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Use of Potassium Iodide by Indian Point Personnel During an Emergency

Prepared by:

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12/10/10
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Effective Date: December 22, 2010

This procedure excluded from further LI-100 review

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Use of Potassium Iodide by Indian Point Personnel During an Emergency

1.0 PURPOSE

The purpose of this procedure is to provide instructions for the use of thyroid blocking Potassium Iodide (KI) by Indian Point Energy Center personnel during an emergency.

2.0 REFERENCES

- 2.1 New York State Implementation of the use of Potassium Iodide (KI) as a Protective Action for the Public.
- 2.2 EPA-400-R-92-001, *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents.*

3.0 DEFINITIONS

- 3.1 EOF is the Emergency Operations Facility
- 3.2 TSC is the Technical Support Center
- 3.3 OSC is the Operations Support Center
- 3.4 CDE is Committed Dose Equivalent
- 3.5 TEDE is Total Effective Dose Equivalent
- 3.6 TODD is Total Organ Dose Equivalent
- 3.7 KI is Potassium Iodide

4.0 RESPONSIBILITIES

- 4.1 Emergency Plant Manager is to approve issuing Potassium Iodide to Entergy workers within the Owner Controlled Area.
- 4.2 Emergency Director is to approve issuing Potassium Iodide to off site Entergy workers.
- 4.3 Offsite Radiological Manager is responsible to supply Emergency Director dose assessment calculations to determine issuing of Potassium Iodide to personnel outside the protected area.
- 4.4 OSC Radiation Protection Team Leader is responsible to supply the Emergency Plant Manager dose assessment calculations to determine issuing of Potassium Iodide within the Protected Area.
- 4.5 Emergency Planning is to maintain a stock of Potassium Iodide at each identified location to assure enough is available to support workers for three (3) days.

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5.0 DETAILS

- 5.1 Activation of the IPEC Emergency Response Organization has occurred and a release of radioactivity has occurred.
- 5.2 Emergency Facilities are staffed as outlined in the IPEC Emergency Plan.
- 5.3 There are two (2) conditions where KI may be issued: a declared General Emergency and/or abnormal radiological conditions.
- 5.4 The OSC Radiation Protection Team Leader and the Offsite Radiological Manager SHALL maintain an awareness of onsite and offsite radiological conditions respectively.
- 5.5 If a General Emergency is declared, then all personnel in the Protected Area are authorized for voluntary use of KI by the Emergency Plant Manager via a Site announcement.
 - 5.5.1 The OSC Radiation Protection Team Leader SHALL ensure that KI is available to all personnel within the Protected Area. This SHALL include Security personnel and personnel at the Emergency Response Facilities.
- 5.6 During a declared General Emergency, the Offsite Radiological Manager SHALL ensure that KI is available to Entergy workers outside the Protected Area. This SHALL include the Field Monitoring Teams and EOF personnel. This SHALL include Security and National Guard personnel. KI tablets are available at the EOF. If necessary assign a member of Dose Assessment to distribute the KI.
 - 5.6.1 The Assembly Area Coordinators SHALL distribute KI to personnel in the EEC and GSB.
 - 5.6.2 Consider distribution of KI during accountability process if radiological conditions warrant.
- 5.7 The following areas, other than the Assembly Areas, are outside the Protected Area where personnel may be located. In the event that KI is to be issued the Assembly Coordinator will contact those personnel to relocate to one of the Assembly Areas: Material and Services Building, IPEC Warehouse, Unit 3 Warehouse, the Maintenance Training Center, the Unit 2 Simulator.
- 5.8 If abnormal radiological conditions exist either on site or off site:
 - 5.8.1 Determine the projected child thyroid dose to personnel as outlined in IP-EP-310, *Dose Assessment*.
 - 5.8.2 If the projected child thyroid dose exceeds 5 REM CDE child thyroid to any personnel, then obtain authorization to issue KI to those personnel for use on a voluntary basis.

