

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: **BRIEFING ON PROPOSED RESOLUTION TO A
PETITION FOR RULEMAKING RELATING TO
USE OF POTASSIUM IODIDE (KI)
FOLLOWING SEVERE ACCIDENT AT A
NUCLEAR POWER PLANT
PUBLIC MEETING**

Location: **Rockville, Maryland**

Date: **Wednesday, November 5, 1997**

Pages: **1 - 81**

DISCLAIMER

This is an unofficial transcript of a meeting of the United States Nuclear Regulatory Commission held on November 5, 1997 in the Commission's office at One White Flint North, Rockville, Maryland. The meeting was open to public attendance and observation. This transcript has not been reviewed, corrected or edited, and it may contain inaccuracies.

The transcript is intended solely for general informational purposes. As provided by 10 CFR 9.103, it is not part of the formal or informal record of decision of the matters discussed. Expressions of opinion in this transcript do not necessarily reflect final determination or beliefs. No pleading or other paper may be filed with the Commission in any proceeding as the result of, or addressed to, any statement or argument contained herein, except as the Commission may authorize.

1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION

3 ***

4 BRIEFING ON
5 PROPOSED RESOLUTION TO A PETITION FOR
6 RULEMAKING RELATING TO USE OF POTASSIUM IODIDE (KI)
7 FOLLOWING SEVERE ACCIDENT AT A
8 NUCLEAR POWER PLANT

9 ***

10 PUBLIC MEETING

11 ***

12 Nuclear Regulatory Commission
13 Commission Hearing Room
14 11555 Rockville Pike
15 Rockville, Maryland
16 Wednesday, November 5, 1997
17

18 The Commission met in open session, pursuant to
19 notice, at 9:30 a.m., the Honorable SHIRLEY A. JACKSON,
20 Chairman of the Commission, presiding.

21 COMMISSIONERS PRESENT:

22 SHIRLEY A. JACKSON, Chairman of the Commission
23 GRETA J. DICUS, Member of the Commission
24 EDWARD McGAFFIGAN, JR., Member of the Commission
25 NILS J. DIAZ, Member of the Commission

ANN RILEY & ASSOCIATES, LTD.
Court Reporters
1250 I Street, N.W., Suite 300
Washington, D.C. 20005
(202) 842-0034

1 STAFF AND PRESENTERS SEATED AT COMMISSION TABLE:

2 JOHN C. HOYLE, Secretary

3 KAREN D. CYR, General Counsel

4 PETER CRANE

5 BILL McNUTT

6 MEGS HEPLER

7 IHOR HUSAR

8 JOSEPH CALLAN

9 MECHANICAL KNAPP

10 FRANK MIRAGLIA

11 THOMAS MARTIN

12 FRANK CONGEL

13

14

15

16

17

18

19

20

21

22

23

24

25

ANN RILEY & ASSOCIATES, LTD.
Court Reporters
1250 I Street, N.W., Suite 300
Washington, D.C. 20005
(202) 842-0034

P R O C E E D I N G S

[9:35 a.m.]

CHAIRMAN JACKSON: Good morning, ladies and gentlemen. This morning we will be briefed by the Federal Emergency Management Agency, Mr. Peter Crane and the NRC Staff regarding the Staff's proposed resolution of Mr. Crane's petition for rulemaking relating to the use of potassium iodine following a severe accident at a nuclear power plant, as well as on the existing policy with respect to stockpiling of potassium iodine.

Before we begin, I would like to especially thank Mr. Hepler and Mr. McNutt, the representatives from FEMA for agreeing to make themselves available for this briefing on a very short notice. And so I understand that the representatives from FEMA will be making the first presentation. So I would ask them to please come forward.

COMMISSIONER MCGAFFIGAN: And, Chairman, I would like to have Mr. Frank Congel from our office of AEOD introduce the FEMA members. He has worked with them over the years.

CHAIRMAN JACKSON: Mr. Congel, would you step to the microphone and do that?

MR. CONGEL: Thank you, Chairman. And good morning, Commissioners.

I am very pleased to have our representatives from

1 FEMA this morning. Leading the group is, as you said
2 earlier, Mr. Megs Hepler. Megs is the director of the
3 Exercises Division and the Preparedness Training and
4 Exercise Directorate of FEMA. He also serves as the Chair
5 of the FRPCC, the Federal Radiological Preparedness
6 Coordinating Committee and, in that capacity, has worked
7 long and hard with us on the issue of KI policy and is
8 uniquely qualified to give you the overview from FEMA
9 perspective, so I am very delighted to have them here.

10 CHAIRMAN JACKSON: Thank you for coming.

11 Mr. Hepler, would you introduce your colleagues,
12 please?

13 MR. HEPLER: Thank you, Frank.

14 Good morning, Chairman Jackson and Commissioners.
15 I also want to thank you for inviting FEMA to appear here
16 this morning at the meeting.

17 I would like to introduce the FEMA staff at the
18 table with me. On my right is Mr. William McNutt. He is a
19 senior policy advisor in FEMA's State and Local Preparedness
20 Division. To my left is Mr. Ihor Husar, who is the chief of
21 the State and Local Regulatory Evaluation and Assessment
22 Branch in the Exercises Division.

23 Joining us also from FEMA are Ms. Elaine Chan from
24 our Office of General Counsel, Ms. Nancy Goldstein from our
25 exercises Division. And Mr. Marcus Weisch from our State

1 and Local Preparedness Division.

2 I am appearing before the Commission this morning
3 on behalf of Ms. Kay C. Goss, the Associate Director for the
4 Preparedness Training and Exercises Directorate. Ms. Goss
5 was called out of town on other business at the last minute
6 and is unable to be with us here this morning but Kay did
7 want me to express her appreciation to all of you for
8 inviting FEMA to appear to discuss the roles and
9 responsibilities of FEMA and the FRPCC in the development of
10 the draft revision of the potassium iodide policy.

11 I have been assigned as the FRPCC chairman since
12 January 1995 because the operational aspects of FEMA's
13 Radiological Emergency Preparedness Program or the REP
14 Program fall under the purview of my division, the Exercises
15 Division. And, as you know, the REP program is responsible
16 for overseeing the offsite radiological emergency planning
17 and preparedness activities of state and local governments
18 and Indian tribal nations around the commercial nuclear
19 power plants.

20 First, I would like to provide some background
21 information on the FRPCC. The FRPCC was established in 1982
22 under Title 44 CFR Part 351 to coordinate all federal
23 responsibilities for assisting state and local governments
24 in emergency preparedness activities for peacetime
25 radiological emergencies. The 351 rule also specifies the

1 federal departments and agencies that are members of the
2 FRPCC and the responsibilities of these departments and
3 agencies. In fact, there are currently 15 departments and
4 agencies that are members of the FRPCC.

5 The regulation also authorizes the establishment
6 of subcommittees to support the FRPCC. These subcommittees
7 have been established to examine specific issues or areas of
8 concern in radiological emergency planning and preparedness.
9 At the present time, we have six standing subcommittees on
10 the FRPCC: Training, Off-Site Instrumentation,
11 Transportation Accidents, Federal Response Exercises and
12 Environment, Food and Health and there are two ad hoc
13 subcommittees one of which is the Potassium Iodide
14 Subcommittee.

15 The initial federal policy as formulated by the
16 FRPCC on the predistribution or stockpiling of potassium
17 iodide around nuclear power plant sites for use as a
18 thyroidal blocking agent by the general public was published
19 in the Federal Register in 1985. Now, the 1985 federal
20 policy stipulated that such a use of potassium iodide is the
21 prerogative of the states and its use should not be
22 federally required.

23 In 1989, the American Thyroid Association
24 requested the FRPCC to reexamine its 1985 policy. So in
25 response to that request, the FRPCC requested the Department

1 of Health and Human Services, as the agency on the FRPCC
2 with major responsibility in this area, to review both the
3 medical and clinical status of the use of potassium iodide.

4 In 1990, the HHS recommended to the FRPCC that,
5 one, the FR -- that the FRPCC 1985 federal policy not be
6 changed since there was no compelling evidence to support a
7 change. HHS also recommended that existing stores of
8 potassium iodide be inventoried and that the FRPCC establish
9 a working group of appropriate FRPCC departments and
10 agencies to address the issue of stockpiling.

11 Now, the FRPCC Ad Hoc Subcommittee on Potassium
12 Iodide was formed in February 1991 in response to the HHS
13 recommendation and this ad hoc subcommittee was charged with
14 two responsibilities: Reexamining the 1985 federal policy
15 on the distribution of potassium iodide and, two,
16 considering the merits of the federal government's purchase
17 and stockpiling of potassium iodide for use by the general
18 public.

19 In carrying out the charge, the ad hoc
20 subcommittee examined scientific aspects of potassium iodide
21 as well as the relationship between the timely
22 administration of the drug and its effectiveness. The
23 subcommittee examined the NRC's cost/benefit analysis and
24 the subcommittee also conducted, through the Conference of
25 Radiation Control Program Directors, the CRCPD, a survey to

1 ascertain the points of view of the states involved.

2 Now, as a result of the review and the data that
3 was collected, this ad hoc subcommittee recommended in
4 September 1994 that no change be made to the potassium
5 iodide policy and that the federal government not purchase
6 and stockpile potassium iodide for the general public.

7 On December 5, 1994, the full FRPCC adopted the
8 report and recommendations of this subcommittee and was in
9 the process of preparing to reaffirm the 1985 federal policy
10 when the September 1995 petition for rulemaking was filed
11 with the NRC and a copy provided to FEMA.

12 In reviewing the petition for rulemaking, FEMA, as
13 chair of the FRPCC, determined that a prudent course of
14 action would be to hold up on reaffirming the 1985 federal
15 policy pending consideration of the information that was
16 presented in the petition. This decision was made in case
17 there was any new information presented in the petition that
18 could potentially affect the policy.

19 During this same time frame, the NRC published a
20 synopsis of the petition and invited the public to review
21 and comment on the petition. The Ad Hoc Subcommittee on
22 Potassium Iodide was reconvened in December 1995 and the
23 full FRPCC was provided a copy of the petition for review at
24 that time.

25 The reconvened subcommittee was charged with

1 reviewing the information that was provided to FEMA and
2 information that had been provided to other federal agencies
3 including the petition for rulemaking, reviewing the
4 comments received by the NRC on the petition and evaluating
5 any relevant new information pertaining to this issue.

6 Mr. William McNutt, who I introduced, was
7 designated as the chairman of the reconvened ad hoc
8 subcommittee and other members were assigned to the
9 subcommittee from the NRC, the Department of Veterans
10 Affairs, the Environmental Protection Agency, the Centers
11 for Disease Control and the Food and Drug Administration.

12 In order to ensure a full and balanced review of
13 this issue, the subcommittee conducted a public meeting in
14 June 1996 to which the commentators on the petition and other
15 interested members of the public were invited to attend and
16 make presentations. Representatives from state governments,
17 the CRCPD, the nuclear utilities, the Nuclear Utility Trade
18 Association and public interest groups as well as a
19 university professor and the Petitioner presented their
20 comments at this June 1996 public meeting.

21 Upon considering the information presented at the
22 meeting, the subcommittee concluded that there was no
23 compelling new information that seriously challenged the
24 basis for the 1985 federal policy. However, the
25 subcommittee did come up with three recommendations.

1 One, without changing the federal policy and
2 without interfering in the states' prerogative to make its
3 own decision on using potassium iodide for the general
4 public, the federal government should purchase a stockpile
5 of KI for any state wishing to include it as a supplemental
6 protective action for the general public. The language in
7 the 1985 federal policy should be softened to be more
8 flexible and balanced. That was the second recommendation.
9 And the third recommendation was local jurisdictions wishing
10 to incorporate the use of potassium iodide in their
11 protective actions should consult with their state officials
12 and be aware that a choice to use potassium iodide would
13 entail the assumption of responsibility for developing plans
14 for its distribution.

15 In October 1996, the full FRPCC unanimously
16 approved the ad hoc subcommittee's recommendations. In
17 addition, in June 1997, as you know, you voted three to two
18 to support the FRPCC's recommendation. The June 1997
19 Commission vote also acknowledged the availability of
20 federal medicinal stockpiles that include potassium iodide
21 under the Nuclear, Biological and Chemical Terrorism
22 Preparedness Program that is being implemented throughout
23 the federal government. The terrorism preparedness program
24 was established pursuant to the June 1995 Presidential
25 Decision Directive PDD-39 and, as a result of,

1 Nunn-Lugar-Domenici legislation directing federal agencies
2 to reduce vulnerabilities to nuclear, biological and
3 chemical terrorism threats.

4 The plans are to have medicinal stockpiles located
5 in 27 metropolitan areas throughout the nation and in three
6 national stockpiles in the eastern, central and western
7 portions of the United States. Medicinal stockpiles have
8 already been established in Washington, D.C.; Denver,
9 Colorado; Los Angeles, California and Durham, North
10 Carolina.

11 So where do we stand today with the FRPCC's draft
12 revised policy? A draft Federal Register notice which
13 embodies the FRPCC recommendations has been prepared. The
14 notice specifies that if a state chooses to select potassium
15 iodide as a supplemental protective action for the public,
16 it can notify FEMA and request NRC funding for its purchase.
17 For those states that do opt to include the use of potassium
18 iodide for the general public as a supplemental protective
19 measure, FEMA's evaluation will be limited to the
20 decisionmaking process only and we view this as an important
21 part of our responsibility in ensuring the public's health
22 and safety.

23 Since the full FRPCC membership vote in October
24 1996, FEMA has been working with the NRC staff to develop
25 the Federal Register notice announcing the revised policy.

1 At the present time, we are waiting for the final NRC
2 concurrence on the wording of the notice. Once we receive
3 the NRC's concurrence, we intend to fulfill our commitment
4 to the rest of the FRPCC members by circulating the final
5 draft notice to the full FRPCC membership for their final
6 review and final concurrence. We have indicated to the
7 FRPCC members all along that this would be the process that
8 we would follow in completing the Federal Register notice.

9 And at this time, once we receive the concurrence,
10 we do not anticipate any major obstacles to finalizing the
11 notice.

12 Once this Federal Register notice is published,
13 there will still be some implementation steps that will need
14 to be taken. For example, we expect to have to consult with
15 the Department of Health and Human Services to help design a
16 public information program on using potassium iodide for
17 those states that might opt to incorporate it as a
18 supplemental protective measure. FEMA and NRC will need to
19 develop procedures for addressing state requests for
20 funding. For example, which states will be eligible for
21 receiving the potassium iodide. Will it be the 10-mile EPZ
22 population or the 50-mile EPZ population and what
23 administrative mechanisms might need to be established to
24 process these requests. Also, the development of any
25 additional guidance for evaluating the state decisionmaking

1 process for using KI might need to be taken.

2 In closing, I would like to acknowledge the
3 contributions of those public groups and individuals who
4 provided very thoughtful and sincere comments and made
5 presentations at our June 1996 public meeting. I also want
6 to emphasize the importance that FEMA and the FRPCC placed
7 on maintaining the integrity and the credibility of our
8 deliberations and recommendations on this issue. I am very
9 proud of the way the FRPCC and FEMA have conducted this
10 review. I have only the highest regard and respect for the
11 professionalism and conscientiousness of the individuals who
12 have been involved and the seriousness with which they have
13 carried out their responsibilities.

14 And I can tell you it has been a privilege for me
15 to be associated with these individuals and I do want to
16 commend them for their dedication to this effort to ensure
17 public health and safety.

18 That concludes my remarks this morning and, again,
19 Chairman Jackson, I thank you for inviting FEMA to appear.

20 THE COURT: Thank you.

21 Will you be submitting your statement for the
22 record?

23 MR. HEPLER: Yes.

24 THE COURT: Thank you.

25 We will just go down the line.

1 Commissioner Dicus?

2 COMMISSIONER DICUS: On the evaluation of the
3 decisionmaking process by a state that chooses to stockpile
4 KI for use by the public, two points. Are you -- are you
5 talking about evaluating -- that this would be something
6 they would need to put into their off-site plans and that
7 would be evaluated and how it stands in the plan, I suppose,
8 by the RAC and, number two, would it become an exercise
9 objective for score in an evaluated exercise?

10 MR. HEPLER: We do currently evaluate the
11 decisionmaking process on potassium iodide for emergency
12 workers and institutionalized persons. So we would just
13 expand that to include the decision for the use by the
14 public and it would probably become another small aspect of
15 the exercise.

16 COMMISSIONER DICUS: Okay, another question, then
17 are you -- for states that have chosen to stockpile but not
18 predistribute, are you looking at their plans for
19 distribution should it be necessary?

20 MR. HEPLER: We would expect them to incorporate
21 the program in their plans but we do not have any intention
22 to embark on a detailed evaluation on the distribution
23 effort.

24 COMMISSIONER DICUS: Okay. And then for those
25 states that choose not to stockpile for the use by the

1 public but because of an instant, be it at a power plant or
2 a foreign incident that impacts the states, which has
3 happened before, or another kind of incident at a
4 radiopharmaceuticals supply house, for example, and then
5 chooses to have KI, what -- what planning process do you
6 have in place to get the KI from a central location to the
7 state and distributed? Where are you in your planning
8 process with that?

9 MR. HEPLER: I'm not aware -- I don't believe we
10 have a planning process for that eventuality.

11 CHAIRMAN JACKSON: So therefore, how are you
12 getting it from the stockpiles to where it might be desired?
13 You don't have that as part of your own plan?

14 MR. HEPLER: No.

15 CHAIRMAN JACKSON: Commissioner Diaz?

16 COMMISSIONER DIAZ: I was trying to get from your
17 presentation, I think it is policy and issues and history is
18 laid out but I haven't heard a specific opinion if RCCP had
19 evaluated the technical merits of itself. Is potassium
20 iodide an effective thyroid blocker that would actually
21 prevent the ingestion and potential damage to the thyroid of
22 radioisotopes that has been released into the air?

23 MR. HEPLER: In the Federal Register notice, we do
24 acknowledge the fact that it is an effective thyroid
25 blocking drug.

1 Bill, did you want to expand on that?

2 MR. McNUTT: It is and it is considered safe and
3 effective.

4 COMMISSIONER DIAZ: Safe and effective.

5 MR. HEPLER: The actual notice does discuss that
6 point.

7 COMMISSIONER DIAZ: And so the key issue is
8 whether KI complements the issues of evacuation and
9 sheltering in a cost-effective manner? Is that on what your
10 decision is based?

11 MR. HEPLER: Yes, we believe it is a supplemental
12 measure to evacuation and sheltering.

13 COMMISSIONER DIAZ: Supplemental or --

14 MR. HEPLER: It could complement but it is
15 supplementary. We still view evacuation and sheltering as
16 the primary preferred protective measures.

17 COMMISSIONER DIAZ: Thank you.

18 CHAIRMAN JACKSON: Commissioner McGaffigan?

19 COMMISSIONER MCGAFFIGAN: I have several questions
20 so bear with me for a minute.

21 Following up on Commissioner Dicus, I was hoping
22 you were going to have a different answer to her last
23 question, namely the planning process for the three national
24 sites and the 27 local sites. Presumably, there is a
25 planning process in another part of FEMA, maybe with

1 military uniforms on, that looks at what happens in a CPW
2 emergency in CPW and is going to be able to deliver whatever
3 is necessary in that event. Is that the case?

4 MR. HEPLER: Well, the entire terrorism
5 preparedness program is currently evolving. It is a fairly
6 new effort in the federal government and there are, like I
7 said, other federal agencies involved and other components
8 of FEMA that are involved in that effort and I just can't
9 answer that question at this point on detailed planning for
10 distribution of KI if there should be a terrorist incident.

11 COMMISSIONER MCGAFFIGAN: The policy states on
12 page 4 the stockpiles would be available on an ad hoc basis
13 in the event of an accident at a commercial nuclear power
14 plant and I am trying to figure out, I was recently involved
15 in an exercise. You know, we always push these exercises to
16 places where they are -- through artificial means where
17 there is a significant release and then you have to think
18 about whether KI is appropriate and in that case we, on an
19 ad hoc basis, we asked the state again, do you want it? And
20 they declined.

21 But if, god forbid, there were an accident in
22 North Carolina today and Durham is right there, we
23 have -- we would have to -- ad hoc really means ad hoc. We
24 do it on the spot, ask the state again, if the plant looks
25 bad enough, there's iodine in it, do you need it, is that

1 the intention at the moment?

2 Does that mean that when we have these exercises
3 which we run and you participate in, we should start
4 building that into the ad hoc decisionmaking in the
5 exercise? You know, have a check point, you know, we think
6 we could get to you within X hours some potassium iodide
7 from one of these 31, 30 locations, do you want it?

8 MR. HEPLER: That might be an interesting aspect
9 to add into the exercises in the future.

10 COMMISSIONER MCGAFFIGAN: Is there a problem -- I
11 come out of the defense sector. Are these locations where
12 the antidotes are all located classified locations? Because
13 you don't want terrorists to be able target them?

14 MR. HEPLER: No, they are mainly going to be in
15 the larger metropolitan areas.

16 COMMISSIONER MCGAFFIGAN: But the exact location
17 is not classified?

18 MR. HEPLER: Exactly where the stockpile or the
19 drug cache is stored itself?

20 COMMISSIONER MCGAFFIGAN: Right.

21 MR. HEPLER: I can't answer that; I don't know.

22 COMMISSIONER MCGAFFIGAN: Okay. I suspect it will
23 be because of the obvious needs for security, from itself
24 being targeted.

25 I just suggest that you really do think through

1 what I see as two parallel streams here. I suspect that
2 this -- because of the proliferation danger, that the
3 military is going to take very seriously -- the CIA just
4 doubled the size of its proliferation center according to
5 the newspaper yesterday. They are going to take very
6 seriously this CBW and NCBW threat and is going to put in
7 place plans. It will probably be the National Guard in each
8 state that will be the natural place for them to work with.
9 And it is a different set of officials from the officials
10 that you normally work with and getting those two parallel
11 tracks to intersect at appropriate points I think would be
12 very useful.

13 MR. HEPLER: In fact, that's already been
14 recognized as an issue that needs to be dealt with in this
15 whole preparedness program, getting the states and the
16 locals and the federal entities all dealing with each other
17 and singing from the same sheet of music.

18 COMMISSIONER McGAFFIGAN: The issue of no new
19 information, I'm not going to beat that horse very hard but
20 did your subcommittee look at the decisions made by other
21 nations? I mean, we are fast becoming an outlier in not
22 building this in as a protective measure. Other nations in
23 Europe, as a general measure, have. And was there any
24 consideration given to the international decisionmaking that
25 has been made?

1 I know that we've softened our policy and I
2 welcome that.

3 MR. HEPLER: Bill, do you want to address that as
4 subcommittee chair?

5 MR. McNUTT: Sure. We considered what other
6 nations were doing as well as the aftermath of Chernobyl.
7 But the differences are around our commercial power plants
8 we have quite comprehensive emergency planning and that, in
9 concert with the states' preferred and primary protective
10 action of evacuation, we -- you know, we took all of this
11 into account.

12 I would like to go back a little bit to the issue
13 of planning in general. During the deliberations of the
14 second subcommittee, the report was issued in September of
15 '94. The subcommittee determined that a stockpile would not
16 be in the best interests of the states. The states in an
17 overwhelming response to our survey stated that evacuation
18 was the best and the whole body of protective action.

19 However, the subcommittee did say, it did state
20 that in the event that a state would opt to use potassium
21 iodide for the general public, there would need to be a
22 stockpile at least close to the EPZ where the drug would be
23 distributed or, perhaps, even distributed into the homes.
24 So we recognize that planning is an essential part.

25 One of the problems that the states stated in

1 opposition to the drug was the logistical problems in the
2 distribution.

3 COMMISSIONER MCGAFFIGAN: Let me just -- I was
4 listening very carefully to your statement and looking at
5 the Federal Register notice simultaneously and there were a
6 couple of edits that you made as you were going along.
7 There is the word supplemental, where you made a change from
8 the previous policy and decided to incorporate KI as a
9 supplemental protective measure. You said "supplemental,"
10 it's not in the page 3 of the draft and probably -- it is in
11 other places.

12 But I think anybody, Peter Crane has only
13 advocated this and the American Thyroid Association as a
14 supplement to evacuation and they believe a complement,
15 because you could put it at the centers and get people to
16 more willingly come to the centers.

17 Again, following up on Commissioner Dicus' first
18 couple questions, when you read your statement you said that
19 this would not be subject to FEMA evaluation and the notice
20 says federal evaluation and I think Commissioner Dicus has
21 already gotten to the point that this would be evaluated in
22 exercise as a small matter but it would be evaluated in
23 exercises.

24 There is also a rule that we have, Part 50, that
25 says a nuclear power reactor licensee may make changes to

1 their plans without Commission approval only if the changes
2 do not decrease effectiveness of the plans and the plans as
3 changed continue to meet the standards of 5047(b).

4 There is a question there. I mean, one of the
5 arguments on the logistical side that have been used against
6 this that Mr. Crane may address and has addressed previously
7 is that this complicates other aspects of the evacuation
8 plan. He doesn't believe that and I guess you all now don't
9 believe that or else you wouldn't be able to state that this
10 is a -- you know, sort of blanket that there won't be any
11 federal evaluation of the change because if there -- if it
12 could be, if the evacuation could get complicated or other
13 aspects could get complicated, then this would kick in and
14 then there would be an NRC evaluation if the licensees
15 change.

