city. 'Soma' Compound with Codeine ...nant woman only if clearly needed. ...shown salicylates to be teratogenic ...tation, and embryocidal when given ...ses considerably greater than usual ...mans. Studies in women who took ...ncy have not demonstrated an in... ...ngenital abnormalities in the off...
...gestion of aspirin near term or prior ...g delivery or lead to bleeding in ...te.
...isoprodol is excreted in human milk ...-four times that in maternal plasma. ...man milk in moderate amounts and ...tende... ...in nursing infants. Because ...ou... ...reactions in nursing in... ...d ... whether to discontinue ...kin... ...account the importance of ...
...and effectiveness in children below ...not been established.

NS

...; discontinue 'Soma' Compound with ...propriate symptomatic and support...
...ts which have occurred with the ad... ...lividual ingredients alone may also ...ation.
...Nervous System—Drowsiness is the ...t and along with other CNS effects ...duction. Observed less frequently are ...taxia. Tremor, agitation, irritability, ...actions, syncope, and insomnia have ...e.
...ratic reactions are very rare. They ... the period of the first to fourth dose ...go previous contact with the drug (see ...
...ythema multiforme, pruritus, eosino... ...eruptions with cross-reaction to mep... ...reported. If allergic reactions occur, ...pound with Codeine and treat symp... ...ting possible allergic reactions, also ...ipients (information on excipients is ... on request).
...rdia, postural hypotension, and ...
...sea, vomiting, epigastric distress and ...
...us blood dyscrasias have been attrib... ...done. Leukopenia and pancytopenia ...ry rarely, in situations in which other ...ns may have been responsible.
...mmon adverse reactions associated ...h ... gastrointestinal, including ...ri... bleeding, constipation and ...ic... ...lema, asthma, rash, pruri... ...been reported less commonly. Tinni... ...serum salicylate levels (see OVER...
...allergic type reactions in aspirin-sensi... ...involve the respiratory tract or the ...e former range from rhinorrhea and ...severe asthma, and the latter may

Codeine Phosphate: Nausea, vomiting, constipation, miosis, sedation, and dizziness have been reported.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: Schedule C-III (see PRECAUTIONS).
Abuse: In clinical use, abuse has been rare.
Dependence: In clinical use, dependence with 'Soma' Compound with Codeine has been rare and there have been no reports of significant abstinence signs. Nevertheless, the following information on the individual ingredients should be kept in mind.
Carisoprodol—In dogs, no withdrawal symptoms occurred after abrupt cessation of carisoprodol from dosages as high as 1 gm/kg/day. In a study in man, abrupt cessation of 100 mg/kg/day (about five times the recommended daily adult dosage) was followed in some subjects by mild withdrawal symptoms such as abdominal cramps, insomnia, chills, headache, and nausea. Delirium and convulsions did not occur (see PRECAUTIONS).
Codeine Phosphate—Drug dependence of the morphine type may result.

OVERDOSAGE

Signs and Symptoms: Any of the following which have been reported with the individual ingredients may occur and may be modified to a varying degree by the effects of the other ingredients present in 'Soma' Compound with Codeine.
Carisoprodol—Stupor, coma, shock, respiratory depression and, very rarely, death. Overdosage with carisoprodol in combination with alcohol, other CNS depressants, or psychotropic agents can have additive effects, even when one of the agents has been taken in the usually recommended dosage.
Aspirin—Headache, tinnitus, hearing difficulty, dim vision, dizziness, lassitude, hyperpnea, rapid breathing, thirst, nausea, vomiting, sweating and occasionally diarrhea are characteristic of mild to moderate salicylate poisoning. Salicylate poisoning should be considered in children with symptoms of vomiting, hyperpnea, and hyperthermia.
Hyperpnea is an early sign of salicylate poisoning, but dyspnea supervenes at plasma levels above 50 mg/dl. These respiratory changes eventually lead to serious acid-base disturbances. Metabolic acidosis is a constant finding in infants but occurs in older children only with severe poisoning; adults usually exhibit respiratory alkalosis initially and acidosis terminally.
Other symptoms of severe salicylate poisoning include hyperthermia, dehydration, delirium, and mental disturbances. Skin eruptions, GI hemorrhage, or pulmonary edema are less common. Early CNS stimulation is replaced by increasing depression, stupor, and coma. Death is usually due to respiratory failure or cardiovascular collapse.
Codeine Phosphate—pinpoint pupils, CNS depression, coma, respiratory depression, and shock.
Treatment: General—Provide symptomatic and supportive treatment, as indicated. Any drug remaining in the stomach should be removed using appropriate procedures and caution to protect the airway and prevent aspiration, especially in the stuporous or comatose patient. Incomplete gastric emptying with delayed absorption of carisoprodol has been reported as a cause for relapse. Should respiration or blood pressure become compromised, respiratory assistance, central nervous system stimulants, and pressor agents should be administered cautiously, as indicated.
Carisoprodol—The following have been used successfully in overdosage with the related drug meprobamate: diuretics, osmotic (mannitol) diuresis, peritoneal dialysis, and hemodialysis (see CLINICAL PHARMACOLOGY). Careful monitoring of urinary output is necessary and caution should be taken to avoid overhydration. Carisoprodol can be measured in biological fluid by gas chromatography (Douglas, J. F., et al: *J Pharm Sci 58*: 145, 1969).
Aspirin—Since there are no specific antidotes for salicylate poisoning, the aim of treatment is to enhance elimination of salicylate and prevent or reduce further absorption; to correct any fluid, electrolyte or metabolic imbalance; and to provide general and cardiorespiratory support. If acidosis is present, intravenous sodium bicarbonate must be given, along with adequate hydration, until salicylate levels decrease to within the therapeutic range. To enhance elimination, forced diuresis and alkalinization of the urine may be beneficial. The need for hemoperfusion or hemodialysis is rare and should be used only when other measures have failed.
Codeine Phosphate—Narcotic antagonists, such as nalorphine and levallorphan, may be indicated.

DOSAGE AND ADMINISTRATION

Usual Adult Dosage: 1 or 2 tablets, four times daily.
Not recommended for use in children under age twelve.

HOW SUPPLIED

'Soma' Compound with Codeine Tablets (carisoprodol, USP 200 mg, aspirin 325 mg, and codeine phosphate, USP 16 mg) are oval, convex, two-layered and inscribed on the white layer with SOMA CC and on the yellow layer with [illegible] are available in bottles of 100

Storage: Store at controlled room temperature 15°–30°C (59°–86°F). Protect from moisture.
Dispense in a tight container.

WALLACE LABORATORIES
Division of CARTER-WALLACE, INC.
Cranbury, New Jersey 08512

Rev. 9/93

Shown in Product Identification Guide, page 339

THYRO-BLOCK® OTC
TABLETS
(POTASSIUM IODIDE TABLETS, USP)
(pronounced poe-TASS-e-um EYE-oh-dyed)
(abbreviated: KI)

TAKE POTASSIUM IODIDE ONLY WHEN PUBLIC HEALTH OFFICIALS TELL YOU. IN A RADIATION EMERGENCY, RADIOACTIVE IODINE COULD BE RELEASED INTO THE AIR. POTASSIUM IODIDE (A FORM OF IODINE) CAN HELP PROTECT YOU. IF YOU ARE TOLD TO TAKE THIS MEDICINE, TAKE IT ONE TIME EVERY 24 HOURS. DO NOT TAKE IT MORE OFTEN. MORE WILL NOT HELP YOU AND MAY INCREASE THE RISK OF SIDE EFFECTS. *DO NOT TAKE THIS DRUG IF YOU KNOW YOU ARE ALLERGIC TO IODIDE.* (SEE SIDE EFFECTS BELOW.)

INDICATIONS

THYROID BLOCKING IN A RADIATION EMERGENCY ONLY.

DIRECTIONS FOR USE

Use only as directed by State or local public health authorities in the event of a radiation emergency.

DOSE

Tablets: ADULTS AND CHILDREN 1 YEAR OF AGE OR OLDER: One (1) tablet once a day. Crush for small children.
BABIES UNDER 1 YEAR OF AGE: One-half (1/2) tablet once a day. Crush first.

Take for 10 days unless directed otherwise by State or local public health authorities.
Store at controlled room temperatures between 15° and 30°C (59° to 86°F). Keep container tightly closed and protect from light.

WARNING

Potassium iodide should not be used by people allergic to iodide. Keep out of the reach of children. In case of overdose or allergic reaction, contact a physician or the public health authority.

DESCRIPTION

Each white, round, scored, monogrammed THYRO-BLOCK® Tablet contains 130 mg of potassium iodide. Other ingredients: magnesium stearate, microcrystalline cellulose, silica gel, and sodium thiosulfate.

HOW POTASSIUM IODIDE WORKS

Certain forms of iodine help your thyroid gland work right. Most people get the iodine they need from foods, like iodized salt or fish. The thyroid can "store" or hold only a certain amount of iodine.
In a radiation emergency, radioactive iodine may be released in the air. This material may be breathed or swallowed. It may enter the thyroid gland and damage it. The damage would probably not show itself for years. Children are most likely to have thyroid damage.
If you take potassium iodide, it will fill up your thyroid gland. This reduces the chance that harmful radioactive iodine will enter the thyroid gland.

WHO SHOULD NOT TAKE POTASSIUM IODIDE

The only people who should not take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or antithyroid drug). Pregnant and nursing women and babies and children may also take this drug.

HOW AND WHEN TO TAKE POTASSIUM IODIDE

Potassium iodide should be taken as soon as possible after public health officials tell you. You should take one dose every 24 hours. More will not help you because the thyroid can "hold" only limited amounts of iodine. Larger doses will increase the risk of side effects. You will probably be told not to take the drug for more than 10 days.

SIDE EFFECTS

Usually, side effects of potassium iodide happen when people take higher doses for a long time. You should be careful not to take more than the recommended dose or take it for longer than you are told. Side effects are unlikely because of the low dose and the short time you will be taking the drug.

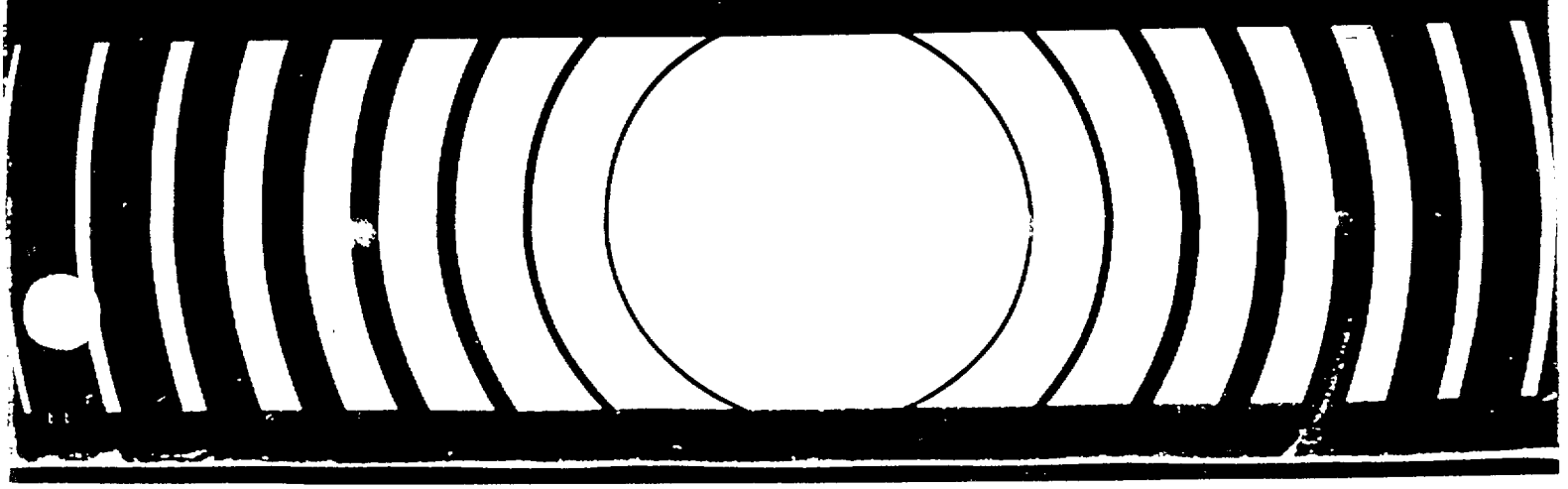
United States
Environmental Protection
Agency

Air And Radiation
(ANR-460)

May 1992

EPA

Manual Of Protective Action Guides And Protective Actions For Nuclear Incidents



ormer PAG for whole body exposure provides public health protection parable to that provided by the new , expressed in terms of effective dose equivalent. This is demonstrated n Table C-9 (Appendix C), which shows comparative doses for nuclear power plant fuel-melt accident sequences having a wide range of magnitudes. The PAG for the thyroid is unchanged. On the other hand, application of these PAGs to alpha emitting radionuclides leads to quite different derived response levels from those based on earlier health physics considerations, because of new dose conversion factors and the weighting factors assigned to the exposed organs (EP-88).

5.5 Protective Actions

This section provides guidance for plementing the principal protective actions (evacuation and sheltering) for protection against the various exposure pathways resulting from an airborne plume. Sheltering means the use of the closest available structure which will provide protection from exposure to an airborne plume, and evacuation means the movement of individuals away from the path of the plume.

Evacuation and sheltering provide different levels of dose reduction for the principal exposure pathways (inhalation of radioactive material, and direct gamma exposure from the plume or from material deposited on surfaces). The effectiveness of evacuation will depend on many factors, such as how rapidly it can be implemented and the nature of the accident. For accidents where the principal source of dose is inhalation, evacuation could increase exposure if it is implemented during the passage of a short-term plume, since moving vehicles provide little protection against exposure (DO-90). However, studies (NR-89a) continue to show that, for virtually all severe reactor accident scenarios, evacuation during plume passage does not increase the risk of acute health effects above the risk while sheltering. Sheltering, which in most cases can be almost immediately implemented, varies in usefulness depending upon the type of release, the shelter available, the duration of the plume passage, and climatic conditions.

Studies have been conducted to evaluate shelter (EP-78a) and evacuation (HA-75) as protective actions for incidents at nuclear power facilities. Reference EP-78b suggests one method for evaluating and comparing the benefits of these two actions. This requires collecting planning information before and data following an incident, and using calculations and graphical means to evaluate whether evacuation, sheltering, or a combination of sheltering followed by evacuation should be recommended at different locations. Because of the many interacting variables, the user is forced to choose between making decisions during the planning phase, based on assumed data that may be grossly inaccurate, or using a time-consuming more comprehensive process after the

incident when data may be available. In the former situation, the decision may not have a sound basis, whereas in the latter, the decision may come too late to be useful.

The recommended approach is to use planning information for making early decisions. The planned response should then be modified following the incident only if timely detailed information is available to support such modifications.

The planner should first compile the necessary information about the emergency planning zone (EPZ) around the facility. For the case of power reactors, some of this information is described in NUREG-0654 (NR-80). It should include identifying the population distribution, the sheltering effectiveness of residences and other structures, institutions containing population groups that require special consideration, evacuation routes, logical boundaries for evacuation zones, transportation systems, communications systems, and special problem areas. In addition, the planner should identify the information that may be available following an incident, such as environmental monitoring data, meteorological conditions, and plant conditions. The planner should identify key data or information that would justify specific protective actions. The evaluation and planning should also include the selection of institutions where persons should be provided with stable iodine for thyroid protection in situations where radioiodine inhalation is projected.

The following sections discuss key factors which affect the choice between evacuation and sheltering.

5.5.1 Evacuation

The primary objective of evacuation is to avoid exposure to airborne or deposited radioactive material by moving individuals away from the path of the plume. Evacuation, if completed before plume arrival, can be 100 percent effective in avoiding future exposure. Even if evacuation coincides with or follows plume passage, a large reduction of exposure may be possible. In any case, the maximum dose avoided by evacuation will be the dose not avoidable by sheltering.

Some general conclusions regarding evacuation (HA-75) which may be useful for planning purposes are summarized below:

1. Advanced planning is essential to identify potential problems that may occur in an evacuation.

2. Most evacuees use their own personal transportation.

3. Most evacuees assume the responsibility of acquiring food and shelter for themselves.

4. Evacuation costs are highly location-dependent and usually will not

be a deterrent to carrying out an evacuation.

5. Neither panic nor hysteria has been observed when evacuation of large areas is managed by public officials.

6. Large or small population groups can be evacuated effectively with minimal risk of injury or death.

7. The risk of injury or death to individual evacuees from transportation does not change as a function of the number of persons evacuated, and can be conservatively estimated using National Highway Safety Council statistics for motor vehicle accidents (subjective information suggests that the risks will be lower).

Evacuation of the elderly, the handicapped, and inhabitants of medical and other institutions may present special problems. When sheltering can provide adequate protection, this will often be the protective action of choice. However, if the general public is evacuated and those in institutions are sheltered, there is a risk that attendants at these institutions may leave and make later evacuation of institutionalized persons difficult because of a lack of attendants. Conversely, if evacuation of institutions is attempted during evacuation of the public, traffic conditions may cause unacceptable delays. If evacuation of institutions is attempted before evacuating the public, increased risk to the public from a delayed evacuation could occur, unless the incident is very slow in developing to the point of an atmospheric release. Because of the above difficulties, medical and other institutions located within the EPZ should be evaluated to determine whether there are any logical categories of persons that should be evacuated after the public (or, when time permits, before).

5.5.2 Sheltering

Sheltering refers here to the use of readily available nearby structures for protection against exposure to an airborne plume.

Sheltering may be an appropriate protective action because:

1. It positions the public to receive additional instructions when the possibility of high enough doses to justify evacuation exists, but is small.

2. It may provide protection equal to or greater than evacuation.

3. It is less expensive and disruptive than evacuation.

4. Since it may be implemented rapidly, sheltering may be the protective action of choice if rapid evacuation is impeded by, a) severe environmental conditions--e.g. severe weather or floods; b) health constraints--e.g. patients and workers in hospitals and nursing homes; or c) long mobilization times--certain industrial and farm workers, or prisoners and guards; d) physical

constraints to evacuation--e.g. inadequate roads.

5. Sheltering may be more effective against inhalation of radioactive particulates than against external gamma exposure, especially for short-term plumes.

The use of large structures, such as shopping centers, schools, churches, and commercial buildings, as collection points during evacuation mobilization will generally provide greater protection against gamma radiation than use of small structures.

As with evacuation, delay in taking shelter during plume passage will reduce the protection from exposure to radiation. The degree of protection provided by structures is governed by attenuation of gamma radiation by structural components (the mass of walls, ceilings, etc.) and by outside/inside air-exchange rates.

If external dose from the plume or from deposited materials is the controlling criterion, shelter construction and shelter size are the most important considerations; ventilation control and filtering are less important. Although sheltering will reduce the gamma exposure rate from deposited materials, it is not a suitable protective action for this pathway for long duration exposure. The main factors which reduce whole body exposure are:

1. Wall materials and thickness and size of structure,

2. Number of stories overhead, and

3. Use of a central location within the structure.

If a major release of radioiodine or respirable particulate materials occurs, inhalation dose will be the controlling pathway. For releases consisting primarily of noble gases, external gamma exposure will be most important. However, when inhalation is the primary exposure pathway, consideration should be given to the following:

1. Ventilation control is essential for effective sheltering.

2. Dose reduction factors for sheltering can be improved in several ways for the inhalation pathway, including reducing air exchange rates by sealing cracks and openings with cloth or weather stripping, tape, etc. Although the risk to health from the action could be a constraint (particularly for infants and the infirm), using wet towels or handkerchiefs as a mask to filter the inhaled air will reduce dose from inhalation.

3. Following plume passage, people should open shelters to reduce airborne activity trapped inside, and they should leave high exposure areas as soon as possible after cloud passage to avoid exposure to deposited radioactive material.

4. Consideration should be given to the prophylactic administration of potassium iodide (KI) as a

thyroid-blocking agent to workers performing emergency services and other groups in accordance with the PAGs in Table 2-1 and the provisions in reference FD-82.[3]

5.5.3 General Guidance for Evacuation and Sheltering

The process of evaluating, recommending, and implementing evacuation or shelter for the public is far from an exact science, particularly in view of time constraints that prevent thorough analysis at the time of an incident. Their effectiveness, however, can be improved considerably by planning and testing. Early decisions should be based on information collected from the emergency planning zone during the planning phase and on information regarding conditions at the nuclear facility at the time of the incident. Best estimates of dose projections should be used for decisions between evacuation and sheltering.

The following is a summary of planning guidance for evacuation and sheltering, based on the information in Sections 5.5.1 and 5.5.2.

1. For severe incidents, where PAGs may be significantly exceeded, evacuation may be the only effective protective action close to the facility.

2. Evacuation will provide total protection from any airborne release if it is completed before arrival of the plume.

3. Evacuation may increase exposure if carried out during the plume passage, for accidents involving inhalation dose as a major contributor.

4. Evacuation is also appropriate for protection from groundshine in areas with high exposure rates from deposited materials.

5. Sheltering may be appropriate (when available) for areas not designated for immediate evacuation because:

a. It positions the public to receive additional instructions; and

b. It may provide protection equal to or greater than evacuation.

6. Sheltering is usually not appropriate where high doses are projected or for exposure lasting longer than two complete air exchanges of the shelter.

7. Because sheltering may be implemented in less time than evacuation, it may be the temporary protective action of choice if rapid evacuation is impeded by a) certain environmental conditions--e.g. severe weather or floods; b) health constraints--e.g. patients and workers

[3]Each State has the responsibility for formulating guidance to define when (and if) the public should be given potassium iodide. Planning for its use is discussed in "Potassium Iodide as a Thyroid-blocking Agent in a Radiation Emergency: Final Recommendations on Use" (FD-82).

in hospitals and nursing homes; or c) long mobilization times--e.g. certain industrial and farm workers, or prisoners and guards; d) physical constraints to evacuation--e.g. inadequate roads.

8. If a major release of radioiodine or particulate materials occurs, inhalation dose may be the controlling criterion for protective actions. In this case:

a. Breathing air filtered through common household items (e.g., folded wet handkerchiefs or towels) may be of significant help, if appropriate precautions are taken to avoid possible suffocation.

b. After confirmation that the plume has passed, shelters should be opened to avoid airborne activity trapped inside, and persons should leave high exposure areas as soon as possible after cloud passage to avoid exposure to deposited radioactive material.

c. Consideration should be given to the prophylactic administration of potassium iodide (KI) as a thyroid-blocking agent to emergency workers, workers in critical industries, or others in accordance with the PAGs in Table 2-1 and reference FD-82.

9. If dose from external gamma radiation is the controlling criterion, shelter construction and size are the most important considerations; ventilation control and filtering are less important. The main factors which reduce whole body external dose are; a) wall thickness and size of structure, b) number of stories overhead, c) central location within the structure, and d) the height of the cloud with respect to the building.

5.6 Procedures for Calculating Dose Conversion Factors

This section provides information used in the development of the DCFs in Tables 5-1 and 5-2. Three exposure pathways are included: whole body exposure to gamma radiation from the plume, inhalation from the plume, and whole body exposure to gamma radiation from deposited materials. Although exposure of the skin from beta radiation could be significant, evaluations show that other exposure pathways will be controlling for evacuation and sheltering decisions. Therefore, DCFs for skin are not provided. Individual DCFs for the three exposure pathways are provided in the following sections. They are each expressed in terms of the time-integrated air concentration so that they may be combined to yield a composite DCF for each radionuclide that reflects all three pathways. These data may be used to facilitate revising the DCFs in Tables 5-1 and 5-2 when more specific or technically improved assumptions are available, as well as to evaluate the relative importance of the individual pathways for specific radionuclide mixes.

From the Associated Press

CONNECTICUT NEWS

Friday
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LATEST NEWS

Group endorses stockpiling of drug to protect against radiation

WATERFORD, Conn. (AP) Residents around the Millstone nuclear power complex should be given a drug to reduce the risk of thyroid cancer from radiation exposure in case of a nuclear accident, a state group recommended.

The Nuclear Energy Advisory Council, which oversees nuclear safety, will encourage the state to set up a two-year trial program for distributing potassium iodide to residents.

Some residents told the council at a meeting Thursday that they want the pills.

''I want it in my purse, I want my children and my grandchildren to have it at the ready,'' said Niantic resident Billie Staub. ''If you're stuck somewhere, I want a pill to take.''

The U.S. Nuclear Regulatory Commission recently reversed its policy on potassium iodide, to require states to consider using the drug as part of state nuclear emergency plans. An NRC report found the drug reduces the risk of thyroid cancer from radiation exposure.

Right now, there is only enough potassium iodide to treat emergency personnel in case of an accident.

The NRC said potassium iodide would be available free to states that wanted larger quantities of it. The council recommended that the state request enough potassium iodide for residents living closest to the three-reactor Millstone complex.

Under the trial program, the drug would go to residents who signed voluntary medical releases, as well as to schools, hospitals, prisons and other institutions that

wanted to participate.

Additional doses would be stored at evacuation centers, and the trial program would be accompanied by a public education campaign.

Council chairwoman Terry Concannon, a Democratic state representative from Haddam, said she feared the drug would be mistaken as a cure-all for radiation exposure and might distract people from efforts to flee an exposed area.

But council member Robert J. Klancko said the government should address the perception that the drug is needed, especially in light of recent troubles in the nuclear industry.

''That perception may overwhelm everything else,'' Klancko said.

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Email The Editor

brate his 52d birthday. He returned at 11:30 P.M. to more telephone calls to advisers including Vice President Al Gore, to chew over a last troubling question about the targets.

He made up his mind, then gave his final go-ahead in a talk with Mr. Berger at 3 A.M. Thursday.

Never has Mr. Clinton's ability to compartmentalize his life been more starkly demonstrated than in the last two weeks. As the one man in the world who held all the information, he walled off meetings with his law-

Continued on Page A8

Like the Ruble

Reuters

... little seen in public lately, posed for a ... Arctic Circle port of Severomorsk yesterday.

...nd less ...e when ...liability, ...in back ...r mar- ...propo- ...ical ex- ...thened ...ans al- ...presi-

Lebed, the former general who now governs the vast Siberian region of Krasnoyarsk, and Yuri M. Luzhkov, the canny Mayor of Moscow.

Both men are strong-willed, even authoritarian rulers. Though Mr. Lebed can be unpredictable, both lean less toward free markets than toward centralized control of the economy. Mr. Luzhkov has a smooth political style. Mr. Lebed is rougher-

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...ille square, was destroyed in the attack, though surrounding areas went unscathed. There were no known deaths at the plant, which was hit at night, when it was closed, but local reports said 10 people were hospitalized, 4 of them in critical condition.

The nation's Islamic Government invited foreign diplomats to tour the ruins today. Afterward, many remained puzzled, saying it was not clear whether the plant, as Washington asserts, made precursors for nerve gas or whether it was purely a medical manufacturing site, as the Sudan contends.

After Friday prayers in the city's mosques, worshipers were urged to attend frenzied rallies, where leading figures of the Government accused the United States of being a terrorist state, and where the American flag was torn, burned and trampled into the ground.

At one rally, pictures of President Clinton and Monica Lewinsky were on prominent display — a juxtaposition that is interpreted as the ultimate mockery in this very conservative society.

The Foreign Minister, Mustafa Osman Ismail, said the Sudan would remain a "tomb for its enemies, whatever this costs us in human lives."

But the most important Sudanese

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INSIDE

Botha Guilty of Contempt

A South African court found former President P. W. Botha guilty of contempt for refusing to testify about apartheid-era atrocities. Page A8.

Wild Ride for Stocks

Stocks plunged before recovering with modest losses. Overseas losses fed Wall Street's turmoil. Page B1.

On the Internet: www.nytimes.com

...on the Treasury Department's list of terrorists and their sponsors, clearing the way for officials to seize his assets. It was not immediately clear, however, whether he has any assets in the United States. It was also unclear why he had not been put on the list earlier.

A NATO diplomat said today that the Administration had begun asking allies in Europe to help in freezing the assets of Mr. bin Laden and groups associated with him.

A man claiming to be a spokesman for Mr. bin Laden told the editor of an Arabic newspaper in London, al-

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Anger, Outrage and Support

Many Muslims voiced fury over the missile strikes, President Yeltsin said he was "outraged," and Europeans offered support. Page A8.

States Will Receive Drug for Public Use In Nuclear Mishaps

By JONATHAN RABINOVITZ

HARTFORD, Aug. 21 — After years of resistance, the Nuclear Regulatory Commission is preparing to distribute to states with nuclear power plants a drug that blocks a type of radiation that causes thyroid cancer, and already, people in Connecticut and other states are clamoring for the medicine.

The move was spurred, in part, by new evidence about thyroid cancer after the 1986 nuclear accident at Chernobyl, and the lower incidence of the disease in areas where the drug, potassium iodide, was widely used.

The policy change also comes at a time when the nuclear agency is revisiting many regulations and addressing what many critics of the nuclear power industry say were the agency's weakest policies.

Although the Federal Government, which stockpiles potassium iodide, had previously argued that the drug might cause dangerous side effects and give people a false sense of security during an accident, some critics had accused the agency of declining to offer it out of a concern that it would promote fears of a nuclear accident.

The N.R.C. oversees the states' emergency plans in case of nuclear disaster. Although potassium iodide has been available for medical use

Continued on Page A16

States to Get Drugs for Use After Mishaps At A-Plants

Continued From Page A1

for about 20 years, the agency does not require states to distribute it after a nuclear accident. But over the last year, the agency has taken steps to encourage states to do so, and has agreed to pay for the supplies.

Already, Alabama, Tennessee and Maine are stockpiling the medicine at evacuation centers, while Ohio is moving toward requesting a supply from the Federal Government. New York is reconsidering its refusal to provide the medicine to the public, and Kristine Smith, a State Health Department spokeswoman, said that only last month, a departmental advisory committee of physicians concluded that access to potassium io- a nuclear accident would ben- lc health.

lterford, Conn., only a few h.. from the Millstone nuclear power station, residents told a state nuclear policy panel Thursday night that they wanted the drug, which is available in pill form. "I want it in my purse," said Billie Staub, 66, a retired correctional officer from Niantic. "I want my children and grandchildren to have it at the ready."

By the end of the evening, the state panel, the Nuclear Energy Advisory Commission, had voted 9 to 2, with one abstention, to recommend that the state distribute the pills to residents living within five miles of the Millstone plant, which until last month had been shut down for more than two years because of safety concerns. The Connecticut Health Department, in conjunction with other state agencies, is considering the recommendation.

The use of potassium iodide to block radiation is not new. It has been used in other countries, including Poland, for a number of years, and Peter G. Crane, an N.R.C. staff lawyer who has lobbied as a private citizen to change the agency's policy, said it was approved by the Food and Drug Administration for medical use in this country in 1978.

Today it costs about 7 cents a pill and can be sold over the counter, although it is not available at pharmacies because it serves no other medical purpose, Mr. Crane said. It ha- - shelf life of five years.

George Rabe for The New

The Millstone nuclear power station in Connecticut. Nearby residents have asked for a drug that block of radiation that causes thyroid cancer. The Nuclear Regulatory Commission is preparing to distrib

Nuclear power regulators, physicians and government health officials emphasized today that potassium iodide should not be viewed as a cure-all for diseases caused by radioactivity from a nuclear accident. It blocks only one of many isotopes — radioactive iodine — that may be emitted from a leak or meltdown.

Still, if no action is taken, radioactive iodine is absorbed by the thyroid gland, where it can cause cancer and other disorders. A 130-milligram dose of potassium iodide can prevent radioactive iodine from entering the thyroid for several days if taken within a few hours of exposure to radiation, health officials say.

"There's no question about its effectiveness," said Jacob Robbins, former president of the American Thyroid Association and a scientist emeritus at the National Institutes of Health.

Still, some civil defense and public health officials harbor doubts about whether providing it is a good idea. They said people may misunderstand what the drug does and fail to evacuate when ordered to. And it is not clear how state officials will make sure that everyone who lives close to an accident site and needs the pills will get them.

Donald Maurer, a spokesman for the New York State Emergency Management Office, said the state contends that in a nuclear accident, the pills would be a distraction. "The bottom line is that we intend to have people out of harm's way before they would need potassium iodide," he said.

There is also the question of liability if people who take the pills suffer side effects. Connecticut and other states are considering whether to require people to sign release forms

Learning a lesson about cancer from the accident at Chernobyl.

before they are given the pills.

Mary Lou Fleissner, the Connecticut Health Department's director of environmental epidemiology, said the side effects of potassium iodide include a risk of cardiac arrest in people with already high levels of potassium and goiters in people with cystic fibrosis.

But Mr. Crane, who has thyroid cancer, caused by exposure to radiation as a child, has lobbied to make the drug more available for 10 years. He downplayed the risks and said the use of potassium iodide after the Chernobyl accident provided strong evidence of its effectiveness

Dr. Robbins said that whi was a high number of thyroi cases — as many as 1,20 Ukraine and other Soviet r that did not use potassium io number was much smaller land, where the drug was dis to about 10 million people ately after the accident.

"There were very few cas kind of trouble because of po iodide," he said, referring effects. Older people tend more problems with the dr younger people, but they are susceptible to thyroid cancer ed.

Mr. Crane also dismissed tions that if the drug is wi tributed, residents of the areas will become complac resist evacuation efforts.

He explained: "Evacuatic best option if you can get pe but you can't always get pe You can have weather cond interruption of the roads. have people getting a dose tion while they evacuate. T issue is: Do you want three or two in your quiver? The At minimal cost, you get a arrow."

The idea of making potas dide available after a nucle dent was raised as early as the Kemeny Commission, v sued a report following the at Three Mile Island in Penn

In 1985, the N.R.C. adopted regulations that called for making potassium iodide available to emergency workers, but not to the neighbors of nuclear plants.

Over the last year, the agency has reconsidered that policy. First, it adopted the recommendation last year of a Federal panel of experts that potassium iodide should be provided to states that request it. Then last month, the agency said it planned to require every state to consider offering potassium iodide as part of its emergency preparedness plans.

"This action is not being taken because of any new insights about risks associated with operating nuclear power, but rather in recognition of the European experience during and following the Chernobyl accident," an agency statement said.

Mr. Crane, who filed the petition that led to the agency's decision earlier this summer, said the agency's previous position was based not only on health considerations, but also on concerns about discrediting the industry. "They were worried that if you prepared too well for an accident, it sends the message that accidents can happen," he said.

Indeed, in Waterford today, some residents expressed dismay over the idea.

"Don't tell me it's safe and then come up with things to do 'just in case,'" said Michael T. Kruse, 45, a manager for a sporting-goods manufacturer who moved to Waterford a year ago. "If they're talking about things like this, there must be a reason."

And several people said they would not take the medicine even if they had it. "They'd have to be darned good pills," said Gerry K. Wade, 55, a waitress at the Village Stop diner. "Whatever there is to catch, we're all going to catch it."

Still, it was the talk of the town today. One woman called the town sanitarian and said she had heard that she needed her potassium iodide right away. Another man called Town Hall and wanted to know if his father-in-law could take the pill because he hated the radiation treatment he undergoes for cancer.

Despite this skepticism, other residents see the plan as a wise — even obvious — precaution. "Life has its harsh realities," said Dennis W. Offen, 44, a railroad laborer. "Better to have it and not need it."

THE FRESH AIR FUND:
JOY OF SUMMERTIME

September 9, 1998

COMMENTS OF OHIO CITIZENS FOR RESPONSIBLE ENERGY, INC. ("OCRE") ON NUREG-1633, "ASSESSMENT OF THE USE OF POTASSIUM IODIDE (KI) AS A PUBLIC PROTECTIVE ACTION DURING SEVERE REACTOR ACCIDENTS," DRAFT REPORT FOR COMMENT

NUREG-1633 is a seriously deficient document in a number of regards. It appears biased in that it overstates the risks of using KI while understating the benefits. It contains a number of misleading statements. The Commission should withdraw this document.

Specific comments:

1. Nowhere does this document mention that the U.S. Food and Drug Administration has found KI to be "safe and effective" as a thyroid blocking agent (in doses of 130 mg for adults) and has approved KI for sale as a non-prescription, over-the-counter drug. The authors are certainly aware of this fact because I raised this point at a meeting on October 28, 1997 in Painesville, Ohio (where two of the authors were in attendance) sponsored by the Ohio Department of Health regarding the KI issue. The FDA's determination, made in 1978, should be the starting point for any discussion of the safety of KI. Its omission from this study is a fatal flaw.

