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

September 3, 1982

Mr. Kevin H. LeClair
Box 525
Belgrade Lakes, ME 04918

IN RESPONSE REFER
TO FOIA-82-371

Dear Mr. LeClair:

This is in response to your letter dated August 11, 1982, in which you requested, pursuant to the Freedom of Information Act, information on the use of potassium iodide as a radiation blocker in nuclear power plant accidents.

The documents listed on Appendix A are responsive to your request. These documents are enclosed.

Appendix B lists additional documents pertaining to potassium iodide. A copy of document 1 may be purchased by writing directly to the address listed below:

National Technical Information Services
5285 Port Royal Road
Springfield, VA 22141
Telephone: (703) 487-4650

Document 2 may be obtained by writing the NRC Public Document Room (PDR), 1717 H Street, N.W., Washington, DC 20555. The telephone number for the PDR is (202) 634-3273 should you wish to phone. The charge for copying records maintained at the PDR is five cents ($0.05) per page, as specified in 10 CFR 9.14(a).

Upon your agreement to pay the copying charges, the PDR will arrange for the record to be copied by a private contractor servicing the PDR. You will be billed by the contractor for copying charges plus tax and postage.

In regard to item 5 of your request, there are some 20 repositories for low-level wastes in the United States. Of these, 14 are operated by the Department of Energy for federally funded programs, and six are commercially operated by private industry (see attached map). Three of these six sites - West Valley, New York; Sheffield, Illinois; and Maxey Flats, Kentucky - are closed and are currently not accepting new wastes.

To date, NRC has not licensed any high-level waste disposal sites. The Department of Energy has the responsibility for Federal radioactive waste generated from defense or research and development activities. For further information concerning DOE's programs, we suggest you contact Dr. Franklin E. Coffman, Deputy Assistant Secretary of Nuclear Waste Management and Fuel Cycle Programs, U.S. Department of Energy, Washington, DC 20545.

Sincerely,

J. M. Felton, Director
Division of Rules and Records
Office of Administration

Enclosures: As stated

Appendix A

1. SECY-79-497, "Thyroid Protection," August 21, 1979.
2. Letter to Honorable Patricia Harris from Joseph M. Hendrie, November 21, 1979.
3. Letter to Honorable Tom Corcoran from Lee V. Gossick, December 3, 1979.
4. Letter to Prof. Frank von Hippel from John F. Ahearne, with enclosures, December 14, 1979.
5. SECY-80-257, "Radiation Protection - Thyroid Blocking," May 20, 1980.
6. SECY-80-257A, "Radiation Protection - Thyroid Blocking," September 18, 1980.
7. Nuclear Power Reactors in the United States, Map and Listing, August 1, 1981.
8. Testimony of Brian K. Grimes regarding Potassium Iodide, undated.
9. List of Nuclear Fuel Assembly Plants Currently in Operation.
10. Map of Low-Level Radioactive Waste Depositories.

Appendix B

1. NUREG/CR-1433, "Examination of Use of Potassium Iodide as Emergency Protective Measure for Nuclear Reactor Accidents." - $4.00

2. ACRS Transcript Concerning Radiation Protection and the Use of Potassium Iodide as a Thyroid Blocking Agent, June 23, 1982. FOIA-82-302 - Susan Hiatt. (357 pages)

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

August 21, 1979 — SECY-79-497

INFORMATION REPORT

For: The Commissioners

From: Robert B. Minogue, Director
Office of Standards Development

Thru: Lee V. Gossick
Executive Director for Operations

Subject: THYROID PROTECTION

Purpose: To provide the Commission with the staff's review of an article in Nuclear Safety entitled "Medical and Legal Implications of a Large Release of Radioiodine." (Enclosure 1)

Discussion: In a June 22, 1979 memorandum, Commissioner Kennedy requested a review of the above referenced article.

This article presents calculations of thyroid cancers that would result from the release of large amounts of radioiodine. In addition it compares, superficially, the alternatives of evacuation, thyroid blocking and confiscation of milk, alteration of dairy cow feed sources and monitoring the food chain. Further, it presents an analysis of long-term legal and medical effects and recommends the distribution and storage of potassium iodide, KI, for use in the case of releases where potential doses are 30 rads or greater.

In reviewing this article, we found no fault in the calculations based on the author's assumptions. The legal problems analyzed in the article related to such subjects as the availability of KI, compensation of cancer cases and the statue of limitations. ELD notes that though it should be granted that the article's authors would have had to spend considerable time and effort to analyze the many highly complex and sophisticated legal issues they had raised, nonetheless their conclusions were not backed by reasoned legal analyses. It should also be noted that the article was written before December 15, 1978, when the FDA published a Federal Register Notice, concluding that KI is safe and effective for use as a thyroid blocking agent in a radiation emergency under certain specified conditions (see Enclosure 2). Therefore, the legal problem of availability envisioned in the article is moot.

Contact:
M. A. Parsont - 35854

The Staff's plan and conclusions with respect to the use of KI are contained in the memorandum on the use of thyroid blocking agents to Commissioner Ahearne from Harold Denton, August 15, 1979 (Enclosure 3).

Robert B. Minogue

Robert B. Minogue, Director
Office of Standards Development

Enclosures:
1. "Medical and Legal Implications of a Large Release of Radioiodine" from Nuclear Safety
2. December 15, 1978 FR Notice
3. Memo to Commissioner Ahearne from H. Denton

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

OFFICE OF THE
CHAIRMAN

November 21, 1979

The Honorable Patricia Harris
Secretary of Health, Education and Welfare
Washington, D.C. 20201

Dear Madam Secretary:

In the last two years, the Nuclear Regulatory Commission has had many requests from State and local governments asking when the Federal government would publish policy and guidance on the use of tnyroid blocking agents to prevent the uptake of radioactive iodine by the thyroid. Although the National Council on Radiation Protection and Measurements (NCRP) Report Number 55 on "Protection of the Thyroid Gland in the Event of Release of Radioiodine" was published in late 1977 and contains some useful guidance, the States are properly looking to the Federal government for additional direction on this protective measure in specific accident situations. The accident at the Three Mile Island nuclear plant has further highlighted this vital area of concern.

The NRC is currently developing recommendations on the extent to which thyroid blocking agents should be stockpiled for use around nuclear power plants. I understand that your Bureau of Drugs is doing some work on the conditions under which thyroid blocking agents should be administered to the general public. We would appreciate any efforts your Department can make to accelerate development of the Bureau of Drugs policy and guidance on this matter.

Sincerely,

Joseph M. Hendrie
Chairman

1661 264

7912310 126

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON D C 20555

TERA

DEC 3 1979

The Honorable Tom Corcoran
United States House of Representatives
Washington, D. C. 20515

Dear Congressman Corcoran:

Mr. William Wilcox at the Federal Emergency Management Agency has asked the NRC to reply to your letter of October 23, 1979 concerning the use of potassium iodide or similar compounds in limiting radiological exposures from inhalation of radioiodine. The NRC has an effort underway to determine the extent to which radioiodine should be stockpiled for use in emergencies resulting from accidents at nuclear power plants. This effort is being coordinated with the Bureau of Radiological Health in the Food and Drug Administration, HHS. FDA has recently approved applications for manufacture of potassium iodine in tablet form and is continuing studies on the health effects of this compound.

I expect that further guidance on stockpiling the drug for emergency use by the public will be available early next year. When the NRC has developed recommendations on the quantities which should be stockpiled and the distance around nuclear power facilities where plans should be made for administering the drug, the NRC will likely request FEMA to take the lead in seeing that appropriate stockpiling and contingency distribution systems are put in place by States or the federal government.

Sincerely,

Original signed by R. G. Smith for

Lee V. Gossick
Executive Director for Operations

cc: Mr. William H. Wilcox
Acting Director
Disaster Response and Recovery
Federal Emergency Management Agency
Washington, D. C. 20472

1755 343

8011160389 /PDR

~~Dick Kr~~

Jodine file

December 14, 1979

Professor Frank von Hippel
Princeton University
Center for Environmental Studies
The Engineering Quadrangle
Princeton, New Jersey 08540

Dear Dr. von Hippel:

Thank you for your letter of June 11, 1979 with a copy of your recent letter to Science, regarding the distribution of potassium iodide (KI) to the public in a radiological emergency. Because there have been almost weekly changes in the information I could give you, I have delayed our reply until now.

The NRC Staff has been aware for some time that potassium iodide can be an effective defense against excessive thyroid dose due to radioiodine intake. The FDA issued a Federal Register notice (43 FR 58790) in December 1978. This notice has the practical effect, as we see it, of removing certain previous restrictions to the non-prescription distribution of KI in an emergency. In the Federal Register notice, FDA also invited new drug applications for the mass production of KI tablets for over-the-counter distribution in an emergency. Recently, the FDA approved an application for the manufacture of potassium iodide for use during emergencies. These actions by the FDA remove the legal impediments to the provisions for mass distribution and stockpiling of KI by State and Federal agencies.

Some concerns have been expressed by some members of our staff with respect to provisions for the broadcast distribution of KI to the general public. The enclosed staff memoranda on the subject provide some perspective on these concerns. The staff is concerned that potassium iodide is only effective if taken shortly before or after radioiodine intake and protects only the thyroid, whereas other protective actions could provide protection for all organs. In many instances, these other protective actions could be consummated before, and possibly more easily than, the broadcast distribution of KI. Of course, where institutional controls can be maintained for lengthy periods (e.g., in hospitals, prisons or reactor control rooms), KI has a greater potential for use in an emergency.

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However, you will note in paragraph 2 of the enclosed August 15, 1979 memorandum for Commissioner Ahearne from Harold Denton that the majority of the NRC staff believe that the use of KI as a thyroid blocking agent is an appropriate part of a complete emergency preparedness program. As part of our program for improving emergency planning activities, we will determine how KI can best be integrated into a total protective action preparedness program. Such a determination will include an evaluation of the effectiveness and reasonableness of KI distribution at large distances where post-accident evacuation might not be feasible and sheltering might not be effective.

I have also enclosed a copy of a recent study by Sandia Laboratories, Examination of Offsite Radiological Emergency Protective Measures For Nuclear Reactor Accidents Involving Core-Melt, which addresses the relative efficacies of evacuation, sheltering and iodine prophylactics as protective measures. As you can see from examination of the study, these protective actions could provide benefits during radiological emergencies.

I am pleased that your letter has prompted the staff to bring these insights to my attention, and I am glad to share them with you.

Sincerely,

/S/

John F. Ahearne

Enclosures:
1. Internal Staff Memos
2. Sandia Study

C/R NOTE: This letter has been cleared with all Commissioners' offices. It was retyped in C/R to incorporate all Cmrs. comments and this final version has been approved for signature.

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(Originated by Kreger, NRR) Mr. Ahearne signs the letter

OFFICE ►	SECY:C/R	OCM	OCM			
SURNAME ►	gschuetze		JAhearne			
DATE ►	12/14/79	12/ /79	12/ /79			

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

JUL 13 1979

MEMORANDUM FOR: Commissioner Richard T. Kennedy
Commissioner John Ahearne

THRU: Executive Director for Operations

FROM: Harold R. Denton, Director
Office of Nuclear Reactor Regulation

SUBJECT: USE OF THYROID BLOCKING AGENTS IN AN EMERGENCY RESPONSE PROGRAM

In your memoranda (dated June 22, 1979 and June 4, 1979) you requested a review of a Dr. Von Hippel letter to Science as well as answers to specific questions regarding the use of thyroid blocking agents. We have reviewed the various material enclosed in your memoranda and are herein providing a few general comments as well as more detailed responses to the specific questions.

Thyroid blocking agents are one possible means for reducing thyroid exposure during a nuclear accident. Other means for reducing exposure include shelter, respiratory protection, and evacuation. For the general public, we believe that thyroid blocking agents would generally be less effective in an emergency than the other protective actions mentioned above. This statement is based on the following considerations: (1) thyroid blocking agents protect only the thyroid; and (2) potassium iodide, the drug most frequently proposed as a blocking agent, must be taken shortly before or within two hours following intake (e.g., via respiration or ingestion). Under many accident scenarios, shelter, respiratory protection, or evacuation would appear to be easier to implement and potentially more effective than the use of potassium iodide.

Contact:
F. Congel, NRR
27955

Where institutional controls could be continuously maintained for long periods of time, provisions for immediate distribution of potassium iodide could be desirable. Hospitals, jails, control rooms, fire stations and police departments are examples of such places. The staff is presently looking into the possibility of requiring that reactor licensees stockpile quantities of potassium iodide for situations in which people would be unavoidably exposed to doses to the thyroid in excess of 10 rem, and institutional control could be maintained for long periods of time.

The NRC staff has been predisposed to require stockpiling of KI. On page 1.101-8 of Annex A to Regulatory Guide 1.101 - Emergency Planning for Nuclear Power Plants, a copy of which is attached, you will find the statements: "Measures that should be considered for persons within the exclusion area include:...3. Use of radioprotective drugs, e.g. individual thyroid protection". The footnote states: "The U.S. Food and Drug Administration is presently developing guidance for the use of radioprotective drugs". Now that FDA has spoken, the NRC staff will be meeting with FDA in the near future to expedite consideration of the matter.

Detailed responses to the specific questions are contained in the enclosure.

Original Signed by
H. R. Denton

Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Enclosure:
Response to Commissioner Ahearne's Questions
Concerning Thyroid Blocking Agents

cc: Chairman Hendrie
Commissioner Gilinsky
Commissioner Bradford
SECY

RESPONSE TO COMMISSIONER AHEARNE'S QUESTIONS CONCERNING THYROID BLOCKING AGENTS

Question 1

Is there other information on the side effects of thyroid blocking with potassium iodide?

Response

The National Council on Radiation Protection and Measurement's (NCRP) Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine", is the most authoritative report on this subject. We are not aware of any more recent publications that would change the major recommendations in NCRP No. 55.

Some side effects have been observed in the clinical use of potassium iodide (KI). These side effects have ranged from blood abnormalities to severe reactions, including death. NCRP has estimated that the risk of an adverse effect would be between 10^{-5} and 10^{-7} per clinical dose (300 mg). Risks for individuals taking other drugs at the same time would be higher. The dose required to block the thyroid (130 mg for an adult) is the same order of magnitude as the clinical dose.*

One of the limitations of KI is that it is only effective if administered within about two hours after intake (see Enclosure 1). Consequently, it would be necessary to either distribute the drug very quickly or to administer the drug prior to the release of radioactivity. Since the effectiveness of KI decreases with time, it would be necessary to administer daily doses throughout the course of the accident. Although the frequency of adverse effects per unit dose is not very large, some effects would be predicted in a large population over the course of an accident.

Assuming the midpoint of the risk estimate given by NCRP No. 55 (i.e., 5×10^{-7} effects/administered dose), if the drug were administered to one million persons over a ten day period, then five adverse effects would be expected. Based on very

*The one reported death was associated with a dose of 15 mg of KI.

limited data (one death out of 165 reactions), the risk of one death from 10^7 doses would be about 1 out of 30.

Risks from the drug should be balanced by a reduction in radiation dose to the thyroid. The NCRP has given some guidance in this area:

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

The "Final Generic Environmental Statement on the Use of Recycle Plutonium in Mixed Oxide Fuel in Light Water Cooled Reactors" (NUREG-0002) contains estimates of mortality and cancer induction from thyroid irradiation. The risk of premature death due to thyroid cancer is estimated to be about 1.3 premature deaths per million thyroid-rem from internally deposited radioactive iodine. The risk of thyroid cancer and benign nodules formation is about 25 times greater than the risk of death. For a dose of 10 rem to the thyroid (NCRP's guideline dose), the risk of adverse reactions from the drug (5×10^{-6} for 10 doses) would be about two orders of magnitude below the risk of thyroid cancers and benign nodules formation from irradiation of the thyroid (3.3×10^{-4}). For a dose of 10 rem to the thyroid, the risk of death from the drug (3×10^{-8} for 10 doses) would be about three orders of magnitude below the risk of death from the thyroid cancers (1.3×10^{-5}). Based on these considerations alone, the drug could be given at an even lower dose than recommended in NCRP No. 55.

In addition to the side effects from the drug, there is also the possibility of injuries resulting from a mass panic to get the drug. The NCRP cautions that:

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

It appears that the NCRP guideline of 10 rem to the thyroid has some built in conservatism to take into account the possibility of a mass panic.

Question 2

Should such blocking be advised as a part of emergency response?

Response

Thyroid blocking agents, such as potassium iodide (KI), are of some use in an emergency response program. However, other elements of an emergency response program would probably be more effective in protecting the general public in most accidents. These elements include shelter, respiratory protection and evacuation.

For low doses of radiation (less than 1 rem to the thyroid), the preferred response would be shelter and respiratory protection. Whereas KI would protect only the thyroid, shelter and respiratory protection would protect the total body as well as the thyroid. Shelter would reduce the whole body gamma cloud dose by a factor ranging from 10% to 80%, depending on the building (see Enclosure 2). For puff releases (less than two hours of exposure), shelter would reduce the inhalation dose by a factor ranging from 15% to 65%, depending on the building ventilation rate (see Enclosure 3). Respiratory protection can be provided by common household items (see Enclosure 4). Several of these items could reduce the inhalation dose by about 90%. In most cases, a combination of shelter and respiratory protection would offer more protection than KI, without any of the potential side effects of KI.

For higher doses of radiation (greater than 1 rem to the thyroid), it may be better to evacuate the population than to distribute the KI. There has been much experience with mass evacuations. The Environmental Protection Agency (EPA) has summarized evacuation experience over the time period 1959 to 1973.* This study has shown that masses of up to 150,000 persons have been evacuated safely in disasters. Distribution of KI during an evacuation could hamper the evacuation.

Thyroid blocking agents would be useful for employees and support personnel working near the facility. Thyroid blocking agents might be given to persons who could not be evacuated easily (e.g., hospital patients or convicts).

Estimates have been made of the thyroid dose to the maximum off-site individual associated with the Three Mile Island (TMI) accident.** The thyroid doses from the TMI accident (less than 10 mrem) were over three orders of magnitude below the NCRP guidelines of 10 rem.

* Evacuation Risks - An Evaluation, EPA-520/6-74-002.
** "Population Dose and Health Impact of the Accident at the Three Mile Island Nuclear Station", NUREG-0558, May 1979.

Question 3

Should stockpiles of KI be maintained?

Response

As stated in our response to questions one and two, potassium iodide (KI) may have a limited application in a protective action program. Small quantities of the drug could be stockpiled for use by employees and support personnel near the accident, as well as institutionalized persons who could not be easily evacuated. However, there would be little use of this drug by the general public. Other protective actions may offer greater reductions in risk from radiation without the side effects of KI. While the cost for producing the KI would not be excessive (Dr. von Hippel quotes a figure of one million dollars), the cost for maintaining a large scale distribution system over a ten or twenty year period would be greater. Due to its shelf life, it would be necessary to check the potency of the KI periodically. There is little incentive to produce, on a large scale, a drug that may not be used by the general public in an emergency.

Question 4

Any comments on Professor von Hippel's material?

Response

Dr. von Hippel's paper, "Thyroid Protection for People Downwind", overemphasizes, in our opinion, the effectiveness of thyroid blocking agents. As stated in our response to questions one and two, it is important to recognize some of the limitations of thyroid blocking agents. First, thyroid blocking agents protect only the thyroid. Other protective actions such as shelter and evacuation protect many organs in addition to the thyroid. Secondly, there are logistic problems with storing and distributing potassium iodide. Potassium iodide has a finite shelf-life. Consequently, it would be necessary to check the potency of the tablets periodically. There are many problems with distributing anything during an emergency. Distributing potassium iodide during an emergency might interfer with some of the more effective protective actions such as shelter or evacuation. Although NCRP discusses the limitations of thyroid blocking agents, Dr. von Hippel's article does not discuss these limitations.

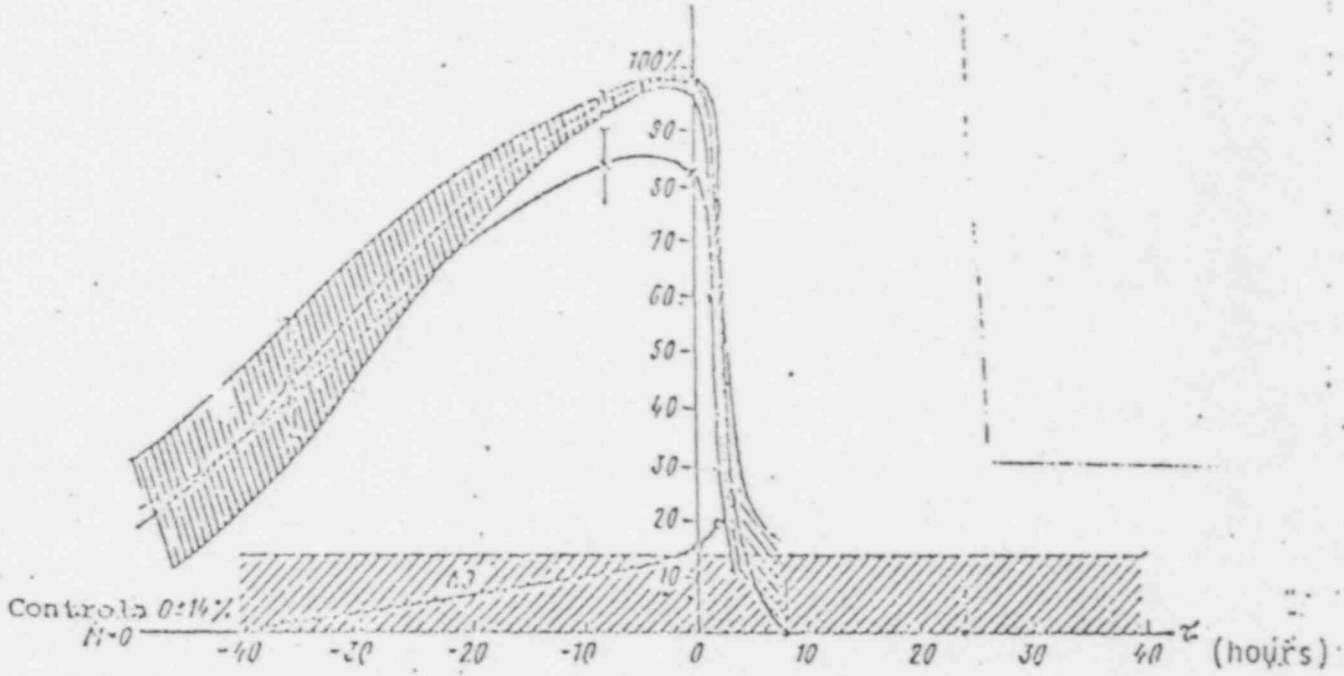

Figure Percent of thyroid blocking as a function of time (in hours) before or after a slug intake of radioiodine.

Ref: Radioactive Iodine in the Problem of Reactor Safety (USSR). USAEC Translation Series AEC-tr-7536.

TABLE VI 11-7. REPRESENTATIVE SHIELDING FACTORS FROM GAMMA CLOUD SOURCE*

Structure or Location	Shielding Factor[a]	Representative Range
Outside	1.0	--
Vehicles	1.0	--
Wood-frame house[b] (no basement)	0.9	--
Basement of wood house	0.6	0.1 to 0.7[c]
Masonry house (no basement)	0.6	0.4 to 0.7[c]
Basement of masonry house	0.4	0.1 to 0.5[c]
Large office or industrial building	0.2	0.1 to 0.3[c,d]

(a) The ratio of the interior dose to the exterior dose
(b) A wood frame house with brick or stone veneer is approximately equivalent to a masonry house for shielding purposes.
(c) This range is mainly due to different wall materials and different geometries.
(d) The reduction factor depends on where the personnel are located within the building (e.g., the basement or an inside room).

