

POOR ORIGINAL

AUG 15 1979

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MEMORANDUM FOR: Commissioner Ahearne

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

(Signed) T.A. 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 meeting, 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 follows. The GSA Federal Register Notice of December 24, 1975 (40 FR 59404) on Radiological Incident Emergency Response Planning: Fixed Facilities and Transportation, states the responsibilities as agreed between certain Federal Agencies. In delineating responsibilities, the GSA notice makes the NRC the lead agency in radiological incident emergency response planning, 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 State health departments, State hospital associations, etc., in the development of plans for the prevention of adverse effects from exposure to radiation including the use of prophylactic drugs to reduce radiation dose to specific organs. This includes health and medical care responses to radiological incidents, consistent with guidelines issued by NRC.

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

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Commissioner Ahearne

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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 foodstuffs 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

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OFFICE	DSE: SA	DSE	DOR	SRK	EDO
SURNAME	NEkreger:osp	W. H. H.	W. H. H.	H. H. H.	H. H. H.
DATE	8/8/79	8/9/79	8/10/79	8/17/79	8/17/79

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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 Parsons - SD
Bill Kreger - NRR/DSE
John Sears - DOR
Ed Branagan - NRR/RAD

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