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Office of the Secretary
Docketing and Service Section
USNRC
Washington, DC 20555

Jan 3, 1996

I support PRM 50-63, which would require stockpiling potassium iodide for use as a thyroid protectant in nuclear accidents.

I am a research chemist wit[illegible]rty years of industrial experience, including some work with ra[illegible]active catalysts and pesticide labelling with radioisotopes. I live in the ten mile emergency protection zone around the Perry Nuclear Power Plant, and helped Lake County develop its plan for offsite response to emergencies at Perry.

I was also a member of the Citizens Advisory Council which submitted its report, "Recommendations for Improving Nuclear Power Safety in Ohio" to Governor Celeste in 1989; a copy of pages 36-41 from that report is enclosed, because it also supports this proposed rule.

Sincerely,

Russell M. Bimber

(encl.)



DS10

# V. POTASSIUM IODIDE AS A THYROID BLOCKING AGENT

A nuclear power plant radiological emergency carries the potential for release of radioactive isotopes of iodine. An atmospheric release of significant quantities of radioiodine poses an immediate health hazard to persons exposed to the plume in that radioiodine, if inhaled, is absorbed into the bloodstream from the lungs and is transported to and concentrated in the thyroid gland. This concentration of radioactive iodine will expose the thyroid gland to elevated levels of ionizing radiation, which can result in thyroid nodules or malignancies. Extremely high levels of radiation may cause the thyroid gland to degenerate, while moderate levels can cause some loss of thyroid function.

According to the U.S. Environmental Protection Agency in its draft Appendix C to EPA 520/1-75-001, on Protective Action Guides for use in radiological emergencies, ablation of the thyroid gland requires doses of 100,000 rads, while the gland can be rendered hypothyroid by doses of 3000 to 10,000 rads. Impaired thyroid capability may occur above a threshold of 200 rads, (Appendix C, pp. C-23 and C-24.) Lower levels of exposure may result in thyroid nodules or cancers. Doses as low as 14 rads to the thyroid have been associated with thyroid malignancy in the Marshall Islanders. The risk of cancer commences about 10 years after initial exposure and continues throughout the life of the exposed individual. Thyroid nodules must be examined, by either surgical removal or needle biopsy, to determine whether they are benign or malignant. Thyroid cancers can be fatal if they are not surgically removed. EPA estimates that 1 rem of thyroid exposure carries a risk of 3.6E-4 (one in 2800), of producing a thyroid cancer of which a small fraction (about 10%) will be fatal, (Id., p. C-37). Based on these considerations, the EPA has established Protective Action Guides ranging from 5 to 25 rems for the thyroid as levels of projected dose for which protective action is advised.

The administration of stable iodine can reduce the uptake of radioactive iodine by the thyroid gland by saturating the thyroid with stable iodine. The Food and Drug Administration has approved the use of potassium iodide (KI) as a thyroid blocking agent for use in radiological emergencies. Recommended doses are 130 milligrams for adults and 65 mg for infants under one year of age, to be taken if the projected

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thyroid dose if 25 rem or greater. Daily doses should be taken for 10-14 days. In these doses and for this purpose, KI was declared "safe and effective" by the FDA and approved for sale as an over-the-counter, nonprescription drug.

To be effective, KI should be taken before or immediately after exposure to radioiodine, and KI should continue to be taken for 10 to 14 days. When used in this manner, KI will limit the uptake of radioiodine by the thyroid to less than 10% of what it would be without the use of a blocking agent. This effectiveness decreases to less than 50% blocking if the administration of KI is delayed until four hours after exposure to radioiodine.

KI should not be taken by persons who are allergic or sensitive to iodine. KI is effective only in reducing radiation doses from radio-iodines which involve mainly the thyroid gland. It is not effective in reducing exposure to other radioisotopes. For this reason, KI should be used in conjunction with evacuation, sheltering, or other protective methods.

The Soviets used KI successfully during the Chernobyl accident. According the NUREG-1250, "Report on the Nuclear Accident at the Chernobyl Nuclear Power Station," KI was taken by 45,000 residents of Pripyat and 90,000 people in 91 villages within 30 km of the nuclear plant. "Thousands of measurements of I-131 activity in thyroids of the exposed population suggest that the observed levels were lower than those that would have been expected had this prophylactic measure not been taken. The use of KI by the Pripyat population in particular was credited with permissible iodine content (less than 30 rad (sic)) found in 97% of the 206 evacuees tested at one relocation center. It is also important to note that no serious side effects of KI use have been reported to date", (NUREG-1250, pp. 7-8 and 7-9, citations omitted). Another source indicates that 5.4 million people received stable iodine after the Chernobyl accident. No mention was made of side effects, (Nuclear Safety, Vol. 29, No. 3, p.261).

The Federal Emergency Management Agency has issued a policy statement on the distribution of KI around nuclear power sites, (50 Fed. Reg. 30258 (July 24, 1985)). This policy statement recommended the stockpiling and distribution of KI to emergency workers and institutionalized individuals. Predistribution or stockpiling KI for use by the general public was not recommended, although the policy

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statement specifically permits State and local governments to make their own policies and decisions on this matter. FEMA also recognized that since the FDA has authorized over-the-counter sales of KI, it is legally available to individuals who, based on their own personal analysis, choose to have the drug immediately available.