16 So I am just trying to probe on this. When you
17 spoke, you said FEMA. Did you mean federal? And if you
18 meant federal, is it a blanket judgment that we are making
19 that this is now a supplemental measure that can only be
20 constructive?

21 MR. HEPLER: When I say FEMA evaluation, I mean
22 FEMA's evaluation as being in charge of the FRPCC and the
23 regional assistance committee members so, in essence, I'm
24 saying federal evaluation.

25 COMMISSIONER McGAFFIGAN: What about -- are you

1 making a blanket judgment that, as a supplemental measure
2 this can only be constructive so that this 50.54(q) doesn't
3 kick in which I just read to you that nuclear power licensee
4 may make changes to these plans only with Commission
5 approval -- without Commission approval only if the changes
6 do not decrease the effectiveness? So we are making a
7 blanket judgment that the incorporation of KI does not
8 decrease effectiveness?

9 COMMISSIONER DICUS: But doesn't that apply to the
10 licensees and not to the off-site authority?

11 COMMISSIONER MCGAFFIGAN: Right, but will our
12 licensees if it's in the plan have to incorporate? I mean,
13 it's a change. Do they have to incorporate it into their
14 overall plans?

15 CHAIRMAN JACKSON: Why don't we --

16 COMMISSIONER MCGAFFIGAN: We can wait for the
17 staff. That may be an unfair question to ask you. We'll
18 ask it of the third panel, perhaps.

19 CHAIRMAN JACKSON: Okay. Are there any other
20 questions?

21 COMMISSIONER MCGAFFIGAN: I think that was the
22 heart of it.

23 CHAIRMAN JACKSON: Okay. Thank you very much,
24 Mr. Hepler, and thank you again for coming out. And I hope
25 that your intention is to remain through the balance of the

1 meetings?

2 MR. HEPLER: It is. Thank you.

3 CHAIRMAN JACKSON: Thank you very much.

4 Next, the commission will hear from Mr. Peter
5 Crane who is appearing before us as a private citizen and as
6 the Petitioner for a rulemaking.

7 Mr. Crane, please.

8 MR. CRANE: Good morning. I'm Peter Crane. I
9 very much appreciate the opportunity to address the
10 Commission. I am here as a private citizen. The statement
11 made is one I prepared at home in my spare time with my own
12 materials and so forth. And I am just like any other member
13 of the public for this purpose and that means not -- that
14 means working off information that is publicly available,
15 not stuff that has come to me in my capacity as an NRC
16 employee.

17 I apologize for the lateness of the written
18 statement. It only occurred to me at about 4:30 this
19 morning that I really ought to have a written statement. So
20 if you see glitches in it, I hope you will be forgiving.

21 CHAIRMAN JACKSON: You are submitting it for the
22 record?

23 MR. CRANE: Yes, I am.

24 I apologize. I went running into Staples at five
25 of 9:00 saying, there is a 9:30 meeting, please give me

1 copies. And I don't have -- I had 20 copies. It is not
2 enough for everybody and I apologize. I think SECY has
3 already one so -- this is the first Commission -- the first
4 Commission meeting on KI in 14 years and I do think it is
5 overdue.

6 Potassium iodide is -- oh, excuse me. Let me back
7 up a second. I just want to say something in praise of
8 FEMA. I have been tremendously impressed by FEMA's handling
9 of this issue. It has been a real privilege getting to know
10 Bill McNutt who has been chairman of the ad hoc
11 subcommittee. The openness, the open-mindedness with which
12 FEMA has approached this, the seriousness and
13 responsibility, they are really coming to grips with the
14 issues has been, I think, admirable. I think the public
15 meeting they had in '96, June of '96 under Mr. McNutt's
16 leadership is really a great example of what
17 Commission -- what government decisionmaking ought to be
18 like and isn't always like. And that included letting
19 people get up and speak from the floor who had things to
20 say, which I'm afraid I'm going to come back to in a less
21 positive context. Because one of the people they heard from
22 was Dr. Jacob Robbins of NIH who is one of the world's
23 foremost specialists in radiation-caused thyroid cancer on
24 several continents. And the American Thyroid Association
25 asked to have 15 minutes for Dr. Robbins to speak on behalf

1 of the ATA and not on behalf of the government and that was
2 turned down and I think that's -- I think the Commission's
3 decisionmaking is impoverished by that decision and I think
4 it's quite regrettable and a little sad.

5 Well, what potassium iodide is all about. It is
6 thyroid cancer. It is preventing thyroid cancer especially
7 in children and we know that it is aggressive, we know that
8 it has a way of spreading to the lymph nodes. The NRC on
9 July 1 issued a press release that announced the
10 availability of KI to the public but it never used the word
11 "cancer" and, to me, that's like announcing Sabin vaccine
12 without mentioning polio. It's not the way to get the word
13 out.

14 The draft Federal Register notice that went to the
15 Commission in June, that mentions the word cancer once and
16 it's buried. It's page 8 of a 13-page draft. Moreover, the
17 notice never says this is a reasonable and prudent measure
18 and states would be well advised to adopt it. Well, if it
19 isn't reasonable and prudent, why are you buying it? And if
20 it is reasonable and prudent, why not say so and say so out
21 loud so the states understand what the issues are, because
22 far too many states don't.

23 At the FEMA meeting, as Mr. McNutt will remember,
24 there was a state official who came in and gave us one of
25 the reasons -- two state officials, one of the reasons not

1 to stockpile, that it wasn't life -- that loss of the
2 thyroid is not life threatening. Well, the loss of a breast
3 isn't life threatening either but the cancer that causes you
4 to lose your thyroid or breast can kill you and, thank
5 goodness it is only rarely fatal but it can be. Senator
6 Harkin of Iowa lost a brother to thyroid cancer last year
7 and speaking as someone who has had thyroid cancer, it can
8 be a very nasty illness even when you don't die of it.

9 Well, I've got to watch my time.

10 The states are beginning to catch on. They've had
11 public meetings. There was one in Maine last December and
12 they decided, their Radiation Advisory Commission decided
13 the same day unanimously to adopt stockpiling and the
14 governor accepted that recommendation. Ohio had a meeting
15 last week. New York State is going to have one in Albany on
16 the 21st. I spoke at the first two. I have asked to speak
17 at the third. Obviously, this is annual leave. I am on
18 annual leave today, by the way.

19 At the meeting in Ohio, I made the point that what
20 do you -- what happens when you don't have KI. Well, the
21 picture -- in Beloruss, Russia and Ukraine, you've got a
22 huge upsurge of childhood thyroid cancer and it is
23 aggressive in children. More aggressive in children than in
24 adults. You see the pictures. What the locals refer to
25 bitterly as the "Beloruss necklace" is a scar that goes from

1 ear to ear. Well, the NRC representative at the Ohio
2 meeting pointed out that that was because of the inadequacy
3 of medical care in the former Soviet Union.

4 So we can take some comfort that if American kids
5 ever get thyroid cancer because there was no KI for them,
6 they will have smaller scars. I would prefer to have no
7 scars.

8 CHAIRMAN JACKSON: Do you want to ask a question?

9 COMMISSIONER MCGAFFIGAN: On this point.

10 CHAIRMAN JACKSON: Sure.

11 COMMISSIONER MCGAFFIGAN: I have heard it argued
12 that in the Ukraine and Beloruss, it was not the respiratory
13 pathway, it was an ingestion pathway that the children that
14 got the children, the cancer, and that that wouldn't happen
15 in this country. You know, the evacuation will take care of
16 the respiration and that ingestion is what, indeed is
17 killing or forcing people to lose thyroids in the Ukraine
18 and Beloruss. But we, you know, would presumably not allow
19 anybody to ingest any of the food that was contaminated by
20 an iodine release. So do you have a response to that
21 argument?

22 MR. CRANE: It is certainly true and, again,
23 Dr. Robbins can speak to this better than I, that the major
24 problem seems to be the milk pathway. Radioiodine deposit
25 on the grass, the cows eat the grass, people eat the milk

1 and there's also agricultural problems. But I don't think
2 you can discount the inhalation pathway either and there is
3 an EPA document from '92 and I could -- it would take me a
4 moment to give you the citation.

5 CHAIRMAN JACKSON: You can provide it for the
6 record.

7 MR. CRANE: Okay. That talks a lot about the
8 inhalation pathway and the danger that people will be
9 exposed during evacuation because according to this
10 automobiles give you only about 10 percent protection. And
11 that document says that the iodine dose to the thyroid may
12 be the driving decision point on whether you have to
13 evacuate or not and there may be circumstances in which
14 sheltering with -- sheltering would be preferable but you
15 can't because the iodine, the dose to the thyroid, would
16 drive the decision.

17 In that case, having KI on hand could make a
18 significant difference and the greatest danger of all as
19 this -- as this EPA report goes into is to the -- to the
20 fetus of the pregnant woman. And the EPA report says that,
21 and again they are not advocating this, but they report it
22 as being in the literature that if you have a dose above 10
23 rads to a pregnant woman, especially I think it is between
24 the tenth and fifteenth weeks of pregnancy, that in Sweden
25 they recommend therapeutic abortion just as a prophylactic

1 measure.

2 Now, the -- I have emphasized all along that I saw
3 KI as a complement. I have compared it to the lifeboats on
4 a ferry. We start from the proposition that ferry boats
5 don't have accidents very often and that if you do have an
6 accident that it's better to be evacuated in a lifeboat.
7 But just in case things go wrong, and things do go wrong,
8 it's better to be safe than sorry and life jackets are --
9 and KI are a very, very cheap insurance policy. How cheap?
10 So cheap that the NRC staff has estimated that for a typical
11 plant, \$1,100 would cover everybody within a five-mile
12 radius of the plant. They've estimated 100,000 to several
13 hundred thousand for the entire country. They've also
14 estimated that it would be -- and this was in '94 -- it
15 would be cheaper to buy a national stockpile of KI than to
16 go on studying whether to do so, which I think is the
17 definition of a no-brainer.

18 You know, I feel very strongly that we have
19 not -- we, the government, and forgive the we's because I've
20 worked here for 22 years and it's easy to slip into that,
21 that the government has not met its responsibility to the
22 states. We are now in a situation where there is KI on hand
23 to protect the sharks at Sea World but not the children who
24 come to see them. This sounds unbelievable but it's true.

25 We have stockpiling in only three states. One of

1 them in Tennessee. And the eight-year-old daughter of the
2 director of Tennessee's program found out that sharks need
3 KI for their health and she persuaded her father that when
4 the KI is out of date, and it's a five-year shelf life, it
5 should be given to Sea World where it goes into the shark
6 tank, which I think is great. It was all written up in
7 National Geographic World. If any of you have small
8 children, ask them for their back issues of National
9 Geographic World.

10 Now, my petition had two major basics. One was
11 that new information, especially the Chernobyl information,
12 makes it very clear that this is something that we ought to
13 do. But I had another basis, which was just as important,
14 which was that the existing policy on KI was flawed from the
15 start. And it was flawed by misinformation that was given
16 to the Commission and to the public and that was at that
17 last Commission meeting of 14 years ago.

18 The transcript of that is a public document and
19 you can see the then commissioners, especially Chairman
20 Palladino, wrestling with the fact that they've been told
21 for years that this is a cheap, sensible measure and
22 Chairman Palladino says, you know, it's only 20 cents. If I
23 survive an accident because of this, I'm going to think
24 that's 20 cents well spent. And the briefer says, surviving
25 is not the issue, it is averting an illness. It is a

1 relatively minor operation, it involves a few days off.

2 I once quoted that "few days off" to a doctor at
3 NIH who was himself a thyroid cancer patient and he turned
4 purple and he said, they should have one, and then
5 immediately went back to being a very professional doctor.

6 In fact, it turned out only later that they were
7 talking about benign nodules. They were talking
8 about -- they used -- they never talked about cancer.

9 Now, last year at the FEMA meeting, I said is
10 there anyone in this room, a two-hour meeting, a two-hour
11 briefing back in '83. I said, is there anyone in this room
12 who thinks you can have an honest discussion of the merits
13 of potassium iodide without talking about cancer. Well, the
14 room was silent.

15 Now, I must say, it disappointed me no end when
16 the commission put out its press release -- maybe I
17 mentioned that already. I got up too early this morning.
18 That the press release of July 1 never mentioned cancer,
19 that the draft Federal Register notice in the June paper
20 mentions cancer only once at page 8 of the 13-page draft.

21 Well, I filed a different professional opinion in
22 1989 and I talked about that misinformation issue. And it
23 was given to a DPO committee and the DPO committee simply
24 refused to touch it. And the director of Research said,
25 yes, when I pointed that out to him. Yes. And he bumped

1 the DPO report for not having dealt with the issue. It
2 never did get dealt with.

3 So I thought when I filed the rulemaking petition
4 in '95 that the staff, as you know, dealt with my DPO for
5 five years before coming up with an answer that basically
6 endorsed it. But that died on a two-to-two vote of the
7 commissioners. So I thought, well, when I file a rulemaking
8 petition they are going to have to confront this issue of
9 misinformation because if any -- if for no other reason the
10 lawyers aren't going to let them get away with leaving it
11 untouched.

12 Well, you don't see a word about that in the paper
13 that purports to be an analysis of the petition and of the
14 comments and I got that paper, I waited, I insisted on
15 getting it only through channels. I got it Friday. I
16 thought I was going to spend my weekend having to analyze
17 it. I look at the paper and I think, this is the best?
18 This is 26 months of study? This, you know?

19 CHAIRMAN JACKSON: Mr. Crane, we have your
20 petition. But I would like you to do two things for us.
21 One is to state for the record what you believe the
22 misinformation is. And then, secondly, to reiterate for the
23 record exactly what you are asking of the Commission in the
24 petition.

25 MR. CRANE: Okay. Okay.

1 First, for the record, the misinformation
2 consisted of presenting the consequences of radiation caused
3 thyroid disease in a way that made it seem trivial. Their
4 contention was that it was more cost effective to let the
5 disease happen, to take the chance of an accident, let it
6 happen and cure it after the fact than to spend even a small
7 amount, pennies, on prevention that took the adage about an
8 ounce of prevention being worth a pound of cure and turned
9 it on its head.

10 Now, that might be a reasonable approach if the
11 illness were trivial. So it was represented as trivial.
12 They talked about nodules but they didn't say benign
13 nodules. And 40 percent of those nodules can be estimated
14 to be cancerous. And of those cancers, between 5 and 10
15 percent are likely to be fatal. Well, that's a very high
16 cure rate.

17 We have 1,200 deaths from thyroid cancer every
18 year out of about 16,000 new cases. But those 1,200 --

19 MR. CRANE: The record was later corrected as to
20 the Commission, but it was not corrected to the public, and
21 when the Commission went out with a policy statement in 1985
22 that said not worthwhile, I think it was doing a terrible
23 disservice, and I think it was a product of that
24 misinformation.

25 Now, what would I like the Commission to do?

1 I would like the Commission, first of all, to
2 state loud and clear that stockpiling potassium iodide is a
3 reasonable and prudent measure, that it is a back-up
4 provision that can give additional protection and that can
5 help prevent children, especially children, from developing
6 thyroid cancer or other thyroid diseases, including
7 hypothyroidism, in the event of a major nuclear accident.

8 I don't want to alarm people about major nuclear
9 accidents, because they are very unlikely. Our plants are
10 basically safe. Accidents are highly ^{UN}likely. Our plants
11 are well-built; our plants are well-run.

12 Nobody should take me as, for some, you know, mole
13 anti-nuke who is trying to exaggerate the dangers of nuclear
14 energy. I'm not.

15 So, first of all, I would like to have a clear
16 statement, because I think, if you say to the states you
17 would be foolish not to have this, instead of sending them
18 15 years of messages that say you would be foolish to have
19 this, the states will fall into line quickly.

20 You should have seen how quickly Maine -- Maine
21 did their homework, the Maine Radiation Advisory Commission.
22 They read the literature.

23 They read Norman & Wolf's paper on the Polish
24 experience, because the Poles gave out 18 million doses.
25 They had two people hospitalized briefly for side-effects,

1 both of whom had known iodine allergies and took it in spite
2 of being warned not to. That's the best data we have on
3 side-effects.

4 Has anybody -- does any of the staff papers you've
5 gotten in the last few months talk about Norman & Wolf and
6 the Polish data? I don't think so.

7 And you know, the Maine people, they got on the
8 phone to a Dr. Bigas at Maine Medical who's a
9 thyroidologist, and I think if you asked them, they would
10 have expressed a lot of disappointment about the fact that
11 -- that they had to get this information from sources other
12 than the Federal Government.

13 So, I have asked that the Commission clarify by
14 rule change the provision in its rules that says a range of
15 protective actions must be developed.

16 Now, where did I get this language about including
17 evacuation, sheltering, and use of stable iodine? Why
18 didn't I say potassium iodide?

19 Because I was taking the language verbatim from
20 FEMA's Federal Radiological Emergency Response Plan, and
21 that plan, which was issued in proposed form in '94 and in
22 final form in '96, has great procedures for making the
23 decision on when to give out potassium iodide.

24 You're going to have an inter-agency group that's
25 formed. They're going to make recommendations to the lead

1 agency. The lead agency is going to make recommendations to
2 the states.

3 And as I pointed out to FEMA, the only problem
4 with this wonderful procedural setup is that there's not
5 going to be any KI to give out, at least there wasn't when I
6 wrote to them.

7 So, I thought that this was a formal way of
8 getting recognition.

9 Now, none of that suggests that KI is the equal of
10 evacuation.

11 I think I've tried to stress in everything I've
12 said, everything I've written, that the preferred method in
13 an emergency is to evacuate people, get them away, because
14 potassium iodide is not a panacea, it only protects one
15 organ, an important organ, to be sure, but it's just one,
16 whereas evacuation, if you can do it, protects everything,
17 but we all know that evacuation is not always feasible, and
18 you know, what I'm saying is hardly radical.

19 It's recommended by the World Health Organization.
20 The World Health Organization said stockpile in schools,
21 firehouses, hospitals.

22 There are international basic safety standards to
23 which we are a signatory that call for evacuation,
24 sheltering, and potassium iodide as part of evacuation
25 plans.

1 Has the staff ever told you about the
2 international basic safety standards, what they have to say
3 about KI? I'm not aware that they have.

4 CHAIRMAN JACKSON: What would change as a
5 consequence of your petition from the existing, slightly
6 changed policy that is being discussed in the Federal
7 Register notice?

8 What is that is fundamentally different in what
9 you're asking from the policy that the Commission voted
10 earlier this year?

11 MR. CRANE: That it would require that
12 consideration of potassium iodide be given in the
13 formulation of emergency plans.

14 Now, this may sound like a major concession on my
15 part, but I would not ram potassium iodide down the throat
16 of a state that emphatically rejected it. I did say
17 consideration should be given.

18 If that meant that a state said we have looked at
19 potassium iodide, and for the following reasons, we think it
20 is inappropriate to the situation in our state, I would live
21 with that, because I appreciate the role of the states in
22 emergency planning, and I don't really want to see that
23 usurped unnecessarily.

24 CHAIRMAN JACKSON: Is that consistent with your
25 petition?

1 MR. CRANE: Yes, it is. This point may be
2 ambiguous as you read my petition, but this is consistent
3 with my petition.

4 But the petition is definitely coupled with issue
5 a policy statement that makes clear that this is, in the
6 opinion of the NRC, a reasonable and prudent measure, and I
7 think if you do that and especially if it's free, you're not
8 going to have states fighting it, you're going to have
9 states wanting to do it.

10 CHAIRMAN JACKSON: Okay. So, let me make sure I
11 understand.

12 So that the two pieces that I hear you saying are
13 that you want a statement by the Commission along the lines
14 that you elaborated, and the second is that you want the
15 Commission to require consideration -- consideration of KI
16 be given in emergency plans that the state develops.

17 MR. CRANE: That's right. I want more than a
18 statement. I want more than a press release. I want a
19 statement of policy --

20 CHAIRMAN JACKSON: I understood that, that you
21 want a statement of policy from the Nuclear Regulatory
22 Commission. We're not the United States Government. We're
23 an agency of the United States Government.

24 MR. CRANE: Fair enough. Although the FRPCC's
25 role in this is such that policy has been coming from the

1 Federal Government generally.

2 CHAIRMAN JACKSON: Are you ready to address some
3 questions from the commissioners?

4 MR. CRANE: I certainly am.

5 CHAIRMAN JACKSON: I should say other questions.

6 MR. CRANE: Let me do one thing first.

7 I said earlier that -- you know, how much I think
8 it would have been good to hear from Dr. Robbins, and I am
9 going to give you the opportunity to hear from Dr. Robbins
10 after all, because he wrote an excellent letter to FEMA,
11 very short, very pithy, in 1996, and I have to say it didn't
12 take him 26 months to prepare it.

13 Number one, the Chernobyl experience has shown us
14 that thyroid cancer is, indeed, a major result of a large
15 reactor accident even when evacuation is carried out.

16 Number two, the Polish experience has shown us
17 that large-scale deployment of KI is safe.

18 Three, the Three Mile Island experience has shown
19 us that it is not easy to obtain a good supply of KI in an
20 emergency.

21 Four, the shelf life of properly packaged KI is
22 extremely long.

23 Five, the advantage of having a supply on-hand for
24 immediate use far outweighs its moderate cost.

25 Six, the problems attendant on pre-distribution

1 are immaterial for the matter of creating a stockpile.

2 Seven, no one questions the ability of KI to
3 protect the thyroid from radioiodine.

4 Eight, even though KI administration before any
5 exposure is ideal, the Chernobyl experience also has shown
6 us that the exposure can continue for days. Institution of
7 KI blockage at any time in this period is beneficial.

8 I know you're going to want questions, but if I
9 could just sort of sum up kind of briefly that one of the
10 Maine people was quoted in the paper, one of the Maine
11 commission members.

12 He said, knowing what we know, I would rather, 10
13 years from now, explain why we erred on the side of caution.
14 I'm sorry. Ten years from now, if we have a release, I
15 would rather say that we erred on the side of conservatism,
16 knowing what we know.

17 And I think that's the crux of the issue, knowing
18 what we know.

19 Twenty years ago, at the time of Three Mile
20 Island, we were only beginning to know. The president's
21 commission wanted us to stockpile then; we said we would.
22 We reneged on that promise.

23 But if there's another accident, God forbid, not
24 that it's likely, I can hardly imagine what people will say,
25 and this mess that we are in -- and it is a mess -- was so

1 avoidable, because I think the NRC staff had it absolutely
2 right three years ago.

3 They advised the Commission in 1994 -- and I quote
4 -- "It appears prudent to stockpile KI for limited
5 populations located close to the operating nuclear power
6 plants. This option represents an inter-office consensus
7 and is recommended by the NRC staff. While NRC encourages
8 the stockpiling of KI, the decision to stockpile,
9 distribute, and use KI would be the responsibility of the
10 individual states." And I think that was an excellent
11 statement.

12 Unfortunately, the Commission deadlocked two to
13 two, and that policy died, and now the staff is taking a
14 different position.

15 So, I'd like to end by quoting Leo Tolstoy. In
16 1896, he described his proposal, which he said had never
17 been tried but was absolutely sure to work, for solving the
18 problems of government.

19 He said to be honest, not to lie, to act and speak
20 so that your motives for action are understandable to your
21 loving seven-year-old son, to act so that your son doesn't
22 say, Papa, why did you say that then but now say and do
23 something quite different?

24 Thank you.

25 CHAIRMAN JACKSON: Thank you.

1 Commissioner Dicus.

2 COMMISSIONER DICUS: No questions.

3 CHAIRMAN JACKSON: Commissioner Diaz.

4 COMMISSIONER DIAZ: So, let me go back to the
5 bottom line.

6 You are really proposing that the Commission
7 considers putting out its public statement or a rule that
8 establishes that, on our belief of the Commission, if we do
9 that, that that is a prudent measure to take in the case of
10 an accident to help to compensate for the potential health
11 effects of an accident, and that's just as far as you go as
12 far -- you know, what the position of the Commission is as
13 far as policy, and second, that, you know, the Commission
14 would support stockpiling so that the states will make the
15 decision of whether to use it or not. Is that correct?

16 MR. CRANE: That is correct.

17 COMMISSIONER DIAZ: Okay. Thank you.

18 CHAIRMAN JACKSON: That's slightly different than
19 what your second point was a minute ago.

20 MR. CRANE: Well, in addition -- I mean I don't
21 think I was changing my tune.

22 In addition, I would see a rule change that would
23 provide that, when we say in the 16 planning standards --
24 and one of those planning standards is a range of protective
25 actions have been developed that a specific rule change be

1 incorporated using the language taken out of FEMA's Federal
2 Radiological Emergency Response Plan to indicate that that
3 range of protective actions refers to three things --
4 evacuation, sheltering, and potassium iodide, and I would
5 like to see clarification which could readily be done in the
6 statement of considerations for such a rule that what we are
7 talking about is that states give consideration to each of
8 these and make a reasoned decision based on the advice that
9 they've got from the NRC.

10 COMMISSIONER DIAZ: So, in a certain sense, it's
11 just adding some definition to what the Commission just
12 voted on as far as what potassium iodide is as a protective
13 --

14 CHAIRMAN JACKSON: It's actually a rulemaking that
15 you're asking for, which would be a requirement that the
16 consideration of evacuation, sheltering, and KI be
17 explicitly considered as part of states' emergency plan. I
18 mean that's what you indicated to me a few minutes ago.

