TEXAS

EMERGENCY MANAGEMENT

PROCEDURES

PROCEDURE 9

RADIOPROTECTIVE DRUGS

Radiological Emergency Procedures of the Radiation Control Program
Texas Department of State Health Services

PROCEDURE 9

RADIOPROTECTIVE DRUGS

APPROVAL AND IMPLEMENTATION

This procedure is hereby approved for implementation and supersedes all previous editions.

4/11/2006
Date

/s/ Richard Ratliff
Radiation Program Officer
Radiation Control Program
Texas Department of State Health Services

DATE OF CHANGE	*INITIALS AND DATE ENTERED*
06/28/04	Revised entire document
06/02/2005	Administrative changes
03/24/2006	Minor Change

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RADIOPROTECTIVE DRUGS

I. Purpose

This procedure provides guidance concerning the distribution and use of potassium iodide (KI), for emergency workers, as a voluntarily self-administered blocking agent to reduce or prevent the uptake of radioiodines by the thyroid.

This procedure is specific to the provision and use of potassium iodide. Other radioprotective drugs, which must be administered by or under the direct supervision of medical authorities, and which function primarily to hasten the excretion of radioisotopes by the body are adequately addressed in other literature and are beyond the scope of this procedure.

II. Discussion

In any radiological emergency involving the release of radioactive iodine to the environment, one of the significant hazards is the uptake of that radioactive material by humans, either through inhalation or ingestion, and its subsequent concentration in the thyroid gland.

The rationale for using a thyroid-blocking agent such as potassium iodide is as follows:

A. Until it becomes saturated, the thyroid gland tends to concentrate any iodine that is present in the body.

B. The thyroid does not differentiate between radioactive iodines and other forms of iodine that are stable (nonradioactive).

C. If taken before or shortly following exposure to radioactive forms of iodine, the stable iodine present in potassium iodide will be available in sufficient concentrations to saturate the thyroid, thereby blocking the later uptake of the radioactive forms.

The use of potassium iodide as a protective action against thyroid uptake of radioiodines is recommended by the Environmental Protection Agency and by the U.S. Food and Drug Administration. While there is a limited risk of adverse side effects, these agencies have concluded that the potential benefit of preventing radiation-induced cancer outweighs this risk at dose commitment values of 25 rad or more.

III. References

A. Federal Register, Vol. 66, No. 13, Friday, January 19, 2001, Nuclear Regulatory Commission, 10 CFR Part 50 RIN 3150-AG11, Consideration of Potassium Iodide in Emergency Plans

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

C. Federal Register, Vol. 47, No. 125, Tuesday, June 29, 1982, Food and Drug Administration notice of availability: Potassium Iodide as a Thyroid Blocking Agent in a Radiation Emergency: Final Recommendations on Use

D. Environmental Protection Agency, Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA-400-R-92-001

E. Procedure 1 To Annex D; Accident Assessment: Plume Exposure Pathway.

F. Procedure 7 to Annex D, Personnel Dosimetry & Exposure Records.

IV. Equipment Required

A. Potassium Iodide (KI), either one 130 mg tablet, two 65 mg tablets or in 21 mg/drop KI Oral Solution USP.

B. Patient Package Insert for the specific form of potassium iodide being issued and Record of Consumption. See Attachment 1.

C. Record of Potassium Iodide Distribution, Radiation Control Program (RCP) form CI-16, or equivalent document. See Attachment 2.

D. Emergency Worker Radiation Exposure Record, RCP form CI-1, or equivalent document. See Attachment 1 in procedure 7.

V. Precautions and Limitations

A. Within the context of this procedure, potassium iodide is only to be used in response to accidents or incidents that pose a potential for inhalation or ingestion of radioactive iodine.

B. Potassium iodide only provides protection against the uptake of radioactive iodine by the thyroid. It provides no protection against any other radionuclide, and provides no protection from the effects of radioiodine on other parts of the body.

C. For maximum effect, potassium iodide should be administered at least 30 minutes to 60 minutes prior to the anticipated exposure.

D. Potassium iodide will be used as the primary method of protection for emergency workers entering the affected area. If a significant radioiodine concentration exists, potassium iodide will be used with other protective measures.

E. Potassium iodide is to be distributed to emergency workers upon the recommendation of the Commissioner of Health or his designated representative. Persons designated to represent the Commissioner in this matter include the Radiation Program Officer and each of the individuals serving as Chief of Field Operations for the Radiation Control Program (RCP) emergency response team. Additionally, for rapidly developing emergencies, the Commissioner has designated the affected County Judge(s) and the Emergency Director/Coordinator for the affected nuclear power plant. The record copy of this policy statement and designation is maintained on file with RCP.