2. At page 11 of the NUREG an edition of the Physician's Desk Reference is quoted to show a number of warnings and contraindications allegedly associated with KI. I suspect these warnings have validity only for the higher dosages of KI contained in cough medications, not the 130 mg dosages that would used for thyroid blocking in a nuclear accident. The claim that KI should not be used by pregnant women is plainly contradicted by the package insert for Thyro-Block. An excerpt is quoted below:

WHO SHOULD NOT TAKE POTASSIUM IODIDE

The only people who should not take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or antithyroid drug). Pregnant and nursing women and babies and children may also take this drug.

SIDE EFFECTS

Usually, side effects of potassium iodide happen when people take higher doses for a long time. . . . Side effects are unlikely because of the low dose and the short time you will be taking the drug.

3. At page 10, it is stated that the authors contacted several local pharmacies regarding KI and found that it was not available in the proper doses for thyroid blocking in a nuclear emergency. Why did the staff not contact the known suppliers of KI for use as a thyroid blocking agent, Carter-Wallace, maker of Thyro-Block, and ANBEX, and inform the public where KI in the correct doses can be obtained? KI can be obtained through mail order. Again, the authors of the NUREG know this because I had a bottle of Thyro-Block, which I purchased through the mail, at the Painesville, Ohio KI meeting. The staff should also be aware of this because it was the subject of an NRC Information Notice issued in 1988: IN 88-15, "Availability of U.S. Food and Drug Administration (FDA) - Approved Potassium Iodide for Use in Emergencies Involving Radioactive Iodine," dated April 18, 1988.

4. The NUREG's discussion of tincture of iodine (pages 18 and 37) suggests that it can be used as a thyroid blocking agent when in fact, it is poisonous and should not be taken internally. This should be clearly stated in the NUREG, but it is not.

5. Any discussion of severe accident source terms and consequent dose calculations should acknowledge that tellurium is an iodine precursor. A number of radioactive isotopes of Te are beta(-) emitters with short half-lives. According to the Handbook of Chemistry and Physics (55th edition) Table of the Isotopes, the following Te isotopes would fall into this category:

Isotope	half-life
Te-129	69 min
Te-131m	30 hours
Te-131	25 min
Te-132	78 hours
Te-133m	50 min
Te-133	12.5 min
Te-134	42 min
Te-135	<2 min

Being beta(-) emitters, these isotopes will decay into the respective isotopes of radioiodine, e.g., Te-131 --> I-131 + beta(-).

It is not clear that the dose calculations in the NUREG take account of Te decay to radioiodine. For two of the source terms cited, the fraction of core inventory released for Te exceeds that for iodine (e.g., RSUR-2 and RSUR-4, 2 hour release duration). For RSUR-1, the fraction of core inventory released for the 2 hour release duration is equal for iodines and Te. At page 10 the NUREG states "A substantial release of these 'other' nuclides would essentially increase the risk of deterministic and stochastic health effects for which KI is ineffective." Being an iodine precursor, Te should not be considered among those "other nuclides" but accounted for in thyroid dose calculations. Computer models should be able to account for radioactive decay and include the Te daughter iodine isotopes in the thyroid dose.

6. At page 22, the NUREG states "One can expect that administration of KI on a mass basis would certainly entail litigation in this country, whereas the government of Poland, which administered KI on a mass-basis, did not appear to be faced with such litigation." A balanced discussion of legal liability should include the consequences of the government's failure to provide a known, safe, and low-cost protective action (KI) if a nuclear accident occurs and people develop thyroid cancer as a result. These consequences are likely to be not only legal, but political, as the accident victims will undoubtedly be outraged that their disease and suffering could have been prevented with a 10-cent pill that was not available because of nuclear industry lobbying to which our government capitulated. The U.S. is the outlier with regard to KI. Most countries with nuclear power plants provide KI for their citizens. That the U.S. did not would certainly compound the outrage. Some analysts believe that the Chernobyl accident was the spark that ignited the revolution that caused the collapse of communism and the Soviet Union. Whether political unrest in this country following a nuclear accident would be that severe is uncertain, but it is highly likely that public distrust of government would be exacerbated.

7. At page 2 the NUREG states that KI's potential benefits "can be realized only if the compound is administered just before the inhalation or ingestion of radioiodines." The fact is that while KI's effectiveness does diminish with time, it can be beneficial even if taken several hours after exposure to radioiodines, according to the FDA's 1982 Federal Register notice (47 FR 28158).

8. At page 2 the NUREG states "it is not known how the public (or public officials) would react to a recommendation to administer KI, especially when school officials are asked to administer KI to children." This is a matter which can be addressed through public education on the benefits and risks of KI. Unfortunately, this NUREG, by omitting key facts such as the FDA's 1978 "safe and effective" determination, will be a detriment to such public education efforts. I would also question the NUREG's preceding statement that the administration of drugs to the general public has no precedence in the U.S. We do have experience with vaccinations in this country, particularly against polio, which, when first initiated, had people standing in line to receive it. Similarly, I recall from my own experiences that schools do (or did) mass screenings of students for TB with skin tests which were slightly invasive. These experiences suggest that the public, when educated, can react properly and that schools can administer medical procedures and products on a mass basis to students. Of course, these considerations do not seem to be an impediment to the use of KI in the rest of the world.

Also, it is not consistent to assume that the public will follow recommendations for other protective actions in a nuclear emergency (for evacuation or sheltering) but will behave irrationally when it comes to the use of KI. If the public can't be trusted to use KI properly, then how can the government take any credit for the assumed proper behavior of the public for evacuation or sheltering, informal alerting of neighbors who may not have heard sirens, or even for the participation of emergency workers, some of whom, such as school bus drivers, do not face hazardous conditions as part of their normal job duties, as do police and fire fighters? You can't have it both ways.

In conclusion, this NUREG is seriously defective and should be withdrawn.

Respectfully submitted,

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Sept. 14, 1998

Incident Response Division
Office for Analysis and Evaluation of Operational Data
USNRC
Washington, DC 20555-0001

Comment on NUREG 1633 (KI as Thyroid Protectant)

<u>For maximum protection, the KI (potassium iodide) must be readily available, such as by predistribution.</u>

Reliance on "National stockpiles", as on page xi, would indeed make the 95% blocking of thyroids difficult to meet (page 7). Requiring people to sign a "KI RECEIPT FORM" during an emergency, as envisioned in the Ohio Department of Health Draft Policy, would also delay use of the protectant drug, and thus reduce its efficacy. Fortunately, the ODH has considered the possibility of allowing advance consent to the use of KI.

There is undue concern for possible adverse effects of KI, such as the page 11 citation of the staff's review of an old (1991) edition of the PDR, with no page references. Instead, we should rely on the Surgeon General's declaration that KI is safe and effective for this use. The latest (16th) edition of the Merck Manual (1992), at page 599, tells of the use of a saturated solution of KI as an expectorant, in doses of 2 to 16 grams per day; it has an unpleasant taste and side effects which "are reversible and subside when the drug is stopped". This dose is so much larger than the thyroid protectant dose, that there seems little justification for concern about side effects of the thyroid protectant dose.

I have done hundreds, maybe thousands, of titrations using potassium iodide as an analytical reagent during more than four decades of employment as an industrial research chemist. I can certify that pure, dry KI sealed in nearly full brown bottles is stable for decades. For possible treatment of large numbers of people at evacuation centers, storage of pure, dry KI would be far less costly than single dose pills. True, IF it were ever used, it would have to be prepared for use, e.g., by preparing a 2/3 saturated solution, and dispensing as one drop per child's dose and two drops per adult dose. Considering the much lower cost of providing protection in this way, and the low probability of use in any one location, I think it is attractive.

The additives used in KI thyroid protectant pills, and their greater exposure to air and moisture are presumably responsible for their shorter shelf life. For predistribution in the localities at greatest risk, the convenience of single dose pills seems worth this tradeoff.

Sincerely,

Russell M. Bimber (M.S.)

From: "N. & H. Fine" <EULER@delphi.com>
To: TWFN_DO.twf2_po(NRCWEB)
Date: Tue, Oct 6, 1998 10:18 PM
Subject: Re: http://www.nrc.gov/

With reference to "Assessment of the Use of Potassium Iodide...", 9/1/98, I wish to make the following comment:

On page 44 of the Document is given a composition for Iodine Tincture which states that it contains "2 percent iodine". This is correct but the tincture also contains in addition 2.4 percent sodium iodide which is a thyroid blocker.

See The Merck Manual, 14th Edition, 1982, page 2301.

Norman Fine
16 Overhill Road
East Brunswick NJ 08816
732-257-2441
e-mail: euler@delphi.com

From: "Jim Hardeman" <hardeman@mindspring.com>
To: TWFN_DO.twf2_po(ASM)
Date: Tue, Sep 15, 1998 12:45 PM
Subject: Personal comments on Draft NUREG-1633

Aby --

The following are my PERSONAL comments related to the draft NUREG-1633, recent decisions by NRC related to the use of potassium iodide (KI) by the general public following a major accident at a commercial power facility, and current and proposed US policy related to KI. These comments should in no way be construed as being representative either of the positions of my employer (State of Georgia) or any organization that I may represent in any official capacity (e.g., CRCPD)

As you well know, the design of US commercial nuclear power reactors is vastly different from the Soviet RBMK design (e.g. Chernobyl), and we should be cautious as to the extent of reliance we place in the experience of countries such as Ukraine, Belarus, Russia and Poland following the Chernobyl accident in 1986. Rather, we should lean more towards the experience in the US following the TMI-2 accident in 1979, in which radioiodine releases were some six orders of magnitude less than releases of noble gases. The mitigative features of containment systems and structures in US reactors, even if some of them are not fully effective, will serve to mitigate and delay the releases of radioiodines.

The report details international efforts related to the distribution of KI to the general public, but does not draw upon the experiences in the US of three states (Alabama, Arizona and Tennessee) who have stockpiled KI and distributed it to the public. These experiences are not overwhelmingly positive, and would serve to highlight the logistical difficulties of large-scale distribution of KI to the public, particularly systems designed to put KI in the hands of the general public prior to a release.

The "Insights and Conclusions" section of NUREG-1633 indicates that the use of KI is not an alternative to prompt evacuation. I agree with the concept that prompt evacuation based upon plant conditions protects a population from all radionuclides and pathways. This should always be preferred to actions that only protect the thyroid. The general public in the US is far more mobile than the population of former Soviet states in 1986, and far less reliant on "public transport". We have significant positive experiences with large-scale evacuations related to natural disasters (most recently the Florida wildfires and Hurricane Bonnie) and technical incidents.

The State of Georgia currently stockpiles sufficient KI to provide thyroid blocking for all emergency workers (state, county, and power plant) and for selected special populations such as those in nursing homes, hospitals, and jails. In my position as the Radiological Emergency Coordinator (REC) for the State of Georgia, I have the option of authorizing the use of KI by emergency workers, and of recommending the use of KI by any one or all of the other groups based upon plant or release conditions.

Although risk of reaction to KI was reported as minimal in the report, a more recent paper by Janusz A. Nauman, "Potassium Iodine Prophylaxis in Case of Nuclear Accident; Polish Experience," reported 4.5 to 4.6% of extrathyroidal side effects after a single dose of KI. I consider these side effects as a significant problem in any recommendation to distribute or administer KI to a large population as opposed to a small group of emergency workers.

I agree with the report's statement that "KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs." In the US, we have the relative luxury (as opposed to most other countries) of being able to substitute uncontaminated foodstuffs grown at large distances from any nuclear accident (including imported foodstuffs) for contaminated foodstuffs. I can think of no reason why I would recommend that contaminated foodstuffs be introduced into commerce or be privately consumed, so the administration of KI would be unwarranted and unwise. A paper presented at the EPA Post-Emergency Response Issues Conference in Washington, DC also indicated that the diet of persons

living near Chernobyl exibited a pre-existing iodine deficiency, potentially enhancing the uptake of radioiodines by the thyroid. The report concluded that widescale distribution of KI to populations which did not exhibit a pre-existing iodine deficiency would not be warranted.

In summary, NUREG-1633 appears to be a mostly sound, technical document. I think that some of the issues addressed above should be included in the document for completeness, and I personally would be willing to work with you to see that these issues are addressed. I am concerned, however, that NUREG-1633 does not appear to support the recent decision by NRC to facilitate state stockpiles of KI for the general public. I recommend that the Commission revisit its recent decision in light of the information presented in NUREG-1633, and more recent publications referenced above.

Thank you for the opportunity to comment on this document.

James C. Hardeman, Jr.
Lawrenceville, GA
hardeman@mindspring.com

From: "Byster, Martin" <BYSTERM@coned.com>
To: '"asm@nrc.gov"' <asm@nrc.gov>
Date: Tue, Sep 15, 1998 4:20 PM
Subject: NUREG-1633

To me personally, it is unconscionable that the Federal, State and local government can not provide individuals, who may be exposed to the hazards of radioactive iodine airborne contamination, access to potassium iodide (KI) on demand with the information they need to weigh the risks and decide for themselves where and when to use it.

R
Marty Byster
914.271.7104

From: <RFraass@aol.com>
To: TWFN_DO.twf2_po(ASM)
Date: Mon, Sep 14, 1998 5:51 PM
Subject: NUREG 1633 Comments

Aby,

Here are my personal comments. Official state comments are comming by letter from our program director.

Ron Fraass
Public Health Physicist

The overall tone of the report was quite bleak with regard to safety of and risks from nuclear power plants. Although the NUREG's tabulated doses to the public can be projected from current models, the projected of doses of 160 rads acute and 19,000 rads thyroid at 10 miles are significantly above levels for probable accident scenarios involving US reactors. NRC and FEMA policy and regulations presume no stochastic effects beyond 10 miles.

My recommendations in Kansas protective action guides are consistent with the "Insights and Conclusions" shown in the study that use of KI is not an alternative to prompt evacuation. Kansas currently stockpiles sufficient KI to provide thyroid blocking for all emergency workers (state, county, and power plant) and for selected special populations such as those in nursing homes, hospitals, and jails. I have the option of recommending use of KI by any one or all of these groups based upon plant or release conditions.

Although risk of reaction to KI was reported as minimal in the report, a more recent paper by Janusz A. Nauman, "Potassium Iodine Prophylaxis in Case of Nuclear Accident; Polish Experience," reported 4.5 to 4.6% of extrathyroidal side effects after a single dose of KI. I consider these side effects as a significant problem in any recommendation to distribute or administer KI to a large population as opposed to a small group of emergency workers.

I agree with the concept that prompt evacuation based upon plant conditions protects a population from all radionuclides and pathways. This should always be preferred to actions that only protect the thyroid.

In section II. Severe Accidents, paragraph two: The sentence: "Without both occurrences, there is no need for any protective actions, including evacuation or administration of KI," is inappropriate in light of current Federal and state guidance. I will recommend precautionary evacuation based upon plant conditions that may lead to severe core damage and containment failure. I recommend changing this sentence to reflect that concept.

I agree with the report's statement that "KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs."

CC: GATED.nrcsmtp("Jim_Hardeman@mail.dnr.state.ga.us")

From: <Ardel1818@aol.com>
To: TWFN_DO.twf2_po(ASM)
Date: Sat, Sep 12, 1998 9:40 PM
Subject: NRC REQUESTS COMMENTS by 9-15

NRC REQUESTS COMMENTS ON DRAFT DOCUMENT ASSESSING USE OF POTASSIUM IODIDE DURING A SEVERE REACTOR ACCIDENT - No 98-126 July 24, 1998 - Comments on the report are due by September 15.

The NRC, Weapons Industry, Nuclear Industry or whoever is involved in any form of nuclear supplies- is hurting the citizens of the United States, by denying them Information on what to do in the event of a nuclear disaster. Prompt sheltering is very important, but first - 1. We have to be advised IMMEDIATELY of any kind of Nuclear disaster. You probably can't rely on electronics. You may have to go back to the old fashion way of communications to be safe. 2. KI has to be taken within the first 12 hours or shorly after. Therefore I advise: All citizens under the age of 40 have their own supply with them at all times. I'm told KI has a long shelf life.
3. To say that Iodine-131 will go a short distance is WRONG and ofcourse "You don't know when or where the problem will arise. The radio-iodines are all produced in high abundance in the course of nuclear fission. Iodine easily becomes airborne. It converts to the gaseous state. 4. It is the radioactive iodine that goes to the thyroid and causes uncurable damage such as deformities and mental retardation in our children. The babies may be born with cancer or it may develope later.
I saw a copy of Swedens response plans on the internet. If haven't seen their plans, please take a look. I don't know where to get a copy, but I expect that the people in the high offices should know. I was unable to download them, but would be very interested in seeing these plans again. They included the children. Sweden must know something you haven't caught on to yet.

Consider the children and the fact we don't X-ray pregnant women. A little Common Sense Couldn't hurt. X-rays are radiation. Consider the fact each Nuclear Plant needs water which becomes radioactive and disposed of WHERE? And we wonder why we have mutated frogs. Consider the fact that I was told my grandchildrens children could be deformed. Who started the Genome Project? Answer:The D.O.E. (Department of Energy). Why?

Housewife, Mother, Grandmother and
Downwinder - Arlene Steffen

P.S. Do your best - Who said? "You can fool some of the people some of the time,but not all the people all of the time?" Hope you don't have to wait for more mutations to believe the saying. "Seeing is believing."

CC: GATED.nrcsmtp("dave@ratmandu.engr.sgi.com")

From: Jim Hardeman <Jim_Hardeman@MAIL.DNR.STATE.GA.US>
To: TWFN_DO.twf2_po(ASM)
Date: Mon, Sep 14, 1998 5:54 PM
Subject: Georgia Comments on NUREG-1633

Aby Mohseni
Division of Incident Response
Office for Analysis and Evaluation of Operational Data
US Nuclear Regulatory Commission
Washington DC 20555-0001

Aby --

Please accept the following comments on the draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents" on behalf of the Georgia Department of Natural Resources (DNR), Environmental Protection Division (EPD).

In general, the document appears to fairly reflect the international experience related to the use of KI, particularly the experience of countries in the former Soviet Union after the Chernobyl accident in 1986. I should note, however, that differences in reactor design, the increased mobility of the American public in general, and our successful experiences in evacuating large populations in the face of natural disasters such as hurricanes, would tend to make one conclude that the administration of KI to the general public would be of little benefit.

The NUREG would benefit greatly from a discussion of the successes and failures of states which already distribute KI to the general public.

We would strongly urge NRC to actively involve states in the development of public information materials related to the distribution of KI, instead of merely allowing us to comment on draft materials already prepared by NRC.

In summary, the NUREG, in my opinion, provides no compelling or new information that would justify NRC's recent decision to change national KI policy. I strongly urge the Commission to revisit its recent decision regarding KI policy.

Thank you for the opportunity to comment on this document. If you have any questions on these comments, please feel free to contact me at the address, phone number and/or e-mail address listed below.

Jim Hardeman, Manager
Environmental Radiation Program
Environmental Protection Division
Georgia Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta, GA 30354
(404) 362-2675 fax: (404) 362-2653
Jim_Hardeman@mail.dnr.state.ga.us

CC: GATED.nrcsmtp("N.M.Maddox@snc.com","apn@nei.org","...

From: "Malmberg, Stephen" <MalmbS@DMA.STATE.WI.US>
To: "'asm@nrc.gov'" <asm@nrc.gov>
Date: Mon, Sep 14, 1998 2:28 PM
Subject: Comment on Draft NUREG-1633, PRM-50-63 and PRM-50-63A.

Aby Mohseni
MS T4A43
Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852-2738

This is in response to request for public comment on the draft "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents" (draft NUREG-1633).

After consultation with state and local agencies involved in the off site response to a nuclear plant radiological incident, the Wisconsin Division of Emergency Management and Department of Health and Family Services - Radiation Protection Unit, do not support stockpiling of Potassium Iodide (KI) for distribution to the general public in the event of a nuclear power plant accident.

Evacuation of potentially affected areas within the 10-mile Emergency Planning Zone is the preferred protective action to protect the health and safety of the general public. Distribution of KI to the general public could inhibit orderly evacuation and divert limited local resources during the early stages of an incident.

Furthermore, the distribution of KI to the general public could impart a false sense of security regarding the prevention of severe health effects resulting from radiation exposure. KI is not effective unless administered prior to or shortly following inhalation or ingestion of radioiodines. Also, KI does not limit dose due to whole body exposure from other radioisotopes potentially present in a radiological release from a nuclear power plant incident.

The Wisconsin Division of Emergency Management and the Department of Health and Family Services - Radiation Protection Unit take the position that the potential problems associated with stockpiling KI for distribution to the general public far outweigh the potential benefits. Therefore, we support the NRC staff recommendation that the Commission deny petitions for Rulemaking PRM-50-63 and PRM-50-63A.

Christine C. Bacon, Director
Bureau of Technological Hazards
Wisconsin Emergency Management
e-mail: baconc@dma.state.wi.us

Paul Schmidt, Supervisor
Radiation Protection Unit
Wisconsin Department of Health and Family Services
e-mail: SCHMIPS@dhfs.state.wi.us

~~~~~~

Stephen Malmberg
Lead Radiological Emergency Preparedness Planner
Wisconsin Emergency Management

office: (608) 242-3243
fax: (608) 242-3249
e-mail: malmbs@dma.state.wi.us

~~~~~~

CC: "Bacon, Christine" <BaconC@DMA.STATE.WI.US>, "Sell...

From: Jim Hardeman <Jim_Hardeman@MAIL.DNR.STATE.GA.US>
To: TWFN_DO.twf2_po(ASM)
Date: Mon, Sep 14, 1998 6:04 PM
Subject: CRCPD Comments on Draft NUREG-1633

Aby Mohseni
Division of Incident Response
Office for Analysis and Evaluation of Operational Data
US Nuclear Regulatory Commission
Washington DC 20555-0001

Subject: Draft NUREG-1633, Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents

Dear Mr. Mohseni (Aby):

The Conference of Radiation Control Program Directors Committee on Emergency Response Planning (E-6) is pleased to provide comments on the above-referenced document. In general, the draft represents a comprehensive and balanced summary of the principal issues surrounding the use of KI, and it should provide a useful reference for State and local governments evaluating their KI policies.

Our principal comment is that the technical content of this document does not support any change in the current national KI policy in the United States — and hence does not support recent decisions by the Commission on this subject. We suggest that the Commission reexamine how its KI policy should evolve based on the information in this draft NUREG.

In addition, several sections should be expanded for completeness, as noted below.

One laudable feature of this document is the explanation of reasons for European reliance on KI and how that situation differs from the one in the US. It should also be explained that the US has extensive experience with successful evacuation of the public for both natural and technological disasters (most recently demonstrated in the evacuation of the North Carolina coast for Hurricane Bonnie in August). This demonstrated success with evacuation renders unlikely the probability of serious thyroid exposures in the plume phase of a reactor accident. Moreover, the size of the US, and the flexibility of its food production and distribution systems, enable the US to implement food interdictions and still feed the population without undue disruption. It is therefore much less necessary to rely on KI to protect the population.

Although the document covers the KI distribution schemes of various European countries, it does not include any discussion of the experiences of the three US States that have actually distributed KI to the public. A section on these experiences should be included.

The discussion of the medical aspects of KI administration, especially its indication for pregnant women, needs further clarification. We urge the NRC to solicit input from the medical profession to ensure that this important aspect is not shortchanged.

We also strongly urge the NRC to involve this committee (and State and local governments in general) in the development of any informational materials on KI. I will be happy to discuss proposals for our involvement at your convenience.

We appreciate the opportunity to comment on this important document, and hope the NRC will incorporate our suggestions to improve it. If you have any questions or concerns regarding our comments, please do not hesitate to contact me at the address, phone number or e-mail address listed below.

Sincerely,

James C. (Jim) Hardeman, Jr.
Chair, Emergency Response Planning Committee (E-6)
Conference of Radiation Control Program Directors, Inc.
c/o Environmental Protection Division
Georgia Department of Natural Resources
4244 International Parkway, Suite 114
Atlanta, GA 30354
(404) 362-2675 fax: (404) 362-2653
Jim_Hardeman@mail.dnr.state.ga.us

cc: E-6 Committee Members and Advisors
Cindy Cardwell (TX)
Chuck Hardin (CRCPD-OED)

CC: GATED.nrcsmtp("shawn.seeley@state.me.us","jkey@mai...

DELAWARE EMERGENCY MANAGEMENT AGENCY

P.O.BOX 527
Delaware City, DE. 19706
(302) 326-6000
1-800-292-9588
Fax-(302)326-6045

DATE: 14 Sep 98 **TIME:** 1048

TO: Mr. Aby Moseini Fax # 301-415-5392

AGENCY: Incident Response Div, Office of Analysis and Eval of Opnl Data.
US Nuclear Regulatory Commission

SUBJECT: Comments on NUREG 1633.

FROM: Kevin Kille, Nuclear, Biological, Chemical Section, DEMA

AGENCY: DELAWARE EMERG MGMT AGENCY.

NUMBER OF PAGES: 3

COMMENTS: Please keep us posted on further developments. Thank you.

Kevin Kille

SOUTH TEXAS PROJECT ELECTRIC GENERATING STATION
P.O. BOX 289
WADSWORTH, TEXAS 77483

TO: Abby Mohseni **FAX #:** 301-415-5392

DATE: 9/8/98 **LOCATION:**

PHONE #: **# OF PAGES:** 2
Including cover sheet

FROM: Lurinda Barton, Offsite Program Manager
Mail Code N4006
512-972-7695
512-972-7935 (Facsimile)
www.lsbarton@stpegs.com

Abby. Our County Judge mailed a letter to you 9/4/98 - to the address listed in the Federal Register. I did not know how long it would take it to get through your mail system using that address, so I am faxing you a copy of the letter.

Thanks,
Lurinda

MATAGORDA COUNTY EMERGENCY MANAGEMENT

1700 7th Street, Room 301
Bay City, Texas 77414
(409)244-7605

Bert Huebner
County Judge
Emergency Management Director

James E. Engbrock
Emergency Management Coordinator

September 8, 1998

Aby S. Mohseni
Division of Incident Response
Office of Analysis and Evaluation of Operational Data
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Use of potassium iodide for the general population during severe reactor accidents

Dear Mr. Mohseni:

We understand the Nuclear Regulatory Commission is considering a petition that would require consideration of the issuance of potassium iodide to the public during a severe nuclear power plant reactor accident. As County Judge/Emergency Management Director (as per Texas law), and as Emergency Management Coordinator for Matagorda County, Texas, we do not feel this is at all necessary.

Per our emergency plans, we dismiss schools within the 10-mile radius of the South Texas Project at the Alert classification and evacuate any school children left in the area at the Site Area Emergency classification. We may evacuate the public at a Site Area Emergency, and certainly at the General Emergency, depending on the situation at the plant. We feel evacuation (and in rare circumstances, shelter) is the most prudent action for the public in our emergency planning zone and is the best precautionary measure we can take.

We hope this letter will assist the Nuclear Regulatory Commission in making a reasonable decision regarding this issue.

Yours truly,

Bert Huebner
County Judge/Emergency Management Director
Matagorda County, Texas

James Engbrock
Emergency Management Coordinator
Matagorda County, Texas

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD, ILLINOIS 62704
217-785-9900
217-782-6133 (TDD)

Jim Edgar
Governor

Thomas W. Ortciger
Director

September 11, 1998

Mr. Aby S. Mohseni
Division of Incident Response
Office for Analysis and Evaluation of Operational Data
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Mohseni:

SUBJECT: Draft NUREG-1633, Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents

The Illinois Department of Nuclear Safety (Department) is the lead agency in Illinois, in cooperation with the Illinois Emergency Management Agency, for preparing emergency plans for, and coordinating emergency responses to, accidents at nuclear power plants. The Department disagrees with the Nuclear Regulatory Commission's policy on the distribution of Potassium Iodide (KI) to the general public. We firmly believe that evacuation is the most effective way to protect the public and avoid needless radiation exposure during a nuclear power plant accident.

The Department has reviewed the referenced document and finds it to be an appropriate summary of the issues surrounding the use of KI by the general public following reactor accidents. It provides a useful description of the historical, technical, and operational aspects of the KI issue for State and local governments evaluating the distribution of KI to the general public.

Some participants in the country's debate concerning the use of KI point to the policy of some European countries to provide KI to the general public while emphasizing the general policy to the contrary in the United States. Section VI-C provides a noteworthy explanation of the major reasons for this difference.

Section III-F, "Medical Aspects of Potassium Iodide", fails to address the discrepancy between United States guidance and World Health Organization guidance on the suitability of KI for use by pregnant women. The document should address this issue for the sake of completeness.

Little information is presented in this document, or for that matter, elsewhere about the location, amounts, dose levels, packaging, and stability the KI stockpiled in support of anti-terrorism initiatives. The effectiveness of KI is strongly dependent on the timing of administration. To be of any use, NRC should provide the necessary information on these stockpiles to the state emergency response agencies. Clandestine stockpiles of KI are enigmatic.

The conclusions in this draft NUREG do not support the rationale cited in the recent Commission policy with respect to the stockpiling of KI for use by the general pubic. Specifically:

- The Commission said its decision was based in part on the Chernobyl accident. Studies cited in the draft NUREG indicate there is no strong correlation between the Chernobyl experience and the data representing "worse case" reactor accidents in the US.

- The Commission said its decision was supported by the experience with KI distribution policies in Europe. The discussion in Section VI-C of the draft NUREG supports the contention that the social and legal circumstances affecting implementation of KI use in Europe differ significantly from those in the United States.

- The Commission found that prevention of potential thyroid cancers justified the stockpiling of KI for the public. The draft NUREG explains in detail the relatively low risk of potential health effects from thyroid exposure to I-131 verses the multiple health hazards posed by delayed or improper ingestion of stable iodine.

- The Commission declared that KI distribution to the public should be considered as a supplemental protective action to evacuation and sheltering. The draft NUREG states that the stockpile concept could potentially undermine the effectiveness of existing emergency response plans and evacuation procedures.

These inconsistencies will undoubtedly pose a significant challenge to the Federal Radiation Protection Coordinating Council (FRPCC). FRPCC will use this document to develop guidelines for use by the Federal Emergency Management Agency (FEMA) in evaluating KI distribution mechanisms in states that may elect to stockpile the drug. We strongly recommend that the Commission reconsider its KI policy in view of the information presented in NUREG 1633.

If you have any questions or concerns regarding our comments contact me at 217/ 785-9868.

Sincerely,

Thomas W. Ortciger
Director

TWO:bdc

cc: Shirley Jackson
James Lee Witt

KANSAS
DEPARTMENT OF HEALTH & ENVIRONMENT
BILL GRAVES, GOVERNOR
Gary R. Mitchell, Secretary

September 15, 1998

MR ABY MOHSENI
MS T4A43
NUCLEAR REGULATORY COMMISSION
11545 ROCKVILLE PIKE
ROCKVILLE MD 20852-2738

Dear Mr. Mohseni

Our staff has reviewed draft NUREG 1633 and has the following comments:

Kansas protective action guides are consistent with the "Insights and Conclusions" shown in the study that use of KI is not an alternative to prompt evacuation. We currently stockpile sufficient KI to provide thyroid blocking for all emergency workers (state, county, and power plant) and for selected special populations such as those in nursing homes, hospitals, and jails. Use of KI by any one or all of these groups will be recommended based upon plant or release conditions.

Although risk of reaction to KI was reported as minimal in the report, a more recent paper by Janusz A. Nauman, "Potassium Iodine Prophylaxis in Case of Nuclear Accident; Polish Experience," reported 4.5 to 4.6% of extrathyroidal side effects after a single dose of KI. Such side effects must be considered prior to recommending distribution or administration of KI to a large population.

We agree with the concept that prompt evacuation based upon plant conditions protects a population from all radionuclides and pathways. This is preferred to protecting only the thyroid.

In section II. Severe Accidents, paragraph two: The sentence: "Without both occurrences, there is no need for any protective actions, including evacuation or administration of KI." is inappropriate in light of current Federal and state guidance. Most communities will be evacuated based upon plant conditions that may lead to core damage and containment failure. Perhaps the sentence could be changed to reflect this concept.

DIVISION OF ENVIRONMENT
Bureau of Air & Radiation

Forbes Field, Building 283
(785) 296-1560

Topeka, KS 66620-0001
FAX (785) 296-0984

We agree with the reports statements that "KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs."

Although the NUREG's tabulated doses to the public can be projected from current models, the projected of doses of 160 rads acute and 19,000 rads thyroid at 10 miles are significantly above levels for probable accident scenarios involving US reactors.

Sincerely,

Vick L. Cooper, Chief
Radiation Control Program
Bureau of Air and Radiation

VLC/psw

State of New Jersey

CHRISTINE TODD WHITMAN
Governor

DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF STATE POLICE
POST OFFICE BOX 7068
WEST TRENTON NJ 08628-0068

PETER VERNIERO
Attorney General

COLONEL CARL A. WILLIAMS
Superintendent
TELEPHONE: (609) 882-2000

ADDRESS REPLY TO:

September 22, 1998

Mr. Aby Mohseni
MS T4A43
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Mohseni:

Subject: Comments on Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents"

The New Jersey Office of Emergency Management (NJOEM) has reviewed the draft publication of the NUREG-1633 which discusses the historical use, technical basis, and domestic and international industry experiences in the use of KI as a supplemental protective action for the general public. Based on our review, we wish to express the following views and concerns:

a. We concur with the position of the NRC and others that the stockpiling of KI for issue to the public as a protective action will not contribute any significant benefit to the existing protective action measures currently in our radiological plans.

b. The issuing of KI may give the public a false sense of security which could slow down the evacuation process.

c. We have profound concerns about the qualifications of emergency workers administering a drug which can result in a serious allergic medical reaction by the person taking KI.

d. New Jersey's policy is to issue KI only to emergency workers when directed by the State Commissioner of Health.

e. A major obstacle to the distribution of KI to school children is the administration of the program. Such issues as parental approval, record keeping, identification of children with allergic reactions, and availability of medical professionals to administer this drug are concerns which would require resolution.

f. From a logistics viewpoint, implementation of a program to administer KI to an EPZ population, which can be as high as 200,000-300,000 during peak summer months, would be extremely difficult to manage. The number of emergency workers required to perform this function alone would seriously impact our ability to perform our other emergency actions in support of evacuation such as the operation of reception and congregate care centers, access and traffic control, route alerting and others.

The New Jersey Office of Emergency Management wishes to thank the U.S. NRC for giving us the opportunity to comment on this document. We sincerely hope that our comments are beneficial to you as you consider your revisions to draft NUREG-1633

If you need any additional information regarding this matter, please contact Jon Christiansen at (609) 538-6070.

Sincerely,

FOR COLONEL CARL A. WILLIAMS
SUPERINTENDENT
STATE DIRECTOR

Thomas P. Davies

Thomas P. Davies, Major
Section Supervisor
Emergency Management Section

jf
G:\USERS\RERP\POLICY\NREG1633.WPD

State of New Jersey

Christine Todd Whitman
Governor

Department of Environmental Protection
Division of Environmental Safety, Health
and Analytical Programs
Radiation Protection Programs
PO Box 415
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Robert C. Shinn, Jr.
Commissioner

September 10, 1998

Document Control Desk
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 29852-2738

SUBJECT: Comments on draft "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents" (draft NUREG-1633)

The New Jersey Department of Environmental Protection welcomes the opportunity to comment on the subject draft document. A sound technical assessment of the use of KI as a public protective action during accidents at nuclear power plants will be a valuable tool for states. The Department believes that the states need a good assessment which identifies both the benefits and risks of using KI as a supplemental protective action. Consequently, we offer the following suggestions to improve, strengthen, and clarify the points presented by the NRC in the draft document.

Recognizing that the abstract presents an overview of the topics reviewed in the paper, the Department suggests that a statement of purpose be included directly in the body of the document. The following statement is suggested for insertion as the first paragraph in the Executive Summary:

> This assessment is intended as an evaluation of the use of potassium iodide as a supplemental public protective action within the plume pathway emergency planning zone during severe reactor accidents. It is not a NRC policy statement. Rather, it is intended solely as a technical assessment, presenting both the benefits and challenges of distributing KI as a public protective action. This assessment is provided as a tool to assist states during their consideration of KI as a supplemental public protective action. It should not be interpreted as either encouraging or discouraging the use of KI as a supplemental public protective action.

The document presents many facts regarding the use of KI. However, the Department believes that revised formatting is needed in some areas to improve upon the balance of information which is emphasized. For example, in section VI.C.1. on pages 21 and 22, the paper lists six key reasons for Europe's reliance on KI. These six bullets are followed by a paragraph which explains response coordination between the United States and Canada. The Department suggests the insertion of the following paragraph before section VI.C.2 on page 22:

> In addition, unlike many European countries, in the past the United States has not distributed KI to the public as a supplemental protective action for the following reasons:
>
> - The continental United States is a contiguous land mass with one common federal government possessing regulatory authority for nuclear power plants operating in different states. Emergency preparedness planning is not constrained or hindered by state borders as is potentially the case with national borders in Europe. Consequently, evacuation of geographic areas can be implemented without regards to political boundaries.
>
> - The United States has extensive successful experience in implementing evacuations of public populations who are threatened by natural occurrences. The most recent example of this experience is the evacuation of the North Carolina coast in the face of approaching Hurricane Bonnie the week of August 24, 1998.
>
> - Distribution of KI to the public during a reactor accident (a task with which the U.S. has little experience) will delay implementation of evacuation orders (a task with which the U.S. has much successful experience).