19 MR. CRANE: Yes.

20 CHAIRMAN JACKSON: Okay.

21 COMMISSIONER DIAZ: I'm trying to understand that
22 the rulemaking is not significantly different from what the
23 Commission already voted on except that it adds for the
24 definition to it.

25 You know, it defines that it is a prudent measure

1 and it defines that it should be considered in the range of
2 actions and it defines that still the state should be the
3 ones to decide.

4 MR. CRANE: The Commission decision that was
5 reached on June 30th is ambiguous. The Commission wisely
6 said in its staff requirements memorandum that the decision
7 it was making on June 30th was not a decision on the
8 petition for rulemaking.

9 So, you could have that Commission decision and go
10 either way on the petition for rulemaking. It's not
11 inconsistent with it. It's not a necessary follow-on from
12 it.

13 COMMISSIONER DIAZ: But I was trying to say that a
14 rulemaking is not inconsistent with the previous position of
15 the Commission but it just adds definition to it.

16 MR. CRANE: It is not inconsistent.

17 I have to say that it is inconsistent with the
18 tone of the Federal Register notice that was proposed to the
19 Commission in that paper, but that Federal Register notice
20 has not yet gone out, and that Federal Register notice would
21 have made clear that there would be no rule change.

22 So, the fact that the Commission, in its staff
23 requirements memo, said we are not making a judgement on
24 whether there was a rule change was a sign that they had not
25 bought, lock, stock, and barrel, the Federal Register

1 notice.

2 So, I think there is time for the Commission to
3 massage that Federal Register notice if it so chooses.

4 COMMISSIONER DIAZ: Okay. Thank you.

5 CHAIRMAN JACKSON: Commissioner McGaffigan.

6 COMMISSIONER MCGAFFIGAN: Let me explore a couple
7 of things with you.

8 In terms of massaging the Federal Register notice,
9 it strikes me that, on page three of the notice -- I don't
10 know whether you've gotten it -- they say that they have
11 decided to soften the Federal position and then they say
12 that they're going to reword a certain part of the previous
13 policy to state it is not required but may be selected as a
14 protective measure at the option of the state.

15 What you're proposing, essentially, is the words
16 "reasonable and prudent" be inserted before "protective" at
17 that point. You're proposing more than that, but that's one
18 thing you're proposing.

19 MR. CRANE: That's one thing.

20 COMMISSIONER MCGAFFIGAN: Do you take any comfort
21 in -- I know from having read some of your previous stuff --
22 the question I asked earlier of FEMA and I'll ask of the
23 staff in a few minutes -- the sort of blanket judgement that
24 this -- that it's implicit or explicit in this notice that
25 there will not be Federal review of any state decision to

1 add this as essentially one of the arguments I know you've
2 been arguing against for years, is that KI poses logistical
3 problems and therefore could detract from evacuation and
4 therefore we shouldn't do it, there's an implicit or
5 explicit recognition in here that that argument is bogus.
6 Do you take any comfort in that?

7 MR. CRANE: Well, I certainly took comfort from
8 what you said. I'm not sure that that was necessary fully
9 in the minds of the authors who put that in, but I think
10 it's a sound logical inference from what's there.

11 COMMISSIONER MCGAFFIGAN: It's a sound logical
12 inference from what's there.

13 MR. CRANE: Yes.

14 COMMISSIONER MCGAFFIGAN: In terms of the 27 plus
15 3 or 4 sites around the country -- I get my arithmetic wrong
16 -- given your advocacy for KI, do you have any
17 recommendations for us with regard to, if these sites are
18 going to be available, any better planning we need to do to
19 take advantage of them on the ad hoc basis?

20 The policy says, on an ad hoc basis, in the event
21 of an accident, these stockpiles would be available.

22 From your experience, what should we be thinking
23 about in terms of planning for the use of these stockpiles?

24 MR. CRANE: Well, I must say I'm troubled about
25 this, because you know, yes, some KI is better than no KI,

1 so the recognition of stockpiles in 27 cities is a good
2 thing. We're better off than we were a year ago.

3 It seems to me, however, that if you want to
4 acknowledge that it's a good thing for a radiological
5 emergency caused by terrorism that it's a good thing for a
6 radiological emergency caused by nuclear power plant
7 accident, as well.

8 The problem is we're talking about a medicine that
9 is time-critical and that's dirt-cheap, we're talking \$1,100
10 a reactor, and I mean this is a medicine that is better if
11 you take it before the accident than after, it's better if
12 you take it one hour after than two hours, two hours than
13 three hours, and so on, and with every moment counting and
14 the cost peanuts, why would you want to have to bring the
15 stuff from Columbus, Ohio, to Cleveland to the Perry plant
16 when you could have it in the Paynesville, Ohio, fire
17 station?

18 COMMISSIONER MCGAFFIGAN: I'm afraid we have to
19 take our progresses step by step in this area.

20 Could you just clarify the 1994 staff
21 recommendation that you site in your statement? Was there a
22 rule change that was going to accompany that?

23 MR. CRANE: No. No.

24 COMMISSIONER MCGAFFIGAN: That's why I asked you
25 the original question. I mean sticking the words

1 "reasonable" and "prudent" into this policy statement -- and
2 maybe there would be some conforming changes that would have
3 to be made -- without having a rule change that would
4 require a formal process in each state to consider this,
5 would that, in and of itself, make significant progress, or
6 in 1994, if the staff was just talking about a policy
7 statement that said it appears prudent to stockpile KI for
8 limited populations located close to operating nuclear power
9 plants and there was no rule change, why was that going to
10 give you comfort if the Commission had not deadlocked then?

11 MR. CRANE: Because I thought that that really
12 would have done the job, it would have made stockpiling a
13 reality. I've said all along -- and people around here have
14 heard me -- that I was more interested in achieving the
15 result than the particular means.

16 The reason I chose a rulemaking option -- I'll be
17 quite candid with you -- is that I wanted to make sure that,
18 if the Commission did not do what I considered to be the
19 right thing, that it would come down in a form that would
20 give rise to judicial review, but I would have been happy
21 with the 1994 outcome, I would have considered that that had
22 done the job.

23 COMMISSIONER McGAFFIGAN: You have the Federal
24 Register notice --

25 MR. CRANE: Yes.

1 COMMISSIONER MCGAFFIGAN: -- of the draft that
2 FEMA has.

3 I'd be interested in, for the record, any changes
4 -- I think you have to be careful -- changes that you
5 consider might be within the confines of the policy that was
6 voted to by a three-two vote, but I personally -- an
7 adjective before "protective" strikes me as something that's
8 in the art of arguing about here, because I also thought
9 that the policy decision was a little bit ambiguous.

10 So, we have to decide how much of an endorsement
11 that we want to give to the states, but if you have any
12 other thoughts as to what could go into the Federal Register
13 notice that would make progress, maybe not as much as you'd
14 like, I'd be interested.

15 MR. CRANE: Well, I could give you a very quick
16 rundown, because there are so many arguments, so many
17 frivolous --

18 CHAIRMAN JACKSON: Could you provide it in
19 writing?

20 MR. CRANE: Oh, sure. Okay.

21 CHAIRMAN JACKSON: And it should not just go to
22 Commissioner McGaffigan.

23 MR. CRANE: Oh, absolutely.

24 CHAIRMAN JACKSON: It should go to the Commission.

25 MR. CRANE: I know that.

1 I think we have to correct the record. I think,
2 when people say there's no new data challenging existing
3 policy, that's nonsense. We've got lots of new data. We've
4 got lots of new data on health effects, we've got data on
5 the safety of KI.

6 When states are under the impression that loss of
7 the thyroid is not life-threatening, we've got to correct
8 them.

9 When we say that it's not cost-effective, well,
10 that cost-effective -- cost-effectiveness is a fine
11 approach, cost-effective analysis, cost-benefit analysis a
12 fine approach, but you've got to use it with reason when
13 you're talking about health measures.

14 You probably know that the way it was used by the
15 staff in the '80s was to say, well, if we balance the cost
16 of the pills against the cost of treating the disease, we
17 find that it's cheaper to treat the disease, so let's let
18 the disease happen and cure it.

19 That makes no sense, and I think we have got to
20 clear the board of this notion about cost-benefit analysis.

21 Even so, you note, probably, that when the staff
22 re-did its cost-benefit analysis several years ago, they
23 said that, for the population within five miles, it was down
24 to a ratio of two to one and with an error band of two
25 orders of magnitude.

1 So, for all we know, it is cost-effective, by
2 their calculations, by as much as 50 to 1.

3 I think we ought to put to rest the notion that it
4 could complicate evacuation.

5 We ought to put to rest the notion that there is a
6 high risk of serious side-effects. I mean has the staff
7 ever told you about their analysis in this NUREG where they
8 talk about 38 million doses without an adverse reaction, or
9 is that news to you all?

10 COMMISSIONER DICUS: That's not news to me.

11 MR. CRANE: Okay.

12 The logistics of distribution need study. They
13 certainly do.

14 There are problems of logistics, but I think the
15 answer to that is the one that Dr. Robbins gave from the
16 floor at FEMA, which is you can make the decision in
17 principle that this makes sense, that it's a reasonable and
18 prudent measure, and then you work out the logistics. We've
19 got enough smarts in this Government to come up with the
20 logistics of how best to get it to people.

21 COMMISSIONER McGAFFIGAN: I had a recent
22 discussion with a state official, and for the first time the
23 argument was thrown out to me that it wasn't the iodine that
24 might have a health effect, it was the potassium that might
25 have a health effect, and I said to this particular person,

1 gosh, maybe we need to make sure people don't eat bananas
2 either.

3 If a person has been told by their doctor not to
4 eat a banana, then they shouldn't take the potassium iodide,
5 but have you ever heard previously or in any of these
6 meetings that you've been involved in for 15 years that the
7 potassium is a health problem, because a state official
8 threw that out at me, and that was news to me.

9 MR. CRANE: Certainly news to me. I don't want to
10 hog the floor more than I already have, but on the issue of
11 allergies -- you know, people who are allergic to iodine, in
12 general, know it, because they're allergic to seafood.

13 On the back of this statement, I stuck the label
14 from our iodized salt, which lists potassium iodide as the
15 agent that's used to iodize it. So, a lot of us may have
16 taken it within the last 24 hours, whether we knew it or
17 not.

18 And as this document also makes clear -- this
19 comes out of the World Health Organization recommendations
20 -- allergic reactions are much less likely in children,
21 infants and children, it's more likely in adults, and that
22 that weighs in favor of giving it to children even when you
23 have -- in an emergency situation -- even when you haven't
24 done a screening, because after all, there are risks that
25 you're going to get hives, you can get pimples, you can get

1 -- in absolutely extreme cases, serious allergic reactions
2 are possible, but we see from Poland and from this data
3 about the 38 million -- and that comes out of cough
4 medicine, because they put KI in cough medicine -- that the
5 risks of thyroid cancer are just so much greater.

6 That was what the Food and Drug Administration
7 said in '78, that the risks of thyroid cancer and all that
8 goes with it just outweigh the risks on the other side.

9 CHAIRMAN JACKSON: Commission Diaz?

10 COMMISSIONER DIAZ: The only thing that I can
11 think of that some people might be taking potassium-sparing
12 diuretics, and as you elevate the amount of potassium, they
13 could get a reaction. There's not a permanent effect. The
14 level of potassium goes down very rapidly.

15 MR. CRANE: Can I have one tiny final word?

16 Everything we know about emergencies says plan,
17 don't do it ad hoc.

18 CHAIRMAN JACKSON: I think we will now hear from
19 the NRC staff.

20 Thank you, Mr. Crane, and if you would submit the
21 information that the commissioners asked for.

22 MR. CALLAN: Good morning, Chairman and
23 Commissioners. The staff will be briefing the Commission on
24 the staff options for resolving the petition relating to
25 potassium iodide.

1 I join this morning with Frank Miraglia, Deputy
2 Director of the Office of NRR, and Mel Knapp, who is going
3 to be the principle presenter, who is the Acting Director of
4 the Office of Research; Tim Martin, who is the Director of
5 the Office of AEOB; and Frank Congel, who is a Division
6 Director under Tim.

7 Mel?

8 MR. KNAPP: Thank you.

9 What I propose is to very, very briefly review the
10 paper, and then we will be available for your questions. In
11 fact, we can proceed directly to the second slide. Many of
12 the things I'm going to say I think have already been
13 visited in this meeting.

14 The first would be to summarize the petition.

15 It is asked that we alter 50.47(b)(10) to be
16 consistent with the material that is provided here in
17 italics.

18 You would add the words, "including sheltering,
19 evacuation, and prophylactic use of iodine have been
20 developed for the plume pathway EPZ for emergency workers
21 and the public," and as he said just a few moments ago, he
22 would have the Commission issue a policy statement saying
23 essentially that KI stockpiling is a sensible and prudent
24 measure necessary to assure that the drug will be available
25 in the event of a major accident.

1 We received that petition in September of '95. In
2 November of '95, we put it out in the Federal Register for
3 public comment.

4 We received 63 comments, 28 were in favor, and
5 that includes environmental groups, members of the public,
6 the American Thyroid Association, as has been mentioned this
7 morning, and there were 35 opposed from utilities, utility
8 organizations, nine states, two state universities, a member
9 of the public, and a letter signed by a number of health
10 physicists.

11 These comments are, to a degree, captured in the
12 six comments that characterize the favorable views and the
13 six that characterize opposing views in enclosure one to the
14 SECY paper.

15 In the paper, as you know, the staff has provided
16 three options for the Commission's consideration: to grant
17 the petition as requested, to include rulemaking; to deny
18 the petition but to develop guidance to address planning for
19 KI distribution for states that include KI for the general
20 public in their planning basis; and to deny the petition but
21 pursue modification of regulations to require licensees to
22 address planning for KI distribution for states that include
23 KI for the general public in their planning basis.

24 With respect to the options, there are some pros
25 and cons which the staff identified.

1 In granting the petition as requested, a few of
2 the pros would be that this would establish a uniform
3 Federal policy on KI -- this was identified by Peter as a --
4 or let's put it this way, when you look at his petition and
5 his views that the policy at the time of the petition were
6 not uniform, this would have provided uniformity, and it
7 would ensure that emergency plans addressed prophylactic use
8 of KI.

9 Among the cons that the staff identified are that
10 this would not, in the staff's view, be consistent with the
11 June '97 SRM and proposed FRPCC recommendations that states
12 should have the option of using KI, and I would note at this
13 point that some of the comments we have here reflects our
14 understanding of the petition as received, and we obviously
15 learned from the discussion this morning a bit more perhaps,
16 and we would also note that, as the rule change, as we would
17 understand it, that licensees and states would be required
18 to incorporate all three protective actions into emergency
19 plans.

20 CHAIRMAN JACKSON: If the Commission granted the
21 petition as requested, what impact would that have on
22 operating reactor licensees?

23 MR. KNAPP: I'd be more comfortable if the folks
24 from AOED were to comment on that.

25 MR. MIRAGLIA: In terms of making it a requirement

1 that would require revisions of the plan, I think more
2 importantly we'd be saying that the licensees would have to
3 prepare without having the state involved, taking the option
4 away from the state.

5 The proposed rule that we talk about in option
6 three would be saying licensees would have to plan if a
7 state chose to use the option.

8 The proposal in the rule would be to make the rule
9 that it's necessary, those three things are necessary in the
10 plan, and so, in terms of how the petition is worded, it
11 would require that KI be considered in emergency plans
12 absent a decision from the state.

13 MR. CALLAN: Chairman, I would like Tim Martin to
14 provide his perspective.

15 MR. MARTIN: Commissioner, there is another issue
16 there.

17 As worded, I would read the proposed rule change
18 to require that -- not only that the three protective
19 actions be considered but that they be required to be
20 developed.

21 I know that at least one site there is a portion
22 where sheltering is not deemed feasible. That could lead to
23 litigation saying that it does not meet the rule and would
24 require possibly an exemption for that particular site.

25 The verbiage we heard from the petitioner today

1 --he was really seeking that it be considered. That's a
2 milder language, and if the language was "considered," I
3 think we can demonstrate in each case that the sheltering
4 and evacuation have been considered, and I think the states
5 would definitely have the ability to consider.

6 I think the second part asking on the policy
7 statement -- we've heard today and we've heard from the
8 Federal Radiological Coordinating Committee that simply
9 stockpiling -- if your decision is to make it available to
10 the general public, stockpiling by itself is not sufficient.

11 You must plan and have a system to distribute in a
12 very timely manner to make it effective, and with those
13 kinds of modifications, then some of the problems with the
14 proposal might be resolved.

15 CHAIRMAN JACKSON: Okay. Thank you.

16 MR. CALLAN: Chairman, I'd like to reinforce that
17 point just briefly, because we had some side-bar discussions
18 during the presentation this morning about this.

19 What we heard this morning was emphasis on
20 consideration of the three mechanisms.

21 The petition, as Mel read it this morning, just
22 now, says that the range of protective actions will be
23 developed, and the distinction between developing them and
24 considering them is, I think, pivotal to the staff's
25 perspective.

1 CHAIRMAN JACKSON: Okay. Thank you.

2 COMMISSIONER MCGAFFIGAN: The logical question
3 that that leads to is, if the petition had read, a range of
4 protection actions including consideration of sheltering,
5 evacuation, and prophylactic use of iodine, maybe put in "as
6 appropriate," have been developed for the plume, would the
7 staff's view have been different?

8 CHAIRMAN JACKSON: Should have been considered.

9 COMMISSIONER MCGAFFIGAN: Well --

10 CHAIRMAN JACKSON: I'm just going on what the
11 petitioner said this morning.

12 COMMISSIONER MCGAFFIGAN: Right. Picking up on
13 what he said, which I agree is different from the words
14 here, you're making the point that that is different.

15 I'm asking the question, if it had been stated in
16 this other way, including consideration of sheltering,
17 evacuation, and prophylactic use of iodine, as appropriate,
18 would the staff's position possibly have changed?

19 MR. MARTIN: It would certainly have muted one of
20 the cons that we saw there. I still think this is very much
21 a state issue.

22 As we examine the pros and cons, we don't feel
23 strongly either way, and it almost -- it's a policy decision
24 at that point, because I don't think that we have found
25 anything that says you must have KI pre-positioned and

1 distributed.

2 We want the people out, we want them evacuated so
3 they don't get exposed to it, we want people to avoid
4 ingesting food that was contaminated, so it's the plume
5 passage that is of concern to us.

6 We recognize that there are difficulties in
7 distribution, not insurmountable. We are smart people, I
8 agree with Peter. If a decision is made by the states to do
9 it, there are smart people there, they could figure out a
10 way to do it.

11 So, we don't see a strong motivation in either
12 direction, and if it's the Commission's decision that, yes,
13 we ought to make it available, the staff will march off and
14 support you.

15 CHAIRMAN JACKSON: Okay.

16 Go ahead.

17 MR. MIRAGLIA: May I make an observation?

18 CHAIRMAN JACKSON: Please.

19 MR. MIRAGLIA: I think the key that we need to
20 focus on is planning. If KI is selected by a state, there
21 has to be appropriate planning to make sure it's there and
22 available for distribution and use.

23 So, it's a key, it's a supplement, and if it's
24 chosen to be used, the key is the plan, and I think the
25 policy statement that we've talked to in the past, that FEMA

1 has alluded to, indicates that that's an important part of
2 the process.

3 If it's used and you have an infrastructure
4 developed, it needs to be considered in the plan, and the
5 decision-making process needs to be understood. So, I think
6 the key is the planning aspect.

7 CHAIRMAN JACKSON: Okay.

8 COMMISSIONER MCGAFFIGAN: That is exactly why I
9 asked that series of questions earlier, and I'll give you
10 the chance to talk about it.

11 The statement now and the statement several months
12 ago included in it the draft FEMA statement, these
13 stockpiles, the 30 sites, would be available on an ad hoc
14 basis in the event of an accident at a commercial nuclear
15 power plant.

16 We heard that there is no planning currently
17 underway for how that ad hoc decision -- I mean I think it
18 has to be a pre-planned decision. You give the state -- you
19 know, one of the arguments used is that we don't need to do
20 this because it's remote.

21 But we now have a plume with iodine in it headed
22 towards a population.

23 Do you give the state, which has previously
24 decided not to stockpile KI, knowing it's second-best,
25 knowing it would have been better to have it there at the

1 site -- do you give them a second chance at that point to
2 try to get KI there from one of these 30 locations, and do
3 we have to exercise that, do we have to plan it, do we have
4 to tell everybody that there will be an ad hoc exercise
5 that, in some ways, intrudes on the plans as they exist at
6 the moment and possibly, you could argue, might make those
7 plans less effective?

8 But suddenly, we have a real situation, we have a
9 plume, which, God forbid, none of us want, and there's
10 iodine in the plume. What do we do then?

11 MR. MIRAGLIA: As I understand the policy
12 statement that was adopted, there is stockpiling of KI being
13 done for other purposes, and as I heard from FEMA, it needs
14 to be a rationalization of the policy that we're talking
15 about here with respect to the commercial nuclear power
16 plants and those aspects and those stockpiles, and there
17 needs to be that kind of activity.

18 But as I understood the policy statement that's
19 being adopted, if a state chooses to use KI, then they would
20 have to do the planning such that you would void those kinds
21 of issues, so you avoid the ad hoc kinds of circumstance,
22 and that it's a decision up front that's planned for and the
23 states and the locals know what to do, when to do, and how
24 the decision process is made.

25 That's not to say that ad hoc kinds of measures

1 for the terrorist -- anti-terrorism kind of thing -- it has
2 a different kind of environment to it that there is not room
3 for that, and it was just recognizing a source and a cache
4 of stockpiled KI that could be used and made available to
5 states who choose to use it in their planning processes, is
6 how I understood it.

7 COMMISSIONER MCGAFFIGAN: I agree entirely it's
8 better to plan in advance, but the policy, as I understand,
9 that the Federal Government is going to put out is these
10 stockpiles would be available on an ad hoc basis in the
11 event of an accident at a commercial nuclear power plant,
12 and I think that that ad hoc can't be quite as ad hoc as it
13 appears to be at the moment.

14 I think it has to be -- that it is a rational
15 decision that would have to be made in the event of a real
16 accident, and therefore, it may be ad hoc, namely
17 non-planned in advance and in the emergency plan, but I
18 would think that we have to exercise how we would make the
19 ad hoc decision in each case and know where the nearest
20 stockpile is and what the number of hours it would be to get
21 there and what the logistics of that might be, it's a
22 logical aspect of the policy, but it sounds like that's
23 details to be worked out later at the moment.

24 CHAIRMAN JACKSON: Information that presumably
25 should be provided.

1 Dr. Knapp, please continue.

2 MR. KNAPP: All right.

3 Returning to option two, among the other pros of
4 this particular option was that we felt that this option
5 would identify at least some of the concerns that the
6 petitioner raised and that no NRC or FEMA review of a
7 state's decision would be required.

8 On the other hand, we recognize that this would
9 not resolve the petition in the specific manner requested.

10 COMMISSIONER MCGAFFIGAN: Can I ask the question I
11 asked earlier? Our regulations, 50.54(q) -- are we making a
12 blanket judgement at this point that this can only be
13 constructive and, therefore, the review under 50.54(q) is
14 not required?

15 MR. CALLAN: First of all, I want to thank you for
16 telegraphing the question. We had a half-an-hour to prepare
17 an answer. But since you gave it to us, I want to ask Frank
18 Congel to provide an answer.

19 MR. CONGEL: The way it is right now, off-site
20 plans aren't directly accountable under 50.54(q).

21 The on-site plans that are the licensee's
22 responsibility refer to having an acceptable off-site plan,
23 and as a result of FEMA's review with, of course, other
24 Federal assistance, including the NRC, the exercises are
25 reviewed every other year and a determination is made that

1 there is reasonable assurance that the public health and
2 safety is protected.

3 Within the context of making that determination,
4 there are many variables, and those variables are not
5 subject to the 50.54(q) type of determination.

6 I can make as an example the basic evacuation
7 scheme that we like to see is at least what we call the
8 keyhole, two miles out, 360 degrees, and downwind out to
9 five miles, and the way individual states carry it out range
10 from that to 360 degrees at five miles and some are 360
11 degrees at 10 miles.

12 There are no determinations made if a state then
13 changes from 10 back to 5. It all is done in the context of
14 the overall evaluation.

15 Only if there was a direct effect on the licensee
16 plan that impacted them directly would that determination
17 have to be made.

18 COMMISSIONER McGAFFIGAN: The heart of this -- and
19 I'm not going to spend a lot of time on it -- seems to be
20 the definition of the word "plan," licensees shall maintain
21 in effect emergency plans which meet the standards of
22 50.47(b), and you're telling me the plan does not encompass
23 this sort of thing, the licensee's plan does not encompass
24 this sort of thing.

25 MR. CONGEL: In that level of detail, yes, sir.

1 COMMISSIONER MCGAFFIGAN: Okay.

2 CHAIRMAN JACKSON: Please go on.

3 MR. KNAPP: All right.

4 To move on to option three, in this option we
5 would deny the petition but pursue modification of
6 regulations to require that licensees address planning for
7 KI distribution, again for states that include KI for the
8 general public in their planning basis, and this is similar
9 to option two except that it does incorporate this concept
10 in rulemaking.