*WASH-1400

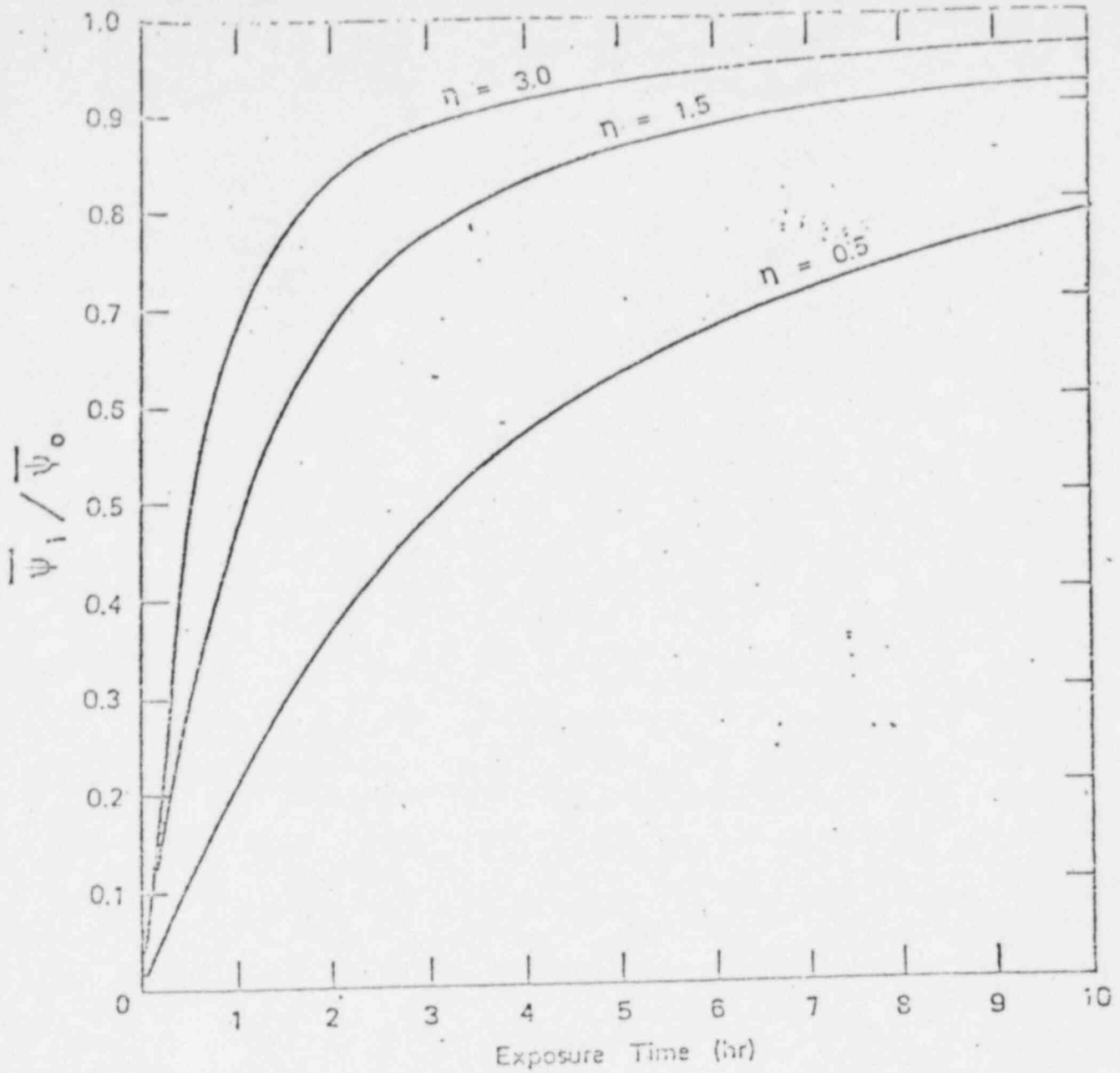

FIGURE VI 11-4 Ratio of the inhaled dose inside a shelter to that outside the shelter as a function of ventilation rate η (air turnovers per hour).*

*WASH-1400

REF: American Industrial Hygiene Assn-1963

TABLE II.5

RESPIRATORY PROTECTION PROVIDED BY COMMON HOUSEHOLD AND PERSONAL ITEMS AGAINST AEROSOLS OF 1 TO 5μ PARTICLE SIZE

Item	Number of Thicknesses	Resistance, mm of H_2O	Number of Observations	Geometric Mean Efficiency, %	95% Confidence Limits for Mean, %	
					Lower	Upper
Handkerchief, man's cotton	16	36	32	94.2	92.6	95.5
Toilet paper	3	13	32	91.4	89.8	92.8
Handkerchief, man's cotton	8	18	32	88.9	85.5	91.8
Handkerchief, man's cotton	Crumpled	--	32	88.1	85.1	90.5
Bath towel, turkish	2	11	32	85.1	83.3	86.8
Bath towel, turkish	1	5	30	73.9	70.7	76.8
Bed sheet, muslin	1	22	32	72.0	68.8	74.9
Bath towel, turkish	1 (wet)	3	31	70.2	68.0	72.3
Shirt, cotton	1 (wet)	>150[a]	15	65.9	57.9	72.3
Shirt, cotton	2	7	30	65.5	60.8	69.6
Handkerchief, woman's cotton	4 (wet)	34[a]	32	63.0	57.3	67.9
Handkerchief, man's cotton	1 (wet)	98[a]	30	62.6	57.0	67.5
Dress material, cotton	1 (wet)	180[a]	31	56.3	49.6	62.0
Handkerchief, woman's cotton	4	2	32	55.5	52.2	58.7
Slip, rayon	1	6	32	50.0	46.2	53.6
Dress material, cotton	1	3	31	47.6	41.4	53.2
Shirt, cotton	1	3	32	34.6	29.0	39.9
Handkerchief man's cotton	1	2	32	27.5	22.0	32.5

a. Resistance obtained when checked immediately after hand wringing. This resistance began to decrease after about one minute when the material started to dry.

6981

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AUG 15 1979

MEMORANDUM FOR: Commissioner Ahearne

FROM: Harold R. Denton, Director, Office of Nuclear Reactor Regulation
(Signed) H. R. Rehm

THRU: Executive Director for Operations

SUBJECT: USE OF THYROID BLOCKING AGENTS

In response to your July 30, 1979 memorandum on the above subject, a meeting was held on August 3, 1979 in which members of the NRC staff who have been involved with this subject further discussed issues that bear on it. An attendance list is enclosed.

In answer to your further comments and question, and in summary of the meet we provide the following information:

1. Our July 13, 1979 memorandum comment regarding a meeting with FDA "to expedite consideration of the matter" can be further explained as foll The GSA Federal Register Notice of December 24, 1975 (40 FR 59804) on Radiological Incident Emergency Response Planning: Fixed Facilities a Transportation, states the responsibilities as agreed between certain Federal Agencies. In delineating responsibilities, the GSA notice mak the NRC the lead agency in radiological incident emergency response pl ning, training and other assistance covered in the notice. EPA has, among other responsibilities, the establishment of Protective Action Guides, and recommendations as to appropriate protective actions which can be taken by government authorities to ameliorate the consequences of a radiological incident. HEW has responsibility for assisting Stat health departments, State hospital associations, etc., in the develop of plans for the prevention of adverse effects from exposure to radiat including the use of prophylactic drugs to reduce radiation dose to sp ific organs. This includes health and medical care responses to radio logical incidents, consistent with guidelines issued by NRC.

   A meeting of NRC staff with the Bureau of Radiological Health of FDA scheduled for August 21, 1979. This meeting will discuss their plans providing further appropriate (medical) guidance, in view of the FDA posed guidance (43 FR 58790) of December 15, 1978 (still not finalize establishing actions to be taken in the event of a contaminating radi ical incident, and the request (43 FR 58793) for submissions of new d

OFFICE	Contact: J.E. Kreger, NRR/DSE				
SURNAME	492-8926	8001080324 PDR			
DATE					

applications for potassium iodide in oral dosage forms for use as a thyroid blocking agent. This latter request concluded that potassium iodide is safe and effective for use as a thyroid-blocking agent in a radiation emergency. FDA approval of one company's drug application is within a couple of weeks of being issued. As mentioned in our earlier response, NRC R.G. 1.101 already mentions that use of radioprotective drugs should be considered for persons within the exclusion area.

2. The majority of the staff present at the July 30 meeting agree that the use of potassium iodide as a thyroid blocking agent in the event of possible inhalation or ingestion of radioiodine is an appropriate part of a complete emergency preparedness program. A complete program would include countermeasures such as source interdiction, sheltering, evacuation, respiratory protection, protective clothing, importing of foodstuff and water, decontamination, chemical treatment and others. The major reason that some staff members disagree on use of KI is that they believe that other measures in the above list are more important for most radiological incidents and that a widespread stockpiling requirement for KI would not be cost effective. It is our intention, however, to press for FDA action in their role as the agency to supply medical guidance, as discussed above. This will be a subject for the August 21 meeting.

3. The action plan for promptly improving (licensee) emergency preparedness has been forwarded as SECY 79-450 of July 23, 1979, an information report. While that report does not specifically address the use of KI, upgrading of licensee plans to meet the guidance of R.G. 1.101 will include the review of their plan to use radioprotective drugs.

Original Signed By
E. G. Case

for Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Enclosure:
Attendance List

cc: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford
SECY
OPE
OGC

OFFICE	DSE:SA	DSE	DOR		EDO	
	WEKreger:cep		Ziemann	Hoglund		
SURNAME	8/8/79	8/9/79	8/10/79	8/10/79	8/ /79	

MEETING RE USE OF KI AS THYROID BLOCKING AGENT

8/3/79

ATTENDEES

T.D. Murphy - NRR/RAB
Jim Martin - NRR/AAB
F. Congel - NRR/RAB
S. Block - NRR/EEB
G. Knighton - NRR/EEB
R. Mason - SP
D.R. Muller - DSE
F.D. Fisher - NMSS
L. Cunningham - IE
Mike Parsont - SD
Bill Kreger - NRR/DSE
John Sears - DOR
Ed Branagan - NRR/RAB

OFFICE ▶						
SURNAME ▶						

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

OFFICE OF THE
COMMISSIONER

July 30, 1979

MEMORANDUM FOR: Harold Denton, Director, NRR

FROM: John Ahearne

SUBJECT: USE OF THYROID BLOCKING AGENTS

Thank you for your memorandum of July 13 on this subject. As you pointed out "The NRC staff has been predisposed to require stockpiling of KI." You also noted that the Reg Guide 1.101 recommendation was qualified because the Food and Drug Administration had not developed guidance for the use of radioprotective drugs.

I understand the FDA has published a Federal Register Notice on the use of KI indicating that it is effective and the FDA does not have any problem with its use.

Your July 13 memorandum indicates that "The NRC staff will be meeting with FDA in the near future to expedite consideration of the matter." I would appreciate knowing what it is that must be expedited and when the meeting with FDA will be held. Also, I conclude from your memorandum that it had only been FDA in action that had prevented the NRC from requiring stockpiling of KI. Now that the FDA has acted, do we intend to impose such a requirement?

cc: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford
Secy
EDO

8001080329
PDR

Rec'd OM, EDO
Date 8/1/79
Time 5:15

August 28, 1979

MEMORANDUM FOR: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford

FROM: John Ahearne

SUBJECT: ACCIDENT CONSEQUENCE MITIGATION STRATEGIES

The staff recently supplied me with answers to some questions raised by Frank von Hippel concerning the use of KI. In his comments on their answers, Frank points out:

> The [NRC] staff memo suggests that, "for doses greater than 1 rem to the thyroid it may be better to evacuate the population than to distribute KI." It then goes on to discuss an EPA study which "has shown that masses of up to 150,000 persons have been evacuated safely in disasters" (p. 3) . . . .
>
> To illustrate the scale of distances involved, I do a simplified calculation in the Appendix [attached] which shows that, for I^{131} releases of the order of ten percent from a 1000Mw(e) reactor, thyroid doses could be above 1 rem for hundreds of miles downwind. Except for coastal sites where the plume is blown out to sea, the population which would have to be evacuated according to the staff's criterion would be on the order of one million over an area of thousands of square miles. If the plume blew towards an urban area (e.g., towards New York City from Three Mile Island), the population which the staff would propose to evacuate would be on the order of 10 million. The logistics of this effort with shifting winds, untrained personnel, and limited transportation capabilities boggle my mind. I would suggest that the staff be asked to work out a plan which would make their strategy credible assuming a 10% release to the atmosphere of the radioiodine in the TMI 1 core.

They should include a discussion of the number of people and areas which would have to be evacuated for various wind speeds and directions and the amount of time which would be available to accomplish these evacuations.

He then proposed the NRC

"develop accident consequence mitigation strategies beyond the evacuation of populations 10-25 miles downwind. . . . I would urge the NRC to give high priority to the initiation of a policy study on consequence mitigation strategies including people from the NRC, FDA, states, (California has already had a task force study the subject), and outside technical critics of the status quo."

I believe this is a sound proposal and request your support.

Attachment

cc: EDO ✓
NRR
I&E
SD
OPE
SP
Secy

NUREG/CR-11
SAND78-0454

Examination of Offsite Radiological Emergency Protective Measures for Nuclear Reactor Accidents Involving Core Melt

Prepared by D. C. Aldrich, P. McGrath, N. C. Rasmussen

Sandia Laboratory

Prepared for
U. S. Nuclear Regulatory
Commission

Princeton University
SCHOOL OF ENGINEERING / APPLIED SCIENCE
CENTER FOR ENVIRONMENTAL STUDIES
THE ENGINEERING QUADRANGLE
PRINCETON, NEW JERSEY 08540

June 11, 1979

Mr. Joseph Hendrie, Chairman
Nuclear Regulatory Commission
1717 H Street, NW
Washington, DC 20555

Dear Joe:

Because of your involvement in policy-making relating to blocking the uptake of radioiodines by thyroids downwind from nuclear accidents, I though that you might be interested in the enclosed letter to Science which summarizes in a convenient form some of the relevant background information.

Sincerely yours,

Frank von Hippel

FvH/jp
Enclosure

8001080343
PDR

Letters

Available Thyroid Protection

Public attention has focused on the immediate risks to the people nearby from a major release of radioactive gases in a nuclear reactor accident. Many more people up to hundreds of miles downwind could, however, be afflicted by thyroid tumors over the following decades as a result of the inhalation of radioactive iodine.

Fortunately, this threat to the thyroid is the radiation risk most easily defended against. The number of thyroid tumors caused by a reactor accident could be reduced 10- to 100-fold—but only if public health authorities take the trouble to make the necessary preparations. These preparations had not been made at the time of the Three Mile Island accident, and it is still not clear whether they will be made to protect against potential accidents in the future.

The risk to the thyroid is especially great in case of a reactor accident for three reasons:

- Radioactive iodine is produced copiously by the fission process;
- Radioiodines are among the first elements to boil off from damaged nuclear fuel; and
- A large fraction of the iodine which is absorbed by the human body concentrates in the thyroid.

As a result the thyroid radiation dose downwind from an accident could be tens to hundreds of times higher than the dose received by the rest of the body.

That the thyroid is sensitive to radiation—especially during childhood—has been well established as a result of the overenthusiastic use of x-rays for the treatment of various real and imagined illnesses during the first half of this century. Many thousands of children received very large doses of x-rays to their thyroids during this period and have as a result experienced a much higher than normal risk of developing thyroid tumors. Fortunately, it appears that thus far very few of these tumors have been fatal (*1*).

The area downwind from a nuclear accident in which there would be a high risk of developing thyroid tumors could extend to great distances. Ten to 60 percent of exposed children 200 miles downwind could eventually develop thyroid tumors after a large release of radioiodine, according to an estimate made in 1975 by the American Physical Society's reactor safety study group (*2*). Baltimore is about 60 miles from Three Mile Island; Wilmington, 70 miles; Washington and Philadelphia, 90 miles; and New York, 160 miles.

The evacuation of such large cities would be impractical in the time available once it was known that a cloud of radioiodine was being blown toward them. The absorption of radioactive iodide by the thyroid can be blocked, however, by taking a large dose of nonradioactive potassium iodide, the form of iodine present in iodized salt. This strategy is well known among health physicists and, according to a study done for the Defense Civil Preparedness Agency in 1972, it would cost only about $1 million to stockpile enough potassium iodide pills for the entire United States (*3*).

To be most effective, potassium iodide would have to be taken before the cloud of radioiodine arrived—and the warning time could be very short. Stockpiling would therefore have to be accompanied by a public information program and the organization of a rapid distribution system. Neither the electric utilities nor their regulators have been eager to make these arrangements.

Nevertheless, the National Council on Radiation Protection and Measurement endorsed the thyroid-blocking strategy in 1977 (*4*) and the Food and Drug Administration (FDA) approved the use of potassium iodide for this purpose in December 1978 (*5*).

At the time of the Three Mile Island accident potassium iodide was not yet available for mass distribution in the proper dosages. The FDA therefore ordered large-scale production on an emergency basis and within a few days had flown enough into Harrisburg for more than a half a million people (*6*).

But this would have been too late if the containment building at Three Mile Is-

accident, and, in any case, thyr
tection was not provided for peop
than a few tens of miles from t
dent.

The containment building did
during the accident at Three Mile
It would be tempting fate, how
delay much longer in having thyr
tection available nationwide.

FRANK VON
*Center for Energy and Environm
Studies, Princeton University,
Princeton, New Jersey 08540*

References

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R. A. Cooper, W. R. Ames, *J. Na
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4. National Council on Radiation Prote
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6. R. Reinhold, *New York Times*, 4 Ap
A16.

May 20, 1980

COMMISSIONER ACTION

SECY-80-257

For: The Commissioners

Thru: Acting Executive Director for Operations

From: Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Subject: RADIATION PROTECTION - THYROID BLOCKING

Purpose: To obtain approval for issuance of an interim policy statement with regard to the stockpiling of potassium iodide for use during reactor emergency conditions. (Enclosure 1)

Discussion: During the past year there has been a resurgence of interest in the use of potassium iodide (KI) as an emergency protective measure for serious reactor accidents. To develop an adequate rationale concerning the storage of KI, it is necessary to evaluate the potential benefits, and potential risks and also to evaluate the costs associated with its public use. This paper summarizes the results of a study (Enclosure 4) performed by Sandia Laboratories for the Office of Research and the NRC staff to provide the needed technical basis for establishing a policy concerning the storage and maintenance of KI for public use in an emergency. After the NRC has made an assessment as to the extent to which the drug should be stockpiled for use around nuclear power plants, the stage would be set for FEMA to select methods of stockpiling and distribution and for State health authorities to make decisions on use of the drug during actual emergencies.

The Sandia analysis was performed using a modified version of the Reactor Safety Study (WASH-1400) consequence model. Four categories of accidents were addressed: release of gap activity to the containment, release of gap activity without containment isolation, core melt with a melt-through release and core melt with an atmospheric release. Thyroid dose calculations show that gap release to the containment does not pose a significant health hazard to the public at any distance from the reactor. For a gap release without containment isolation and melt-through categories, doses in excess of recommended protective action guidance levels (PAGs) (5-25 rem to the thyroid) are confined to areas within approximately 10 to 15 miles of the reactor. For a low likelihood core melt with a direct atmospheric release, however, thyroid doses may exceed plume pathway PAGs at distances of 100 to 200 miles. These results are consistent with the results of the NRC/EPA task force report on the recommended planning basis for offsite emergency preparedness.

XA

CONTACTS: Brian Grimes, NRR
Ext. 27415

8009090643/CF

Roger Blond, RES
28388

A cost-benefit analysis for the use of KI was performed by Sandia, the results of which are summarized in table 1. Cost-benefit ratios ($/thyroid nodule prevented) are given assuming that no other protective measures are taken. (KI would protect only the thyroid, not other body organs, and only from radioiodine, and then only if ingested within about 2 hours after radioiodine inhalation, or within about 12-24 hours before radioiodine inhalation.) Other key assumptions made in performing the analysis are also noted. Uncertainties due to health effects parameters, accident probabilities and costs were assessed, as well as the effect of other potential protective measures, such as evacuation and sheltering, on predicted ratios. The potential impact on children (critical population) was also evaluated. The estimated cost-benefit ratios are high, and it appears that the distribution of KI to the general public is at best marginally cost-effective even close to a nuclear power plant.

Finally, a simple risk-benefit analysis, based upon the FDA published Federal Register Notice (43 F.R. 58798, December 15, 1978) showed the risk of adverse reaction posed by KI to be small at the recommended action levels and dosages. It should be noted, however, that recent reports (see Attachment 2) indicate that there is a significantly higher risk associated with use of the drug among certain segments of the population. Because of this, the NRC has requested the FDA to provide additional guidance on the conditions under which potassium iodide should be administered to the general public (letter from J. Hendrie to P. Harris dated November 21, 1979). Until this review is complete, an NRC recommendation for extensive stockpiling of the drug for general public use would be premature. A conference on Nuclear Reactor Accidents and Iodine Prophylaxis will be held in June (see attachment 3) during the National Meeting of the Endocrine Society which also bears on this aspect. It is the staff's recommendation that the Commission adopt an interim policy encouraging storage of potassium iodide for use during a reactor accident of quantities needed for the following segments of the population where controls can be clearly maintained for the required lengths of time:

1. Site personnel;

2. Offsite emergency response personnel; and

3. Offsite institutions within about 10 miles (e.g., hospitals, prisons) where immediate evacuation may be infeasible or very difficult.

TABLE 1

SUMMARY OF KI COST-BENEFIT ANALYSIS[a]

Distance Interval (Miles)	KI Purchase Cost ($/year)		Cost Benefit Ratio[b] ($/thyroid nodule prevented)
	100 people/sq mile	1000 people/sq mile	
0-5	790	7,900	320,000
5-10	2,400	24,000	420,000
10-25	16,000	160,000	730,000
25-50	59,000	590,000	2,000,000
50-100	240,000	2,400,000	6,200,000
100-150	390,000	3,900,000	20,000,000
150-200	550,000	5,500,000	42,000,000

[a] Key Assumptions

1. 99% effective KI (i.e., all persons take drug before cloud passes).
2. No other protective measures are taken.
3. WASH-1400 accident probabilities.
4. Estimated cost of KI program = $0.10 per person per year. Cost includes only purchase price of KI, but not the storage, distribution, monitoring and administrative expenses.
5. Only 1 reactor (3200 MWt PWR) within distance indicated.
6. WASH-1400 dose-effects coefficients (assumption of a 0.1 effectiveness factor for I-131 dose would increase the costs per benefit received by about a factor of three).

[b] Uncertainties are large and scale approximately proportional with assumed KI effectiveness, accident probabilities, cost, multiple reactors, and dose-effects coefficients.

Since the use of KI may have possible harmful side effects for certain individuals, the proposed policy statement suggests that the persons who would administer KI be made aware of this fact in advance and that those to whom the KI is administered be alerted to this at any time it is distributed.

A proposed policy statement which expresses this interim position is provided in Enclosure 1. The Sandia report is being provided to FEMA, HEW, to certain State and local organizations involved in emergency preparedness and radiation protection, and to certain individuals for any comments they may wish to make.

Recommendation: The Commission approve the interim policy statement in Enclosure 1 which encourages stockpiling of potassium iodide for onsite and offsite emergency workers and for certain institutions within 10 miles of nuclear power plants.