- Significant differences in reactor design, operation, and safety systems exist between the nuclear power generating stations which operate in the United States and those commercial reactors operating in Europe. These differences result in the development of significantly different accident scenarios. Worst case accident scenarios for U.S. nuclear generating stations allow for the presence of ample indicators and sufficient lead times to permit the safe evacuation of threatened populations prior to the release of radioactive materials.

- Because of demonstrated success in evacuating large populations, thyroid exposures to radioiodines during the plume phase of an accident in the U.S. is unlikely. Exposures during the ingestion phase are minimized as a result of protective actions to interdict contaminated foodstuffs. Unlike some areas within Europe, the U.S. possesses the resources to destroy locally contaminated foods and still feed evacuated communities with products from other areas of the nation.

- KI protects the thyroid from internal exposure to radioiodines. KI does not protect against internal exposure to other radioisotopes and does not protect against external irradiation. Although thyroid doses associated with a severe accident scenario would numerically be much higher than the whole body doses, the adverse health effects of the thyroid doses would be much less severe than those of the whole body doses.

Although the draft document provides extensive information on the experiences of European countries with the administration of KI to the public, there is no discussion of the experiences of state governments in the United States. To the Department's knowledge, three U.S. states have experience with distribution of KI to the public. They are Alabama, Arizona, and Tennessee. The Department believes that the assessment of the use of KI will be more comprehensive if it includes the experiences of these three states.

The Department offers the following suggestions for improving and clarifying the Insights and Conclusions:

The last sentence of the fifth Insight and Conclusion reads "Logistics and liability are significant issues probably best handled by the States." This sentence should be deleted. The last sentence of the sixth Insight and Conclusion reads "Realistically, the State and local

officials are in the best position to deal with these issues, and determine how best to allocate State's resources following a severe accident." This sentence should also be deleted.

The Department believes that the NRC must address medical procedures, logistics, liability, and implementation processes in order for this assessment to be truly useful as a tool by the states. For example, the Department questions how, at the height of a nuclear power plant emergency, KI can be responsibly and effectively administered to members of a large population while at the same time assuring proper medical oversight for each individual. The NRC assessment cannot simply report that this issue will be addressed by the states. If there is insufficient information available at this time to properly address these issues, then the assessment should acknowledge this fact.

The Department requests that the following paragraph be included as an Insight and Conclusion, possibly between the sixth and seventh Insight and Conclusion (all except the last sentence of this paragraph was taken from the body of the draft document):

> KI protects the thyroid from internal exposure to radioiodines. KI does not protect against internal exposure to other radioisotopes and does not protect against external irradiation. Although thyroid doses associated with a severe accident scenario would numerically be much higher than the whole body doses, the adverse health effects of the thyroid doses would be much less severe than those of the whole body doses. For example, a person who receives a very high thyroid dose might experience serious thyroid damage (ablation), but would also very likely receive a lethal whole body dose. Consequently, at release levels which would lead to ingestion of KI to protect the thyroid, the exposed individual would die from the whole body exposures.

The Department suggests that the eighth Insight and Conclusion be replaced with the following paragraph:

> National stockpiles of KI have previously (prior to and independent of this assessment) been recommended along with chemical antidotes, serin vaccines and antibiotics for response to nuclear, biological, and chemical weapons. Note that this recommendation pertains to a response for *weapons*, not nuclear power plants. If state agencies should determine that they wish to use KI as a supplemental public protective action in response to nuclear power plant accidents, the U.S. government has agreed to make its KI stockpiles available to state officials.

It is not clear whether the NRC intends to make KI available to the states for only the initial distribution of KI to the public, or for all subsequent distributions as well as the initial distribution. The Department requests that this point be clarified in the final assessment.

The Department suggests the last sentence of the ninth Insight and Conclusion ("Cultural and legal differences between the U.S. and other countries may be the basis for differing perspectives on drug use.") be replaced with the following:

> Significant differences exist between the United States and other nations which can explain different approaches to the use of KI. These differences include: 1) the geography of the continental U.S. with centralized regulatory authority for on-site nuclear power plant operation and off-site emergency preparedness; 2) extensive successful experiences in the U.S. in evacuating large populations; 3) no experience in the U.S. with the wide-spread distribution of a drug to large populations without medical supervision; 3) differences in reactor design, operation, and safety systems; 4) sufficient resources to allow for interdiction of contaminated foods; 5) and accident scenario models which point to whole body doses as a greater constraint than thyroid doses.

The Department has several concerns regarding the medical aspects associated with the unsupervised ingestion of KI. Therefore, we urge the NRC to make every effort to solicit comments from the various national medical associations. If it is necessary to assure an ample opportunity for these groups to submit their comments, the comment period should be extended.

Lastly, the Department notes that the Federal Register Notice states that NRC staff will develop an information brochure based on NUREG-1633 to assist states and local planners regarding KI as a supplemental protective action. The Department requests that the states and local planners be given an opportunity to comment on the draft of this brochure before it is finalized.

Document Control Desk
U.S. Nuclear Regulatory Commission
September 10, 1998

The Department wishes to thank the U.S. NRC for publication of the draft document and for the opportunity to offer comments for its improvement. I believe that our comments improve the balance of information presented on the benefits and risks of KI as a supplemental protective action and hope that they are useful as you prepare the final KI document. If any of our comments need further clarification, please call Kent Tosch, Manager of the Bureau of Nuclear Engineering, at 609-984-7700.

Sincerely,

Jill Lipoti

Jill Lipoti, Ph.D., Assistant Director
Radiation Protection Programs

c: Aby Mohseni
MS T-4A43
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 29852-2738

Director Gerald P. Nicholls, Ph.D.
Manager Tosch
Nick DePierro

STATE OF MICHIGAN

JOHN ENGLER, Governor
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RUSSELL J. HARDING, Director

REPLY TO:

DRINKING WATER & RADIOLOGICAL
PROTECTION DIVISION
3423 N MARTIN L KING JR BLVD
PO BOX 30630
LANSING MI 48909-8130

August 27, 1998

Mr. Frank J. Congel, Director
Division of Incident Response
Office for Analysis and Evaluation
of Operational Data
United States Nuclear Regulatory Commission
Washington, DC 20555-001

Dear Mr. Congel:

The purpose of this letter is to respond to a request for comments published in the Federal Register (Vol. 63, No. 138, July 20, 1998) on the U.S. Nuclear Regulatory Commission (NRC) draft NUREG-1633, entitled "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents."

From a radiological protection perspective, the draft NUREG presents significant technical information that would seem to preclude the use of KI by members of the public as an effective protective action in the event of a severe nuclear power plant reactor accident. If the selected reactor accident scenarios presented in the NRC analysis are representative of the relevant radiation exposure data to consider, then the use of KI for the general public during a nuclear reactor emergency event could cause more radiological harm than benefit. Although there is clear evidence that the use of KI can reduce the radiation dose to the thyroid from internal ingestion or inhalation of radioiodines, other radiological risk factors need to be considered for public protection in reactor accidents. The potential risks associated with the distribution and ingestion of KI during a reactor accident are likely to exceed the potential benefit to be derived by the general public.

Planning for effective protective action for the public currently involves evacuation as the primary emergency response action for nuclear reactor accidents by off-site authorities in Michigan. The information provided in the draft NUREG seems to provide a convincing rationale to continue this approach. Expanding public protective actions beyond evacuation to include the routine use of KI by the general public may prove ineffective and potentially counterproductive, when compared to preferred protective action alternatives such as evacuation alone.

We are also concerned about the extensive adverse medical aspects associated with ingestion of KI by the public en masse, including additional significant contraindications, as described in the draft NUREG. We strongly recommend that the U.S. Food and Drug Administration conduct a thorough review of the medical risks and benefits associated with KI use by the public in the

context of an emergency response action. Similarly, the U.S. Environmental Protection Agency (EPA) may need to reconsider its thyroid dose action levels and associated recommendations for use of KI as currently presented in its "Manual of Protective Action Guides and Protective Actions for Nuclear Incidents" (EPA 400-R-92-001) to address the risk/benefit issues described in the draft NUREG. We suggest that the Federal Radiological Preparedness Coordinating Committee be contacted to coordinate a federal assessment of the relevant information and advise the NRC appropriately before the NRC takes any action to change its current policy concerning KI.

Sincerely,

David W. Minnaar, Chief
Radiological Protection Section
517-335-8197

DWM:RT

cc: Mr. Daniel Sibo, MDSP
Mr. Art Davis, MDCH
Ms. Ellen Karpe, Consumers Energy
Mr. Rod Krieger, AEP
Mr. Kevin Morris, Detroit Edison
Mr. Dennis Hahn, MDEQ

63FR 38865
July 20, 1998

COUNTY OF PICKENS

DS09 EMERGENCY SERVICES
Emergency Preparedness
A. Mohseni
EMS

September 22, 1998

Mr. David L. Meyer
Chief, Rules Review and
Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Sir:

Pickens County Emergency Preparedness Agency is responsible for the off-site planning and coordination of the 10-mile EPZ affected by the Oconee Nuclear Station.

We have reviewed the Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Protective Action During Severe Reactor Accidents."

Our Emergency Plans call for Evacuation of the population of the EPZ in a timely fashion to prevent exposure to radiation from the Oconee Nuclear Station. We do not feel issuing potassium iodide to the general public would add any measure of safety. In fact, maintaining, administering and record keeping would be a night-mare to a local operation.

Currently, we do have plans to issue potassium iodide to our emergency workers who would be required to provide services within the 10-mile EPZ for an extended period of time.

If there are any questions regarding my comments, contact me at 864-898-5945.

Sincerely,

William D. Evett
Director

Emergency Operations Center
307 Pendleton Street . Pickens, South Carolina 29671 . Telephone (864) 898-5945 . Fax (864) 898-5947/5797

Linn County
Emergency Management Agency

50 2nd Avenue Bridge
Cedar Rapids, Iowa 52401-1256

Phone: (319) 363-2671 Day or Night • Fax: (319) 398-5316 • E-Mail: linnema@jmbest.net

4 September, 1998

Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: Response on the Use of Potassium Iodide for Emergencies at Nuclear Power Plants

Dear Sirs;

I wish to provide input to the NRC from the local Emergency Management Agency level concerning the stockpiling of Potassium Iodide (KI) for public use in the event of an emergency at a nuclear power plant.

I strongly recommend this NOT be adopted and that the existing policy of using KI only for emergency workers remain in effect.

I am the Director of Emergency Management for Linn County, Iowa. I am responsible for the protection of the general population within the Emergency Planning Zone of the Duane Arnold Energy Center, located in Palo, Iowa. My county has a population of approximately 160,000 in the effected EPZ that I would have to address providing KI to over and above the 2,500 emergency workers I currently am prepared to support.

There are several reasons why requiring the stockpiling of KI for the general population is not the best way to protect the public from the effects of a radiological accident.

First, Evacuation has been shown to be the best way to protect the public. This keeps the public from exposure by removing them from the source of the radiation. I feel it is better to move the public away from the problem instead of treating the public after exposure. Our plans are very extensive in alerting the public in the event of an emergency and I believe we can quickly and effectively evacuate our population out of harms way. This is especially true for our plan to protect the children, who are at the greatest risk of radiation exposure. Much of our planning and training is oriented on moving the children out of the EPZ early on in an emergency situation.

Second, the logistics of storage and distribution of KI is tremendous, especially for the potentially affected population that I serve. There is a great deal of effort to store over 1,650 boxes of KI for the general population and the emergency workers, maintain accountability, and rotate the stock as required. This amount of effort does not address the problems of distribution of the KI to the general population and the necessity to instruct the population on how and when to take the KI and to inform them of the potential health risks. Again, the utility and the emergency management community put forth a great deal of effort annually, to train the emergency workers on the use of KI. This task would be multiplied many times to serve the general population at the minimum standard that would be expected. Also it sends a message of false security to the public which implies that individuals can stay in an affected area instead of evacuating and the government will provide them a pill that will solve all of their problems. This implied message does more to hurt the public safety than helping it.

The only real value I see in adopting this proposal would be the benefit to the pharmaceutical companies, and would be a job security benefit. Both the local emergency management agencies and the utility emergency planning departments would have to hire additional staff to administer this program and the bottom line is "Will the public be any better served?" I feel it would not!

In closing I believe this draft proposal is without merit and does not meet the reality check of meeting the public safety needs. **This proposed regulation should NOT be adopted!**

If you have any questions, please contact me. Thank you for your support.

Respectfully;

WALTER E. WRIGHT, CEM
Director of Emergency Management

September 11, 1998

Mr. John C. Hoyle
Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

ATTENTION: Docketing and Services Branch

Dear Mr. Hoyle:

Subject: **Comments by Bureau of Radiation Protection, Ohio Department of Health to Draft for Public Comment, NUREG-1633, entitled: " Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Core Accidents."**

Attached are the subject comments. These have been prepared in response to the USNRC request for comments, published in the Federal Register, Notice 63FR38865, dated July 20, 1998.

Sincerely,

Roger L. Suppes, Chief
Bureau of Radiation Protection

RLS/HBB/hb
File: ki\n1633com.trn

Attachment

pc: Deborah L. Arms, ODH,Prevention
Harvey B. Brugger, ODH-BRP
Frank J. Congel/Aby S. Mosheni, NRC-AEOD

September 11, 1998

For transmittal to Internet address: asm@nrc.gov

To: Aby S. Mosheni, Division of Incident Response,
Office for Analysis and Evaluation of Operational Data,
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

Subject: Comments by Bureau of Radiation Protection, Ohio Department of Health to Draft for Public Comment, NUREG-1633, entitled: "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Core Accidents."

1.0 OVERALL IMPRESSION

The NRC report needs to be more neutral in presenting the benefits and detriments of adoption of KI as a supplement to evacuation. Whatever the original intent of this report, it will make objective consideration of the use of KI more difficult for State and local officials. This is despite the NRC Commissioners approval of this course of action as a valid supplementary protective measure for the public. This is a very strange situation, when considering the fact that this issue was brought to the fore by the NRC's offer to pay for purchase of KI for the public in a news release, No. 97-102, July 1, 1997. This situation is also strange in that using KI was a consideration that was previously rejected by most states for very good reasons.

The apparent bias of draft NUREG-1633, is also contrary to the positions taken in support of public distribution by many prestigious national and international organizations, such as the American Thyroid Association, the World Health Organization, the International Atomic Energy Agency, the U.S. National Council on Radiation Protection and Measurements and the International Commission on Radiological Protection. They all favor KI use for the public as a protective measure for reactor core accidents. Other nations producing nuclear-electric power, such as Germany, France, the United Kingdom, Finland, Sweden and Switzerland all make great efforts to ensure their accident affected populations will have KI immediately on hand to take. As an example of draft NUREG-1633 bias, it contains a discussion of why Americans are different than Europeans, because our thyroids are already partially blocked by eating salty fast food. (See draft NUREG-1633, Page 14.) This situation is not true for all Americans, for example, it is obviously not true for neonates. Aside from the fast food statement, we are told that differences in our cultural, legal and political organizations would make the logistics of distribution and administration much more difficult than in Europe. We believe this is a very valid point and that the NRC should reconsider their funding offer in light of it. That is, the NRC should bear more of the burden of costs, since apparently the NRC Commissioners' intent was to eliminate economics in the local consideration of whether to adopt us of KI. (Reference: SECY 97-124, June 16, 997, Page 11, Option 2 highlights, second bullet.)

State and local officials in Ohio have been approached by citizens to take up consideration of the NRC funding offer. However, we find ourselves confronted with draft NUREG-1633, which argues against distribution, using principally the idea that KI is a dangerous drug. If one reads the package insert for THYRO-BLOCK that was prepared by its manufacturer, Wallace Laboratories, it is obvious that the manufacturer doesn't consider KI a dangerous drug when used in the doses prescribed for radiation protection. (THYRO-BLOCK is provided for emergency workers and institutionalized populations by the Ohio Department of Health(ODH) in the 10-mile EPZ.) Further, the Ohio Board of Pharmacy has advised ODH that KI is not a prescription drug, if used for radiation protection.

If the NRC continues to believe that the severe core accident scenario is valid for use of KI as a Cleveland, Akron and Columbus, and all the places in between, because local and State officials would be totally overwhelmed by the logistics of that task. Further, the entire concept currently used throughout the Nation for evacuation planning is that of a 10-mile EPZ. This would be negated by the severe reactor accident scenario, with the consequence that all State and local emergency planning would have to be redone. Certainly, the NRC doesn't require nuclear power plants to be (re)designed to accommodate a severe reactor accident scenario. Why then should the NRC suggest that the Nation's nuclear power plant emergency response efforts consider this accident scenerio? The lack of consistency is troubling. If this accident isn't a design basis accident, then why is the NRC seeking to expend federal, state and local emergency response resources to deal with it? Is this not ratcheting up the emergency response requirements?

In conclusion, we would request that you withdraw draft NUREG-1633 and instead, possibly prepare another report that objectively addresses the real issues of logistics of distribution, and if at all possible, proffers workable solutions in the way of making KI use effective as a supplement to evacuation. We would further request that NUREG-1633, if not withdrawn, address a more realistic accident scenario than the severe core accident, an accident at least 20 times less probable than those for which current nuclear power plants in the U.S.A. are designed. You can not address local emergency response measures for an extremely unrealistic scenario, the severe core accident, and at the same time limit those measures to a 10-mile EPZ. We believe that organizing effective emergency response protective measures for severe reactor core accidents may be impossible, given the societal resources that would need to be deployed for a severe core accident that would negatively impact the health of the population out to several hundred miles from the plant. This is in comparison to the FEMA planning distance for evacuation of 10 miles around a nuclear power plant. This disparity between the evacuation emergency planning zone (10-mile EPZ) and the expected distance of radioactive plume affect is a fact borne out by reading a scholarly study prepared for the NRC by Sanford Cohen & Associates, and published by the NRC as NUREG-6310, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident", February 1995.

2.0 DETAILED COMMENTS

2.1 Limiting consideration of use of KI to the 10 mile emergency planning zone (EPZ) is an artificiality, in that given the title of the NUREG, "Assessment ...Severe Reactor Accidents", for this highly unlikely scenario, the pathway where KI intervention would be effective is several hundred miles. Consider changing the title and/or be prepared to provide enormous funding to both pay for KI and distribute it in the severe accident pathway, since the resources required would overwhelm State and local governments and would be a lot more than any nuclear-electric utility would be willing to fund. According to NUREG-6310, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident", 1995, "thyroid risks are based on external exposures ranging from about 5 to 1500 Rads" (page 2-10) and "...in the downwind sector, the child thyroid dose of at least 50 rem has a probability of nearly 100% for distances out to about 50 miles. Between 50 and 175 miles, the probability of exceeding 50 rem declines steadily..."(Page 4-16).

2.2 The artificiality of considering KI for just the 10-Mile EPZ is borne out by NUREG-1633 itself in the statement "For the two most severe accident scenarios considered, reductions in thyroid doses are dwarfed by the physiological effects of the accompanying acute whole body doses. Early death or very serious effects would occur to all individuals exposed out to nearly 10 miles. (See the report Executive Summary, bottom of Page 3.)

2.3 The artificiality of the 10-Mile EPZ is further borne out by the report (Page 21) statement that the vast majority of thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the (Chernobyl) site. The current emergency planning and projections for purposes of recommending protective actions are based upon a straight line downwind trajectory being followed by the radioactive plume. Nature doesn't behave this way very often. Wind dispersion and meteorological conditions can be erratic, as evidenced in the Chernobyl accident, where the plume rose about 1000 feet and then dispersed, thus sparing the close-in population from bearing the brunt of the thyroid cancer incidence. Hence planning for just the 10-mile EPZ for KI or any other protective measure, including evacuation, is oversimplification. In NUREG-1633 (the authors' own words), (Page 28) "meteorological parameters do not lend themselves to simple extrapolation to distances beyond the EPZ. For example, the Chernobyl release produced a pattern that was extremely difficult, if not impossible, to project."

2.4 The report (Page 28) goes on to state two dangerous fallacies: (1) that "...the potential for large doses is limited to the 10-mile EPZ..." and (2) "The preparations made in the 10-mile EPZ allow public officials to expand their protective action beyond 10 miles if needed on a case-by-case basis." In fact, most states, with FEMA approval, have emergency plans, procedures and preparations that deal specifically with evacuation of populations in the 10-mile EPZ only. There is no established alert and notification

system, nor planned evacuation routes, nor planned reception centers, nor even any effort to bring officials from the downwind counties beyond the 10-mile EPZ into any semblance of emergency preparedness for the eventuality of having to respond to a telephone call requesting they evacuate their threatened populations.

2.5 In at least two places in NUREG-1633, reference is made to administration of KI to " women and children" as "requiring a high degree of caution", (Pages 5 and 32.) This contrasts with the package insert on the KI that the State of Ohio currently distributes to emergency workers and institutionalized populations, which states "Pregnant and nursing women and babies and children may also take this drug." (Reference: Wallace Laboratories, Patient Package Insert for Thyro-Block Tablets, Potassium Iodide Tablets, USP, IN-0472-03, Rev. 5/94). This contradiction detracts from the valid consideration of the real issue of distribution that needs to be addressed.

2.6 Page 32 of the report states that "The use of KI in conjunction with evacuation could potentially delay evacuations." This statement is prejudicial toward a dispassionate consideration of the issues for and against adopting KI as a supplement to evacuation. Is it not possible that if KI is pre-distributed to people within the plume pathway, or made available to them outside of the evacuated area, there would be no reason to delay evacuation in order to get it. Indeed, there may be every reason for the public to make speed in evacuation, so that they could get to the place outside the evacuated area where KI could be obtained.

2.7 NUREG-1633 fails to address the public education effort needed for people to understand why they should take KI and when they should take it. Public outreach is a resource consuming but necessary effort. There is no way for KI to be an effective supplement to evacuation without public education. It is difficult enough just to get permanent residents to understand what to do when they hear the sirens in the 10-mile EPZ, let alone the seasonal and transient populations. Educational outreach to prepare the public to take KI is also an effort that could easily have negative implications for communities that have nuclear plants and also have a substantial tourism element to their economies. How do you educate people in order to make KI usage effective without scaring away the tourists or making the populace fear nuclear power?

2.8 The original NRC news release wherein the NRC offered to fund KI for nuclear power plants also elaborated on the Federal Government plans for stockpiling of nuclear, biological and chemical antidotes around the country, (No. 97-102, July 1, 1997). Draft NUREG-1633 also holds out the availability of these anti-terrorism stockpiles for nuclear accidents. (Page 33). Although, we understand that the NRC needs to coordinate its emergency response efforts with other federal agencies, we believe that use of KI as a supplement to evacuation for a nuclear power plant accident should be a stand alone issue to be addressed by the NRC, out of the Federal Radiological Preparedness

Coordinating Committee (FRPCC) context of anti-terrorist activity. Doing otherwise feeds a public misperception that nuclear devices and nuclear power plants are synonymous, which they are not.

RLS/HBB/hb
file: n1633com.r-3

TO: Aby Mohseni
Nuclear Regulatory Commission

FROM: Cheryl K. Rogers, LLRW Program Manager
HHS Regulation & Licensure
State of Nebraska

SUBJECT: Comments on Draft "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents"

DATE: October 7, 1998

I hope these comments will be useful to you even though we did not meet the September 15, 1998 deadline. This request for comment did not come to our attention until early September.

1. Document Purpose

The Assessment does a good job of providing both the background history and the impact of more recent events such as Chernobyl concerning KI usage. By bringing the international guidance and experience into the discussion, the standard practice in the United States is compared and contrasted. I think this is useful in showing why the US continues to emphasize evacuation.

2. Public Health Officials Ability to Order Use of KI

We have struggled with the question of how is it possible for the public health officials to order the use of a prescription drug. It was helpful to read that it is not considered a prescription drug if needed in a public health emergency. (Of course, the decision to recommend the optional use of KI must still be balanced with consideration of medical side effects.)

3. Use of the Document to Make an Informed Decision

This document is very well written and provides information that can be used by technical staff to brief decision makers. The informed decision should be made prior to the emergency situation concerning what the policy will be on use of KI as timing is important. (It is noted that the benefit of using KI is useful in mitigating dose by a maximum of a factor of 10 and would not provide any benefit for the most serious situations when radiation levels are extremely high.)

4. US Population Specific Factors

The Assessment provided useful information concerning the US Population, specifically, that an average of 31 evacuations of more than 1000 people are performed each year and that the ICRP model concerning KI uptake does not apply in general to US citizens because the thyroid is already partially blocked.

5. Chernobyl-Most Affected Populations Experience

The assessment indicates that the affected populations for Chernobyl were diagnosed for those living more than 31 miles from the site. For US planning, an appropriate alternative for this population group is interdiction of food stuffs and the emphasis in emergency planning should be in providing for an adequate process to embargo affected areas.

Summary:
The Assessment of the Use of KI is very well done and the Nuclear Regulatory Commission is commended for producing this document. It will be useful to inform local decision makers concerning the background and history of the use of KI in severe reactor accidents.

STATE OF NEW YORK
DEPARTMENT OF HEALTH

II University Place Albany, New York 12203-3399

arbara A. DeBuono, M.D., M.P.H.
Commissioner

Dennis P. Whalen
Executive Deputy Commissioner

September 29, 1998

Aby Mohseni
MS T4A43
Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Mohseni:

Thank you for the opportunity to comment on draft NUREG-1633, "Assessment of the Use of Potassium Iodide as a Public Protective Action During a Severe Reactor Accident" issued on March 30, 1998. In 1997, the New York State Department of Health sought the assistance of its Radiological Health Advisory Committee in reviewing the health aspects of the prophylactic use of potassium iodide (KI) as one of the protective measure options in a severe nuclear power plant emergency. The committee found no health related reasons why KI could not be used for such a purpose and recommended that NY State reexamine its policy which precludes KI use for the public. As a result NY State is in the process of initiating a review to determine if there are logistical and legal reasons for why its current policy should not be changed.

The department had looked forward to NRC's report in the hope that it would assist us in the review. Unfortunately, we find the document to have been prepared to justify a position advocating against the use of KI for public protection, rather than as an objective review of the relevant information. This bias raises doubt as to the value of the document.

Enclosed are general and specific comments on the draft report. No specific comments are made on the Executive Summary since these are covered in the comments on the main report. Please feel free to contact me if you have questions or wish to discuss any of our comments.

Sincerely,

for Karim Rimawi, Ph.D.
Director
Bureau of Environmental Radiation Protection

Enclosure

NEW YORK STATE DEPARTMENT OF HEALTH
COMMENTS ON NRC'S DRAFT NUREG-1633
ASSESSMENT OF THE USE OF POTASSIUM IODIDE AS A PUBLIC PROTECTIVE ACTION DURING A SEVERE REACTOR ACCIDENT

General Comments

1. The report appears to have been prepared to justify a position which opposes the prophylactic use of KI for public protection. It selectively references sources that support that point of view and ignores others that tend to justify the use of KI. More balance is needed in presenting factual information that is relevant to this issue. A more complete presentation of the information will make the document more useful to those states that will be examining whether to use KI for public protection.

2. The document seems to be based on the premise that protective actions will be **either** evacuation of the affected population **or** the use of KI. It does not consider the implications of using KI as a supplement to other measures which is a more appropriate approach, since no one ever advocated KI use to replace evacuation and sheltering.

3. The document limits the discussion to accidents where the acute radiation doses are in the lethal range. The report should include a discussion of the possible role for KI use in accidents where the projected doses are sublethal and where the primary risk is that from doses to the thyroid.

4. The report does not address the health implications associated with the possibility that in the absence of the tablets approved by FDA, a portion of the population will seek alternative sources of KI which are not intended for prophylactic use.

5. While the report claims not to deal with legal issues, it does not refrain from presenting legal arguments for why KI should not be used in the US. It would be more useful to

include a discussion of the types of legal issues that need to be addressed by a state or local government that is considering the use of KI.

Specific Comments

The following are specific comments on the different sections of the main report. The indicated section numbers and titles are those given in the draft NUREG-1633.

I. Introduction

2nd paragraph - The last sentence states that attention to radioiodines "has led to misunderstandings about their radiological significance." The basis for this statement is not clear. Also, it does not specify who misunderstood the radiological significance of radioiodine nor how. The statement should be clarified and justified, or deleted. Many view the added risk to the thyroid from radioiodine to justify additional protection besides measures such as evacuation and sheltering. For example, the US Environmental Protection Agency (EPA) considers the thyroid to be at disproportionately high risk for induction of nodules and cancer, compared to other organs, to warrant developing specific guidance for thyroid exposure as part of EPA's recommended Protective Action Guides (PAG). Is it NRC's position that such protective guides are not warranted?

4th paragraph - This paragraph discusses the criteria and intervention levels that have been developed over the years to aid decision makers in determining the most appropriate protective actions and indicates that such criteria are found in EPA's PAG manual. It goes on to discuss evacuation and sheltering as such measures, but fails to mention that criteria for the prophylactic use of KI are also included in the EPA PAG manual, and that the US Food and Drug Administration (FDA) developed specific criteria for such use. For completeness, FDA and EPA criteria for the use of KI should be added.

5th paragraph and 6th paragraph - The report mounts a strong defense of evacuation as a protective measure. There is no problem with this position. However, it seems the authors view evacuation and use of KI as two mutually exclusive options. We do not believe anyone proposes this position. It is more appropriate for the report to view the use of KI as a protective measure which supplements evacuation and sheltering, rather than supplants them.

7th paragraph - The statement that there is just one pathway in which KI provides thyroid protection appears to be in error. KI would protect the thyroid from radioactive iodine that is either inhaled or ingested. The ingestion may come before contaminated food and water is interdicted, or from any contaminated source that is ingested. Also KI is of potential benefit, though at reduced protection levels, if taken several hours before or a few hours after iodine intake, not only if "administered just before" intake.

8th paragraph - Legal factors associated with the use (or non use) of KI are very important issues in decisions on the role of KI for the general public. While some issues may be state specific, a general discussion of potential legal ramifications would have been appropriate for this report, and helpful for states who will need to consider the issue.

II. Severe Accidents

1st paragraph - The statement that in a large break, loss-of-coolant accident (LB-LOCA) there will be a significant delay before there is a large release of radioactive material into the containment is not accurate. For example, the Surry reactor analysis in NUREG-1150 shows that the core can be uncovered in a LB-LOCA within 5 to 10 minutes. Maybe release to the "environment" rather than into "containment" was intended in this statement.

8th (last) paragraph - We agree that due to uncertainties in predicting the source term in an accident, emergency preparedness must accommodate considerable uncertainty. For this reason, we believe that those responsible for making the preparations for protecting public health need to

avail themselves of all possible options. These options should include the potential use of KI to supplement evacuation and sheltering, unless there are compelling logistical or legal reasons indicating otherwise

III. Health Effects

2nd and 3rd paragraphs - The footnote on page 5 should be moved to this location as both rad and rem are used here. Also, it would be helpful if the radiogenic risk factor is given in the second paragraph.

3rd paragraph - The word "narcosis" of the skin should be replaced with "necrosis".

III. A. Thyroid and Whole Body Doses

2nd paragraph - In this paragraph, the report makes the argument that adverse health effects from the whole body dose are much more severe than the effects to the thyroid. As an example, the report points out that if the thyroid receives an ablation dose, the whole body dose is likely to be fatal. The report fails to address the less severe situations where the whole body dose is well below the lethal dose and where the primary risk to the exposed population is more likely to be due to the radiation dose to the thyroid.

III. B. Doses

1. Whole Body Doses

1st sentence - The basis for this sentence is not clear. Radionuclides that concentrate in a single organ have always been of concern, as in the case of radium ingestion by dial painters in the 30's; early radiation protection criteria have been based on the critical organ concept; EPA PAGs include values for thyroid doses in addition to whole body dose, and current 10 CFR Part 20

regulations include limits for organ doses in addition to the total effective dose equivalent (TEDE).

Last sentence of 1st paragraph, last paragraph and footnote #3 - ICRP-26 and ICRP- 60 concepts and quantities are different. Using ICRP-60's tissue weighing factors to calculate committed dose equivalent (as defined by ICRP-26) is not appropriate. The report should adopt one system or the other, and should not mix the two.

3rd paragraph - The statement that radiation-related carcinogenesis that has been observed to date is "predominantly attributable to irradiation of the whole body" is not correct. While this is the case in the Japanese bomb survivors, it is not true for the many groups studied following medical or occupational exposures where partial body exposure was more the rule than the exception.

The next sentence, (sentence #4 in the same paragraph) is also not correct. Increased thyroid and breast cancer were observed among children irradiated for treatment of tinea capitis in Israel where the average thyroid and breast doses were 9 rad and 1.6 rad, respectively. It appears that this paragraph intends to address external exposure vs. internal, rather than whole body vs. organ irradiation.

III. B. 2. Thyroid Doses

3rd paragraph - This paragraph gives the impression that there is still doubt as to whether radioiodine causes thyroid cancer. The quotation from NCRP-80 that "I-131 has not been shown to be carcinogenic in people", while correct in 1985 when the NCRP report was written, is not correct today. Quoting it in this report is not appropriate since it does not reflect current knowledge. It should be deleted from the report. Also, this paragraph should state that recent evidence has shown that many thyroid cancers observed among children in Europe following the Chernobyl accident are attributable to radioiodine exposure.

III. D. Thyroid Uptake and Thyroid Dose

5th paragraph - The second sentence mentions the ICRP 30 model, however, this is not included in the references.

III E. Risk As a Function of Thyroid Dose

2nd paragraph - Same comment as made on the third paragraph of section III.B.2. Also, the report should give the value of the risk factor for radiogenic thyroid cancer given by NCRP.

III. F. Medical Aspects of Potassium Iodide

This section liberally sites a long list of possible side effects that can be caused by KI and throws doubt at the NCRP's risk estimate of 5×10^{-7} for adverse health effects from 130 mg per day, the relevant KI dose for this discussion. The fact that US FDA found that the risk from the uptake of radioiodine outweighs the risk of side effects from KI in doses of 130 mg per day for adults and 65 mg per day for children below 1 year of age if the projected thyroid dose is 25 rem or greater, should also have been included.

3rd paragraph - The discussion in this paragraph expresses unwarranted doubt as to the findings of the Nauman and Wolff study of adverse effects from use of KI in Poland. The report also contrasts the NCRP's risk estimate with the 0.2% rate of medically significant adverse reactions reported in Poland. The risk of severe adverse effects observed in Poland, 2 cases in 7 million adults and none in 10.5 million children, is of the same order of magnitude as the NCRP's estimate.

- The reference to the 0.2% adverse reactions from KI in Poland is not complete without a description of what those reactions were. From the descriptions given in reference 17, most appear to be relatively minor.

- When severe reactions are considered, there does not appear to be any basis in the report for the last statement in the paragraph that there were serious differences in outcome when KI is given to a general population rather than prescribed individually.

4th and 5th paragraphs - The report should clarify if these warnings are based on experience and testing (or lack of testing) with specific groups and with prescription strength or stronger medications. Since other organizations, knowledgeable of the information on these side effects, such as FDA, WHO, American Thyroid Association, IAEA, NCRP and ICRP, have concluded that these side effects are not of sufficient level to prevent the use of KI in emergencies, NRC staff needs to review the rationale behind these organizations' position and present it in the report.

6th paragraph - The wording here would lead the reader to the conclusion that the wide range of adverse health effects reported were likely due to KI but not verified, and that there is some evidence, but not solid, that other unreported effects occurred. If this is the intent, staff needs to support these statements by giving references to their sources.

7th paragraph - Identifying groups who are at increased risk of reactions to KI is important. Also as important, is the relationship between these reactions and the administered KI dosage. As these reactions can be reduced at the low radiation protection dosages, it is hard to draw the conclusion from the information presented that this is of "sufficient significance" to prevent the general use of KI for public protection.

IV. Emergency Preparedness

5th paragraph - This paragraph gives some situations in which shelter is the appropriate, or only available, protective measure. The report fails to indicate that KI can be used in these situations to supplement the protection provided by the shelter.