11 Principle advantages would be it is consistent
12 with the current and proposed Federal policy, retains the
13 state's prerogative as to whether they choose to use KI, but
14 we do think it's possible that, to have a rulemaking like
15 this, there will be interest from a variety of parties and
16 the rulemaking could be protracted.

17 In consideration of the three options, the staff
18 has provided a position, and that is that we would favor
19 option two for the reasons that it's consistent with the
20 policy as endorsed by the Commission in June, that it
21 reflects the willingness of the Federal Government to
22 provide a stockpile of KI and guidance for its distribution
23 but that it is directed to only those states that include KI
24 for members of the public in their planning basis.

25 CHAIRMAN JACKSON: Further questions? Commission

1 Dicus?

2 COMMISSIONER DICUS: If we were to go with option
3 three, do we have the resources in the budget to do the
4 rulemaking?

5 MR. KNAPP: No, ma'am. I believe the staff paper
6 indicates that that was not within the context and would
7 require reexamination of resources.

8 COMMISSIONER DICUS: Second question or request,
9 maybe, for the record.

10 As you know, in response to the activities that
11 occurred in 1994, a NUREG document was to be put together
12 for states and local governments to use describing KI and
13 the process and decision-making if they chose to use it, and
14 as staff recognized, as you let us know recently, that had
15 never occurred, which we are aware of, the NUREG document
16 was never written, and you suggested it wasn't necessary
17 anymore, and I think you also know I came back and said yes,
18 it is.

19 It is very important that state and local
20 governments have a concise document put together with many
21 of the things we have been talking about, the information
22 that's available to them, and I just would like to know
23 where we are with doing that.

24 Does anyone have an answer?

25 CHAIRMAN JACKSON: Nobody has an answer?

1 MR. CONGEL: I'm very familiar with the
2 interactions that took place regarding the NUREG document.
3 There are two components that we're doing.

4 First of all, as a result of the June 30th SRM, we
5 are providing various forums whereby we're discussing, for
6 example, the all agreement statement meeting, the reg info
7 conference in April, we plan to discuss the KI policy and
8 where we are.

9 In terms of putting together a package where
10 everything is together and hopefully in a coherent sense, as
11 a result of our conversations, I will consult up the line,
12 and I presume we intend to do it.

13 I would like to do it, of course, after we've
14 reached a final resolution on this issue.

15 CHAIRMAN JACKSON: Was there any explicit
16 instruction to the staff in the SRM based on the summer
17 decision of the Commission to develop those guidance
18 documents?

19 MR. CONGEL: No, ma'am.

20 CHAIRMAN JACKSON: Okay.

21 Commissioner Diaz.

22 COMMISSIONER DIAZ: Since the question has been
23 asked, will it be possible, when the Commission receives the
24 information from the staff on this, to consider what will be
25 the particular effects of the changes proposed by the

1 petitioner to the original rulemaking?

2 I don't know whether it is legal or not, but if it
3 were possible to provide an option in which the word
4 "consider" would be in the petition --

5 MR. CALLAN: Let me clarify something, because
6 there's some ambiguity here.

7 What I understand, Commissioner Diaz, that you're
8 asking -- and I'll just read it the way I think you're
9 proposing -- a range of protective actions, including
10 sheltering, evacuation, and use of iodine have been
11 considered for emergency workers.

12 I think Commissioner McGaffigan had words more to
13 the effect of have been -- consideration --

14 COMMISSIONER MCGAFFIGAN: Including consideration
15 of sheltering, evacuation, and prophylactic use of potassium
16 iodide, as appropriate, have been developed, a range of
17 protective actions have been developed which can include any
18 or all of the above, as appropriate.

19 MR. CALLAN: Without the "development" in there, I
20 think if we just considered -- which is what the petitioner
21 had focused on this morning -- I think that's probably --

22 COMMISSIONER MCGAFFIGAN: The "developed" is in
23 the current reg, as I understand it, and what he's adding is
24 the words "including sheltering, evacuation, and
25 prophylactic use."

1 So, what he is trying to do is take the existing
2 regulation in 10 CFR 50.47(b)(10) and the underlying words
3 -- and I'm looking at page two of the SECY -- are the
4 addition that he was proposing, and in order not to change a
5 whole lot of words, I suggested working only within the
6 language -- because you want the actions developed. I mean
7 that's what the current reg is.

8 So, including consideration of sheltering,
9 evacuation, and prophylactic use of iodine, as appropriate,
10 then continue with the reg as it exists at the moment -- I
11 don't know whether that would do what Peter Crane wants.

12 CHAIRMAN JACKSON: I think that I want to make an
13 over-arching comment.

14 I think that, before we can try to sit here and
15 individually try to suggest strongly or instruct the staff
16 to do anything, the Commission has to decide how it wants to
17 resolve the questions relative -- the options relative to
18 the existing petition, whether it wants to consider some
19 slight revision in that, as suggested by the petitioner this
20 morning, or whether it wants to feel that it can address or
21 come to some concurrence relative to some amplification of
22 what's in the existing policy.

23 Then, on that basis, if there is some additional
24 follow-on work that the staff needs to do in terms of
25 development of guidance or anything else, then it is

1 appropriate based on that base to ask them to do it, and so,
2 I think --

3 CHAIRMAN JACKSON: We can't send them off down
4 several parallel paths before the Commission itself has made
5 its fundamental policy decisions on where it wants to go in
6 this, and so I think we can't wordsmith here at the table.
7 We can't have them develop guidance on policy that we
8 haven't decided yet.

9 I think what we wanted was to have a complete
10 airing, which we are obviously in the process of doing, of
11 all the thoughts of all the members of the Commission as
12 well as the various interested parties.

13 Commissioner Dicus, you had a comment.

14 COMMISSIONER DIAZ: I, of course, agree. This is
15 why I was putting it as a question. Would the Staff answer
16 the question whether changes to the actual petition would
17 result in a different position from the Staff and in that
18 respect -- that's the question -- not going and doing what
19 the Chairman did, period.

20 CHAIRMAN JACKSON: Commissioner Dicus.

21 COMMISSIONER DICUS: This is a theoretical
22 question but if down the road for whatever reason the
23 language would change to this very what I call permissive
24 language, consideration of -- et cetera, would that not also
25 in putting shelter and evacuation and the use of iodine,

1 would that also not open up the door for a state to go back
2 and reconsider all their planning and perhaps decide not to
3 do evacuations, for example, because then is it permissive,
4 very permissive on what they are going to do.

5 Does anyone want to --

6 MR. MARTIN: I think the issue there is the
7 requirement would still be to develop a range of protective
8 actions.

9 That would still be a requirement, but the
10 consideration would be --

11 COMMISSIONER DICUS: They would still have to
12 develop a range of protective actions but they certainly
13 could go back and rewrite plans on what they are currently
14 doing.

15 MR. MIRAGLIA: An observation would be that
16 whether that language is in the rule versus a policy
17 statement. If it was put in a rule, there may be other
18 implications that need to really be fully evaluated.

19 COMMISSIONER DICUS: I think that is probably
20 true.

21 CHAIRMAN JACKSON: I think perhaps we can get some
22 concurrence from the Commission since we are all here as to
23 whether we at least want the Commission -- I mean want the
24 Staff to consider what its position would be if we can get
25 from the petitioner a distinct, succinct statement in terms

1 of his somewhat revised statement, to have the Staff
2 consider what the effect would be in terms of their pros and
3 cons -- if he wants to submit a revision to his petition, as
4 stated today.

5 MR. CALLAN: Be happy to do so.

6 CHAIRMAN JACKSON: Okay, and you can do this
7 within the week?

8 MR. CALLAN: Yes.

9 CHAIRMAN JACKSON: Okay, and therefore the Staff
10 can give its additional feedback to the Commission. Is it
11 appropriate within a week of that or two weeks of that, so
12 that by the end of the month we can have this revisited --
13 just to add it to what you have already done.

14 MR. CALLAN: Mel, you'll be the action officer, so
15 why don't you answer that?

16 CHAIRMAN JACKSON: Can you do that within two
17 weeks of the time, so within three weeks of now?

18 MR. KNAPP: We will do our best. Candidly,
19 because there are many offices involved and a number of
20 views --

21 CHAIRMAN JACKSON: So we can get you to come
22 back --

23 MR. KNAPP: About three weeks, yes.

24 CHAIRMAN JACKSON: -- but we can agree that --

25 MR. KNAPP: You certainly can in the near term.

1 CHAIRMAN JACKSON: -- that we will have that
2 occur, that process.

3 COMMISSIONER DICUS: And we will not --

4 CHAIRMAN JACKSON: And we will not take action on
5 the existing petition until that occurs, okay?

6 MR. CALLAN: Very good.

7 CHAIRMAN JACKSON: All right. We all understand
8 then.

9 All right. I think it is time to end this
10 meeting.

11 COMMISSIONER McGAFFIGAN: I have several
12 questions. I haven't had my chance.

13 CHAIRMAN JACKSON: Oh, you didn't have? I thought
14 that is what you were doing. Okay. Fine.

15 COMMISSIONER McGAFFIGAN: Just one comment on the
16 issue that Commissioner Dicus raised, the potential for a
17 rule change having unforeseen consequences.

18 As I read the rule -- I know our practice has been
19 to require evacuation, but as I read the rule at the moment
20 it says "A range of protective actions have been developed
21 for the plume exposure pathway for emergency workers and the
22 public."

23 That is all that is required in the rule. I
24 suspect there is a Reg Guide out there or something,
25 somewhere that says in every instance in this country you

1 will have an evacuation plan, so I am not sure --

2 CHAIRMAN JACKSON: Your Staff member is saying no.

3 COMMISSIONER McGAFFIGAN: Is that no? Well, maybe
4 we don't. Maybe it just de facto turned out that everybody
5 has required evacuation, but let me ask a couple questions.

6 Can the Staff explain --

7 MR. CONGEL: Excuse me. Just let me address that,
8 please, because we have NUREG 0654 that has the planning
9 standards listed and the essential elements in each of those
10 planning standards that are reviewed as part of the offsite
11 evaluation and clearly evacuation is up there as one of the
12 principal things.

13 In addition, we have Supplement 3 to NUREG 0654,
14 which is a compilation of about 20 years' worth of severe
15 accident studies that indicate that the overwhelming
16 protective action that is the most effective in protecting
17 people from doses at all is early effective evacuation, so
18 it is certainly well defined what the fundamental
19 requirement is here, and that is why we are dealing with
20 this other aspect in terms of supplement.

21 COMMISSIONER McGAFFIGAN: Okay. Let me ask the
22 question -- a suggestion that I am making for Peter Crane
23 listening to the testimony this morning, would the Staff
24 object to the words "reasonable and prudent" being put in
25 the sentence --

1 CHAIRMAN JACKSON: I think what I am trying to get
2 them to do is to in fact consider that. I think we can
3 decide and pass to them questions.

4 I don't think it is fair to them to ask them to
5 sit here today and to answer that question, and so I have no
6 objection, and I don't think any of the colleagues do, of
7 our putting the question to them --

8 COMMISSIONER MCGAFFIGAN: Okay.

9 CHAIRMAN JACKSON: -- but I don't believe that --

10 COMMISSIONER MCGAFFIGAN: The question will be
11 "Should the words 'reasonable' and 'prudent' be put in the
12 statement."

13 Listening to Peter earlier, there were two bases
14 for his petition.

15 One was that there were changes, as he described
16 it. I haven't read the full petition. I am taking it at
17 his word that one was there had been changes since the
18 policy was adopted, and we have discussed that.

19 The other was that the Commission acted on bad
20 information in its initial policy and obviously the claim is
21 that there's been bad information since.

22 Do you have any response to that bases for -- I
23 think it is fair to say that if that was a basis highlighted
24 in his petition that that isn't addressed in the SECY paper
25 at the moment.

1 You are a whole new team practically, but do you
2 have any discussion of this matter? The only person at the
3 table with that kind of corporate memory is Tim and Frank.

4 MR. MARTIN: I became aware of -- as a result of a
5 Peter Crane letter to the FEMA that in the SECY paper we
6 provided you in June of this year where we attempted to
7 describe the background of the KI policy we misrepresented
8 one of the bases upon which the ad hoc subcommittee for KI
9 based their recommendation not to change the policy and not
10 to stockpile.

11 That particular was one of five and it was the
12 fifth one that said that there is a lack of support by the
13 primary Federal regulatory agency, and then in parentheses
14 said FEMA. Clearly FEMA is not the primary Federal
15 regulatory agency, and it could be read to imply that FEMA
16 did not support it.

17 I will let FEMA speak for themselves. It was NRC,
18 if you go back and read the actual report of that
19 subcommittee, although they don't label it as NRC, the clear
20 context and what my staff tells me, it was NRC that was what
21 was their fifth basis for their conclusions.

22 Now that one I am aware of, and let the record so
23 state that we made an error there, but Frank --

24 MR. CONGEL: Well, I was not involved in the early
25 determination of the KI policy, so at least you can say

1 everybody sitting here is a fresh group.

2 I became involved with it probably at about the
3 time of the filing of the DPV in 1988-89 timeframe and have
4 been involved since.

5 In any case, some of the considerations that Peter
6 brought up, historical ones, I just simply don't have an
7 answer for.

8 What I do have though is the fact that the
9 considerations that he brought up have been subject to
10 discussion in many different forums and as we all know,
11 sitting around the table, this is not an easy issue to find
12 a resolution to, and if it was we wouldn't be. We would
13 have had an answer already.

14 But the many things ranging from the experience at
15 Chernobyl to the American Thyroid Association's statements
16 to all of the other history you heard, they have resulted in
17 much dialogue, both within the Staff and outside of the
18 Staff and I would just like to point out that what we have
19 in papers presented from the June Commission paper to the
20 petition response does reflect that, and if it turned out
21 that there was a clear determination of one way or the
22 other, we would have presented that, but there are
23 equivocations and some of the information --

24 Just as one example, there are no new data to
25 change the dose factors that we use for thyroid right now.

1 The same dose per microcurie inhaled or ingested that we use
2 today is virtually identical to what we used in the early
3 '80s.

4 The situation with Chernobyl and Eastern Europe is
5 the subject of intense study right now and the bases for the
6 observed thyroid cancers are being studied. There is not a
7 determination yet that indicates that something happened
8 there that undermines the data basis we have right now. We
9 have heard that and that is just one example.

10 I only want to point out that the Staff here has
11 spent a substantial amount of time in trying to be fair,
12 objective and open in all cases, and this is where we are.

13 CHAIRMAN JACKSON: One last question.

14 COMMISSIONER McGAFFIGAN: One last question. The
15 change from the Staff position in 1994 to the Staff position
16 at present, is that simply the change in Staff that has
17 occurred, in a sense, or I guess is that a fair -- this
18 group has a different view from whomever was in your set of
19 positions in 1994 when the different recommendation that
20 Peter cited was made to the Commission?

21 Let me ask Frank again. He's the only continuity.

22 MR. CONGEL: I would say that that is a very good
23 representation. The group of managers sitting here now with
24 of course the additional information of the NBC data
25 resulted in the proposal that we put forth. The NBC info,

1 of course, wasn't available and it, of course, predated the
2 tragedy in Oklahoma City.

3 CHAIRMAN JACKSON: That's enough because --

4 MR. MIRAGLIA: -- participated in '94 but as read
5 versus the statement or policy that the Commission adopted
6 in June of this year, I didn't see substantive differences.

7 CHAIRMAN JACKSON: Right. Okay. I think we are
8 going to close this meeting and so I wish to thank Mr. Crane
9 and Mr. Hepler and his colleagues from FEMA and the NRC
10 Staff for their presentations.

11 You know, it is important whatever the decision or
12 any revision of decision that may occur to have a full and
13 robust and open discussion on these issues and it is also
14 important to clear the air and I think we have had some
15 opportunity to do that.

16 The information gained today and that has been
17 asked for will be helpful to the entire Commission as we
18 make the decision on the Staff's proposed options for
19 resolving Mr. Crane's petition or any potential amendment of
20 it as suggested today.

21 So, with that, I am adjourning the meeting.

22 [Whereupon, at 11:34 a.m., the meeting was
23 concluded.]

24

25

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON PROPOSED RESOLUTION TO A
PETITION FOR RULEMAKING RELATING TO
USE OF POTASSIUM IODIDE (KI)
FOLLOWING SEVERE ACCIDENT AT A
NUCLEAR POWER PLANT
PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Wednesday, November 5, 1997

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Chris Cutchall

Reporter: Jan Delmonte



STAFF OPTIONS FOR RESOLVING A PETITION RELATING TO POTASSIUM IODIDE

**Malcolm Knapp, Acting Director
Office of Nuclear Regulatory Research**

November 5, 1997

SUMMARY OF PETITION

- **Petitioner requested -**
 - **Revise 10 CFR Part 50.47(b)(10) to read**
“A range of protective actions including sheltering, evacuation, and prophylactic use of iodine, have been developed . . . for emergency workers and the public.”
 - **Issue a policy statement declaring that KI stockpiling is a sensible and prudent measure, necessary to assure that the drug will be available in the event of a major accident.**

PUBLIC COMMENTS:

- **63 comment letters received**
- **28 in favor - 5 environmental groups, 22 members of public, American Thyroid Association**
- **35 opposed - 20 utilities, 9 States, 2 utility organizations, 2 State universities, 1 member of public, 1 letter signed by 12 health physicists**

STAFF PROVIDED THREE OPTIONS (SECY-97-245)

- **Grant petition as requested**
- **Deny petition, but develop guidance to address planning for KI distribution for States that include KI for the general public in their planning basis**
- **Deny petition, but pursue modification of regulations to require licensees to address planning for KI distribution for States that include KI for the general public in their planning basis**

OPTION 1 - GRANT PETITION AS REQUESTED

- **Pros:**
 - **Would establish uniform Federal policy on KI**
 - **Would ensure plans address use of KI**
- **Principal cons:**
 - **Would contradict June 1997 SRM and proposed FRPCC recommendations that States should have option of using KI**
 - **Licensees and States would be required to incorporate all three protective actions into emergency plans**

**OPTION 2 - DENY PETITION, BUT DEVELOP GUIDANCE
TO ADDRESS PLANNING FOR KI DISTRIBUTION FOR
STATES THAT INCLUDE KI FOR THE GENERAL PUBLIC
IN THEIR PLANNING BASIS**

- **Pros:**

- **Consistent with June SRM endorsing draft FRPCC policy**
- **Addresses some of petitioner's concerns**
- **No NRC or FEMA review of a State's decision required**

- **Con:**

- **Does not resolve petition in the manner requested**

**OPTION 3 - DENY PETITION, BUT PURSUE MODIFICATION
OF REGULATIONS TO REQUIRE LICENSEES TO ADDRESS
PLANNING FOR KI DISTRIBUTION FOR STATES THAT
INCLUDE KI FOR THE GENERAL PUBLIC IN THEIR
PLANNING BASIS**

- **Principal pros:**
 - **Consistent with current and proposed
Federal policy**
 - **Retains States' prerogative on use of KI**
- **Principal con:**
 - **Rulemaking may be protracted**

STAFF POSITION:

Staff favors Option 2 because it is consistent with proposed Federal policy as endorsed by the Commission, reflects the willingness of the Federal Government to provide a stockpile of KI and guidance for its distribution, but only for those states that include KI for members of the public in their planning basis.

***FEMA AND FEDERAL
RADIOLOGICAL PREPAREDNESS
COORDINATING COMMITTEE
(FRPCC) RESPONSIBILITIES IN KI
DELIBERATIONS***

***O. Megs Hepler, III
Chairman, FRPCC***

November 5, 1997



INTRODUCTION

- ◆ FEMA's Radiological Emergency Preparedness (REP) Program falls under the Exercises Division
- ◆ Director of the Exercises Division is the Chairman of the FRPCC

FRPCC - BACKGROUND

- ◆ Established in 1982 under 44 CFR 351
- ◆ Coordinates all Federal responsibilities for assisting State and local governments in emergency planning for peacetime radiological emergencies
- ◆ Fifteen departments and agencies are members
- ◆ Six standing subcommittees
- ◆ Two ad hoc subcommittees, including the KI subcommittee

FRPCC ROLE IN KI

- ◆ Initial Federal policy on KI, formulated by FRPCC, published in Federal Register in 1985
 - Use of KI by general public is prerogative of States
- ◆ In 1989, ATA asked FRPCC to reexamine its position
- ◆ FRPCC then asked HHS to review medical and clinical status

HHS RECOMMENDATIONS

◆ In 1990, HHS recommended to FRPCC that:

- FRPCC 1985 policy not be changed
- Existing stores of KI be inventoried
- FRPCC establish a working group

FRPCC AD HOC SUBCOMMITTEE

- ◆ FRPCC Ad Hoc Subcommittee on KI, formed in February 1991, charged with:
 - Reexamining 1985 policy
 - Considering merits of Federal Government purchasing and stockpiling KI for use by the general public
- ◆ Ad Hoc Subcommittee then:
 - Examined scientific aspects of KI
 - Examined NRC's cost-benefit analysis
 - Conducted, through CRCPD, a survey of the States

SUBCOMMITTEE RECOMMENDATIONS

- ◆ September 1994, Subcommittee recommended:
 - No change in KI policy
 - Federal Government not purchase and stockpile KI
- ◆ December 5, 1994, full FRPCC adopted Subcommittee recommendations
- ◆ September 1995, Petition for Rulemaking filed

PETITION FOR RULEMAKING

- ◆ In response to Petition, FRPCC delayed reaffirmation of 1985 policy
- ◆ NRC published synopsis for comment
- ◆ Ad Hoc Subcommittee on KI was reconvened in December 1995 and charged to:
 - Review information, including Petition
 - Review comments on Petition
 - Evaluate new information

SUBCOMMITTEE ACTIVITIES

- ◆ Subcommittee conducted public meeting, June 1996
- ◆ Commenters on Petition and other members of the public invited to make presentations
- ◆ Attendees included representatives from States, CRCPD, utilities, and public interest groups, plus a university professor and the petitioner.

SUBCOMMITTEE RECOMMENDATIONS

- ◆ Subcommittee concluded there was no challenge to 1985 policy but recommended:
 - Federal Government purchase stockpile of KI for any State wishing to use it as supplemental protective action for general public
 - Language in 1985 policy be softened
 - Local jurisdictions desiring KI should first consult with their State
- ◆ October 1996, full FRPCC approved Subcommittee's recommendations
- ◆ June 1997, NRC Commissioners voted 3-2 to support FRPCC's recommendations

NBC STOCKPILE

- ◆ NRC Commissioners also recognized availability of KI in NBC stockpiles
- ◆ Stockpiles initially located in 27 areas throughout the nation and 3 national stockpiles in Eastern, Central, and Western United States
- ◆ Already established in Washington, D.C., Denver, Los Angeles, and Durham, NC

FEDERAL REGISTER

NOTICE

- ◆ Draft Federal Register notice of the FRPCC recommendation has been prepared
- ◆ Notice specifies that a State choosing KI as a supplemental protective action can request funding
- ◆ FEMA's evaluation is limited to decisionmaking process
- ◆ FEMA is waiting for NRC concurrence
- ◆ Then full FRPCC membership will review and give final concurrence

IMPLEMENTATION STEPS

- ◆ After Federal Register notice, steps must be taken, e.g., development of:
 - Suitable information program for KI use
 - Procedures for addressing State requests for funding
 - Guidance for evaluating State decisionmaking aspects



RULEMAKING ISSUE

(Notation Vote)

October 23, 1997

SECY-97-245

FOR: The Commissioners

FROM: L. Joseph Callan
Executive Director for Operations

SUBJECT: STAFF OPTIONS FOR RESOLVING A PETITION FOR RULEMAKING (PRM-50-63) RELATING TO A RE-EVALUATION OF THE POLICY REGARDING USE OF POTASSIUM IODIDE (KI) AFTER A SEVERE ACCIDENT AT A NUCLEAR POWER PLANT

PURPOSE:

To obtain Commission approval of an option to resolve a petition for rulemaking that requested changing the NRC regulations regarding emergency planning.

BACKGROUND:

On September 9, 1995, a petition for rulemaking (PRM-50-63) was submitted to the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to include a requirement that the range of protective actions include the prophylactic use of potassium iodide as well as sheltering and evacuation. The specific request was to amend one of the 16 planning standards in 10 CFR 50.47 to assure that the option of using potassium iodide be included in emergency plans. The planning standards currently do not identify specific protective actions that must be included in emergency plans prepared by licensees or the States.

The current Federal guidance to State and local governments on the distribution of KI was promulgated in 1985 by the Federal Emergency Management Agency (FEMA) in its capacity as Chair of the Federal Radiological Preparedness Coordinating Committee (FRPCC) (50 FR 30285; July 25, 1985) and as the Federal agency charged with establishing policy and providing leadership via the FRPCC (44 CFR 351 Subpart C). The FRPCC was established to coordinate all Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime radiological emergencies. On June 16, 1997, the Commission was provided a proposed revision to the Federal policy regarding the use of

CONTACT:
Mike Jamgochian, RES/DRA
(301) 415-6534

NOTE: TO BE MADE PUBLICLY AVAILABLE
WHEN THE FINAL SRM IS MADE AVAILABLE

potassium iodide (SECY-97-124). The Commission approved the staff's option of endorsing the FRPCC recommendations. The Commission informed the staff not to view its approval of this option as a denial of the petition for rulemaking (PRM 50-63) and directed the staff to prepare an assessment of the petition and submit it to the Commission for its consideration.

