UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

April 18, 1988

NRC INFORMATION NOTICE NO. 88-15: AVAILABILITY OF U.S. FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED POTASSIUM IODIDE FOR USE IN EMERGENCIES INVOLVING RADIOACTIVE IODINE

Addressees:

Medical, Academic, and Commercial licensees who possess radioactive iodine.

Purpose:

This notice is intended to provide information on the storage and use of potassium iodide as a thyroid blocking agent in incidents involving exposure to radioactive iodine. It is expected that licensees will review this information for applicability to their licensed activities and distribute this notice to responsible radiation safety staff. However, suggestions contained in this information notice do not constitute new NRC requirements, and no written response is required.

Description of Circumstances:

During a nuclear pharmacy inspection, NRC and the licensee discussed the possibility of maintaining a supply of potassium iodide at each pharmacy location. This supply would be used as a thyroid blocking agent in case of an iodine-131 sodium iodide spill with possible personnel contamination. The licensee asked for a statement of NRC's policy regarding on-site storage of potassium iodide for use in incidents involving radioactive exposures. There is an NRC and Federal Emergency Management Agency (FEMA) policy addressing on-site storage of FDA-approved "radiation emergency potassium iodide" as a thyroid blocking agent for power reactor emergency workers (Federal Register, Vol. 50, No. 142, p. 30258, July 24, 1985).

Discussion:

There is no NRC policy on non-reactor licensees using FDA-approved "radiation emergency potassium iodide" (i.e., the generic drug nomenclature). However, as discussed below, licensees may wish to provide for its availability in case of an emergency.

The FDA has evaluated the medical and radiological risks of administering potassium iodide for thyroid blocking under emergency conditions. The FDA has concluded that FDA-approved "radiation emergency potassium iodide" is safe and effective and has approved it for over-the-counter sale for this purpose (Federal Register, Vol. 50, No. 142, p. 30258, July 24, 1985). FDA guidance states that risks of side effects, such as allergic reactions, from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency, are outweighed by the risks of radioiodine-induced thyroid nodules or cancer, if the projected dose to the thyroid gland is 25 rems or greater. Because FDA has authorized the non-prescription sale of "radiation emergency potassium iodide," it is legally available to organizations or individuals who, based on their own corporate or personal analysis, choose to have the drug immediately available.

At this time, ANBEX, Inc. (Box 863, Radio City Station, New York, NY 10019) and Carter-Wallace, Inc. (P.O. Box 1001, Cranbury, NJ 08512) are the only companies that have received FDA new drug application (NDA) approval for their non-prescription "radiation emergency potassium iodide" drugs. These drugs are not stocked in pharmacies and must therefore be ordered directly from the companies. The non-prescription "radiation emergency potassium iodide" is manufactured at the proper adult dosage for thyroid blocking, is readily absorbed by the body, and has a package insert providing information on the dosage, method of action, warnings and storage. The directions in the package insert should be followed. Other forms of potassium iodide are available by prescription, only.

Potassium iodide is effective as a thyroid blocking agent. It reduces thyroid gland accumulation of radioiodine that has entered the body through inhalation or ingestion if the potassium iodide is administered before, or immediately after, exposure to the radioiodine. If potassium iodide is administered later than four hours after an individual has suffered an acute ingestion or inhalation of radioiodine, its effectiveness as a thyroid blocking agent is less than 50 percent.

If the licensee wants to implement a potassium iodide thyroid blocking program, the potassium iodide should be on hand (because it is not readily available), and guidelines should be developed to ensure rapid determination of whether a radioactive iodine spill or leak warrants administration of the potassium iodide. The guidelines should also address the more detailed measurements, surveys, and other followup procedures needed to determine whether continued treatment with potassium iodide is needed.

It is important to stress that the use of potassium iodide is not a substitute for preventive measures; e.g., proper handling techniques, control measures, and emergency procedures that protect the individual from exposure to radioactive material.

Licensees are also advised that although FDA has approved "radiation emergency potassium iodide" for non-prescription sales, licensees or individuals still may wish to consult with a physician about any medical risks of use in an emergency.