8th paragraph - This lists numerous arguments for why KI should not be considered one of the protective measures used in an emergency. The arguments were listed without any discussion of their validity or examination of their implications to emergency planning. For example, one of the arguments for not using KI is that accidents during storms result in a reduction of the overall radiologic hazard. No data were presented to demonstrate that thyroid doses equal to or greater than 25 rem are not possible in an emergency under such conditions. Also, the argument that distribution of KI during seismic or icy conditions is difficult, appears to argue more for giving the public access to KI tablets prior to the emergency, rather than relying on distributing it after the fact or abandoning the idea of its use.

9th paragraph - This appears to imply that the use of KI is appropriate if done as part of the medical evaluation of exposed individuals and states that it is available to the medical community. These are misleading statements. Medical follow up is not likely to occur until days after exposure, when it is too late for KI to be of use. Also, KI is not generally available in the strengths recommended for radiation protection and is not available where needed for use in a timely manner if it is needed.

V. B. Poland Experience

6th paragraph - A description of the "medically significant" reactions should be given.

VI. C. Comparison Between US and International Practice

The relevance of this section to the discussion is not clear. The argument that the public in the US should be denied possible protection because of potential law suits is not valid and should not be advocated by NRC, an agency charged with protecting the public.

VII. Sample Calculations

Table 4: The values of the frequency per year need to be entered in the table. Also, the fraction of noble gas core inventory released in scenarios PSUR-1 and PSUR-4 is indicated to be 10. Should this have read 1?

9th paragraph - It is stated that thyroid dose coefficients were taken from ICRP-60. Should the reference have been ICRP-53?

VIII. Insights and Conclusions -

Reactor Accident Frequencies and Protective Actions

1st paragraph - This paragraph argues that because of planning criteria used in the US, there could be numerous evacuations when there are no actual releases from the reactors. This gives the impression that a member of the public will be placed at undue risk numerous times more than necessary. The paragraph fails to give the projected time period over which these "numerous evacuations" will take place. Accepting the annual frequency of 1.7×10^{-4} given in Section VII for accidents leading to core damage, it is projected that an evacuation may be indicated once every 5900 reactor years. At this frequency, we fail to see the significance of the argument made in the report.

VIII. Benefits and Challenges and International Practices

In this section, as in prior sections, the report reemphasizes the US Pharmacopia Drug Information monograph's statements about situations in which KI is contraindicated. No discussion is given of the data and circumstances leading to these warnings. The report also fails to indicate that the FDA approval of the drug did not exclude its use for pregnant women and children.

OFFICE OF THE GOVERNOR
Georgia Emergency Management Agency

ZELL MILLER
GOVERNOR

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Atlanta, Georgia 30316-0055
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GARY W. McCONNELL
DIRECTOR

September 15, 1998

Mr. David L. Meyer
Chief
Rules Review and Directives Branch
Office of Administration
United States Nuclear Regulatory Commission
Mail Stop T-6 D69
Washington, D.C. 20555-0001

Dear Mr. Meyer:

This letter is in reference to your request for comments on the Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents." (63 Fed. Reg. 38865, July 20, 1998)

It is the position of the Georgia Emergency Management Agency (GEMA) that the pre-distribution and stockpiling of Potassium Iodide (KI) as a protective measure in the event of a severe reactor accident will not significantly reduce the risk to the citizens of Georgia. The extensive planning and preparedness of local and state governments along with a rigorous public awareness program is the surest method to ensure the safety of the general public living near a Nuclear Power Generating facility.

The problems associated with decision making and the logistical distribution of KI to the general public in the event of a severe accident may actually have a negative impact on the primary defensive measure, evacuation. Clearly, the most efficient and effective strategy to protect the public is to remove them from the danger. Any requirement that may delay this evacuation would be considered counterproductive.

KI is well recognized for its ability to protect the Thyroid Gland from exposure to radioactive iodine. As you are surely aware, KI offers no protection for any other organs and provides no protection from whole body dose exposure. Care must be taken to ensure the public is not lulled into a false sense of security that a pill will provide all the protection they may need. Evacuation, again, is the optimum protective measure and is the key to protecting the public.

The use of KI by emergency workers who may be required to remain in an affected area is well recognized. Appropriate levels of KI inventory at the local level is already incorporated into Georgia's plans for distribution to the emergency workers when required.

Extensive planning, coordination, and preparedness has been accomplished across the spectrum from the utilities through the local communities and at the state level. All of these plans and preparations are regularly evaluated by federal authorities to include the Federal Emergency Management Agency (FEMA) and the Nuclear Regulatory Commission. These emergency plans consider every possible tool for protecting the general public and are evaluated then from a benefit point of view. When these plans of the state and local governments are implemented, it is felt by this agency that Potassium Iodide will not offer any significant protection to the population at best, and at worst, may negatively impact on the execution of other important aspects of those emergency plans.

We appreciate the opportunity to provide comments and opinions prior to the consideration for approval of this new regulation. Should any additional information be required please contact Patrick Cochran at (404) 635-7233.

Sincerely,

GARY W. McCONNELL
Director

GWM/cd

DSC9
L. Mahsen

63FR 38865
July 29, 1998

(13)

Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000
Sandra B. Nichols, M.D., Director • Mike Huckabee, Governor

September 16, 1998

Mr. David L. Meyer
Chief, Rules Review and
Directives Branch
Mail Stop T-6 D69
Office of Administration
Unites States Nuclear Regulatory Commission
Washington, D. C. 20555-0001

Subject: Draft NUREG-16333, Assessment of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents.

Dear Mr. Meyer:

The Arkansas Department of Health does not agree with the concept of stockpiling and distributing KI to the general public. The State's primary protective actions in response to an event at a nuclear power plant are "evacuation and sheltering". These actions better ensure the safety of the public and correspond to the "conservative approach" the State takes in response to an event.

If you have require additional information or if you have any questions, please call me at (501) 661-2301.

David D. Shellings, Jr., Director
Division of Radiation Control and
Emergency Management

Texas Department of Health

William R. Archer III, M.D.
Commissioner

1100 West 49th Street
Austin, Texas 78756-3189
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Radiation Control
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Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

September 14, 1998

Mr. Abby Mohseni
Nuclear Regulatory Commission
Mail Stop T-4D18
11545 Rockville Pike
Rockville, Maryland 20852-2738

Dear Mr. Mohseni:

In reply to your request for our policy on the administering of potassium iodide to the general public within the 10-mile planning zones, the Texas Department of Health (TDH) endorses the voluntary use of potassium iodide as a thyroid-blocking agent by emergency workers responding to accidents involving the airborne release of radioactive iodine. Subject to those same precautions and limitations, TDH also endorses the use of potassium iodide by persons in institutions and other persons whose mobility is impaired to the extent that they could not readily be evacuated.

TDH's current policy for potassium iodide is presently being prepared for review by Dr. William Archer III, the Commissioner of Health. Under the current policy, TDH does not recommend the use of potassium iodide by members of the general public, and will neither supply nor administer this product to those persons. Use of potassium iodide for the general public is not an alternative to evacuation. The benefits of potassium iodide can be fully realized only if it is administered just before the inhalation of radioiodine. The use of potassium iodide in conjunction with evacuation could potentially delay evacuation, increasing exposure to the radioactive plume. Instead, TDH recommends that persons in areas affected by an accidental release of radioactive materials follow the advice of local officials and evacuate or seek shelter when instructed to do so.

Sincerely,

for Robert C. Ratliff

Richard A. Ratliff, P.E., Chief
Bureau of Radiation Control

September 15, 1998

Mr. Aby Mohseni
Division of Incident Response
Office for Analysis and Evaluation
of Operational Data
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Mohseni:

Attached please find a copy of the Georgia Emergency Management Agency's comments on the Draft NUREG - 1633. Please consider these comments when consideration for the approval of this draft is made.

We appreciate the opportunity to submit comments and are anxious to be of whatever assistance we can. Should you desire any further input or information please do not hesitate to call. I may be reached at (404) 635-7233 or email at Pcochran@gema.state.ga.us.

Sincerely,

H. Patrick Cochran
Senior Planner

HPC/cad
Enclosure

September 15, 1998

Mr. David L. Meyer
Chief, Rules Review and
Directives Branch
Mail Stop T-6 D69
Office of Administration
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Meyer:

This letter is in reference to your request for comments on the Draft NUREG - 1633, "Assessment

of the Use of Potassium Iodide (KI) As a Protective Action During Severe Reactor Accidents." (63 Fed. Reg. 38865, July 20, 1998)

It is the position of the Georgia Emergency Management Agency that the pre-distribution and stockpiling of Potassium Iodide (KI) as a protective measure in the event of a severe reactor accident will not significantly reduce the risk to the citizens of Georgia. The extensive planning and preparedness of local and state governments along with a rigorous public awareness program is the surest method to ensure the safety of the general public living near a Nuclear Power Generating facility.

The problems associated with decision making and the logistical distribution of KI to the general public in the event of a severe accident may actually have a negative impact on the primary defensive measure, evacuation. Clearly, the most efficient and effective strategy to protect the public is to remove them from the danger. Any requirement that may delay this evacuation would be considered counterproductive.

KI is well recognized for it's ability to protect the Thyroid Gland from exposure to radioactive iodine. As you are surely aware, KI offers no protection for any other organs and provides no protection from whole body dose exposure. Care must be taken to ensure the public is not lulled into a false sense of security that a pill will provide all the protection they may need. Evacuation again is the optimum protective measure and is the key to protecting the public.

The use of KI by emergency workers who may be required to remain in an affected area is well recognized. Appropriate levels of KI inventory at the local level is already incorporated into Georgia's plans for distribution to the emergency workers when required.

Extensive planning, coordination and preparedness has been accomplished across the spectrum from the utilities, through the local communities and at the state level. All of these plans and preparations are regularly evaluated by federal authorities to include the Federal Emergency Management Agency and the Nuclear Regulatory Commission. These emergency plans consider every possible tool for protecting the general public and are evaluated them from a benefit point of view. When these plans of the state and local governments are implemented, it is felt by this agency that Potassium Iodide will not offer any significant protection to the population at best, and at worst, may negatively impact on the execution of other important aspects of those emergency plans.

We appreciate the opportunity to provide comments and opinion prior to the consideration for approval of this new regulation. Should any additional information be required please contact H. Patrick Cochran of this agency at (404) 635-7233.

Sincerely,

Gary W. McConnell
Director

From: "Cowley, Richard" <rrc0303@doh.wa.gov>
To: TWFN_DO.twf2_po(ASM)
Date: Thu, Sep 10, 1998 5:29 PM
Subject: comments on draft KI report

Here are our comments on the draft KI report. They are a compilation of comments from Dr. Kreger, Susan, Anine, and myself. The report provides a lot of useful information that the states and locals should use to evaluate how they should deal with the KI question. As you will see from our comments that we think there are other factors that should be taken into consideration and possibly evaluated in the final report.

If you have any questions regarding our comments please contact either Susan or me (I'll be on vacation from Sept. 17 through Oct. 6).

Thanks again for the opportunity to comment on this report.

This message from...

Dick Cowley
Radiation Protection
7171 Cleanwater Lane, Bldg. 5
Tumwater, WA 98501
mailing address:
PO Box 47827
Olympia, WA 98504-7827
phone: (360) 236-3272
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CC: GATED.nrcsmtp("wek0303@hub.doh.wa.gov")

September 10, 1998

Aby Mohseni
MS T4A43
Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Aby,

The State of Washington appreciates the opportunity to review your draft report on the *"Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Reactor Accidents"* draft Nureg-1633. In this report, the NRC has provided a good deal of useful information for the States and locals to use in determining how they could best utilize KI for protecting the public in the event of an accident at a commercial nuclear power plant.

Washington has a number of concerns and questions regarding this draft report. First, it is our understanding that the NRC has publicly endorsed the policy of the federal government providing KI for the general public to the state and local governments for stockpiling or distributing. However, this report leaves us with the impression that NRC staff does not necessarily support this policy. Many arguments made in the report minimize the efficacy of KI in providing the desired protection.

The report does not appear to consider the advantages of pre-distributing KI to those most likely to be affected by a reactor accident. It is our opinion that pre-distribution to the population at risk could provide those individuals with the most timely opportunity to administer KI (only upon instruction via approved EAS messages and with prior education) while not delaying their evacuation. Washington firmly believes that evacuation, thus avoidance of any exposure, is the best protective action that can be taken but pre-distribution may provide the best protection to those who can only shelter or who must evacuate through the plume. Pre-distribution will create additional logistical and management problems but these need to be weighed against the additional protection provided. The key to the proper and effective use of pre-distributed KI is in educating those who could need it.

We agree with your report regarding not using KI for protection from the ingestion of contaminated foodstuffs. With the availability of food from other sources in the United States, people should not experience any difficulty obtaining uncontaminated food.

We also would like to see your report address the possibility of the use of other, non-prescription forms of iodine available to the public. There are a number of items available in grocery and health food stores that could possibly be used to provide an adequate supply of stable iodine without having to use a prescription drug. Ingesting kelp tablets or powder or even applying betadine to the skin provides iodine to the system. Also, the currently available dosages of pharmaceutical KI are not compatible with the dosages recommended by the World Health Organization. It would be difficult to give infants and children the recommended dosage of KI using the 130mg tablets currently provided to emergency responders.

Your report also mentions possible legal ramifications brought on by the implementation of a protective action such as KI distribution and its potential adverse effects. In today's society, you are in a no-win situation. The failure of a response organization to provide all the protection possible may actually make you even more vulnerable to prosecution than if you were over protective.

Please feel free to call or eMail Susan May or Richard Cowley of the Nuclear Safety Section if you have any questions. We appreciate the NRC's diligence in helping the state and local government resolve this issue.

Sincerely,

Susan May, Supervisor
Nuclear Safety Section

STATE OF MICHIGAN

JOHN ENGLER, Governor

DEPARTMENT OF STATE POLICE

COL. MICHAEL D. ROBINSON, Director

EMERGENCY MANAGEMENT DIVISION

4000 COLLINS ROAD
P.O. BOX 30636
LANSING, MI 48909-8136

August 28, 1998

Mr. Aby Mohseni
Division of Incident Response
Office for Analysis and Evaluation of Operational Data
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Mohseni:

The Michigan State Police, Emergency Management Division (EMD), would like to take this opportunity to comment on draft NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents."

The EMD is the agency in Michigan charged with the overall coordination of emergency planning and response to an accident at a commercial nuclear power plant under Public Act 390, as amended. The EMD assists both state and local government agencies in the development of appropriate plans and procedures for emergency response. This agency also provides training assistance, and coordinates exercises and drills aimed at demonstrating adequacy of plans and procedures to protect public health and safety. All plans were initially reviewed by FEMA for compliance with federal guidance, and are now reviewed annually.

In developing a recommendation to the Governor for his protective action order, the EMD relies on a number of agencies to provide technical support and analysis. These agencies include the Michigan Department of Environmental Quality-Radiation Protection Section, the NRC, the affected utility, and the Technical Support Group in the State Emergency Operations Center.

In our view, NUREG 1633 is a valuable addition to the NRC documents available to the states in developing emergency response plans and implementing procedures. It encapsulates the information and experiences related to the use of KI as a protective measure during a radiological emergency. The state has always considered the issuance of KI during a radiological emergency as a valuable, and appropriate protective measure for emergency workers who may have to enter affected areas, and for institutionalized persons who cannot be evacuated from affected areas. The state has felt, and continues to feel, that the prompt evacuation of the general public from the area around the plant is the most effective protective action. In the development of implementing procedures, the state did consider the issuance of KI to the public as a protective measure, but felt that evacuation and in-place shelter were the most appropriate measures. The State of Michigan recently changed its default protective action procedures, in conjunction with the affected utilities in Michigan, to one that embraces NUREG 0654, Sup 3: default evacuation of all sectors to 2 miles and downwind to 5 miles in affected sectors, unless plant conditions or radiation readings/projections indicate otherwise.

We feel that a new rulemaking by the NRC on the use of KI as a protective measure by the general public is not warranted, as the states have always had the option to issue KI to the public. The information presented in the document does not lead us to a change in state policy at this time. We concur with the comments made by the Michigan Department of Environmental Quality-Radiation Protection Section, regarding the risks associated with the use of KI. The NRC is to be complimented on their analysis of this issue and the comprehensive nature of NUREG 1633.

If you have any questions, please feel free to contact Mr. Daniel Sibo at 517-333-5021.

Sincerely,

Captain Robert C. Tarrant
Deputy State Director of
Emergency Management

cc: Ms. Ellen Karpe, Consumers Energy
Mr. Dennis Loope , AEP
Mr. Kevin Morris, Detroit Edison
Mr. David Minnaar, DEQ

STATE OF DELAWARE
DEPARTMENT OF PUBLIC SAFETY
DELAWARE EMERGENCY MANAGEMENT AGENCY
P.O. BOX 527
DELAWARE CITY, DELAWARE 19706

OFFICE OF THE
DIRECTOR

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MEMORANDUM

TO: Mr. Aby Moseini,
MS T4A43
Incident Response Division
Office of Analysis and Evaluation of Operational Data.
U.S. Nuclear Regulatory Commission
11545 Rockville Pike
Rockville, MD 20852-2738

FROM: Delaware Emergency Management Agency
12 Penns Way
New Castle, DE 19720

SUBJECT: Comments on NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998)

DATE: 14 September 1998

Selected staff members of the Delaware Emergency Management Agency (DEMA) have reviewed the draft publication of NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) as a Protective Action During Severe Reactor Accidents," (63 Fed. Reg. 38865, July 20, 1998). The draft reviews the historical use, technical basis, and domestic and international industry experiences, in the use of KI as a supplemental protective action for the general public.

While the document is to be considered a technical assessment, a reader may misconstrue this document as being a statement of NRC policy. However, the document appears to lean away from the issuance of KI to the general public, in favor of other protective actions such as evacuation and shelter. What may be further confusing is that NUREG 1633 appears to diverge from recent NRC policy pronouncements stating that states should "consider" stockpiling KI as a protective action (Associated Press news article, July 2, 1998).

DEMA concurs with the position taken by the nuclear industry and reiterated in Draft NUREG-1633 that considering the stockpiling or predistribution of KI for issue to the public, as a protective action, will not add any significant public health and safety benefit to the adequate level of protection currently provided by existing emergency planning.

Although the Eastern European experience points out the high number of cases of thyroid cancer occurring after the Chernobyl accident, we concur with the NUREG that the vast majority of these cases could have been prevented by timely evacuation and the quarantine/interdiction of contaminated food and drink. Issuance of KI would not have protected those who were evacuated several hours or days after plume exposure, and certainly would not have protected those who ingested contaminated food and drink.

DEMA shares the NUREG's concern that a policy of issuance of KI to the public as a routine protective measure could conceivably lead to the actual issuance of KI numerous times without any associated exposure to radioiodines. This could happen in a case where there may have been an emergency at a nuclear power plant, but a release offsite did not occur. This could even be counterproductive considering that the safety of KI is not necessarily absolute. In fact, as the NUREG points out, KI is medically contraindicated for various groups of people. It is possible, or even likely, that there are people who are not aware that KI could be harmful to them. In short, the issuance of KI to the general public, without proper medical oversight, could cause more harm than good, especially if the affected public has been already evacuated out of harm's way.

DEMA supports the basic U.S. model for emergency preparedness planning, and subscribes to the premise that evacuation of an area is the most effective response for protecting the public health and safety. Sheltering is also integral to our planning under certain circumstances, but evacuations are mandated for any area where there is any possibility of plume exposure. Where evacuations are performed, we believe that KI issuance to general population evacuees would not add any measure of safety to this proven approach. In comparison with European models and experience, we suggest placing more emphasis in the NUREG on the overall highly successful US experience with evacuations.

In the interest of developing a more balanced assessment, we would suggest more information about the experiences of the US states which now issue KI to the public (Alabama, Tennessee, and Arizona). We would be interested in how effective the program is, are populations theoretically "exposed" to the "plume" during .exercises and simulations, and if so, is the KI administered in time to be effective, what kind of medical oversight is there, etc..

Delaware policy calls for issuance of KI only to emergency workers and certain limited populations. The ingestion of KI by these emergency workers and populations is strictly controlled and monitored Even with these groups, standing operating procedures provide for them to avoid and/or to be removed from health-threatening exposure to radioactive environments.

DEMA staff reviewing the NUREG noticed on page ix and on page 4 statements to the effect that about 50 percent of individuals receiving acute doses greater than about 400 rad die within about 90 days. This is somewhat different from EPA 400 which states that LD 50/60 is 300 rad (i.e. given a 300 rad dose, 50% of a group will die within 60 days).

The staff of DEMA appreciates the opportunity to review the draft of NUREG 1633. The point of contact in DEMA for this subject is Kevin Kille, Nuclear-Biological-Chemical (NBC) Section, (302) 326-6021/6000.

Texas Department of Health

Bureau of Radiation Control

1100 West 49th Street
Austin, Texas 78756-3189

TDH

Date Sent ▸	# of Pages ▸
TO: Mr Alex Mohseni	FROM: John E. Rawlston
COMPANY/AGENCY: NRC	COMPANY/AGENCY: TDH/BRC
DEPARTMENT/DIVISION:	DEPARTMENT/DIVISION: Radiation Control
FAX/TELEPHONE #: 301 415-~~5299~~ 6352 / 301-415-6409	FAX/TELEPHONE #: 512-~~834-6654~~ 832-9715 / 512-834-6688 X-202

Texas Department of Health

William R. Archer III, M.D.
Commissioner

1100 West 49th Street
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Radiation Control
(512) 834-6688

Patti J. Patterson, M.D., M.P.H.
Executive Deputy Commissioner

September 14, 1998

Mr. Abby Mohseni
Nuclear Regulatory Commission
Mail Stop T-4D18
11545 Rockville Pike
Rockville, Maryland 20852-2738

Dear Mr. Mohseni:

In reply to your request for our policy on the administering of potassium iodide to the general public within the 10-mile planning zones, the Texas Department of Health (TDH) endorses the voluntary use of potassium iodide as a thyroid-blocking agent by emergency workers responding to accidents involving the airborne release of radioactive iodine. Subject to those same precautions and limitations, TDH also endorses the use of potassium iodide by persons in institutions and other persons whose mobility is impaired to the extent that they could not readily be evacuated.

TDH's current policy for potassium iodide is presently being prepared for review by Dr. William Archer III, the Commissioner of Health. Under the current policy, TDH does not recommend the use of potassium iodide by members of the general public, and will neither supply nor administer this product to those persons. Use of potassium iodide for the general public is not an alternative to evacuation. The benefits of potassium iodide can be fully realized only if it is administered just before the inhalation of radioiodine. The use of potassium iodide in conjunction with evacuation could potentially delay evacuation, increasing exposure to the radioactive plume. Instead, TDH recommends that persons in areas affected by an accidental release of radioactive materials follow the advice of local officials and evacuate or seek shelter when instructed to do so.

Sincerely,

Richard A. Ratliff, P.E., Chief
Bureau of Radiation Control

MDE

MARYLAND DEPARTMENT OF THE ENVIRONMENT
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Parris N. Glendening
Governor

Jane T. Nishida
Secretary

August 27, 1998

Mr. Aby Mohseni
Division of Incident Response
Office for Analysis and Evaluation of Operational Data
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Mohseni:

I have reviewed the draft report for comment NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Reactor Accidents." The document is a well-researched analysis of past experiences, potential benefits and challenges for the use of KI as an emergency protective measure following a serious nuclear accident.

I concur with the document's "Insights and Conclusions" section, particularly the subsections on the Chernobyl Experience and KI Benefits and Challenges. Dose from direct exposure to radioactive noble gases is a principal concern in the early phases of a nuclear accident. In the early phase, evacuation remains the protective action of choice. KI is an effective supplement when used to protect emergency workers or institutionalized popluations.

Thyroid and other organ doses assume greater importance in the intermediate or late phases of an accident. State and local officials can best prevent accident-induced thyroid cancers and other health effects by appropriately interdicting food and water supplies which may have been contaminated. As the draft NUREG so eloquently states, "given the significant alternative food supplies in the United States, KI would not (and should not) be an option to protect the public from ingesting radioactively contaminated foodstuffs."

I believe that the proposed national-level stockpiles of KI, including the KI stockpiled for the Metropolitan Medical Strike Teams (MMST), would be an appropriate tool for state and local officials to have available when considering KI distribution as part of their emergency plans. Previous NRC documents have demonstrated that pre-distribution (and maintenance) of KI is quite expensive and time-consuming. Should state officials desire to distribute KI, these stockpiles would preclude the kind of "last-minute" attempts to procure KI which occurred during the Three Mile Island accident, and could be deployed rapidly.

Please feel free to contact me at (410) 631-3868, FAX (410) 631-7056 or e-mail msharon@mde.state.md.us if you have any questions or need additional information. Thank you for your continuing support of the Maryland Department of the Environment and radiological emergency preparedness.

Sincerely,

Michael J. Sharon
Chief, Nuclear Power Plant
Emergency Division

To: Mr. Aby Mohseni,
Nuclear Engineering Coordinator,
Office for Analysis and Evaluation of Operational Data,
NRC USA
Fax: + 001-301-415-5392
Number of pages including cover page: 5
Date: 25.09.1998

From: Dr. Elena Buglova,
Head of Laboratory of Radiation Hygiene and Risk Analysis,
Research and Clinical Institute of Radiation Medicine and Endocrinology,
Fax: + 375-172-26-93-60

Dear Mr. Mohseni,

Please, find attached the comments for the NUREG-1633 "Assessment of the Use of Potassium Iodide (KI) as a Public protective Action During Severe Reactor Accidents", that we discussed last week. Hope that you will consider the comments in new version of the document. The file with the comments I will send also to the e-mail address of Mr. T. McKenna. It will be easy to work with the computer file.

Sincerely yours,

Dr. Elena Buglova

Specific comments

1.Page iii, 4 para, 2 line. KI should be added to the types of protective actions considered for use during the early phase of an accident. Discuss the effectiveness of KI for those within 2-3 miles if evacuation is impossible or delayed (e.g., snow) and for those sheltered beyond 3 miles.

2.Page iv, 3 para, 6 line. Change the sentence to the following: "The effects of whole body doses greater than 25 rem can be seen as transient changes in blood chemistry, and dose 100 rem is the threshold for acute radiation sickness.

3.Page iv, last para, last sentence. My understanding is that the frequency of core damage is very low (10^{-4} - 10^{-6}), therefore use word "numerous" describing the number of times of KI would be administered to a general public without any associated exposure to radioiodines is misleading. Therefore this should be revised to clarify that administration of KI based on plant conditions should be a very rare event.

4.Page v, para 3, line 2. Change "all the affected children" to "all the exposed children with thyroid cancer" to make it clear that "affected" means sick but not only exposed.

5.Page vs, para 5, line 1. KI is definitely not "an alternative to evacuation" for areas with a high risk of deterministic health effects (e.g., within 3 miles). However, KI should be used along with sheltering or evacuation. While this section is titled "KI Benefits and Challenges", no "Benefits" of KI are stated. I propose that this section be expanded to discuss the situations for which KI would be beneficial. KI could be beneficial for the area within 3 miles if sufficient planning was performed to allow its use without delaying the evacuation. KI should also be beneficial in areas where evacuation may not be recommended until after a release is detected (e.g., beyond 3 miles in the US system). KI would beneficial in areas where evacuation would be not warranted or possible (for example, timely evacuation of large territories).

6.Page v, para 5, line 2. This sentence is misleading. I propose it be revised to read "KI is most effective in reducing thyroid intake if administered before or shortly after the inhalation of radioiodines." Also add consideration of the benefit of KI in the case of a prolonged release (several days) when the beneficial effect of KI could be seen even if administered a day or more after the start of the release.

7.Page vi, para 2, line 3. I agree that "distribution/ administration of a drug could slow evacuation", therefore we have to organize and test the system of KI administration (e.g, predistribution etc) during the development of emergency preparedness.

8.Page vi, para 4, last sentence. Could you, please add some examples of the mentioned cultural differences and cite your basis/references.

9.Page VI last para. Add: "WHO, based on Chernobyl experience: 1) recommends predistribution of KI pills in the area close to the NPP and stockpiles-in the far areas, 2) considers KI effective for protecting the thyroid from inhalation or ingestion of radioiodines and 3) considers KI safe for use by the public if accompanied with the appropriate instructions."

10. Page 2, para 3, line 6 .The same comment as Comment 6.

11. Page 2 last para, 3 and 4 sentence. There is basic difference between emergency preparedness and response. Possibly, it will be not necessary to administer

KI blocking but we have to be prepared to do so. These sentences present only one set of accident circumstances as being important. That is core melt with early containment failure. However, if the core is melted, the failure of the containment (e.g. release) could not be predicted and there are a wide range of release amounts and timing with similar probability. Some of these releases could warrant taking KI more than 10-20 miles from the NPP to protect the public from inhalation. This spectrum of possible accident scenarios should be recognized and the usefulness of KI discussed for the full spectrum.

12. Page 4, para 4, last line. It is absolutely wrong that "stochastic effects are not discernable from doses of 10 rem or less". Classical knowledge and published data on thyroid cancer incidence in Belarus after the Chernobyl accident (e.g., Table 1 in your Report) contradict this statement.

13.Page 5, para 2, last 2 sentences. To change "50 miles and even more".

14.Page 6, para 5 line 2. Change as the following: "doses to the thyroid of as little as 500 rad" (See Safety Series No 109 IAEA, p.36).

15.Page 11, para 2, last sentences. It seems to me that this gives the wrong impression concerning the Polish experience. You should clearly state that based on published data, the Polish officials found KI blocking to be a safe and effective measure. In addition, it is not clear for me for what reason you have used an expression "to the extent that we believe the report." The Polish data was discussed and published widely, there is no point to use such an expression.

16.Page 12, para 5, line 5. To change as follow: "will be directed to go indoors and use KI". To my mind, you should discuss the benefits, effectiveness and problems of sheltering and evacuation in comparison with KI. If you want to give a decision-maker a chance to decide about the necessity of KI blocking, you must provide a comparison of the effect of different protective actions for different accident situations. For example, sheltering can decrease inhalation dose for thyroid on 50 % or even less while KI can provide 95% protection from inhalation. In addition, evacuation of large areas (prolonged release, change of wind speed) can be difficult or even impossible.

17.Page 17, para 1, last sentence. Change as follows: Information about thyroid dose reconstruction in Belarus could be found in REFERENCE – Drozdovitch V., et al. Thyroid dose reconstruction for the population of Belarus after the Chernobyl accident. Radiat. Environ.Biophys (1997) 36:17-23.

18. Page 13, para 3, last sentences. I disagree with the word "limited" concerning the benefit of KI. My previous comments and experience as a physician prove that the benefit could be real and important. If we had given KI promptly during Chernobyl it could have prevent numerous thyroid cancers and human suffering. If there were a major ground level release in the US, prompt use of KI could also prevent considerable suffering. This is not a "limited" benefit.

19.Page 13, para 4, line 3. There could be situations where people in the centers should be protected by taking KI (e.g, large prolonged release, change of wind, etc.).

20.Page 14, para 1, line 4. Revise percent of radioiodine released to be 50-60%.

21.Page 15, after Fig. 3, line 8. Change as follows: "...relationship between the increases and exposure from the Chernobyl accident...".

22.Page 15, after Fig 3, line 9. Change as follows: "...not seem to have been the significant reason for...".

23.Page 16, para 1. Reference (19). Change for the following: (Kenigsberg J., Buglova E. Assessment of the thyroid protection efficiency for Belarusian children after the Chernobyl accident. / Proceedings of the International Congress on Radiation Protection. -Austria: Vienna, - 1996. - P. 245-246).

24.Page 16 para 3, last line. Reference (19) change for the following (Buglova E. et al. Reactor accidents and thyroid cancer risk: use of the Chernobyl experience for emergency response. Proceeding of the International Symposium on Radiation and Thyroid Cancer. 1998).

25.Page 16, last para. Change the numbers of prognosed thyroid cancer cases as follows: exposed at age 0-6 years – 3500 cases during life, all exposed population – more than 6000 cases during life (***Reference*** 21 and Buglova E. et al. Reactor accidents and thyroid cancer risk: use of the Chernobyl experience for emergency response. Proceeding of the International Symposium on Radiation and Thyroid Cancer. 1998).DELETE references 18 and 19.

The number of cases as a function of distance from NPP (Fig 5) is for persons exposed in age 0-18 (0-18 years old in 1986) (REFERENCE - Buglova E. et al. Reactor accidents and thyroid cancer risk: use of the Chernobyl experience for emergency response. Proceeding of the International Symposium on Radiation and Thyroid Cancer. 1998).

26.Page 17, para 2, line 4: 3 (three) children died because of thyroid cancer. Also add that: Based on the Chernobyl experience, Belarus implemented a system to provide KI to the inhabitants in the event of an accident at the Ignalina Nuclear NPP that is located in Lithuania .

27.Page 18 last para , 2 sentences. Based on Prof. Naumann presentations, discussions and publications, "medically significant reactions" means that the reactions were registered or reported but were not important medically. This section gives wrong impression and should be changed.

28.Page 20. Revise Table 2 and Appendix 1 to reflect the following practice in Belarus (REFERENCE - Buglova E. et al. Reactor accidents and thyroid cancer risk: use of the Chernobyl experience for emergency response. Proceeding of the International Symposium on Radiation and Thyroid Cancer. 1998).

> Following the Chernobyl accident, Belarus implemented a system to protect the thyroid of the inhabitants in the event of an accident at the Ignalina Nuclear NPP that is located in Lithuania. Stable iodine has been distribution in advance to the more than 20,000 Belarussians living within 30-km of Ignalina. Tablets of stable iodine, along with instruction on their use, are located in the family first-aid sets and additional stocks of the tablets are in local medical services. Local medical services have specially prepared staff and transport to distribute additional tablets of stable iodine when necessary. This combination of predistribution of stable iodine to households and additional support by local medical services should ensure that the first dose of stable iodine could be taken by those within 30 km during the first hours after the decision to perform iodine prophylaxis. The decision is made by the head of medical service at the district level based on gamma dose rate criterion. Beyond 30 km, thyroid-blocking tablets are not predistributed; however, there

are centralized stocks of stable iodine in medical services and pharmacies. After the decision about thyroid blocking the distribution of the tablets will be performed through the medical system. Efficacy of this system was tested during emergency response exercises conducted in the areas of Belarus within the 30-km zone of Ignalina. The results of the exercises showed that within 3-6 hours of a decision to take stable iodine was made, iodine prophylaxis was performed for 95% of the population.

29.Page 22, para 5 (point 2). In my opinion, it is a necessity to make provisions to provide KI during an accident. Your paper should consider possible ways to solve legal questions if these questions would prevent the necessary preparations. For example, laws similar to those used to protect vaccination drug companies could be considered.

General Comments.

The necessity to give stable KI during early phase of the reactor accident is recognized by many different countries as well as by international organization (IAEA, WHO). This is based on the evident risk of thyroid cancers after inhalation exposure, low probability of side effects and positive cost-benefit analysis generally.

Stable KI protects the thyroid from inhalation of radioiodines thus could significantly reduce human suffering if there were given during an accident as part of an overall program of protective action. In the case of severe accident high thyroid doses from inhalation are possible at great distances from NPP (in particular after ground level release).

The probability of high thyroid doses from inhalation exists not only near, but also far from the plant. It appears the people within 3-10 miles and beyond do not evacuate until after a release and therefore most likely will be exposed to radioiodine. The people within 3 miles may not be able to evacuate before the release arrives. In each of these cases KI could be beneficial. The paper should discuss all these situations so that decision-makers can develop a full understanding of the issues.

F. Conzel AVM.
F/I
→ Copy to Alwy
Letter to Frau I

Klinik und Poliklinik für Nuklearmedizin
der Universität Würzburg
Direktor: Prof. Dr. Chr. Reiners

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Würzburg, 08.09.98
Rei-dk

Peter G. Crane
4809 Drummond Avenue

Chevy Chase, MD 20815, USA

by Fax No. 001/301-415-3200

Dear Mr. Crane,

we met on the occasion of the International Seminar on Radiation and Thyroid Cancer in July in Cambridge. You asked me for the recommendations of the German Commission on Radiological Protection on Iodine blockade of the thyroid in the event of a nuclear accident.

Enclosed I send you a copy.

Yours sincerely

Prof. Dr. Chr. Reiners

Encl.

Iodine blockade of the thyroid in the event of a nuclear accident

Recommendation of the German Commission on Radiological Protection (SSK)
passed in the 136th session of the Commission on Radiological Protection on 22/23 February 1998

1. Recommendation

The Commission on Radiological Protection recommends to adopt the 1989 recommendations of the World Health Organization (WHO) [1] on iodine blockade of the thyroid. These contain the following changes as compared to the 1981 recommendations currently in force in the Federal Republic of Germany [2]:

- Reduction of the iodine dose, which is administered as one single intake per day according to the following dosage pattern:

Age group	Dose per day (mg iodine)
<1 month	12.5
1 - 36 months	25
3 - 12 years	50
13 - 45 years	100
>45 years	0

- Pregnant and breast-feeding women receive the same dose as adolescents and adults. For newborn children the intake should be restricted to one day, for pregnant and breast-feeding women to two days.

