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State of New Jersey
DEPARTMENT OF HEALTH AND SENIOR SERVICES
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DONALD T. DIFRANCESCO
Acting Governor

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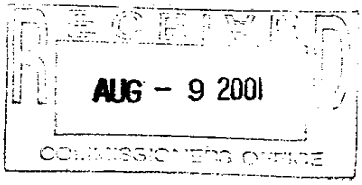
CHRISTINE GRANT, JD, MBA
Commissioner

August 6, 2001

The Honorable Robert C. Shinn, Jr.,
Commissioner
Department of Environmental Protection
401 E. State Street
P.O. Box 402
Trenton, NJ 08625-0402



Dear Commissioner Shinn:

On January 19, 2001 the Nuclear Regulatory Commission (NRC) amended its emergency planning regulations regarding commercially operated nuclear generating stations. The final rule, "Consideration of Potassium Iodide in Emergency Plans," requires that States and local jurisdictions consider the use of potassium iodide (KI) as a protective measure for the general public that would supplement the options of sheltering and/or evacuation in the event of a nuclear power plant incident. The effective date for the rule was April 19, 2001.

As the New Jersey Radiation Accident Response Act authorizes and directs our Department to provide technical assistance to the Division of State Police and the Department of Environmental Protection on health issues related to the New Jersey Radiological Emergency Response Plan, enclosed is a copy of NJDHSS Policy on Prophylactic Use of Potassium Iodide by the General Public in the 10 mile Emergency Planning Zone (EPZ) for you review and consideration. To this end, the Department has made several recommendations, in part, which includes developing a state stockpile of KI for the public who would be within the ten mile emergency planning zone surrounding the nuclear generating stations at the time of a release.

If you should have any questions or need additional information, please contact Mr. Joseph Kolakowski, the Department's Coordinator of Emergency Management Activities at 609-588-7463.

Sincerely,

Christine Grant

Christine Grant
Commissioner

Enclosure
C: J. Kolakowski

NEW JERSEY
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New Jersey Department of Health and Senior Service Policy on Prophylactic Use of Potassium Iodide by the General Public in the 10 mile Emergency Planning Zone (EPZ)
July 25, 2001

On January 19, 2001 the Nuclear Regulatory Commission (NRC) amended its emergency planning regulations regarding commercially operated nuclear generating stations. The final rule "Consideration of Potassium Iodide in Emergency Plans" requires that States and local jurisdictions consider the use of potassium iodide (KI) as a protective measure for the general public that would supplement the options of sheltering and/or evacuation in the event of a nuclear power plant incident. The effective date for the rule was April 19, 2001.

Following are some of the major factors that were considered regarding the administration of KI to the general public within the 10 mile EPZ:

Should KI be considered as a Supplemental Protective Action?

It is recognized that evacuation is the most effective protective action, since this action would completely interrupt the exposure pathway. If it is chosen to evacuate people who are downwind of the accident site, and if those people are moved promptly, the use of KI may not be necessary. Evacuation, when it is a logistically feasible option, is a more effective method of reducing thyroid exposure, and is a more desirable protective action, especially for the population at high risk from such exposure, i.e., infants, children, and pregnant women. However, when evacuation is not feasible, sheltering in place could afford partial protection by shielding from the radioactive plume. The use of KI could supplement either of these protective actions.

It should be well understood that KI provides protection only to the thyroid gland and only against radioiodines in the body. It does not protect the thyroid or any other parts of the body from other radionuclides that could be released during a nuclear incident, nor does it protect against external exposure or to other radionuclides in the plume or deposited on the ground.

Should KI be made available to the general public, and if so, how?

There are two possible methods of making KI available to the general public: (1) make KI directly available to individuals (NJDHSS is aware of one distributor that will sell directly to the public); and (2) establish State-operated and/or regional stockpiles to be distributed according to the emergency plan. The NRC did not direct State or local jurisdictions to either develop a stockpile or to distribute KI directly to the public. Rather, the States were advised to evaluate all possible options based on their specific circumstances. It was acknowledged that regional (federal) stockpiling of KI for public use would complicate, rather than simplify, emergency planning activities.

Designing a plan to make KI available to every individual within the 10 mile EPZ is not likely to be an effective protective action for the following reasons.

- As our population is very mobile and will change over the years through people moving in and out of the 10 mile EPZ, it would be very difficult to track realty transactions and continue to resupply those moving into these areas.
- The population within the 10 mile EPZ surrounding the Oyster Creek nuclear generator station can double during the summer tourist season and can change on

a weekly basis. There appears to be no practical way to distribute KI directly to this population.

- Ingestion of KI may give people a false sense of security, as they may think that they are protected from all types of radioactive materials. This may hinder evacuation of an affected area.
- The State of Tennessee instituted a program that provides KI directly to the public. This program has been only partially successful. The program, in part, requires that individuals living in the 10 mile EPZ go to designated locations to obtain new packages of KI every five years (KI has a five year expiration date). It has been estimated that less than a quarter of those living in this area have taken advantage of this program.

Although there will be significant logistical problems, a system which involves stockpiling KI at various locations near the nuclear generator stations is preferable to attempting to issue it to each individual who might be within the EPZ at an arbitrary time. Guidelines should be developed by the Radiological Emergency Response Plan's standing committee to ensure rapid determination of whether a release of radioiodines warrants the administration of KI.