No specific action or written response is required by this information notice. If you have any questions regarding this matter, please contact the person listed below or the appropriate NRC regional office.

Richard E. Cunningham, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Donna-Beth Howe, NMSS
(301) 492-0636

Attachments:
1. Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent
2. List of Recently Issued NRC Information Notices

FEDERAL EMERGENCY MANAGEMENT AGENCY

Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent

AGENCY: Federal Emergency Management Agency.

ACTION: Notice of Issuance of Federal Policy—correction.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) is publishing this notice to provide guidance to State and local agencies responsible for radiological emergency planning and preparedness regarding the distribution of potassium iodide for use as a thyroidal blocking agent by the general public in the vicinity of nuclear power plants. The Federal Emergency Management Agency (FEMA) chairs the FRPCC, thereby assuming the responsibility for this publication.

In FR Doc. 85–14810 beginning on page 25624 in the issue of Thursday June 20, 1985, the statement of Federal Policy was inadvertently not included. The complete policy is stated herein. In addition, a portion of the Supplementary Information has been deleted because it was inconsistent with previously published Food and Drug Administration policy.

FOR FURTHER INFORMATION CONTACT: Gerard W. Smith, Technological Hazards Division, Office of National and Technological Hazards Programs, State and Local Programs and Support, Federal Emergency Management Agency, 500 C Street SW., Washington, D.C. 20472 202–646–2869.

SUPPLEMENTARY INFORMATION:

Background

This guidance on distribution of potassium iodide as a thyroidal blocking agent to the general public in the vicinity of nuclear power plants is part of a Federal interagency effort coordinated by the Federal Emergency Management Agency (FEMA) for the Federal Radiological Preparedness Coordinating Committee (FRPCC). FEMA issued a final regulation in the Federal Register of March 11, 1982, (47 FR 10758), which reflected governmental reorganizations and reassigned agency responsibilities for radiological incident emergency response planning. 44 CFR 351 A responsibility assigned to the Department of Health and Human Services (HHS) and in turn delegated to the Food and Drug Administration (FDA) is the responsibility to provide guidance to State and local governments on the use of radioprotective substances and prophylactic use of drugs (e.g. potassium iodide) to reduce radiation dose to specific organs including dosage and projected radiation exposures at which such drugs should be used.

In the Federal Register of June 29, 1982 (47 FR 28158), FDA published recommendations for State and local agencies regarding the projected radiation dose to the thyroid gland at which State and local health officials should consider the use of potassium iodide.

The guidance published here contains the rationale on the use of potassium iodide for emergency workers and institutionalized individuals. It also incorporates the considerations that should be made in deciding to implement the distribution and use of potassium iodide for the general population. The decisions on distribution and use of potassium iodide for thyroidal blocking to protect the public health and safety resides with the State and, in some cases, local health authorities. It suggests that any decision by State and local authorities to use potassium iodide should be based on the site environment and conditions at the time of an emergency for the specific operating commercial nuclear power plant and should include detailed plans for distribution, administration, and medical assistance.

The Federal position with regard to the predistribution or stockpiling of potassium iodide for use by the general public is that it should not be required.

Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agency

The purpose of this document is to provide Federal policy and guidance with regard to distribution of potassium iodide (KI) and its usage as a thyroid blocking agent around operating nuclear power sites. The issue has been addressed in terms of two components of the population that might require or desire potassium iodide use: (1) Emergency workers and institutionalized individuals, and (2) general population. This guidance is advisory to State and local governments who, within the limits of their authority, should consider these recommendations in the development of emergency plans and in determining appropriate actions to protect the general public. In summary, the policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring predistribution or stockpiling for the general public. The bases for these recommendations are given below. It is recognized, however, that options on the distribution and use of KI rests with the States, and hence, the policy statement permits State and local governments, within the limits of their authority, to take measures beyond those recommended or required nationally.