  In the Federal Republic of Germany, a region deficient in iodine, an iodine blockade is not recommended for persons over the age of forty-five, because of the increased risk of iodine blockade side effects due to metabolic disturbances in the thyroid (functional autonomy) which become more frequent with advancing age and because of the steeply decreased risk of radiation-induced thyroid carcinoma at an advanced age.

- Assessment of the following secondary thyroid doses as intervention levels:

Age group	Organ dose
0 - 12 years, pregnant women	50 mSv
13 - 45 years	250 mSv

Iodine tablets should be stocked in amounts sufficient to supply at least all children up to the age of twelve and pregnant women.

2. Justification

2.1 Current knowledge on iodine release

The reassessment of the consequences of the Chernobyl reactor accident gives rise to reconsider the recommendations on preventing the absorption of radioactive iodine into the thyroid from taking, due to the administration of iodine tablets.

The Chernobyl experience has demonstrated that following a reactor accident, airborne radioactive iodine may, in certain circumstances, be transported in the atmosphere over several hundred kilometres. While the population can effectively protect themselves against the intake of radioiodine with food by refraining from eating fresh vegetables and drinking milk, the prevention of an intake of radioiodine with respiratory air is considerably more difficult. Although remaining indoors after a reactor accident does offer some degree of protection, nevertheless, it may become necessary to initiate additional protective measures (such as taking iodine tablets).

2.2 The effect of iodine blockade

"Iodine blockade" involving doses in the range of 100 mg of iodide and more reduces the absorption of radioactive iodine into the thyroid by a factor of 90 and more - provided that the tablets are taken in good time [3]. If possible, iodine tablets should be taken before radioactive iodine is absorbed. A satisfactory blockade can still be achieved, if radioactive iodine was absorbed less than two hours ago. Even a few hours after the uptake of radioactive iodine its residence time in the body is reduced by iodine tablets. However, the first application should not be later than one day after the uptake of radioactive iodine, since otherwise the excretion of the latter will be delayed [4].

Radioiodine may cause both stochastic and deterministic effects in the thyroid. Whereas no dose thresholds can be established for stochastic effects (occurrence of thyroid cancer), experience shows that deterministic effects (thyroiditis, hypothyrosis) occur rarely below an organ dose of 10 Gy. However, it must be expected that in the immediate vicinity of nuclear reactors serious accidents can result in incorporations of considerable radioiodine activities, which may cause thyroid doses of several Gy.

2.3 Previous recommendations for the Federal Republic of Germany

The Federal Republic of Germany was one of those states giving recommendations on the iodine blockade of the thyroid in the event of nuclear emergencies very early - in 1975 (published 1977 in [5]). According to the "intervention levels for sheltering, administration of stable iodine and evacuation" [2], the lower intervention level for taking iodine tablets is 200 mSv, the upper 1000 mSv. These lower and upper intervention levels are by a factor of 4 higher than those recommended by WHO [1]. This is justified on the grounds that most parts of the Federal Republic of Germany are iodine-deficient areas and that the administration of iodine tablets involves an increased risk of undesired side effects.

The „iodine information sheets" (Jodmerkblätter) [2] provide the following dosage plan (the figures apply to tablets of 100 mg potassium iodide corresponding to approximately 80 mg iodide):

Adults, including pregnant women: initial dose of two tablets of 100 mg potassium iodide each, thereafter one tablet approximately every eight hours up to a total of ten tablets within three to four days.

Children (up to a weight of 40 kg): initial dose of one tablet, thereafter ½ tablet every eight hours up to a total of five tablets.

Toddlers and infants (up to a weight of 20 kg): ½ tablet per day up to a total of two tablets.

2.4 1989 WHO recommendations

As mentioned above, the WHO intervention levels [1] are lower by a factor of 4 (lower intervention level at 50 mSv, upper intervention level at 250 mSv) than the corresponding intervention levels in the Federal Republic of Germany. The dosage recommendations also differ (the WHO relates its dosage figures to tablets of 100 mg iodide corresponding to 130 mg potassium iodide):

Adults, pregnant women and young people over the age of twelve: one tablet daily.

Children aged between three and twelve: ½ tablet daily.

Small children aged between one month and three years: ¼ tablet daily.

Infants *up to the age of one month: $^1/_8$ tablet daily.*

The WHO recommends that the total dose for pregnant and breast-feeding women and new-born children should be restricted: new-born children should receive no more than 1 x 2.5 mg of iodide, pregnant women a maximum of 2 x 100 mg. This means that in the event of an accident involving continuous release or absorption, these risk groups must be evacuated from the affected regions within one to two days at the most.

2.5 Adjustment of the German iodine blockade recommendations to the international iodine blockade recommendations

There are several reasons to harmonize the German and international recommendations. One reason is that it is very difficult for the population to understand why, after a reactor accident in a neighbouring country, the local population receives iodide tablets whereas, due to higher intervention levels in Germany, the German population which might be living at a distance of only a few kilometres does not. However, the most important argument in favour of changing the German intervention levels derives from experiences following the Chernobyl reactor accident: it was found that the frequency of thyroid cancer in children increased significantly, even in areas of Belarus and

Ukraine lying in a distance of several hundred kilometres. Follow-up examinations in the A-bomb survivors of Hiroshima and Nagasaki revealed that the additional relative risk of thyroid cancer following radiation exposure is age-dependent and, at 6.4 per Gy for 0 to four-year-olds, 3.7 per Gy for five- to nine-year-olds and 2.1 per Gy for ten- to nineteen-year-olds, distinctly increased for children and adolescents, whereas there is only a minimal increase for older persons, at 0.7 per Gy in the case of twenty- to twenty-nine-year-olds, 0.9 per Gy in the case of thirty- to thirty-nine-year-olds and 0.0 per Gy in the case of the over forty-fives [8]. But it had not been anticipated that considerable incorporations of radioiodine and a resulting increase in the frequency of cancer in children can occur in areas far removed from the location of an accident [4].

These experiences justify the recommendations of the German Commission on Radiological Protection (SSK) to adjust the German intervention levels to the international recommendations and to plan appropriate organizational measures in areas remote from nuclear reactors.

2.6 Determination of an upper limit of age for the iodine blockade of the thyroid

The Federal Republic of Germany is an iodine-deficient region, where, according to recent studies, a previously postulated south-north gradient involving a distinctly inadequate supply of iodine in the south and an adequate supply of iodine in the north is at most of minor significance. According to studies conducted on adolescent schoolchildren in the age of puberty, the frequency of a goitre from iodine-deficiency among this age group is between 40% and 60% [7]. While the administration of high iodine doses in the order of 1000 times the daily iodine-intake with food for younger people is relatively uncritical, it may lead to considerable complications in the case of older people with long-standing iodine-deficiency goitres for many years. In long-standing iodine-deficiency goitres, a disturbance of the iodine metabolism of the thyroid, termed "functional autonomy", frequently occurs. Postulating that the frequency of iodine-deficiency goitres among citizens of the Federal Republic of Germany between the ages of forty and fifty is approximately 20% to 30%, and taking into account recent studies on the frequency of functional autonomy, it can be assumed that about 10% of the citizens of the Federal Republic of Germany between forty and fifty have such a disturbance of the iodine metabolism of the thyroid [8]. In such persons an iodine blockade may cause a serious and barely controllable development of hyperthyroidism. Since this risk is higher than the low, virtually non-existent risk of radiation-induced thyroid carcinoma, persons who are older than approximately forty-five years should be excluded from iodine blockade of the thyroid [3].

However, this recommendation accepts that in the event of an accidental release, unprotected persons over forty-five years staying in the vicinity of nuclear reactors may suffer deterministic radiation damage. This involves relatively harmless disorders, such as temporary thyroiditis and hypothyrosis easy to correct by medication. Given the additional fact that the number of people living in the vicinity of a nuclear reactor assumed to be affected, is far lower than the older population living in a remote area, it is recommended that iodine blockade should generally not be administered on over forty-fives.

2.7 Bibliography

[1] Iodmerkblätter. Gemeinsames Ministerialblatt no. 13, 1981, pp. 191-195.

[2] Schicha, H.: Iodblockade der Schilddrüse, in: Medizinische Massnahmen bei Strahlenunfällen. Veröffentlichungen der Strahlenschutzkommission, volume 27, published by the Federal Minister for the Environment, Nature Conservation and Nuclear Safety. Gustav Fischer Verlag, Stuttgart-Jena-New York, 1994, pp. 187-205.

[3] Reiners, Chr.: Prophylaxe strahleninduzierter Schilddrüsenkarzinome bei Kindern nach der Reaktorkatastrophe von Tschernobyl. NuklearMedizin 33 (1994), pp. 229-234.

[4] Iodmerkblätter. Gemeinsames Ministerialblatt no. 5, 1989, pp. 91-94.

[5] World Health Organization (WHO): Guidelines for Iodine Prophylaxis following Nuclear Accidents. Published on behalf of the WHO Regional Office for Europe by FADL, Copenhagen, 1989.

[6] Akiba, S., Lubin, J., Ezaki, J. et al: Thyroid cancer incidence among atomic bomb survivors in Hiroshima and Nagasaki 1958-1979, in: Technical Report, TR 5-91 Radiation Effect Research Foundation, Hiroshima, 1991.

[7] Gutekunst, R., Smolarek, H., Hasenpusch, U., Stubbe, C., Friedrich, H-J., Wood, W.G., Scriba, PC.: Goitre Epidemiology: Thyroid volume, Iodine excretion, Thyroglobulin and Thyrotrophin in Germany and Sweden. Acta Endocrinol 112 (1986), pp. 494-501.

[8] Bähre, M., Hilgers, R., Lindemann, C., Emrich, D.: Thyroid autonomy: Sensitive detection in vivo and estimation of its functional relevance using quantified high resolution scintigraphy. Acta Endocrinol 117 (1988), pp. 145-153.

September 28, 1998

Mr. Aby S. Mohseni **BY FAX**
Division of Incident Response
Office for Analysis and Evaluation of Operational Data
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Mohseni,

Thank you for the opportunity to comment on draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents." I apologize for not meeting the comment deadline.

My comments are quite simple. I believe that a key factor that must be considered by medical officials contemplating the administration of potassium iodide (KI) as a protective measure for a severe reactor accident is the potential benefit provided by the KI. Recent research (see "Thyroid Cancer after Diagnostic Administration of I-131," Per Hall, Anders Mattson and John D. Boice, Radiation Research, Vol. 145, pp 86-92, 1996) indicates that thyroid cancer due to exposure to I-131 has **NOT** been convincingly demonstrated in adults. While epidemiological studies of the aftermath of the Chernobyl accident in the Ukraine do indicate statistically significant increases in thyroid cancers in children, there is no evidence of an increase in adults. Since the emergency planning situation in the US is completely different than that in the former Soviet Union, one cannot extrapolate findings from the Ukraine to the US. In the US, we require early precautionary evacuations of schools thereby reducing the risk of childhood thyroid cancers before there is even a risk of exposure. Moreover, the cited research paper showed that for adults, the risk was not elevated even at a thyroid dose of 1.1 Gy (110 rad) which is significantly greater than the criterion at which we would recommend evacuation of the general population.

The treatment of I-131 induction of thyroid cancer in NUREG-1633 is excellent. However, in Section III.B.2, addition of a summary statement from Hall, Mattson and Boice appears advisable. That summary could be: "Recent research indicates that thyroid cancer due to exposure to I-131 has not been convincingly demonstrated in adults." Reference to: "Thyroid Cancer after Diagnostic Administration of I-131," Per Hall, Anders Mattson and John D. Boice, Radiation Research, Vol. 145, pp 86-92, 1996. The discussion in Section V is again thorough but does not sufficiently stress that there is no likely benefit to KI administration to adults. With little or no benefit for adults and early evacuation of children, there is little need for consideration of KI as a protective measure in US emergency planning.

Again, thank you for the opportunity to provide comments.

Eric M. Goldin, Ph.D.
Certified Health Physicist
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Oceanside, CA 92056

HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

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October 9, 1998

Dr. Frank J. Congel, Director
Incident Response Division
Office for Analysis and Evaluation of Operational Data
U. S. Nuclear Regulatory Commission
TWFN 4-D-28
Washington, DC 20555-0001

RE: DRAFT REPORT FOR COMMENT ENTITLED "ASSESSMENT OF THE USE OF POTASSIUM IODIDE (KI AS A PUBLIC PROTECTIVE ACTION DURING SEVERE REACTOR ACCIDENTS" (NUREG-1633)

Dear Dr. Congel:

I appreciate the opportunity to comment on the referenced report. I offer these comments as a Certified Health Physicist currently serving as President of the Health Physics Society. As an Instructor of Environmental Science and Engineering, Department of Environmental Health, Harvard School of Public Health, I have served as the course director for approximately ten continuing professional education courses over the last five years on the subject of nuclear emergency planning and dose projections from accidental releases of radioactivity. I believe this makes me qualified to provide the following comments which have been developed with the assistance of other members of the Health Physics Society.

My interest in the national policy for administration of KI to the general public in the event of a severe reactor accident rests in the Health Physics Society's objective of protection of people and the environment from unnecessary exposure to radiation and its concern for controlling the risks from radiation exposure relative to the benefits derived from the activities that produce the exposures.

In developing the following comments, I, and the other members of the Society assisting in their development, have reviewed the Commission's June 26, 1998, memorandum, the March 31, 1998, NRC staff position, and the referenced document.

Regarding the general topic of administration of KI to the general public as a thyroid protection measure, I consider that evacuation and in-place sheltering provide adequate protection for the general public during the early phases of a severe accident at a nuclear power plant and that relocation and food and water controls provide adequate protection for the general public in later phases of recovery from such an accident.

Regarding comments to the referenced document, I have concluded this document provides a comprehensive and technically sound assessment of the various scientific and technical issues related to the petition. However, I do offer the following two comments for your consideration. First, I feel the report should have an introductory section explaining the thyroid's function, the type of thyroid diseases that occur and their prevalence in the U.S. population, treatments for thyroid diseases and their success rates, and the health implications of contracting a thyroid disease. Secondly, I feel the report should include a discussion of the experience in the U.S. of the two states, Alabama and Tennessee, that did stockpile and pre-distribute KI at one time.

I hope you find these comments helpful in this matter.

Sincerely,

Keith H. Dinger, CHP

63FR 38865
July 20, 1998

(21)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

0509
A. Mohseni

OFFICE OF
AIR AND RADIATION

October 1, 1998

SUBJECT: Comments on "Assessment of the Use of Potassium Iodide (KI) as a Public Protective Action During Severe Reactor Accidents," U.S. Nuclear Regulatory Commission, NUREG-1633

FROM: Timothy Margulies
Environmental / Nuclear Engineer
Center for Risk Modeling and Emergency Response

TO: W. Craig Conklin, Director
Center for Risk Modeling and Emergency Response

Jerome S. Puskin, Team Leader
Risk Modeling Section
Center for Risk Modeling and Emergency Response

After review of the subject document the following comments and analyses are summarized.

- The report's assessment scope pertains only to the 10-mile plume exposure pathway planning zone even though severe radioactive releases from nuclear accidents would cause thyroid nodules and cancers at significantly greater distances. The health physics protection goals of minimizing time in the contaminated areas, increasing the distance, in addition to maximizing shielding and minimizing unfiltered toxic air intake should be emphasized.

- The report presents calculations with representative severe accident source terms for radiological modeling of consequences off-site. Table 1 compares estimates of large releases from the Reactor Safety Study, the Siting Source Term (SST-1) used in the safety goal sensitivity studies, the US NRC NUREG-1150 updated and expanded reactor safety study, and Chernobyl accident. Large amounts of iodines and non-iodine particulates and noble gases are expected to directly enter the atmospheric pathway.

- The discussion of emergency preparedness alternatives did not consider other protective measures such as filtering by masks to provide substantial dose savings from radioactive iodine as well as other harmful radioactive particulates. Furthermore, it is noted that Karl Z. Morgan had proposed engineering a release of non-radioactive iodine to compete with any radioactive iodine source during an accident to modify the pathway distributions and reduce human receptor uptake.

- The benefits, risks, and costs of chemical prophylaxes to the populations of pets such as dogs and cats and farm animals in the event of severe nuclear accidents were neglected.

- The historical overview did not discuss the role of the Food and Drug Administration during the Three Mile Island nuclear power plant accident in manufacturing and stockpiling potassium iodide.

- An independent set of radiological dose and risk calculations were made for the Calvert Cliffs nuclear plant to estimate potential impacts and resources for emergency preparedness or for design improvements .

The two power generating units reside approximately 35 miles south of Annapolis, Maryland each supplying 845 mega-watts. Unit I began operating in 1975 and Unit II in 1977; hence, their licenses given by the U.S. Nuclear Regulatory Commission permitting them to operate expire in the years 2014 and 2016, respectively.

The dominant safety issues addressed concern severe accident scenarios such as a station black-out or containment bypass (Event V), each with approximately a one chance per one-hundred thousand likelihood of occurrence. Station black-out refers to the conditions that the alternating electrical supply onsite and offsite are unavailable for running cooling pumps and safety systems. Event V pertains to an "Achilles heel" of the containment where check valve (V) failures would release coolant and radioactivity directly to the environment outside containment.

The transport calculations sample meteorological conditions, and include wind direction probabilities while simulating radiological exposures to over three million people within fifty miles of the plants and extending to people within 350 miles using the MACCS (MELCOR Accident Consequence Code System). Refer to the bar chart showing the population distributed at various distances surrounding the site.

Thyroid and whole body doses versus distance are provided in addition to estimates of thyroid nodule incidences and person-rem accumulated in each distance interval. RSUR-1, RSUR-2, and RSUR-4 source terms were scaled to the equilibrium inventory of radioactivity in the reactor core at the plant for the accident consequence simulation. The results indicate that most of the stochastic health effects occur beyond the first ten mile (interval 2) planning zone. The annual levelized expected cost results for various interest rates for a unit are provided in the attached figures. The costs in the following figures represent potential maximum expenditures to improve the safe operation over the remaining lives of the plants and to prevent undue risk to the

public from the consequences of reactor fuel damage accidents. Improvements such as masks worn by the public, instrumentation and monitoring to minimize a bypass scenario, and supplemental filtering and scrubbing to the present containments are considered viable based on these analyses. Allocations of resources to emergency preparedness measures such as stockpiling potassium iodide for thyroid protection would not have the additional protection benefits of reducing substantial non-inhalation pathway contributions of severe accident radioactivity releases to offsite whole body doses, as well as, protecting land from contamination.

Table 1:

Severe Reactor Accident
Radioactive Releases (Percentages Of Core Inventory)
Table I: Radioactive Releases (% Core Inventory)

	SST - 1	PWR / BWR RSS	V (Surry Nureg-1150)	Cherno-byl
Xe , Kr	100	90 / 100	80 - 100	100
I , Br	45	70 / 40	25 - 70	20
Cs , Rb	67	40 / 40	20 - 70	13
Te	64	40 / 70	12 - 46	15
Ba , Sr	7	5 / 5	3 - 20	4 - 5.6
Ru	5	40 / 50	.5 - 3	3.9
La	.9	.3 / .5	.15 - 1	

SST - 1: Siting Source Term 1 (NUREG-0773); RSS: Reactor Safety Study (Wash- 1400); V (Event V Containment bypass); NUREG-1150 Mean - 95 percentile Ranges shown ; Chernobyl: Accident Release Estimates (DOE; 1987)

References:

1. "Ways of Reducing Radiation Exposure in a Future Nuclear Economy," by Karl Z. Morgan, in Nuclear Power Safety, edited by J Rust and L. Weaver, Pergamon Press, 1976.

2. "Calculation of Potential Radiological Effects From An Accidental Release At The Three Mile Island Nuclear Generating Station," T. Margulies, L.C. Kohlenstein, Johns Hopkins University Applied Physics Laboratory Report CPE 7902, April 3, 1979.

3. "Projected Dose Probability Distributions From Hypothetical Accidental Releases At the Calvert Cliffs Nuclear Power Plant," T. Margulies, T. Eagles, Johns Hopkins University Applied Physics Laboratory Report PPSEE T-15, October, 1979.

4. "Variability of Site Reactor Risk," T. Margulies and R. M. Blond, In Risk Analysis:An International Journal, Vol. 4, No. 2, p. 89, 1984.

5. "Dose Calculations For Severe LWR Accident Scenarios," T. Margulies, J. Martin Jr.,Nuclear Regulatory Commission report, NUREG-1062, May, 1984.

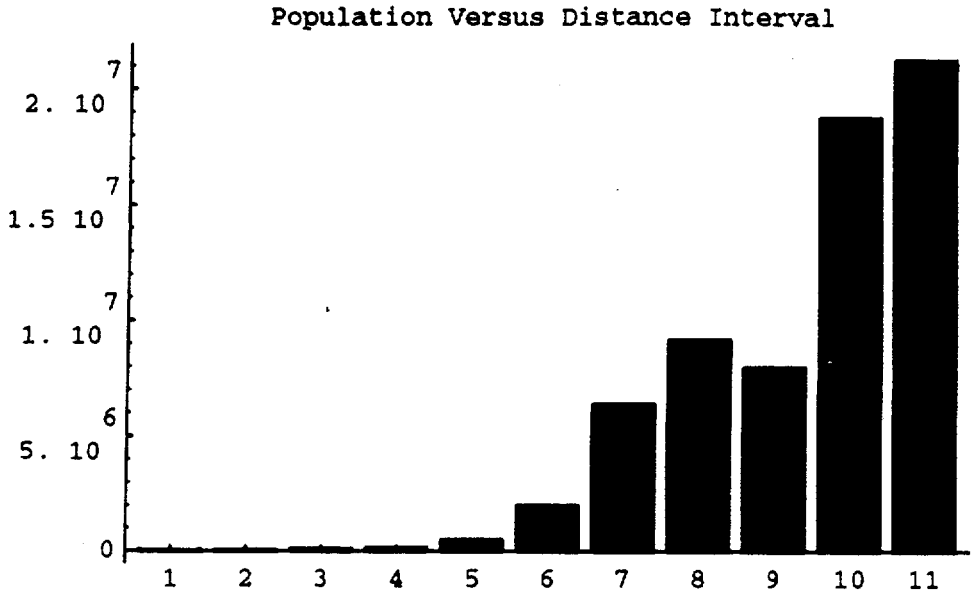
6. "Precalculated Doses for Emergency Response," T. Margulies, J.A. Martin, Jr., R.M. Blond, and T.W. Eagles, Proceedings of Fifth International Meeting On Thermal Nuclear Reactor Safety," Karlsrhue, Germany, September, 1984.

7. "The Development of Severe Reactor Accident Source Terms: 1957 -1981," T. Margulies, R.M. Blond, M. Taylor,, M. Cunningham, P. Baronowski, Cybulskis, and R. Denning, U.S. Nuclear Regulatory Commission report, NUREG-0773, November, 1992.

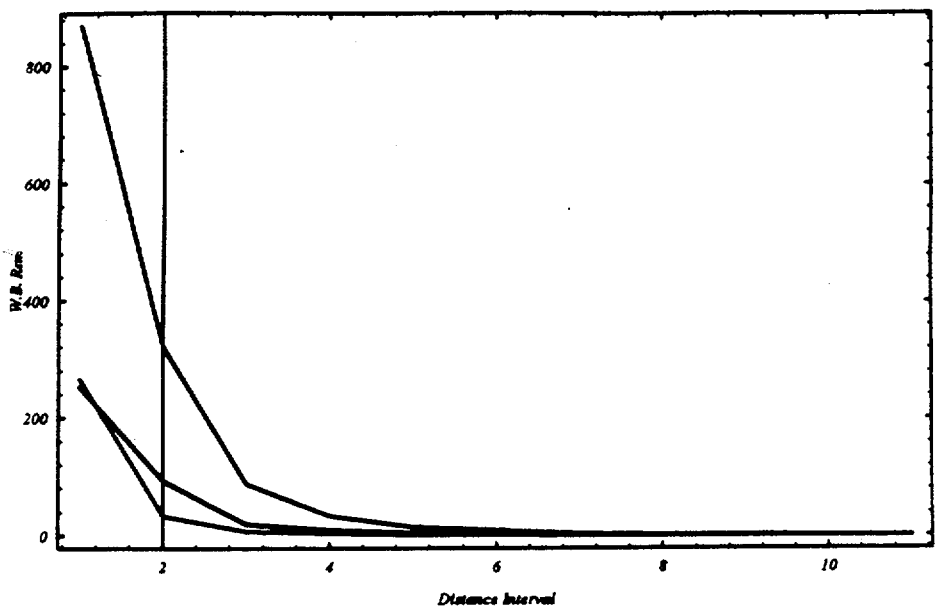
8. "Safety Goal Evaluation: Sensitivity Studies," T. Margulies, R.M. Blond and R.P. Burke, "International Meeting of Probabilistic Safety Assessment," San Francisco, California, February 24 - March 1, 1985.

9. "Nuclear Power Hazard and Economic Risk Analysis," T. Margulies, Safety and Engineering Risk Analysis, American Society of Mechanical Engineers, Winter Meeting, November 1997, H01101, Dallas,Texas.

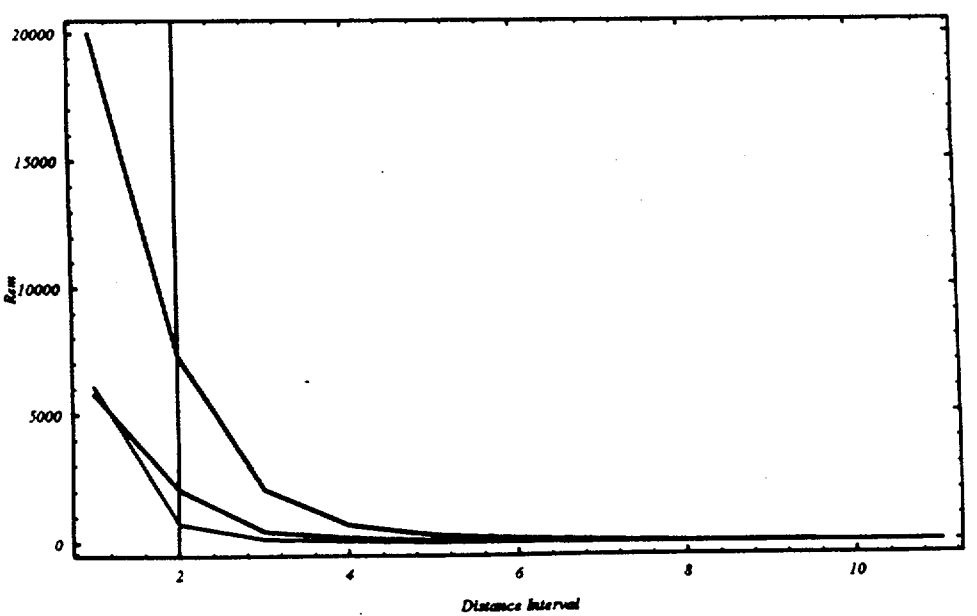
10. "Cost-Benefit Risk Analyses: Radioactive Waste Systems for Light Water Reactors," T. Margulies, U.S. Environmental Protection Agency, Draft 1998.


Population Versus Distance Interval
2. 10^7
1.5 10^7
1. 10^7
5. 10^6
0
1
2
3
4
5
6
7
8
9
10
11

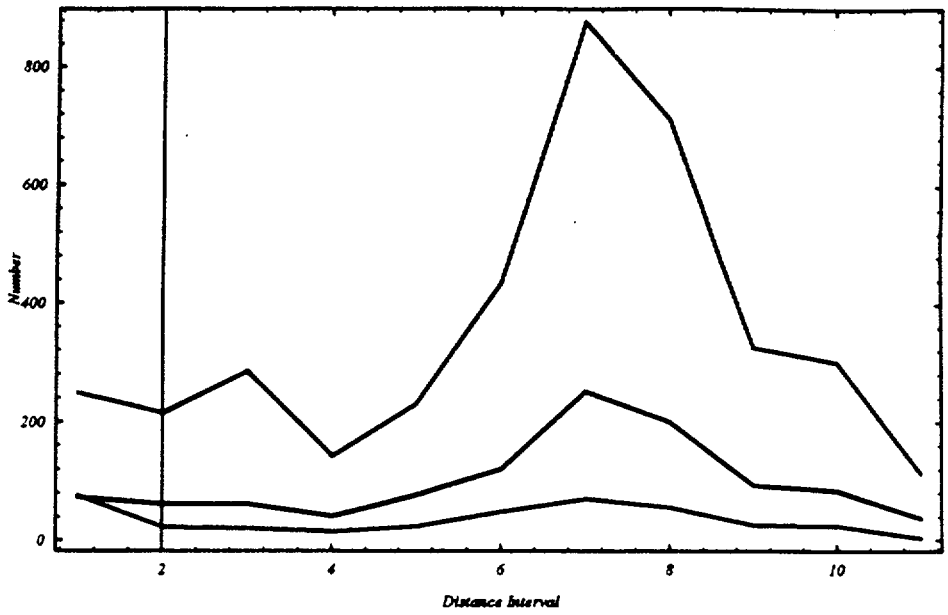
Severe Accident Scenarios
Whole Body Dose
Versus Distance



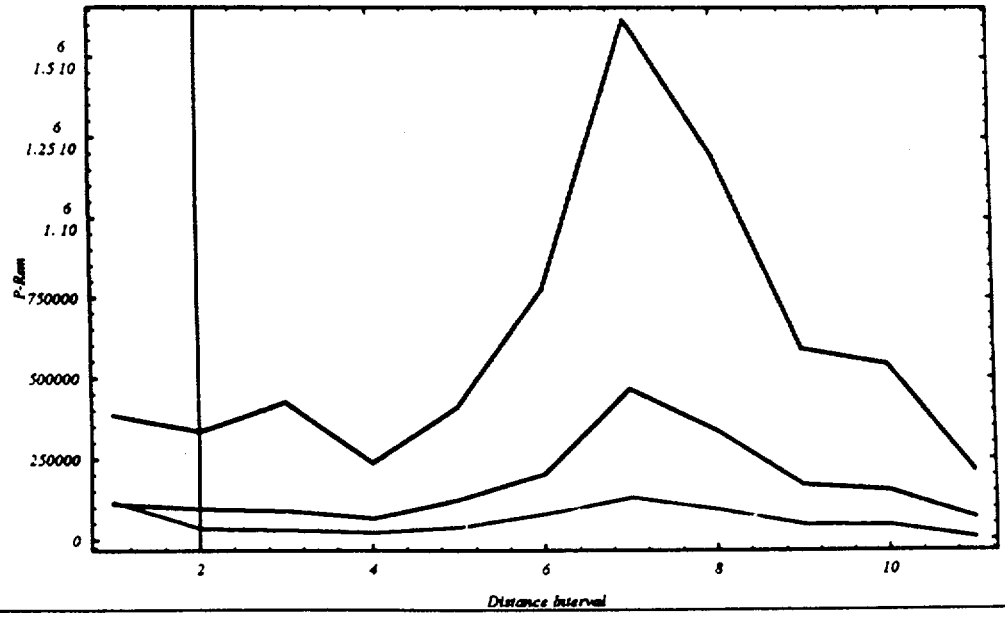
Severe Accident Scenarios
Thyroid Dose
Versus Distance

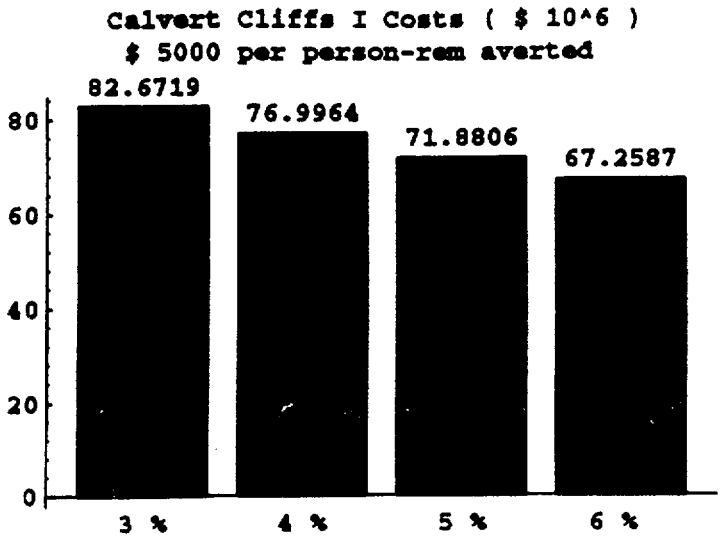


Severe Accident Scenarios
Cancer Nodules
Versus Distance



Severe Accident Scenarios
Person-Rem
Versus Distance




Calvert Cliffs I Costs ($ 10^6)
$ 5000 per person-rem averted
82.6719
76.9964
71.8806
67.2587
80
60
40
20
0
3 %
4 %
5 %
6 %

From: JEROME PUSKIN <PUSKIN.JEROME@EPAMAIL.EPA.GOV>
To: GATED.nrcsmtp("LYMAN.RITCHEY@EPAMAIL.EPA.GOV")
Date: Mon, Oct 5, 1998 1:42 PM
Subject: KI Comments

Ritchey,

I understand that you are collating comments on NRC's KI report.
Attached are comments from Neal Nelson & myself.

Thanks,
Jerry

CC: GATED.nrcsmtp("NELSON.NEAL@EPAMAIL.EPA.GOV")

COMMENTS ON DRAFT NUREG-1633: ASSESSMENT OF THE USE OF POTASSIUM IODIDE (KI) AS A PUBLIC PROTECTIVE ACTION DURING SEVERE REACTOR ACCIDENTS

J. Puskin and N. Nelson

We have one additional concern with the prophylactic use of KI, not discussed in the report. Often patients given iodine for medical purposes show no ill effects on the first occasion, but they become sensitized to iodine and experience adverse reactions upon subsequent administrations. While we are aware of no data on the question, it seems plausible that the administration of KI to a large population may sensitize many of them to iodine. Thus, many adverse iodine reactions in the future might result from the combination of KI used as a block with subsequent medical use of iodine. In addition, due to the uncertainty in timing of release from a damaged reactor, it seems possible that KI might be administered more than once during a nuclear emergency. Sensitization by an initial treatment with KI could produce a much higher rate of adverse reactions in a second treatment than would be expected, e.g., from the Polish data on KI use in response to the Chernobyl accident.

p. 6, ¶ 2: *"...but the possibility of radiogenic cancer from lower doses cannot be ruled out."* This emphasis is wrong in our view. Suggest the following wording: *"...but it is generally assumed that the risk of radiogenic cancer at lower doses is proportional to dose."*

p. 7, ¶ 1: *Tinea Capitis* study should be mentioned along with study of thymus irradiated children. Also, where it says *"...high doses to their thyroids..."* suggest adding the words *"from radiodines"*.

p. 8: *"Of course, the high level of stable iodine ..."* Delete *"Of course"*.

p. 9: *"Finally, the risk of radiogenic thyroid cancer is decidedly non-linear..."* A more recent paper (Ron *et al.*, *Radiation Research* 141, 259-277, 1995) found a linear dose response.

p. 10: *"Of course, people who received high doses could suffer the same acute (deterministic) effects whether or not the thyroid is blocked."* The meaning here is unclear. Blocking the thyroid may reduce the thyroid dose to the point where the deterministic effects are prevented.

16 Sept. 1998

Dear Mr. McKenna,

The recent fax of our meeting and a portion of the material in NUREG-1633 have given me the impression that there is some artful misunderstanding or reinterpretation of my comments and the use of some of the material in that document. I hope that you will, therefore, forgive me in writing you so that my criticisms are available in my own words. I am, of course, speaking strictly for myself and not the NIH.

1. The 10 mile EPZ is unrealistic in view of what has been learned from Chernobyl. The plume does not stop at the 10 mile border. The continued insistence on this restriction makes a sham of emergency planning.

2. Inhalation remains much more important than stated. Certainly this is true in the near field but from measurements of radioiodides in Warsaw it is not only the near field, and inhalation will remain a problem for some days after the release even if food substitution is rapidly instituted. Hence the critical importance of KI. Has there been a test of whether or not a stock of food is available and can be distributed? The very high levels of short-lived isotopes (more than ^{131}I) in Warsaw air on day 3 emphasizes the importance of inhalation. It would be difficult to evacuate that city in say 12-24 hours whereas KI distribution over short periods turned out to be remarkably successful. You may also recall that Buglova stated that food replacement was far from complete and that KI would have decreased the thyroid burden from food as well.