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NOTE:
For those individuals known to be allergic to KI consider use of alternative personnel prior to issuing KI

- 5.9 To all personnel who are issued KI issue one (1) 130 mg KI tablet and a copy of Attachment 9.1, *Insert for Thyro-Block Potassium Iodide* and Attachment 9.3, *Use of KI During Radiological Emergencies-Information for the Public*, to each individual projected to receive >5 Rem CDE child thyroid. KI tablets are available in the Control Rooms, Technical Support Center/Operations Support Center, EOF, Assembly Area in the Energy Education Center, and Assembly area in the IPEC Training Building.
- 5.10 Continue to issue one (1) 130 mg KI tablet and a copy of Attachment 9.1 once per day as long as the personnel are expected to receive >5 Rem CDE child thyroid.
- 5.11 After the initial issuance of KI, consideration may be given to discontinue ongoing issuance if a release is no longer occurring or is unlikely. Receive concurrence from Emergency Director and Emergency Plant Manager.

6.0 INTERFACES

- 6.1 IP-EP-410, *Protective Action Recommendations*
- 6.2 IP-EP-250, *Emergency Operations Facility*
- 6.3 IP-EP-230, *Operations Support Center*
- 6.4 IP-EP-310, *Dose Assessment*

7.0 RECORDS

NONE

8.0 REQUIREMENTS AND COMMITMENT CROSS-REFERENCE

NONE

9.0 ATTACHMENTS

- 9.1 *Insert for Thyroid Block Potassium Iodide*
- 9.2 *Locations of Potassium Iodide*
- 9.3 *DOH: Use of KI during Radiological Emergencies-Information for the Public*
- 9.4 *New York State Policy on Potassium Iodide (updated June 2009)*

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Attachment 9.1

PATIENT PACKAGE INSERT FOR THYRO-BLOCK POTASSIUM IODIDE

Sheet 1 of 1

**iosat™
Tablets**

(Potassium Iodide Tablets, U.S.P.)
Pronounced *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.

DOSE

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

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

DOSAGE: Take for 10 days unless directed otherwise by State or local public health authorities. Store at controlled room temperature between 15° and 30° C (59° and 86° F). Keep package dry and foil packets intact.

WARNING

POTASSIUM IODIDE SHOULD NOT BE USED BY PEOPLE ALLERGIC TO IODIDE. Keep out of the reach of children. In case of overdose or allergic reaction, contact a physician or public health authority.

DESCRIPTION

Each IOSAT™ Tablet contains 130 mg of potassium iodide.

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 or 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 breathed or swallowed. It may enter the thyroid gland and damage it. Children are most likely to have thyroid damage.

If you take potassium iodide, it will fill up your thyroid gland. This lessens 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 antithyroid drug). Pregnant and nursing women and babies 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

Usually 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).

Taking iodide may rarely cause overactivity of the thyroid gland, underactivity of the thyroid gland, or 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 potassium iodide. Then, if possible, call a doctor or public health authority for instructions.

HOW SUPPLIED

IOSAT™ Tablets (Potassium Iodide Tablets, U.S.P.) packages of 14 tablets (NDC51803-001-01) Each white round scored tablet contains 130 mg potassium iodide.

Distributed by
ANBEX, INC
10 East 40th Street
New York, NY 10016
www.anbex.com

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Attachment 9.2

LOCATIONS OF POTASSIUM IODIDE

Sheet 1 of 1

Potassium Iodide is to be stored in the following locations for issuance during a declared emergency.

1. Unit 2 Central Control Room
2. Unit 3 Central Control Room
3. Technical Support Center/Operations Support Center
4. Assembly Area in the Energy Education Center
5. Assembly Area in the IPEC Training Building
6. Emergency Operations Facility

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Attachment 9.3

DOH: USE OF KI DURING RADIOLOGICAL EMERGENCIES INFORMATION FOR THE PUBLIC

Sheet 1 of 2

Use of Potassium Iodide (KI) During Radiological Emergencies Information for the Public

This fact sheet is about a new policy for people, especially those who live within ten miles of a nuclear power plant, who may be exposed to radiation from a nuclear plant emergency. In December 2001, the Federal Food and Drug Administration (FDA) said if there was a radiological emergency people should take a drug that would help protect them from thyroid cancer. This drug is called potassium iodide (KI). The New York State Health Department agrees." The questions and answers below will give you more information.