The U.S. Nuclear Regulatory Commission (NRC) and the *Federal Emergency Management Agency (FEMA) have already issued guidance* to State and local authorities as well as licensees of operating commercial nuclear power plants in NUREG–0654/FEMA–REP–1, Rev. 1, *recommending* the *stockpiling* and *distribution* during emergencies of KI for thyroidal blocking *to emergency workers* and to *institutionalized individuals.* That recommendation is endorsed as an available protective action in the event of an incident at a nuclear power plant. Thyroid blocking for emergency workers and institutionalized individuals was recommended because:

(1) These individuals would be more likely to be exposed to the radioiodine in an airborne radioactive release from the plant in the event of an accident;

(2) The number of individuals involved at any site is relatively small and requires a limited supply of KI that can be readily distributed;

(3) The storage, distribution, and administration of KI can be readily controlled;

(4) The known sensitivity to potassium iodide of this limited number of individuals can be reviewed; and

(5) These individuals can be readily monitored for adverse side effects by medical personnel.

The Federal position with regard to the predistribution or stockpiling of potassium iodide for use by the general public is that it should not be required. While valid arguments may be made for the use of KI, the preponderance of information indicates that a nationwide requirement for the predistribution or stockpiling for use by the general public would not be worthwhile. This is based on the ability to evacuate the general population and the cost effectiveness of a nationwide program which has been analyzed by the NRC and DOE National Laboratories (NUREG/CR–1433). While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation problems indicates that the decision to use KI (and/or other protective actions) should be made by the States and, if appropriate, local authorities on a site specific basis.

It is important to stress that the use of potassium iodide in a radiation emergency is not a panacea in that it does not block the uptake of other radionuclides and does not protect against external radiation. Furthermore, its use needs to be balanced against the cost and effectiveness of other protective measures such as sheltering and evacuation. This recommendation is made in full recognition of the potential positive effects of the drug, action by the FDA permitting KI over-the-counter sales, and the authority of State and local health officials to elect to distribute and use the drug based on the specific needs of individual sites.

The use of KI is effective as a thyroidal blocking agent in reducing accumulation by the thyroid gland of radioiodine which has entered the body through inhalation or ingestion. Radioiodine accumulation in the thyroid can be reduced to less than 10 percent of what it would be without a blocking agent by a daily oral intake of (130 milligrams for adults, 65 milligrams for infants) KI providing administration is started before or immediately after the exposure to the radioiodine, and treatment continues for at least 48 hours beyond the time of the last exposure. This effectiveness decreases to less than 50 percent blocking of the radioiodine uptake, if administration of the KI is delayed until 4 hours after an acute ingestion or inhalation.

It is recognized that the *options on distribution and use* of KI for thyroidal blocking to protect the public health and safety *resides with* the *State* and, *in some cases, local health authorities.* Therefore, with the exception of Federal agency and utility personnel, the decision for use of KI during an actual emergency by the general public is the responsibility of these authorities. In deciding whether to distribute and use KI for the general population, *these authorities must consider a number of factors.*

One of the considerations in deciding whether to implement the distribution and use of KI for the general population is that KI blocking effectively reduces the radiation exposure of only the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not nearly as effective as measures which protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and total body. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering, evacuation, or other protective methods.

The Food and Drug Administration (FDA) has evaluated the medical and radiological risks of administering KI for thyroidal blocking under these emergency conditions and has concluded that it is safe and effective and has approved over-the-counter sale of the drug for this purpose. FDA guidance states that risks from the short term use of relatively low doses of KI for thyroidal blocking in a radiation emergency are outweighed by the risks of radioiodine induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem or greater. Since FDA has authorized the nonprescription sale of KI, it is *legally available to individuals who,* based on their own personal analysis, *choose to have the drug immediately available.*

Other considerations and problems to be evaluated by the State and local authorities in deciding whether to institute this program include: (1) Whether the KI should be distributed to the population before an accident occurs or as soon as possible after an accident occurs; (2) whether the risks of exposure to radioactivity will be lower if the evacuation of the general population is initiated or if the general population is sheltered and the administration of KI initiated; (3) how the KI will be distributed during the emergency; (4) what medical assistance will be available to assist the individuals who may have some adverse reaction to KI; (5) how medical authorities will advise the population to take KI and under what circumstances this advice will be given; (6) if KI is predistributed, what assumptions should be made about its actual availability and use in the event of an incident; (7) how the authorities will provide KI to transient populations; and (8) whether use of other respiratory protection (e.g., dust masks, or breathing through wet towels) may be equally effective, especially in conjunction with sheltering.