3. Every thyroidologist in the US will tell you that prompt KI distribution would have prevented most of the childhood papillary cancers in Byelorus and Ukraine. I get the impression that you have no thyroid specialist on your board.

4. I was shocked by the use of references of popular publications or unrefereed journals and handbooks which rely totally on case reports.

As I mentioned, these have no denominator, although these would probably be very large. Such statements are used in package inserts primarily for legal reasons. Nauman's data are the only statistically significant data extant and comparing these with NCRP 55 or other guesstimates, as on p11, seems intended to show that the numbers found in Poland are high. They are not when compared with the benefits. The reactions were mostly minor and may also occur in other panics such as evacuation. They are also inflated because many took tincture of iodine due to panic and against advice.

5. Finally, I am disappointed by the NRC staff's presistent stance that accidents are so extremely unlikely with Western reactors as to approach zero probability; this is disingenuous. I hope they are right, but you don't do emergency planning on that basis. Given the calculations in WASH-1400, which were followed by two sizeable accidents, this point of view strikes me as untenable no matter how many calculations are made.

The reluctance of the authors of this report to recommend KI is quite apparent in NUREG-1633 because of the heavy emphasis on side issues such as evacuation, the repeated emphasis on food replacement which is certainly important but not enough, the repeated mention of various other radioactive elements, the repeated statement that with severe releases external radiation and not the thyroid is what is important (true, but not relevant- even in Rongelap external radiation amounted to only ~10% of the thyroid dose; I am excluding whole body effects from this discussion). Thus, I suggest that quite drastic changes are required to make this Draft Report into a balanced proposal.

Sincerely yours,

J. Wolff

Jan Wolff

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September 11, 1998

Dr. Frank J. Congel, Director
Incident Response Division
Office for Analysis and Evaluation of
Operational Data
Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Dr. Congel:

Thank you for forwarding a copy of NUREG-1633 entitled "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Reactor Accidents". I found the report to provide a thoughtful and complete discussion of the issues involved. The discussion of the emergency planning, relevant accident scenarios, and the summary of international practices were of particular help to me.

I appreciate the acknowledgment of my small contributions to the project. Please feel free to call upon me for any additional dosimetry information you might need in the work.

Congratulations on a job well done.

Sincerely,

Keith

Keith F. Eckerman, Ph.D.
Research Group Leader
Life Sciences Division
Oak Ridge National Laboratory
P. O. Box 2008
Oak Ridge, TN 37830-6480

KFE/kjr

To: Collins, NRR

FC

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AUTHOR: RICHARD WILSON
AFFILIATION: MASSACHUSETTS

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HARVARD UNIVERSITY
PHYSICS DEPARTMENT

August 26, 1998

Letters to the Editor
New York Times
229West 43rd Street
New York, NY 10036
FAX: 212 556 3622

Dear Sir,

In your lead article of today (August 26th) you take a common U.S. approach of recommending a pill for everything - in this case to help in nuclear power safety. The impetus has come from the 1000 or so non-fatal thyroid cancers found among children after Chernobyl.

It has long been known that a major potential problem in a nuclear accident is the chain: radioactive iodine depositing on grass, eaten by cows, concentrating in milk, drunk by children and concentrating in the thyroid. The easiest and most reliable way to break the chain is to stop drinking milk from the region for the three weeks the iodine takes to decay. This was known to the responsible scientists in the USSR and they were reminded of it by U.S. colleagues by phone, telex and television interviews. But the USSR government chose to keep the accident a secret for the crucial two weeks and the leading scientists went along with this. A school teacher and an army general warning people on their own initiative were reprimanded by the KGB. In our open society that could not happen. If the children had not drunk milk (even breast milk) most of the cancers would have been avoided.

The addition of potassium iodide pills will be a minuscule addition to safety. I, and others, are far from convinced that the risk of misuse though also small, is not large enough to make the net benefit negative. Without potassium iodide the risk of living near a nuclear power plant is already far less than the safety goals promulgated by NRC in the 1980s. There is therefore no justification for a compulsion by NRC or anyone else. But anyone who wishes should still be allowed to take potassium iodide provided that it is approved by the FDA.

Yours sincerely,

Richard Wilson

Richard Wilson
Mallinckrodt Professor of Physics

Richard Wilson was Chairman of a 1995 American Physical Society study on the consequences of severe nuclear accidents.

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August 15, 1998

Frank J. Congel and Charles A. Willis
USNRC

RE: Assessment of the Use of KI as a Public Protective Action

I reviewed the subject draft assessment. First, I would like to recognize the significant and dedicated effort that this draft represents. Based both on the draft itself and my previous experience as a RPM at a nuclear power plant and as the Supervisor of Emergency Planning, I want to express the opinion that the distribution of KI to "civilians" is a very bad idea. I base my opinion on:

1. Distribution will be difficult, if not impossible.
2. Re-distribution and assurance that outdated supplies in individual homes will be destroyed will be VERY difficult.
3. If not carefully controlled, some will obtain more KI than is needed or recommended on the theory that "a lot is better than a little" and may take too much.
4. If not carefully controlled, some will take KI as an ongoing "prevention" dose.
5. Some will take KI at the first declaration of a "problem" at a plant, even if the problem does not require its use.
6. The presence of KI in homes may cause some people to believe that they have an antidote for radiation and not follow evacuation orders.
7. As with all medicines, children will eat some and result in emergency intervention.
8. Some (few) people may have side effects from KI. These people will sue everyone available (the utility, the governmental agencies, the drug manufacturer, etc.)

I believe that there is an easy and effective alternative. Supplies of KI could be stored at nearby medical facilities and evacuation centers. A simple (GM or scintillation probe) survey of arriving personnel can be made to determine if they have an indication of iodine uptake. KI could then be administered based on a few medical screening questions. This process should not entail significant delay in administration. The delay in this process should be less than 45 minutes from the time that an evacuation is ordered.

If I can be of assistance please call at (510) 643-7976.

Sincerely,

Paul Lavely
Director, Radiation Safety and
Radiation Safety Officer

ANBEX INC.
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ALAN MORRIS
PRESIDENT
813-784-7889

September 3, 1998

Mr. Aby Mohseni
United States Nuclear Regulatory Commission
Mail Stop T-4A43
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Mohseni:

As one of the two FDA-approved suppliers of potassium iodide for use as a thyroid-blocking agent in a radiation emergency, I take exception to the position of Draft NUREG-1633, "Assessment of the Use of Potassium Iodide (KI) As a Public Protective Action During Severe Reactor Accidents," which appears to be an attempt justify a policy that the Nuclear Regulatory Commission has —for good reasons—already abandoned.

My concerns include the following:

- LACK of BALANCE: The section of this paper entitled *KI Benefits and Challenges* fails to list even a single benefit of KI. Yet there are strong reasons that KI has been endorsed by the FDA, the American Thyroid Association, the NCRP, the Kemeny Commission and others, and these issues clearly merit discussion. For example, the fact that that elevated levels of thyroid cancer due to Chernobyl are seen today in areas where KI was not distributed—and are absent in areas where it was available, is essentially ignored. And while NUREG-1633 quotes, it neither analyzes nor considers the finding by the World Health Organization that:

> *Evidence of a marked excess of thyroid cancer in young children in the population affected by fallout from the Chernobyl accident has now been established. It is overwhelmingly probable that the excess of thyroid cancer resulted from exposure to the radioactive isotopes of iodine from the Chernobyl accident. Therefore this indicates that stable iodine prophylaxis would be beneficial, especially for young children, after nuclear accidents...Moreover, the experience in Poland following the Chernobyl accident shows that the risk of serious side effects from a single dose of stable iodine are very low (less than 1 in 10,000,000) in this age group.*
>
> *Current evidence reinforces the benefits of stable iodine prophylaxis. The risk of side effects are now believed to be minimal.*

- SCOPE: The failure in NUREG-1633 to find any value in thyroid blocking by KI may reflect the decision to limit the scope of the report. That is, instead of an assessment of the use of KI "by the general public," NUREG-1633 assesses the use of K: 'by the general public within the 10-mile EPZ" (Emergency Planning Zone). This is not an insignificant difference, since KI protects against thyroid cancer, and most thyroid danger is seen well *outside* the EPZ. NUREG-1633 itself acknowledges this fact:

Four years after the [Chernobyl] accident, an increase in the number of thyroid cancers was detected in Belarus, Russia, and Ukraine. Notably, this increase, seen in areas more than 150 miles (300 km) from the site, continues to this day and primarily affects children who were 0-14 years old at the time of the accident.

But within the EPZ, the value and effectiveness of thyroid blocking is lessened because:

...reductions in thyroid doses are dwarfed by...accompanying acute whole body doses. Early death or very serious effects would occur to all individuals exposed out to nearly 10 miles.

In other words, within the zone, death occurs before cancer can develop, while most cancer develops away from the immediate vicinity of the reactor, as NUREG-1633 notes:

...the vast majority of the thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the site.

Thus, the limitation in this document to evaluate the value of thyroid protection in the EPZ—where thyroid damage is a secondary concern, and not outside the EPZ—where most thyroid damage occurs, severely reduces the value of this analysis.

- DENIAL of NEED: Chernobyl demonstrated the possibility that severe accidents can spread radiation hundreds of miles downwind, affecting thousands of square miles. Fortunately, at 30 to 200 miles from an accident, early deaths would be minimal, but low level radiation could have an impact on millions. At this distance, the potential for thyroid damage, especially among children, would be large, and KI the only feasible defense. Evacuation of an area this size would be unrealistic; and there are few assurances that supplies of food, milk, water, and vegetables could be effectively interrupted. Further, inhalation would remain a problem.

Yet NUREG-1633 raises no health concerns for those located outside the EPZ or considers alternatives to KI (other than evacuation). It denies the possibility that medical authorities might see the need for wide distribution, so it sees no need to stockpile the product. Unfortunately, this strategy guarantees that in a serious accident we can expect a repeat of the Three Mile Island experience, where the absence of pre-planning led to a frantic search for KI, and the delivery of insufficient supplies of an inferior product which did not arrive until the accident was virtually over. Is this what we have to show after 20 years of planning since TMI?

- SAFETY and SIDE EFFECTS: Having denied possible need for the product, NUREG-1633 challenges KI's safety. It reports 36,000 "medically significant" side effects resulted from distribution to 18 million people in Poland after Chernobyl, and details all of the possible adverse effects that *can* appear. However, it does not clearly tell us that these effects did *not* occur. About 99.8% who took KI had no side effects whatsoever, and virtually all the "medically significant" side effects were trivial. Sixty-seven percent were mild gastric or headache problems and 23% were minor skin rashes (so mild that no dermatologist was consulted in any case). There were a few cases of "shortness of breath" and a small number of "other" non-serious effects.

In fact, there was not a single major side effect among the general population that took stable iodine. Only two serious adverse reactions were seen, and both of these involved adults with a known (rare) sensitivity, *who had been told not to take KI*—but did so anyway out of a fear of radiation. Yet the tone of this report would suggest to the casual reader that KI is a very dangerous drug. Further, it fails to mention that the US FDA has found KI to be "safe and effective."

In fact, the FDA has long recognized KI's safety, yet this report attempts to suggest the opposite—that the FDA has some special concern about KI. Through the use of an out-of-context quotation, NUREG-1633 implies that a generic FDA caution (page 10) is somehow a specific "FDA warning" about the safety of KI. For completeness, I believe this analysis should note the FDA has stated:

> "The known potential for potassium iodide to cause serious side effects in a small sensitive population is not sufficient grounds from which to conclude, or even to suggest, a significant and quantifiable proportion of serious reactions..." [*Recommendations on the Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Accidents: An FDA Update.* Printed in the Proceedings on the Symposium on the Health Aspects of Nuclear Power Plant Incidents - Vol. 59, No. 10, December, 1983]

NUREG-1633 is also inaccurate in statements and implications regarding KI contraindications. It confuses us by referring to prescription "medications containing KI," with statements such as:

> *The various reports concerning the medications containing KI ...consistently state that the products are contraindicated for various groups of people (principally pregnant women; nursing mothers; and people with hyperthyroidism, enlarged thyroids, or sensitivity to iodine).*

without telling us that these contraindications are generally not due to the KI. In fact, had NUREG-1633 reviewed products that only contain KI, it would have found that these generally carry few warnings and are contraindicated only in the obvious case of a known sensitivity to iodide.

Further, the maximum radio-protective dose (130 mg. per day) is much smaller than the recommended prescription dose (up to 2400 mg. per day). Indeed, the FDA is so confident of the safety of KI at the smaller dose, that labeling guidelines specifically state "pregnant and nursing women and babies and children may also take this drug." Also, statements in NUREG-1633 such as "use of KI with other medications (such as anti-thyroid agents, diuretics (potassium sparing), and lithium) could lead to problems of major clinical significance" are inconsistent with the FDA position at the lower dosage.

- <u>USEFULNESS</u>:

KI's usefulness is frequently challenged by pointing out that it "only protects the thyroid" or "only protects against iodine." While these statements are true, their significance is questionable since iodine-induced thyroid damage represents the overwhelming radiation health threat at distances beyond the EPZ. This was first seen in 1954 in the Marshall Islands, where thyroid damage was the only effect reported from the radioactive fallout; again at Windscale, where this report tells us, radioiodne "dominated the resulting offsite contamination"; and was also clearly demonstrated at Chernobyl, as NUREG-1633 notes:

> *As of 1996, except for thyroid cancer, there has been no confirmed increase in the rates of other cancers including leukemia, among the first responders, liquidators, or the public, that have been attributed to releases from the accident. In addition, there is no evidence of any excess hereditary diseases in children born after the accident.*

Consequently, KI's ability to prevent injuries due to iodine would greatly reduce casualties in an accident. Had all children within 200 miles of Chernobyl taken KI (as was the case in Poland), the actual effect of the accident on human health would have been local, minimal, and (probably, by today) virtually forgotten.

- AN APPROACH TO EFFECTIVE DISTRIBUTION:

NUREG-1633 suggests (with no analysis) that KI could not be distributed quickly in the event of a possible release. However, it postulates a "significant delay" (presumably a matter of days) for core damage and loss of containment. Anbex believes this would provide ample time for people located very near the reactor to evacuate—and for KI distribution to those further away. (Note that the successful distribution in Poland did not begin until 4 days after the reactor explosion.) To achieve wide distribution in this time frame, Anbex recommends a plan in which the NRC would arrange for KI to be stored at—and distributed from—postal facilities.

Though postal distribution has not been previously considered, discussions with postal authorities confirm that post offices represent ideal KI storage and distribution points. As part of its daily routine, the post office delivers to about 97% of all households in a given area in 6 to 8 hours. They have the equipment, knowledge, training, and pre-planned routes. Their facilities are secure, and the personnel are responsible public officials. A large suburban post office might serve 25,000 households. Ample KI for this number would require very little space; it would fit on one 4X4 pallet. In an emergency, Anbex estimates it would take no more than a few hours to deliver one or two packages to every home on an ordinary postal route. (When a postal official was questioned about the feasibility, cost, timing, etc. of KI distribution, his simple answer was "slap a 32 cent stamp on it, get it to me in the morning, and I'll have it out by the afternoon.")

- COST and SHELF-LIFE ISSUES:

Of course, any plan for KI stockpiling must consider cost, shelf-life, and other storage issues. To best deal with these, Anbex recommends an alternative to simple purchase which would eliminate shelf life, replacement, and other concerns—as well the expense for administration and storage. Under this plan, the KI supplier would assume the obligation to assure the integrity of the stock-piled product. The government would have no initial product or subsequent replacement costs. It would only pay an annual service fee which would be contingent upon yearly demonstrations that the stockpiles meet all specifications. In volume, this fee (which would cover initial product acquisition, replacement as necessary, annual assay testing, indemnification, stockpile administration, and inspection) might be as low as 12 cents per year per package of 14 tablets.

The benefits of this approach are obvious. Freshness and integrity are guaranteed (or no fee is paid), and the government is relieved of any financial or actual responsibility to assure compliance with shelf-life or storage requirements. The up-front expense is very small, and total program cost after five years are well below alternative purchase methods. Further, should utilities ultimately assume the cost and pass it on to consumers, the penny per month per package is not likely to cause substantial public outcry.

- WHO SHOULD RECEIVE KI?

Finally, Anbex believes that limiting access to KI to just the 10-mile EPZ is inappropriate and inconsistent with the mission of the NRC and Chairman Jackson's recent statement that "safety is paramount" at the agency. Accordingly, we believe the NRC is obligated to support accident-response measures to protect anyone who might be at actual, potential, or perceived risk from the type of accident that occurred at Chernobyl—one in which iodine represents a threat to people located at great distances from the source of the radiation and where KI would have a pronounced positive impact. This would mean storing KI for all children (and possibly adults) located within 200 miles of a reactor—or enough for virtually every family in the country—an action which should be difficult to oppose given the proposed low cost of KI stockpiles.

In reality, the alternative to "enough KI for everyone" is "only enough KI for some" which, in an emergency, could lead to potential political and social consequences that could be much worse than the accident itself. How people who do not get the drug (but yet who perceive themselves to be at risk) might respond is difficult to say, but reports of 6% of Poles drinking poisonous tincture of iodine, or giving it to their children, following Chernobyl suggest the existence of extraordinary levels of anxiety and stress. For people in these circumstances (sensing danger from sources they do not understand while feeling utterly helpless), the palliative effect of KI distribution could be extremely important. At Three Mile Island, millions watched in anxiety as the accident developed, but authorities had only 237,000 bottles of KI available, and the fear of rioting or civil disturbance (if a selective distribution had been attempted) was palpable to the officials in charge. It would have been far better, and highly calming, had the State been able to confidently assure people that ample supplies of thyroid-protective medicine were available, on hand, and ready to be distributed to all if needed.

As NUREG-1633 correctly notes, the issue of KI is complex and without precedence in the US. Planners must work in an environment of murky assumptions which are untested by experience or validated by consensus of opinion. Yet, it is realistic to expect that a nervous public will undoubtedly demand that every possible measure be taken to protect and reassure them in the event of an accident, and certainly iodine tablets will be among their first requests. Thus, officials should recognize that arguments and compromises which appear rational to planners prior to an emergency, may seem utterly irrelevant to people involved in one—and may lead citizens to suspect that authorities are unable or unwilling to protect them. Consequently, their response and behavior may become unpredictable.

Given this, Anbex believes large stockpiles of KI represent a wise investment. If stored and never needed, little is lost. However, should an accident occur, the consequences of not having it (or, worse, not having enough) could be devastating.

Sincerely,

Alan Morris

CC: Chairman Jackson - with sample IOSAT
Commissioner Diaz - with sample IOSAT
Commissioner McGaffigan - with sample IOSAT
Commissioner Dicus - with sample IOSAT
Senator Joseph Lieberman - with sample IOSAT
Senator Tom Harkin - with sample IOSAT

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ALAN MORRIS
PRESIDENT
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August 13, 1998

Mr. Aby Mohseni
United States Nuclear Regulatory Commission
Mail Stop T-4A43
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Mr. Mohseni:

I appreciated speaking with you last week regarding your response to my request for a copy of Draft NUREG-1633 (which I received today). As I described, Anbex is an FDA approved supplier of KI for radiation protection; and I have considerable interest in this topic. Accordingly, I would like to introduce my comments into the debate on the product.

In addition, I am interested in eliciting discussion and exploration of the three broad issues that must be resolved for the question of KI stockpiling to have any practical value. These are:

1 How could KI be stockpiled to permit rapid distribution?

2 What is the true "loaded" cost of stockpiling, including the administrative costs of storage, quality assurance, and KI replacement as necessary?

3. How much KI should be stockpiled?

As I mentioned in our telephone conversation, Anbex believes a stockpiling strategy can be devised to assure timely distribution, and that issues concerning cost, stockpiling integrity, and other matters can be resolved satisfactorily. Essentially, our position is as follows:

1. How could KI be stockpiled to permit rapid distribution?

   Obviously, unless there is a reasonable chance that KI could be distributed in time to be of value following an accident, terrorism, or act of war, there is little reason to store it. While some have suggested pre-distributing KI, Anbex does not support this strategy since it introduces potential problems of loss or misuse. Instead, we favor an approach that stores the product near people (for fast distribution) but out of their hands (to keep it safe).

   Our plan assumes that (under most circumstances) there would be a minimum of one to two days before a release for planners to decide if KI should be distributed to people located in the EPZ, and that a longer time would be available for distribution to those outside the zone should this be required. Anbex believes this would be sufficient time for wide distribution of KI under the following approach:

First, small amounts would be kept in certain obvious locations such as schools, police/fire stations, and hospitals. Since KI by Anbex is small, lightweight, and unbreakable; a school, for example, could keep enough for all students in a small, inconspicuous space (say, on the top of a closet). If an accident occurred during school hours, children would be sent home with one package (enough for 3 days for a family, or two weeks for an individual).

Second, moderate amounts would be kept at postal facilities. On an average day, the post-office picks-up and delivers to 97% of all household and businesses in an area in 6 to 8 hours. They have equipment, knowledge, and pre-planned routes. Their facilities are secure, and the personnel are responsible public officials. A large office might serve 25,000 households and enough KI for this number of households could fit on a 4X4 pallet. In an emergency, it would take no more than a few hours to deliver one package to every home. (The Anbex product has been designed to fit in a mailbox or through a mail slot.)

Third, large amounts would be kept at predetermined evacuation centers. This would provide an incentive for individuals to go to the centers to obtain additional product.

While this plan obviously does not guarantee complete distribution to all people under all possible circumstances, it does represent an approach that is both reasonable and prudent. Prior to a release, it would give authorities the option of distributing KI early (helping to mitigate the population's feeling of helplessness), before having to make the far more drastic decision to evacuate if a release appears likely. It would also provide effective crucial protection if a release occurs and large areas are jeopardized (making an evacuation unrealistic). And having accessible KI would be preferable to what occurred at Three Mile Island--where it took six days to deliver an insufficient quantity of an inferior product. Having seen that happen once before, emergency planners have the obligation to assure it never occurs again.

2 What is the true "loaded" cost of stockpiling, and how can product integrity be assured?

Currently, the two FDA approved suppliers of KI (Carter-Wallace and Anbex) sell a package of tablets for about $0.75 with a shelf life of up to 5 years (after which replacement might be required). But costs associated with KI storage (including program administration, site monitoring, testing to assure product efficacy and integrity, etc.) could be significant and should not be ignored. Further, periodic product replacement must be assumed, since KI can be damaged by high humidity and/or extreme temperature fluctuations. And if suppliers of the product have no control over the storage conditions, they may be reluctant to offer shelf-life guarantees longer than 5 years.

To deal with these issues, Anbex recommends an alternative to simple purchase which would eliminate shelf-life, replacement, and other concerns, as well as any government storage expense. Under this plan, there would be no initial product or subsequent replacement costs. Instead, the KI supplier would assume the obligation to assure the integrity of the stockpile, and bear the complete responsibility, and all necessary costs, to guarantee the condition and suitability of the product if it is ever needed. For this, the supplier would receive an annual "service" fee, which would be payable only upon yearly demonstrations that the stockpiles meet or exceed all specifications. In volume, this fee might be as low as 12 to 14 cents per year per package.

The benefits of this approach are obvious. Freshness and integrity are guaranteed, or no fee is paid, and the government is relieved of any financial or actual responsibility to assure compliance with shelf-life or storage requirements. The up-front expense is very small, and total program costs after five years are well below alternative purchase methods.

3. How much KI should be stockpiled?

This is the most difficult question to answer. I note that NUREG-1633 concerns itself only with "options related to the use of KI by the general public within the 10 mile EPZ." Yet clearly, the amount of KI that would needed following an accident will depend on the size of the area and the number of people that might be affected by radio-iodine, regardless of where they are located. Regarding this, NUREG-1633 notes, there are "difficulties in predicting the areas that will be impacted during the course of an accident."

What is known is that every accident is likely to be different, and will reflect the specific cause, geography, and weather conditions, among other factors. Further, the behavior, type, and amount of radionuclides that might be released, and their local and extended health impact, is far from well understood. At Chernobyl, for example (according to NUREG-1633) "the initial release is thought to have risen to over 1 km in altitude, thereby resulting in much lower doses close to the site than those expected from a ground level release" (and, presumably, much greater doses than expected in areas far from the plant).

The possibility of substantial atmospheric iodine dispersal, for hundreds of miles downwind from a reactor, had been previously predicted by Beyea and Von Hipple, and the health impact of this had been calculated in NUREG/CR-1433. This seems consistent with what occurred at Chernobyl, since NUREG-1633 also reports that atmospheric radioactivity was detected in Poland (hundreds of miles distant) and that there has been an increase in thyroid cancer "in areas more than 150 miles (300 km) from the site..." It mentions that "the contribution of inhalation cannot be assessed because air sampling was not effectively conducted early in the accident" and that "the vast majority of the thyroid cancers were diagnosed among those living more than 50 km (31 miles) from the site." But then concludes (surprisingly, without any supporting evidence) that the injured children "are believed to have been irradiated as a result of consuming contaminated foodstuffs."

But, as noted above, every accident is likely to be different, and what took place at Chernobyl cannot be viewed as a model that other accidents would necessarily duplicate. Instead, Chernobyl, and the decision by Polish medical authorities for nationwide distribution, should be seen as unmistakable evidence for the real possibility of this type of nuclear emergency—one in which iodine represents an atmospheric threat for people located at great distances from the source of the radiation. Consequently, limiting KI to just the 10 mile EPZ is wholly inappropriate, and inconsistent with Chairman Jackson's recent statement that "safety is paramount" at the NRC, as well as with the agency's mission for "protection of public health and safety". Accordingly, it would seem undeniable that the NRC is <u>obligated</u> to endorse response measures to protect anyone who might be at actual or perceived risk from this type of accident. And this could mean storing KI for anyone located within 200 miles of a reactor—or enough for virtually everyone in the country—an action which should be difficult to oppose given the low cost of KI stockpiles.

In reality, the alternative to "enough KI for everyone" is "only enough KI for some" which, in an emergency, could lead to potential political and social consequences that could be worse than the accident itself. How people who do not get the drug (but yet who perceive themselves to be at risk) might respond is difficult to say, but reports of 6% of Poles drinking tincture of iodine following Chernobyl suggests the existence of extraordinary levels of anxiety and stress among the population. For people in these circumstances (sensing danger from sources they do not understand while feeling utterly helpless), the palliative effect of KI distribution could be extremely important. At Three Mile Island, millions watched in anxiety as the accident developed, but authorities had only 237,000 bottles of KI available, and the fear of rioting or civil disturbance (if a selective distribution had been attempted) was palpable to the officials in charge. It would have been far better, and highly calming, had the State been able to confidently assure people that ample supplies of thyroid protective medicine were available, on hand, and ready to be distributed to all if needed.

These are matters that are germane to the debate over KI. I would like to address these points, and others, in my response to NUREG-1633. Hopefully, as a result of the recent NRC policy change, thoughtful people will explore difficult questions, and suitable answers will emerge.

To help with the question, I have enclosed a number of samples of IOSAT (Anbex brand of potassium iodide) which I hope you will circulate around the agency. I hope you will not hesitate to contact me if you feel more would be of value or if you have any questions about the product or the position of Anbex on this matter. But under any circumstances, I will contact you in the next few weeks to determine the status of this project.

Sincerely,

Alan Morris

ENCLOSURE 4

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

***

BRIEFING ON

PROPOSED RESOLUTION TO A PETITION FOR

RULEMAKING RELATING TO USE OF POTASSIUM IODIDE (KI)

FOLLOWING SEVERE ACCIDENT AT A

NUCLEAR POWER PLANT

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PUBLIC MEETING

***

Nuclear Regulatory Commission

Commission Hearing Room

11555 Rockville Pike

Rockville, Maryland

Wednesday, November 5, 1997

The Commission met in open session, pursuant to notice, at 9:30 a.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission

GRETA J. DICUS, Member of the Commission

EDWARD McGAFFIGAN, JR., Member of the Commission

NILS J. DIAZ, Member of the Commission

CHAIRMAN JACKSON: I think what I am trying to get them to do is to in fact consider that. I think we can decide and pass to them questions.

I don't think it is fair to them to ask them to sit here today and to answer that question, and so I have no objection, and I don't think any of the colleagues do, of our putting the question to them --

COMMISSIONER McGAFFIGAN: Okay.

CHAIRMAN JACKSON: -- but I don't believe that --

COMMISSIONER McGAFFIGAN: The question will be "Should the words 'reasonable' and 'prudent' be put in the statement."

Listening to Peter earlier, there were two bases for his petition.

One was that there were changes, as he described it. I haven't read the full petition. I am taking it at his word that one was there had been changes since the policy was adopted, and we have discussed that.

The other was that the Commission acted on bad information in its initial policy and obviously the claim is that there's been bad information since.

Do you have any response to that bases for -- I think it is fair to say that if that was a basis highlighted in his petition that that isn't addressed in the SECY paper at the moment.

You are a whole new team practically, but do you have any discussion of this matter? The only person at the table with that kind of corporate memory is Tim and Frank.

MR. MARTIN: I became aware of -- as a result of a Peter Crane letter to the FEMA that in the SECY paper we provided you in June of this year where we attempted to describe the background of the KI policy we misrepresented one of the bases upon which the ad hoc subcommittee for KI based their recommendation not to change the policy and not to stockpile.

That particular was one of five and it was the fifth one that said that there is a lack of support by the primary Federal regulatory agency, and then in parentheses said FEMA. Clearly FEMA is not the primary Federal regulatory agency, and it could be read to imply that FEMA did not support it.

I will let FEMA speak for themselves. It was NRC, if you go back and read the actual report of that subcommittee, although they don't label it as NRC, the clear context and what my staff tells me, it was NRC that was what was their fifth basis for their conclusions.

Now that one I am aware of, and let the record so state that we made an error there, but Frank --

MR. CONGEL: Well, I was not involved in the early determination of the KI policy, so at least you can say

everybody sitting here is a fresh group.

I became involved with it probably at about the time of the filing of the DPV in 1988-89 timeframe and have been involved since.

In any case, some of the considerations that Peter brought up, historical ones, I just simply don't have an answer for.

What I do have though is the fact that the considerations that he brought up have been subject to discussion in many different forums and as we all know, sitting around the table, this is not an easy issue to find a resolution to, and if it was we wouldn't be. We would have had an answer already.

But the many things ranging from the experience at Chernobyl to the American Thyroid Association's statements to all of the other history you heard, they have resulted in much dialogue, both within the Staff and outside of the Staff and I would just like to point out that what we have in papers presented from the June Commission paper to the petition response does reflect that, and if it turned out that there was a clear determination of one way or the other, we would have presented that, but there are equivocations and some of the information --

Just as one example, there are no new data to change the dose factors that we use for thyroid right now.

ENCLOSURE 5

POLICY ISSUE
(Notation Vote)

June 16, 1997 SECY-97-124

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: PROPOSED FEDERAL POLICY REGARDING USE OF POTASSIUM IODIDE AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

PURPOSE:

To provide the Commission with options concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents.

SUMMARY:

As part of the Federal effort to reevaluate the Federal policy on KI based on a request by a petitioner, the Federal Radiological Preparedness Coordinating Committee (FRPCC) adopted recommendations that would result in a revised Federal policy statement. NRC staff has participated in the FRPCC activities and has worked closely with the Federal Emergency Management Agency (FEMA) in this area.

There are three options that can be taken with regard to the FRPCC recommendations: (1) recommend no change in the existing Federal policy, (2) recommend the adoption of the FRPCC recommendations, with the added recognition of recent developments regarding medicinal stockpiles for nuclear, biological, and chemical events, or (3) recommend modifications to the FRPCC recommendations.

CONTACT: Frank J. Congel, AEOD
(301) 415-7476

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEBN THE FINAL SRM IS MADE AVAILABLE

The staff recommends either option 2 or option 3(b). In light of the fact that this is a national policy issue, Commission guidance is requested.

BACKGROUND:

Federal Policy on KI (1985)

The current Federal guidance to State and local governments on the distribution of KI was promulgated in 1985 by FEMA in its capacity as Chair of the FRPCC (50 FR 30285) and as the Federal agency charged with establishing policy and providing leadership via the FRPCC (44 CFR 351 Subpart C). The FRPCC was established in accordance with 44 CFR Part 351 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 are: Federal Emergency Management Agency (FEMA), Nuclear Regulatory Commission (NRC), Environmental Protection Agency (EPA), Department of Health and Human Services (HHS), Department of Energy (DOE), Department of Transportation (DOT), Department of Agriculture (USDA), Department of Defense (DOD), Department of Commerce (DOC), Department of Interior (DOI), Department of State (DOS), Department of Veterans Affairs (DVA), General Services Administration (GSA), National Communication System (NCS), and National Aeronautics and Space Administration (NASA).

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. It recognizes, however, that options on the distribution and use of KI rest with the States. Hence, the policy statement permits State and local governments, within the limits of their authority, to take measures beyond those recommended or required nationally.

DPO (1989)

In 1989, Peter G. Crane, a member of the NRC staff, filed a Differing Professional Opinion (DPO) which alleged that there were deficiencies in the original cost-benefit analysis (NUREG/CR-1433) provided to the FRPCC by the NRC. The DPO suggested that the staff discussion at a November 1983 Commission briefing on KI might have left Commissioners and members of the public with insufficient understanding of the adverse consequences (thyroid disease) that the use of KI could avert. The DPO also suggested that the cost-benefit analysis, by simply balancing the dollar costs of a KI program against the dollar costs of treating radiation-caused thyroid illness, did not adequately consider the non-monetary costs of an illness.

In SECY-91-321, the DPO panel developed a simplified analysis of the value and impact of the KI policy, including revisions to several factors used in NUREG/CR-1433. The panel concluded that no change in the Federal policy was warranted. However, in order to consider all of the issues raised by the DPO and incorporate new data, the Office of

Nuclear Regulatory Research performed a detailed update of the NRC's KI policy basis, taking into account both qualitative and quantitative factors.

The staff presented its recommendation to resolve the DPO in SECY-93-318 (November 23, 1993) and SECY-94-087 (March 29, 1994). The staff recommended that the NRC, in coordination with HHS and FEMA, revise current Federal KI policy as a matter of prudency to make KI available to the States. The Commission's vote on the above staff recommendation was split 2 to 2 (SRM dated May 6, 1994). Thus, the policy remained unchanged.

American Thyroid Association's Request and Establishment of KI Subcommittee (1989)

In September 1989, the American Thyroid Association (ATA) submitted a letter to the Chairman of the FRPCC requesting that the Committee reconsider the issues involved in stockpiling KI. The ATA proposed that:

> "As best as can be determined at this time, no substantial stockpile of potassium iodide is available for public use. Despite the unlikely event of an emergency requiring its use, the ATA believes that the option of potassium iodide distribution should be available for consideration to those responsible for public health measures. To this end, the ATA believes that it would be prudent to have available at central locations a suitable stockpile of KI for possible distribution should its use be contemplated."

In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide and asked the HHS to review the medical and clinical status of the use of KI. In an initial response, HHS reviewed the then current scientific literature on KI and its use as a blocking agent. HHS reported to the FRPCC in February 1990 that no new scientific data had been found that would affect the basis for the 1985 guidance to refrain from stockpiling or predistributing KI for the public. To ensure a more comprehensive review, HHS also decided to solicit new data, scientific opinions, and reports on the experience of States concerning KI use and distribution.

HHS convened a meeting of experts on July 24, 1990 in Atlanta, Georgia. Representatives of the State and Federal agencies responsible for medical research, drug regulation, and radiological emergency response, representatives of medical associations, and nationally recognized experts in the fields of endocrinology and nuclear medicine attended. Daniel A. Hoffman, Ph.D, M.H.P., Assistant Director for Science, Center for Environmental Health and Injury Control, Centers for Disease Control chaired the meeting.

Following the experts' meeting, HHS made the following recommendations to the FRPCC in October 1990:

1. The 1985 FRPCC guidance need not be changed at this time since no compelling evidence to support a modification was presented.

2. Existing stores of KI should be inventoried. The FDA would determine the locations and size of KI supplies by identifying large customers of KI manufacturers[1]. The FRPCC should request that the Conference of Radiation Control Program Directors identify appreciable supplies of KI within the States by surveying State Radiation Control Programs.

3. The FRPCC should establish a working group to address the issue of stockpiling. Group objectives should be to:

   - Review and catalog type, location, and expiration of existing suitable supplies of KI.
   - Review and determine feasibility of specific stockpiling recommendations made by meeting participants.
   - Make final recommendations to FRPCC on U.S. Government KI stockpiling policy.

The FRPCC Subcommittee on KI followed up on these recommendations.

An Analysis of KI for the General Public in the Event of a Nuclear Accident

Under the sponsorship of NRC's Office of Nuclear Regulatory Research, S. Cohen & Associates completed a report entitled, "An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident" in April 1992. The analysis was updated and published in February 1995 (NUREG/CR-6310).