1. What is potassium iodide (KI) and what is it used for?

If there is a radiological emergency from a nuclear plant, large amounts of something called radioiodine could be put into the air and this could hurt your thyroid gland, or even cause thyroid cancer later on. You could breathe in the radioiodine or eat food that has some radioiodine in it. When you take the KI pill, it protects your thyroid gland from being harmed.

2. How does potassium iodide work?

When you take the KI pill, it fills your thyroid with a kind of iodine that prevents your thyroid gland from taking in any of the radioactive kind of iodine.

3. What age group has the highest risk from exposure to radioiodine?

Young children have the highest risk. We have learned this from looking at children in Russia and other areas who were exposed to the radioiodine from the Chernobyl nuclear power plant accident.

4. When should KI be taken?

You need to take KI before or just after you are exposed to radioiodine. You can also take it 3 or 4 hours later, but it will not be as helpful.

5. How will I know if I should take KI?

If there is an emergency, you will hear an announcement from your local or state health officials. Your local health department will tell you when you should start taking KI and they will also tell you when you can stop taking it.

6. Does KI work in all radiation emergencies?

KI will only protect you from radioactive iodine. It does not protect you from other kinds of radioactive material. KI works very well to protect your thyroid gland. However, it protects only your thyroid, not other parts of your body.

7. What will happen in an emergency?

You will be told what if any actions you should take to protect yourself. This might include leaving the area, staying inside with your windows closed and/or taking KI.

8. Can people have reactions to KI?

In general, most people who have taken KI have not had any reactions (side effects) if people did have a reaction it did not last very long. In a few cases, babies had a reaction in their thyroids. Adults who had reactions had stomach problems or a rash. The Federal Government thinks the benefits of taking KI are much greater than the risks.

9. Are there some people who should not take KI?

Most people can take KI, but you should talk to your doctor before taking it. Talk to your doctor before an emergency occurs. It is not a good idea to take it if you have certain medical conditions or problems. Babies need to be watched carefully if they take KI.

10. How much KI do I take?

The table below shows the smallest KI dose that different age groups can take which will protect the thyroid. At the moment, the pill only comes in a 130 mg tablet. Since it is hard to cut many pills the State Health Commissioner says that, in an emergency, it is safe for children at school or day care centers to take the whole pill. For children or babies who cannot take pills, parents and caregivers can cut or crush the pill to make lower doses. For example, if 130 mg pill were dissolved in 8 ounces of juice or other liquid, one ounce would contain 16 mg of KI.

Attachment 9.3

DOH: USE OF KI DURING RADIOLOGICAL EMERGENCIES INFORMATION FOR THE PUBLIC

Sheet 2 of 2

Use of Potassium Iodide (KI) During Radiological Emergencies Information for the Public

Age Group	KI Dosage	Number of 130 mg tablets
Adults over 18 years	130 mg	1
Over 3 – 18 years	65 mg	1/2
Over 1 month to 3 years	32 mg	1/4
Birth – 1 month	16 mg	1/8

11. How often should KI be taken?

KI is helpful for about 24 hours. You should keep taking it until the health department says to stop or you are out of the emergency area.

12. Does KI come in liquid or pill form?

KI can come as a pill or a liquid, but right now it is only available as a pill. It may also be available as a liquid soon.



13. If KI has been stored for a while, is it still OK to use?

The manufacturers say KI stays 'fresh' for 3 – 5 years. If you keep it in a dry dark and cool place, it should last for many years.

