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 implemer and potentially more effective than the use of potassium iodide.

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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^{-6} 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 168 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 70 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.

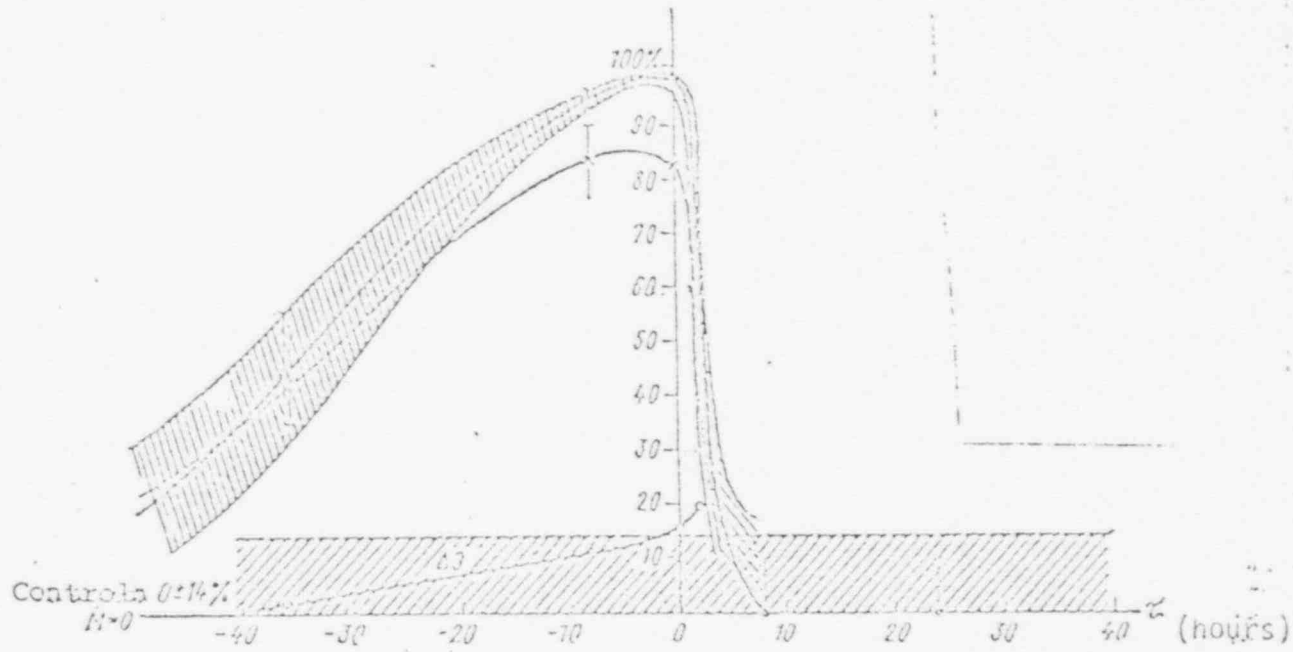

Figure Percent of thyroid blocking as a function of time (in hours) before or after a slug intake of radioiodine.