DISCUSSION:

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. None of the State governmental agencies that commented on the petition for rulemaking supported granting the petition. (See the Enclosure 1 for a detailed analysis of the public comments.)

The petitioner requested that the "planning standard" in 10 CFR Part 50, section 50.47(b)(10) be revised to read.

(10) A range of protective actions including sheltering, evacuation, and prophylactic use of iodine, have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public. 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.

The petitioner also requested that "the NRC also issue, either on its own or in conjunction with other agencies, a policy statement declaring that KI stockpiling is a sensible and prudent measure, necessary to assure that the drug will be available in the event of a major accident. This statement would make clear that KI, while no panacea, can be used in conjunction with evacuation and sheltering to maximize protection to the public."¹ The full text of the petitioner's request can be found in Enclosure 2.

The staff has evaluated the various options for addressing the petitioner's concerns and is providing three options for the Commission's consideration in resolving this petition. The first option would grant the petition as requested by the petitioner. The second option would deny the petition for rulemaking. However, the NRC in coordination with the States and other Federal agencies would develop guidance to address planning for KI distribution for those States that include KI in their planning basis, consistent with the FRPCC policy. In the third

¹ The petitioner further stated that, "I am not proposing house-to-house predistribution of KI, which I think would be ineffective and a source of confusion during an actual emergency. Rather, I am suggesting that state and local authorities have ready access to supplies of the drug so that they can administer it if it is needed."

option the staff proposes to deny the requested petition for rulemaking but would pursue a modification to the regulations to require licensees to address planning for KI distribution for those States that include KI in their planning basis.

Option 1: To grant the petition for rulemaking strictly in accordance with the petitioner's request.

The petitioner proposed that section 50.47(b)(10) be amended to read as follows:

A range of protective actions including sheltering, evacuation, and prophylactic use of iodine, have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public. 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. *[the underlined text would be added to the existing standard in 50.47]*

Pros: 1. Would resolve the issue as requested by the petitioner. Advantages of this option as identified by the petitioner are: a.) would establish a uniform Federal policy on KI and b.) would ensure that emergency plans address the prophylactic use of KI.

Cons: 1. By requiring KI as a protective measure this option would contradict the June 30, 1997, SRM and the 1997 proposed FRPCC recommendations that States should have the option of using KI as a protective measure.

2. Revising the regulation as requested by the petitioner would mean that licensees and States would be required to incorporate all three protective actions into their emergency plans. Failure to do so by a State would result in a situation where a State's decision would conflict with the new requirement.

3. May give the appearance that the use of KI, as a protective measure, could be equated to the use of evacuation and sheltering.

4. Would require NRC and FEMA resources to revise the regulations and guidance documents, and to review revised plans and procedures.

5. The Rulemaking required by this option would be protracted in that extensive coordination with the States, other affected Federal agencies, licensees and the public would be required prior to adoption as a final rule.

6. During the public comment period, state governments identified significant implementation problems associated with this option.

Option 2: Deny the petition for rulemaking as requested by the petitioner. However, NRC in coordination with the States and other Federal agencies would develop guidance to address planning for KI distribution for those States that include KI in their planning basis.

Pros: 1. Would be consistent with the June 30, 1997, SRM endorsing the draft FRPCC policy discussed in SECY-97-124 to fund the purchase of KI for States at their request.

2. The proposed FRPCC policy addresses some of the petitioner's concerns. This is based on the following aspects of the proposed policy: 1) regional stockpiles will be made available to the States that request them in the event of an emergency, and 2) the Federal government will purchase KI for any State requesting it.

3. No NRC and FEMA review of a State's decision would be required.

Cons: 1. Does not resolve the petition in the manner requested by the petitioner.

Option 3: Deny the petition for rulemaking as requested by the petitioner. However under this option a modification to the regulations would be pursued to require licensees to address planning for KI distribution for those States that include KI in their planning basis.

Pros: 1. Would be consistent with the current and proposed federal policy on KI, that States should have access to KI as a protective measure.

2. Retains the States' prerogative to incorporate the use of KI into their emergency protection measures in the event of an accident.

3. Codifies the relief given in Option 2.

Cons: 1. The rulemaking required by this option may be protracted in that extensive coordination with the States, other affected Federal agencies, licensees and the public would be required prior to adoption as a final rule.

2. Would require NRC and FEMA resources to revise the regulations and guidance documents, and to review revised plans and procedures.

Staff position:

It is the staff's position that a revision to the regulations is not necessary to assure that KI, as a protective measure for the public, is available for use by the States. This position would support the Commission decision in its SRM dated June 30, 1997 to endorse the draft FRPCC policy on the distribution of KI.

The staff favors Option 2 because it is consistent with proposed Federal policy as endorsed by the Commission and addresses the overall policy change requested by the petitioner, i.e., the willingness of the Federal government to provide a stockpile of KI to the States upon request. This would be accomplished without the burden of a rulemaking.

Nonetheless, the staff has developed Option 3 should the Commission wish to codify these proposed policy changes in a rulemaking, which would involve coordination with the States, other Federal agencies, licensees and the public.

RESOURCES:

The resources needed to resolve this petition in accordance with Option 2 are included in the current budget. Resources to conduct rulemaking (Options 1 and 3) as well as resources to purchase KI have not been included in the current budget.

Under any of these options the Commission must make a determination that NRC funding for purchases of KI at the request of States would make a direct contribution to fulfilling the NRC's regulatory responsibility to protect the public health and safety during a radiological emergency. This determination provides the necessary legal basis for NRC expending appropriated funds for the purchase of KI. The NRC would also have to obtain Congressional reprogramming approval.

Additionally, the cost considerations of purchasing KI were fully discussed in SECY 97-124.

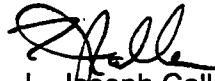
COORDINATION:

The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections. A copy of this paper was sent to the ACRS and the CRGR for information.

RECOMMENDATION:

That the Commission:

Approve an option to resolve the Petition for Rulemaking (PRM-50-63).


L. Joseph Callan
Executive Director
for Operations

Enclosures: As stated

Commissioners' comments or consent should be provided directly to the Office of the Secretary by COB Friday, November 7, 1997.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT October 31, 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 should be apprised of when comments may be expected.

DISTRIBUTION:

Commissioners
OGC
OCAA
OIG
OPA
OCA
CIO
CFO
EDO
SECY

ENCLOSURE 1

DETAILED INFORMATION RELATING TO KI STOCKPILING

Enclosure 1

Detailed information Relating to KI Stockpiling

o FRPCC Members

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).

o Detailed Analysis of Public Comments

Opposition to granting the petition for rulemaking could generally be characterized by the following comments:

1. "There is simply no conceivable means to distribute potassium iodide to potentially affected members of the public within the appropriate time after initiation of a hypothetical nuclear accident. Predistribution is completely out of the question, since there would be no means to control misuses, overdoses, shelf life, etc."
2. "A radioactive release from a nuclear power plant that results in a substantial thyroid dose would undoubtedly include a significant whole body dose as well. Potassium iodide offers no protection for this dose. If plans were in place to administer potassium iodide to the public, the potential would be created for evacuation orders to be ignored due to perceived protection by potassium iodide."
3. "The logistics for advanced distribution of KI to the general public within the plume EPZ [plume exposure pathway Emergency Planning Zone] would require a significant initial and at least annual commitment of resources for a small increase in any potential dose savings. There are many questions and problems associated with advanced KI distribution that would need to be addressed to ensure its availability in an emergency. How to ensure distribution to 100 percent of all households (permanent, seasonal, and transient)? Would the KI be kept in the households? Could they locate it in an emergency? What percentage of households would have retained the KI after 3 months? 6 months? 1 year? Would 100 percent distribution to all households have to be made each year to ensure that a supply is available? What percentage of households would have to demonstrate ready availability to satisfy Federal requirements? Who would assume liability if the KI was used prior to the

Governor ordering its use?"

4. "Potassium iodide is a drug with side effects, some of which are profound. The following contraindications are listed in the medical literature: hypersensitivity to iodides, acute bronchitis, hyperthyroidism, Addison's disease, acute or chronic renal disease, tuberculosis acute dehydration. The following precautions are listed in the medical literature: use cautiously or avoid use in patients with a history of thyroid disease; use care during initial administration of potassium iodide because of risk of hypersensitivity; persons with goiter or autoimmune thyroid disease are at particular risk for adverse reactions; administration of potassium iodide during pregnancy may cause fetal harm, abnormal thyroid function and goiter."
5. "If the NRC adopts a policy of issuance of KI to the general public as a protective action recommendation, it will be considered as being contrary to State policy and will not be accepted. This will have the net result of negating much of the planning and preparedness effort of Federal, State and local governments since Three Mile Island."
6. "The added function of distributing KI during an evacuation will increase the time required to complete the evacuation. This increase in evacuation time during a release from a nuclear power plant will result in an increased radiation exposure to evacuees and emergency workers."

Support for granting the petition for rulemaking could generally be characterized by the following comments:

1. "A host of countries--France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Great Britain, Sweden, Slovakia, and others--protect themselves with stockpiles of KI. Soaring rates of thyroid cancer are appearing in children in the Soviet Union who were exposed to the Chernobyl nuclear accident, but received too little potassium iodide, and too late."
2. "If the World Health Organization recommendation is followed, and the drug is stockpiled locally in firehouses, police stations, etc., it should be possible to get the drug to much of the affected population within a short time after an accident. The EPA Manual [Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-001 (May 1992)] quotes the Food and Drug Administration as stating that potassium iodide 'will have substantial benefit even if it is taken 3 or 4 hours after acute exposure.'"
3. "The U.S. is currently engaged in a \$15 million study of radiation - caused thyroid disease in the Ukraine. I firmly believe that it is money well spent, but I can imagine how Americans would react, if there were ever a nuclear accident in this country, on learning that our government was willing to spend millions to study radiation-caused thyroid disease abroad, while balking at spending a fraction of that amount to prevent radiation caused thyroid disease at home."

4. "If stockpiled potassium iodide were available, it could be given to members of the public to protect them during the evacuation -- but the current Federal policy assures that this will not even be an option."
5. "Just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine? That's like saying, 'Don't ever make flu vaccine available because there are so many strains and they can mutate from year to year.'"
6. "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, a possible adverse reaction to KI seems relatively minimal, and people absolutely should have the choice of making an informed decision and assuming possible risk."

o The 1996 FRPCC Ad-Hoc Subcommittee on KI Recommendations:

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 NRC 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 [respect to] ...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.

o The Highlights of the 1997 proposed FRPCC Federal Policy on KI:

1. 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.

2. 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.
3. A stockpile of KI is being established by the Federal Government. The Federal Government is required to prepare for a wider range of radiological emergencies¹. 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.
4. 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.
5. 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

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. Twenty-six Metropolitan Medical Strike Teams (MMST) are being established for response to such events, each with a cache of medicinal supplies. Medical supplies, including KI, are also 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.

effective and adequate to protect the public health and safety.

ENCLOSURE 2

**PETITION OF PETER G. CRANE FOR RULEMAKING TO IMPLEMENT THE RECOMMENDATION OF
THE PRESIDENT'S COMMISSION ON THE ACCIDENT AT THREE MILE ISLAND (KEMENY COMMISSION)
THAT THE UNITED STATES STOCKPILE THE DRUG POTASSIUM IODIDE FOR THYROID PROTECTION
DURING NUCLEAR ACCIDENTS**

4809 Drummond Avenue
Chevy Chase, MD 20815
September 9, 1995

Mr. John C. Hoyle, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Petition of Peter G. Crane for rulemaking to
implement the recommendation of the President's
Commission on the Accident at Three Mile Island (Kemeny
Commission) that the United States stockpile the drug
potassium iodide for thyroid protection during nuclear
accidents

Dear Mr. Hoyle:

Enclosed for filing please find the above-captioned petition. Please note that it is 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 information available to the public in the NRC's Public Document Room.

Sincerely,

Peter G. Crane

Peter G. Crane



BEFORE THE UNITED STATES NUCLEAR REGULATORY COMMISSION

Petition of Peter G. Crane for rulemaking to implement the recommendation of the President's Commission on the Accident at Three Mile Island (Kemeny Commission) that the United States stockpile the drug potassium iodide for thyroid protection during nuclear accidents

I. Summary

The subject of this petition should be of nationwide concern: the fact that the United States, unlike virtually all other countries in the developed world, does not stockpile the drug potassium iodide (KI) to prevent thyroid cancer and other thyroid diseases after nuclear accidents. KI prevents the absorption of harmful radioactive iodine by saturating the thyroid gland with iodine in a harmless form. The drug is extremely inexpensive. In recommending stockpiling in 1994, the NRC technical staff estimated that a supply sufficient to protect the population nearest to all U.S. nuclear plants could be established for a total of at most "a few hundred thousand dollars," or ten cents per year for each person protected.

Present U.S. policy, adopted in 1985 by an interagency policy statement, with NRC concurrence, holds that it is "not worthwhile" to require KI stockpiling. The policy reflects a "cost-benefit analysis" which calculated that the drug was not likely to pay for itself over time, and that it would be cheaper in the long run to refrain from buying KI, and treat the resulting thyroid disease, than use KI to prevent the disease. Looking only at dollar costs, the analysis did not take into account what we all know intuitively: that the worst part of illness is not necessarily the economic consequences.

Currently, the federal government is sending confused and confusing messages both about whether KI is useful and whether it is available. In September, 1994, the Federal Emergency Management Agency issued a proposed Federal Radiological Emergency Response Plan describing the duties of federal agencies during nuclear emergencies. The NRC, as the lead agency for accidents at nuclear power plants, is to advise state and local governments about "measures that they should take to avoid or reduce exposure of the public to radiation," including "emergency actions such as sheltering, evacuation, and prophylactic use of iodine." In an emergency, an interagency panel will offer guidance to the NRC on when KI should be used. While the authors of the Plan plainly understand the drug's value in radiological emergencies, they seem not to realize that because of the 1985 policy, all the elaborate procedures for making decisions about

KI are pointless: in an emergency, there will be none to give out.

The 1985 policy statement was the complete rejection of one of the major recommendations of the President's Commission on the Accident at Three Mile Island (Kemeny Commission). During the TMI accident, state and federal officials looked for KI and discovered that none was available. The drug had to be manufactured on short notice. The Kemeny Commission strongly criticized the failure to stockpile, and recommended that regional stockpiles be established. Its report recognized that evacuation is not invariably the preferred response to an emergency, and that even when evacuation is desirable, it may not be feasible. A KI stockpile means that emergency response officials have three arrows in their quiver: evacuation, sheltering, and iodine.

Initially, in 1979, the NRC warmly endorsed the Kemeny Commission's position on KI and announced that it intended to make the availability of KI for the general public a necessary part of every emergency response plan. As late as September 1982, all the responsible federal agencies were in agreement that KI stockpiling was desirable. A draft federal policy statement to that effect was circulated for agency approval. Only a few weeks later, for reasons still unclear, FEMA and the NRC staff did a complete about face. FEMA cancelled its plans to purchase KI, the draft policy statement was withdrawn, and the NRC staff adopted a strongly negative stance toward KI.

The NRC Commissioners' acceptance of the NRC staff's changed position came after a November 1983 briefing in which staff officials; none of whom is now with NRC, offered a seriously inaccurate description of the nature of the disease that KI could be expected to prevent. Never discussing cancers or fatalities, the briefers advised the Commissioners and the audience that if a member of the public was exposed to radioactive iodine during an accident, the result could be a "nodule," easily removed, that would mean "a few days" of absence from work. The briefers did not mention that 40% of those radiation-caused nodules would be cancerous, and that 5 to 10% of the cancers would be fatal.

The actual consequences of radiation-caused thyroid disease are far more serious than "a few days" away from work, as the recent news reports on the young victims of Chernobyl make grimly clear. Though usually curable, thyroid cancer is lethal enough to kill 1,120 Americans each year, according to American Cancer Society figures. Even when non-fatal, the disease and related tests and treatment can severely affect the quality of life.

In 1986, only a year after the policy statement was issued, the Chernobyl accident demonstrated how dangerously flawed the new U.S. policy was. In Poland, where the authorities moved vigorously to administer KI, 18 million doses were given out, with the result that 97% of all Polish children were protected and an upsurge of disease was averted. In the then Soviet Union, on the other hand, too little KI was given out, too late. Russia, Belarus, and Ukraine are now experiencing soaring rates of childhood thyroid cancer -- in some places, 200 times pre-accident levels -- and the worst may be yet to come.

U.S. policy did not change in response to the Chernobyl accident, however, despite an urgent request from the American Thyroid Association in 1989. In 1991, the World Health Organization declared that thyroid protection was "critical" during accidents, and said, "Stocks of iodine should be stored strategically at points including hospitals, schools, and fire and police stations." France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Britain, Sweden, Slovakia, and a host of other countries now protect their children with stockpiles of KI. They follow the "International Basic Safety Standards," issued by the International Atomic Energy Agency in 1994, which provide for giving out KI when projected doses exceed specified guidelines. The U.S. Government supported adoption of the Basic Safety Standards, which represent the consensus judgment of the world's radiation safety experts, but ignores them where KI is concerned.

The current policy goes against the best judgment of the NRC's own technical staff, which in 1994 declared, commendably, that "prudence" called for KI stockpiling and recommended to the NRC Commissioners that the U.S. Government buy the drug and make it available to states at no cost. While the NRC staff's proposal for a change in policy was pending before the Commissioners, Senators Alan K. Simpson and Joseph I. Lieberman, in an April 20, 1994 letter, urged the Commission to bring American policy on KI into line with the recommendations of medical and scientific experts and international practice. They also stressed the "moral responsibility" of the federal government to be candid with the public about the risks of federally-licensed activities and ways of lessening those risks.

The only group to endorse the existing policy was an industry trade association, which urged among other things that stockpiling KI might make the public fear that nuclear plants were unsafe. And so the lines were drawn: on the one side, the Kemeny Commission, the American Thyroid Association, the World Health Organization, the two Senators, the NRC's own technical

staff, and the example of the rest of the developed world; on the other side, the industry trade association. When the Commissioners cast their votes, the outcome was a 2-2 tie. Under NRC procedures, the deadlock meant that the NRC staff proposal failed. The old discredited policy remains in place today.

FEMA's 1994 Federal Radiological Emergency Response Plan takes the worst of all possible approaches, for it gives states and the public the illusion of KI protection without the reality. The Government must choose: either to create stockpiles of KI, thereby making the Plan accurate, or revise the Plan and publicly explain that because of the existing federal policy, use of the drug will not be an option in a nuclear emergency.

This petition would resolve the dilemma by improving protection rather than correcting the Plan. It requests that the Commission amend its rules (10 CFR Section 50.47(b)(10)) to specify that the "range of protective actions" required to be set forth in State and local emergency plans includes sheltering, evacuation, and provision to administer KI, as envisioned by the Federal Radiological Emergency Response Plan. It asks the NRC to issue a policy statement explaining that KI is a sensible and prudent emergency planning measure, when used in conjunction with evacuation and sheltering, and declaring NRC support for federal funding of local and regional stockpiles. This approach would cost utilities nothing, and should not burden them in any way. For a pittance, it could save thousands of Americans from thyroid cancer and other diseases if a major nuclear accident occurred.

KI may be compared to the lifejackets on a ferryboat: needed only rarely, but vital if the need does arise. We require ferries to carry lifejackets not because we expect them to pay for themselves over time, but because it is the reasonable and prudent thing to do. Likewise, we vaccinate our children against polio and diphtheria to prevent needless suffering and deaths, not because we have calculated that this is a way to save money.

The U.S. Government recently agreed to spend \$15 million over 15 years studying radiation-related thyroid cancer in Ukrainian children. This was sensible and appropriate. But can a rational Government decide that it is worthwhile to spend \$15 million to study thyroid cancer in Ukrainian children, and not worthwhile to spend a fraction of that amount to prevent the same disease in American children? This petition says that it can't. America's families deserve no less protection from radiation than is provided to children and their parents throughout the rest of the developed world. The NRC staff has pointed the way, and the Commission and the U.S. Government should follow.

II. Factual Background

A. Potassium iodide and its uses.

Potassium iodide (KI) protects the thyroid gland -- which, especially in children, is highly sensitive to radiation -- from the radioactive iodine that would be released in extremely serious nuclear accidents. By saturating the gland with iodine in a harmless form, potassium iodide prevents any inhaled or ingested radioactive iodine from lodging in the thyroid gland, where it could lead to thyroid cancer or other illnesses.

In addition to preventing deaths from thyroid cancer,¹ KI prevents radiation-caused illnesses that although not fatal, can disrupt and even blight a person's life. Thyroid cancer, curable in 90-95% of cases, generally means surgery, radiation treatment, and a lifetime on medication.² The changes of medication that go with periodic scans put many patients on a physiological and

¹ The American Cancer Society estimates the number of new cases in 1995 at 13,900, and the number of deaths at 1,120. Thyroid cancer represents about 1 percent of cancer cases nationwide.

² See letter of Joseph E. Rall, M.D., Ph.D., Deputy Director for Intramural Research, National Institutes of Health, to Central Docket Section, Environmental Protection Agency, February 9, 1990:

In the United States, there are approximately 10,000 new cases of thyroid cancer per year. After initial surgical removal, ablation with I-131 is used to complete the thyroidectomy in in at least half of these patients (i.e. ~5000) in doses ranging from 30 to 150 mCi. Most of these patients then receive one or more test doses of I-131 (2 to 10 mCi) to detect the occurrence of metastases. A conservative estimate of the number of patients who develop metastatic thyroid cancer who could benefit from I-131 therapy is 2000 cases per year. These patients receive from one to ten treatment doses of 150 to 300 mCi over a period of up to 20 years or more. This treatment is curative in some cases and prolongs disease-free survival in many cases.

It should also be noted that unlike some cancers, which if they have not recurred within a set period (such as five years) can be considered cured forever, the thyroid cancer patient must be monitored for life.

psychological rollercoaster.³ Hypothyroidism (an insufficiency of thyroid hormone, which can result from radiation damage to the gland) can cause permanent retardation in children and, if undiagnosed, can condemn adults to a lifetime of fatigue, weakness, and chills.⁴ The drug has a long shelf life -- at least five years -- and causes negligible side effects.⁵

B. U.S. policy on KI prior to the Three Mile Island accident.

In December 1978, the Food and Drug Administration announced that it had determined that potassium iodide was safe and effective for thyroid protection in nuclear accidents. The issue attracted little attention, however, and the NRC and the Federal Government as a whole took no public position on the drug.

Barely three months later, on March 28, 1979, the Three Mile Island accident began to unfold. After two days of unsuccessful efforts to bring the reactor under control, it was still uncertain whether a major release of radioactivity could be averted. Federal and state officials, searching for supplies of KI in case it should be needed, discovered that there was none to be had, in Pennsylvania or elsewhere. A supply therefore had to

³ Some years ago, for example, Senator John East of North Carolina committed suicide because, according to his widow, an incorrectly treated thyroid imbalance had made his life unendurable. President George Bush, after being treated with radioactive iodine for an overactive thyroid (Graves' disease), displayed symptoms characteristic of patients returning to thyroid hormone after the hypothyroidism caused by radioiodine treatments: physical exhaustion, frequent talkativeness, and a tendency to emotionalism. The media may have missed the story (as President Bush's former press secretary observed in recently published memoirs), but at the time, old thyroid patients understood exactly what was going on.

⁴ As I had occasion to see when I was in the Marshall Islands as an administrative judge with the Nuclear Claims Tribunal in 1991, many people who are chronically chilly and exhausted from hypothyroidism may be unaware that their problems are symptoms of a treatable illness. As a result, they may never receive the drug (synthetic thyroid hormone) that would quickly relieve their symptoms and allow them to live a normal life.

⁵ "Iodide Prophylaxis in Poland after the Chernobyl Reactor Accident: Benefits and Risks," Janusz Nauman, M.D., Ph.D., Jan Wolff, M.D., Ph.D., The American Journal of Medicine, Vol. 94, p. 524 (May, 1993).

be manufactured, literally overnight. At 3 a.m. on Saturday, March 31, a Food and Drug Administration official arranged with the Mallinckrodt Chemical Company for the immediate production of 250,000 doses of KI. Without a written contract or a purchase order, the company began production (Parke-Davis soon followed suit), and the first shipment of the drug arrived in Pennsylvania 24 hours later.⁶

C. The President's Commission on the Three Mile Island accident recommends KI stockpiling.

After the accident, President Carter appointed John Kemeny, President of Dartmouth College, to head a commission to investigate the accident. Its report, issued in October, 1979, was strongly critical of the failure to stockpile KI. It said:

For over 25 years, the use of blocking agents such as potassium iodide to prevent the accumulation of radioiodine in the thyroid gland has been known. The effectiveness of potassium iodide administration for thyroid gland protection in the event of releases of radioiodine was recognized by the National Council on Radiation Protection and Measurement in 1977. The Food and Drug Administration authorized use of potassium iodide as a thyroid-blocking agent for the general public in December 1978. However, at the time of the TMI accident, potassium iodide for this use was not commercially available in the United States in quantities sufficient for the population within a 20-mile radius of TMI.⁷

Among the Kemeny Commission's major recommendations was the following:

⁶ "Report of the Office of Chief Counsel on Emergency Response to the President's Commission on the Accident at Three Mile Island," (October 1979), p. 91. See also Dr. Jerome Halperin, "Potassium Iodide as a Thyroid Blocker -- Three Mile Island to Today," DICP, The Annals of Pharmacotherapy, Vol. 23 (May 1989), which includes an insider's account of the effort to procure not only supplies of the drug, but also bottles, labels, and droppers, and get them to Pennsylvania.