14. Do you need a prescription to get KI?

No. You are allowed to get it over the counter.

15. Can KI be purchased at local pharmacies?

It is not widely available in drugstores yet, but since it is not a prescription drug, you can buy it over the internet. We hope to give a supply of KI to people who live within 10 miles of a nuclear power plant in New York State.

For additional information contact:

New York State Department of Health info line 1-800-458-1158, extension 2-7550 or BERP@health.state.ny.us

Other sources of information:

www.1da.gov/oder/guidance/4825fnt.htm

www.int/environmental_information_resources.documents/iodine/quide.pdf

www.health.state.us/nysdoh/consumer/environ/homeenvi.htm

June 2002

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Attachment 9.4
New York State Policy on Potassium Iodide
(Updated June 2009)
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Introduction

This Policy updates the 1982 New York State Policy on the use of potassium iodide (KI) for the general public to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. The recommendations in this policy address KI dosage and the projected radiation exposure at which the drug should be used.

These recommendations are based on guidance provided by the United States Food and Drug Administration (FDA), "Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies", in December of 2001.

Background

The FDA has provided guidance previously on the use of KI as a thyroid blocking agent. First, in 1978, the FDA announced its conclusion that KI is a safe and effective means by which to block uptake of radioiodines by the thyroid gland in a radiation emergency under certain specified conditions of use. In 1982 FDA announced final recommendation on the administration of KI to the general public in a general emergency. Those recommendations were formulated after reviewing studies relating the radiation dose to thyroid disease risk that relied on estimates of external thyroid irradiation after the nuclear detonation at Hiroshima and Nagasaki and analogous studies among children who received therapeutic radiation to the head and neck. The former New York State Policy on KI was based on previous FDA recommendations for administering KI to emergency workers and selected captive populations. This former policy which stated: "The FDA recommends that potassium iodide in doses of 130 mg per day per adult and children above one year, and 65 mg per day for children below one year of age, be considered for thyroid blocking in radiation emergencies in those persons who are likely to receive a projected radiation dose of 25 rem or greater to the thyroid gland from radioiodines released to the environment. The decision to administer KI will be made with the concurrence of local and State Health officials."

The policy that follows revises New York State's 1982 policy recommendation on the use of KI for thyroid cancer prophylaxis based on the recent FDA's recent comprehensive review of the data relating radioiodine exposure to thyroid cancer risk, accumulated in the aftermath of the 1986 Chernobyl reactor accident.

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Rationale for Revising the Existing KI Policy

The New York State Department of Health (NYSDOH) has reviewed the new guidance for prophylactic use of KI prepared by the FDA and is hereby recommending that the New York State Policy on KI distribution to the general public be revised. The rationale for the revision is given below.

- Studies conducted after the Chernobyl accident in 1986 have provided the most reliable information available to date on the relationship between internal thyroid radioactive dose and cancer risk. These studies suggest that the risk of thyroid cancer is inversely related to age, and that, especially in young children, it may accrue at very low level of radioiodine exposure. The FDA relied on Chernobyl data to formulate its specific recommendations.
- The effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well established, as are the doses necessary for blocking uptake. As such, it is reasonable to conclude that KI will likewise be effective in reducing the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodines.
- Short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults. The risks of stable iodine administration are detailed in the FDA guidance document (FDA01).

The NYSDOH, in consultation with its Radiological Health Advisory Committee, concluded that there was no medical reason not to make KI available to the general public during a radiological emergency where a large release of radioiodines had taken place. In August 1998, the NYSDOH Commissioner (Dr. DeBuono) made that recommendation to Mr. Edward Jacoby, then Chairman of the Disaster Preparedness Commission (DPC). The present NYSDOH Commissioner, Dr. Novello, reiterated that recommendation when the FDA released its final guidance on the use of KI for the general public in December, 2001.

Based on information available to date, New York State has decided to revise its KI policy to reflect current FDA recommendations.