F. Potassium iodide should be used only after a specific recommendation to do so has been issued by the Commissioner of Health or his designated representative as identified above. That recommendation may be issued simultaneously with the recommendation to distribute; it may be issued at a later time; or the nature of the event may be such that no recommendation to use potassium iodide is issued at all. In any case, neither the recommendation to distribute nor the act of distributing potassium iodide constitutes a recommendation for its use.

G. Even if potassium iodide has been provided to emergency workers and its use has been recommended, actual usage or refusal to use potassium iodide will be at the discretion of the individual.

H. As a thyroid-blocking agent, potassium iodide should only be used in the dosages specified in this procedure.

I. Once initiated, use of potassium iodide should continue for ten consecutive days, including the day on which the first dose is taken.

J. Persons who have a known allergy to iodide shellfish should not take potassium iodide. Anyone whose emergency response team assignment could reasonably involve exposure to radioiodines should consult a physician for iodide sensitivity screening.

K. Although such occurrences are rare, the use of potassium iodide may result in certain undesirable side effects. Possible side effects and appropriate response if they occur are described on the Patient Package Insert, which is provided to each person receiving a supply of potassium iodide under this procedure.

VI. Prerequisites

A. Each recipient of potassium iodide must be given a copy of the Patient Package insert for the specific product provided.

B. Each recipient of potassium iodide must sign RCP form CI-16, or an equivalent document acknowledging receipt of the product and the appropriate Patient Package Insert and must acknowledge an understanding that use of potassium iodide is a voluntary decision to be made by the individual recipient.

C. Each recipient must be advised concerning the conditions under which potassium iodide is being provided and the appropriate dosage in which it is to be used.

D. Each recipient must record the date and time they consume potassium iodide on attachment 1.

VII. Procedure

A. Issuance

Typically, distribution of potassium iodide to RCP emergency response team members will be accomplished by having persons return to the staging area, by having RCP courier deliver potassium iodide supplies to various team elements at their assigned duty stations, or by having individuals pick up supplies from RCP Contamination Control teams at any of the various manned access control points which may be established during an emergency response. Distribution to site personnel will be at the discretion of the Emergency Director/Coordinator, or as otherwise provided in plant procedures. Distribution to offsite emergency personnel other than RCP emergency response team members will be accomplished in accordance with local government emergency response plans. Local plans should include provisions for distribution to persons in institutions and other persons whose mobility is impaired to the extent that they could not be readily evacuated.

B. Recommendations for Use

The use of potassium iodide may be recommended any time there is an accident or incident that poses a potential for inhalation or ingestion of radioactive iodine and at a minimum it **must** be recommended when projected dose to the thyroid equals or exceeds 25 rads. Dose projections may be based on the calculations of the DSHS Accident Assessment team, the assessment team of the involved nuclear power generating facility-operating utility, or the assessment team of a competent federal agency.

C. Dosage

1. Daily dosage shall consist of one 130 mg tablet, two 65 mg tablets or six drops of 21 mg/drop KI Oral Solution USP in one-half glass of liquid.

2. Daily dosage shall be repeated for ten consecutive days, inclusive of the first dose; or shall be as otherwise directed by the Commissioner of Health or his designee. In no event shall dosage be continued beyond ten days without specific individual instructions from a competent medical authority.

Note: The inclusion in this procedure of dosage information for children should not be construed as an intention to distribute potassium iodide to such individuals. It is the policy of the Department of State Health Services that potassium iodide will only be provided to, and its use will only be recommended for emergency workers. DSHS does not advocate the use of potassium iodide by members of the general public.

D. Documentation

1. The Chief of Field Operations or appointed designee determines when and who should take potassium iodide. The Chief of Field Operations will sign and distribute a memo documenting the decision and inform all RCP emergency response team members.

2. A record of date, time and signature for each dose of potassium iodide taken will be documented on attachment 1.

3. RCP emergency response team members will be distributed potassium iodide prior to emergency operations where radioiodine may be present. Attachment 2 will be used to record distribution of potassium iodide.

VIII. Acceptance Criteria

Signature acknowledging receipt and understanding the use of potassium iodide is a voluntary decision to be made by the individual recipient.

Potassium Iodide Tablets

THYRO-BLOCK ®

TABLETS
(POTASSIUM IODIDE TABLETS, USP)
(pronounce9d poe-TASS-e-um EYE-oh-dyed)
(abbreviated: KI)

TAKE POTASSIUM IODIDE ONLY WHEN PUBLIC HEALTH OFFICIALS TELL YOU. IN A RADIATION EMERGENCY, RADIOACTIVE IODINE COULD BE RELEASED INTO THE AIR. POTASSIUM IODIDE (A FORM OF IODINE) CAN HELP PROTECT YOU.