In summary, the use of KI to prevent radioidine from accumulating in the thyroid gland can be an effective ancillary protective action during a nuclear power plant accident. However, many factors make stockpiling and/or pre-distribution to the general public questionable. Whether KI should be stockpiled and distributed to the general public around a particular site depends on local conditions. Additionally, decisions on its use or the use of alternative protective measures during an emergency depends on accident and environmental conditions that may prevail at the time. Any decision by State and local authorities to use KI should be based on the conditions and site environment for the specific operating commercial nuclear power plant and should include detailed plans for distribution, administration, and medical assistance. The following reference are intended to assist State and local authorities in decisions related to use of KI.

1. National Council on Radiation Protection and Measures (NCRP), Protection of the Thyroid Gland in the Event of Releases of Radioiodine. NCRP Report No. 55, August 1, 1977.

2. Food and Drug Administration (HEW), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency. 43 FR 58798, December 15, 1978.

3. Halperin, J.A., B. Shleien, S.E. Kahana, and J. M. Bilstad, Background Material for the Development of the Food and Drug Administration's Recommendations on Thyroid-Blocking with Potassium Iodide, FDA 81-8158, U.S. Dept. of Health and Human Services (March 1981).

4. Food and Drug Administration, Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Final Recommendations on Use. (Notice of Availability) 47 FR 28158, June 29, 1982.

5. Food and Drug Administration, Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency: Recommendations on Use. (April 1982) *Prepared by the Bureau of Radiological Health and Bureau of Drugs, Food and Drug Administration, Department of Health and Human Services.*

6. Nuclear Regulatory Commission, Examination of the Use of Potassium Iodide (KI) As an Emergency Protective Measure for Nuclear Reactor Accidents (NUREG/CR-1433, March 1980). Prepared by Sandia National Laboratories for the NRC.

Richard W. Krimm,

Chairman, Federal Radiological Preparedness Coordinating Committee.

[FR Doc. 85-17171 Filed 7-23-85; 8:45 am]

BILLING CODE 6718-01-M

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
88-14	Potential Problems with Electrical Relays	4/18/88	All holders of OLs or CPs for nuclear power reactors.
88-13	Water Hammer and Possible Piping Damage Caused by Misapplication of Kerotest Packless Metal Diaphragm Globe Valves	4/18/88	All holders of OLs or CPs for nuclear power reactors.
88-12	Overgreasing of Electric Motor Bearings	4/12/88	All holders of OLs or CPs for nuclear power reactors.
88-11	Potential Loss of Motor Control Center and/or Switchboard Function Due to Faulty Tie Bolts	4/7/88	All holders of OLs or CPs for nuclear power reactors.
88-10	Materials Licensees: Lack of Management Controls Over Licensed Programs	3/28/88	All NRC licensees authorized to use byproduct material.
87-44, Supp. 1	Thimble Tube Thinning in Westinghouse Reactors	3/28/88	All holders of OLs or CPs for nuclear power reactors that employ a Westinghouse NSSS.
88-09	Reduced Reliability of Steam-Driven Auxiliary Feedwater Pumps Caused by Instability of Woodward PG-PL Governors	3/18/88	All holders of OLs or CPs for nuclear power reactors.
88-08	Chemical Reactions with Radioactive Waste Solidification Agents	3/14/88	All NRC licensees generating or processing low level radioactive waste.

OL = Operating License
CP = Construction Permit

Licensees are also advised that although FDA has approved "radiation emergency potassium iodide" for non-prescription sales, licensees or individuals still may wish to consult with a physician about any medical risks of use in an emergency.

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Original Signed by
Richard E. Cunningham

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