

ENTERGY NUCLEAR NORTHEAST  
JAMES A. FITZPATRICK NUCLEAR POWER PLANT  
P.O. BOX 110, LYCOMING, NY 13093  
DOCUMENT TRANSMITTAL AND RECEIPT ACKNOWLEDGEMENT FORM

DATE: September 29, 2003  
CONTROLLED COPY NUMBER: 34

TO: U.S.N.R.C. Document Center/Washington, DC  
FROM: CATHY IZYK - EMERGENCY PLANNING DEPARTMENT  
SUBJECT: EMERGENCY PLAN AND IMPLEMENTING PROCEDURES

Enclosed are revisions to your assigned copy of the JAFNPP Emergency Plan and Implementing Procedures. Please remove and **DISCARD** the old pages. Insert the attached, initial and date this routing sheet and return the completed routing sheet to *Cathy Izyk in the Emergency Planning Department within 15 days*. If this transmittal is not returned within 15 days, your name will be removed from the controlled list.

**THESE PROCEDURES ARE EFFECTIVE**  
**Tuesday September 30, 2003**

VOLUME 2 Update List Dated September 30, 2003			
DOCUMENT	PAGES	REV. #	INITIALS/DATE
EAP-14.6	REPLACE ALL	16	
EAP-19	REPLACE ALL	23	

AD45

# EMERGENCY PLAN IMPLEMENTING PROCEDURES/VOLUME 2 UPDATE LIST

CONTROLLED COPY # **34**

Date of Issue: SEPTEMBER 30, 2003

Procedure Number	Procedure Title	Revision Number	Date of Last Review	Use of Procedure
N/A	TABLE OF CONTENTS	REV. 19	02/98	N/A
IAP-1	EMERGENCY PLAN IMPLEMENTATION CHECKLIST	REV. 31	08/03	Informational
IAP-2	CLASSIFICATION OF EMERGENCY CONDITIONS	REV. 24	05/03	Informational
EAP-1.1	OFFSITE NOTIFICATIONS	REV. 49	08/03	Informational
EAP-2	PERSONNEL INJURY	REV. 26	01/03	Informational
EAP-3	FIRE	REV. 23	08/02	Informational
EAP-4	DOSE ASSESSMENT CALCULATIONS	REV. 33	06/03	Informational
EAP-4.1	RELEASE RATE DETERMINATION	REV. 16	05/03	Informational
EAP-5.1	DELETED (02/94)			
EAP-5.2	DELETED (04/91)			
EAP-5.3	ONSITE/OFFSITE DOWNWIND SURVEYS AND ENVIRONMENTAL MONITORING	REV. 9	08/02	Informational
EAP-6	IN-PLANT EMERGENCY SURVEY/ENTRY	REV. 17	05/03	Informational
EAP-7.1	DELETED (02/94)			
EAP-7.2	DELETED (02/94)			
EAP-8	PERSONNEL ACCOUNTABILITY	REV. 62	08/03	Informational
EAP-9	SEARCH AND RESCUE OPERATIONS	REV. 11	05/03	Informational
EAP-10	PROTECTED AREA EVACUATION	REV. 17	05/03	Informational
EAP-11	SITE EVACUATION	REV. 19	05/03	Informational
EAP-12	DOSE ESTIMATED FROM AN ACCIDENTAL RELEASE OF RADIOACTIVE MATERIAL TO LAKE ONTARIO	REV. 11	04/02	Informational
EAP-13	DAMAGE CONTROL	REV. 15	09/03	Informational
EAP-14.1	TECHNICAL SUPPORT CENTER ACTIVATION	REV. 23	05/03	Informational
EAP-14.2	EMERGENCY OPERATIONS FACILITY ACTIVATION	REV. 21	05/03	Informational
EAP-14.5	OPERATIONAL SUPPORT CENTER ACTIVATION	REV. 14	03/00	Informational