IF YOU ARE TOLD TO TAKE THIS MEDICINE, TAKE IT ONE TIME EVERY 24 HOURS. DO NOT TAKE IT MORE OFTEN. MORE WILL NOT HELP YOU AND MAY INCREASE THE RISK OF SIDE EFFECTS. *DO NOT TAKE THIS DRUG IF YOU KNOW YOU ARE ALLERGIC TO IODIDE.* (SEE SIDE EFFECTS BELOW.)

INDICATIONS

THYROID BLOCKING IN A RADIATION EMERGENCY ONLY.

DIRECTIONS FOR USE

Use only as directed by State or local public health authorities in the event of a radiation emergency.

ADULTS AND CHILDREN 1 YEAR OF AGE OR OLDER:
One (1) tablet once a day. Crush for small children.

BABIES UNDER 1 YEAR OF AGE:
One-half (1/2) tablet once a day. Crush first.

Take for 10 days unless directed otherwise by State or local public health authorities.

Store at controlled room temperature between 15º and 30ºC (59º to 86ºF). Keep container tightly closed and protect from light.

WARNING

People allergic to iodide should not use potassium iodide. Keep out of reach of children. In case of overdose or allergic reaction, contact a physician or the public health authority.

DESCRIPTION

Each THYRO-BLOCK® TABLET contains 130mg of potassium iodide. Other ingredients: magnesium stearate, microcrystalline cellulose, silica gel, and sodium thiosulfate.

HOW POTASSIUM IODIDE WORKS

Certain forms of iodine help your thyroid gland work right. Most people get the iodine they need from foods like iodized salt and fish. The thyroid can "store" or hold only a certain amount of iodine.

In a radiation emergency, radioactive iodine may be released in the air. This material may be inhaled or

ingested. It may enter the thyroid gland and damage it. The damage would probably not show itself for years. Children are most likely to have thyroid damage.

If you take potassium iodide, it will fill up your thyroid gland. This reduces the chance that harmful radioactive iodine will enter the thyroid gland.

WHO SHOULD NOT TAKE POTASSIUM IODIDE

The only people who should not take potassium iodide are people who know they are allergic to iodide. You may take potassium iodide even if you are taking medicines for a thyroid problem (for example, a thyroid hormone or anti thyroid drug). Pregnant and nursing women, and children may also take this drug.

HOW AND WHEN TO TAKE POTASSIUM IODIDE

Potassium Iodide should be taken as soon as possible after public health officials tell you. You should take one dose every 24 hours. More will not help you because the thyroid can "hold" only limited amounts of iodine. Larger doses will increase the risk of side effects. You will probably be told not to take the drug for more than 10 days.

SIDE EFFECTS

Typically, side effects of potassium iodide happen when people take higher doses for a long time. You should be careful not to take more than the recommended dose or take it for longer than you are told. Side effects are unlikely because of the low dose and the short time you will be taking the drug.

Possible side effects include skin rashes, swelling of the salivary glands, and "iodism" (metallic taste, burning mouth and throat, sore teeth and gums, symptoms of a head cold, and sometimes stomach upset and diarrhea).

A few people have an allergic reaction with more serious symptoms. These could be fewer and joint pains, or swelling of parts of the face and body and times severe shortness of breath requiring immediate medical attention.

Taking iodide may rarely cause the thyroid gland to be over-active or under-active. It may also cause an enlargement of the thyroid gland (goiter).

WHAT TO DO IF SIDE EFFECTS OCCUR

If the side effects are severe or if you have an allergic reaction stop taking the potassium iodide. Then, if possible, call a doctor or public health authority for instructions.

HOW SUPPLIED

THYRO-BLOCK® TABLETS (Potassium Iodide Tablets, USP) are supplied in bottles containing 14 tablets (NDC 0037-0472-20). The white, round and scored tablets contain 130mg potassium iodide.

Record of Potassium Iodide Consumption

Name _____

Day	Date	Time	Signature
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

After you complete taking Potassium Iodide for 10 days or as directed by the Commissioner of Health or his designee, turn in this attachment to the Staging Area Coordinator.

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RECORD OF POTASSIUM IODIDE (*KI*) DISTRIBUTION

I have received a supply of potassium iodide and a copy of the appropriate Patient Package Insert. I understand that the use of potassium iodide is voluntary. If I am advised to take potassium iodide, I have the right to do so or to refuse. I also understand that the distribution of potassium iodide does not constitute a recommendation for its use. I understand that I should not use this potassium iodide until I am advised by the Texas Department of Health to do so.

Date	Time	Name & Signature	Social Security No.	Address/Phone No.

CI-16 (2/05)