How Effective is KI as a Thyroid Blocking Agent?

Potassium iodide is most effective as a prophylactic measure if it is ingested immediately prior to, during, or immediately after exposure to radioiodines. KI's effectiveness is significantly lessened if it is administered more than a few hours before or after exposure. KI can reduce the uptake of radioiodines by up to 90 percent if administered within one hour of exposure, and can provide approximately 50 percent protection if administered within five hours of exposure. If KI is administered more than five hours after an individual has suffered an acute ingestion or inhalation of radioiodine, its effectiveness as a thyroid blocking agent may be less than 50 percent. If administered twelve to fifteen hours after being exposed to radioiodines, it is not likely to provide much protection; i.e. the blockage of the thyroid will not be as effective.

What is the Comparative Risk of Using KI ?

Iodides are used as expectorants and diuretics, and iodine is frequently used as a disinfectant, *e.g.*, povidone iodine. However, some individuals are allergic to iodine or iodides. Iodides can cause fever in some individuals. A mildly toxic syndrome called iodism can result from chronic iodide ingestion and from the repeated administration of small doses of iodine including KI. Iodism is characterized by salivation, sneezing, conjunctivitis, headache, fever, laryngitis, bronchitis, stomatitis (lesions of the mouth), parotitis (iodine mumps), and various skin rashes.

The relative risk of adverse effects associated with the use of KI varies according to age. Dose adjustment by age group, based on body size, is recommended in accordance with the principle of minimum effective dose. The risk of adverse effects from the use of KI by the general population is estimated to be about 5 in a million.

The Food and Drug Administration (FDA) has approved KI as an over-the-counter medication and has found it to be effective and safe. As stated by FDA in their *draft* guidance document "Potassium Iodide as a Thyroid Blocking Agent in a Radiation Emergency," FDA concludes in the final recommendations that the health risks from the short-term use of relatively low doses of KI for thyroid blocking in a radiation emergency are less than health the risks of

radioiodine-induced thyroid nodules or cancer.

The FDA's draft document recommends that KI in doses of 130 mg per day for adults and children above 12 years, 65 mg for children between 3 to 12 years of age, 32 mg for infants (1 month to 3 years) and 16 mg for neonates (birth to 1 month) be considered for thyroid blocking in radiation emergencies in those persons who are likely to receive a projected radiation dose of 5 rem or greater to the thyroid gland from radioiodines released into the environment. The World Health Organization (WHO), in its *"Guidelines for Iodine Prophylaxis following Nuclear Accidents"*, recommends that stable iodine prophylaxis for children up to the age of 18 years be considered at a projected thyroid (radiation) dose of 10 rem, but that stable iodine prophylaxis for adults over 40 years not be recommended unless the (radiation) dose to the thyroid from inhalation is expected to exceed levels that would threaten thyroid function (ca. 500 rem).

What is the cost and shelf life of KI?

The NRC has estimated that KI costs approximately 18-20 cents per tablet (130 mg), when purchased in bulk quantities. It is estimated to have a shelf life over ten years, but the expiration date has been set by the manufacturer at five years. The NRC would fund the purchase of KI for those states that choose to stockpile it for use by the public, but not for use by emergency workers. For fiscal year 2001, the NRC has set aside $400,000 and is projecting a similar amount for 2002. Any expenses associated with emergency planning, training, public awareness, outreach programs, storage, and disposal are the responsibility of the States.

NJDHSS Recommendations

(1) In the event of a release of radioactive material, the most effective protective action is the evacuation of individuals from the EPZ. This action would eliminate the potential exposure pathways associated with the airborne plume, i.e., direct contact with, and inhalation of, radioactive materials. Other control actions, such as identification and restriction of contaminated foodstuffs, water supplies, and farm crops, would eliminate the potential exposure pathways associated with the so-called ingestion pathway.

(2) Current NJDHSS policy on the administration of KI to emergency workers and institutionalized persons should continue – Specifically, "The Department of Health and Senior Services is responsible for recommending and evaluating the State's KI program for emergency workers and institutionalized persons who cannot be evacuated in a timely fashion..."

(3) Since KI has been determined to be reasonable, prudent, and safe, and is an inexpensive supplement to evacuation and sheltering, the State of New Jersey should stockpile KI for use by the public who are within the 10 mile EPZ for the Oyster Creek and Artificial Island Nuclear Generating Stations. A plan should be devised that describes a method of disseminating the appropriate dose of KI according to age groups.

(4) The State of New Jersey should develop a plan to move stockpiles of KI to designated areas for distribution to individuals who are evacuated to these locations. The NJDHSS believes it would not be appropriate or effective to distribute KI directly to the public in advance of an unplanned release.

(5) The stockpile should contain sufficient KI tablets to supply approximately 450,000 individuals for two days. This would cover the population increase during the summer tourist

season. Repeated administration of KI over two days is not advisable since the risk of potential side effects will increase, and additional exposure pathways would be eliminated by other protective actions.

(6) The FDA, as noted, has issued a draft document that recommends doses for different risk groups and protective action recommendations (PAR). When this document is finalized, the NJDHSS will incorporate any new recommended doses and PAR.