# EMERGENCY PLAN IMPLEMENTING PROCEDURES/VOLUME 2 UPDATE LIST

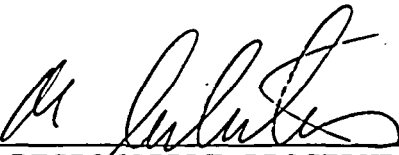
Date of Issue: SEPTEMBER 30, 2003

Procedure Number	Procedure Title	Revision Number	Date of Last Review	Use of Procedure
EAP-14.6	HABITABILITY OF THE EMERGENCY FACILITIES	REV. 16	09/03	Informational
EAP-15	EMERGENCY RADIATION EXPOSURE CRITERIA AND CONTROL	REV. 11	06/02	Informational
EAP-16	PUBLIC INFORMATION PROCEDURE	REV. 7	05/03	Informational
EAP-16.2	JOINT NEWS CENTER OPERATION	REV. 3	09/03	Informational
EAP-17	EMERGENCY ORGANIZATION STAFFING	REV. 107	08/03	Informational
EAP-18	DELETED (12/93)			
EAP-19	EMERGENCY USE OF POTASSIUM IODINE (KI)	REV. 23	09/03	Informational
EAP-20	POST ACCIDENT SAMPLE, OFFSITE SHIPMENT AND ANALYSIS	REV. 9	06/02	Informational
EAP-21	DELETED (12/85)			
EAP-22	DELETED (02/98)			
EAP-23	EMERGENCY ACCESS CONTROL	REV. 12	09/03	Informational
EAP-24	EOF VEHICLE AND PERSONNEL DECONTAMINATION	REV. 9	06/02	Informational
EAP-25	DELETED (02/94)			

ENTERGY NUCLEAR OPERATIONS, INC.  
JAMES A. FITZPATRICK NUCLEAR POWER PLANT  
EMERGENCY PLAN IMPLEMENTING PROCEDURE

HABITABILITY OF THE EMERGENCY FACILITIES  
EAP-14.6  
REVISION 16

APPROVED BY:

  
RESPONSIBLE PROCEDURE OWNER

DATE:

9/23/03

EFFECTIVE DATE:

September 30, 2003

FIRST ISSUE ☐

FULL REVISION ☐

LIMITED REVISION ☒

*****	*****
* INFORMATIONAL USE *	* TSR *
*****	*****
* ADMINISTRATIVE *	CONTROLLED COPY # <u>34</u>
*****	

PERIODIC REVIEW DUE DATE:

MAY 2008

## REVISION SUMMARY SHEET

## REV. NO.

- 16
  - Revised values in section 4.4.3 to reflect child thyroid per NY state law.
- 15
  - Changed Emergency Director to Emergency Plant Manager.
  - Clarified Rad Monitor Setpoints in Step 3.3.2.
  - Added issuance of KI to Step 4.4.3.
- 14
  - Added "OSC Manager, Rad Support Coordinator" to Section 4.3 on page 5.
  - Added note to section 4.4.1, page 5, advising of potential for increased dose following a refuel accident.
- 13
  - Reformat per AP-02.01, Rev. 5.
  - Level of use changed to "Informational" for consistency with AP-02.04, Control of Procedures

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## 1.0 PURPOSE

The purpose of this procedure is to describe the necessary radiological checks to determine the radiological habitability of the Control Room, TSC, OSC, and Security Building areas.

## 2.0 REFERENCES

### 2.1 Performance References

2.1.1 EAP-6, IN-PLANT EMERGENCY SURVEY/ENTRY

2.1.2 EAP-15, EMERGENCY RADIATION EXPOSURE CRITERIA AND CONTROL

### 2.2 Developmental References

2.2.1 IAP-2, CLASSIFICATION OF EMERGENCY CONDITIONS

2.2.2 EAP-6, IN-PLANT EMERGENCY SURVEY/ENTRY

2.2.3 EAP-14.1, TECHNICAL SUPPORT CENTER ACTIVATION

2.2.4 EAP-14.5, OPERATIONAL SUPPORT CENTER ACTIVATION AND OPERATION

2.2.5 EAP-15, EMERGENCY RADIATION EXPOSURE CRITERIA AND CONTROL

2.2.6 EPA-400-R-92-001, May 1992, Manual of Protective Action Guides and Protective Actions for Nuclear Incidents

## 3.0 INITIATING EVENTS

3.1 An Unusual Event or higher classification has been declared in accordance with procedure IAP-2, CLASSIFICATION OF EMERGENCY CONDITIONS, and;

3.2 The TSC and/or OSC are operational, and;

3.3 Abnormal radiological conditions exist as indicated by one or more of the following or the Emergency Plant Manager or TSC Manager feel that habitability monitoring is warranted.