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

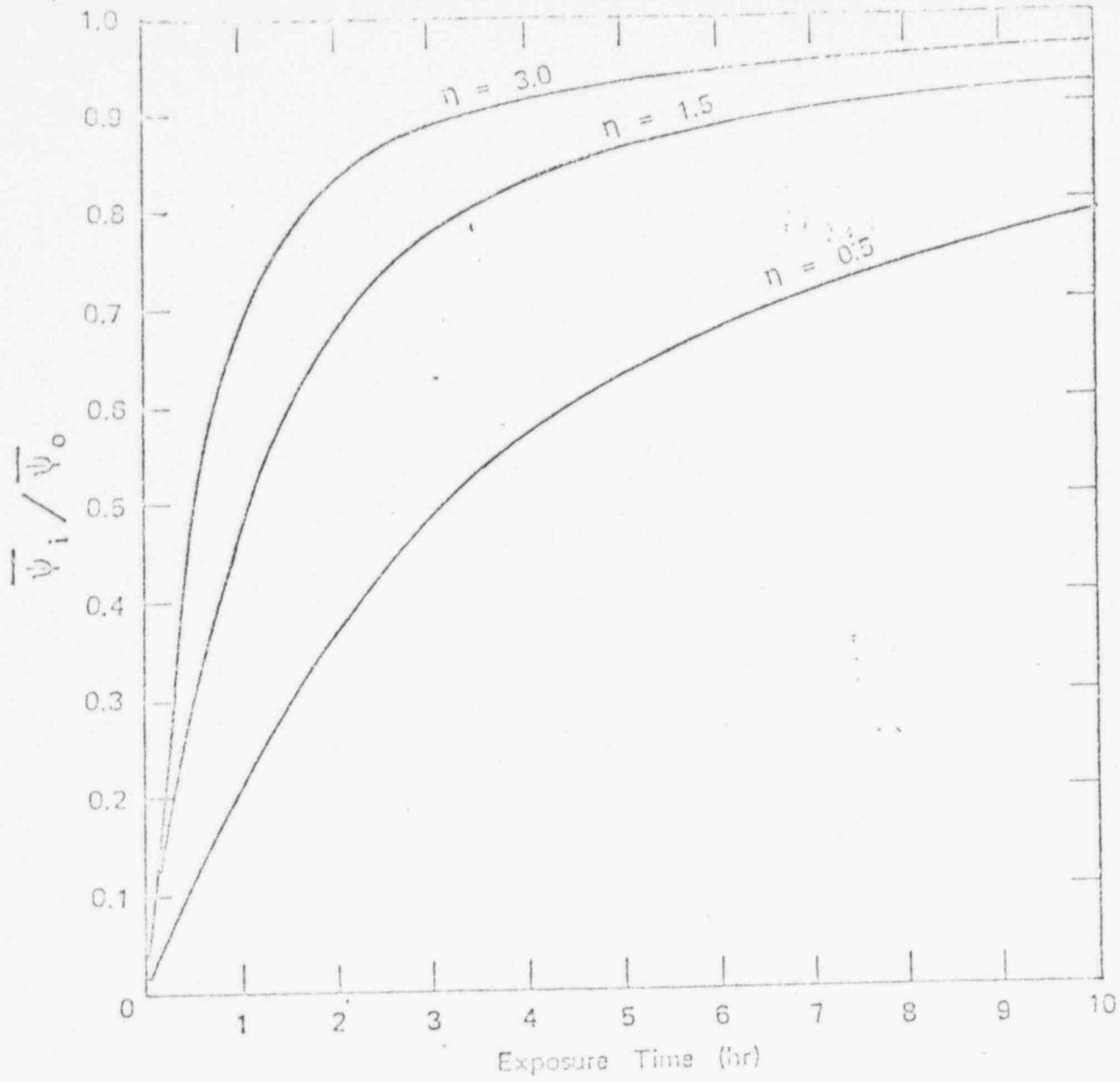

FIGURE VI 11-4 Ratio of the inhaled dose inside a shelter to that outside the shelter as a function of ventilation rate η (air turnovers per hour).*

*WASH-1400

TABLE 11.5

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

Item	Number of Thick-nesses	Resist-ance, mm of H_2O	Number of Obser-vations	Geometric Mean Efficiency, %	95% Confidence Limits for Mean, %	
					Lower	Upper
Handkerchief, man's cotton	16	36	32	94.2	92.5	95.5
Toilet paper	3	13	32	91.4	89.8	92.8
Handkerchief, man's cotton	8	18	32	88.9	85.5	91.6
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)	>180[a]	15	65.9	57.9	72.3
Shirt, cotton	2	7	30	65.[illegible]	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	5	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.