The Commission should note that:

(1) On completion of the FDA review of effects of potassium iodide on certain segments of the population and after receipt of any comments on the Sandia study, the staff will bring the matter again to the Commission for a policy decision on the extent to which potassium iodide should be stockpiled for use by the general population. The Sandia report indicates that, even using costs which are clearly underestimated, if the cost/benefit ratio were the only decision criterion stockpiling for the general public would not be warranted. However, the absolute cost may be low enough that a policy judgment to encourage national or regional stockpiling of the drug could be justified provided the FDA review on side effects indicates general distribution is acceptable.

(2) The staff will discuss with FEMA incorporation of the policy guidance into the joint NRC/FEMA criteria for radiological emergency response plans. (The criteria now require plans for distribution to onsite and offsite emergency workers but contain no guidance on institutions.)

Coordination: The Office of Research, which participated in the Sandia study, concurs in this recommendation. The Office of the Executive Legal Director has no legal objection.

Harold R. Denton

Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Enclosures:
1. Interim Policy Statement
2. Recent Reports on Side Effects
3. Conference Announcement
4. Sandia Study (under separate cover) SAND80-0981; NUREG/CR-1433

Commissioners' comments should be provided directly to the Office of the Secretary by c.o.b. Thursday, June 5, 1980.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT May 29, 1980, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ENCLOSURE 1

NUCLEAR REGULATORY COMMISSION

Statement of Interim Commission Policy on Stockpiling Potassium Iodide For Use During a Reactor Accident

STATEMENT OF POLICY

The Nuclear Regulatory Commission has adopted an interim policy on the stockpiling of potassium iodide for use during a reactor accident. The Commission encourages storage of potassium iodide for use during a reactor accident of quantities needed for the following segments of the population where controls can be clearly maintained for the required length of time:

1. Nuclear power plant site personnel;
2. Offsite emergency response personnel; and
3. Offsite institutions (e.g., hospitals, prisons) within about 10 miles of reactors where immediate evacuation may be infeasible or very difficult.

Although the effective use of potassium iodide could significantly reduce the number of thyroid nodules resulting from a serious accident, it would have little or no impact on other accident consequences; including immediate deaths or injuries, delayed cancer deaths, and land contamination. Therefore, the availability of potassium iodide provides only a supplemental strategy to be considered along with other possible protective measures.

SUPPLEMENTARY INFORMATION

During the past year there has been a resurgence of interest in the use of potassium iodide (KI) as an emergency protective measure for serious reactor accidents. To develop an adequate rationale concerning the storage of KI, it is necessary to evaluate the costs, potential benefits, and potential risks

associated with its public use. A study has been performed by Sandia Laboratories and the NRC staff to provide the needed technical basis for establishing a policy concerning the storage and maintenance of KI for public use in an emergency.

The Sandia analysis was performed using a modified version of the Reactor Safety Study (WASH-1400) consequence model. Four categories of accidents were addressed: release of gap activity* to the containment, release of gap activity without containment isolation, core melt with a melt-through release and core melt with an atmospheric release. Thyroid dose calculations show that gap release to the containment does not pose a significant health hazard to the public at any distance from the reactor. For a gap release without containment isolation and melt-through categories, doses in excess of recommended protective action guidance levels (PAGs) (5-25 rem to the thyroid) are confined to areas within approximately 10 to 15 miles of the reactor. For a low likelihood core melt with a direct atmospheric release, however, thyroid doses may exceed plume pathway PAGs at distances of 100 to 200 miles. These results are consistent with the results of the NRC/EPA task force report on the recommended planning basis for offsite emergency preparedness.

A cost-benefit analysis for the use of KI was performed by Sandia, the results of which are summarized in table 1. Cost-benefit ratios ($/thyroid nodule prevented) are given assuming that no other protective measures are taken. (KI would protect only the thyroid, not other body organs, and only from radioiodine, and then only if ingested within about 2 hours after radioiodine

*Gap activity is the limited amount of radioactive gaseous material which collects within the tube which holds the uranium dioxide fuel pellets during normal reactor operation.

inhalation, or within about 12-24 hours before radioiodine inhalation.) Other key assumptions made in performing the analysis are also noted. Uncertainties due to health effects parameters, accident probabilities and costs were assessed, as well as the effect of other potential protective measures, such as evacuation and sheltering, on predicted ratios. The potential impact on children (critical population) was also evaluated. The estimated cost-benefit ratios are high, and it appears that the distribution of KI to the general public is at best marginally cost-effective even close to a nuclear power plant.

Finally, a simple risk-benefit analysis, based upon the FDA published Federal Register Notice (43 F.R. 58798, December 15, 1978) showed the risk of adverse reaction posed by KI to be small at the recommended action levels and dosages. It should be noted, however, that some recent reports indicate that there is a significantly higher risk associated with use of the drug among certain segments of the population. Because of this, the Commission suggests that the persons who would administer KI be made aware in advance that KI may have possible harmful side effects and that those to whom KI is administered be alerted to this during any distribution. In addition, the NRC has requested the FDA to provide additional guidance on the conditions under which KI should be administered to the general public. When the FDA guidance is received, the Nuclear Regulatory Commission will again consider the advisability of stockpiling KI for use by members of the general public during a reactor accident.

FOR FURTHER INFORMATION CONTACT: Brian K. Grimes, Program Director, Emergency Preparedness Program Office, Office of Nuclear Reactor Regulation, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, phone 301-492-7415, or

Roger Blond, Probabilistics Analysis Staff, Office of Nuclear Regulatory Research, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, phone 301-492-8388.

Dated at Washington, D. C., this day of 1980.

FOR THE NUCLEAR REGULATORY COMMISSION

Samuel J. Chilk
Secretary of the Commission

TABLE 1

SUMMARY OF KI COST-BENEFIT ANALYSIS[a]

Distance Interval (Miles)	KI Purchase Cost ($/year)		Cost Benefit Ratio[b] ($/thyroid nodule prevented)
	100 people/sq mile	1000 people/sq mile	
0-5	790	7,900	320,000
5-10	2,400	24,000	420,000
10-25	16,000	160,000	730,000
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100-150	390,000	3,900,000	20,000,000
150-200	550,000	5,500,000	42,000,000

[a] Key Assumptions

1. 99% effective KI (i.e., all persons take drug before cloud passes).
2. No other protective measures are taken.
3. WASH-1400 accident probabilities.
4. Estimated cost of KI program = $0.10 per person per year. Cost includes only purchase price of KI, but not the storage, distribution, monitoring and administrative expenses.
5. Only 1 reactor (3200 MWt PWR) within distance indicated.
6. WASH-1400 dose-effects coefficients (assumption of a 0.1 effectiveness factor for I-131 dose would increase the costs per benefit received by about a factor of three).

[b] Uncertainties are large and scale approximately proportional with assumed KI effectiveness, accident probabilities, cost, multiple reactors, and dose-effects coefficients

References

1. WASH-1400 (NUREG 75/014), U.S. Nuclear Regulatory Commission, October 1975.
2. D. C. Aldrich, P. E. McGrath and N. C. Rasmussen, Examination of Offsite Radiological Emergency Protective Measures for Nuclear Reactor Accidents Involving Core Melt, SAND78-0454 (NUREG/CR-1131) Sandia Laboratories, Albuquerque, New Mexico (1978).
3. J. G. Cural, et. al., Potassium Iodide Sensitivity in Four Patients with Hypocomplementemic Vasculitis, Annals of Internal Medicine, Vol. 91, No. 6, December 1979.
4. B. J. Rosenstein, et. al., Iodide-Induced Hypothyroidism without a Goiter in an Infant with Cystic Fibrosis, Journal of Pediatrics, Vol. 93, No. 2, August 1978.
5. D. C. Aldrich, R. M. Blond, Examination of the Use of Potassium Iodide (KI) As An Emergency Protective Measure for Nuclear Reactor Accidents, SAND80-0981 (NUREG/CR-1433) Sandia Laboratories, Albuquerque, New Mexico (March 1980).

ENCLOSURE 2

Potassium Iodide Sensitivity in Four Patients with Hypocomplementemic Vasculitis

JOHN G. CURD, M.D.; HENRY MILGROM, M.D.; DONALD D. STEVENSON, M.D.; DAVID A. MATHISON, M.D.; and JOHN H. VAUGHAN, M.D.; La Jolla, California

During metabolism studies of radiolabeled proteins in 126 participants four patients were suspected of being sensitive to potassium iodide (KI) because they repeatedly developed urticaria and other symptoms after KI administration. Two of the four patients suspected of KI sensitivity and 10 control patients were orally challenged with KI to document and characterize KI sensitivity and to evaluate the possible association(s) of KI sensitivity with urticaria, hypocomplementemia, and vasculitis. The KI challenges in the two sensitive patients precipitated urticaria, angioedema, polymyalgias, conjunctivitis, and coryza. One of these two patients also developed a severe systemic illness characterized by fever, headache, peritonitis, episcleritis, and pneumonitis. The four sensitive patients were strikingly similar in that they exhibited hypocomplementemia and dermal vasculitis associated with chronic urticaria or systemic lupus erythematosus, suggesting that other patients with similar clinical features may be sensitive to KI and that KI may precipitate severe systemic illness in them.

IODIDE AND IODINE administration in patients rarely has been associated with sensitivity reactions. The reported sensitivity reactions have been extremely diverse and included acute skin eruptions, angioedema, fever, iododerma, pulmonary infiltrations, and periarteritis nodosa (1-15). Between 1974 and 1978 we administered potassium iodide (KI) to 126 adults who participated in metabolism studies of radiolabeled proteins. During these studies four patients, described in this report, repeatedly exhibited clinical signs and symptoms attributable to KI sensitivity. Two of the four sensitive patients were orally challenged with KI in order to document KI sensitivity and to study the KI sensitivity reactions. Our studies suggest that hypocomplementemic vasculitis in patients with chronic urticaria or systemic lupus erythematosus may be associated with KI sensitivity and that KI can precipitate life-threatening systemic illness in sensitive persons.

Subjects and Methods

PATIENT DATA

Since 1974, 126 adults have participated in metabolism studies of radiolabeled proteins at Scripps Clinic and Research Foundation. All participants received KI (0.5 g) numerous times during the studies to block thyroidal uptake of radioiodine. In recent studies KI was given on the first, second, third, sixth, and 11th day of the studies. Review of the records of all participants revealed that four patients repeatedly developed sensitivity reactions after KI administration. The case reports of these four patients are presented below. Sensitivity to KI was not observed in the other 122 participants in the metabolism studies. These participants included 57 patients and 65 normal adults. The 57 patients comprised 44 women and 13 men, with diagnoses of rheumatoid arthritis in 44, systemic lupus erythematosus in seven, cryoglobulinemia in three, hereditary angioedema in two, and chronic urticaria in one.

CASE REPORTS

Case 1: Patient A was a 47-year-old white woman with chronic idiopathic urticaria. Acute urticaria occurred when she was 22 and resolved. In 1964 chronic idiopathic urticaria and Raynaud's phenomena began. Since 1964 intermittent abdominal angioedema and laryngeal edema, one episode of giant swelling of the foot, and daily urticaria of the face, trunk, and extremities have occurred. Treatment has consisted primarily of antihistamine medications. The family history included one uncle in whom chronic urticaria developed after penicillin therapy.

The physical examination revealed many urticarial lesions that decreased in the afternoon. Petechiae have not been observed. Laboratory findings were unremarkable except for a mildly elevated sedimentation rate, decreased total hemolytic complement, low C1q levels, and the presence of 7S C1q precipitins (Table 1). A skin biopsy in 1975 revealed a vasculitis similar to that observed in Patient C. Acute exacerbations of her urticaria occurred on the second, third, and sixth days of the metabolism study.

Case 2: Patient B was a 37-year-old white woman with inflammatory arthritis since age 3. The initial diagnosis was juvenile rheumatoid arthritis. Treatment with gold precipitated a skin rash. Fevers, myalgias, skin rashes, polyserositis, thrombocytopenia, Raynaud's phenomena, angioedema, and dermal vasculitis subsequently have developed as well as antinuclear antibodies and hypocomplementemia, substantiating the diagnosis of systemic lupus erythematosus. Treatment has consisted of varying dosages of aspirin, prednisone, chlorambucil, and propranolol.

The physical examination showed marked subungual erythema, small digital infarctions, and dermal infarctions bilaterally near the olecranon. Petechiae were not present except during one episode of thrombocytopenic purpura. Periarticular swelling was present in the hands, wrists, elbows, shoulders, knees, and feet. Mild hyperextension deformities were present in several proximal interphalangeal joints of the hands. Anemia, leukopenia, lymphopenia, thrombocytopenia, proteinuria (1.9 g/24 h) and an abnormal urinary sediment as well as the serologic abnormalities of systemic lupus erythematosus were present from 1976 to 1978 (Table 1). A skin biopsy in 1970 showed vasculitis with round cell and polymorphonuclear cell infiltration as well as immunoglobulin deposition at the dermal-epidermal junction. The KI sensitivity reactions were observed during two separate metabolism studies done in 1975 and 1978. During the first metabolism study, urticaria developed on the low back, thighs, and buttocks on the second day and was mistakenly attributed to local irritation. During the second metabolism study, urticaria developed near the elbows and on the lower extremities on the third and fifth days. The urticaria was accompanied by myalgias and fever.

From the Department of Clinical Research and Molecular Immunology, Scripps Clinic and Research Foundation, La Jolla, California.

Annals of Internal Medicine 1979; 91:853-857

Table 1. Laboratory Evaluation of Potassium Iodide-Sensitive Patients

Laboratory Values*	Patient				Normal
	A	B	C	D	
Hematocrit, %	38	32	42	34	37–47
Leukocyte count, mm^3	4500	3900†	6500	3600†	4800–11 800
Sedimentation rate, *mm/h*	(13–22)	(38–84)	(13–30)	(44–94)	<20
Rheumatoid factor	0	0	0	+[1280]	<1:80
Antinuclear antibodies	0	+[256]	0	+[256]	<1:4
Anti-Sm	0	+	0	...	0
Anti-RNP	0	+	0	0	0
Anti-DNA binding ratio, %	4	55	0	15	<10
Immunoglobulin level, *mg/dL*					
G	1400	1728	900	2625	650–1800
M	213	182	100	375	100–300
A	84	172	168	280	40–200
Raji immune complexes, μg equivalents of aggregated gamma globulin	(12–25)	>600	0	50	<12
CH_{50} units	(12–62)	(0–31)	(8–31)	(0–261)	40–60
C1 activity‡	32	...	23	75	100
C2 activity‡	27	...	29	48	100
C3 activity‡	44	31	38	54	100
C4 activity‡	15	25	24	...	100
C1q level‡	(0–31)	111	(0–26)	58	100
7S C1q precipitin	+	0	+	0	0

* ( ) indicates range of several determinations; + indicates determination is positive; [ ] indicates serum dilution at positive determination. The platelet count, Coombs test, VDRL, heterophil, and hepatitis B antigen test were normal or not detected in all four patients.

† Patients B and D have lymphopenia.

‡ Complement component activities and C1q levels are expressed as percent of measurement in pooled normal serum.

Case 3: Patient C was a 35-year-old white woman with a 3-year history of chronic idiopathic urticaria and hypocomplementemia. In 1973 she developed urticaria that has chronically involved the face, extremities, and trunk. Other symptoms occurring intermittently since 1973 included lymphadenopathy, migraine headaches, arthralgias of the knees and hands, and abdominal angioedema. Angioedema of the lip, tongue, and eyelids has been infrequently observed as has periarticular swelling of metacarpal phalangeal joints, elbows and knees. Treatment has consisted primarily of prednisone in a dosage of 10 to 20 mg/d. As a child, the patient experienced transient rhinitis. There is no family history of atopy, asthma, or urticaria. Physical examination revealed features of Cushing's syndrome with small urticarial lesions (1 to 3 cm) near the belt line and on the extremities. Petechiae and purpura were present on the thighs in areas of resolving urticaria. Low levels of C1q protein ranging from 0 to 26% of normal and 7S C1q precipitins were present (Table 1). Skin biopsies obtained in 1976 and 1978 showed dermal vasculitis with inflammatory cells including polymorphonuclear leukocytes in the dermal tissue and vessels. Complement components C1q, C3, properdin, and C6 and IgG, IgM, and IgA were detected at the dermal-epidermal junction and in vessel walls by immunofluorescence.

Sensitivity reactions occurred during two separate metabolism studies of radiolabeled proteins and after challenge with KI. The clinical record noted marked exacerbations of urticaria on the first, second, third, and seventh days of both studies. The urticaria typically began a few hours after the KI ingestion and was "burning" in character. The urticaria was substantially improved on days when no KI was given. Notably, exacerbations followed the first dose of KI during both studies. This indicates KI was responsible for the reaction, because the radiolabeled proteins are not injected until the morning of the second day. The exacerbations of urticaria were originally attributed by the patient and her physicians to emotional factors.

Case 4: Patient D was a 38-year-old white woman with systemic lupus erythematosus and chronic urticaria. In 1967 allergic rhinitis began and improved with hyposensitization therapy for molds and weeds. In 1971 diffuse lymphadenopathy developed, and a biopsy of an axillary node showed follicular lymphoid hyperplasia consistent with acute lymphadenitis. The lymphadenopathy resolved without treatment. In 1973 chronic urticaria developed as well as angioedema, Raynaud's phenomena, photosensitivity, hypergammaglobulinemia, and hypocomplementemia. Polyarthralgias, polyarthritis, and antinuclear antibodies were observed in 1976. Treatment has consisted of prednisone, ranging from 10 to 15 mg/d, nonsteroidal anti-inflammatory agents, and antihistamine medications.

The physical examination revealed isolated urticarial lesions on the neck, back, and extremities. Alopecia, dry eyes confirmed by Schirmer test, tenderness of metacarpophalangeal joints, petechiae on the lower extremities, an effusion of the left knee, and a murmer of mitral regurgitation were also present. The laboratory revealed a chronically elevated sedimentation rate ranging from 44 to 94 mm/h, positive rheumatoid factor test, hypergammaglobulinemia, and hypocomplementemia (Table 1). Antinuclear antibodies were present, and the DNA-binding ratio was elevated. A skin biopsy in 1976 revealed an "allergic vasculitis" with polymorphonuclear cell infiltration of the dermal tissue and vessels. Immunoglobulins and C3 were detected at the dermal-epidermal junction by immunofluorescence. Marked exacerbations of her urticaria occurred during radiolabeled protein studies in 1974 and 1975 and after KI challenge. Fever, myalgias, and a nonproductive cough were also noted during one of the studies.

The clinical characteristics of the KI sensitive patients and the manifestations of their KI sensitivity is summarized in Table 2.

Challenge Studies with Potassium Iodide: Two of the four suspected iodide sensitive patients and 10 selected controls were challenged with KI. The diagnoses in the selected controls included chronic idiopathic urticaria in four (all four had normal serum complement levels), hereditary angioedema in four, nonhereditary angioedema in one, and Sjögren's syndrome and hypergammaglobulinemic purpura in one. The challenge participants were hospitalized on the day before KI challenge, and their medications were continued. The following morning the participants were given 1 g of KI (Upsher-Smith Lab., Inc., Minneapolis, Minnesota) in orange juice. The KI was administered twice daily until sensitivity reactions occurred or for 2 d. The skin rashes resulting from KI challenge were photographed, and one lesion near the hip was biopsied.

Table 2. Clinical Characteristics of Potassium Iodide-Sensitive Patients and Their Reactions

Patient	Manifestations of Disease					Manifestations of Potassium Iodide Sensitivity				
	Chronic urticaria	Angioedema	Arthritis Arthralgia	Petechiae		Urticaria	Angioedema	Fever	Polymyalgia	Coryza
A	+	+	0	0		+	0	0	0	0
B	0	+	+	0		-	0	+	+	0
C	+	+	+	+		+	+	+	+	+
D	+	+	+	+		+	+	+	+	+

Serologic Analyses: Blood specimens were obtained by venipuncture before KI administration and at 4, 8, 12, 33, and 48 h after the initial KI ingestion. Samples were processed immediately. Serum samples were clotted at 37° C for 20 min and the serum separated by centrifugation at 4° C. Samples of heparinized plasma (Vacutainer; Becton, Dickinson, Inc., Orangeburg, New York) and ethylenediaminetetracetate plasma (Vacutainer; Becton Dickinson, Inc., Orangeburg, New York) were separated immediately by centrifugation at 4° C. All samples were frozen at −70° C until analysis. The plasma levels of C1q, C1r, C1s, C3, C4, and factor B were determined by radial immunodiffusion (16). The hemolytic titrations of C1, C2, C3, C4, and CH_{50} were done according to published procedures (17). The C5 activity was ascertained in plasma immunochemically depleted of C5 (C5d). Antibody sensitized erythrocytes (5×10^7 cells), C5d (20μL), and the diluted test serum were incubated at 37° C for 30 min in veronal buffered saline containing gelatin (17). The hemolysis was compared to the C5 in normal serum and to C5d containing purified C5.

Complement 1q precipitins were determined according to the modified method (18) of Agnello and associates (19) in plasma and after sucrose density gradient ultracentrifugation of patients' plasmas.

Analyses of Skin Biopsies: The skin lesions resulting from KI administration were biopsied and divided. One portion of the biopsy was fixed with 10% formalin and sections were stained with hematoxylin and eosin or toluidine blue. A second portion was fixed with isopentane, and sections were stained with fluorescein isothiocyniate conjugates of antibodies specific for IgG, IgM, and IgA and for complement components C1q, C4, C3, C5, C6, and properdin. Electron microscopic analyses were done on a third portion fixed in 0.72% glutaraldehyde, 1.02% formalin in 0.14 sodium cacodylate (pH 6.8) and stained with osmium tetraoxide.

Results

Sensitivity to KI was confirmed by oral challenge in two (Patients C and D) of the four patients suspected of KI sensitivity and not in 10 selected control patients. Two hours after receiving her initial KI dose, Patient C developed acute urticaria involving more than 50% of her skin (Figure 1). The urticaria was painful, "burning," and nonpruritic. It increased for 2 to 4 h despite treatment with hydroxyzine. Conjunctivitis, scleral edema, coryza, and polymyalgias also developed during this period. Two hours after receiving KI, Patient D developed sensations of warmth and nervousness. Four to 6 h after ingestion, angioedema appeared near a venipuncture site and isolated urticarial lesions appeared on the back, face and arms; angioedema of the lip and polymyalgias also developed. The urticaria, myalgias and angioedema improved during the first day in both patients and resolved in Patient D in 48 h.

However, on the second day, Patient C developed fever that persisted and increased during the next 3 d. The fever was one manifestation of a severe systemic illness characterized at different times by headache, diffuse peritonitis and abnormal liver function tests, mild proteinuria, erythrocytes in the urine, episcleritis, severe angioedema of the lip, and a left upper lobe pneumonitis. The temporal relation of these features is shown in Figure 2. Psittacosis, mycoplasma, adenovirus, influenza virus, parainfluenza virus, cytomegalovirus, toxoplasmosis, hepatitis B virus, Legionnaires' agent, and bacteria were excluded as the cause of the illness in Patient C. Empirical treatment with prednisone (80 mg/d) and tetracycline (for suspected psittacosis) produced rapid improvement. The fever resolved after 4 d of treatment and did not recur during a rapid reduction of prednisone (Figure 2).

Figure 1. Acute urticaria in Patient C 2 h after oral potassium iodide. The lesions were raised areas of central pallor with circumscribed red borders.