The analysis, whose central objective was to conduct a cost-benefit analysis of KI, assigned monetary values to thyroid health effects. The report addressed not only the scientific aspects of the use of KI but also the economic costs and benefits to society. The report indicated that a fair evaluation of KI cannot be limited to an assessment of the cost-benefit ratios, but must include a thorough understanding of how these ratios were derived.

[1] According to FEMA, the FDA inquiry conducted in late 1996 showed that Carter Wallace, one of the largest manufacturers of KI, had an inventory of 70 cases of KI. Each case contains 1000 bottles. Each bottle contains 14 tablets, a 14-day supply. According to this inquiry, Carter Wallace can manufacture 40-50 cases a day if necessary. Roxanne, another manufacturer of KI, has an unknown inventory of liquid KI in 30 ml bottles.

The analysis utilized the technical insights from both the National Academy of Sciences, BEIR V Committee (NAS 1990) and the National Council on Radiation Protection and Measurements (NCRP 1987) regarding iodine and thyroid dosimetry.

The analysis also addressed the effectiveness of KI. According to the analysis, given the rapid uptake of iodine (radioactive or stable), there is a limited benefit of KI administration following exposure to radioiodines. For KI to serve as an efficient blocking agent, the report continued, it must be administered in sufficient quantities before or concurrently with radioiodine exposure.

This report estimated the cost/benefit ratio of stockpiling KI prophylaxis as a function of estimated population within radial distances from a plant. The results of this analysis showed that the cost-benefit ratio ranged from 2.22[2] for populations within 5 miles to 81.8 for populations within 50 miles. This means that for the 0- to 5-mile population cell, $2.22 would be spent for stockpiling KI in order to avoid the economic equivalent cost of $1.00. For the 0- to 50-mile population cell, $81.8 would be spent to avoid the economic equivalent of $1.00. The cost-benefit ratios for population cells increased nearly exponentially with distance.

As basis for the cost-benefit analysis, the authors used four accident categories postulated for the Surry nuclear power plant as described in NUREG-1150. The analysis used the accident consequence code to calculate the thyroid dose to individuals as a function of age, gender, and distance. For the worst case that was analyzed, the whole body doses close to the plant at the plume centerline were high and likely to be fatal[3]. Doses decrease with distance and away from the plume centerline. Within 5 miles, where the cost-benefit ratio for stockpiling KI was estimated to be 2.22, the whole body doses may still exceed thresholds for early health effects[4] for which administration of KI is ineffective. It was precisely such insights that led to the NRC's recommendation for prompt evacuation of areas close to the plant and five miles downwind as the preferred protective action. This guidance is contained in NUREG-0654 Rev. 1 Supp. 3 entitled Criteria for Protective Action Recommendations for Severe Accidents published in July 1996.

State Survey (1994)

In June 1993, the April 1992 report was provided to the representatives of FEMA and HHS who co-chaired the FRPCC Potassium Iodide Subcommittee. The subcommittee reported on the NRC-sponsored analysis at a meeting of the FRPCC in September 1993. It recommended initiating two studies to secure State input on implementation strategies for providing KI to the public: (1) request the Conference of Radiation Control Program

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[2]In SECY-94-087, the staff applied correction factors to the cost-benefit ratios and produced a modified ratio of 11 instead of 2.2.

[3]Assuming no protective actions, such as evacuation or sheltering.

[4]The health effects include nausea, fatigue, vomiting, epilation, diarrhea, and hemorrhage.

Directors (CRCPD) to survey those States with nuclear power plants for opinions regarding Federal purchase and stockpiling of KI and regarding the feasibility of States providing KI to the public under emergency conditions and (2) request the International Atomic Energy Agency to provide information on existing plans and procedures from member nations related to the storage, distribution, and dosage of KI. The latter study, which involved the IAEA, was never conducted. The first study, which consisted of a survey of States in connection with a Federal purchase and stockpiling of KI, was completed in mid-1994. All 32 States with nuclear power plants responded, as well as 11 States without plants. In general, the responses were as follows:

	Yes	No
Does your State favor a Federal KI Stockpile?		
- States with nuclear power plants	7	25
- States without nuclear power plants	3	8
Total	10	33

The primary reason given by States for not supporting Federal purchase and stockpiling of KI was that the State policy did not include KI as a protective measure for the general public. The State use of KI was specified only for emergency workers. Many States emphasized that the distribution of KI to the general public would be difficult in the event of a radiological emergency. The difficulty stems from logistical challenges presented for timely distribution of KI to permanent and non-permanent populations and the liabilities associated with the misuse of KI.

Of the 10 States that supported the Federal purchase and stockpiling of KI, one State preferred one centrally located national stockpile, four preferred Federal regional stockpiles, and five preferred a stockpile within their State.

In early 1995, the FRPCC subcommittee was prepared to recommend that:

1. The FRPCC Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent (50 FR 30258), should not be changed.

2. The Federal government should not purchase and stockpile KI for use by the public.

The basis for these recommendations were:

1. The results of the State survey,

2. The 1992 NRC cost-benefit study,

3. The lack of new data challenging the 1985 guidance on KI stockpiling,

4. The lack of justification that the subcommittee could find for a Federal stockpile, and

5. The lack of support for such an initiative by the States and the primary Federal regulatory agency (FEMA).

However, FEMA did not issue the results of these findings because of a petition for reconsideration.

Petition for Rulemaking (1995)

On September 9, 1995, Mr. Crane, who filed the DPO, filed a petition for rulemaking (PRM-50-63) with the NRC as a private citizen. He requested that the NRC amend its emergency planning regulations to require that emergency planning protective actions include sheltering, evacuation, and the prophylactic use of KI. The request would amend one of the 16 planning standards in 10 CFR 50.47, which licensees' and offsite agencies' emergency plans are required to meet, in order to assure that the option of using KI is included in emergency plans.

The staff's resolution of the petition is currently under consideration. The implications of the policy options on the petition are discussed later.

Stockpile of Medicinal Supplies for Nuclear, Biological, and Chemical Agents (1995)

In June 1995, the White House issued Presidential Decision Directive 39 (PDD-39) on US Policy on Counterterrorism. The PDD-39 directed the Federal agencies to take a number of measures to reduce vulnerability to terrorism, to deter and respond to such acts, and to strengthen capabilities to prevent and manage the consequences of terrorist use of nuclear, biological, and chemical (NBC) weapons including weapons of mass destruction. The PDD-39 assigned to FEMA the task of ensuring that the Federal Response Plan (FRP) was adequate to respond to the consequences of terrorism.

FEMA, in coordination with the Catastrophic Disaster Response Group (CDRG)[5], developed a draft report to the President entitled, "An Assessment of Federal Consequence Management Capabilities for Response to Nuclear, Biological or Chemical (NBC) Terrorism," dated June 12, 1996. The report recommended, among other things, that the Federal government purchase and stockpile thyroid blocking agents (KI) for the general public that could be used in the event of a nuclear terrorist event. The NRC was a member of the Core Group which generated the recommendations and was instrumental in adding KI to the list of medicinal supplies to be stockpiled nationally.

[5]The CDRG is the headquarters-senior-level coordinating group which addressees policy issues regarding the Federal Response Plan (FRP). The CDRG is chaired by FEMA and comprises representatives of Federal departments and agencies with responsibilities under the FRP. The NRC is represented by the Incident Response Division Director.

The Core Group concluded that as the result of recent events, significant threats over the past few years, and the increased availability and proliferation of nuclear, biological, or chemical materials, there is an increasing concern for the potential of terrorist incidents. NBC events, the report continued, may occur as a local event with potentially profound national implications. In responding to these events, the first responders must be able to provide critical resources to the victims. These include, but are not limited to, chemical nerve antidotes, vaccines for anthrax, and antibiotics[6]. It was therefore determined that there is a need to purchase and preposition stockpiles of adequate medical supplies at the Federal, State, and local level. While KI was not considered as vital as chemical nerve antidotes and vaccines, the NRC staff was successful in getting KI included with other medicinal supplies for NBC events because of the unusual characteristics of these events:

1. NBC events are unpredictable with many unquantifiable parameters. In contrast to nuclear power plant accidents, NBC events can occur in major metropolitan areas. The group postulated NBC scenarios for which evacuation and sheltering were not effective or even possible.

2. NBC events can have consequences ranging from low to disastrous. Some may not escalate beyond the threat stage while others may occur without a threat stage with devastating consequences, with everything in between.

3. Even with the significant amount of planning at the Federal, State, and local level, NBC events still have potential for mass casualties.

Because of the special characteristics of NBC events, the Core Group recommended a broader range of protective actions. The NRC concurred in the findings of the report by letter from AEOD Director to FEMA Director dated September 25, 1996. The report was subsequently presented to the President in February 1997 and approved for distribution in May 1997.

The staff believes that such a stockpile of KI substantially addresses the issue raised by the American Thyroid Association.

FRPCC Subcommittee on KI (1996)

In parallel with petitioning the NRC, Mr. Crane also requested that FEMA review his petition and reconsider the Federal policy. In early 1996 the FRPCC convened an Ad-Hoc Subcommittee on Potassium Iodide to request and review new information on this matter from interested parties. The subcommittee conducted a public meeting on June 27, 1996. The subcommittee evaluated all comments from the June 27 public meeting and concluded in its report to the FRPCC that "while the viewpoints presented at the public meeting were

[6]Some of these medicines can save lives only when administered urgently. The timely distribution remains an issue.

compelling, the 1996 Subcommittee on Potassium Iodide heard no new information that seriously challenges the bases for the 1985 recommendation concerning public use of KI." However, the Subcommittee made the following recommendation 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 Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe with the Federal policy is the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded 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 the State or, in some cases, local governments."

3. The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

Proposed Federal Policy on KI (1996)

The full FRPCC endorsed the subcommittee's recommendations with some modifications and plans to publish a revised Federal policy statement on distribution of KI. Because of the NRC's interest and recognized expertise in emergency planning around nuclear power plants, NRC staff agreed to work closely with FEMA to propose language that would integrate the FRPCC subcommittee's recommendations, the FRPCC's endorsement, and the recent developments in the areas regarding preparedness for terrorism.

FRPCC and Interagency Assignments

Under 44 CFR 351, the FRPCC is the Federal coordinating body responsible for assisting FEMA in providing policy direction for the program of Federal assistance to State and local governments in their radiological emergency planning and preparedness activities. FEMA, as chair of the FRPCC, establishes policy and issues guidance to State and local governments. The FRPCC member agencies jointly review and evaluate the status of emergency planning periodically. Part 351.21 (f) requires the NRC to assist FEMA in developing and promulgating guidance to State and local governments for the preparation of radiological emergency plans. Part 351.21 (i) requires the NRC to provide representation to and support for the FRPCC. The NRC has fully participated in FRPCC activities. Because of its special interest in emergency planning for nuclear power plants,

the NRC staff worked closely with FEMA and other Federal agencies in developing the proposed KI policy. The staff recognized the importance of working closely with health agencies such as HHS and DVA regarding the use of KI by the general public. Throughout this process, the staff worked collegially with other key Federal agencies to ensure a broader consensus on the Federal policy.

The NRC's representative to the FRPCC has agreed to propose language that integrates what was already recommended and endorsed by various Federal committees and working groups. By virtue of its regulatory functions, the NRC staff had to consider some additional fine points. For example, the NRC staff considered the licensing implications of the proposed KI policy, the need for additional guidance to the licensees or States, and the potential impact on FEMA's responsibilities in offsite emergency planning.

If accepted by the FRPCC, the proposed policy will be noticed in the *Federal Register*. Since FEMA chairs the FRPCC, it assumes the responsibility for this publication.

Options

Option 1. **Recommend no change in existing policy.**

This option would result in continuation of the present policy, i.e., stockpiling KI for use by emergency workers and institutionalized persons but predistribution or stockpiling of KI for use by the general public should not be required.

This option would require that NRC staff request that the FRPCC reconsider its current recommendations and not consider the existing Federal stockpile for NBC events. The staff does not believe that other key Federal agencies on the FRPCC would be receptive to this option because of the activities that have taken place since 1985.

This option does not update the current policy to reflect the recent developments. The staff believes that the time is appropriate to update the present policy. A Federal stockpile of KI, among other medicinal supplies, already was available for the Olympics and the national political conventions. There is a new national impetus for expanding the Federal preparedness to include medicinal supplies for NBC events. While the FRPCC determined that there is no new information that seriously challenges the basis of the current policy regarding reactor accidents, it did recommend that the Federal government fund the purchase of KI for any State upon their request and soften the language in the present policy.

Option 2. **Recommend the adoption of the FRPCC recommendations recognizing the recent developments in preparation for NBC events.**

This is one of the options favored by the staff. As pointed out in option 1, the staff believes that the present policy should be updated. Attachment 1 contains a proposed Federal policy on KI that reflects the key elements of this option. It incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, acknowledges the

developments in the area of NBC events regarding KI but does not alter the current emergency planning requirements. The principal differences between option 2 and the 1985 version are the addition of the willingness of the Federal Government to purchase a supply of KI for States at their request, and the establishment of a Federal stockpile.

The highlights of option 2 proposed policy are as follows:

- KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of the State or, in some cases, the local government.

- The Federal government will establish funding for the purchase of a supply of KI. It is recognized that the State or the local government, within the limits of their authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have available to them the option to use KI if they so elect, the Federal government will be prepared to provide funding for the purchase of a supply of KI. Any State or local government which selects the use of KI as a protective measure for the general public may notify FEMA and request funding for the purpose of purchasing a supply of KI. Guidance would have to be developed in this area jointly with FEMA.

- A stockpile of KI is being established by the Federal government. The Federal government is required to prepare for a wider range of radiological emergencies[7]. 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, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency at any time.

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[7]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast (Washington, DC), Central (Denver), and West coast (Los Angeles). The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

- Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

- The incorporation of a program for KI stockpiling, distribution, and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and that the existing emergency planning and preparedness guidance for nuclear power plants are effective and adequate to protect the public health and safety.

Analysis of Option 2 Proposed Policy

To ensure that the KI policy adheres to the principles of good public policy, NRC staff identified key factors that should be taken into account:

1. The preeminent role of State and local governments in the protection of offsite public health and safety;

2. The application of good science to the development of any new guidance regarding KI;

3. The value added of any new guidance in the context of existing planned protective measures;

4. The recognition that KI is not without side effects which have been discussed at length throughout the past years. Before the NRC actually participates in the purchase and supply of KI, it will prepare through consultation with HHS, a suitable product warning to be used by the State and local governments.

5. The implementation challenges of any new guidance.

The NRC staff considered these factors in developing the proposed Federal policy on KI. Furthermore the staff believes that the proposed policy does the following:

1. Integrates the subcommittee's recommendations with the recent developments in the area of preparedness for NBC events, namely the establishment of national medicinal stockpiles, including KI;

2. Recognizes the central role of State and local governments in protecting public health and safety, and honors the State's prerogative to determine whether it wishes to add KI as a supplemental protective measure for the general public;

3. Does not encumber the States and local governments who choose to retain their existing plans if they believe that the implementation of a KI program may reduce

the effectiveness of implementing prompt evacuation as a preferred protective action for the general public;

4. Provides added assurance to those States and local governments that a Federal stockpile of KI is available, should it be needed;

5. Is consistent with the recently published draft guidance (NUREG-0654 FEMA-REP-1 Rev. 1 Supplement 3) by NRC and FEMA on "Criteria for Protective Action Recommendation for Severe Accidents;"

6. Does not result in a rule change which is a two-year process and may require a backfit analysis;

7. Maintains the foundation of offsite emergency planning by confirming that the existing guidance and requirements are adequate.

The proposed policy is also strengthened by the already existing stockpile of KI that was available for the Olympics and the national political conventions. The staff believes that given these stockpiles, unlike the TMI experience, KI could be made available in a more timely manner if needed in the future.

This option has some fiscal implications for the NRC associated with its offer to purchase KI for any State that requests it.

Fiscal Implications of Proposed KI Policy

The option 2 proposed Federal policy contains an offer by the Federal government (most likely the NRC) to fund the purchase of a supply of KI for any State that chooses to add KI to its options of protective actions in response to an emergency at a NRC licensed nuclear power plant. To fulfill this proposed obligation, staff's estimate of the range of NRC costs is given in three scenarios in Attachment 2. Currently, resources are not budgeted for the purchase of KI and funds would have to be reprogrammed should a State (or States) request funding through FEMA.

The cost estimate does not include the administrative costs associated with the KI purchase. The more likely scenario is that several sites may request funding each year for a few years. In that case, the estimate is about $50,000 each year for a period of three years and repeated every seven years, thereafter.

Option 3. **Recommend modifications to the FRPCC recommendations.**

There are a number of possible modifications to the FRPCC recommendations that can be recommended. The staff has prepared a limited number of cases to scope the wide range of possibilities.

a) **Endorse FRPCC recommendations without the offer to fund the purchase of KI.**

> There are already two States which have KI for the general public under the current policy. The staff is not aware of any cases where funding to purchase a supply of KI is the obstacle for adding KI as a protective measure for the general public. The staff believes that the costs associated with a KI program could be significant when activities such as public education and the logistics associated with the distribution are added to the cost to purchase KI supplies. The FRPCC's offer to fund the purchase of KI is intended to demonstrate a good faith effort on behalf of the Federal government to assure that if any State wishes to add this supplemental measure, there is no implicit discouragement from the Federal government.

If this option is selected, the staff would have to request that the FRPCC reconsider its recommendation regarding Federal funding for the purchase of KI.

b) **Recommend that the staff, in coordination with HHS and FEMA, revise current Federal KI policy to make KI available to the States.**

This was recommended by the staff in SECY-94-087. The revised policy would state that:

> KI will be purchased by the Federal government (most likely by the NRC) and made available through FEMA to the States. While the NRC encourages the stockpiling of KI, the decision to stockpile, distribute, and use KI would be the responsibility of the individual States. At the option of the State, procedures incorporating the use of KI in State emergency plans would be developed with the assistance of FEMA. The details regarding this option would be developed and coordinated through the FRPCC.

This option contains some of the essential elements of option 2 and is the other option favored by the staff. For example: (1) it is a State option to determine whether it wishes to include KI in its plans, and (2) the Federal government (most likely the NRC) will purchase KI for the States. This option could have fiscal implications up to scenario 3 in option 2. The principal difference with option 2 is that in this option the Federal government openly encourages the stockpile of KI by States for prudency.

The States may perceive the NRC encouragement to stockpile KI by the States as going beyond what is necessary. This is based on the statements presented by States' representatives at the public meeting conducted by the subcommittee on KI in 1996. Not only were they not convinced that there is a benefit to a KI stockpile, but believed that it may hamper the implementation of prompt evacuation which is the preferred protective measure. Indeed, it was after these testimonies and a careful examination of issues and information presented to the subcommittee, that FRPCC recommended a position that reflected a more subtle encouragement (as reflected in option 2).

SECY-94-087 was silent on cases where States did not opt to have a local stockpile of KI. In today's environment, those States could rely on the NBC stockpile to use KI on an ad hoc basis if needed.

This option was favored by the staff in 1994 and, in recognition of the NBC development, remains one of the two recommended options today.

c) **Direct the staff to effect a rule that requires KI as a protective measure for the general public.**

This option is based on the presumption that stockpiling KI for limited populations located close to operating nuclear power plants, if not cost-beneficial, is, nonetheless, prudent.

The option would require that emergency plans be revised to include a KI distribution system for the public and the criteria for its administration in an accident.

This option would be at odds with the FRPCC recommendations and according to the polls, the States would not view this option favorably. The FRPCC recommendations were, in part, based on the notion that the State or local governments are ultimately responsible for the decisions regarding protective actions and their implementation. To have a national stockpile of KI allows the States to use KI on an ad hoc basis if needed.

This option would also have wide-spread implications for emergency planning. It would require the States and local governments to make significant changes to their plans and procedures in order to ensure that KI can be distributed to the public (permanent and transient populations) in a timely manner, preferably without reducing the effectiveness of prompt evacuation if necessary. It would require that Federal agencies develop additional guidance for FEMA evaluation of the changed plans. The NRC and staff would have to revise the existing Federal guidance on protective actions for severe accidents, such as Supplement 3 to NUREG-0654. The State and local officials would have to conduct public training for public use of KI. Public health officials and school officials would need specific instructions for dispensing KI to the general public and school children.

For the purpose of placing this option in perspective using the two States which currently stockpile KI for the general public, the staff contacted officials from Alabama and Tennessee. In each case, KI supplies would be made available at reception centers following an accident. Under the direction of the Health Officer, KI tablets would be administered to members of the public reporting to these centers. Neither State has a planned distribution system to provide KI to the members of the public in case evacuation would not be feasible. Under these circumstances, KI would be distributed on an ad-hoc basis.

In short, this option has the potential to undo the web of emergency planning without any significant added benefit.

Implications of Options on the Petition for Rulemaking

Before discussing the implications of the options on the Petition for Rulemaking, the contributions of Mr. Peter Crane of the NRC, the petitioner, should be recognized for their value in illuminating all aspects of this issue. He has persevered, over many years and in the face of technical disagreement on intangible issues, in keeping this important issue before the agency and without his efforts even the policy changes recommended in this paper would not likely have been made.

Option 1: No change to existing policy.

If this option were approved, then the petition would be denied. The staff could still grant part of the petition by referencing the NBC developments which will result in a Federal stockpile.

Option 2: Endorse FRPCC recommendations recognizing the recent developments in preparation for NBC events.

If the proposed Federal policy is accepted, there will be no rule change to amend 10 CFR 50.47 to require that KI be included in the emergency plans. Thus, the petition would be denied. However, the staff believes that the Federal offer to fund the purchase of KI for the States at their request and the Federal stockpile of KI for NBC events[8] substantially addresses the fundamental concerns behind the petition, without requiring changes in State and local emergency plans.

There are currently two States which stockpile or distribute KI for the general public around nuclear power plants. More States may choose to add KI to their protective actions for the general public.

Option 3 (a): Endorse option 2 with no funding.

The petition would be denied. The Federal stockpile for NBC events partly addresses the fundamental concerns behind the petition.

Option 3 (b): In coordination with HHS and FEMA, revise current policy to make KI available to the States.

[9]As pointed out in the proposed Federal policy, the Federal stockpile of KI will be available to any State for any type of radiological emergency.

The petition would be denied. The availability of KI would substantially address the fundamental concerns behind the petition.

Option 3 (c): Effect a rule change.

This option would grant the petition by directing the staff to make the requested rule change.

Coordination

The Office of the General Counsel has reviewed this paper and has no legal objection. The Office of the Chief Financial Officer has no objection to the resource estimates contained in this paper.

RECOMMENDATION:

The staff requests that the Commission approve either option 2 or option 3(b).

L. Joseph Callan
Executive Director for Operations

Attachments:
1. Proposed Federal Policy on KI
2. Estimation of Cost

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Wednesday, July 2, 1997.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT June 25, 1997, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat shoudl be apprised of when comments may be expected.

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FEDERAL EMERGENCY MANAGEMENT AGENCY

DRAFT

Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

AGENCY: Federal Emergency Management Agency.

ACTION: Issuance of Federal Policy on Potassium Iodide.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) is issuing this revised Federal policy concerning the purchase, stockpiling, and use of potassium iodide (KI) as a prophylaxis for the thyroid in the unlikely event of a major radiological emergency at a commercial nuclear power plant. Taken in time, KI blocks the thyroid's uptake of airborne radioactive iodine, and thus could help reduce thyroid diseases caused by such exposure.

The Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

ATTACHMENT 1

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[1]. 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, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency, at any time.

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[1]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The policy herein incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, and supersedes the 1985 Federal policy (50 FR 30258). The principal difference between this revised policy and the 1985 version are the addition of the offer of the Federal Government to purchase a supply of KI for States at a State's request and the establishment of a Federal stockpile. The Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

For Further Information Contact: William F. McNutt, Senior Policy Advisor, Rcom 634, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2857; facsimile (202 646-4183.

Background

This policy on use of KI as a thyroidal blocking agent is the result of a Federal interagency effort coordinated by FEMA for the FRPCC. On March 11, 1982, FEMA issued a final regulation in the Federal Register (47 FR 10758), which delineated agency roles and responsibilities for radiological incident emergency response planning (44 CFR 351). One of the responsibilities assigned to the Department of Health and Human Services (HHS) and in turn delegated to the Food and Drug Administration (FDA) was providing guidance to State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., KI) to reduce radiation doses to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the June 29, 1982 Federal Register (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of KI. The Federal policy on stockpiling and distribution of KI was published in the July 24, 1985 Federal Register (50 FR 30258). On September 11, 1989, the American Thyroid Association requested FEMA, as Chair of the FRPCC, to reexamine the 1985 policy and to revisit the issue of stockpiling and distribution of KI for use by the general public. In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide. On December 5, 1994, the FRPCC adopted the report and recommendations of the Ad Hoc Subcommittee on Potassium Iodide, which reaffirmed the Federal position as expressed in the 1985 policy.

On April 3, 1996, in connection with a September 9, 1995 Petition for Rulemaking submitted to the Nuclear Regulatory Commission (NRC) on this issue, the FRPCC established a new Subcommittee on Potassium Iodide to review current information. The Subcommittee conducted a public meeting on June 27, 1996. Based on the information collected, the Subcommittee concluded that there was no new information that seriously challenges the bases for the 1985 recommendations concerning public use of KI for radiological emergencies at nuclear power plants. However, several recommendations were made to the FRPCC. The Subcommittee's three recommendations were: 1) without changing the Federal policy by interceding in the State's prerogative to make its own decisions on whether or not to use KI, the Federal government (NRC, or through FEMA) should fund the purchase of a stockpile for any State that, hereinafter, decides to incorporate KI as protective measure for the general public; 2) The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe in the Federal policy is in the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded 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 the State or, in some cases, local governments." and 3) The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

The full FRPCC endorsed the subcommittee's recommendations with some modifications.

Policy on Distribution of KI Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

The purpose of this document is to provide Federal policy and guidance with regard to distribution of KI, and its usage as a thyroid blocking agent, around operating nuclear power generating facilities. The issue has been addressed in terms of two components of the population that might require or desire KI use: (1) Emergency workers and institutionalized individuals close to the nuclear power plant site, and (2) the nearby general population. This guidance is for those State and local governments who, within the limits of their authority, need to consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public.

The Federal policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of public protective actions for severe accidents at commercial nuclear facilities, the best technical information indicates that evacuation and in-place sheltering provide adequate protection for the general public. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[2]. 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, a stockpile of KI is being established by the Federal government. This Federal stockpile will be available to any State for any type of radiological emergency, at any time.

The bases for these recommendations are given below.

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[2]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism, involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The NRC and FEMA issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, Revision 1, in 1980. This guidance recommends the stockpiling and distribution of KI during emergencies to emergency workers and to institutionalized individuals. Thyroid blocking for emergency workers and institutionalized individuals was recommended because these individuals are more likely to be exposed to radioiodine in an airborne radioactive release than other members of the public. In addition, the number of emergency workers and institutionalized individuals potentially affected at any site is relatively small and requires a limited supply of KI that can be readily distributed.

For the general public, in the event of a radiological emergency at a commercial nuclear facility, evacuation and in-place sheltering are considered adequate and effective protective actions. It is well-recognized that the inclusion of KI as a protective measure, in addition to evacuation and sheltering, is beneficial only in very remote circumstances. The use of KI is not without controversy. On the one hand, KI has been shown to be an effective drug for protecting the thyroid from thyroid nodules or cancer caused by the uptake of radioiodine, especially in children fifteen years of age or younger. On the other hand, there are logistical difficulties, and potential medical side effects associated with the drug, in distributing the drug to the general public in a radiological emergency. Also, KI effectively reduces the radiation exposure of only the thyroid gland from ingested or inhaled radioiodines. While this in an important contribution to the health and safety of the individual, it is not as effective as measures which protect the total body. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and the total body. It is very important to remember that the use of KI is not an effective means

by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods. Therefore, while the use of KI can provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation indicates that the decision to use KI (and/or other protective actions) should be made by the States and, if appropriate, local authorities on a site-specific, accident-specific basis.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

The 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. Since FDA has authorized the nonprescription sale of KI, it is available to individuals who, based on their own personal analysis, choose to have the drug immediately available.

Attached is a list of ten references intended to assist State and local authorities in decisions related to the use of KI.

Conclusion

The FRPCC did not find any new information that would require a change in the basis of the existing Federal policy concerning the stockpile or pre-distribution of KI for the general public in the event of a radiological emergency at a commercial nuclear plant. The policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies, but leaves the decision for the stockpiling, distribution, and use of KI for the general public to the discretion of State, and in some cases, local governments. Any State or local government that selects the use of KI as a protective measure for the general public may so notify FEMA and may request funding for the purpose of purchasing an adequate supply.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the

existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs or legal liabilities associated with this program.

As an added assurance, for a broader range of 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, a stockpile of KI will be established by the Federal government. Such a stockpile would consist of individual KI caches at VA hospitals in major metropolitan centers across the country. This supply would be available to any State or local government for any type of radiological emergency.

References

1. National Council on Radiation Protection and Measures (NCRP), "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," NCRP Report No. 55, August 1, 1977.

2. Food and Drug Administration (HHS), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, 43 FR 58798, December 15, 1978.

3. Halperin, J. A., B. Shleien, S. E. Kahans, and J. M. Bilstad; "Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid Blocking with Potassium Iodide," FDA 81-8158, U.S. Department of Health and Human Services (March 1981).

4. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use (Notice of Availability) 47 FR 28158, June 29, 1982).

5. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1992). Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.

6. Nuclear Regulatory Commission; Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents (NUREG/CR-1433, March 1990). Prepared by Sandia National Laboratories for the NRC.

7. Nuclear Regulatory Commission; An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident (NUREG/CR-6310, February 1995). Prepared by S. Cohen and Associates, Inc. and Scientech, Inc. for the NRC.

8. Nuclear Regulatory Commission; Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-93-318, November 23, 1993).

9. Nuclear Regulatory Commission; Addendum to SECY-93-318, Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-94-087, March 29, 1994).

Signed:

_____

O. Megs Hepler, III
Chair
Federal Radiological Preparedness Coordinating Committee

Estimation of the Cost to Purchase KI for the States in Using Three Scenarios

The option 2 proposed Federal policy contains an offer by the Federal government (most likely the NRC) to fund the purchase of a supply of KI for any State that chooses to add KI to its options of protective actions in response to an emergency at a NRC licensed nuclear power plant. Currently, resources are not budgeted for the purchase of KI and funds would have to be reprogrammed should a State (or States) request funding through FEMA.

To fulfill this proposed obligation, staff's estimate of the range of NRC costs is given below:

	No. of Sites Added Each Year	No. of Years	Cost in k$/yr Year 1-3	Cost in k$/yr Year 4-5	Cost in k$ Year 8	Cost k$/yr Year 9-10	Cost in k$/yr Year 11-12
Scenario 1[3]	3	3	48		48	48	
Scenario 2	10	5	160	160	160	160	160
Scenario 3	70	1	1,120		1,120		

Table: Cost of KI purchase in $1000 for three scenarios

The cost estimate does not include the administrative costs associated with the KI purchase. Although the cost/benefit ratio to purchase KI for the population in the 10-mile Emergency Planning Zone (EPZ) may be excessive for most sites, the NRC staff used the 10-mile EPZ population as the basis for cost estimation. The cost range is from $48,000/year for the first three years and repurchased every seven years, to a maximum of $1,280,000 the first year and repurchased every seven years. The higher estimate assumes all sites would request funding for the purchase of KI in the first year, which staff believes is highly unlikely. The more likely scenario is that several sites may request funding each year for a few years. In that case, the estimate is about $50,000 each year for a period of three years and repeated every seven years, thereafter.

Three scenarios were used to estimate the cost to purchase KI for the States who request such funding. The first is based on the assumption that one State per year (with three sites) requests funding for a period of three years. The second scenario assumes three States per year (with a total of 10 sites) request funding for a period of five years. The third scenario assumes every State with a nuclear power plant requests funding the first year.

ATTACHMENT 2

[8]The three scenarios are described in Attachment 2.

The start-up cost would be: C = S*P*T*c = 10*80,000*2*0.1 = $160,000/year, or $800,000 for five years.

Scenario 2	1998	1999	2000	2001	2002
No. of Sites Added	10	10	10	10	10
Cost ($1000)	160	160	160	160	160

The replacement cost would be the same plus inflation, every seven years.

Scenario 3

Number of sites, S: 70
Average number of people per site (within 10-mile EPZ), P: 80,000
Average number of KI tablets/person, T: 2
Average cost/KI tablet, c: $0.10
Average shelf life of KI, L: 7 years

If every State with a nuclear power plant site requested funding in the first year, the start-up cost would be: C = S*P*T*c = 70*80,000*2*0.1 = $1,120,000

Scenario 3	1998
No. of Sites	70
Cost ($1000)	1,120

The replacement cost would be $1,120,000, plus inflation, every seven years.

'Population Data within the Nuclear Power Plant Emergency Planning Zones

SITE	'PERMANENT 0-2 MILES	0-5 MILES	0-10 MILE	TRANSIEN 0-10 MILE	'Total 0-10 miles	
KANSAS	853	7,320	25,394	6,000	31,394	1
BEAVER VALLEY	3,676	16,658	142,268	3,400	145,668	2
BELLEFONTE	309	4,696	25,050	2,437	27,487	3
BIG ROCK POINT	269	4,368	9,274		9,274	4
BRAIDWOOD	3,545	11,490	26,015	8,105	34,120	5
BROWNS FERRY	148	2,414	27,678	19,600	47,278	6
BRUNSWICK	711	4,373	10,583	21,000	31,583	7
BYRON	371	7,140	21,393	43,762	65,155	8
CALLAWAY	82	632	5,759	4,545	10,304	9
CALVERT CLIFFS	241	3,501	19,972	1,150	21,122	10
CATAWBA	340	1,058	81,423	46,879	128,302	11
CLINTON	48	918	12,666	28,472	41,138	12
COMANCHE PEAK	29	2,684	10,731	8,918	19,649	13
COOPER STATION	40	830	5,417	3,000	8,417	14
CRYSTAL RIVER	0	825	13,595	1,010	14,605	15
DC COOK	723	12,364	53,755	16,089	69,844	16
DAVIS BESSE	1,030	2,572	16,427		16,427	17
DIABLO CANYON	10	57	18,099	53,700	71,799	18
DRESDEN	613	7,498	39,289	5,900	45,189	19
DUANE ARNOLD	235	3,821	79,323		79,323	20
FARLEY	27	1,577	10,681	1,420	12,101	21
FERMI	3,004	13,460	71,517		71,517	22
FITZPATRICK	242	3,909	35,155	20,790	55,945	23
FORT CALHOUN	207	7,666	15,254	871	16,125	24
GINNA	930	9,979	39,162	5,863	45,025	25
GRAND GULF	180	2,025	7,255	2,873	10,128	26
HADDAM NECK	2,345	12,129	74,080	29,415	103,495	27
HARRIS	110	1,545	15,795	11,000	26,795	28
HATCH	107	894	5,312	150	5,462	29
HOPE CREEK	0	1,209	22,556	5,539	28,095	30
INDIAN POINT	15,165	74,755	240,455	92,852	333,307	31
KEWAUNEE	163	1,600	11,086		11,086	32
LASALLE	130	1,145	13,913	3,130	17,043	33
LIMERICK	4,349	100,364	164,870	23,165	188,035	34
MAINE YANKEE	372	2,001	28,730	42,338	71,068	35
MCGUIRE	420	4,189	46,233	31,178	77,411	36
MILLSTONE	5,176	48,648	110,166	83,129	193,295	37
MONTICELLO	279	7,611	20,153		20,153	38
NINE MILE POINT	242	3,909	35,155	20,790	55,945	39
NORTH ANNA	225	1,639	8,688	1,166	9,854	40
OCONEE	401	4,670	50,841	20,000	70,841	41
OYSTER CREEK	4,700	14,950	71,440	73,676	145,116	42
PALISADES	959	5,203	32,773		32,773	43
PALO VERDE	10	205	761	4,000	4,761	44
PEACH BOTTOM	512	6,153	28,647	9,858	38,505	45
PERRY	1,882	17,238	71,902	53,271	125,173	46

PILGRIM	1,716	15,249	41,401	1,200	22,194	48
POINT BEACH	239	1,256	20,994		21,462	49
PRAIRIE ISLAND	290	4,228	21,462	12,035	48,480	50
QUAD CITIES	224	5,740	36,445	13,700	36,572	51
RIVERBEND	601	4,053	22,872	5,000	31,908	52
ROBINSON	1,164	10,435	26,908	40,000	134,854	53
ST LUCIE	210	9,417	94,854	5,539	28,095	54
SALEM	0	1,209	22,556	25,900	83,050	55
SAN ONOFRE	3,650	28,450	57,150	116,988	217,708	56
SEABROOK	6,040	32,060	100,720	24,000	62,972	57
SEQUOYAH	890	7,503	38,972	4,622	7,172	58
SOUTH TEXAS	4	268	2,550	2,000	10,869	59
SUMMER	220	1,883	8,869	63,755	137,166	60
SURRY	49	1,399	73,411	3,720	54,952	61
SUSQUEHANNA	1,177	13,317	51,232	6,335	167,844	62
THREE MILE ISLAND	2,331	27,466	161,509	4,500	97,164	63
TURKEY POINT	0	30	92,664	3,544	35,453	64
VERMONT YANKEE	2,086	9,231	31,909	200	2,869	65
VOGTLE	517	1,133	2,669	7,000	67,009	66
WATERFORD	914	13,756	60,009	8,000	21,916	67
WATTS BAR	209	2,696	13,916	1,100	6,620	68
WOLF CREEK	24	3,698	5,520	11,824	13,162	69
WNP-2	0	80	1,338	65,750	310,756	70
ZION	12,981	59,247	245,006			
SUM	90,946	697,696	3,111,627	1,320,238	4,431,865	

These are estimates of 1982 population which were developed by NRC staff
Transient population estimates were based on information obtained from FSARs, E Plans, NUREG/CR -1856 (1981) and on licensee estimates. Transient population data are considered to include a large degree of 'uncertainty

Average population per site	63,312
Ave pop/site assuming 20% increas	75,975

ENCLOSURE 5a

POLICY ISSUE
(Notation Vote)

November 10, 1998

SECY-98-264

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: 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

PURPOSE:

To obtain Commission approval to publish a proposed rule in the Federal Register for a 90-day public comment period, that would grant petitions for rulemaking (PRM 50-63 and 50-63A). These petitions requested changing the NRC policy on the use of potassium iodide (KI) as a radioprotective agent for the general public in the event of a severe reactor accident.