⁷ Report of the President's Commission on the Accident at Three Mile Island, October 1979, at 41-42. With a single change -- from 25 years to 40 -- this would be also be an accurate statement of current preparedness to administer KI.

An adequate supply of the radiation protective (thyroid blocking) agent, potassium iodide for human use, should be available regionally for distribution to the general population and workers affected by a radiological emergency.⁸

Elsewhere in its report, the Kemeny Commission explained that different types of accidents, depending on their particular circumstances, might require different kinds of emergency response:

A variety of possible accidents should be considered during siting, particularly "smaller" accidents which have a higher probability of occurring. For each such accident, one should calculate probable levels of radiation releases at a variety of distances to decide the kinds of protective action that are necessary and feasible. Such protective actions may range from evacuation of an area near the plant, to the distribution of potassium iodide to protect the thyroid gland from radioactive iodine, to a simple instruction to people several miles from the plant to stay indoors for a specified period of time. ... Emergency plans must have built into them a variety of responses to a variety of possible kinds of accidents.⁹

The last point is particularly significant, because it shows the Kemeny Commission's recognition that in some accident situations, evacuation may not be the emergency planning measure of choice.

D. The federal agencies back the Kemeny Commission recommendation.

Initially, the Kemeny Commission's recommendation in favor of KI stockpiling seemed so obviously sensible as to be non-controversial. In NUREG-0632, "NRC Views and Analysis of the Recommendations of the President's Commission on the Accident at Three Mile Island," issued in November, 1979, the NRC declared:

The President's Commission recommends that an adequate supply of potassium iodide be available for both workers and the general public. NRC agrees and is

⁸ Id. at 75.

⁹ Id. at 16-17.

planning to require licensees to have adequate supplies of this agent available for nuclear power plant workers. For the general population, NRC expects to include the availability of potassium iodide as a necessary part of an acceptable State emergency response plan. Plans have not been finalized as to exactly how and to what extent the agent should be stockpiled and distributed, but studies are underway to resolve this matter at an early date.

For the next several years, the three agencies most concerned -- the Food and Drug Administration, responsible for approving drugs; NRC, expert in radiation protection; and the Federal Emergency Management Agency, with responsibilities for emergencies generally -- were all on the same track, favoring the stockpiling of potassium iodide. In May 1982, however, the Atomic Industrial Forum, a nuclear industry trade association, declared itself against potassium iodide.¹⁰

The NRC staff was strongly in favor of KI stockpiling as late as September 27, 1982, when it sent the Commissioners a memorandum numbered SECY-82-396 ("Development of a Federal Policy Statement on the Distribution and Use of Potassium Iodide for Thyroidal Blocking in the Event of a Nuclear Power Plant Accident"). In that paper, the staff proposed that the Commission agree with a draft interagency policy statement supporting KI stockpiling.

The draft policy statement is worth quoting at length, because it describes with clarity and accuracy both the benefits of KI and the limitations of the drug. It says:

....KI blocking only effectively reduces the radiation exposure of the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not nearly as effective as measures which protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the total body. As an example, if a precautionary evacuation can be instituted with little or no radiation exposure, this may be the most effective

¹⁰ "Statement on the Use of Potassium Iodide by the Atomic Industrial Forum Committee on Environment," cited in the "Industry White Paper, Review of Federal Policy on Use of Potassium Iodide," December 1993, at 7.

protective action. However, there are instances where evacuation may not be preferred. Evacuation may be unnecessary because the amount of protection afforded by in-place sheltering is adequate....There are also possible situations when evacuation cannot be accomplished in time to prevent exposing large numbers of individuals to a significant amount of radiation during the evacuation. In those instances where shelter is used because the evacuation cannot be completed in time to avoid a substantial radiation insult, the administration of KI could be a useful ancillary protective action which could provide some additional exposure reduction to the thyroids of the exposed individuals. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from an airborne release of radioactivity from a nuclear power plant accident and therefore should be used in conjunction with sheltering, evacuation or other protective methods. ... In summary, the use of KI to prevent radioiodine from accumulating in the thyroid gland can be an effective ancillary protective action during a nuclear power plant accident.¹¹

E. The NRC and FEMA reverse themselves.

For reasons that have never been explained publicly, the policy statement was almost immediately scuttled. Less than three weeks after sending the draft policy statement to the Commission for approval, the staff sent a supplementary paper, SECY-82-396A (October 15, 1982), withdrawing the September 27 memorandum. The new memo informed the Commissioners that NRC's Office of Research could, by January 1, 1983, produce a paper showing that KI was "significantly less cost beneficial than previously assumed." The staff proposed sending this document, when completed, to the other federal agencies "with a recommendation that a policy statement recommending against the stockpiling and distribution of potassium iodide for the general public be developed." The staff paper added a significant piece of information: "The Commission should also be aware that FEMA has recently reversed its previous decision to purchase a large quantity of potassium iodide for a national stockpile." The reason for FEMA's action was not stated, however.

In a November 22, 1983 Commission meeting, open to the

¹¹ SECY-82-396 (September 27, 1982), Attachment 3, at 3-4.

public, Jack Zerbe, head of the NRC's Office of Policy Evaluation, expressed his unease at the NRC staff's sudden about-face:

I guess one of the things that was of concern to us was that in 9/27/82, the staff had recommended that they adopt this thing that had been worked on for four years by the three agencies, and essentially two weeks later they shifted that recommendation to go in just the opposite direction.

Transcript at 79.

The implied question -- why the reversal had occurred -- went unanswered. No claim was made, then or later, that the change was based on new scientific, technical, or medical information.

The purpose of the November 22, 1983 meeting was for the NRC staff to brief the Commissioners on the staff's proposal to take a strong position against KI. At the outset, the three staff briefers¹² emphasized that the NRC had the primary role within the U.S. Government as a source of technical expertise on the KI issue.¹³ One of the briefers explained:

We, at the NRC, have the responsibility to provide the technical rationale and make some recommendation either for potassium iodide, a neutral statement one way or another, or against it. And that's where we have to come down, in some sense. It is our responsibility to provide that technical information.

Transcript at 7.

A problem for the briefers, in making the case against KI, was that the Commissioners had been hearing ever since the Three Mile Island accident that stockpiling the drug was a cheap, effective, and sensible protective measure. As Commissioner Bernthal commented at one point, "I just think stockpiling is such a cheap and easy preventative, that even if the odds are 1 percent, why not?" (Transcript at 28.) The briefers undertook to prove that even though KI might cost only ten cents per pill, it was nevertheless not "cost-effective."

¹² None of the three is still with the NRC.

¹³ This was correct then and remains so today.

The briefers' central claim was that it would take \$10,000,000 worth of KI to prevent each "nodule,"¹⁴ whereas if KI were not used, the cost of dealing with each nodule that did occur would be at most \$20,000. The transcript is clear on this point:

At the bottom of this [slide], you see a dashed line at about the \$20,000 figure, and that represents what we feel the cost-benefit breakpoint would be. If the cost of averting one nodule is on the order of \$20,000, that's the cost that will be represented by the medical treatment and the loss of productivity of an individual if he had a thyroid nodule. And it's on the upper end of the values which we have seen. There's a few days' loss from -- it's a relatively simple operation that's involved in removing the thyroid or removing the nodules¹⁵ -- [Emphasis added.]

Transcript at 52-53.

The briefers claimed to have performed the analysis "with a bias in favor of potassium iodide if anything." (Transcript at 53.) They continued:

And our analysis still comes down and shows that even if our most optimistic view -- which is the bottom line of these curves -- would indicate that this is not a viable measure to be taken, it is not something that we should consider in terms of policy. As far as we're concerned, the message couldn't be any clearer. ... We have taken every factor that we can think of into account; it's not just single arguments that we throw at each other; we have factored in all the uncertainties that we can think about, and this is where we come down to it, and the message is clear.

Transcript at 54.

The transcript shows the Commissioners' response:

¹⁴ The \$10,000,000 figure reflected the assumption that an accident in which KI would be useful could occur only once a millenium.

¹⁵ Compare this description of thyroid disease with that quoted in footnote 2, above.

CHAIRMAN PALLADINO: But it sounds crass. It doesn't satisfy me as an individual.

COMMISSIONER ASSELSTINE: I must say I share that view.

CHAIRMAN PALLADINO: Something just does not sit with me right.

[Staff briefer]: Let's move on to the next slide.

(Laughter.)

Transcript at 54.

The Commissioners' misgivings were well-founded. While the briefers' clear and unequivocal message was that the worst consequence of failing to stockpile KI was that a "nodule" might appear, they neglected to mention that their figures were based not on all nodules, but only on harmless benign ones. Their own analysis showed that some 40% of all accident-caused nodules will turn out to be cancerous, and that 5% to 10% of the cancers will be fatal.¹⁶

Chairman Palladino persisted. Told that the NRC should provide its cost-benefit analysis to other federal agencies and state and local governments "because these other agencies do look to the Nuclear Regulatory Commission," (Transcript at 57), he replied:

I'm not ready yet to even address that because I don't understand in the cost analysis -- for example, you say it costs -- what were your dollars? \$10 million per nodule averted, and you said boy, that's pretty high. But then you tell me it's a low cost operation. So now to me, for example, as an individual, what would it cost me for my pill. Twenty cents. ... As an individual, I say boy, that's among the lowest-cost protection. ...

... I guess I was taking a more personal view of cost-benefit. 20 cents or some nominal amount of money every year or every five years to replace them seems

¹⁶ This fact was buried in the fine print of the thick memorandum that accompanied the briefing. The transcript suggests that the Commissioners had not picked up on this critical point.

like small change compared to the risk, from my perception.

Transcript at 57, 59, 60-61.

One of the staff briefers responded by comparing potassium iodide to insurance policies with low premiums but with coverage that turns out, on close examination, to require "that there has to be a stampeding elephant that kills you." (Transcript at 61.)

CHAIRMAN PALLADINO: ...You said something that bothers me a little bit. You said that we were paying a low cost for something that wasn't worthwhile. You related it to a worthless insurance policy. But as an individual, I may say the potential benefit is that I might survive a nuclear accident at that plant, which I live near.

COMMISSIONER ASSELSTINE: Or that you may not have to go through an operation --

[Staff briefer]: Except that -- the surviving question is not the question, and that's the piece that really should also be emphasized.¹⁷ [Emphasis added.]

CHAIRMAN PALLADINO: All right, survive in the terms of I avert --

[Another staff briefer]: An illness. I will avert an illness which I might incur. But my father's argument in buying his insurance policies was the very same. He might leave my mother \$10,000 from an accident insurance policy. There was a residual chance that he would be killed by that stampeding elephant. It was not a well thought-out choice.

¹⁷ The clear implication of this statement was that potassium iodide cannot save lives. The staff briefer treated Chairman Palladino's comment as referring only to immediate, short-term survival. To be sure, potassium iodide will not prevent quick deaths during an accident (if people die from radiation in the short term, it will be because of whole-body doses, not thyroid doses), but it may prevent slow deaths from cancer in the years afterwards. For the three or four Americans who die of thyroid cancer each day, and all the thyroid cancer patients who, being human, worry that the disease may kill them, "the surviving question" is thus very much the question.

Transcript at 63.

Continuing the theme that the drug was a useless remedy against a non-existent problem, one of the staff briefers added that the staff did not feel it necessary to come out in opposition to the purchase of KI by individuals: "If somebody wants to wear that amulet and have that available to them, that's their business...." (Transcript at 68.)

The issue was not finally resolved that day, but in the end, the NRC's negative views on the drug were communicated to an interagency group studying the issue.¹⁸ The result was the 1985 Policy Statement, still in effect today, which declared:

While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC....¹⁹

The net effect of the Policy Statement was to dispose of the Kemeny Commission's recommendation in favor of KI stockpiling,

¹⁸ I do not mean to suggest that the Commissioners remained under the impression that thyroid cancer was never fatal. As I described in my Differing Professional Opinion, the Office of General Counsel pointed out to the Commission that the staff's figure of \$20,000 referred only to the costs associated with having a harmless benign thyroid nodule. In reply, the staff acknowledged that if both benign and malignant nodules were taken into account, the costs would go up by a factor of five, to \$100,000. No public announcement of this was made, however, so the recalculation would have been of no benefit to those members of the public who attended the November 22 briefing at which the \$20,000 figure was touted.

¹⁹ "Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent," 50 Fed. Reg. 30258 (July 24, 1985). Note that the Policy Statement does not say that KI itself is not worthwhile; it is the requirement to stockpile or predistribute the drug that is described as not worthwhile. But the ordinary reader will not notice this artful distinction, and will understand the Government to say that the drug itself is worthless. Note also the implication that it will always be possible to evacuate the affected population if an accident occurs.

seemingly once and for all. What could not have been predicted, however, was that only a year later, a nuclear catastrophe in the Soviet Union would give tangible proof of the value of the drug in radiological emergencies.

F. Chernobyl and its aftermath

During the Chernobyl accident of 1986, the damaged reactor spewed radioactive iodine not only into the immediate vicinity of the plant (located near Kiev in Ukraine), but also over wide areas of the Soviet Union and nearby Poland. Russia, Ukraine, and Belarus, where the distribution of KI was inadequate and untimely, are now experiencing extraordinarily high levels of childhood thyroid cancer, as recent newspaper articles have described.²⁰ The reports from Eastern Europe make clear that

²⁰ "Chernobyl's Young Victims Pay Toll: Thyroid, Other Cancers Are Belarus's Legacy of Nuclear Disaster," a front page article in The Washington Post, June 24, 1995: "In 1986, before Chernobyl, according to Yevgeny Demidchuk, director of the republic's Scientific and Practical Center of Thyroid Cancer in Minsk, Belarus registered just two cases of thyroid cancer in children under 14, about a typical number for a country its size. By 1992 that number had soared to 66 cases and last year to 82, a surge so sudden and severe that international experts, initially skeptical about Belarus's post-Chernobyl health claims, now acknowledge it can only be explained by Chernobyl fallout. ... Pre-cancerous thyroid conditions in children are even more widespread. 'This is on a mass scale, several million kids who might develop thyroid cancer,' said Konoplya [director of the Radiobiology Institute of Belarus's Academy of Sciences]."

See also, "Cancers Soar in Region of Chernobyl," The Washington Post, March 25, 1995: "The rate of thyroid cancer in a region north of the Chernobyl nuclear plant is nearly 200 times higher than normal, according to research published in the British Medical Journal. Scientists from Russia, Ukraine, Belarus and the World Health Organization said abnormally high rates of thyroid cancer in children had been detected farther away in the northern Ukraine and parts of Russia.

... The cancer has appeared most in children because they are more sensitive to radiation and their thyroid glands are smaller, so a given amount of radioactive iodine represents a larger dose for a child's thyroid gland than for an adult's.

... In Gomel, a city in Belarus 70 miles north of Chernobyl, 143 cases of thyroid cancer were diagnosed between 1991 and 1994 in children under 15, the scientists said. That was a rate of 96.4 per million, compared with the normal rate of 0.5 per million."

radiation-caused thyroid disease entails much more than "a few days off." In Poland, on the other hand, where KI was administered to 97% of the nation's children, there has been no similar increase in thyroid cancer. The Polish example is proof positive of the benefits of a well-prepared KI program.²¹

In view of the grave medical news from the former Soviet Union, the United States Government is currently spending many millions of dollars -- some of it supplied by the NRC -- to study radiation-caused thyroid cancer in Ukraine and Belarus. Announcing a \$15 million, 15-year program that will follow 70,000 children in Ukraine, the Department of Energy declared, in a June 13, 1995 press release, that the studies "provide a unique opportunity to understand the thyroid cancer risk of exposure to radioiodine." The DOE press release explained: "The release of radioiodine is likely to figure prominently in any nuclear power plant disaster and knowledge of its carcinogenic potency is inadequate, especially in children."

In addition, the U.S. Government has spent generously to bring Ukrainian doctors to this country for training in thyroid surgery, because mishandled operations can mean damaged nerves and larynxes, and children rendered permanently mute. There could not be a better example of wise and humane foreign aid.

G. Post-Chernobyl developments on KI policy.

The Chernobyl accident demonstrated beyond the shadow of a doubt that potassium iodide worked; that it was no mere "amulet," as one of the briefers had scornfully described it to the Commissioners; and that countries which failed to stockpile and distribute it could find themselves with serious public health problems on their hands. The NRC staff, however, was not immediately ready to acknowledge that the new information from Chernobyl called for a revision of U.S. policy.

In early 1989, the NRC issued NUREG-1251, "Implications of the Accident at Chernobyl for Safety Regulation of Commercial Nuclear Power Plants in the United States," in which it concluded that the Chernobyl experience did not suggest a need for changing U.S. policy on KI. "Evacuation is generally feasible," it said, "and when carried out is more effective in dose reduction than administration of KI, since it can reduce the dose for all body organs and not merely the thyroid gland. ... The apparently

²¹ See Nauman & Wolff, footnote 5 above.

successful use of KI at Pripjat [a city close to Chernobyl] does not alter the validity of guidance that recognizes that evacuation of the general public in the affected area could result in a greater overall dose reduction."²² It is worth noting that no claim was made that evacuation was always feasible, just "generally" feasible.

H. The NRC reconsiders the KI issue.

In June 1989, in accordance with NRC procedures, I filed a "Differing Professional Opinion" urging a change in policy on potassium iodide. In order to allow the reader to understand any bias that I might bring to the issue, I made clear my own personal interest: in 1973, when I was 26, I had surgery for a malignant thyroid tumor, the probable result of x-ray treatment for enlarged tonsils and adenoids when I was two years old. In 1988, my doctors detected a recurrence, which required five radiation treatments over a three-year period to be eradicated.

On November 27, 1989, the American Thyroid Association wrote to the Commission, urging KI stockpiling on a nationwide basis. In 1990, the NRC announced that it was reconsidering the existing federal policy.²³ While the issue was under consideration at NRC, the World Health Organization's "Working Group on Strategy for Public Health Action in Relation to Nuclear Emergencies" issued a report stating that "implementation of [KI] prophylaxis is critical," and stating: "Stocks of iodine should be stored strategically at points including hospitals, schools, and fire and police stations."²⁴

In April 1992, a contractor under the sponsorship of NRC's Office of Research issued a report which included a revised cost-benefit analysis of the use of potassium iodide. To the credit of the contractor and the NRC staff, this included a serious attempt to rectify the past downplaying of the consequences of radiation-caused thyroid disease. As far as its weighing of costs and benefits, however, it was bound by the staff's estimates of accident probabilities. Using those figures, the report concluded that stockpiling continued to be non-cost-effective, but that the difference between costs and benefits was

²² NUREG-1251, Section 4.2.3, "Assessment."

²³ 55 Fed. Reg. 39768 (September 28, 1990).

²⁴ World Health Organization, EUR/ICP/CEH 102(S), Section 4.3.3. (1991).

significantly narrower than had been calculated by the NRC staff in the early 1980's. For the population within a 5-mile radius, "the cost-benefit ratio for use of potassium iodide by the general public approaches a value of two," the staff reported in November 1993.²⁵

In December 1993, an industry trade group, the Nuclear Management and Resources Council, sent a "White Paper" to the Commission arguing against any change in current KI policy. (It was the only group to do so.) The White Paper suggested that a change in policy would cause members of the public to "want to know if the federal policy is being changed because the plants are less safe." It added: "Public confidence in the technology could be affected by the decision."²⁶

The industry White Paper also quoted Dr. David Becker, an eminent thyroidologist who is currently heading the NRC-sponsored research into thyroid cancer in Belarus, in such a way as to make it appear that he opposed KI stockpiling. This was taking a

²⁵ SECY-93-318, p. 4. Thus by these calculations, KI almost pays for itself for the closest-in populations. This averaged figure does not take into account either the difference in safety between plants of different designs or the wide margin of error (a factor of 100) in the estimates of accident probability. If accidents are 100 times more probable than estimated, then KI for these nearby residents will pay for itself 50 times over, by the NRC staff's own calculations. My contention, however, is not that KI will necessarily pay for itself. Rather, it is that the uncertainty in the actual probability of major accidents makes these cost-benefit calculations of little value, and argues for letting prudence and good judgment drive the decision on KI.

²⁶ "Review of Federal Policy on Use of Potassium Iodide," Nuclear Management and Resources Council (December 1993), p. 8. The industry's argument echoes the claim of environmentalists and residents of the Three Mile Island area, in the early 1980's, that the NRC was required to consider the fears of the local population, and the probable "psychological impacts" on them, in determining whether to allow resumed operation of the Three Mile Island Unit 1 reactor. The NRC, supported by industry, took the position that a scientific and technical agency should base its decision on the best available scientific and technical evidence, not on people's fears. A unanimous Supreme Court upheld the NRC, after I briefed, argued, and lost the case in the D.C. Circuit Court of Appeals. Metropolitan Edison Co. v. People Against Nuclear Energy, 460 U.S. 766 (1983), reversing People Against Nuclear Energy v. NRC, 678 F.2d 222 (D.C. Cir. 1982).

chance, in light of the fact that Dr. Becker was one of the signers of the November 1989 American Thyroid Association letter urging KI stockpiling, and the New York Times had published a letter from him to the same effect. After Dr. Becker protested, a senior NRC official sent a letter of rebuke to the industry group, declaring that its characterization of Dr. Becker's views was "completely contrary" to his actual position. Copies were sent to Dr. Becker and the NRC's Public Document Room.²⁷

I. The NRC staff backs KI stockpiling, but its proposal for a change in policy is blocked when the Commissioners deadlock.

On March 29, 1994, the NRC staff declared its support for KI stockpiling. In its final memorandum to the Commission on the subject, it wrote:

Although a reactor accident requiring KI is unlikely and KI is only effective as a protective measure for the dose to the thyroid due to radioactive iodine, the cost to purchase and stockpile amounts sufficient to administer to populations within five miles of operating nuclear power plants is relatively low. [In a footnote, the staff estimated the cost at \$.10 per person per year.] Consequently, it appears prudent to stockpile KI for limited populations located close to the operating nuclear power plants.²⁸ [Emphasis added.]

The staff reported that it had engaged in dialogues with FEMA and the Department of Health and Human Services, and that the two agencies "would cooperate with the NRC in working toward adoption of a revised federal policy on KI." The staff proposed that the federal government buy the drug and make it available through FEMA to the states, which would be encouraged (but not compelled) to stockpile it.

On April 20, 1994, while the issue was pending before the Commissioners, Senators Alan Simpson, Republican of Wyoming, and

²⁷ Letter of June 1, 1994, from James L. Milhoan, Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to J. Phillip Bayne, President and CEO, Nuclear Energy Institute (NEI). NEI was the successor organization to NUMARC, which was in turn the successor to the Atomic Industrial Forum of the early 1980's.

²⁸ SECY-94-087, "Addendum to SECY-93-318 Re-evaluation of Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant," at 2.

Joseph Lieberman, Democrat of Connecticut, wrote a concise and forceful letter to the Commission, urging that U.S. policy on potassium iodide be brought into line with expert opinion and international practice. After marshaling the many arguments for KI, they dealt with the claim that KI stockpiling could result in "negative public perception." They wrote:

[N]o evidence has been provided that any of the existing policies in other nations or in the states that provide for the use of KI by the general population has caused any undue panic or apprehension to the general public. Moreover, the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced.²⁹

When the staff proposal came to a vote, however, the four Commissioners divided 2 to 2,³⁰ and under NRC internal procedures, a tie vote on a proposal means that it fails. There was, therefore, no decision on the merits of the NRC staff's recommendation.

J. KI and the federal government -- current status.

The tie vote on the staff's proposal for a change in policy seems to have been misunderstood completely by an interagency committee considering the KI issue. The February 1995 issue of "CRCPD Newbrief," the newsletter of the Conference of Radiation Control Program Directors, reported that at a December 1994 meeting of the Federal Radiological Preparedness and Coordination Committee (FRPCC), an ad hoc subcommittee on KI presented and discussed a report on the drug. According to the newsletter, "the subcommittee indicated that there is a lack of new data challenging the [1985] FRPCC Federal Policy" on KI. The story continued: "A lack of justification for a federal stockpile was identified by the subcommittee. There is also a lack of support for federal stockpile initiative by the states and the primary

²⁹ A copy of the letter is attached to this petition.