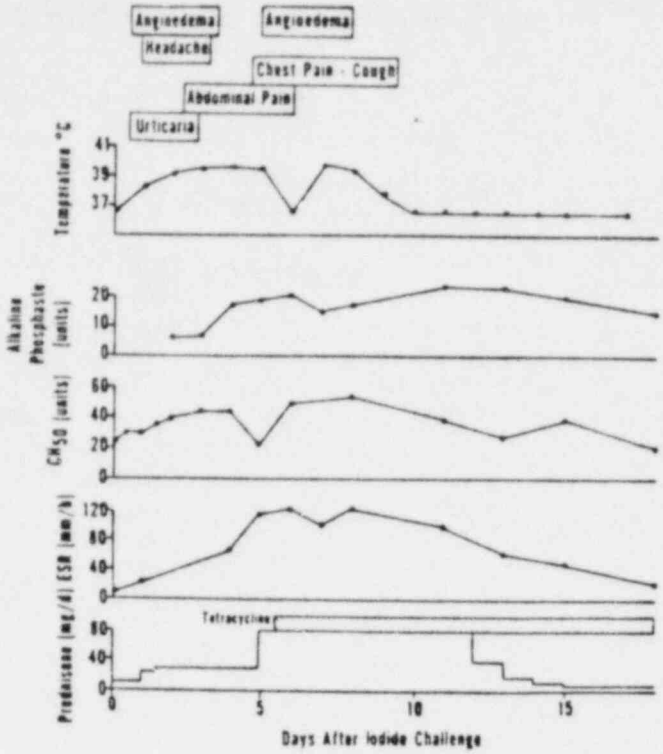

Figure 2. Clinical features of systemic illness observed in Patient C after potassium iodide challenge. ESR = erythrocyte sedimentation rate.

The pneumonitis and abnormal liver function tests slowly improved over 2 weeks and resolved by 6 weeks.

During the acute KI sensitivity reaction, leukocytosis, thrombocytopenia, and eosinophilia were not detected in either Patient C or D. The skin biopsies of the KI-induced urticaria showed edema and inflammatory cell infiltration. The inflammatory cells that were abundant in the biopsy obtained from Patient C consisted of numerous polymorphonuclear cells, some eosinophils, and a normal number of mast cells. The skin tissue obtained from Patient D showed fewer inflammatory cells primarily in a perivascular location and a decreased number of mast cells. Immunofluorescent studies showed IgG, IgA, IgM, C1q, C3, C4, and perhaps properdin at the dermal-epidermal junction and in the vessels of Patients C and D. The amounts of immunoreactive material appeared greater in Patient C than in Patient D. The distribution of the immunoreactants suggested widespread immune complex deposition within the dermal-epidermal junction and, to a lesser extent, throughout the dermis. The electron microscopic studies of both biopsies were normal.

Complement analyses done on samples obtained before KI administration were compared to samples collected during the KI sensitivity reactions observed in Patients C and D. The levels of C3, C4, and Factor B and the activities of C2, C3, C4, and C5 did not significantly change in the samples. In Patient C the C1 activity and levels of C1r decreased by approximately 30% during the KI sensitivity reaction and returned to the prechallenge level by 48 h. In Patient D no significant decrease in C1 activity or C1r level occurred.

Discussion

Sensitivity to KI was historically recognized in four patients, and this sensitivity was studied in two of the sensitive patients by oral challenge. The administration of KI to the sensitive patients resulted in acute urticaria in one patient and exacerbations of pre-existing chronic urticaria present in the other three sensitive patients. The pre-existence of chronic urticaria in three of the sensitive patients clearly delayed recognition of the KI sensitivity because the exacerbations observed in Patients A, C, and D were originally attributed to emotional or physical factors. The occurrence of urticaria in both Patient A and Patient B during one metabolism study in 1978 prompted us to investigate the relation between KI administration and possible sensitivity reactions. In retrospect, the temporal relation between KI administration and urticarial reactions was clear because urticarial exacerbations had been noted in these four patients after the majority of 33 KI ingestions. In addition to urticaria, KI administration was followed on one or more occasions by polymyalgias (three of four patients), angioedema (two of four patients), conjunctivitis (two or four patients), coryza (two of four patients), and fever (three of four patients).

In the present study Patients C and D were challenged, and the challenges precipitated reactions similar to the reactions noted during the metabolism studies. Challenges of the four control patients who had chronic urticaria without hypocomplementemia and vasculitis did not exacerbate their urticaria nor did challenges of control patients with angioedema precipitate severe angioedema. Thus, KI sensitivity was associated with a particular group of patients represented by Patients A, B, C, and D. These four sensitive patients were all middle-aged women. Hypocomplementemia with classical pathway activation and dermal vasculitis were present in all four, associated with chronic urticaria or systemic lupus erythematosus. Raynaud's phenomena were also noted in three of the four sensitive patients. Both Patients A and D showed low levels of C1q and 7S C1q precipitins as well as chronic urticaria and represent a syndrome that may be similar to systemic lupus erythematosus [9-23]. The clinical similarities observed in the four sensitive patients may suggest one or more common immunopathologic processes related to KI sensitivity; however, no single clinical or immunologic feature was associated with KI sensitivity.

The inflammatory processes responsible for the manifestations of KI sensitivity are unknown. We hypothesized that KI administration resulted in the formation of oxidized C2(^{ox}C2) and the formation of stabilized C3 and C5 convertases containing ^{ox}C2a [24]. Such stabilized convertases would have activated more C3 and C5 and released the C3 and C5 anaphylatoxins that can produce urticaria [25]. The measurements of plasma C2, C3, C4, and C5 suggested that this hypothesis was incorrect because neither C3 nor C5 levels decreased during the KI sensitivity reactions produced in Patients C and D. In Patient C the decreases in C1 activity and C1r antigenicity both indicated that C1 activation occurred [26]. Kallikrein can cleave C1r, C1s, and kininogen and may

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Iodide-induced hypothyroidism without a goiter in an infant with cystic fibrosis

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IT HAS BEEN SUGGESTED that patients with cystic fibrosis may have an intrinsic abnormality of thyroid function that may be enhanced by the administration of iodides. We wish to report an infant with CF in whom hypothyroidism developed, in the absence of a goiter, following short-term iodide therapy.

CASE REPORT

Patient S, an ESTI girl infant, was the product of a gestation complicated by polyhydramnios. Family history was negative for CF and thyroid disease. The neonatal course was complicated by respiratory distress, the meconium ileus syndrome, jaundice and laryngospasm of prematurity. [illegible] on the third hospital day [illegible] mEq/l. Physical examination revealed [illegible] ends, patent ductus arteriosus, and pectus excavatum. At 2 weeks of age, treatment was started with 2 drops of a saturated solution of potassium iodide each day.

The infant was admitted to the hospital at age 5 months with a one week history of increased cough, anorexia, lethargy, and constipation. Positive findings included cyanosis, hypotonia, bilateral rales and wheezes, abdominal distention, a 1 cm umbilical hernia, a depressed nasal bridge, and protruding tongue. The skin and hair texture were normal and there was no enlargement of the thyroid gland. Following antibiotic therapy, there was progressive clinical improvement. Because of the patient's appearance, thyroid studies were obtained. Serum thyroxine concentration, by column, was 1.1 μg/dl (normal 2.9 to 6.4) and serum thyrotropin level, by radioimmunoassay, was 11.3 μU/ml (normal 0 to 7). Roentgenograph of the knee showed the presence of the distal femoral epiphysis and absence of the proximal tibial epiphysis, consistent with a newborn bone age. She was treated with desiccated thyroid, starting at a dose of 15 mg/day and increasing to 60 mg/day. Iodide therapy was discontinued. Following discharge, the infant appeared clinically euthyroid, and serial triiodothyronine (T3) and TSH values remained normal. Thyroid antibodies were not present in the patient's [illegible]

Abbreviations used	
CF	cystic fibrosis
T4	thyroxine
T3	triiodothyronine
TSH	thyrotropin

DISCUSSION

The development of a goiter, with or without hypothyroidism, has been well documented in adults and children following chronic administration of iodide. The occurrence of this complication in patients with CF was first reported by Dolan and Gibson, who observed that of 55 patients with CF who were treated with iodides, 47 developed goiters and 14 had clinical or laboratory evidence of hypothyroidism. In two of these 14 patients, hypothyroidism occurred in the absence of a goiter. Subsequent studies of thyroid metabolism in patients with CF have [illegible]

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ENCLOSURE 3

NUCLEAR REACTOR ACCIDENTS AND IODIDE PROPHYLAXIS

A Symposium in Washington, D. C.

Although the National Council on Radiation Protection Report No. 55 recommended wide-spread distribution and use of potassium iodide in the case of a nuclear emergency, this suggestion has yet to be implemented. The recommendation was based on the fact that radioiodides are major products of nuclear fission and that orally administered potassium iodide effectively inhibits the concentration of radioiodide in the thyroid, thus reducing thyroid irradiation by one or more orders of magnitude. However, there has been considerable informal discussion among thyroid experts as to the wisdom of this recommendation. Hence, it seems appropriate at the time of its Annual Meeting in Washington for the Endocrine Society to sponsor a Public Symposium dealing with these matters.

The Symposium entitled, "Iodide; Good or Evil After Nuclear Accients". will be held in the Sheraton Hall of the Sheraton-Washington Hotel at 8:00 P.M., June 18, 1980. Dr. J.E. Rall, Scientific Director of the NIAMDD, will chair the Symposium and will be one of the speakers. Other speakers include Dr. John Kouts, Chairman of Department of Nuclear Energy, Brookhaven National Laboratory, Dr. Jan Wolff, Medical Director, Clinical Endocrinology Branch, NIAMDD, and Dr. Rosalyn S. Yalow, Senior Medical Investigator, Veterans Administration.

[illegible] concentrations were [illegible] significantly low. I concentrations were seen in 23 of his 41 patients, suggesting a defect in the peripheral deiodination of T4 to T3. Iodides were administered to 18 patients with CF, following which eight developed goiters and four had clinical or laboratory evidence of hypothyroidism. Segall-Blank et al.[4] studied 24 patients with CF using an iodide-perchlorate discharge test and were unable to demonstrate a defect in thyroidal iodide organification. They found normal TSH reserve and a normal response to endogenous TSH stimulation.

Our experience with this patient confirms the apparent sensitivity of the thyroid gland to the effect of iodides in a patient with CF. It also re-emphasizes that iodide induced hypothyroidism may occur in the absence of thyroid gland enlargement. Failure to appreciate this point initially led to the erroneous diagnosis of congenital hypothyroidism in our patient. In view of the demonstrated complications of iodide therapy, and the lack of documentation of [illegible] therapy as a mucolytic or expecto-

[illegible] developed that such therapy has a role in the [illegible] patients with CF. However, if iodides are [illegible] patients with CF, careful clinical and laboratory [illegible] thyroid function, as well as size, is essential.

The authors thank Mrs. Terry Langevin for her assistance in the preparation of the manuscript.

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Association of primary hypothyroidism and slipped capital femoral epiphysis

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[illegible]

ALTHOUGH MANY CAUSES have been ascribed to slipped capital femoral epiphysis, the exact cause has not been identified. Because the highest incidence occurs both during the adolescent growth spurt and in "obese" children, epiphyseal changes during puberty, combined with mechanical strain in the hip joints, are assumed to be the predominant factors. Among endocrine diseases known to have an association with SCFE is primary hypothyroidism.[1]

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We report four patients, ages 9, 10, 14, and 17 years, respectively, who had both hypothyroidism and SCFE. We also present a tabular review of four additional patients described in the English literature.[2] The pertinent features are described in Table I. The diagnosis of

Abbreviation used
SCFE slipped capital femoral epiphysis

primary hypothyroidism was established in our patients by laboratory tests. All had limitation of motion in the involved hip joint and radiographic evidence of SCFE. After obtaining euthyroid state, each patient underwent hip pinning. These four patients were seen in a period of two years. The clinical findings are presented briefly.

A 9 10/12 year-old boy (Patient 1) had a five-month history of right hip pain but no historical evidence to suggest hypothyroidism and no growth failure. The diag-

ENCLOSURE 4

Enclosure 4

DRAFT

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EXAMINATION OF THE USE OF POTASSIUM IODIDE (KI) AS AN EMERGENCY PROTECTIVE MEASURE FOR NUCLEAR REACTOR ACCIDENTS

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ABSTRACT

Following the recent accident at Three Mile Island, there has been a resurgence of interest in the use of thyroid blocking as an emergency protective measure for reactor accidents. An analysis has been performed to provide guidance to policymakers concerning the effectiveness of potassium iodide (KI) as a blocking agent in realistic accident situations, the distance to which (or area within which) it should be distributed, and its relative effectiveness compared to other available protective measures.

The analysis was performed using the Reactor Safety Study (WASH-1400) consequence model. Four categories of accidents were addressed: gap activity release accident (GAP), GAP without containment isolation, core melt with a melt-through release (Melt-Through), and core melt with an atmospheric release (Atmospheric). Thyroid dose calculations show that the GAP category does not pose a significant health hazard to the public at any distance from the reactor. For the GAP without containment isolation and Melt-Through categories, doses in excess of recommended protective action guidance levels (PAGs) (5-25 rem) are confined to areas within approximately 10 and 15 miles of the reactor, respectively. For the Atmospheric category, however, thyroid doses are likely to exceed PAGs out to 100's of miles.

A cost-benefit analysis for the use of KI was also performed. Cost-benefit ratios ($/thyroid nodule prevented) are given assuming that no other protective measures are taken. Uncertainties due to health effects parameters, accident probabilities and costs are assessed, as well as the effect of other potential protective measures, such as evacuation and sheltering, on predicted ratios. The impact on children (critical population) is also evaluated. The estimated cost-benefit ratios are high, and it appears that the distribution of KI is only marginally cost-effective, at best.

Finally, using statistics provided in NCRP Report No. 55, a simple risk-benefit analysis showed the risk of adverse reaction posed by KI at the recommended action levels and dosages to be small compared to its potential benefits. However, if adverse reaction rates are higher than assumed, this conclusion would have to be reassessed.

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PROLOGUE

During the first few critical days of the accident at Three Mile Island, many spontaneous decisions were made concerning off-site emergency protective measures. The sense of the moment dictated action. Plans were conceived and implemented with little or no time available to determine the potential benefits and costs associated with alternatives. Specific plans were developed to evacuate the population within 20 miles of the reactor; the Governor ordered a five mile precautionary evacuation of pregnant women and small children; and Potassium-Iodide medication (KI) was manufactured and shipped to the area for possible distribution. The process by which decisions were made could only be described as chaotic.

To provide an adequate planning basis for future potential accidents, it is necessary to determine how frequently they would occur; to estimate their anticipated impacts on the surrounding population; and to evaluate the potential benefits of alternative protective measures. There have been studies which focused on these questions and attempted to provide guidance in these areas.[1,2,3] It is also possible to estimate the costs associated with various protective measure strategies. With this information (i.e., probability of accident occurrence; impact on public; benefit of various protective measures; and associated costs) a rational basis would be available to make planning decisions.

It is the intent of this report to focus on one emergency protective measure (Potassium Iodide) and present the information

needed to make a decision concerning a program for its use. There are many uncertainties associated with the information, methods, and techniques which are used in this analysis. As our knowledge and experience expands, the results and conclusions of this type of study should be reevaluated, and if necessary, changes made to the emergency planning strategy.

1. Introduction

Potential accidents at nuclear reactors, however unlikely, could result in substantial offsite radiation exposures, and pose a serious threat to the health and safety of the surrounding public. If an accident was sufficiently severe, resulting radiological consequences could include immediate deaths or injuries, delayed cancer deaths, thyroid nodules, and long-term contamination of land and property.[1] Any immediate effects, even for the worst accidents, would probably be confined to areas relatively close to the reactor (a few tens of miles),[1,2] and could be significantly reduced by implementing immediate protective measures. However, cancer deaths and thyroid nodules could occur over much larger distance (100's of miles), and would therefore be less affected by immediate protective measures taken near the site.

The risk posed by potential accidents to the thyroid of exposed individuals is especially great for several reasons:

- Radioactive iosotopes of iodine are produced in abundance by the fission process.
- Iodine and iodine compounds are normally quite volatile. Therefore, a sizeable fraction of core radioiodine inventories could be available for release to the atmosphere.
- Inhaled or ingested radioiodines are quickly absorbed into the bloodstream and concentrate preferentially in the thyroid.
- Iodines are eliminated from the thyroid with a relatively long biological half-life.

As a result, the radiation dose to the thyroid is likely to far exceed the dose to the rest of the body, and thyroid damage is likely to affect more individuals than any other accident-induced health effect.[1,3] Taken in large enough quantities, potassium iodide (KI) acts to block the absorption of radioiodines by the thyroid, reducing the thyroid dose. If taken at, or shortly before, the time of exposure, an almost complete iodine block (90% or greater) is possible. For this reason, KI has for many years been discussed as a potential protective measure for use in the event of a serious reactor accident.[4]

The availability of KI would provide a supplemental strategy to be considered along with other possible protective measures. However, KI should not be considered a panacea for reactor accidents. Although its effective use could significantly reduce the number of thyroid nodules resulting from an accident, it would have no impact on long-term land contamination, almost no impact on immediate health effects, and only a moderate impact on delayed cancer deaths. Use of KI is also not the only protective action that will reduce thyroid dose, nor is it without its difficulties and problems:

- The drug is not completely risk free; adverse reactions are possible.
- Making KI available would involve a cost to society; dollars that perhaps could be used to more effectively reduce risk elsewhere.

- There are serious storage and distribution logistical problems associated with ensuring that the public would receive the drug in sufficient time to be effective.
- It must be assured that any KI distribution strategy implemented would not reduce the effectiveness of other protective actions taken, e.g., if people are required to receive KI at a distribution center, they may be "caught" by the cloud while outdoors, and receive a higher dose than if they had stayed at home.

Potassium iodate, a drug similar to KI, has been distributed for use within a few miles of reactors in Great Britain.[5] A recent analysis by Beyea and von Hippel[3,6] recommends planning for the use of KI to much larger distances in the U.S., on the order of 100 or more miles from all reactors. A timely decision on the potassium iodide issue is required of responsible policy-makers. This report summarizes a study performed to provide them with technical guidance on that issue. It is intended (1) to provide insight concerning the effectiveness of KI in potential accident situations, (2) to help determine the merits of KI as an emergency protective option, (3) to establish the population and the distance to which (or area within which) it should be distributed, and (4) to determine under what conditions it should be implemented. Simple cost-benefit and risk-benefit analyses have been performed as part of this study. The effects of other protective measures, such as evacuation and sheltering, are addressed as well. Specific alternative strategies for stockpiling and distributing KI have not been addressed, although that would be

essential before making KI available to reduce costs and assure effectiveness.

The analysis reported here was performed using an updated version of the Reactor Safety Study (RSS) consequence model,[1] CRAC, for a range of potential reactor accidents. Four categories of accident releases are examined; from fuel pin gap activity release accidents to complete core meltdowns with containment failure directly to the atmosphere. It is important to note that there is a great deal of uncertainty in our knowledge of these releases, and their probabilities, as well as dose-health effect relationships for the thyroid. In some cases, these uncertainties hinder our ability to provide definitive guidance. However, they are addressed to the extent possible in our analysis.

2. KI as a Protective Measure

Inhaled or ingested iodine is rapidly and almost completely absorbed into the bloodstream. Almost one third of the iodine concentrates in the thyroid where it has a biological half-life of approximately 120 days. The absorption of radioiodines by the thyroid is greatly reduced if body fluids are saturated with stable iodine prior to exposure.[4] For most individuals, after a short-term exposure, the majority of radioiodine uptake by the thyroid occurs within 12 hours. The initial administration of a blocking agent will therefore be of some value even that long after the exposure period. However, essentially complete curtailment (90% or greater) of radioiodine uptake by the thyroid requires that stable iodine be administered shortly before or

immediately after the initiation of exposure. A block of 50 percent is attainable only during the first 3 or 4 hours after exposure. For releases of long duration, and therefore prolonged exposure to radioiodines, thyroid blocking agents would be useful at any time during the exposure.

Several chemical compounds of stable iodine are suitable as blocking agents, including potassium iodide (KI) and potassium iodate.* The Food and Drug Administration (FDA) has recommended and approved oral administration of potassium iodide (KI) as a blocking agent, in dosages of 130 mg (tablet or liquid form).[4,7] Continued administration of this daily dose appears to maintain an essentially complete block. A minimum of 3 to 7 days administration would probably be needed, and use of the drug is not expected to exceed 10 days.[7]

There is presently no definitive guidance concerning when, or under what conditions, KI should be used as a blocking agent. The NCRP recommends that it be considered for use if the projected** thyroid dose to an individual in the general public exceeds 10 rem.[4] Protective Action Guides (PAGs) for thyroid

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*Radiological emergency plans in Great Britain include thyroid-blocking using 100 mg tablets of potassium iodate, since in the British experience, the shelf-life of the iodate is appreciably longer than that of iodide tablets. The iodate form could be employed in the U.S. only by compliance with FDA requirements that include gathering the pertinent clinical data for the iodate.

**The projected thyroid dose is the estimated dose that would be received within a few days following the release if no protective actions are taken.

exposure to accidental airborne releases have been promulgated by the EPA.[8] PAGs for projected thyroid dose range from 5 to 25 rem. Protective action is recommended at the lower level for sensitive populations (pregnant women, children), or if there are no local constraints to providing protection at that level. Protective actions would be required in all cases if the projected dose exceeds the higher value. However, only evacuation and controlled area access were discussed in the EPA document,[8] and the use of KI was not specifically cited as an appropriate protective measure.

Because the prompt administration of KI in the event of an accident is critical to its effectiveness as a protective measure, some method of rapid distribution or availability to the public is required. There is little current definitive planning for such methods. Stockpiling supplies of KI in "distribution centers" such as schools, police stations, or firehouses has been recommended.[4] An alternative would be to provide each household with a sufficient supply for all members of the household. The feasibility and effectiveness of these and other alternative strategies, as well as their likely implementation costs, should be investigated.

There is considerable experience with the use of KI as a therapeutic drug.[4] It has been used for a number of years in high doses, and on a long-term basis, for the treatment of various pulmonary disorders. The reported incidence of adverse reactions to the drug is low, and the risk posed by the short-term use of the relatively low doses that would be involved with response to an

accident is judged to be minimal. The NCRP[4] estimates the adverse reaction rate to be between 1×10^{-7} and 1×10^{-6} per dose, and concludes that the administration of KI would not result in significant immediate side effects, even if given to large segments of the population.*

3. Accident Releases Considered

Release magnitudes for potential accidents of offsite significance range from relatively small releases of gap activity to the large releases predicted for full core-melt accidents in which the containment fails directly to the atmosphere.** The RSS[1] grouped this spectrum of reactor accidents into nine release categories for pressurized water reactors (PWR) with large dry containments and five for boiling water reactors (BWR) with Mark I containment. These categories are presented in Table 1 along with their estimated probabilities of occurrence, release magnitudes, and other parameters that characterize the release.*** It

*Note that warning would be given cautioning against the use of KI by individuals who are sensitive to iodine.

**A large light water power reactor typically contains about 10 billion curies of radioactive material. The spectrum of potential accidents addressed in this study would release from 10^{-7} (1000 curies) to about one half (5×10^{9} curies) of this radioactive material directly to the atmosphere.

***The time of release is the time interval between thee initiation of the accident and the release of radioactive material from the containment strducture to the atmosphere. The duration of release is the period of time during which radioactive material is emitted to the atmosphere. The warning time for evacuation is the projected time interval between awareness of impending coremelt and the release of radioactive material from the containment building. For those accidents in which core-melting does not occur, there is no projected warning time. Finally, the height of release and the energy content of the released plume influence the height to which the plume rises and thus the exposure to persons near the site.

should be noted that, because of the lack complete understanding of the physical processes associated with core-melting and the resulting release of radioactive material to the environment, there is a large degree of uncertainty and overlap in these groupings. There is also a large degree of uncertainty associated with their estimated probabilities,[9] a point which will be discuss later in this report.