BACKGROUND:

On September 9, 1995, a petition for rulemaking (PRM 50-63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY-97-245, dated October 23, 1997, the staff presented three options to the Commission for resolving PRM 50-63.

CONTACT:
Mike Jamgochian, NRR/DRPM/PGEB
(301) 415-3224

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address the views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition, PRM 50-63A (Enclosure 1). The petitioner made two requests:

> A statement be made clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and
>
> A proposed rule change to 10 CFR 50.47(b)(10), which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

The petitioner also provided a marked-up version of the proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) Federal Register notice concerning a revision to the Federal policy relating to the use of KI for the general public.

On June 26, 1998, the Commission directed the staff in SRM 98-061 (Enclosure 2) to grant the petition for rulemaking PRM 50-63A by revising 10 CFR 50.47(b)(10).

PUBLIC COMMENT ON THE AMENDED PETITION:

On November 27, 1995 (60 FR 58256), a Notice of Receipt of the Petition for Rulemaking was published in the Federal Register requesting public comment. A total of 63 comment letters were received, of which 20 utilities, 9 State governmental agencies, 2 utility interest organizations, 1 letter signed by 12 health physicists, 2 State universities and 1 member of the public were against the granting of the petition for rulemaking. Those 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.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition 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 82 comment letters were received, of which 13 utilities, 3 State government agencies, 1 utility interest association, and 1 member of the public were against granting the petition for rulemaking. The letters in favor of granting the petition came from 8 public interest groups, 46 members of the public (including 1 from the petitioner), 3 physicians, 2 U.S. Senators, and 1 State Representative. A detailed analysis of the issues raised by the public comments along with the Commission response to those issues is in the proposed Federal Register Notice (Enclosure 3).

DISCUSSION:

In the revised petition (PRM 50-63A) dated November 11, 1997 the petitioner requested that consideration be given to including KI as a protective measure for the general public. This is a change from the original petition in which the petitioner requested that the regulations be amended to require emergency plans to include KI as a protective measure. In both the original and the amended petitions, the proposed rule language lists sheltering and evacuation as protective measures along with KI. The planning standard (10 CFR 50.47(b)(10)) currently does not identify any specific protective actions, but indicates that a range of protective actions should be developed for the plume exposure pathways zone (EPZ) for emergency workers and the public, and included in emergency response plans. Additionally, the petitioner requested that a statement be made clearly recommending stockpiling of KI as a reasonable and prudent protective measure.

On June 26, 1998, the Commission voted 3 to 1 to grant the petition for rulemaking. Accordingly, the staff was directed to proceed with rulemaking to change 10 CFR 50.47(b)(10) by inserting the following sentence, or similar words, 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." In addition, the statement of considerations for the proposed rule should include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions. The Commission also noted that, consistent with the Commission's decision on June 30, 1997, the Federal government (most likely NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request. The NRC staff also was directed to work with other relevant agencies to ensure that there are established procedures to enable the national stockpile, for response to terrorism, to be effectively and timely used by States that have not established local stockpiles and wish to make use of the national stockpiles in the event of a severe nuclear power plant accident.

The attached Federal Register notice implements the Commission's decision by publishing the proposed amendment to 10 CFR 50.47(b)(10) for a 90-day public comment period.

RESOURCES:

Approximately one FTE is budgeted to resolve this petition by conducting a rulemaking in accordance with the Commission direction. The cost of purchasing KI was discussed in SECY 97-124 (Enclosure 4) with the estimates ranging from $48K to $1.3M. The staff has recently found these estimates to be overly conservative by approximately a factor of 2.5 due to the increased costs of purchasing the KI tablets. Therefore, the revised estimate range is $117K to $3.25M depending on the number of States that request funding. These resources are not currently budgeted and would have to be reprogrammed from existing agency programs or carryover. A more detailed cost and funding analysis will be provided prior to the final rulemaking. Additionally, prior to FEMA going forward with the issuance of the FRPCC Federal KI policy, a letter from the NRC committing the above funds will be necessary.

COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The CRGR has reviewed this Commission paper but does not agree with the staff's no backfit analysis (see Enclosure 6). The Office of the Chief Information Officer has reviewed this Commission paper for information technology impacts and compliance with the Paperwork Reduction Act and concurs in it. The Office of the General Counsel has no legal objection.

RECOMMENDATION:

That the Commission:

1. Approve publication of the proposed rule in the Federal Register.

2. Note:

   a. The proposed rule change would be published in the Federal Register for a 90-day public comment period.

   b. Appropriate Congressional committees will be notified.

   c. The Office of Public Affairs draft public announcement is attached (Enclosure 5).

   d. The evaluation of a need for a backfit analysis was prepared by OGC. The EDO accepts OGC's position that this rule change does not constitute a backfit under 10 CFR 50.109; therefore, a backfit analysis is not required.

   e. FEMA has been provided with an advance copy of this rulemaking package.

William D. Travers
Executive Director
for Operations

Attachments:

1. Revised Petition for Rulemaking (PRM 50-63A)
2. SRM 98-061, dated June 26, 1998
3. Proposed Federal Register Notice
4. SECY 97-124
5. Draft Public Announcement
6. CRGR comment letter dtd. October 23, 1998

Commissioners' completed vote sheets/comments should be provided directly to the Office of the Secretary by COB Friday, November 27, 1998.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT November 19, 1998, with an information copy to the Office of the secretary. If the paper is of such a nature that it requires additional review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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November 11, 1997

Mr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Amendment to Petition for rulemaking (PRM-50-63)

Dear Mr. Hoyle:

At the Commission meeting on potassium iodide held on November 5, 1997, Chairman Jackson asked me whether I could submit, within the week, language reflecting the modified position that I outlined during the meeting. Attached to this letter is a draft of a proposed rule change, accompanied by a statement of considerations explaining the change.

Under the approach I outlined in the meeting, the NRC would "require that consideration of potassium iodide be given in the formulation of emergency plans," but "would not ram potassium iodide down the throat of a state that emphatically rejected it." I made clear that I was asking for two things: a statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and a rule change identifying what is meant by a "range of protective actions" (i.e., evacuation, sheltering, and KI) and requiring their consideration.

In the meeting, I sometimes referred to the "reasonable and prudent" statement as a "statement of policy," while elsewhere I talked about "clarification which could readily be done in the statement of considerations for such a rule." (At one point, Commissioner Diaz observed, and I agreed, that I was proposing that the Commission, in a "public statement or a rule," express the belief that stockpiling was a prudent measure.) In short, there may have been ambiguity as to whether I was seeking two separate documents -- a rule change and a policy statement explaining it -- or just one, a rule change with policy stated and explained in the statement of considerations. Plainly, the latter makes more sense (in any event, to propose a rule change, the NRC would have to offer its reasons for doing so) and seems most consistent with the Commission's interest in resolving the KI issue in an efficient and timely way.

In the attached proposal, which represents an amendment to my petition, the Commission's expression of policy therefore would take place in the context of the rule change, i.e., in the statement of considerations. I trust that no one will view this as any deviation from what I was proposing in the meeting.

I realize that it is an ancient negotiating ploy to press for more than you think you can possibly get, as a prelude to bargaining. The fact that this proposal does not do that, but instead is squarely in line with what I described

ENCL 1

on November 5, is an indication that I take this amendment of my petition very seriously, without game-playing. I would like as much as anyone to see this protracted process brought to closure, with broad consensus acceptance. Accordingly, I have tried to produce a solution that satisfies the NRC's obligations to protect and inform the public, that does not encroach unnecessarily on state prerogatives, and that enables the Commission to put a difficult and divisive issue behind it.

I have also tried in this draft Statement of Considerations to present the KI issue in such a way that no one can accuse the Commission, if it adopts this approach, of being alarmist, or of failing to put safety issues in their proper perspective. Moreover, although I have often, in past submissions, discussed troubling past events, such as those I referred to in the November 5 meeting, I have omitted these historical matters from the proposed Statement of Considerations that I am offering today. This reflects a conscious decision to look forward, not to the past, in the recognition that for a health and safety agency, the central question must always be: What makes sense today, in light of what we know now?

I believe that if the approach I am proposing is accepted, it would be viewed as so patently reasonable that if challenged legally, it would be sustained by any reviewing court, whether the challenge came from those who thought it went too far or from those who thought it did not go far enough. In the memorable words of the late Judge Harold Leventhal of the U.S. Court of Appeals for the D.C. Circuit, "When agencies make good sense, courts are loth to find that it is not good law." On issues of litigation risk, however, the Commission should of course rely on the General Counsel and the Solicitor for advice.

A rulemaking of this kind need not consume significant resources. Though it was suggested at the November 5 Commission meeting that a rulemaking would take two additional years (i.e., for a total of more than four years since the filing of the petition), this seems exaggerated. It is a matter of public record, for example, that the Commission's last major emergency planning rulemaking, the "realism" rule of 1987, did not require any two years, though it involved many extremely complicated issues and elicited more than 38,000 comments (including many duplicates), all of which had to be read. In that case, a 66-page memorandum to the Commission was prepared in which the issues and comments were analyzed and discussed in detail, with the arguments on both sides fairly presented. A Commission briefing was also held at which the merits of the competing arguments were discussed at length. In the end, the analysis and the final rule were sufficiently airtight, both as policy and as law, that none of those dissatisfied with the rule -- and there were many -- decided to seek judicial review. The entire process, from proposed rule to final rule, took 9 months.

A KI rulemaking along the lines I am proposing would be a minor, not a major rulemaking. It would involve fewer issues and, to judge from the 60 or so comments filed on the petition, would probably elicit comments numbered in the dozens, not in the tens of thousands. If the staff turns to the KI rulemaking with a will, and it is given a firm deadline for turning it around, there is no reason why it could not be completed in significantly less time than the nine months that the "realism" rule required.

I was also asked to provide for the record the citation to an Environmental Protection Agency document that I referred to. The document is the Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-001, published by EPA in May, 1992. On November 11, 1995, I wrote to you, as Secretary of the Commission, that at the time I filed my rulemaking petition two months earlier, I had been unaware of this document. I therefore wished "to draw the Commission's attention to this document and to ask that this letter and its attachment [a detailed discussion of the EPA Manual and its implications for the KI issue] be considered as a comment supplementing my petition." This letter and its attachment are in the rulemaking docket as comment no. 5, docketed November 13, 1995.

Finally, I was asked to provide a suggested markup of the draft Federal Register notice proposed to the Commission in SECY-97-124. First, I would like to put the notice in context. SECY-97-124 asked for Commission approval of an approach, not of the appended Federal Register notice.[1] Neither the SRM nor the vote sheets of Chairman Jackson or Commissioner Dicus, who voted for Option 2, referred specifically to the draft Federal Register notice in Attachment 1. Nor did the Commission's Staff Requirements Memorandum of June 30, 1997. Thus I do not think that the Commission's vote for Option 2 should be regarded as a vote for the Federal Register notice as drafted by the NRC staff, and my criticisms of the notice are directed at the NRC staff, not at the Commission.

The NRC staff has already acknowledged, at the November 5 Commission meeting, that SECY-97-124 misinformed the Commission as to one element of the procedural history of the KI issue: it was the NRC, not FEMA, whose opposition to stockpiling helped produce -- almost -- the reaffirmation of the 1985 policy in 1995. The same lack of perspective (to use the mildest term possible) that was responsible for that misstatement can be seen in the staff's

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[1] All that SECY-97-124 had to say about the draft notice was the following, at p. 10: "Attachment 1 contains a proposed Federal policy on KI that reflects the key elements of this option. It incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, acknowledges the developments in the area of NBC events regarding KI but does not alter the current emergency planning requirements."

draft Federal Register notice, both in the selection of the facts it chooses to report and in its overall tone, which is heavily slanted against KI.

I would therefore be remiss if I did not candidly advise the Commission that the draft Federal Register notice, if issued in its present form, is likely to bring nothing but opprobrium to the NRC and to FEMA. In large measure, the notice's failings speak for themselves. What is one to say about a notice that does not get around until page 8 to mentioning that the prevention of cancer is the primary purpose of using KI? What is one to say about a purported history of the KI issue that describes how the FRPCC almost reaffirmed the 1985 KI policy two years ago, but does not mention Chernobyl, even though that accident has produced an extraordinary wealth of new data both on radiation-caused thyroid cancer and on the safety and efficacy of KI?

Can the NRC staff really mean to suggest that it is important that the public learn all about petty bureaucratic maneuverings that occurred in 1994 and 1995, but nothing about the upsurge of childhood thyroid cancer taking place now in the former Soviet Union? This is the way to court not merely criticism, but also ridicule and contempt.

I have tried, therefore, to offer suggestions to make the notice more informative to the reader, more balanced in substance and tone, and less susceptible to being quoted out of context.

For example, I think it is unwise for the NRC and FEMA to embrace too vigorously the line, "no new information that seriously challenges the bases for the 1985 recommendations." It is worth asking the staff to explain exactly what that line means. The ordinary reader is likely to interpret it to mean that there is no new information bearing significantly on the KI issue. That, however, would be demonstrably untrue. Rather, the sentence seems to mean that the 1985 policy was based on a cost-benefit analysis which showed that KI was not cost-beneficial, and the Government has not received any new information suggesting otherwise.[2] But of course, the discussion of KI in the last several years, including the Government's decision to stockpile the drug for NBC terrorist events, has all been based on prudency, not on cost-benefit considerations.

If the Commissioners or the EDO were sometime called upon to explain this sentence, and it turned out to mean what I suggest it seems to mean, would

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[2] It would not even be correct to say that there is no new information challenging the cost-benefit analysis that was the basis of the 1985 "not worthwhile" policy. The reanalysis of costs and benefits in 1992 showed the ratio of costs and benefits to be almost equal for close-in populations, whereas the cost-benefit analysis that underlay the 1985 policy showed an extremely high ratio of costs to benefits.

they feel comfortable that the notice had done a good job of informing the public? Or would the sentence seem, on examination, to be a cleverly worded way of disguising the fact that an enormous amount of new information bearing on the value of KI has emerged since 1985? I believe that Government agencies should be careful to speak so clearly and forthrightly on issues like these that they never leave themselves open to the charge, just or unjust, of having used words artfully to create a misleading impression.

At one point, I have included the words "reasonable and prudent," on the assumption that the Commission would not be proposing to offer KI to states and localities, and the Government would not be stockpiling KI now, if stockpiling of KI were not regarded as a reasonable and prudent measure. I highlight this only because I do not want to give anyone the excuse to accuse me of trying to slip something into the notice without the Commission's being aware of it.

Finally, I have also suggested some additions to, and one deletion from, the list of references.

Please note that this submission is, as in the past, submitted in my capacity as a member of the public, not in my official capacity as Counsel for Special Projects in the NRC's Office of the General Counsel. It was written on my own time, at home, using my own computer and materials, and relying on information available to the public in the NRC's Public Document Room.

Sincerely,

Peter Crane

Peter G. Crane

Attachments: Draft rule change with Statement of Considerations
Markup of draft Federal Register notice from SECY-97-124

cc: Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Executive Director for Operations
General Counsel
Director, Federal Emergency Management Agency

PROPOSED RULE CHANGE

For the reasons set forth in the Statement of Considerations, the NRC is proposing to change the planning standard in 10 CFR §50.47(b)(10) by adding one sentence, as indicated by underlining:

> (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.

STATEMENT OF CONSIDERATIONS

The Nuclear Regulatory Commission is proposing to amend its emergency planning rules, codified at 10 CFR §50.47(b)(10), to clarify the requirement that emergency plans must demonstrate that "a range of protective actions has been developed" for protecting the public in the unlikely event of a radiological emergency.

As amended, the regulation will spell out that in developing emergency plans, states must consider the following: evacuation, sheltering, and the use of radioprotective drugs (i.e., potassium iodide, or KI).

Potassium iodide, if taken in time, can protect against radiation-caused thyroid cancer, as well as hypothyroidism and benign thyroid nodules. Children's thyroid glands are particularly sensitive to these effects. Since the efficacy of KI in protecting the thyroid depends on timing (i.e., administering it either before or within a few hours after the exposure to radioactive iodine), the NRC believes that stockpiling of KI in the vicinity of nuclear power plants is a reasonable and prudent measure.

This proposed rule change 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 accident. Rather, the rule change primarily reflects lessons learned from the Chernobyl disaster of 1986, both about the consequences of an accident and about the safety and efficacy of KI.

The Chernobyl accident demonstrated that thyroid cancer can indeed be a major result of a large reactor accident. Moreover, although the Food and Drug

Administration declared KI "safe and effective" as long ago as 1973, the drug had never been deployed on a large scale until Chernobyl. The experience of Polish health authorities during the accident has provided confirmation that large scale deployment of KI is indeed safe. Further reassurance about the safety of KI comes from a U.S. study of potential adverse reactions to KI, which is an ingredient in many cough and cold medicines. This study showed 38 million equivalent doses without a single adverse reaction being reported. According to the World Health Organization, children are even less likely than adults to experience allergic reactions to KI.

The NRC therefore recommends that states make KI stockpiling one of their tools to prepare for the unlikely event of a major nuclear accident with offsite releases of radioactivity. While NRC strongly encourages the stockpiling of KI by the states, it does not mandate it under this rule change. The rule change requires only that states consider KI stockpiling in developing the "range of protective actions" mandated by the NRC's emergency planning rules.

The NRC has previously decided (on June 30, 1997) to support a change in federal policy by which supplies of KI will be made available, paid for by the Federal Government, to states that request it. The rule change proposed in this notice is consistent with that change in policy, and clarifies the effect of the policy change on the NRC's emergency planning rules.

The use of potassium iodide is intended to complement, not to replace, other protective measures. This rule change thus represents no alteration in 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, when that is feasible. (Evacuation protects the whole body, whereas potassium iodide 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.

The approach taken in this rule change is consistent with International Basic Safety Standards issued by the International Atomic Energy Agency, et al.; with the Federal Radiological Emergency Response Plan, issued by the Federal Emergency Management Agency in 1996; and with recommendations of the President's Commission on the Accident at Three Mile Island, the World Health Organization, and the American Thyroid Association, which represents physicians specializing in thyroid disease. Stockpiling of the drug is currently the practice in numerous European countries, as well as Japan, Canada, and three U.S. states: Alabama, Tennessee, and Maine.

In the event that a state, having considered the NRC's recommendation to stockpile KI, nevertheless decides not to include KI stockpiling in its emergency plan, it would still have access, in the event of a radiological emergency, to the various stockpiles of the drug that have been created by the Federal Government as part of readiness for acts of "NBC" (nuclear, biological, and chemical) terrorism. These stockpiles will be available on an ad hoc basis for radiological emergencies of all kinds. However, because experience shows that pre-planning is more effective than ad hoc responses to emergencies, and because pre-positioning of KI is likely to mean quicker access to supplies of the drug in an emergency, the NRC believes that it is reasonable and prudent to maintain stockpiles in the vicinity of nuclear reactors and to include provisions for their distribution in emergency plans.

The NRC recognizes that the decision to stockpile KI presents issues of how best to position and distribute the medicine, to ensure, e.g., that optimal distribution takes place in an emergency, with first priority given to protecting children; that persons with known allergies to iodine not take it; that members of the public understand that KI is not a substitute for measures that protect

the whole body; etc. To date, these issues have been addressed in different ways in the numerous countries that currently stockpile KI. The NRC intends to work with states and localities to develop guidance on these and other points relating to the use of KI. The NRC believes that these implementation issues are soluble, given the level of expertise in the relevant federal and state agencies.

It is expected that FEMA or the FRPCC will provide guidance to states to assist their consideration of the issue of KI stockpiling, and that it will offer technical assistance to help those states which decide in favor of stockpiling to incorporate it into their emergency plans. It is expected that states will inform FEMA and the NRC of the results of their consideration of whether or not to opt for stockpiling. This will enable the Federal Government to provide KI as expeditiously as possible to states which desire it, as well as to provide any further assistance that may be called for, and it will also allow the Government to engage in better contingency planning for states that decide against stockpiling KI.

Billing Code 6718-06-P April 16, 1997

FEDERAL EMERGENCY MANAGEMENT AGENCY

DRAFT

Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

AGENCY: Federal Emergency Management Agency.

ACTION: Issuance of Revised Federal Policy on Potassium Iodide for Thyroid Protection in Radiological Emergencies.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) is issuing this revised Federal policy concerning the purchase, stockpiling, and use of the drug potassium iodide (KI) as a prophylaxis to protect the thyroid gland in the unlikely event of a major radiological emergency at a commercial nuclear power plant. Taken in time, KI blocks the thyroid's uptake of airborne radioactive iodine, and thus could help [reduce] prevent thyroid cancer and other thyroid diseases, especially in children, caused by such exposure. It can therefore complement other protective actions, i.e., evacuation and in-place sheltering, used to protect the general public in a radiological emergency. Believing that KI stockpiling is a reasonable and prudent measure, the Federal Government will purchase supplies of KI for those states (or in some cases, local governments) that elect to make KI part of their emergency plans.

Current [The] Federal policy [is] already provides that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of [public] protective actions for the general public for severe accidents at commercial nuclear facilities, the [best] available technical information indicates that evacuation and in-place sheltering provide [adequate] the best protection for the general public, because they protect the whole body. KI provides additional protection for one radiation-sensitive organ, the thyroid, when used in conjunction with evacuation and/or sheltering. However, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

ATTACHMENT 1

by the Federal Government.

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[1]. 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, a limited stockpile of KI is being established by the Federal government at a number of sites around the U.S. These ~~This~~ Federal stockpiles will be available to any State for any type of radiological emergency, at any time.

[1]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The policy herein incorporates changes recommended by the FRPCC's Subcommittee on Potassium Iodide, and supersedes the 1985 Federal policy (50 FR 30258). The principal difference between this revised policy and the 1985 version are the addition of the offer of the Federal Government to purchase a supply of KI for States at a State's request, and the establishment of a Federal stockpile. The Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

For Further Information Contact: William F. McNutt, Senior Policy Advisor, Room 634, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2857; facsimile (202 646-4183.

and the explicit recognition by the Federal Government, reflected in the offer to purchase KI, that this medicine can complement other protective measures and thereby enhance protection of the public

Background

This policy on use of KI as a thyroidal blocking agent is the result of a Federal interagency effort coordinated by FEMA for the FRPCC. On March 11, 1982, FEMA issued a final regulation in the Federal Register (47 FR 10758), which delineated agency roles and responsibilities for radiological incident emergency response planning (44 CFR 351). One of the responsibilities assigned to the Department of Health and Human Services (HHS) and in turn delegated to the Food and Drug Administration (FDA) was providing guidance to State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g., KI) to reduce radiation doses to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the June 29, 1982 Federal Register (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of KI. The Federal policy on stockpiling and distribution of KI was published in the July 24, 1985 Federal Register (50 FR 30258). On September 11, 1989, the American Thyroid Association requested FEMA, as Chair of the FRPCC, to reexamine the 1985 policy and to revisit the issue of stockpiling and distribution of KI for use by the general public. In response, the FRPCC established an Ad Hoc Subcommittee on Potassium Iodide. [On December 5, 1994, the FRPCC adopted the report and recommendations of the Ad Hoc Subcommittee on Potassium Iodide, which reaffirmed the Federal position as expressed in the 1985 policy.]

[

COMMENT: IT IS A STRANGE APPROACH TO HISTORY THAT FINDS THE FRPCC VOTE WORTH MENTIONING TO THE PUBLIC BUT NOT CHERNOBYL. THE FRPCC DETERMINATION WAS NOT PUBLISHED BECAUSE FEMA REALIZED THAT IT HAD BEEN BASED ON INCOMPLETE INFORMATION. THUS THIS SENTENCE MAY LEAD THE READER ASTRAY.

THE PHRASE "WITHOUT CHANGING FEDERAL POL.?" CAN EASILY LEAD TO CONFUSION.

On April 3, 1996, in connection with a September 9, 1995 Petition for Rulemaking submitted to the Nuclear Regulatory Commission (NRC) on this issue, the FRPCC established a new Subcommittee on Potassium Iodide to review current information. The Subcommittee conducted a public meeting on June 27, 1996. Based on the information collected, the Subcommittee concluded that there was no new information that seriously challenges the bases for the 1985 recommendations concerning public use of KI for radiological emergencies at nuclear power plants. However, several recommendations were made to the FRPCC. The Subcommittee's three recommendations were: 1) without changing the Federal policy [that it is] by interceding in the State's prerogative to make its own decisions on whether or not to use KI, the Federal government (NRC, or through FEMA) should fund the purchase of a stockpile for any State that, hereinafter, decides to incorporate KI as protective measure for the general public; 2) The Subcommittee believes the language in the 1985 policy should be softened to be more flexible and balanced. For example, the problem many intervenors observe in the Federal policy is in the italicized statement "The Federal position with...potassium iodide for use by the general public is that it should not be required." It would not be as negative if the last phrase were reworded 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 the State or, in some cases, local governments." and 3) The subcommittee recommends that local jurisdictions who wish to incorporate KI as a protective action for the general public should consult with the State to determine if such arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

NOTE: I RECOGNIZE THAT THIS IS WHAT THE SUBCOMMITTEE SAID. THE PROBLEM IS THAT THE KEY PHRASE IS "THE BASES FOR THE 1985 RECOMMENDATIONS" -- I.E., COST-BENEFIT THE PHRASE "NO NEW INFORMATION" IS EASILY TAKEN OUT OF CONTEXT. IT LAYS THE GOVERNMENT OPEN TO THE QUESTION, "SO NO NEW INFORMATION CAME OUT OF CHERNOBYL?"

The full FRPCC endorsed the subcommittee's recommendations with some modifications.

Policy on Distribution of KI Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

The purpose of this document is to provide Federal policy and guidance with regard to distribution of KI, and its usage as a thyroid blocking agent, around operating nuclear power generating facilities. The issue has been addressed in terms of two components of the population that might require or desire KI use: (1) Emergency workers and institutionalized individuals close to the nuclear power plant site, and (2) the nearby general population. This guidance is for those State and local governments who, within the limits of their authority, need to consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public.

Current Federal policy already provides that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies. In developing the range of ~~public~~ for the general public protective actions for severe accidents at commercial nuclear facilities, the ~~best~~ available technical information indicates that evacuation and in-place sheltering provide ~~adequate~~ the best protection for the general public, ~~However~~, the State (or in some cases, the local government) is ultimately responsible for the protection of its citizens. Therefore, the decision for local stockpiling and use of KI as a protective measure for the general public is left to the discretion of State (or, in some cases, local government.)

because they protect the whole body. KI provides additional protection for one radiation-sensitive organ, the thyroid, when used in conjunction with evacuation and/or sheltering.

by the Federal government.

It is recognized that the State (or in some cases, the local government), within the limits of its authority, can take measures beyond those recommended or required. The availability of KI as a protective measure for the general public supplements other options for public officials responsible for protective action decisions. A few States have indeed included KI as a protective action for the general public. The FRPCC does not want to usurp the State prerogative to incorporate the use of KI as a protective measure for the general public. Therefore, to ensure that States have the option to use KI if they so elect, the Federal government is prepared to provide funding for the purchase of a supply of KI. Any State (or in some cases, local government) which selects the use of KI as a protective measure for the general public may so notify FEMA, and may request funding for the purpose of purchasing a supply of KI.

In addition, the Federal government is also required to prepare for a wider range of radiological emergencies[2]. 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 to any State for any type of radiological emergency, at any time.

The bases for these recommendations are given below.

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[2]In response to new threats, the Federal government broadened the scope of emergency response preparedness to include terrorism, involving nuclear, biological, and chemical agents. As a result, and in support of State and local governments, new resources were identified to be needed in response to such events. About two dozen Metropolitan Medical Strike Teams (MMST) are being established for response to such events. Medical supplies, including KI, are being stockpiled nationally for the use by MMSTs in three locations: East coast, Central, and West coast. The quantity of supplies stockpiled uses a planning basis of 100,000 people for a period of two days.

The NRC and FEMA issued guidance to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG-0654/FEMA-REP-1, Revision 1, in 1980. This guidance recommends the stockpiling and distribution of KI during emergencies to emergency workers and to institutionalized individuals. Thyroid blocking for emergency workers and institutionalized individuals was recommended because these individuals are more likely to be exposed to radioiodine in an airborne radioactive release than other members of the public. In addition, the number of emergency workers and institutionalized individuals potentially affected at any site is relatively small and requires a limited supply of KI that can be readily distributed.

For the general public, in the event of a radiological emergency at a commercial nuclear facility, evacuation and in-place sheltering are considered adequate and effective protective actions. It is well-recognized that the inclusion of KI as a protective measure, in addition to evacuation and sheltering, is beneficial only in very remote circumstances. The use of KI is not without controversy. On the one hand, KI has been shown to be an effective drug for protecting the thyroid from thyroid nodules, ~~or cancer~~ caused by the uptake of radioiodine, especially in children fifteen years of age or younger. On the other hand, there are logistical difficulties, and potential medical side effects associated with the drug, in distributing the drug to the general public in a radiological emergency. Also, KI effectively reduces the radiation exposure of only the thyroid gland from ingested or inhaled radioiodines. While this in an important contribution to the health and safety of the individual, it is not as effective as measures which protect the total body. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and the total body. It is very important to remember that the use of KI is not an effective means

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COMMENT: TO RAISE THE SPECTRE OF SIDE EFFECTS WITHOUT MENTIONING FDA "SAFE EFFECTIVE" OR THE CHERNOBYL DATA LEAVES THE DOOR OUT. OPEN TO CHARGE OF EMPHASIZING THE NEGATIVES AND WITHHOLDING THE POSITIVES. THE FDA IS MENTIONED SEVERAL PARAGRAPHS LATER, TO BE SURE, BUT THIS PARAGRAPH, IF QUOTED BY ITSELF, CAN ONLY BE SEEN AS STRONGLY DISCOURAGING STOCKPILING.

by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods. Therefore, while the use of KI can provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation indicates that the decision to use KI (and/or other protective actions) should be made by the States and, if appropriate, local authorities on a site-specific, accident-specific basis.

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs associated with this program.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.

← THIS CAN'T BE CORRECT; SEE DISCUSSION IN NOUS MEETING.

The 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. Since FDA has authorized the nonprescription sale of KI, it is also available to individuals who, based on their own personal analysis, choose to have the drug immediately available.

Attached is a list of ten references intended to assist State and local authorities in decisions related to the use of KI.

Conclusion

The FRPCC did not find any new information that would require a change in the basis of the existing Federal policy concerning the stockpile or pre-distribution of KI for the general public in the event of a radiological emergency at a commercial nuclear plant. The policy is that KI should be stockpiled and distributed to emergency workers and institutionalized persons during radiological emergencies, but leaves the decision for the stockpiling, distribution, and use of KI for the general public to the discretion of State, and in some cases, local governments. Any State or local government that selects the use of KI as a protective measure for the general public may so notify FEMA and may request funding for the purpose of purchasing an adequate supply.

The incorporation of a program for KI stockpiling, distribution and use by any State or local government into the emergency plans will not be subject to Federal evaluation. This is based on the recognition that the use of KI by the State for the general public is a supplemental protective measure, and on the Federal government's determination that the

AGAIN, STRONG POTENTIAL FOR CRITICS TO ASK IF THE FEDERAL GOVT IS UNAWARE OF THE NEW DATA FROM CHERNOBYL, WHICH IS NOT MENTIONED IN THIS NOTICE

SHOULD DELETE PARAGRAPH

← SEE COMMENT ABOVE

existing emergency planning and preparedness guidance for nuclear power plants is effective and adequate to protect the public health and safety.]

Those States or local governments which opt to include KI for the general population will be responsible for the maintenance, distribution, and any subsequent costs or legal liabilities associated with this program.

As an added assurance, for a broader range of 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, a stockpile of KI will be established by the Federal government. Such a stockpile would consist of individual KI caches at VA hospitals in major metropolitan centers across the country. This supply would be available to any State or local government for any type of radiological emergency.

References

1. National Council on Radiation Protection and Measures (NCRP), "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," NCRP Report No. 55, August 1, 1977.

2. Food and Drug Administration (HHS), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, 43 FR 58798, December 15, 1978.

3. Halperin, J. A., B. Shleien, S. E. Kahans, and J. M. Bilstad; "Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid Blocking with Potassium Iodide," FDA 81-8158, U.S. Department of Health and Human Services (March 1981).

4. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use (Notice of Availability) 47 FR 28158, June 29, 1982).

5. Food and Drug Administration; Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1982). Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.

6. Nuclear Regulatory Commission; Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Reactor Accidents (NUREG/CR-1433, March 1990). Prepared by Sandia National Laboratories for the NRC.

7. Nuclear Regulatory Commission; An Analysis of Potassium Iodide (KI) Prophylaxis for the General Public in the Event of a Nuclear Accident (NUREG/CR-6310, February 1995). Prepared by S. Cohen and Associates, Inc. and Scientech, Inc. for the NRC.

BY NOW, THIS SHOULD BE REGARDED AS DISCREDITED. AT THE VERY LEAST, IT HAS BEEN SUPERSEDED BY THE REANALYSIS IN NUREG/CR-6310 (ITEM 7).

8. Nuclear Regulatory Commission; Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-93-318, November 23, 1993).

9. Nuclear Regulatory Commission; Addendum to SECY-93-318, Re-Evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant (SECY-94-087, March 29, 1994).

Signed:

O. Megs Hepler, III
Chair
Federal Radiological Preparedness Coordinating Committee

I WOULD SUGGEST ADDING THE FOLLOWING REFERENCES

-- EPA-400-R-92-001, MANUAL OF PROTECTIVE ACTION GUIDES AND PROTECTIVE ACTIONS FOR NUCLEAR INCIDENTS (MAY, 1992)

-- WHO GUIDANCE (QUOTED IN NUREG ICR 6310, BUT DESERVES SEPARATE LISTING).

-- INTERNATIONAL BASIC SAFETY STANDARDS FOR PROTECTION AGAINST IONIZING RADIATION AND FOR THE SAFETY OF RADIATION SOURCES (INTERIM EDITION), IAEA (VIENNA, 1994).

-- NAUMAN, J., and WOLFF, J., "IODIDE PROPHYLAXIS IN POLAND AFTER THE CHERNOBYL REACTOR ACCIDENT: BENEFITS AND RISKS," AMERICAN JOURNAL OF MEDICINE, VOL. 94, p. 524 (MAY, 1993).

-- REPORT OF THE PRESIDENT'S COMMISSION ON THE ACCIDENT AT THREE MILE ISLAND (1979)

-- HALPERIN, J., "POTASSIUM IODIDE AS A THYROID BLOCKER -- THREE MILE ISLAND TO TODAY," DICP, THE ANNALS OF PHARMACOTHERAPY, VOL 23 (MAY 1989).