³⁰ The Commission's "Staff Requirements Memorandum" of May 6, 1994 recorded Commissioner Rogers's vote in favor of the staff recommendation but was silent as to the individual positions of the other three Commissioners. Commissioner Rogers is the only one of the four still on the Commission.

federal regulatory agency [NRC]."³¹

The FRPCC subcommittee's position is all the harder to fathom in light of the publication by FEMA in September 1994 of a proposed "Federal Radiological Emergency Response Plan"³² which expressly envisions the use of KI during radiological emergencies. Clearly, this implies that the authors of the Plan recognize the drug's usefulness. Under the Plan, NRC will be the "Lead Federal Agency" during emergencies at nuclear power plants, and its duties will include providing

...advice to State and local governments on measures that they should take to avoid or reduce exposure of the public to radiation from a release of radioactive material. This includes emergency actions such as sheltering, evacuation, and prophylactic use of iodine.³³

The Plan further provides for an interagency "Advisory Team for Environment, Food, and Health" to help the "Lead Federal Agency" formulate its advice, by providing, among other things,

Guidance on the use of radioprotective substances (e.g. thyroid blocking agents), including dosage and projected radiation doses that warrant the use of such drugs.³⁴

Thus the new Plan envisions that in an emergency, the interagency panel will advise the NRC on when KI should be used, the NRC will then advise the state and local governments, and the

³¹ One has to wonder where the subcommittee has been getting its information if it is unaware of any "new data challenging" the 1985 policy. The subcommittee might begin by reading the American Thyroid Association's letter of 1989; the March 1994 memorandum by the NRC staff, endorsing a change in federal policy; the April 1994 letter from Senators Simpson and Lieberman, summing up the arguments for KI stockpiling; the International Basic Safety Standards, adopted in 1994 with U.S. Government support; and the newspapers, which regularly carry articles on Chernobyl-related thyroid disease in the former Soviet Union.

³² 59 Fed. Reg. 46086 (September 6, 1994).

³³ 59 Fed. Reg. at 46091.

³⁴ Id.

states and localities will then administer the drug. What the Plan's authors either do not realize or do not choose to mention is that in a real emergency there will be no KI to give out, thanks to the current federal policy on the drug.³⁵

Also in 1994, the Board of Governors of the International Atomic Energy Agency, with U.S. Government support, adopted new "International Basic Safety Standards." These standards represent the consensus of the world's experts on radiation safety. With regard to emergency planning, they provide, among other things: "Intervention levels for immediate protective actions, including sheltering, evacuation, and iodine prophylaxis, shall be specified in emergency plans...."³⁶ Thus the international radiation protection community, like the Kemeny Commission in 1979 and the short-lived draft federal policy statement of 1982, recognized that effective preparedness for radiological emergencies meant having three arrows in the quiver, not just one or two.

³⁵ Several years ago, Dr. Jerome Halperin, who as an FDA official was involved in the effort to obtain KI during the Three Mile Island accident lamented in a medical journal article that the nation was still in a pre-TMI state of readiness for emergencies requiring the drug. "Potassium Iodide as a Thyroid Blocker -- Three Mile Island to Today," DICP, The Annals of Pharmacotherapy, Vol. 23, May, 1989. His statement was accurate at the time he wrote and remains so today.

³⁶ International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (interim edition), International Atomic Energy Agency (Vienna, 1994), at 73.

III. Argument

1. The U.S. Government cannot rationally conclude that it is worthwhile to spend \$15 million to study radiation-caused thyroid cancer in Ukraine, but not worthwhile to spend a much smaller sum to prevent radiation-caused thyroid cancer in this country.

The project now underway to study thyroid cancer in Ukrainian children will cost the United States about \$200.00 for each child studied. At the same time, the U.S. Government refuses to spend \$.10 per child to prevent thyroid cancer in American children. To make clear, I am not criticizing the expenditure on the study in Ukraine, I applaud it. But I question whether, at \$15 million dollars, it is 50 or 60 times more valuable to the American people than would be a national potassium iodide stockpile, costing a few hundred thousand dollars, that could prevent large numbers of cancers, some of them fatal, in the event of a serious accident. The United States should be able to afford both.³⁷ The NRC staff has estimated that KI is so cheap that buying the drug would cost less than continuing to study whether it is cost-effective to buy it.

Nuclear accidents can happen, here as well as abroad. If accidents can happen, that means that given enough time, eventually they will happen. If a major accident ever occurs in this country, we do not want American children go through what the children of Belarus, Ukraine, and Russia are suffering today. A stockpile of KI can help assure that they do not.

This is not a radical proposition by any means. As noted above, all the relevant agencies of the United States Government, including the NRC, initially agreed with the Kemeny Commission recommendation that KI stockpiling was sensible, prudent, and worthwhile. The wisdom of that recommendation was confirmed by Chernobyl in 1986. Whatever the reason for the Government's abrupt reversal late in 1982, it was a serious mistake, and correction is long overdue.

³⁷ It need hardly be added that if there is ever a major nuclear release in this country, we will spend hundreds of millions of dollars identifying, treating, and compensating harm that might have been prevented by the timely expenditure of that few hundred thousand dollars.

2. Evacuation is not necessarily the protective measure of choice in every emergency, and even when it is the preferred option, it is not always feasible.

The 1985 federal policy statement, declaring that KI stockpiling would not be worthwhile, explained: "This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC...."

There are two problems with the underlined portion of this statement. It implies (1) that evacuation is necessarily the protective measure of choice in every emergency, and (2) that authorities would always have the "ability to evacuate the general population." Both propositions are false, and the existing policy may therefore give states and the public a false sense of security.

As the Kemeny Commission report explained (see p. 8 above), different types of accidents, and the particular circumstances presented, may call for different protective measures. A KI stockpile assures that responsible authorities have an additional type of protection in their arsenal.

The NRC has never claimed, nor could it claim, the "ability to evacuate the general population" whenever a serious accident occurs. On the contrary, it has repeatedly made clear that a finding of adequate emergency planning does not translate into a guarantee that the entire affected public can necessarily be evacuated. The most NRC that asserts (for example, in NUREG-1251, issued in 1989) is that evacuation is "generally" feasible. In the real world, unexpected things happen, such as severe weather conditions or blocked highways, that can make complete evacuation impracticable.

This means that sometimes, either by choice or necessity, authorities may be sheltering people or telling them to remain indoors rather than evacuating them. Any time that people are sheltered or told to stay indoors, it may be desirable to administer KI. In addition, any time that evacuation routes may take people through areas of radiological contamination, it makes sense to give them KI. Finally, any time (as in the case of Chernobyl) that there is a large airborne release high in the atmosphere, with uncertainty about where the radiological contamination will descend, it makes sense to be ready to administer the drug, since one cannot know whom to evacuate. Obviously, you do not have the option of administering KI if

there is none to administer.³⁸

The opponents of KI often make the argument that to be in favor of KI stockpiling amounts to downplaying the importance of evacuation. Evacuation protects the whole body, they say, whereas KI protects only the thyroid gland, so to support stockpiling is to indicate a willingness to leave the rest of the body at risk from radiation, thereby diminishing public protection. This argument is factually incorrect, illogical, and disingenuous. The advocates of KI stockpiling, from the Kemeny Commission through the International Basic Safety Standards, have always envisioned the drug as complementing other emergency planning measures, not replacing them. There is no way that the availability of KI could increase risk to the public. Would the existence of a supply of pills on a shelf in local schools and firehouses cause all the public officials responsible for managing radiological emergencies to forget about evacuation as an option if an emergency occurred? Would it impede an evacuation? Of course not.

3. The decision on stockpiling KI should turn on whether, given the enormous consequences of being without it in a major accident, it is a prudent measure, not on whether the drug will necessarily pay for itself over time.

The opponents of KI have framed the issue in terms of whether the drug is "cost-effective" -- that is, whether it would pay for itself over time in terms of reduced medical expenditures to treat radiation-caused thyroid disease. The implied premise is that if KI is not cost-effective in dollar terms, it is therefore not worth having.

That premise, however, is false. KI, like all other emergency planning measures, represents a kind of catastrophic-coverage insurance policy, offering protection for events which, while they occur only rarely, have such enormous consequences when they do occur that it is sensible to take special

³⁸ Compare the point made by Commissioner Rogers, in voting for the staff's recommendation, as recorded in the NRC Secretariat's "staff requirements memo" of May 6, 1994: "Commissioner Rogers believes that, in order for FEMA, State or local authorities to have a viable option for a KI program, it would be prudent for the U.S. government to assure the availability of a supply of KI."

precautions.³⁹ Health and life insurance policies are not intended to be cost-effective for the average purchaser. (If they were cost-effective, every insurance company would go bankrupt.) Does that mean that people are foolish to carry insurance? Of course not; it is the people who fail to carry insurance who are considered foolhardy. In addition to buying insurance, we spend money on countless other preventive measures in everyday life -- vaccinations for our children, smoke detectors and fire extinguishers for the home, a first aid kit for the car -- because they are sensible, not because we necessarily expect them to pay for themselves.

The best analogy to KI may be the lifejackets that ferryboats carry. We start with the assumption that ferryboat sinkings are unlikely, and we readily acknowledge that if an accident does occur, it is better to leave the ship in a lifeboat than bob in a lifejacket in the water. But sometimes things do not happen in real life the way they happen in drills. If there is no lifeboat available when the ferry sinks, the lifejacket may keep you from harm while waiting to be rescued, and if no lifeboats can be launched, you are better off with a lifejacket than with nothing at all. So we equip our ferries with lifejackets; we do not spend more money than the lifejackets themselves would cost studying whether to buy them; and we do not find the ferry operators writing White Papers to prove that if passengers knew that there were lifejackets on board, they would be too frightened to travel by boat.

4. The estimates of KI's "cost-effectiveness" all depend on estimates that are no more than informed guesses about the probability of severe accidents.

The cost-benefit analysis upon which the current KI policy is based relies on certain assumptions about the probability of severe accidents. Those assumptions need to be recognized for what they are: informed guesses, not hard facts. The NRC's cost-benefit analysis of the early 1980's was based on the assumption that a severe accident with a major release of

³⁹ At the 1983 Commission meeting on KI, one of the briefers compared KI to an insurance policy which, when you read the fine print, covers only death by stampeding elephants. The problem with this analogy is that the United States has never to my knowledge experienced an elephant stampede, and it is never likely to. The United States has, however, experienced the partial meltdown of a nuclear power plant (at Three Mile Island), and it could do so again.

radioactivity could occur in this country only once every 1000 years (with 100 reactors operating). But the all-important margin of uncertainty was huge: the agency acknowledged that accidents might be as much as 100 times more likely than that. In the past, optimistic predictions have not always been borne out by events. The Three Mile Island accident was also considered highly improbable, until it happened.

If it were really true that serious accidents with a release of radioactivity "can't happen here," then there would be good reason not only not to reject stockpiling of KI, but also to dispense with all the rest of emergency planning. One could then ignore Chernobyl, and disregard the use of KI in the rest of the developed world, by saying that while foreign reactors may suffer serious accidents, ours will not. But the NRC has never claimed that accidents in this country are impossible. In 1985, the same year that the current policy statement was adopted, the NRC Commissioners were advising the Congress that the estimated likelihood of a core melt accident at a U.S. reactor by the year 2000 was 45%.⁴⁰

Granted, not every accident results in a core melt, and not every core melt accident necessarily leads to offsite releases. One can be quite sure, however, whenever there is a serious accident, authorities will be looking for KI just in case it progresses to the point of a large offsite release. (We can assume that for every catastrophic accident, there will be a number of these lesser accidents.) Thus it is not sufficient to say that accidents with major offsite releases occur only rarely; the more relevant question is the chance of an accident serious enough to make authorities start hunting for a supply of KI.

5. If KI is not cost-effective, the rest of nuclear emergency planning is probably not cost-effective either.

The argument that KI should not be part of radiological emergency planning because it is not "cost-effective" carries the implication that those measures which are currently part of NRC-required emergency planning (sirens, exclusion zones, periodic emergency exercises, etc.) have been found to be cost-effective. This is not the case. KI is the only emergency planning measure to have been scrutinized with a cost-benefit analysis. The NRC's Advisory Committee on Reactor Safeguards pointed out long ago that all the other elements of the NRC's emergency planning requirements (such as sirens and periodic emergency exercises)

⁴⁰ The New York Times, April 17, 1985.

were put in place without a cost-benefit analysis and might well not pass that test.⁴¹ If serious accidents are really possible only every one or two thousand years, it is unlikely that any element of current nuclear emergency planning could be found "cost-effective," in the sense of being likely to pay for itself over time. Does that mean that the United States should leave the public at even greater risk by declaring that for American reactors, no emergency planning whatsoever is necessary? Of course not.

6. Cost-benefit analysis is a technique that needs to be applied with good sense, especially where public health measures are concerned.

Cost-benefit analysis, as valuable a tool as it can be when properly applied, needs to be performed with a measure of good sense, which includes a recognition that sometimes, costs and/or benefits may not lend themselves to quantification in dollar terms. This is particularly true in the area of public health.

Here, the evaluation of KI that preceded the 1985 federal policy statement was of a kind to give cost-benefit analysis a bad name. Strictly limited to economics -- the dollar costs of KI pills on the one hand, the dollar costs of having radiation-caused thyroid disease on the other -- it wholly ignored the quality-of-life impacts of thyroid cancer and other radiation-caused diseases.

Common sense tells us that if given a choice between a case of disease prevented and a case of disease cured, we would all prefer the former, even if the cure did not cost us a penny. But the cost-benefit analysis of KI proceeded from the assumption that there was no difference in desirability between prevention of radiation-caused thyroid disease and cure; thus the only factor to be considered in evaluating KI was the difference in cost. The old proverb that an ounce of prevention is worth a pound of cure went out the window, as the U.S. Government

⁴¹ The ACRS said: "The risk-benefit analyses conducted by the NRC Staff on this subject do not appear to be compatible with (or comparable to) approaches used in evaluating other aspects of nuclear emergency planning. For example, if the same evaluations were made, would there be justification for the conduct of emergency drills or the installation of warning sirens? Similarly the question could be raised as to whether there would be justification for population evacuations." Attachment to SECY-83-362 (August 30, 1983).

determined that instead of spending money to prevent radiation-caused thyroid disease, society should spend its money treating the disease if and when it occurred.

Any child knows that the negative impacts of illness are not limited to the economic costs. Any parent knows that people do not immunize their children against polio and diphtheria primarily to save money. In the real world, people pay to immunize their children against diseases first and foremost to spare them the misery and the danger that go with these illnesses.

But the cost-benefit analysis of KI ignored that obvious point, and as a result, it was valueless from the start. Indeed, it was worse than valueless, because it provided a rationalization for ignoring the Kemeny Commission's sensible recommendation in favor of KI stockpiling. The non-economic impacts of illness may be difficult to translate into dollar terms, but that does not mean that they can be ignored.

7. The existing policy on KI was defective from the start, as it was based in part on inaccurate information provided to the NRC Commissioners.

Decisionmakers who must weigh costs and benefits also need accurate data. The transcript of the 1983 staff briefing makes clear that the information provided to the NRC Commissioners seriously understated the significance of radiation-caused thyroid disease and thereby understated to an equal degree the value of KI. The briefers' central failure was to mention that when referring to "nodules," they were not taking into account the 40% of nodules that would be cancerous. It is as though staff members of the Department of Transportation informed the Secretary that airbags were of no value in "collisions" without mentioning that their definition of the word excluded every collision more serious than a fender-bender. Whatever additional information the Commissioners later received on the subject of thyroid disease, it is not at all clear that the Commission had any idea of the real nature of post-accident thyroid disease at the time they adopted an anti-KI position. Certainly, the public never received notice that the information provided at the 1983 meeting was erroneous.

8. Existing policy purports to leave the judgment on stockpiling KI to the states, but assures that the states do not have an adequate basis for making informed decisions.

In theory, the existing federal policy on KI leaves the

decision on stockpiling to the states. Since 1983, however, the federal government, and NRC in particular, have failed to provide the states with sound technical advice on the subject. Without accurate and current information on KI -- including the Chernobyl experience and the consensus of international experts -- states cannot make an informed judgment.

In their April 1994 letter to the Commissioners, Senators Simpson and Lieberman said pointedly that "the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced."

Since that time, however, the government's record on providing the public with "complete and accurate information" has actually taken a turn for the worse, with the publication in September 1994 of FEMA's "Federal Radiological Emergency Response Plan." As described above, at p. 22, the Plan provides that in an emergency at a nuclear power plant, an interagency Advisory Team will provide guidance on KI to the NRC, and the NRC will "provide advice to State and local governments on measures that they should take to avoid or reduce exposure to the public," including "sheltering, evacuation, and prophylactic use of iodine."

No state or local official or member of the public, reading this Plan, could possibly imagine that in a real emergency, there would be no iodine to administer. This raises a number of questions. If KI stockpiling is not worthwhile, why is administration of the drug one of the protective measures identified in the Plan? If KI is worthwhile, as the Plan implies, why isn't something being done to make sure that it is available? Does FEMA not know the actual state of KI preparedness?

The federal government cannot have it both ways. Either it should change the 1985 policy, and make the use of KI a viable option in a real emergency, or it should explain loud and clear why the United States has decided that KI will not be an option. What it cannot responsibly do is withhold protection, on the one hand, and on the other hand, represent to the public that this protection is already in place.

IV. The Remedy

The purpose of this petition, which takes the form of a rulemaking petition under 10 CFR § 2.802, is to raise the potassium iodide issue before the Commission and ensure that it receives a definitive resolution.

My specific request is for a minor change in the NRC's existing emergency planning rules, 10 CFR § 50.47. These rules include 16 planning standards by which emergency plans are to be evaluated. The tenth of these standards reads as follows:

(10) A range of protective actions have been developed for the plume exposure pathway EPZ [Emergency Planning Zone] for emergency workers and the public. 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.

I propose that the NRC amend this provision to read, "A range of protective actions, including sheltering, evacuation, and prophylactic use of iodine, have been developed..."

This language is taken verbatim from FEMA's September 1994 Federal Radiological Emergency Response Plan. If this change is adopted, the Plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

I suggest that the NRC also issue, either on its own or in conjunction with other agencies, a policy statement declaring that KI stockpiling is a sensible and prudent measure, necessary to assure that the drug will be available in the event of a major accident. (This policy statement could be modeled on the excellent draft statement of 1982, which regrettably was withdrawn.) This statement would make clear that KI, while no panacea, can be used in conjunction with evacuation and sheltering to maximize protection to the public.⁴²

⁴² I am not proposing house-to-house predistribution of KI, which I think would be ineffective and a source of confusion during an actual emergency. Rather, I am suggesting that state and local authorities have ready access to supplies of the drug so that they can administer it if it is needed.

The policy statement would also state the willingness of the NRC to provide a stockpile of the drug to states and localities upon request (unless FEMA or some other federal agency is prepared to do so). In addition, the statement would support the Kemeny Commission's recommendation for the creation of regional stockpiles of the drug as a backup for emergencies.

This policy would mean negligible cost to utilities. Contrary to the apprehensions of the nuclear industry, it would not send a message that nuclear plants have suddenly become more dangerous; it would simply mean that the U.S. Government, figuratively speaking, was putting a first aid kit into the car, after having neglected to do so for far too many years. Would members of the public suddenly become newly frightened of nuclear accidents because KI is being stockpiled? As Senators Lieberman and Simpson pointed out, the presence of KI does not seem to have panicked the population in the places where it is stockpiled today, and there is no reason why it should. If the World Health Organization recommendation is followed, and KI is stored strategically in firehouses, hospitals, police stations, etc., few people are likely even to be aware that the drug is being stockpiled.

The amount of potassium iodide stockpiled around each nuclear plant would not be great. Most nuclear plants are sited away from large concentrations of population in order to keep down the risk to the public. In an emergency, the drug might be needed in a wider area than just the immediate radius around the plant (at Chernobyl, for example, much of the radioactive iodine came to ground far downwind), but the existence of regional stockpiles would mean that the nation had a backup supply to draw upon in case of need.

If there should ever be a nuclear accident in this country serious enough to make authorities need KI, or even consider its use, and there was no KI to be found, what would the American people say? The anger and recrimination afterwards would be enormous, both for the failure to protect and the failure to inform. NRC, having promised in 1979 to put a KI program in place and then not done so, would have the most to answer for, especially in light of the the wealth of recent data from Chernobyl on thyroid effects and the 1994 recommendation of its own technical staff in favor of stockpiling. FEMA would be in the unenviable position of having to explain why its 1994 Plan implies not only that KI is valuable in emergencies, but also

can administer it if it is needed.

that it is currently available.

But pointing fingers after the fact will do no good to any child who got a dose of radioactive iodine in the thyroid because KI was lacking when it was needed. We cannot afford to wait until another accident or near-accident, and the resulting hue and cry, compel a change of policy. There is ample evidence now that the current policy is ill-founded, irrational, and dangerously complacent. The time to put a lock on the barn door is before the horse is stolen. If it should turn out that no attempt to rob the barn is made in our lifetimes, so much the better -- it's a very cheap lock.

Today, the Nuclear Regulatory Commission has the opportunity and the responsibility to resolve the KI issue sensibly and straightforwardly, as the NRC staff proposed doing in 1994. There is no good reason why American children should continue to be unprotected with KI, when the governments of other developed countries around the globe provide this cheap and effective protection for their children as a matter of course. The NRC staff has pointed the way, and the Commission and the Federal Government should follow.

Attachment:

Letter of Senators Alan K. Simpson and Joseph I. Lieberman,
April 20, 1994

DANIEL PATRICK MOYNIHAN, NEW YORK
 GEORGE J. MITCHELL, MAINE
 FRANK R. LAUTNER, NEW JERSEY
 GARY H. RUDOLPH, ILLINOIS
 BOB CANNON, FLORIDA
 JOSEPH I. LIEBERMAN, CONNECTICUT
 EDWARD H. METZGER, OHIO
 RICHARD M. ROBERTS, PENNSYLVANIA
 BARBARA DICKERSON, CALIFORNIA
 JOHN H. CHAFFET, MISSISSIPPI
 ALAN E. CRAPPE, OYOMING
 DAVID BURTON, MINNESOTA
 JOHN W. WARREN, VIRGINIA
 ROBERT D. BENTLEY, NEW HAMPSHIRE
 LAUREN F. BARTLEY, NORTH CAROLINA
 BILL CRISTOFER, IDAHO

PETER L. SCHULZ, STAFF DIRECTOR
 STEVEN J. SHERRER, SENATE STAFF DIRECTOR AND CHIEF COUNSEL

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
 WASHINGTON, DC 20510-6175

April 20, 1994

The Honorable Ivan Selin
 Chairman
 U.S. Nuclear Regulatory Commission
 Washington, DC 20555

Dear Chairman Selin:

We are writing to urge the Nuclear Regulatory Commission (NRC) to revise its current policy regarding the availability and use of potassium iodide (KI) in the event of an emergency at a nuclear power plant.

The NRC's current policy is that state and local governments should consider stockpiling KI for emergency use by emergency workers and institutionalized persons, but not for the general public. This policy was established in the early 1980's. Since that time, however, new information has arisen and additional experience has been gained on the costs and benefits of the prophylactic use of KI by the general population. We believe that this new information and experience requires a new approach to this issue.

It is well-established scientifically that KI is extremely effective in preventing the uptake of radioactive iodine by the thyroid. If taken in the proper dose prior to exposure to radioactive iodine, KI can completely block the uptake of the radioactive iodine.

The distribution of KI to the general population in the event of a nuclear emergency is a widely accepted protective measure. The World Health Organization has recommended its use for people living near a nuclear power plant if radiation levels are expected to exceed a predetermined dose. A number of foreign governments--including the United Kingdom, the Czech Republic, Switzerland, Canadian provinces with nuclear power plants, and the former Soviet Union--stockpile KI for distribution to and use by the general public in the event of a nuclear emergency. In the U.S., three states--Alabama, Tennessee, and Arizona--have plans to distribute or already have distributed KI to people living near one or more nuclear power plants within those states.

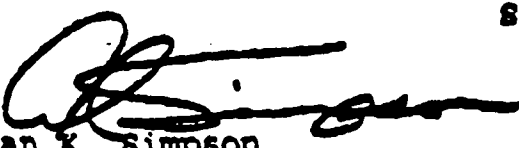
A recent cost-benefit study of this issue conducted for the NRC indicates that the costs of stockpiling KI for people who live within five miles of a nuclear power plant are minimal-- approximately ten cents per person per year. This means that for a typical population of 10,000 people living within five miles of a nuclear power plant, it would cost approximately \$1,000 to make KI available for distribution. The NRC staff projects that the cost of stockpiling KI for everyone in the country within five miles of a nuclear power plant would be on the order of several hundred thousand dollars per year. This is only a small fraction of the expenses already spent on emergency planning. As the NRC staff has noted, "[c]osts in this range present no significant barrier to stockpiling and are probably less than the cost of the continued studies."

Some concern has been expressed that public education on the use of KI may result in a potentially significant negative public perception. However, no evidence has been provided that any of the existing policies in other nations or in the states that provide for the use of KI by the general population has caused any undue panic or apprehension to the general public. Moreover, the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced.


In sum, therefore, KI can be an extremely effective countermeasure to prevent damage to the thyroid in the event of a radiological emergency. It can also be made available for the general population living near a nuclear power plant for minimal costs. The NRC should revise its policy to provide this additional potential protective measure for nuclear emergency planning.

We thank you for your time and consideration.

Sincerely,



Alan K. Simpson
Ranking Minority Member
Subcommittee on Clean Air
and Nuclear Regulation



Joseph I. Lieberman
Chairman
Subcommittee on Clean Air
and Nuclear Regulation

STATEMENT OF PETER CRANE
before the Nuclear Regulatory Commission
Open Meeting on Potassium Iodide (KI)
November 5, 1997

I appreciate the opportunity to address the Commission at this meeting on the radiation antidote potassium iodide (KI). This is the first meeting that the Commission has held on the subject in 14 years, and it is long overdue. I am here strictly in my private capacity, as an interested citizen as the petitioner in a rulemaking, not in my official capacity as Counsel for Special Projects in the NRC's Office of General Counsel. This statement was written at home, on my own time, and I am on annual leave as I speak to you this morning.