For the purpose of this study, the PWR accident release spectrum has been grouped into 4 categories:*

	RSS Release Categories
1. Gap Activity Release Accident (GAP)	PWR9
2. Gap Activity Release Accident without Containment Isolation (GAP w/o Isolation)	PWR8
3. Core Melt with Melt-Through Release (Core Melt Melt-Through)	PWR6-7
4. Core Melt with Atmospheric Release (Core Melt Atmospheric)	PWR1-5

PWR9 represents a gap activity release accident in which only the activity initially contained within the gap between the fuel pellet and cladding would be released into the containment. All engineered safeguards are assumed to function properly. PWR8 is the same as PWR9, except that the containment fails to isolate properly on demand. Again, all other engineered safeguards, including containment sprays, are assumed to function properly.

*These 4 categories are comprised of the RSS release categories from which they are defined, each weighted by its respective probability as calculated in the RSS.

PWR categories 1 through 7 are accidents in which core melt is assumed to occur. PWR 6 and 7 are dominated by accident sequences involving containment failure by containment vessel melt-through. PWR1-5, on the other hand, consist of accidents in which containment failure is assumed to occur directly to the atmosphere as a result of either inadequate isolation of containment openings or penetrations, a reactor vessel steam explosion, hydrogen burning, or overpressure. To reduce the required time and cost of computation, BWR accidents have not been dealt with specifically in this analysis. However, the information and conclusions presented for large dry containment PWRs should be roughly applicable to other PWR designs and for BWRs as well, given a similar type of accident and mode of containment failure.*

4. Thyroid Dose and Health Effects Calculations

Dose to the thyroid is estimated as the sum of 1) external dose from the passing cloud (cloud exposure), 2) external dose from contaminated ground (ground exposure), 3) internal dose during the first 30 days from all inhaled radionuclides except

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*BWR5 represents the BWR gap activity release accident. BWR1-4 are accidents that involve core-melt. For the specific BWR design investigated in the RSS, the probability of containment failure by containment vessel melt-through is essentially zero, i.e., the containment is assumed to always fail directly to the atmosphere. BWR4 is dominated by accident sequences involving containment isolation failure in either the drywell or wetwell, whereas BWR1-3 are dominated by accidents in which the containment fails from either a steam explosion in the reactor vessel or containment, or from overpressure resulting in release through the reactor building or directly to the atmosphere. Other containment designs (e.g., PWR ice condenser, BWR Mark II or BWR Mark III) would have somewhat different probabilities for the various containment failure modes.

I-131, and 4) internal dose during the first 30 days from inhaled I-131. Thyroid dose from ingestion via the grass-cow-milk-man pathway and chronic exposure has not been included in this analysis because those pathways would not require an immediate emergency response in the event of an accident.

The dose received by a child's thyroid is likely to be higher than that received by an adult for several reasons, including differences in thyroid mass and breathing rate. The RSS assumed age dose factors* of 1.0 for children of ages 0-1 years, 1.9 for ages 1-10 years, and 1.6 for ages 10-20 years. Somewhat higher factors (up to 5) have been assumed in other studies.[3,10]

There is considerable uncertainty concerning the effects of radiation exposure on the thyroid.[1,4,10] Thyroid nodules are the effect of primary concern, and would typically be observed from 10 to 40 years after exposure.[1] A nodule is an abnormal growth that could be either benign (non-cancerous) or malignant (cancerous). Nodules that are thought to be possibly malignant would most likely be surgically removed.

Most thyroid cancers are well differentiated, slow growing, and relatively amenable to therapy. Their mortality rate is therefore much lower than that for most other forms of cancer. The RSS[1] conservatively assumed a 10 percent mortality rate for malignant thyroid nodules.

*Ratio of child to adult inhalation dose.

Based on the results of animal experiments, and clinical data for humans, the RSS[1] assumed that internal irradiation of the thyroid by I-131 would be only 1/10th as effective as external x-rays in producing both benign and malignant nodules.* This factor of 0.1 for I-131 dose was disputed by the American Physical Society (APS) study group on reactor safety,[10] which assumed a range of factors from 0.3 to 1.0. Because this issue remains unresolved, calculations have been performed in this analysis both with and without a 0.1 factor for I-131 dose effectiveness.

Sufficiently high radiation doses** would result in ablation of the thyroid, with no subsequent risk of either benign or malignant nodules.[1] However, because of the high doses required, thyroid ablation is unlikely to occur except for persons very near the reactor following the most severe accidents. Ablation would probably require surgical removal of the thyroid, and the affected individual would need to take substitute hormone pills on a daily basis. Thyroid damage, including both nodules and ablation, has been addressed in this analysis.

*On a purely radiological basis, it is thought that the more uniform distribution of dose within the thyroid from external irradiation might increase the efficiency of inducing clinical hypothyroidism.

**The RSS[1] assumed that doses in excess of 5000 rem (50,000 rem from I-131) would result in thyroid ablation.

The RSS calculation of the expected number of thyroid nodu per million adult-rem* is reproduced in Table 2. The assumed total incidence rate is 334 thyroid nodules per 10^6 adult-rem, percent of which are benign, 40 percent malignant. Although no specifically computed, a dose-effects coefficient for a child's thyroid can be derived from the RSS[1] data to be approximately a factor of 2 higher.** Beyea[3] assumes the RSS values as lower bounds, and upper bounds of 650 per 10^6 adult-rem for adults, and 6500 per 10^6 adult-rem for children.

Most of the calculations performed in this study assumed the RSS[1] risk coefficient of 334 thyroid nodules per 10^6 adult- This corresponds to an assumed risk, or probability, of a thyro nodule for an individual of 3.34×10^{-4}/rem, i.e., 100 rem to an individual implies a probability of contracting thyroid nodu of 3.34×10^{-2} . For this assumed coefficient, a dose to an individual of 3000 rem gives a thyroid nodule probability of approximately 1.0. Therefore, the following is assumed:

Thyroid Dose

$\leq$ 3000 rem	p(thyroid nodule)	= $(3.34 \times 10^{-4}$/rem)(dose in rem
> 3000 rem	p(thyroid nodule)	= 0
	p(ablated thyroid)	= 1.0

*For convenience, and to avoid confusion, all coefficients are given in terms of adult-rem to the thyroid.

**For age group 1-10: (years at risk) (age dose factor) (risk coefficient) = 30 x 1.9 x (8 + 4.3) - 707 thyroid nodules pe 10^6 adult-rem.

The effect of uncertainty in the thyroid dose-effect relationship is assessed by repeating some calculations using the upper bound values proposed by Beyea[3] and the APS.[10]

Thyroid Dose Calculations

A series of calculations was performed using an updated version of CRAC, the RSS consequence model,[1,11] to determine 1) the magnitude of the threat to the thyroid of exposed individuals, 2) the distance to which that threat is likely to be of concern, and 3) the relative contributions of different exposure pathways and radioisotopes to the thyroid dose, for each of the four accide categories defined in the previous section. All calculations were performed for a 3200 MWt PWR using 1 year of meteorological data taken from a single reactor site.* From the year's data, 91 different weather sequences were selected by stratified sampling[1] and used to generate probability distributions of thyroid dose versus distance. Shielding and breathing rate parameters appropria for a person located outdoors[1,2,13] are assumed: breathing rate = 2.66×10^{-4} m^3/s, shielding factors = 1.0 (cloud exposure) and 0.7 (ground exposure).

*Site-to-site variations in meteorological histories have been shown to have little effect on the prediction of long-term public health effects.[12] Therefore, the use of meteorological data from a single site should be sufficient for this study.

For each accident category, Table 3 presents the mean thyroid dose that would be received by an exposed adult located outdoors at selected distances from the reactor. The corresponding dose to a child's thyroid would be approximately a factor of 2 higher. Table 4 presents the associated probability of thyroid damage for the same individuals. The values shown equal the doses in Table 3 multiplied by the RSS risk coefficient of 3.34×10^{-4} per adult-rem to the thyroid.

The probability of thyroid damage to an individual following a gap activity release accident (GAP) is extremely low, ranging from less than 2×10^{-5} (1 in 50,000) 1 mile downwind of the site to less than 4×10^{-9} (1 in 250,000,000) at 100 miles. Probabilities are somewhat higher for the GAP w/o Isolation and Core Melt Melt-Through accidents; they also appear to be approximately equal for these two categories. Thyroid damage probabilities for the Core Melt Atmospheric accidents are much higher, and such accidents would pose significant health hazards to persons at distances of more than 100 miles* from the site. These results agree with those of previous studies.[2,3]

The fractional components of mean thyroid doses are provided in Table 5 for selected distance intervals; 0-25 miles, 25-100

*Caution must be used in interpreting the large distances indicated. The RSS consequence model assumes an invariant wind direction following the release of radioactive material. However, because of the time required by the cloud to travel large distances, jit is likely that the wind direction will, in fact, shift and that the predicted dose levels would not be observed at the reported radial distance. Rather, the distance applies more closely to the distance along the trajectory of the released cloud.

miles and >100 miles. Within these intervals, the relative contributions to thyroid dose will not differ significantly. The dose is divided into components for the inhalation of radioiodines, inhalation of non-radioiodines, cloud exposure and ground exposure. Radioiodine inhalation is further divided into components for I-131 and other iodines. It is evident from Table 5 that the thyroid dose is dominated by the inhalation of radioiodines for each of the four accident categories. Inhalation of I-131 alone accounts for 60-80 percent of the total dose, and other iodines contribute another 10-25 percent. Inhalation of non-radioiodines, cloud exposure and ground exposure are all small contributors to total thyroid dose.

The probabilities of exceeding thyroid doses of 0.01 and 0.1 rem versus distance from the reactor are shown in Figure 1, conditional on the occurrence of a gap activity release accident (GAP). The probabilities are calculated for an exposed adult located outdoors. The dose levels, 0.1 and 0.01 rem, are far lower than any recommended action levels, and are still confined to areas very close to the reactor. Therefore, it is evident that the GAP accident does not pose a significant hazard to the public.

Figures 2 and 3 show the probability of exceeding thyroid doses of 1, 5, 10 and 25 rem versus distance for the GAP w/o Isolation and Core Melt Melt-Through accidents. The 5, 10 and 25 rem dose levels were chosen because they represent the range of action levels that have been recommended for the initiation of emergency protective measures. The 1 rem level was added as a lower bound

for doses of interest. It is evident from these results that, for all practical purposes, projected thyroid doses of concern are confined to areas within a few 10's of miles of the reactor, for these types of accidents, and in most cases to areas considerably closer. For the GAP w/o Isolation accidents, doses in excess of 5 rem are confined to about 10 miles; those in excess of 25 rem to about 5 miles. The same dose levels are confined to approximately 15 and 7 miles, respectively, for the Core Melt Melt-Through category.

The conditional probabilities of exceeding thyroid doses of 1, 10 and 25 rem for the Core Melt Atmospheric category are shown in Figure 4. The thyroid dose levels of concern are likely to be exceeded at very large distances from the reactor (and correspondingly over very large areas) if this type of accident were to occur.

5. Other Protective Measures

It was shown in the previous section that, for each of the 4 accident categories addressed, the thyroid dose is dominated by the inhalation of radioiodines. Therefore, in order to be effective in reducing the thyroid dose and resulting health impacts, a protective measure must reduce that inhalation dose. KI does this by blocking the absorption of inhaled radioiodines by the thyroid. However, other protective measures, including both evacuation and sheltering, could also act to reduce inhalation dose.

Evacuation, which is the expeditious movement of the population to avoid immediate exposure, is considered to be the primary protective measure in most radiological emergency planning

within the United States.[14, 15, 16, 17] Evacuation could potentially be 100 percent effective in reducing all dose if accomplished before arrival of the radioactive cloud. On the other hand, it could be ineffective in reducing inhalation doses if not initiated until after the cloud has passed.*

Sheltering might also provide some reduction in thyroid dose, and could potentially be implemented at much larger distances than evacuation. Sheltering is the deliberate action by the public to take advantage of the protection against radiation exposure afforded by remaining indoors, away from doors and windows, during and after the passage of the cloud of radioactive material. The shielding inherent in normally inhabited structures offers some degree of protection against external penetrating radiation from airborne and surface deposited radionuclides. Furthermore, the exclusion of a significant amount of airborne radioactive material from the interior of a structure, either by natural effects or by certain ventilation strategies, can reduce the amount of inhaled radionuclides as well.[18] A recent study[19] suggests that a factor of 2 reduction in inhalation dose can be assumed for sheltered individuals. That factor has been assumed in this analysis.

Finally, other potential measures such as breathing through either respirators or common household items, e.g., handkerchiefs and towels,[20,21] may provide additional protection against dose

*Even in situations where the radioactive cloud has passed, evacuation could be valuable to reduce exposure to ground contamination. However, since thyroid dose is dominated by radioiodine inhalation, it would not be significantly reduced in this case.

from inhalation of radionuclides. However, further research is required to determine their effectiveness in realistic accident situations, and they have not been addressed in this analysis.

6. Cost-Benefit Analysis

The decision to use potassium iodide as a protective measure should be based, at least in part, on its cost-benefit relative to other available protective or safety measures. To analyze the costs and potential benefits of KI, the following information is needed:

- Costs;
- Potential impact of accidents;
- Potential reduction in accident impacts; and
- Accident probabilities.

The cost of implementing a KI program would include: the purchase price of the KI in tablet or liquid form (both original and periodic replacement costs); costs for stockpiling, distributing and monitoring the status of the drug; and administrative expenses associated with the program. The potential impact of the accident is measured here by the mean number of thyroid nodules that would occur within selected distance intervals. The reduction in accident impact is measured as the difference between the number of thyroid nodules predicted if no protective actions are taken (normal activity) and the number predicted if various protective actions are implemented. Accident probabilities are their expected occurrence rate per year of reactor operation. By combining the costs with the accident probabilities and the estimated

reduction in effects, a cost-benefit ratio is generated. The cost-benefit ratio for KI is interpreted as the expected number of dollars to prevent a single thyroid nodule.

The cost-benefit ratio has been evaluated for the GAP w/o Isolation, Core Melt Melt-Through and Core Melt Atmospheric accident categories over selected distance intervals out to 200 miles from the reactor. Because few, if any, nodules are likely for the gap activity release accident (GAP), that category has not been addressed. Calculations were performed for a 3200 MWt PWR using a modified version of CRAC[1] in the same manner as described in Section 4. Several additional assumptions were made to facilitate the analysis and to allow the presentation of results in a concise and easily interpretable manner. All calculations assume that KI is 99 percent effective in reducing the dose to the thyroid from inhaled radioiodines. This is obviously a limiting case in that it assumes that all affected individuals take the drug before or immediately after the cloud passes. A 50 percent average reduction* for the population as a whole might be more realistic for an actual accident situation. A uniform population density of 100 persons per square mile is assumed in calculating thyroid nodules.** Results for real, or site-specific, population distributions can be estimated by scaling

*e.g., 50 percent of the people take the drug before the cloud arrives (99% reduction) and 50 percent do not take the drug in time (0% reduction).

**Because costs are also assumed to be proportional to population density, this assumption does not impact the cost-benefit ratios calculated.

the 100 persons/mile^2 results within each distance interval. Finally, calculations were performed both with and without the 0.1 effectiveness factor for I-131 discussed in Section 4.

Costs

The stockpiling, distribution, monitoring and administrative costs of a KI program would depend on the specific strategy of implementation, and are difficult to estimate. Therefore, only the original purchase and replacement costs of the drug are addressed in this analysis. The following assumptions are made:

1) Cost of KI per individual (14 tablets in a bottle) = $0.50.*
2) KI is replaced every five years (i.e., 5 year shelf life).**
3) KI is available for all persons within a given distance interval.
4) No redundancy of KI locations (i.e., no extra tablets are available).***

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*This value is consistent with the price range ($0.41 to 0.75, depending on quantity) quoted by a U.S. drug firm that manufactures KI.

**KI tablets and solution currently approved by the U.S. Food and Drug Administration (FDA) for marketing bear 2-year expirations. However, improved product stability should be possible. Therefore, a 5-year shelf-life is assumed here.

***Considering the importance of prompt distribution and administration of KI, some redundancy of storage locations would be desirable. However, the extra cost that this would incur has not been included here.

The cost per year to provide KI for all persons within an interval is therefore equal to the number of persons in the interval x $0.50/person x 1/5 years.

For the uniform population density of 200 persons/mile^2 assumed in generating the preceeding results, the number of persons located within distance intervals would be as follows:

Distance Interval (miles)	No. Persons in Interval	Cumulative No. Persons
0-5	7,900	7,900
5-10	23,600	31,400
10-25	165,000	196,000
25-50	589,000	785,000
50-100	2,360,000	3,140,000
100-150	3,930,000	7,070,000
150-200	5,500,000	12,600,000

Using this information, the estimated annual cost for a KI program within each interval is given below.

Distance Interval (miles)	Cost($/year)
0-5	790
5-10	2,400
10-25	16,000
25-50	59,000
50-100	240,000
100-150	390,000
150-200	550,000

At an assumed cost of $0.10 per person per year, the annual cost to implement a KI program for the entire U.S. would be about $20 x 10^6. Other distribution strategies, such as regional storage, could substantially reduce this cost.

Potential Impact of the Accidents

The mean number of thyroid nodules* that would occur within selected distance intervals for the 3 accident categories addressed are given in Table 6a, b and c. Results are presented separately for 4 protective measure combinations: 1) normal activity, i.e., no protective actions taken,** 2) normal activity plus 99 percent effective KI, 3) sheltering*** and 4) sheltering plus 99 percent effective KI. Although results are not specifically presented for evacuation, they would range from 0 within all distance intervals to approximately the values shown for normal activity (see Section 5).

Potential Reduction in Thyroid Nodules

The potential reduction in the mean number of thyroid nodules that would result by the use of KI is presented in Table 7. The values provided were determined from those given in Table 6 a, b and c. As an example, for the GAP w/o Isolation accident, the mean number of nodules in the 0-5 mile interval is 1.77 for normal activity and 0.09 for normal activity plus 99 percent effective KI (Table 6a). The difference between these two numbers (1.68) is the reduction afforded by using KI.

*For the Core Melt Atmospheric accident category, thyroid doses can be sufficiently high to result in ablated thyroids as well as nodules. Mean numbers of ablated thyroids in each distance interval are given in parenthesis in Table 6c.

**Shielding factors = 0.75 (cloud exposure) and 0.33 (ground exposure). 1-day exposure to ground contamination.

***Shielding factors and ground exposure same as for normal activity. 50 percent reduction in inhalation dose.

Accident Probabilities

The probability of occurrence estimated by the RSS[1] for the accident categories addressed in this analysis can be obtained from the data in Table 2.

	RSS Categories	Estimated Probability (per reactor-year)
GAP	PWR9	4×10^{-4}
GAP w/o Isolation	PWR8	4×10^{-5}
Core Melt Melt-Through	PWR6-7	4.6×10^{-5}
Core Melt Atmospheric	PWR1-5	1.4×10^{-5}

The uncertainties in these probabilities are large. Error bounds of factors of 1/5 and 5 on the values above were estimated in the RSS. In 1978, the risk assessment review group (Lewis Committee),[9] chartered by NRC to review the Reactor Safety Study, concluded - "We are unable to determine whether the absolute probabilities of accident sequences in WASH-1400 are high or low, but we believe that the error bounds on those estimates are, in general, greatly understated." Operating experience data for light water reactors (LWR) can also be used to estimate an upper bound for the probability of core melt.[22] Through the end of 1979, there had been approximately 450 years of LWR experience in the U.S., without a core melt event.*[23] Assuming a χ^2 distribution for such potential events, it can be shown that the probability of core melt is less

*Although the accident at Three Mile Island involved serious core damage, it was not a core melt event.

than 1.5×10^{-3} with 50 percent confidence, and less than 6.7×10^{-3} with 95 percent confidence.*[22] These upper bound probabilities are approximately factors of 25 and 100 times the RSS values above ($4.6 \times 10^{-5} + 1.4 \times 10^{-5} = 6.0 \times 10^{-5}$).

The RSS probabilities were used with the results in Table 7 to determine the potential reduction in the mean number of thyroid nodules per year of reactor operation by implementing a KI strategy. Those values, which are shown in Table 8, include contributions from all 3 of the accident categories considered.** Note that the contribution from the Core Melt Atmosphereic category dominates (95-100%).

Cost-Benefit Ratio

Combining the estimated costs and the results in Table 8, estimated cost-benefit ratios for the use of KI are presented in Table 9 in terms of $ per nodule prevented, i.e., the expected number of dollars to prevent a single thyroid nodule. The estimated ratios range from 3.2×10^5 $/nodule prevented (for the 0-5 mile interval, normal activity, and no 0.1 effectiveness factor for I-131) to 3.7×10^8 $/nodule prevented for the 150-200 mile interval, sheltering and 0.1 effectiveness factor.

*Worldwide LWR experience through 1979 was closer to 1000 reactor-years.[22] Using this value rather than 450 years results in probability estimates of 7×10^{-4} with 50 percent confidence, and 3×10^{-3} with 95 percent confidence.

**The expected reduction per reactor year = $\sum_i$ (potential reduction)$_i$ (accident probability)$_i$, where i is the accident category.

Sensitivities

Table 10 summarizes a cost-benefit analysis performed specifically for the use of KI by children. The risk coefficient assumed, 668 per 10^6 adult-rem,* is a factor of 2 higher than that assumed in Table 9. Other assumptions include: no 0.1 effectiveness factor for I-131, RSS accident probabilities, normal activity, and a uniform population density of 100 persons/square mile. Only the Core Melt Atmospheric accident category was addressed, although, as shown earlier, this has a negligible effect on the predicted results. The cost-benefit ratios in Tables 9 and 10 are not significantly different for the intervals close to the reactor. This is because the doses within those intervals are sufficiently high to result in nodules for essentially all affected individuals, regardless of the coefficient assumed. At larger distances, the cost-benefit ratio in Table 10 is a factor of 2 lower, as expected.

Finally, Figure 11 summarizes an identical analysis performed for children using the APS upper bound risk coefficient of 6500 thyroid nodules per 10^6 adult-rem to the thyroid. In this case, the estimated cost-benefit ratios range from 4.9×10^5 \$/nodule prevented within 0-5 miles to 2.2×10^6 \$/nodule prevented within 150-200 miles. Note that the ratio for the 0-5 mile interval is actually higher than in Tables 9 and 10.**

*This is also very close to the risk coefficient assumed by Beyea[3] for adults (see Section 4).

**For this assumed risk coefficient, the thyroid dose is still high enough to cause significant numbers of thyroid nodules, even with 99% effective KI.

The cost-benefit ratios given in each of the tables above were calculated for selected distance intervals from a single reactor. However, if, for example, there were 2 reactors at a particular site, the probability of an accident at that site would be twice as high, and the cost-benefit ratio for each distance interval would be a factor of 2 lower. Similarly, in many areas of the U.S., several reactors at different sites may contribute to an individual's risk of thyroid damage. The extent to which this would reduce the cost-benefit ratio for KI depends on a number of factors, including the specific location with respect to neighboring plants, wind direction frequencies, reactor power levels, etc. For example, there are approximately 13 reactors* currently operating within 200 miles of New York City. Using the data provided in Table 9 above, and ignoring wind direction frequencies and differences in reactor power level and design, the cost-benefit ratio specific to New York City can be estimated to be approximately a factor of 4 lower than if only one of the Indian Point reactors was considered alone.** Similarly, for the city of Chicago (which has more than 10 operating plants within

*Reactors (power level > 200 MWe) within 25-50 mile interval: Indian Point 2 and 3; 50-100 miles: Oyster Creek, Haddam Neck, Millstone 1 and 2; 100-150 miles: Salem, Vermont Yankee, Peach Bottom 2 and 3; 150-200 miles: Three Mile Island 1 and 2, Pilgrim.