The State of Ohio has followed FEMA and FDA recommendations on the use of KI and has no plans to supply the drug to the general public. The Emergency Evacuation Review Team, however, recommended that the State should encourage pharmacies to carry KI. Despite the educational efforts of the Department of Health, pharmacies within the plume EPZ of the Perry Nuclear Power Plant do not carry KI for use as a thyroid blocking agent. In fact, the Nuclear Regulatory Commission recently issued an Information Notice on KI which stated that the drug is not stocked in pharmacies and must be ordered from the companies that produce it, (NRC Information Notice 88-15, April 18, 1988, "Availability of U.S. Food and Drug Administration (FDA) - Approved Potassium Iodide for Use in Emergencies Involving Radioactive Iodine").

NUREG-0654, FEMA-REP-1, Rev. 1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," states that public education and information efforts should include information on radioprotective drugs, (Planning Standard G, Evaluation Criterion 1). The emergency information handbooks distributed in the plume EPZs for Perry and Davis-Besse do not contain any information on radioprotective drugs.

**RECOMMENDATION ONE**

A public education effort should be conducted to inform the public of the benefits and risks of KI and where it may be obtained.

The following is an example text for public education materials on KI:

*A nuclear power plant accident may release radioactive iodine. If you inhale radioactive iodine, it will be absorbed by your body and accumulate in your thyroid gland, giving a radiation dose to your thyroid. This may cause damage to the gland in high doses, and lower doses may cause thyroid cancer to occur later. There is a drug you can use to prevent radioactive iodine from harming your thyroid gland. This drug is potassium iodide. You may wish to use potassium iodide in a nuclear power plant emergency for added personal protection. The Food and Drug Administration has approved potassium iodide for use as a thyroid blocking agent in daily doses of 130 mg for adults and 65 mg for infants under one year of age. Potassium iodide should only be taken if there is a nuclear power plant emergency. If you plan to use potassium iodide, you should take it if you are advised to evacuate or take shelter during such an accident. You should then continue to take daily doses of potassium iodide for 10 days. People who are allergic or sensitive to iodine should not use potassium iodide. Persons experiencing any side effects or adverse reactions from potassium iodide should discontinue its use and seek medical attention. You should consult with your physician for more information on potassium iodide to determine whether you should or should not use it. If you want to use potassium iodide during a nuclear emergency, you should have it on hand in your home. You should be able to buy potassium iodide for use as a thyroid blocking agent from your pharmacy without a prescription. If you cannot obtain it from a pharmacy, you can order it from ANBEX, Inc., 15 West 75th Street, New York, NY 10023 or P.O. Box 863, Radio City Station NY, NY 10019, phone (212) 580-2810: ANBEX's trade name for potassium iodide is IOSAT. Be sure to read and follow the directions for use on the package or package insert.(*). Potassium iodide is only effective against radioactive iodine and not against other radioactive materials which may be released in a nuclear accident. Therefore, you must follow directions for sheltering or evacuation during an accident, even if you decide to use potassium iodide.*

*(*) The directions for use will say to take potassium iodide only when public health officials tell you to do so. You should be aware that public health authorities do not plan to issue directions on the use of potassium iodide in a nuclear power plant emergency. Therefore, you should take potassium iodide, if you choose to use it, when advised to evacuate or take shelter in a nuclear accident, or upon the advice of your physician.*

## REFERENCES FOR FURTHER READING ON POTASSIUM IODIDE:


FDA, "Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, " 43 Fed. Reg. 58798 (December 15, 1987).

FDA, "Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use," 47 Fed. Reg. 28158 (June 29, 1982).

FEMA, "Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent,"50 Fed. Reg. 30258 (July 24, 1985).

NRC, NUREG/CR-1433, "Examination of the Use of Potassium Iodide (KI) as an Emergency Protective Measure for Nuclear Power Reactor Accidents," (March 1980).

FDA, "Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid Blocking with Potassium Iodide," HHS Publication FDA 81-8158, (March 1981).

NCRP Report No. 55, "Protection of the Thyroid Gland in the Event of Releases of Radioiodine," Recommendations of the National Council on Radiation Protection and Measurements, August 1977, Reprinted (October 1979).

Diane G. Crocker, "Nuclear Reactor Accidents - The Use of KI as a Blocking Agent Against Radioiodine Uptake in the Thyroid - A Review", Health Physics, Vol. 46, No. 6, pp. 1265-1279, (June 1984).

EPA, Draft Appendix C to EPA 520/1-75-001, Manual or Protective Action Guides, (June 22, 1988).

Report of the Environmental Hazards Committee of the American Thyroid Association, The Use of Iodine as a Thyroid Blocking Agent in the Event of a Reactor Accident, Revised Report, (December 1982).

Recommendations on the Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Accidents: An FDA Update, Symposium on the Health Aspects of Nuclear Power Plant Incidents - 1983. Subcommittee on Environmental Health.

Committee on Public Health. New York Academy of Medicine and New York State Department of Health, (April 1983).

Perspective on Potassium Iodide (KI) as a preplanned protective measure. Policy Issue. SECY-83-362. USNRC (August 30, 1983).