

CRCPD's Committee on Emergency Response Planning

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Conference of Radiation Control Program Directors, Inc. (CRCPD)
A Partnership Dedicated to Radiation Protection

March 6, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, RM 1061
Rockville, MD 20852

RE: Docket 00D-1681

Subject: Comments on FDA's Draft "Guidance on Potassium Iodine as a Thyroid Blocking Agent in Radiation Emergencies", December 2000.

The Emergency Response Planning Committee (E-6) appreciates the opportunity to comment on FDA's draft guidance on potassium iodide (KI). Although the majority of states potentially affected by a release of radioactive iodine from a nuclear power plant do not plan to provide KI to the general public, recent actions by the Nuclear Regulatory Commission have prompted all states to review their KI policies. Your agency's new draft guidance on KI is an essential part of that review process.

In this letter, I have provided a synopsis of the comments I have received from E-6 members and other state radiation protection staff. This synopsis represents the view of the E-6 Committee rather than a Conference of Radiation Control Program Directors' position.

We agree that KI provides partial protection of the thyroid gland when radioactive iodine is present in the blood stream whether by ingestion, inhalation, or injection. For that reason, states have procedures in place to protect radiation workers from excessive thyroid dose through use of stable KI.

We agree that KI, in order to be effective, must be taken before or within a few hours of exposure. Page 7, lines 293-294 indicate "substantial protective effect even if taken 3 or 4 hours after exposure." Published curves, NRC RTM 96, page J-6, indicate rapid drop in effectiveness beyond 1-2 hours. In the event that continued ingestion of contaminated food is occurring, timeliness is less important than continued prophylaxis.

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**Office of the Committee Chairperson
Ronald G. Fraass**

Supervisor, Environmental Radiation and Emergency Preparedness
Kansas Radiation Control Program

Forbes Field, Building 283 • Topeka, Kansas 66620-0001
Telephone: 785/296-1569 • Fax: 785/296-0984

E-mail: rfraass@kdhe.state.ks.us • CRCPD Home Page: www.crcpd.org

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Dosages of KI, down to 1/8th of a 130 mg tablet will be very difficult for members of the general public to administer.

The recommendation for adults over 40 to not receive KI unless expected dosages exceed 500 cGy (500 rem) is not in keeping with standard radiation practice of keeping doses As Low As Reasonably Achievable (ALARA). Although ALARA is only mandated for regulated exposures, it is appropriate in any situation involving radiation exposure.

The recommendation that large segments of the public be protected at expected doses of 5 cGy (5 rem) is a reduction by a factor of 5 from current guidance in use by most states. In light of the comments in line 242, page 6, that the "WHO recommends a 1 cGy threshold for this group"; it may be necessary to adjust evacuation guidelines downward. To be consistent with the revised FDA guidance, states may need to change their protective action guides to indicate evacuation of the public at projected thyroid doses of 1-5 cGy (1-5 rem) instead of the current 5-25 cGy (5-25 rem).

FDA's guidance and information on significant health risks at 5 cGy (5 rem) thyroid dose will probably require action by the Federal Radiological Protection Coordinating Committee (FRPCC) subcommittee on Protective Action Guides. A new draft of EPA-400 has been produced that still references FDA's guidance on protection at 25 cGy thyroid dose.

The World Health Organization (WHO) "Guidelines for Iodine Prophylaxis Following Nuclear Accidents," updated 1999, states: "Precautionary evacuation will pre-empt the need for stable iodine administration, . . ." Most state emergency plans include options for precautionary evacuation of the public based upon nuclear power plant conditions even if no release has occurred. Under these conditions, KI prophylaxis is not needed for those not exposed to a release.

The next four comments relate to the FDA emphasis that, "the use of KI should be as an adjunct to evacuation (itself not always feasible), sheltering, and control of foodstuffs."

--The WHO document also states: "For this route of exposure or pathway [ingestion of contaminated food], food control is generally preferable to the use of stable iodine prophylaxis." It is highly unlikely that any US population will be permitted to consume or continue to consume

food contaminated with significant amounts of radioactive material. Recent FDA guidance on food products will limit thyroid dose to less than 5 cGy.

--Some state emergency response plans call for precautionary evacuation of school age children if a nearby nuclear power plant declares a Site Area Emergency (SAE). Doses at a SAE are by definition not expected to exceed EPA Protective Action Guide exposure levels, except at the site boundary.

--There is some concern among Committee members and others that members of the public may feel completely protected by taking KI. This attitude may prevent individuals and families from following evacuation recommendations by state and local officials. In addition, persons may delay evacuation to find and take KI. In either case, total dose and thyroid dose will probably be increased.

--Although numerous individuals have commented publically on how difficult it may be to properly administer KI to the public, those problems should be overcome if it is the right thing to do to protect the public.

Because KI is available either through local or national suppliers, members of the public can maintain their own supply. It is important for local and state emergency response organizations to provide simple information so that those who choose to take KI under any circumstances can do so safely. It would be appropriate for FDA to include an appendix to this guidance that includes a short public information guide. State and local organizations could publish or provide copies of the guide with local information included. Information mailings, handouts, calendars and similar materials are provided annually to most residents near nuclear power plants.

FDA's recommendation of KI for neonates includes a recommendation for significant medical monitoring. Such monitoring would be unlikely in the event of public distribution of KI and recommendations for the public to take it.

Members of the public may have significant problems in breaking or dividing KI tablets to obtain the fractional dosages recommended. Even if 65 mg tablets became widely available, the dosages recommended may require division of tables into quarters if given to neonates.

FDA's guidance for KI usage by pregnant or lactating women on page 7, lines 259-267, also indicate additional risk for members of the public if KI is distributed and its use recommended.

We appreciate FDA's emphasis on page 8, lines 326-329, that KI only protects the thyroid from radioiodine. KI does not reduce intake, only uptake by the thyroid. For this reason, most states continue to emphasize evacuation, sheltering, and control of food as the primary means to protect the general public from radiation doses to the thyroid. Radiation workers who must enter radioactive plumes or contaminated areas are typically protected from radioiodine by KI and protective clothing which may include respirators or self contained breathing apparatus.

Thank you again for the opportunity to comment on this draft guidance.

Sincerely;

A handwritten signature in black ink, appearing to read "Ronald G. Fraass", with a long horizontal flourish extending to the right.

Ronald G. Fraass, Chair
Emergency Response Planning Committee (E-6)

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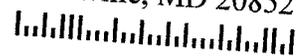
STATE OF KANSAS
DEPARTMENT OF HEALTH AND ENVIRONMENT

BUILDING 283—FORBES FIELD

TOPEKA, KANSAS 66620-0001

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Food and Drug Administration
5630 Fishers Lane, RM 1061
Rockville, MD 20852



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