**From Table 9, for normal activity and no 0.1 effectiveness factor, NYC cost-benefit ratio for a single Indian Point reactor = 2.0×10^6 \$/thyroid nodule. Including all 13 reactors:

$$\frac{1}{\text{cost-benefit ratio}} = \frac{2}{2.0\times10^{6}} + \frac{4}{6.2\times10^{6}} + \frac{4}{2.0\times10^{7}} + \frac{3}{4.2\times10^{7}}$$

and cost-benefit ratio = 5.2×10^5 \$/thyroid nodule.

200 miles), the cost-benefit ratio is approximately 5 times lower than the ratio if only a single reactor was considered.

7. Risk-Benefit Analysis

As reported in Section 2, the risk posed by the use of KI as an emergency protective measure for reactor accidents was judged by the NCRP to be minimal. Nevertheless, a brief analysis is presented here to determine under what conditions, if any, the risk posed by the drug might outweigh its potential benefits.

Assuming a risk of adverse reaction of 10^{-6} per dose of KI (see Section 2), and that 10 doses would be administered to each individual following an accident, the risk posed by the drug equals 10^{-5}. To estimate the thyroid dose for which the potential benefit (reduced risk of nodule) and risk of KI are equivalent, the following additional assumptions are made: risk coefficient for individual = 3.34×10^{-4}/rem, no 0.1 effectiveness factor for I-131, and 99 percent effective* use of KI reduces total thyroid dose by 90 percent.** Then $10^{-5} = 0.9 \times (3.34 \times 10^{-4}/\text{rem}) \times$ (equivalent dose), and the equivalent dose = 3×10^{-2} rem. What if other assumptions are made? Higher risk coefficients, such as those for children (see Section 3), would result in lower predicted equivalent doses. The administration of KI to everyone within 360° of a site rather than only to exposed persons would increase the equivalent dose. For example, if the radioactive

*99 percent reduction in dose from inhaled radioiodines.

**Actual percentage reduction depends on the composition of the release. For the accident categories addressed in this study, roughly 90 percent of the thyroid dose is due to inhaled radioiodines (see Table 5).

plume was 15' wide, the equivalent dose would be a factor of 24 (i.e., 360/15) higher* (= 0.8 rem). Assuming only 50 percent effective KI (rather than 99%), as well as 360' administration, the equivalent dose would become 2 rem. Finally, if a 0.1 effectiveness factor for I-131 is also assumed, the equivalent dose is increased to approximately 5 rem.**

The range of equivalent doses calculated above for various assumptions are all below the recommended level for use of KI (10 rem, see Section 2). Therefore, at the recommended level, the risk posed by the drug does appear to be small compared to its potential benefits.*** However, several recent reports[24, 25] suggest that the risk associated with the drug may be significantly higher than 10^{-6} per dose for certain segments of the population. If this is confirmed, the risk-benefit conclusion for KI would have to be reassessed.

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*The individual would now be expected, on the average, to take the drug 24 times as often (assuming a uniform probability distribution for wind direction), and thus his risk would increase by that factor.

**I-131 contributes approximately 75 percent of the dose from inhaled iodines (see Table 5). With a 0.1 effectiveness factor, the effective dose from inhaled iodines is reduced by a factor of (0.75)(0.1) + (0.25) = 0.33. The potential benefit of 50 percent effective KI = 0.9 (0.33)(0.5)(3.34 x 10^{-4})(thyroid dose). Setting this equal to 24 (10^{-5}), the equivalent dose = 5 rem.

***If the adverse reaction risk was 10^{-7} rather than 10^{-6} per dose (see Section 2), the risk posed by KI would be minimal compared to its potential benefits.

8. Conclusions and Recommendations

This study was undertaken to provide guidance to policymakers concerning the use of potassium iodide (KI) as an emergency protective measure for reactor accidents. Analyses were performed to determine 1) the effectiveness of KI in realistic accident situations, 2) the population and distance to which (or area within which) it should be distributed, and 3) its relative effectiveness compared to other available protective measures. Although the effective use of KI could significantly reduce the number of thyroid nodules resulting from a serious accident, it would have no, or only minor, impact on other accident consequences; including immediate deaths or injuries, delayed cancer deaths, and long-term land contamination. Therefore, the availability of KI would provide only a supplemental strategy to be considered along with other possible protective measures.

The study was performed using an updated version of the Reactor Safety Study (WASH-1400) consequence model, CRAC. Four categories of accidents were addressed: gap activity release accidents (GAP), GAP without containment isolation (GAP w/o Isolation), core melt with a melt-through release (Core Melt Melt-Through) and core melt with an atmospheric release (Core Melt Atmospheric). A series of thyroid dose calculations showed that the GAP category does not pose a significant health hazard to the public at any distance from the reactor. For the GAP w/o Isolation and Core Melt Melt-Through categories, doses in excess of recommended protective action guidance levels (PAGS)(5-25 rem) are confined to areas within approximately 10 and 15 miles of the

reactor, respectively. For the Core Melt Atmospheric category, however, thyroid doses are likely to exceed PAGs out to 100°s of miles.

A cost-benefit analysis for the use of KI was also performed, the results of which are summarized in Table 12. Cost-benefit ratios ($ per thyroid nodule prevented) are presented for selected distance intervals, assuming that no other protective measures are taken. The effect of evacuation and sheltering on the predicted ratios is shown in Table 9 and discussed in Section 5. Evacuation has the potential to be 100% effective in reducing all dose if accomplished before arrival of the radioactive cloud. Sheltering was assumed in this analysis to provide a factor of 2 reduction in thyroid dose. Therefore, in both cases, the thyroid dose reduction afforded by the supplemental use of KI would be reduced, and the KI cost-benefit ratios presented in Table 12 would be correspondingly increased.

The uncertainties in the estimated cost-benefit ratios are very large. Key assumptions made in deriving the ratios are noted in Table 12. The KI was conservatively assumed to be 99% effective (i.e., all persons take the drug before the cloud passes). A more realistic effectiveness value might be 50%. WASH-1400 accident probabilities were assumed. Probability uncertainties have been estimated to be at least an order of magnitude (see Section 6). Estimated costs for a KI program were conservatively based on only the purchase price of the drug, and did not include costs for distribution, monitoring and administrative expenses. The ratios presented in Table 12 are appropriate if

there is only a single reactor within 200 miles. Many actual sites would be influenced by several reactors, and cost-benefit ratios could be reduced by factors of 2 to 5 (see Section 6). Uncertainties in dose and health effects parameters are also large and could result in either higher or lower cost-benefit ratios.

To some extent, the large uncertainties in the above assumptions hinder our ability to provide definitive guidance. Nevertheless, for the assumptions made, the predicted cost-benefit ratios are high; and even including uncertainties, KI appears to be only marginally cost-effective, at best.*

Finally, using statistics provided by the NCRP[4], a simple risk-benefit analysis showed the risk of adverse reaction posed by KI at the recommended action levels and dosages to be small compared to its potential benefits. However, several recent reports[24, 25] suggest that there is a significantly higher risk associated with use of the drug among certain segments of the population. If this is confirmed, the risk-benefit conclusion for KI would have to be reassessed.

Based on the above analysis, the following additional recommendations and comments are made:

*Although the total cost associated with a case of thyroid nodules was not specifically addressed, an approximate upperbound of $17,000 can be inferred from the information presented in reference 26 assuming 1) average hospital care costs of $2,000, 2) that hospital costs are 60% of all direct costs, and 3) that indirect costs (economic losses due to mortality and morbidity) are 4 times higher than direct costs.

- The risk of thyroid nodules was shown to be dominated by the large releases associated with core melt accidents in which the containment fails directly to the atmosphere. Therefore, if design modifications, such as filtered containment venting systems, are implemented to reduce the liklihood of those releases, the potential benefit of KI could be substantially reduced.
- Before any KI program is implemented, specific alternative strategies for stockpiling and distributing the drug should be examined to reduce costs and assure effectiveness.
- The use of common household items (e.g., handkerchiefs and towels) as respiratory filters may provide significant additional protection against dose due to inhaled radionuclides and should be considered further in the development of protective strategies.
- If a KI program is implemented, responsible government agencies should give priority to establishing guidance (PAGs) concerning when, or under what conditions, the drug should be used.
- Finally, whether or not a public KI program is implemented, it might be wise to have sufficient quantities of the drug available at or near reactor sites for use by 1) site personnel, 2) offsite emergency response personnel, and 3) controlled populations in offsite institutions (e.g., hospitals, prisons) where immediate evacuation would be difficult or infeasible.

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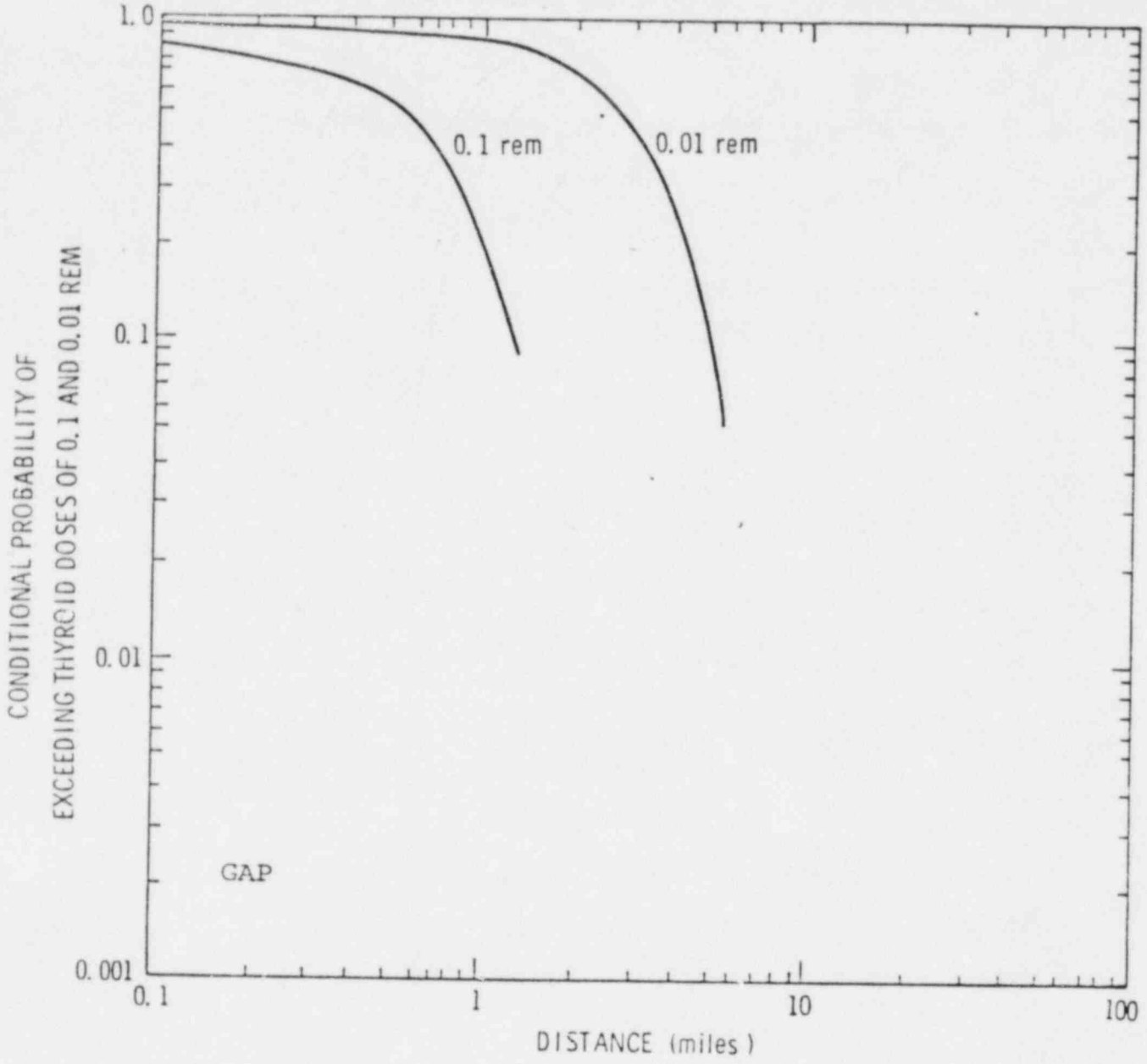

Figure 1. Conditional Probability of Exceeding Thyroid Doses of 0.01 and 0.1 rem versus Distance for an Exposed Adult Located Outdoors. Probabilities are Conditional on a Gap Activity Release Accident (GAP).

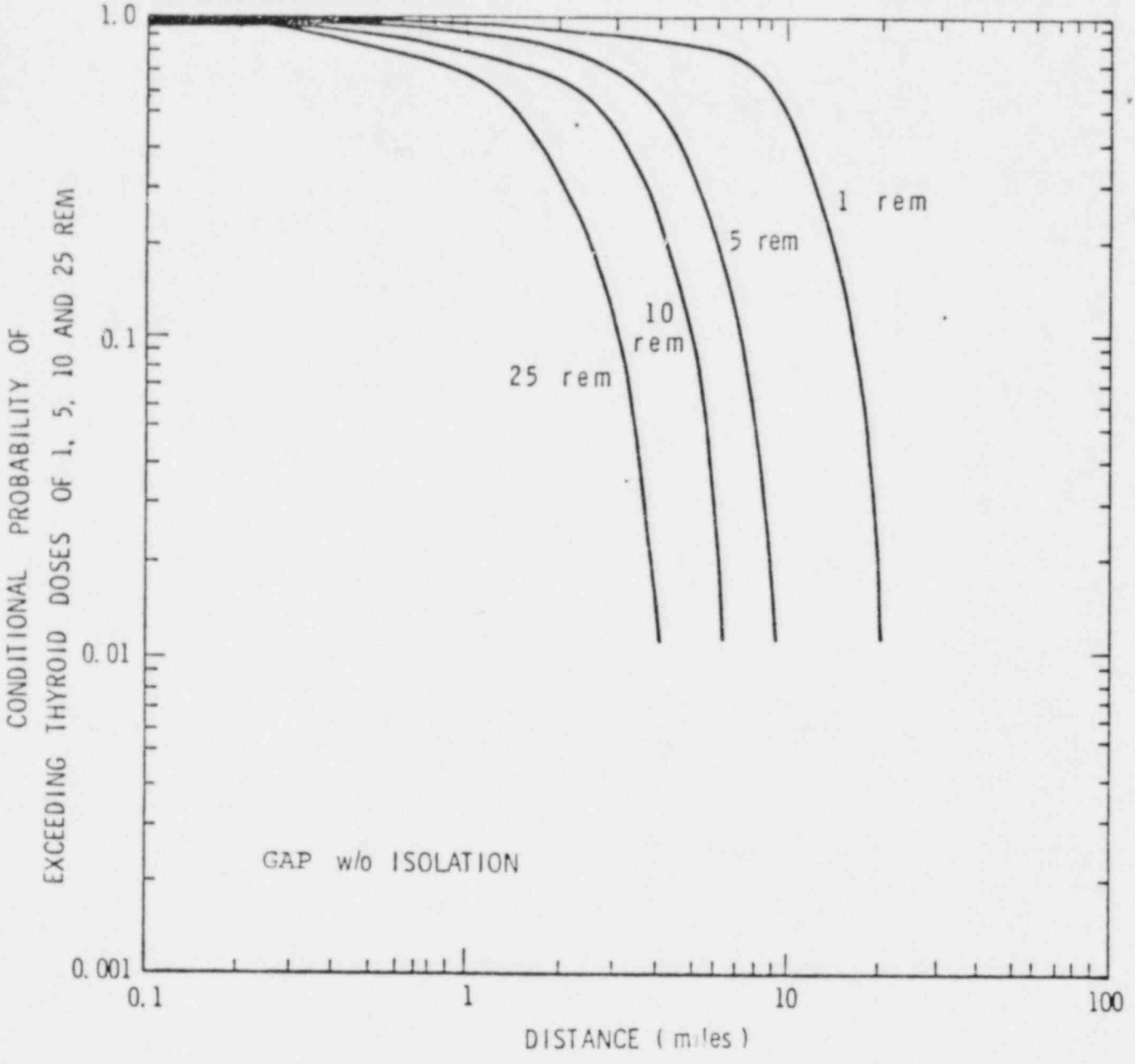

Figure 2. Conditional Probability of Exceeding Thyroid Doses of 1, 5, 10 and 25 rem for an Exposed Adult Located Outdoors. Probabilities are Conditional on a GAP w/o Isolation Accident.

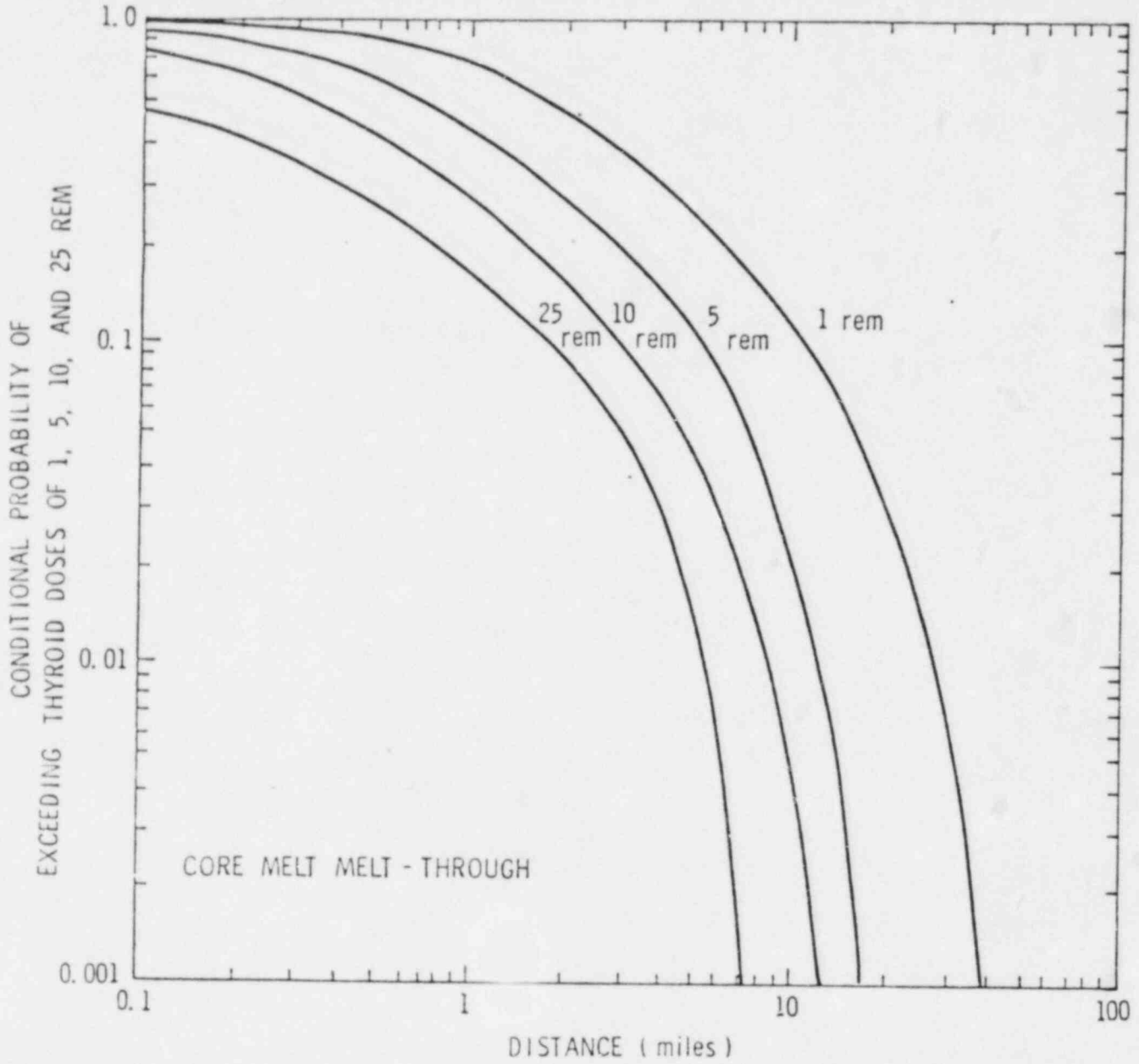

Figure 3. Conditional Probability of Exceeding Thyroid Doses of 1, 5, 10 and 25 rem for an Exposed Adult Located Outdoors. Probabilities are Conditional on a Core Melt Melt-Through Accident.

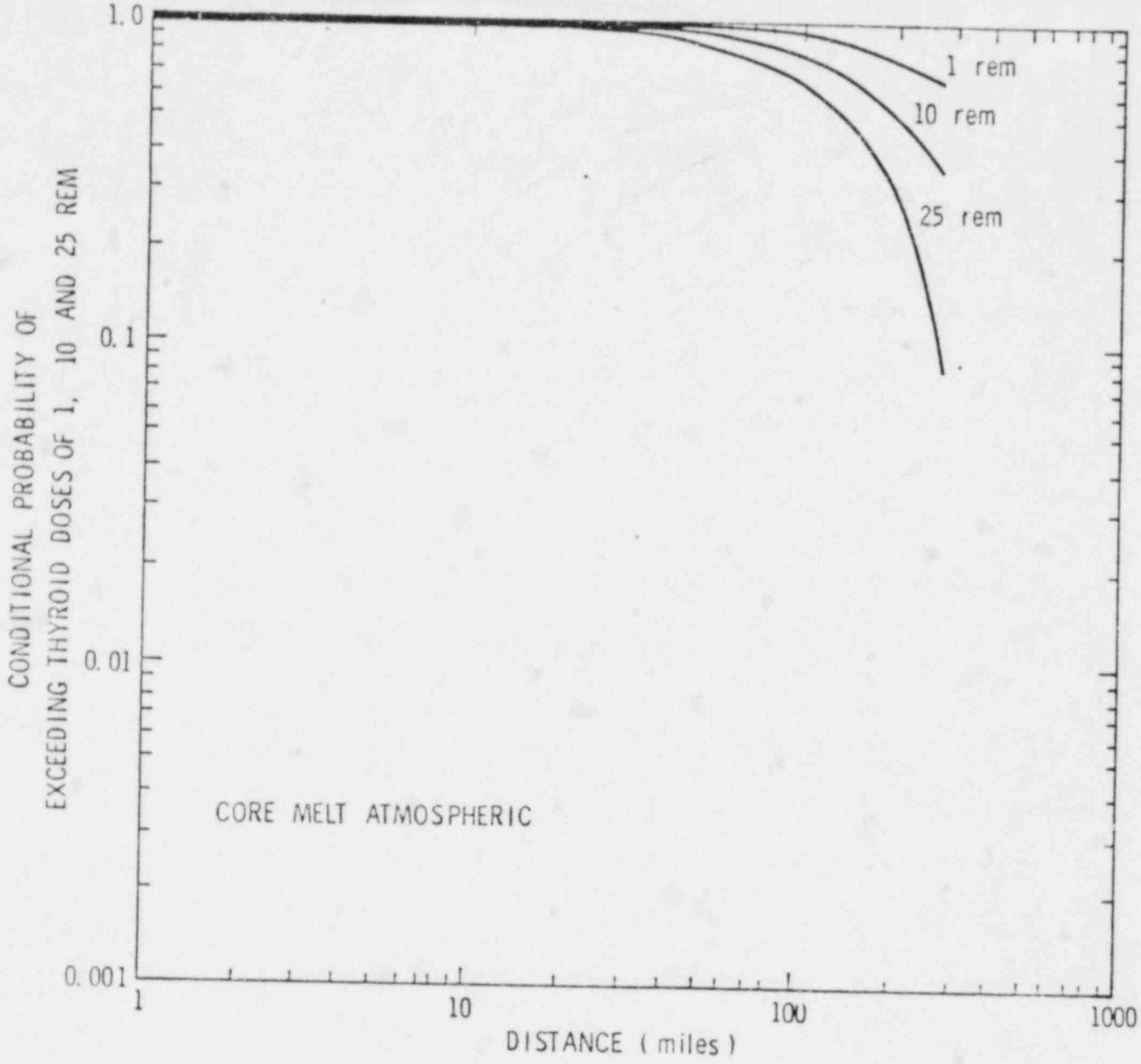

Figure 4. Conditional Probability of Exceeding Thyroid Doses of 1, 10 and 25 rem for an Exposed Adult Located Outdoors. Probabilities are Conditional on a Core Melt Atmospheric Accident.