Potassium iodide is an effective, safe, and cheap medicine, with a long shelf life. It prevents thyroid cancer and other thyroid diseases by blocking the absorption of inhaled or ingested radioactive iodine. We have seen from Chernobyl what happens when you don't have KI to give out in an emergency: aggressive childhood thyroid cancers, in large numbers, appearing only a few years later.

On July 1, the NRC issued a press release saying that the Commissioners had decided to back a new policy that would make supplies of KI available to states that ask for it. The press release never used the word "cancer." That's like announcing the availability of Sabin vaccine without using the word "polio."

The draft Federal Register notice announcing this policy, sent to the Commission by the staff in June, and not yet issued, uses the word "cancer" just once -- buried at page 8 of a 13-page notice. Moreover, that notice never tells states that stockpiling is a reasonable and prudent measure. If it isn't reasonable and prudent, why is the NRC offering it? And if it is reasonable and prudent, why not say so loud and clear?

The states are beginning to catch on to what the Federal Government hasn't been telling them. Maine held a public meeting in December and its Radiation Advisory Commission voted unanimously for stockpiling that same day. Ohio had its meeting last week, and New York's meeting will be in Albany on November 21. I spoke at the first two of those and I hope to speak at the third. I certainly plan to be there.

At that meeting in Ohio, which was called by state and local health and emergency authorities, I talked about the cancers in Belarus, Russia, and Ukraine. I mentioned that the photographs of the young victims show incisions running from ear to ear, because in these children, the cancer tends to spread rapidly to the lymph nodes. The representative of the NRC countered that these scars were bigger than they had to be, because of the quality of medicine in the former Soviet Union.

Maybe that's true; I'm not a doctor. Maybe it's true that if, God forbid, there should ever be a major accident in which American children unnecessarily develop thyroid cancer, because KI was not there when it was needed, their surgical scars will be smaller than those on the necks of the children in Belarus. But I don't want American children to have any scars, big or little, when we can prevent the disease for pennies.

The person who could answer these and other questions about thyroid cancer is

sitting in the audience. He is Dr. Jacob Robbins of the National Institutes of Health, as distinguished an expert on radiation-associated thyroid cancer as there is anywhere in the world, with decades of experience on several continents. He could be sitting at the table today. But he isn't, because the Commission rejected the request of the American Thyroid Association (representing the nation's thyroid specialists) that he be allowed to speak for 15 minutes. For a Commission that has so often stressed the value of listening to the interested public, this was, I think, a sad day.

So today, just as at the last such meeting, in November 1983, the Commission will have to depend on its technical staff for expert medical advice. Let's hope they do better today than they did then. I described in my petition how the staff misled the Commissioners and the public in 1983, because I was making the point that the existing federal policy, adopted in 1985, is grounded in misinformation, and thus was defective from the start. I included lengthy portions of the transcript of the meeting, where the staff tells the Commissioners that "it's a relatively minor operation," involving "a few days off," and never even talks about cancer. The staff was arguing -- successfully, in the end -- that instead of spending pennies on prevention, society should put its resources into curing the thyroid disease if and when it occurred, because this was more cost-effective. This was taking the old adage about an ounce of prevention is worth a pound of cure and turning it upside down.

I was looking forward to seeing how the staff dealt with the misinformation issue in their paper analyzing my rulemaking petition, because they have dodged the issue for many years. They don't even mention it. As in the past, it's as though I had never said it.

I'll say it again, then. My petition had two bases. The first is that the wealth of new data from Chernobyl -- both about the health consequences of a major accident and the safety and efficacy of KI -- call for having KI stockpiling as a backup safety measure for use in the unlikely event of a major accident. The second is that existing U.S. policy is grounded in misinformation for the Commissioners and the public. The evidence of that misinformation is the publicly available transcript of the November 22, 1983, Commission meeting. That evidence is there for all to see, even if the NRC staff puts its fingers in its ears and refuses to hear.

What's the result? That today, children in other countries, from Japan to Poland and from Canada to Switzerland, have a protection that American children don't have. In the United States, believe it or not, we have KI to protect the sharks at Sea World but not the children who come to see them.¹

¹ The 8-year-old daughter of Charles Pond, the director of Tennessee's program, having somehow learned that sharks in captivity require KI for their health, persuaded her father that as the state's KI reaches the end of its shelf life (5 years), it should be donated to Sea World, where it is added to the sharks' water. See her father's statement at p. 57 of the transcript of the public meeting on KI held at FEMA on June 27, 1996. Young Ms. Pond's accomplishment was written up in the "Kids Did It!" section of a recent issue of the children's magazine, "National Geographic World".

All over the world, countries know that if you are serious about being prepared to protect the public in nuclear emergencies, you should have three arrows in your quiver. Those are: (1) evacuation, which is the ideal solution -- when it is feasible; (2) sheltering, which means taking cover; and (3) potassium iodide. Having all three options gives you the flexibility to choose among them, or use them in combination, depending on the particular circumstances.

If you can evacuate the entire population before the radioactivity arrives, and don't need to use KI, so much the better. But in the real world, bad weather, congested roads, or changing winds can make a full evacuation impossible. In that case, it's better to be safe than sorry.

The French, Germans, Swedes, Slovaks, etc., all know this, and they stockpile KI. It's cheap enough, at about 10 cents per person protected, that the Poles keep 90 million doses on hand. In fact, three years ago the NRC's technical staff calculated that it would be cheaper to buy a national stockpile of KI -- for a total of a few hundred thousand dollars total, or \$1100 for the average plant -- than to go on studying whether to do so.

Isn't that the definition of a "no-brainer"? Only in Washington would we spend more money studying whether a medicine to protect our children is worth buying than the medicine itself would cost.

Today, at international conferences on the health effects of Chernobyl, you can hear American doctors lamenting that though the value of KI is the number one health lesson learned from that accident, the U.S. continues to lag behind other countries in protecting its children.

It's not as though experts in the U.S. haven't known better for a long time. Almost 20 years ago, during the Three Mile Island accident, federal and state authorities went looking for KI and discovered there was none to be had. An official at the Food and Drug Administration had to get on the phone to a pharmaceutical company executive in the middle of the night and beg him to start up the production line and rush the drug to Pennsylvania.

Afterwards, the Presidential Commission that investigated the accident was scathing in criticizing the Government's failure to stockpile KI. Stockpiling, it said, was long overdue. In its response to the Presidential Commission's report, the NRC agreed wholeheartedly, and it promised to require KI stockpiling in the vicinity of nuclear power plants. Later it reneged.

Ten years after the accident, the FDA official, Jerome Halperin, wrote an article for a medical journal in which he lamented that KI preparedness was still in a pre-TMI state. He could write the same article today.

Wholly apart from the question of what the Federal Government did before Chernobyl, after Chernobyl, and especially after the reports of widespread thyroid cancer among children in the former Soviet Union were confirmed, there was no excuse to leave the Government's anti-KI policy in place. But it was left in place, and the Federal Government did nothing to alert the states and the public to the new data. In fact, the NRC staff keeps repeating, like a mantra, "No new data, no new

data." That is simply untrue. We know much more than we did, both about induction of childhood thyroid cancer and about the use of KI in a major accident. But the person who is truly learned about those subjects is Dr. Robbins, and the Commission doesn't want to hear him.

Only three states currently stockpile KI: Tennessee, Alabama, and Maine. One reason for the states' hesitation is that 15 years of inaccurate and incomplete information from the Federal Government have left some of them with little understanding of the stakes involved. Last year, for example, in a public meeting on KI at the Federal Emergency Management Agency, officials of two states justified their refusal to consider KI by declaring, in writing, "Loss of the thyroid is not life-threatening."

Try telling that to Senator Tom Harkin of Iowa, who lost a brother to thyroid cancer last year.

In fact, thyroid cancer is curable -- usually. About 16,000 Americans are diagnosed with the disease each year, and it kills only about 1200. Those 1200, however, are just as dead as the people who die of usually fatal cancers. And because the hormones produced by the thyroid gland affect the whole body, even a non-fatal case of thyroid cancer can have significant impacts on the quality of life. Just ask some patients. They will tell you about surgery and a lifetime on medication, at the very least; about radiation treatments that require hospitalization in radiological isolation, because the patients themselves are giving off radioactivity; about changes of medication in preparation for tests and treatments that leave patients exhausted and chilled to the bone; and about the anxiety that goes with any cancer. Having had thyroid cancer myself -- first when I was in my twenties, with a recurrence 15 years later that required five hospitalizations over three years -- I know that it is nothing I would wish on my children, nor would you wish it on yours.

Fortunately, we don't have to be completely without the benefit of Dr. Robbins's expertise today, because he put the arguments for KI stockpiling very succinctly in a letter to FEMA in July 1996. There is more analysis of the real issues in his brief letter than in the decision paper given to the Commission last week (SECY-97-245), and unlike the NRC staff, it didn't take him 26 months to prepare it. Here is what he had to say:

- "1. The Chernobyl experience has shown us that thyroid cancer is indeed a major result of a large reactor accident, even when evacuation is carried out;
2. The Polish experience has shown us that large scale deployment of KI is safe;
3. The Three Mile Island experience has shown us that it is not easy to obtain a good supply of KI in an emergency;
4. The shelf life of properly packaged KI is extremely long;
5. The advantage of having a supply on hand for immediate use far outweighs its moderate cost;
6. The problems attendant on predistribution are immaterial for the matter of creating a stockpile;
7. No one questions the ability of KI to protect the thyroid from radio iodine;
8. Even though KI administration before any exposure is ideal, the Chernobyl experience also has shown us that the exposure can continue for days;

institution of KI blockade at any time in this period is beneficial."

I urge the Commissioners to make the NRC staff tell you what is wrong with that analysis.

The case for KI stockpiling was also made in a 1994 letter sent jointly by Senator Joseph Lieberman, a Connecticut Democrat, and Senator Alan Simpson, a Wyoming Republican. Again, there is more real grappling with the issues in its two pages than in all the recent NRC staff papers on KI put together.

Let me emphasize that I am not an alarmist about nuclear power, any more than Senators Lieberman and Simpson. I have been defending NRC nuclear safety decisions in court for 20 years. I think that a major release is unlikely, because, generally speaking, our plants are well built and well run. But we have emergency planning because we know that accidents can happen, and that their consequences can be serious. If we are going to have emergency planning at all, it might as well be done right. I have often compared KI to the lifejackets on a ferryboat. Ferryboat accidents are very rare, and if one does occur, it is better to be evacuated in a lifeboat than to jump into the sea in a lifejacket. But in the real world, the unexpected happens, so we have lifeboats and lifejackets. We don't do fancy cost-benefit analyses; we don't study the issue for 15 years, we just do it, because it would be reckless and irresponsible not to.

The opponents of stockpiling can be expected to make the argument that because the Federal Government has recently decided to stockpile KI in 27 cities for acts of nuclear terrorism, that states and localities with nuclear power plants can safely forget about the issue. That major shift in U.S. policy on KI is a good thing -- no question about it. But we are talking about a medicine whose value is entirely dependent on time. Before the exposure to radiation is better than after, one hour after is better than two hours after, and so so. Thus it makes sense to have the drug on hand locally as well -- in schools, firehouses, and hospitals, for example, as the World Health Organization recommends -- with plans in place for its use. If there is one thing we know about emergencies, it is that planning is always preferable to improvised, ad hoc responses.

The real significance of the Federal Government's decision to stockpile KI for acts of terrorism is the recognition that the drug is useful in radiological emergencies. If it is valuable for emergencies caused by acts of terrorism, then it is also valuable for emergencies caused by accidents.

Some states worry that they could be held liable for side effects caused by KI. That is not a realistic concern. First, we know from the Polish experience during Chernobyl that side effects of KI are minimal. They gave out 18 million doses and two people were hospitalized briefly, both of whom men who had known iodine allergies and took the medicine against doctors' advice. There is also a study in the U.S. that reported on KI consumption in cough and cold medications. It said, in 1995, "for the most current data involving 38 million equivalent doses of KI consumed, there were no reports of adverse reactions." [Emphasis in the original.]

Second, KI would be given to the public only after the Federal Government advised that the emergency called for it. (See the Federal Radiological Emergency Response

Plan, issued by FEMA in 1996.) If states want to worry about liability, they should think about the legal consequences of not having stockpiled, given all the information available to them.

Last December, when the Maine Advisory Commission on Radiation voted unanimously to support stockpiling, one of its members explained his vote in these words: "Ten years from now, if we have a release, I would rather say that we erred on the side of conservatism, knowing what we know."

"Knowing what we know" -- that is the crux of the issue. As the word filters down to the states, at long last, individual states will be having to decide on KI. Because if ever there is an accident or act of terrorism at a nuclear plant in which Americans are harmed because KI was not available, those states must expect their citizens to ask: "When you knew that the Federal Government was offering free supplies of this medicine, and that the thyroid doctors unanimously said we should have it, and that other countries were protecting their children with it, how could you nevertheless have decided to leave our children unprotected?"

I don't have to spell out the questions that will be asked of the NRC if that ever comes to pass.

The pity of it is that all this present mess was completely avoidable. The NRC staff had it absolutely right in March 1994, when they advised the Commission:

"[I]t appears prudent to stockpile KI for limited populations located close to the operating nuclear power plants. This option represents an interoffice consensus and is recommended by the [NRC] staff. ... While NRC encourages the stockpiling of KI, the decision to stockpile, distribute, and use KI would be the responsibility of the individual States...

But the then Commissioners, on a deadlocked 2-2 vote, did not accept that sound advice.

I'd like to close by quoting Leo Tolstoy, who in 1896 described his proposal for solving the problems of Government:

"to be honest, not to lie, to act and speak so that your motives for action are understandable to your loving seven-year-old son; to act so that your son doesn't say: 'Papa, why did you say that then, but now say and do something quite different?'"

Thank you.

Attachments:

Letter from Dr. Jacob Robbins, July 8, 1996

Letter from Senators Lieberman and Simpson, April 20, 1996

Op-ed piece from Cleveland Plain Dealer, October 27, 1997

Wrapper from iodized salt package



National Institute of Diabetes
and Digestive and Kidney Diseases
Genetics and Biochemistry Branch
Bldg 10 Room 8N315
10 CENTER DR MSC 1766
BETHESDA, MD 20892-1766
301-496-5761
FAX 301-402-0387

National Institutes of Health
Bethesda, Maryland 20892

8 July 1996

William F. McNutt, Chairman
Federal Radiological Coordinating Committee
Ad Hoc Committee on Potassium Iodide
Federal Emergency Management Agency
Washington, D.C. 20472

Dear Mr. McNutt,

I very much appreciated the opportunity to participate in the 27 June meeting to consider stockpiling KI. I want to thank you for conducting an interesting and well run meeting, and also to reinforce my wish that those of us who recommended stockpiling convinced your committee that this is long overdue. The reasons are clear enough:

1. The Chernobyl experience has shown us that thyroid cancer is indeed a major result of a large reactor accident, even when evacuation is carried out;
2. The Polish experience has shown us that large scale deployment of KI is safe;
3. The Three Mile Island experience has shown us that it is not easy to obtain a good supply of KI in an emergency;
4. The shelf life of properly packaged KI is extremely long;
5. The advantage of having a supply on hand for immediate use far outweighs its moderate cost;
6. The problems attendant on predistribution are immaterial for the matter of creating a stockpile;
7. No one questions the ability of KI to protect the thyroid from exposure to radio iodine.
8. Even though KI administration before any exposure is ideal, the Chernobyl experience also has shown us that the exposure can

continue for days; institution of KI blockade at any time in this period is beneficial.

I sincerely hope that the subcommittee has been convinced by these arguments, and that the full committee will now devote its effort to creating one or more stockpiles and to developing the methodology for rapidly distributing the KI to a region where an accident is imminent or has already taken place.

I should add that the forgoing presents my personal opinion. I represent myself and the American Thyroid Association in this matter, but not the Public Health Service.

Sincerely yours,

A handwritten signature in cursive script, reading "J Robbins".

Jacob Robbins, M.D.
Scientist Emeritus

DAVID PATRICK COVATTA, NEW YORK
GEORGE J. MITCHELL, MAINE
FRANK R. LAUTENBERG, NEW JERSEY
RALPH REG. NYQUIST
BOB GRAMM, FLORIDA
JOSEPH I. LIEBERMAN, CONNECTICUT
HOWARD M. BENTLEY, OHIO
MARKS WENFORD, PENNSYLVANIA
BARBARA BOXER, CALIFORNIA

JOHN H. CHAFFET, MISSISSIPPI
ALAN E. CRAPPE, WYOMING
DAVE BUNTING, MINNESOTA
JERRY W. WAGNER, VIRGINIA
ROBERT BARTH, NEW HAMPSHIRE
LAUREN FARR, NORTH CAROLINA
SEN. CHRISTOPHER, IDAHO

PETER L. BROWN, STAFF DIRECTOR
STEVEN J. BRANDELL, SENIORITY STAFF DIRECTOR AND CHIEF COUNSEL

United States Senate

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

WASHINGTON, DC 20510-6175

April 20, 1994

The Honorable Ivan Selin
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Selin:

We are writing to urge the Nuclear Regulatory Commission (NRC) to revise its current policy regarding the availability and use of potassium iodide (KI) in the event of an emergency at a nuclear power plant.

The NRC's current policy is that state and local governments should consider stockpiling KI for emergency use by emergency workers and institutionalized persons, but not for the general public. This policy was established in the early 1980's. Since that time, however, new information has arisen and additional experience has been gained on the costs and benefits of the prophylactic use of KI by the general population. We believe that this new information and experience requires a new approach to this issue.

It is well-established scientifically that KI is extremely effective in preventing the uptake of radioactive iodine by the thyroid. If taken in the proper dose prior to exposure to radioactive iodine, KI can completely block the uptake of the radioactive iodine.

The distribution of KI to the general population in the event of a nuclear emergency is a widely accepted protective measure. The World Health Organization has recommended its use for people living near a nuclear power plant if radiation levels are expected to exceed a predetermined dose. A number of foreign governments--including the United Kingdom, the Czech Republic, Switzerland, Canadian provinces with nuclear power plants, and the former Soviet Union--stockpile KI for distribution to and use by the general public in the event of a nuclear emergency. In the U.S., three states--Alabama, Tennessee, and Arizona--have plans to distribute or already have distributed KI to people living near one or more nuclear power plants within those states.

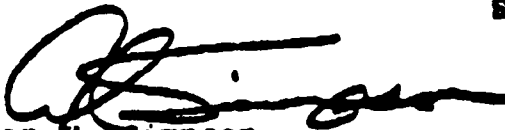
A recent cost-benefit study of this issue conducted for the NRC indicates that the costs of stockpiling KI for people who live within five miles of a nuclear power plant are minimal--approximately ten cents per person per year. This means that for a typical population of 10,000 people living within five miles of a nuclear power plant, it would cost approximately \$1,000 to make KI available for distribution. The NRC staff projects that the cost of stockpiling KI for everyone in the country within five miles of a nuclear power plant would be on the order of several hundred thousand dollars per year. This is only a small fraction of the expenses already spent on emergency planning. As the NRC staff has noted, "[c]osts in this range present no significant barrier to stockpiling and are probably less than the cost of the continued studies."

Some concern has been expressed that public education on the use of KI may result in a potentially significant negative public perception. However, no evidence has been provided that any of the existing policies in other nations or in the states that provide for the use of KI by the general population has caused any undue panic or apprehension to the general public. Moreover, the federal government has a moral responsibility to provide the public with complete and accurate information regarding the risks from federally-licensed activities and ways in which those risks may be reduced.

In sum, therefore, KI can be an extremely effective countermeasure to prevent damage to the thyroid in the event of a radiological emergency. It can also be made available for the general population living near a nuclear power plant for minimal costs. The NRC should revise its policy to provide this additional potential protective measure for nuclear emergency planning.

We thank you for your time and consideration.

Sincerely,



Alan K. Simpson
Ranking Minority Member
Subcommittee on Clean Air
and Nuclear Regulation



Joseph I. Lieberman
Chairman
Subcommittee on Clean Air
and Nuclear Regulation

Give radiation antidote fair hearing

By Peter Crane

State and Lake County officials will hold a public meeting tomorrow in Painesville on whether the radiation antidote potassium iodide — "KI" in scientific shorthand — should be stockpiled in Ohio for use in case of a nuclear power plant accident. The federal government recently has offered states a free supply of the medicine.

Nuclear industry lobbyists would like Ohio to reject this offer. The industry has admitted its concern that stockpiling KI will make the public anxious about the safety of nuclear plants.

Taken in time, KI prevents thyroid cancer by blocking the absorption of inhaled or ingested radioactive iodine. The Food and Drug Administration long ago declared it "safe and effective." The drug has a long shelf life, and at 10 cents per person protected, it is so cheap that the Nuclear Regulatory Commission staff once calculated that it would cost less to buy a national stockpile than go

The NRC commissioners recently voted to make KI available, at federal expense, to any state requesting it. Two commissioners — Republican Nils Diaz and Democrat Edward McGaffigan — would have gone even further. They favored making KI stockpiling mandatory, but were outvoted.

Countries around the globe understand that full preparedness for nuclear emergencies means keeping three weapons in their safety arsenal: evacuation, sheltering and KI. (Evacuation, the ideal solution, may not be feasible if weather or road conditions are

unfavorable.) Having these three tools gives authorities maximum flexibility.

The value of KI in nuclear emergencies hit home when the presidential commission investigating the Three Mile Island accident sharply criticized the government's failure to stockpile the drug. The NRC responded by promising to require KI stockpiling near every nuclear plant. Later, it quietly reneged. A bipartisan plea for stockpiling from Sens. Alan Simpson, Republican of Wyoming, and Joseph Lieberman, Democrat of Connecticut, was ignored.

Today, only three states stockpile KI: Tennessee, Alabama and Maine. Why not more? In part because after 15 years of inaccurate information from Washington, many states don't know better. Just last year, for example, in a public meeting on KI in Washington, a state official declared, "Loss of the thyroid is not life-threatening."

Try telling that to Sen. Tom Harkin of Iowa: He recently lost a brother to thyroid cancer.

In fact, thyroid cancer usually is curable. It kills only about 1,200 Americans each year, when about 16,000 Americans actually develop the disease. But those 1,200 are just as dead as the people who die of statistically more lethal cancers. And even a non-fatal case can be a heavy burden, as any patient can tell you. So can the thyroid doctors of the American Thyroid Association. They recently voted unanimously to back stockpiling of KI.

I've had thyroid cancer — first at 26, followed 15 years later by a lengthy recurrence. There are many worse illnesses, but still I would not wish this on anyone. If a dime's worth of medication on the shelf of a school or hospital someday can prevent an Ohio child from developing thyroid cancer, it will be a dime well spent.

Last December, after Maine's Advisory Commission on Radiation voted unanimously to support stockpiling, one member explained: "Ten years from now, if we have a release, I would rather say that we erred on the side of conservatism."

That is the issue for Ohio today. If ever there is a nuclear accident in which people are harmed because KI was not available, citizens will be asking state officials: "When you knew that the federal government was offering free supplies of this medicine, and that the thyroid doctors unanimously said we should have it, and that other countries were protecting their children with it, how could you have decided to leave our children unprotected?"

What will the answer be?

Crane is a lawyer with the federal government.

Full preparedness
for nuclear
emergencies means
keeping three
weapons:
evacuation,
sheltering and KI.

on studying whether to buy it.

The 1986 Chernobyl accident revealed what can happen when KI is lacking. Since 1991, Russia, Belarus and Ukraine have seen an upsurge of aggressive childhood thyroid cancers — well over 1,000 cases already. No such problems have occurred in Poland, where virtually all children received KI during the accident.



IODIZED

SALT®

THIS SALT SUPPLIES IODIDE, A NECESSARY NUTRIENT.

NET WT 26 OZ (1 LB 10 OZ) 737 g

Nutrition Facts

Serving Size 1/4 tsp (1.5 g)

Servings Per Container About 491

Amount Per Serving

Calories 0

% Daily Value*

Total Fat 0g 0%

Sodium 590mg 25%

Total Carbohydrate 0g 0%

Protein 0g

Iodine 60%

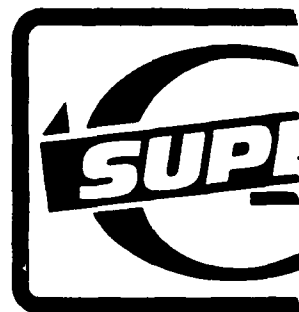
Not A Significant Source Of Calories From Fat, Saturated Fat, Cholesterol, Dietary Fiber, Sugars, Vitamin A, Vitamin C, Calcium And Iron.

*Percent Daily Values are based on a 2,000 calorie diet.

INGREDIENTS: Salt, Sodium Silicoaluminate, Dextrose, Potassium Iodide.

DISTRIBUTED BY SUPER G, INC.
LANDOVER, MD 20785 U.S.A.

©1993 SUPER G, INC.



IODIZ

SA

THIS SALT SUPPLIES IODIDE, A N

NET WT 26 OZ (1 LB