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New York State Policy on Potassium Iodide
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New Policy

The New York State Plan endorses the 2001 FDA recommendation regarding KI. The revised New York State Policy on KI is revised as follows:

“The New York State Department of Health states that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thereby reduce the risk of thyroid cancer in the event of a radiation emergency. The Department will follow the FDA’s lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than those previously recommended in 1982 (see Table 1). The recommendation to take KI by the general public will be issued by the Local or State Commissioner of Health, or his/her designee, during a radiological emergency where the potential to exceed the new FDA dose limits may be exceeded by the general public. This recommendation will be based on a projected thyroid dose to one-year old child of 5 Rem.

The NYSDOH continues to recommend that the radiation emergency response plans include:

- Provisions (in the event of a radiation emergency) for informing the public about the magnitude of the radiation hazard;
- The manner of use of KI and its potential benefits and risks; and
- Medical contact, reporting, and assistance systems.

The NYSDOH recognizes FDA recommendations on availability as well as administration of KI in advance of exposure to radioiodine. The NYSDOH stresses that KI provides protection only for the thyroid from radioiodines. It has no impact on the impact on the uptake by the body of other radioactive materials and provides no protection against external irradiation of any kind. The NYSDOH emphasizes that the use of KI should be as an adjunct to recommended protective actions such as evacuation (itself not always feasible), sheltering, and control of foodstuffs.”

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Attachment 9.4
New York State Policy on Potassium Iodide
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Dosing Guidelines

In addition to 130 mg tablets, KI is now FDA-approved and available in 65 mg tablets and liquid (65 mg/ml).

The FDA guidance contains a number of age dependent doses (see Table 1). These recommendations are the lowest effective dose. Emergency planners and others should understand that absolute precision in dosing is generally not critical to safety or efficacy. Higher doses (e.g., up to 130 mg) would be equally effective and, particularly among school-age children, extremely safe.

Table 1

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups				
	KI dose (mg)	# ml liquid (65 mg/ml)	# of 65 mg tablets	# of 130 mg tablets
Adults over 40 yrs	130	2	2	1
Adults over 18 through 40 yrs				
Pregnant or lactating women				
Adolescents over 12 through 18 yrs who weigh at least 150 pounds	130	2	2	1
Adolescents over 12 through 18 yrs who weigh less than 150 pounds	65	1	1	1/2
Children over 3 through 12 yrs	65	1	1	1/2
Over 1 month through 3 years	32	1/2	1/2	1/4
Birth through 1 month	16	1/4	1/4	1/8

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New York State Policy on Potassium Iodide
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A scheme of graded dosing may be difficult to implement during a radiological emergency involving large numbers of people. If local emergency planners conclude that graded dosing is logistically impractical, for populations at risk for radioiodine exposure, the overall benefits of taking up to 130 mg of KI instead of the lower doses recommended for certain age groups far exceed the small risks of overdosing. NYSDOH supports the administration of the 130-mg tablet for children in settings such as schools or childcare centers in the event of emergencies. This is in agreement with FDA statements. (Ref) This dose is safe and well within the recommended therapeutic range of KI for other indications. The blocking effect of iodide on the thyroid lasts only a few days (daily dosing is needed as long as the child is exposed to radioiodine) and any suppressive effect of KI on thyroid function has been shown to be minimal, even in young children. However, where feasible, adherence to FDA guidance should be attempted when dosing infants due to the potential for a transient hypothyroidism, which can impact intellectual development.

The logistics of providing KI to persons too young to take pills are more complicated. KI tablets can be crushed and dissolved in small amounts of juice or formula. For instance, if a 130-mg tablet were dissolved in 8 ounces of liquid, one ounce would contain 16 mg of KI. The FDA has noted that absolute precision in dosing is generally not critical to safety or efficacy, and has emphasized in their guidance document that across populations at risk for radioiodine exposure, the overall benefits of KI far exceed the risks of overdosing, especially in children.

Reference

FDA01 Guidance, Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies, US Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research. December 2001.