Table 1. Summary of Release Categories Representing Hypothetical Nuclear Reactor Accidents (from Ref. 1)

Release Category	Probability (reactor-yr^{-1})	Time of Release (hr)	Duration of Release (hr)	Warning Time for Evacuation (hr)	Elevation of Release[g] (meters)	Energy Release (10^6 Btu/hr)	Fraction of Core Inventory Released[a]							
							Te-Ag	Organic I[b]	I[b]	Sr-Rb	Te-Sb	Ba-Sr	Ru[c]	La[d]
PWR 1	9×10^{-7}[e]	2.5	0.5	1.0	25	20 and 520[e]	0.9	6×10^{-3}	0.7	0.4	0.6	0.05	0.4	1×10^{-3}
PWR 2	8×10^{-6}	2.5	0.5	1.0	0	170	0.9	3×10^{-3}	0.7	0.5	0.3	0.04	0.02	6×10^{-3}
PWR 3	4×10^{-6}	5.0	1.5	2.0	0	6	0.8	6×10^{-3}	0.2	0.2	0.3	0.02	0.01	1×10^{-3}
PWR 4	3×10^{-7}	2.0	3.0	2.0	0	1	0.6	2×10^{-3}	0.09	0.06	0.01	5×10^{-3}	3×10^{-3}	6×10^{-4}
PWR 5	7×10^{-7}	2.0	4.0	1.0	0	0.3	0.3	2×10^{-3}	0.01	9×10^{-3}	5×10^{-3}	1×10^{-3}	6×10^{-4}	7×10^{-5}
PWR 6	6×10^{-6}	12.0	10.0	1.0	0	N/A	0.3	2×10^{-3}	8×10^{-4}	8×10^{-4}	1×10^{-3}	9×10^{-5}	7×10^{-5}	2×10^{-5}
PWR 7	4×10^{-5}	10.0	10.0	1.0	0	N/A	6×10^{-3}	2×10^{-5}	2×10^{-5}	1×10^{-5}	2×10^{-5}	1×10^{-6}	6×10^{-6}	2×10^{-7}
PWR 8	4×10^{-3}	0.5	0.5	N/A[f]	0	N/A	2×10^{-3}	5×10^{-6}	1×10^{-4}	5×10^{-4}	1×10^{-6}	1×10^{-6}	0	0
PWR 9	4×10^{-4}	0.5	0.5	N/A	0	N/A	3×10^{-6}	7×10^{-9}	1×10^{-7}	6×10^{-7}	1×10^{-9}	1×10^{-11}	0	0
BWR 1	1×10^{-6}	2.0	0.5	1.5	25	130	1.0	3×10^{-3}	0.40	0.40	0.30	0.05	0.5	5×10^{-3}
BWR 2	6×10^{-6}	30.0	3.0	2.0	0	30	1.0	7×10^{-3}	0.90	0.50	0.30	0.10	0.01	4×10^{-3}
BWR 3	2×10^{-5}	30.0	3.0	2.0	25	20	1.0	7×10^{-3}	0.10	0.10	0.10	0.01	0.02	4×10^{-4}
BWR 4	3×10^{-6}	5.0	2.0	2.0	25	N/A	0.6	7×10^{-4}	8×10^{-4}	5×10^{-3}	4×10^{-3}	6×10^{-4}	6×10^{-4}	1×10^{-4}
BWR 5	1×10^{-4}	3.5	5.0	N/A	150	N/A	5×10^{-4}	2×10^{-9}	6×10^{-11}	4×10^{-9}	8×10^{-12}	8×10^{-14}	0	0

(a) Background on the isotope groups and release mechanisms is presented in Appendix VII.

(b) Organic iodine is combined with elemental iodines in the calculations. Any error is negligible since its release fraction is relatively small for all large release categories.

(c) Includes Pu, Rh, Co, Mo, Tc.

(d) Includes Y, La, Zr, Nb, Ce, Pr, Nd, Np, Pu, Am, Cm.

(e) Accident sequences within PWR 1 category have two distinct energy releases that affect consequences. PWR 1 category is subdivided into PWR 1A with a probability of 4×10^{-7} per reactor-year and 20×10^6 Btu/hr and PWR 1B with a probability of 5×10^{-7} per reactor-year and 520×10^6 Btu/hr.

(f) Not applicable.

(g) A 10 meter elevation is used in place of zero representing the mid-point of a potential containment break. Any impact on the results would be slight and conservative.

Table 2. RSS Calculation of Expected Cases per Million Man-Rem of Benign and Cancerous Thyroid Nodules (from Ref. 1).

Age Group (years)	Fraction of Population	Life Expectancy (years)	Latent Period (years)	Years at Risk	Age Dose Factor[a]	Benign Nodules		Cancers	
						Risk Coefficient[b]	Expected Cases	Risk Coefficient[b]	Expected Cases
0 - 0.99	0.014	71.3	10	30	1.0	8	3.4	4.3	1.8
1 - 10	0.146	69.4	10	30	1.9	8	66.6	4.3	35.8
11 - 20	0.196	60.6	10	30	1.6	8	75.3	4.3	40.5
21 - 30	0.164	51.3	10	30	1	4	19.7	4.3	21.1
31 - 40	0.118	42.0	10	30	1	4	14.2	4.3	15.2
41 - 50	0.109	32.6	10	22.6	1	4	9.9	4.3	10.6
51 - 60	0.104	24.5	10	14.5	1	4	6.0	4.3	6.5
61 - 70	0.080	17.1	10	7.1	1	4	2.3	4.3	2.4
71 - 80	0.044	11.1	10	1.1	1	4	0.1	4.3	0.2
80+	0.020	6.5	10	0	1	4	0	4.3	0
TOTAL							200		134

[a]Ratio of child to adult inhalation dose. See Tables VI-8-5 and 9-8 in reference 1.

[b]Number of cases per million population per rem per year.

Table 3. Mean[a] Thyroid Dose[b] (rem) versus Distance for Exposed Adult Located Outdoors[c] The mean thyroid dose for a child would be approximately a factor of 2 higher.[d]

	Accident Category			
Distance (miles)	GAP	GAP w/o Isolation	Core Melt Melt-Through	Core Melt Atmospheric
1	5.7×10^{-2}	55	25	1.3×10^{4}
5	4.0×10^{-3}	3.9	1.7	5.8×10^{3}
10	1.1×10^{-3}	1.1	5.2×10^{-1}	3.2×10^{3}
25	1.7×10^{-4}	1.7×10^{-1}	7.6×10^{-2}	1.1×10^{3}
50	4.2×10^{-5}	4.2×10^{-2}	2.0×10^{-2}	3.8×10^{2}
100	1.1×10^{-5}	1.1×10^{-2}	5.9×10^{-3}	1.0×10^{2}
150	3.8×10^{-6}	3.8×10^{-3}	2.0×10^{-3}	36
200	1.9×10^{-6}	1.9×10^{-3}	1.0×10^{-3}	16

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[a] 91 weather sequences were used to calculate a probability distribution of dose at each distance. The mean doses presented are the mean of those distributions.

[b] Calculated doses include: dose from inhaled radionuclides from cloud passage, plus external dose due to the passing cloud plus 1-day exposure to ground contamination.

[c] Breathing rate = 2.66×10^{-4} m^3/s. Shielding factors = 1.0 (cloud exposure) and 0.7 (ground exposure).

[d] RSS[1] assumed age dose factor of 1.9 for children aged 1-10 (see Section 3).

Table 4. Conditional Probability[a] of Thyroid Damage[b] versus Distance for Exposed Adult Located Outdoors. Probabilities are conditional on the accident occurring. Probabilities would be approximately a factor of 2 higher for a child.[c]

	Accident Category			
Distance (miles)	GAP	GAP w/o Isolation	Core Melt Melt-Through	Core Melt Atmospheric
1	1.9×10^{-5}	1.8×10^{-2}	8.4×10^{-3}	0.6[d]
5	1.3×10^{-6}	1.3×10^{-3}	5.7×10^{-4}	0.7[d]
10	3.7×10^{-7}	3.7×10^{-4}	1.7×10^{-4}	0.7[d]
25	5.7×10^{-8}	5.7×10^{-5}	2.5×10^{-5}	0.4[d]
50	1.4×10^{-8}	1.4×10^{-5}	6.7×10^{-6}	1.3×10^{-1}
100	3.7×10^{-9}	3.7×10^{-6}	2.0×10^{-6}	3.3×10^{-2}
150	1.3×10^{-9}	1.3×10^{-6}	6.7×10^{-7}	1.2×10^{-2}
200	6.3×10^{-10}	6.3×10^{-7}	3.3×10^{-7}	5.3×10^{-3}

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[a] No 0.1 effectiveness factor for I-131 dose is assumed. Values presented equal doses in Table 3 multiplied by assumed risk coefficient of 334 thyroid nodules per 10^6 adult-rem to the thyroid.

[b] Thyroid damage includes thyroid nodules (both benign and cancerous) and ablated thyroids.

[c] See Section 3.

[d] Probabilities are less than 1.0 because for some accidents and weather conditions, the energy of release is sufficiently high to result in significiant plume rise. In these cases, the plume would travel over the heads of individuals near the reactor, and resulting thyroid doses would be low.

Table 5. Fractional Components of Mean Thyroid Dose for Exposed Individual Located Outdoors

Distance Interval (miles)	Inhaled Radioiodines[a] I-131	Other Iodines	Inhaled Non-radioiodines[a]	Cloud Exposure[b]	Ground Exposure[c]
A. GAP					
0-25	0.67	0.25	0.02	0.03	0.03
25-100	0.70	0.22	0.02	0.04	0.02
>100	0.77	0.16	0.03	0.02	0.02
B. GAP w/o Isolation					
0-25	0.68	0.25	0.02	0.02	0.03
25-100	0.71	0.23	0.02	0.02	0.02
>100	0.78	0.16	0.02	0.02	0.02
C. Core Melt Melt-Through					
0-25	0.65	0.16	0.10	0.06	0.03
25-100	0.63	0.15	0.10	0.09	0.03
>100	0.63	0.09	0.09	0.16	0.03
D. Core Melt Atmospheric					
0-25	0.67	0.21	0.07	0.01	0.04
25-100	0.72	0.20	0.05	0.01	0.02
>100	0.77	0.16	0.05	0	0.02

[a] Breathing rate = 2.66×10^{-4} m^3/s.
[b] Shielding factor for exposure to cloud = 1.0.
[c] 1-day exposure to ground contamination. Shielding factor = 0.7.

Table 6a. GAP w/o Isolation. Conditional Mean Number of Thyroid Nodules Within Selected Distance Intervals. A uniform population density of 100 persons/mile^2 is assumed. Risk coefficient = 334 thyroid nodules per 10^6 adult-rem to thyroid.

Without 0.1 effectiveness factor for I-131

Distance Interval (miles)	Normal Activity[a]	Normal Activity 99% KI	Sheltering[b]	Sheltering 99% KI
0-5	1.77	0.09	0.90	0.06
5-10	0.35	0.02	0.18	0.01
10-25	0.43	0.03	0.22	0.02
25-50	0.32	0.02	0.16	0.01
50-100	0.36	0.02	0.18	0.01
100-150	0.17	0.01	0.09	0.01
150-200	0.11	0.01	0.06	0

With 0.1 effectiveness factor for I-131

0-5	0.66	0.07	0.35	0.05
5-10	0.13	0.02	0.07	0.01
10-25	0.16	0.02	0.08	0.02
25-50	0.11	0.02	0.06	0.01
50-100	0.12	0.02	0.06	0.01
100-150	0.05	0.01	0.03	0.01
150-200	0.03	0.01	0.02	0

[a] Shielding factors = 0.75 (cloud exposure) and 0.33 (ground exposure). 1-day exposure to ground contamination.

[b] Shielding factors and ground exposure same as for normal acitivity. Inhalation reduction furtheer = 0.5.

Table 6b. Core Melt Melt-Through. Conditional Mean Number of Thyroid Nodules Within Selected Distance Intervals. A uniform population density of 100 persons/mile^2 is assumed. Risk coefficient = 334 thyroid nodules per 10^6 adult-rem to thyroid.

Without 0.1 effectiveness factor for I-131

Distance Interval (miles)	Normal Activity[a]	Normal Activity 99% KI	Sheltering[b]	Sheltering 99% KI
0-5	2.34	0.36	1.22	0.23
5-10	0.53	0.09	0.28	0.06
10-25	0.66	0.12	0.36	0.09
25-50	0.52	0.10	0.28	0.07
50-100	0.56	0.11	0.30	0.08
100-150	0.30	0.07	0.17	0.05
150-200	0.21	0.05	0.12	0.04

With 0.1 effectiveness factor for I-131

0-5	0.91	0.34	0.50	0.22
5-10	0.21	0.09	0.12	0.06
10-25	0.27	0.12	0.16	0.09
25-50	0.21	0.10	0.13	0.07
50-100	0.23	0.11	0.14	0.08
100-150	0.12	0.07	0.08	0.05
150-200	0.08	0.05	0.06	0.04

[a]Shielding factors = 0.75 (cloud exposure) and 0.33 (ground exposure). 1-day exposure to ground contamination.

[b]Shielding factors and ground exposure same as for normal activity. Inhalation reduction factor = 0.5.

Table 6c. Core Melt Atmospheric. Conditional Mean Number of Thyroid Nodules (Albated Thyroids) Within Selected Distance Intervals. A uniform population density of 100 persons/mile^2 is assumed. Risk coefficient = 334 thyroid nodules per 10^6 adult-rem to thyroid.

Without 0.1 effectivenss factor for I-131

Distance Interval (miles)	Normal Activity[a]	Normal Activity 99% KI	Sheltering[b]	Sheltering 99% KI
0-5	81 (137)	49 (0)	76 (92)	31 (0)
5-10	192 (292)	81 (0)	210 (146)	48 (0)
10-25	1110 (610)	181 (0)	918 (102)	109 (0)
25-50	2110 (210)	193 (0)	1190 (30)	115 (0)
50-100	2970 (20)	234 (0)	1520 (0)	140 (0)
100-150	1580 (0)	119 (0)	802 (0)	70 (0)
150-200	992 (0)	76 (0)	503 (0)	45 (0)

With 0.1 effectivenss factor for I-131

0-5	73 (73)	46 (0)	76 (25)	29 (0)
5-10	231 (63)	75 (0)	158 (8)	46 (0)
10-25	735 (31)	168 (0)	403 (3)	102 (0)
25-50	836 (22)	177 (0)	448 (0)	107 (0)
50-100	995 (0)	214 (0)	520 (0)	129 (0)
100-150	473 (0)	108 (0)	247 (0)	64 (0)
150-200	280 (0)	68 (0)	147 (0)	41 (0)

[a]Shielding factors = 0.75 (cloud exposure) and 0.33 (ground exposure). 1-day exposure to ground contamination.

[b]Shielding factors and ground exposure same as for normal activity. Inhalation reduction factor = 0.5.

Table 7. Potential Reduction in Mean Number of Thyroid Nodules (Ablated Thyroids) by Use of KI. 99% effective KI is assumed. Numbers are determined from Table 6.

Distance Interval (miles)	Without 0.1 effectiveness factor for I-131		With 0.1 effectiveness factor for I-131	
	Normal Activity	Sheltering	Normal Activity	Sheltering
GAP w/o Isolation				
0-5	1.68	0.84	0.59	0.30
5-10	0.33	0.17	0.11	0.06
10-25	0.40	0.20	0.14	0.06
25-50	0.30	0.15	0.09	0.05
50-100	0.34	0.17	0.10	0.05
100-150	0.16	0.08	0.04	0.02
150-200	0.10	0.06	0.02	0.02
Core Melt Melt-Through				
0-5	1.98	0.99	0.57	0.28
5-10	0.44	0.22	0.12	0.06
10-25	0.54	0.27	0.15	0.07
25-50	0.42	0.21	0.11	0.06
50-100	0.45	0.22	0.12	0.06
100-150	0.23	0.12	0.05	0.03
150-200	0.16	0.08	0.03	0.02
Core Melt Atmospheric				
0-5	32 (137)	45 (92)	27 (73)	47 (25)
5-10	111 (292)	162 (146)	156 (63)	112 (8)
10-25	929 (610)	809 (102)	567 (31)	301 (3)
25-50	1920 (210)	1080 (30)	659 (22)	341 (0)
50-100	2740 (20)	1380 (0)	781 (0)	391 (0)
100-150	1460 (0)	732 (0)	365 (0)	183 (0)
150-200	916 (0)	458 (0)	212 (0)	106 (0)

Table 8. Potential Reduction[a] per Year of Reactor Operation in Mean Number of Thyroid Nodules[b] by Use of KI. 99% effective KI is assumed. RSS probabilities are assumed.

Distance Interval (miles)	Without 0.1 effectiveness factor for I-131		With 0.1 effectiveness factor for I-131	
	Normal Activity	Sheltering	Normal Activity	Sheltering
0-5	2.5×10^{-3}	2.0×10^{-3}	1.4×10^{-3}	1.0×10^{-3}
5-10	5.7×10^{-3}	4.3×10^{-3}	3.1×10^{-3}	1.7×10^{-3}
10-25	2.2×10^{-2}	1.3×10^{-2}	8.4×10^{-3}	4.3×10^{-3}
25-50	3.0×10^{-2}	1.6×10^{-2}	9.5×10^{-3}	4.8×10^{-3}
50-100	3.9×10^{-2}	1.9×10^{-2}	1.1×10^{-2}	5.5×10^{-3}
100-150	2.0×10^{-2}	1.0×10^{-2}	5.1×10^{-3}	2.6×10^{-3}
150-200	1.3×10^{-2}	6.4×10^{-3}	3.0×10^{-3}	1.5×10^{-3}

[a] Reductions calculated from values in Table 7.

Expected reduction per reactor-year $= \sum_i (\text{potential reduction})_i \, (\text{accident probability})_i$, where i is the accident category.

[b] Includes ablated thyroids.

Table 9. Estimated Cost-Benefit Ratios for Use of KI ($ per nodule prevented[a]) 99% effective KI is assumed. RSS probabilities are assumed.

Distance Interval (miles)	Without 0.1 effectiveness factor for I-131		With 0.1 effectiveness factor for I-131	
	Normal Activity	Sheltering	Normal Activity	Sheltering
0-5	3.2×10^{5}[b]	4.0×10^{5}	5.6×10^{5}	7.9×10^{5}
5-10	4.2×10^{5}[c]	5.6×10^{5}	7.7×10^{5}	1.4×10^{6}
10-25	7.3×10^{5}[d]	1.2×10^{6}	1.9×10^{6}	3.7×10^{6}
25-50	2.0×10^{6}[e]	3.7×10^{6}	6.2×10^{6}	1.2×10^{7}
50-100	6.2×10^{6}[f]	1.3×10^{7}	2.2×10^{7}	4.4×10^{7}
100-150	2.0×10^{7}[f]	3.9×10^{7}	7.6×10^{7}	1.5×10^{8}
150-200	4.2×10^{7}[f]	8.6×10^{7}	1.8×10^{8}	3.7×10^{8}

[a] Includes both nodules and ablated thyroids. Approximately 4% of the thyroid nodules will be fatal.
[b] Approximately 80% of the reduced thyroid damage cases are ablated thyroids, 19% are nodules and 1% are thyroid cancer fatalities (from Table 7).
[c] Approximately 70% are ablated thyroids, 29% are nodules and 1% are thryoid cancer fatalities.
[d] Approximately 40% are ablated thyroids, 58% are nodules and 2% are thyroid cancer fatalities.
[e] Approximately 10% are ablated thyroids, 86% are nodules and 4% are thyroid cancer fatalities.
[f] Approximately 96% are nodules and 4% are thyroid cancer fatalities.

Table 10. Cost-Benefit Analysis for Use of KI by Children. Assumptions: risk coefficient = 668 thyroid nodules per 10^6 adult-rem to thyroid,[a] no 0.1 effectiveness factor for I-131, Core Melt Atmospheric accident category only, RSS accident probabilities.

Distance Interval (miles)	Thyroid Nodules[b] (mean)[c]		Potential Reduction[c]	Reduction (nodules/yr)[c]	Cost-Benefit Ratio ($/nodule prevented)
	Normal Activity	Normal Activity 99% KI			
0-5	270	91	179	2.5×10^{-3}	3.2×10^{5}
5-10	625	157	468	6.5×10^{-3}	3.7×10^{5}
10-25	2510	361	2150	3.0×10^{-2}	5.3×10^{5}
25-50	4190	386	3800	5.3×10^{-2}	1.1×10^{6}
50-100	5930	467	5460	7.6×10^{-2}	3.2×10^{6}
100-150	3170	238	2930	4.1×10^{-2}	9.5×10^{6}
150-200	1980	151	1830	2.6×10^{-2}	2.1×10^{7}

[a]Includes age dose factors and risk coefficients from RSS (see Section 3).
[b]Includes both nodules and ablated thyroids.
[c]Assumes a uniform population density of 100 persons/mile^2.

Table 12. Summary Table for KI Cost-Benefit Analysis[a,b] (from Table 9)

Distance Interval (miles)	Normal Activity Cost-Benefit Ratio ($/thyroid nodule prevented)
0-5	3×10^5
5-10	4×10^5
10-25	7×10^5
25-50	2×10^6
50-100	6×10^6
100-150	2×10^7
150-200	4×10^7

[a]Key Assumptions

1. 99% effective KI (i.e., all persons take drug before cloud passes).
2. No other protective measures are taken.
3. WASH-1400 accident probabilities.
4. Estimated cost of KI program = $0.10 per person per year. Assumed cost includes only the purchase price of KI, i.e., no costs for distribution, monitoring and administrative expenses.
5. Only 1 reactor (3200 MWt PWR) within 200 miles.
6. WASH-1400 dose-effects coefficients (no 0.1 effectiveness factor for I-131 dose).

[b]Uncertainties are large and scale approximately linearly with assumed KI effectiveness, accident probabilities, cost, multiple reactors, and dose-effects coefficients.

Table 11. Cost-Benefit Analysis for Use of KI by Children. Assumptions: APS[a] upper-bound risk coefficient for children of 6500 thyroid nodules per 10^6 adult-rem to thyroid,[b] no 0.1 effectiveness factor for I-131, Core Melt Atmospheric accident category only, RSS accident probabilities.

