

HEALTH AFFAIRS

## THE ASSISTANT SECRETARY OF DEFENSE

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JAN 24 2002

## MEMORANDUM FOR SECRETARY OF THE ARMY SECRETARY OF THE NAVY SECRETARY OF THE AIR FORCE CHAIRMAN OF THE JOINT CHIEFS OF STAFF

SUBJECT: Policy for the Use of Potassium Iodide for Protection of U.S. Personnel and Family Members – Revised

Reference the subject memorandum dated November 19, 2001. The referenced memorandum provides policy and notes that draft guidelines recently issued by the FDA reduce the dosage recommendations for children by age group. KI dosage to different age groups, action levels and other guidance were suggested in these draft FDA guidelines, available on the internet: <u>http://www.fda.gov/cder/guidance/3698dft.pdf</u>. It was noted that pending the final FDA guidelines, the dosage recommendation contained in the draft guidelines may be considered as part of the practice of medicine in the provider-patient relationship. The memorandum also stated that this DoD policy would be reviewed when the FDA publishes the final guidance on KI use.

The subject guideline was approved by the FDA and published on December 10, 2001 (excerpt attached). It is available on the internet at: (<u>http://www.fda.gov/cder/guidance/4825fnl.pdf</u>). This memorandum directs the final FDA guidelines dosages for use of potassium iodine as revised policy.

As stated in the policy memorandum of November 19<sup>th</sup>, CINCs shall evaluate the threat of radioactive iodine release from nuclear power plants and risk of exposure to U.S. personnel in their areas of responsibility and develop their implementation plan on the use of potassium iodide (KI) in coordination with the Services. Services must ensure availability of supply of KI through normal logistic procedures. KI is an over-the-counter drug approved by the FDA for use in a radiation emergency to protect the thyroid gland from harmful radioactive iodine.

My point of contact is COL Robert Eng, Director of the Armed Forces Radiobiology Research Institute, at (301) 295-1210/0267 and email, <u>eng@mx.afrri.usuhs.mil</u>.

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Attachment: As Stated

cc: Surgeon General of the Army Surgeon General of the Navy Surgeon General of the Air Force

## Food and Drug Administration Guidance Potassium Iodide (KI) as a Thyroid Blocking Agent in Radiation Emergencies (December 10, 2001)

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI					
for Different Risk Groups					
	Predicted	KI dose (mg)	# of 130 mg tab	# of 65	
	Thyroid exposure(cGy			mg tablets	
Adults over 40 yrs	≥500	130	1	2	
Adults over 18-40 yrs	≥10				
Pregnant or lactating won	≥ 5				
Adolesc. over 12-18 yrs*		65	1/2	1	
Children over 3-12 yrs					
over 1 month-3 years		32	1/4	1/2	
birth-1 month		16	1/8	1/4	

\* adolescents approaching adult size ( $\geq$  70 kg) should receive the full adult dose (130 mg)

http://www.fda.gov/cder/guidance/4825fnl.pdf: December 10, 2001

1 Action Levels for KI administration to protect against thyroid cancer risk:

5 cGy or greater:	Children aged 0-18 years and pregnant or lactating women
10 cGy or greater:	Adults up to 40 years of age
500 cGy or greater:	Adults over 40 (to prevent hypothyroidism)

## 2. KI Dose Schedule

Age	<b>Dosage</b>
Adults over 40 yrs: Adults over 18 - 40 yrs Pregnant or lactating women	130 mg
Adolesc. Over 12-18 yrs Children over 3-12 yrs	65 mg
Over 1 month - 3 yrs	32 mg
Birth - 1 month	16 mg

- 3 For optimal protection against inhaled radioactive iodines, KI should be administered before or immediately coincident with passage of the radioactive plume, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should therefore be dosed daily, until a risk of significant exposure to radioactive iodines by either inhalation or ingestion no longer exists. Individuals intolerant of KI at protective doses and pregnant and lactating women (in whom repeat administration of KI raises particular safety issues) should be given priority with regard to other protective measures (i.e., sheltering, evacuation, and control of the food supply).
- 4. Note that sheltering with windows and doors closed and taped and ventilation to the outside turned off can provide significant protection to the occupants. Protective factors of 25 and greater are achievable.