Distance Interval (miles)	Thyroid Nodules[c] (mean)[d]		Potential Reduction[d]	Reduction (nodules/yr)[d]	Cost-Benefit Ratio ($/nodule prevented)
	Normal Activity	Normal Activity 99% KI			
0-5	374	262	112	1.6×10^{-3}	4.9×10^5
5-10	1020	586	434	6.1×10^{-3}	3.9×10^5
10-25	5590	2430	3160	4.4×10^{-2}	3.6×10^5
25-50	12,600	3500	9100	1.3×10^{-1}	4.5×10^5
50-100	31,600	4530	27,100	3.8×10^{-1}	6.3×10^5
100-150	28,400	2320	26,100	3.7×10^{-1}	1.1×10^6
150-200	19,300	1470	17,800	2.5×10^{-1}	2.2×10^6

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[a] American Physical Society [9].
[b] Includes age dose factor of 5.0.
[c] Includes both nodules and ablated thyroids.
[d] Assumes a uniform population density of 100 persons/mile^2.

September 18, 1980

SECY-80-257A

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COMMISSIONER ACTION

For: ~~The Commissioners~~

Thru: Acting Executive Director for Operations

From: Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Subject: RADIATION PROTECTION - THYROID BLOCKING

Purpose: To provide additional information with respect to the possible side effects of potassium iodide and to obtain approval for the issuance of a revised interim policy statement with regard to the stockpiling of potassium iodide for use during reactor emergency conditions. (Enclosure 1)

Discussion: As requested by the Commission, members of the staff attended a session entitled "Iodine: Good or Evil After Nuclear Accidents" at the June 18, 1980 meeting of the National Endocrine Society.

A meeting report, authored by two staff members from the Office of Standards Development is enclosed (Enclosure 2) which summarizes the session. The Food and Drug Administration now has in process a more detailed analysis of the potential side effects discussed at this session.

In a related development, the Interorganizational Advisory Committee (IOAC) on Radiological Emergency Planning and Preparedness has reviewed the recommendations in SECY-80-257 and has provided comments which are in Enclosure 3. As requested by Commissioner Bradford, the interim policy statement has been revised to reflect that NRC practice now requires the stockpiling of potassium iodide for at least onsite and offsite emergency workers in conjunction with new emergency plan approvals. (Enclosure 1)

The staff believes that while the recommendations below could be effected by inclusion of criteria in the revision of the joint NRC/FEMA criteria document (NUREG-0654; FEMA-REP-1) it is desirable for the Commission to go on record in this policy area.

CONTACTS: Brian Grimes, NRR
Ext. 27415

Roger Blond, RES
Ext. 28388

Recommendation: It remains the staff recommendation that the Commission adopt an interim policy (Enclosure 1) encouraging storage of potassium iodide for use during a reactor accident of quantities needed for the following segments of the population where controls can be clearly maintained for the required length of time:

1. Site personnel;

2. Offsite emergency personnel; and

3. Offsite institutions within about 10 miles (e.g., hospitals, prisons) where immediate evacuation may be infeasible or very difficult.

After consideration of the recommendations in the IOAC position statement (Enclosure 3) the staff concludes that consideration should also be given to sending a letter to FEMA requesting a study of the feasibility of establishing a single national stockpile and developing a distribution plan and system including estimates of times to transport and distribute the KI to the general public within various regions of the country. A draft letter to FEMA is provided in Enclosure 4.

Coordination: The Office of Research and the Office of Standards Development concur in this recommendation. The Office of the Executive Legal Director has no legal objection.

Harold R. Denton, Director
Office of Nuclear Reactor Regulation

Enclosures:
1. Interim Policy Statement
2. Meeting Report of Endocrine Society Meeting
3. IOAC Comments on NRC Statement of Interim Commission Policy
4. Draft Letter to FEMA

Commissioners' comments should be provided directly to the Office of the Secretary by c.o.b. Monday, October 6, 1980.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT September 21, 1980, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ENCLOSURE NO. 1

NUCLEAR REGULATORY COMMISSION

Statement of Interim Commission Policy on Stockpiling Potassium Iodide For Use During a Reactor Accident

STATEMENT OF POLICY

The Nuclear Regulatory Commission has adopted an interim policy on the stockpiling of potassium iodide for use during a reactor accident. The Commission encourages storage of potassium iodide for use during a reactor accident of quantities needed for the following segments of the population where controls can be clearly maintained for the required length of time:

1. Nuclear power plant site personnel;
2. Offsite emergency response personnel; and
3. Offsite institutions (e.g., hospitals, prisons) within about 10 miles of reactors where immediate evacuation may be infeasible or very difficult.

Although the effective use of potassium iodide could significantly reduce the number of thyroid nodules resulting from a serious accident, it would have little or no impact on other possible accident consequences (immediate deaths, injuries, delayed cancer deaths, and land contamination). Therefore, the availability of potassium iodide provides only a supplemental strategy to be considered along with other possible protective measures.

Current NRC practice for approval of new emergency plans for the use of potassium iodide as reflected in NUREG-0654 "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants", January 1980, and NRC Task Action Plan III.A.1 is to require adequate supplies for individuals in the first two categories listed above.

SUPPLEMENTARY INFORMATION

During the past year there has been a resurgence of interest in the use of potassium iodide (KI) as an emergency protective measure for serious reactor accidents. To develop an adequate rationale concerning the storage of KI, it is necessary to evaluate the costs, potential benefits, and potential risks associated with its public use. A study has been performed by Sandia Laboratories and the NRC staff to provide the needed technical basis for establishing a policy concerning the storage and maintenance of KI for public use in an emergency.

The Sandia analysis was performed using a modified version of the Reactor Safety Study (WASH-1400) consequence model. Four categories of accidents were studied: release of gap activity* to the containment, release of gap activity without containment isolation, core melt with a melt-through release and core melt with an atmospheric release. Thyroid dose calculations show that gap release to the containment does not pose a significant health hazard to the public at any distance from the reactor. For a gap release without containment isolation and melt-through categories, doses in excess of recommended protective action guidance levels (PAGs) (5-25 rem to the thyroid) are confined to areas within approximately 10 to 15 miles of the reactor. For a low likelihood core melt with a direct atmospheric release, however, thyroid doses may exceed plume pathway PAGs at distances of 100 to 200 miles. These results are consistent with the results of the NRC/EPA task force report on the recommended planning basis for offsite emergency preparedness (NUREG-0396 "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants".

*Gap activity is the limited amount of radioactive gaseous material which collects within the tube which holds the uranium dioxide fuel pellets during normal reactor operation.

A cost-benefit analysis for the use of KI was performed by Sandia, the results of which are summarized in table 1. Cost-benefit ratios ($/thyroid nodule prevented) are given assuming that no other protective measures are taken. (KI would protect only the thyroid, not other body organs, and only from radioiodine, and then only if ingested within about 2 hours after radioiodine inhalation, or within about 12-24 hours before radioiodine inhalation.) Other key assumptions made in performing the analysis are also noted. Uncertainties due to health effects parameters, accident probabilities and costs were assessed, as well as the effect of other potential protective measures on predicted ratios, such as evacuation and sheltering. The potential impact on children (critical population) was also evaluated. The estimated cost-benefit ratios are high, and it appears that distribution of KI to the general public would be, at best, marginally cost-effective even close to a nuclear power plant.

Finally, a simple risk-benefit analysis, based upon the FDA published Federal Register Notice (43 FR 58798, December 15, 1978) showed the risk of adverse reaction posed by KI to be small at the recommended action levels and dosages. It should be noted, however, that some recent reports indicate that there is a significantly higher risk associated with use of the drug among certain segments of the population. Because of this potentially higher risk to certain individuals, the administration of KI requires decisions by qualified medical personnel. In addition, those to whom KI is administered should be alerted to possible harmful side effects. To the maximum extent practicable, such decisions and alerts should be made in advance as a part of the emergency preparedness program. In addition, the NRC has requested the FDA to provide

additional guidance on the conditions under which KI should be administered to the general public. When the FDA guidance is received, the Nuclear Regulatory Commission will again consider the advisability of stockpiling KI for use by members of the general public during a reactor accident. NRC has also requested that the Federal Emergency Management Agency (FEMA) conduct a study to determine the feasibility of stockpiling and distributing KI to the general public in the event of an emergency.

FOR FURTHER INFORMATION CONTACT: Brian K. Grimes, Program Director, Emergency Preparedness Program Office, Office of Nuclear Reactor Regulation, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, phone 301-492-7415, or Roger Blond, Probabilistics Analysis Staff, Office of Nuclear Regulatory Research, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, phone 301-492-8388.

Dated at Washington, D. C., this day of 1980.

FOR THE NUCLEAR REGULATORY COMMISSION

Samuel J. Chilk
Secretary of the Commission

TABLE 1

SUMMARY OF KI COST-BENEFIT ANALYSIS[a]

Distance Interval (Miles)	KI Purchase Cost ($/year)		Cost Benefit Ratio[b]
	100 people/sq mile	1000 people/sq mile	($/thyroid nodule prevented)
0-5	790	7,900	320,000
5-10	2,400	24,000	420,000
10-25	16,000	160,000	730,000
25-50	59,000	590,000	2,000,000
50-100	240,000	2,400,000	6,200,000
100-150	390,000	3,900,000	20,000,000
150-200	550,000	5,500,000	42,000,000

[a] Key Assumptions

1. 99% effective KI (i.e., all persons take drug before cloud passes).
2. No other protective measures are taken.
3. WASH-1400 accident probabilities.
4. Estimated cost of KI program = $0.10 per person per year. Cost includes only purchase price of KI, but not the storage, distribution, monitoring and administrative expenses.
5. Only 1 reactor (3200 MWt PWR) within distance indicated.
6. WASH-1400 dose-effects coefficients (assumption of a 0.1 effectiveness factor for I-131 dose would increase the costs per benefit received by about a factor of three).

[b] Uncertainties are large and scale approximately proportional with assumed KI effectiveness, accident probabilities, cost, multiple reactors, and dose-effects coefficients.

References

1. WASH-1400 (NUREG 75/014), U. S. Nuclear Regulatory Commission, October 1975.
2. D. C. Aldrich, P. E. McGrath and N. C. Rasmussen, Examination of Offsite Radiological Emergency Protective Measures for Nuclear Reactor Accidents Involving Core Melt, SAND78-0454 (NUREG/CR-1131) Sandia Laboratories, Albuquerque, New Mexico (1978).
3. J. G. Cural, et al., Potassium Iodide Sensitivity in Four Patients with Hypocomplementemic Vasculitis, Annals of Internal Medicine, Vol. 91, No. 6, December 1979.
4. B. J. Rosenstein, et. al., Iodide-Induced Hypothyroidism without a Goiter in an Infant with Cystic Fibrosis, Journal of Pediatrics, Vol. 93, No. 2, August 1978.
5. D. C. Aldrich, R. M. Blond, Examination of the Use of Potassium Iodide (KI) As An Emergency Protective Measure for Nuclear Reactor Accidents, SAND80-0981 (NUREG/CR-1433) Sandia Laboratories, Albuquerque, New Mexico (March 1980).

Enclosure No. 2

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

July 9, 1980

MEMORANDUM FOR: Michael A. Parsont, Chief
Radiological Health Standards Branch, OSD

FROM: Harold T. Peterson, Jr., RHSB
Robert E. Baker, RHSB

SUBJECT: ENDOCRINE SOCIETY MEETING ON THYROID BLOCKING AS A PROTECTIVE ACTION FOLLOWING NUCLEAR ACCIDENTS

Purpose: To report on the meeting which is related to an interim Commission policy statement on thyroid blocking proposed by NRR and RES (SECY-80-257).

MEETING REPORT

On June 18, 1980, the Endocrine Society* sponsored a symposium, "Iodine: Good or Evil After Nuclear Accidents."

The meeting was chaired by Dr. J. E. Rall, Scientific Director of the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD). The participants were:

Dr. Jan Wolff, Medical Director, Clinical Endocrinology Branch, NIAMDD

Dr. Herbert Kouts, Chairman, Department of Nuclear Engineering, Brookhaven National Laboratory

Dr. Rosalyn S. Yalow, Senior Medical Investigator, Veteran's Administration

Other speakers included Dr. Eugene Saenger (Chairman of the Ad Hoc Committee on Thyroid Blocking of the National Council on Radiation Protection and Measurements) and Dr. Frank von Hipple (Princeton University).

Dr. Rall presented a brief review of data on radiation induced thyroid cancers (carcinomas) and benign thyroid tumors and nodules (adenomas). From these data, he concluded that:

1. Exposure to radiation can be carcinogenic for the thyroid (2.5×10^{-6} cases per year per rad for adults).

2. The age of the exposed individual is an important factor (risk for children might be 2 to 10 times greater than that for adults), particularly for young girls ($\leq$ 10 years old), where the relative risk may be 14.2 compared to 5.5 for adult females.

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*The thyroid gland is an endocrine (hormone-secreting) organ and the society is composed of medical practioners and research workers in the field of endocrinology.

3. the risk from exposure to I-131 is less than that from equal exposures to x-rays (doses from I-131 appear to be less carcinogenic than from x-rays by a factor of 1/2 to 1/5). More conclusive evidence to support this might be forthcoming from a joint NIH-FDA (BRH) epidemiological study.

4. Certain drugs (such as methyl thiouracil) which stimulate thyroid hormone production can enhance the production of thyroid cancers following irradiation.

5. Current projections of the thyroid cancer risk from radiation appear to significantly overestimate the risk compared to the findings of a large Swedish epidemiological study (Lars-Erik Holm, 1980).

Dr. Kouts briefly discussed the results of the Reactor Safety Study (WASH-1400) and the iodine inventories in large nuclear reactors. He noted that, although the cumulative probability curves for thyroid nodule production in WASH-1400 appear to show large numbers of nodules, the expected value integrated over all accidents is around 0.01 nodule per reactor-year, which is low. He also noted that in the Three Mile Island Accident there were large releases of iodines from the fuel but comparatively little release to the environment. One possible mechanism for the large observed iodine retention might be the release of iodine from the fuel as cesium iodide (CsI) which is highly soluble in water. Based upon the experience at Three Mile Island, Dr. Kouts suggested that the Reactor Safety Study may have substantially overestimated the thyroid doses and their health impact.

Dr. Wolff reviewed the effectiveness of potassium iodide (KI) as an agent for blocking radioiodine uptake by the thyroid. He pointed out that the effective blocking amount (130 milligrams of KI) was lower than the dose (300 mg) of KI commonly taken by asthmatics. The duration of the blockage was 24-36 hours with this dose, but for most effective blocking, KI administration should be repeated daily for 10-14 days if the need persists. Given in an oral dose, the KI takes at least 30 minutes to become effective and is most effective when administrated before or directly after exposure to radioiodine.

Dr. Wolff also discussed the side effects of KI. These could be divided into two classes: interthyroidal and extrathyroidal. The interthyroidal effects include:

1. Thyroiditis - an inflamation of the thyroid -- is associated with large doses and is very rare.

2. Hypothyroidism -- suppression of thyroid function. One report in the U.K. found 3 cases out of 31 treated with KI, but this would mean 50,000-100,000 cases in the U.S. for the size of the population presently taking iodine compounds for medical reasons, whereas only 5 cases per year might be reported.

3. Jodbasedow -- an iodine-induced thyrotoxicosis (toxic effect) -- this is generally associated with large doses of iodine given to persons with existing iodine deficiencies.

4. Goiter -- (Swelling of thyroid). This appears to be the most serious effect as it can result in respiratory distress in infants. Caution is indicated in administering KI to pregnant women or infants.

The extrathyroidal effects include:

1. Saladenitis (iodine mumps) -- swelling of the parotid and submaxillary glands (goes away when administration of KI is stopped).

2. Rinorhea -- polyp formation in the nasal and sinus cavities.

3. Iodine fever -- high temperature -- similar to flu.

4. General toxic effects (accompanied by metallic taste): nausea, pains in the joints, diarrhea.

These toxic effects generally occur with KI doses greater than 100 mg doses recommended for prophylactic measures, if they occur at all.

Other extrathyroidal effects could appear in people with allergic sensitivity to iodine. These effects include:

1. Skin rashes (treatable with sulfa hormones)

2. Edema (retention of water)

3. Swelling around joints.

4. Depletion of certain white blood cells (eosinophilia periarteritis)

5. Enlargement of and discoloration of blood vessels (thrombocytopenic purpura)

Dr. Wolff said that most of these effects were relatively rare and not serious. Few effects have been reported despite the use of 50 million doses per year of 300 milligrams of KI. Because of the effectiveness of KI in blocking thyroid uptake and the small and non-severe nature of the side effects, he favored distribution and stockpiling of potassium iodide for nuclear emergencies. He noted that precautions would be advisible for:

1. Pregnant women beyond 3-4 weeks in term because of the possible risk of iodine goiter in newborn infants.

2. People with nodular goiters.

3. People with hypocomplementemic vasculitis (vascular disease).

4. Persons with dematitis herpetitomis, a skin disease which is characterized by a hypersensitivity to iodine.

Dr. Rosalyn Yalow of the Veteran's Administration represented the case against administration of KI to the general public without adequate medical supervision. She believes that existing estimates of radiation-induced thyroid cancer are overestimates:

1. The thyroid doses received by the Marchallese were underestimated as evidenced by the high percentage of hypothyroidism found. This is generally associated with very high (kilorad) doses.

2. The Utah fallout study (45-100 rads to children's thyroid) showed no obvious effects. The only two thyroid cancers were found in unexposed controls.

3. The risks estimated in WASH-1400 (von Hipple's risk estimate would be twice as high) would lead to estimates of 334,000 thyroid nodules and 70,000 thyroid cancers in patients exposured (1948-1968) to in-vivo* thyroid diagnostic tests with radioiodine-131. As the expected natural incidence of thyroid nodules would be only 1000 year, it is unusual that more cases were not observed.

4. The normal incidence of thyroid cancer in Japan is almost ten times greater than that in the U. S. Therefore, risk derived from the atomic bomb followup might not be applicable to the U. S.

Dr. Yalow also indicated that most of the side effects of potassium iodide would not be significant enough to be reportable to the FDA or unusual enough to be reported in medical journals and, therefore, would be under reported. She noted one reported case involving rhumatoid arthritis or lupis that could have had fatal complications if it had not been promptly treated. (3% of the U. S. population has rhumatoid arthritis). She also noted that the dermatological reactions to iodine are fairly common (1% of the population is sensitive) and that about one fifth of these may be serious.

Dr. Yalow also stressed the lack of pre-planned methods of distribution and the possible panic reactions of a population in trying to obtain KI in the event of a nuclear emergency. She noted that the cost estimates for KI do not include warehousing and distribution costs which are apt to be larger than just the purchase cost of the drug. Regarding the lack of serious side-effects in the U. S. population using 48,000,000 doses of KI annually, she noted that a typical asthmatic takes 3-6 doses daily (1100-2200 doses per year) so that only 22,000-44,000 people, a small fraction of the U. S. population, are involved. She advocated reliance upon other prophylatic measures (staying indoors, sealing up houses, or evacuation) which would be preferable to unsupervised distribution of KI to the general public.

*These tests have been generally replaced by in-vitro radioimmuno assay (RIA) tests that do not involve radioiodine administration to the patient.

Dr. von Hipple noted the high incidence of thyroid cancer in the Marchallese following their exposure to close-in atomic fallout and the thyroid projections for serious nuclear accidents as reasons for distribution and stockpiling of KI. He also mentioned a 1973 Oak Ridge study that indicated that it might not be possible to distribute KI quickly enough (within 1-2 hours) to be effective following a nuclear accident.

Dr. Saenger briefly reviewed the findings of NCRP Report 55 on thyroid blocking. He noted that most pharmaceutical manufacturer's were reluctant to produce this dosage of KI because of the lack of a continuing market. He mentioned that the NCRP was trying to organize a symposium on thyroid blocking in conjunction with the World Health Organization. This might he held in Washington next year. Dr. Saenger also suggested that individuals living near reactors might individually procure KI if they were concerned.

During a panel discussion, Dr. Wolff noted that, following a 100 milligram blocking dose, daily doses of only 15 mg of KI would still provide 98-97% blocking of radioiodine uptake compared to the 99.5+% blocking afforded by a 100 mg KI daily dose. This would trade-off the higher 2-3% radioiodine uptake against less side effects. One commentor from the audience noted concern regarding the potassium content and its possible fatal effects on people with renal hypertension. These potential effects had been overlooked.

CONCLUSIONS

There appeared to be general agreement that agencies responsible for decisions on the use of thyroid blocking drugs should further study the problem and give careful consideration to the management and administration of the program.

Dr. Yalow was asked whether she believed that administration of KI to reactor operators and emergency personnel was advisable provided:

1. that is was done under medical supervision (private or company physician)

2. individuals were pre-screened for iodine sensitivitity with small doses of KI.

Dr. Yalow agreed that this would be desireable as these workers could be subjected to repeated exposures to radioiodine and constitute a controlled population.

Harold T. Peterson, Jr.
Radiological Health Standards Branch
Office of Standards Development

Robert E. Baker
Radiological Health Standards Branch
Office of Standards Development

ENCLOSURE NO. 3

Comments Regarding the NRC Statement of Interim Commission Policy on Stockpiling Potassium Iodide For Use During a Reactor Accident

The Interorganizational Advisory Committee (IOAC) or Radiological Emergency Planning and Preparedness reviewed the above document at its meeting June 2-5, 1980 and submits the following comments for consideration by the NRC:

1. We are in accord with the concept of stockpiling of potassium iodide (KI) for use during a reactor accident by:

   a. Nuclear power plant site personnel;

   b. Off-site emergency response personnel (including telephone repairmen, etc.); and

   c. Off-site institutions (hospitals, prisons, etc.) within about 10 miles of reactors where immediate evacuation may not be feasible or very difficult.

2. The IOAC recommends a local stockpile of KI equivalent to that necessary to provide the general public three days' doses. Further, the federal government should stockpile on a regional or national basis four-seven days' doses for the largest population within ten miles of a nuclear plant within the region or nation. Purchase of the local supply should either be by the utility or federal government.

3. Due to the widespread publicity regarding use of KI at Three Mile Island, the general public is aware of the potential benefits of taking the drug and is already inquiring about stockpiles around plants. To advise them we aren't going to store it could cause another undue roadblock in the development of nuclear power plant emergency response capabilities.

4. The use of the cost-benefit ration (dollars per thyroid module prevented) is very questionable. The caluculation includes use of accident probabilities (core melt = 5×10^{-5}) and is fraught with uncertainty.

5. The document implies side-effect risks are considerably higher than was discussed in the December 1978 notice in the Federal Register on this subject. Has there been additional data obtained or is this simply a different interpretation?

6. Although procedures may preclude timely distribution of the stockpiled drug, subsequent releases from the power plant may enchance the use of KI as a thyroid blocking agent.

Enclosure No. 4

DRAFT LETTER TO FEMA

Mr. John W. Macy, Jr.
Director
Federal Emergency Management Agency
Washington, D. C. 20472

Dear Mr. Macy:

During the Commission's deliberations on the need for potassium iodide to reduce radiation exposures to the thyroid gland in a reactor emergency, the potential side effects of this drug as well as its potential benefits were at issue. While we still await further word from FDA on the potential side effects, the NRC believes that the nature of the hazard warrants interim measures to encourage use at [illegible] under controlled conditions. A policy statement which the NRC pla[illegible]o publish and which we hope can be incorporated in joint NRC/FEMA criteria documents is enclosed.

In addition, it appears warranted to use to request FEMA to study the feasibility of establishing a national stockpile of the drug and developing a distribution plan and system including estimates of times to transport and distribute potassium iodide to the general public within various regions of the country.

Your thoughts on this proposal, and course of action should you agree with the proposal, would be appreciated.

Sincerely,

John F. Ahearne
Chairman

Enclosure:
Policy Statement