3.3.1 Control Room inlet ventilation radiation monitor and/or ARM #3 exceeds alarm setpoint.

- 3.3.2 TSC area radiation monitor exceeds alarm setpoint of 5 mR/hr or either of the CAMs (IM-1A for iodine/AMS-3 for particulate) in the TSC hallway exceeds their alarm setpoint of 500 cpm greater than background.
- 3.3.3 A refuel accident is in progress.
- 3.3.4 OSC ARM #1 and/or portal monitors exceed alarm setpoints, or general area radiation monitor exceeds 5 mR/hr.
- 3.3.5 Security Building portal monitors exceed alarm setpoint.

OR

- 3.4 Abnormal radiological conditions exist, are suspected, or are projected as determined by the Rad Support Coordinator (RSC), or designee.

#### 4.0 PROCEDURE

- 4.1 The Emergency Plant Manager, Rad Support Coordinator, or designee shall:
  - 4.1.1 Instruct personnel not to eat, drink or smoke until it is determined that abnormal radiation conditions do NOT exist.
  - 4.1.2 Dispatch Radiation Protection Technician(s) to perform continuous habitability surveys in accordance with procedure EAP-6, IN-PLANT EMERGENCY SURVEY/ENTRY, in the Control Room, TSC, OSC and Security Building. Surveys shall be performed approximately every 30 minutes as long as abnormal radiological conditions exist or are suspected. Surveys should include dose rate surveys and air samples.
  - 4.1.3 Instruct personnel in the Control Room, TSC, OSC, and Security Building to notify the Rad Support Coordinator if alarm setpoints in Section 3.3 are exceeded.
  - 4.1.4 Consider issuing DRDs and TLDs to personnel who do not already have them.



- 
- 4.1.5 Inform the Emergency Plant Manager and other personnel of potential radiological hazards determined as a result of habitability surveys.
  - 4.1.6 If access is needed to areas other than those surveyed in Step 4.1.2 (such as the Warehouse), then assign a Radiation Protection Technician to accompany personnel in accordance with EAP-6, IN-PLANT EMERGENCY SURVEY/ENTRY.
  - 4.1.7 Determine the suitability of area environments using information gathered by the following sources:
    - A. EAP-6, IN-PLANT EMERGENCY SURVEY/ENTRY
    - B. EAP-15, EMERGENCY RADIATION EXPOSURE CRITERIA AND CONTROL
    - C. Habitability guidance listed in Section 4.4 of this procedure.
  - 4.1.8 Repeat the above steps as necessary when a release is ongoing.
  - 4.2 The Radiation Protection Technician shall:
    - 4.2.1 Perform habitability surveys as directed.
    - 4.2.2 Record and report results of habitability surveys to RSC or designee.
    - 4.2.3 Notify the Rad Support Coordinator if alarm setpoints in Section 3.3 are exceeded.
  - 4.3 The Emergency Plant Manager, OSC Manager, Rad Support Coordinator, or designee shall:
    - 4.3.1 Relocate the OSC to the Alternate OSC (AOSC) if the OSC environment is unacceptable and the AOSC environment is surveyed and found to be acceptable. The Work Center portion of the AOSC is within the Control Room Ventilation System boundary.
    - 4.3.2 Restrict access to areas in the TSC if the environment is unacceptable.

#### 4.4 Habitability Guidance

- 4.4.1 Various factors and conditions must be considered when deciding on the habitability of the areas, such as:

NOTE: A refuel accident may cause dose in the TSC to increase shortly following the accident.

- A. whole body, beta and iodine doses
- B. accident conditions and circumstances
- C. status of release (duration, termination, etc.)
- D. advantages and disadvantages of facility relocation
- E. dose projections, prior to any relocation offsite.

4.4.2 Beta and Gamma External Dose Guidance

- A. If a dose rate of greater than 10 mR/hr is present in a facility, relocate that facility if feasible.
- B. If a dose rate of greater than 500 mR/hr is present in a facility, relocate that facility.

4.4.3 Iodine Dose Guidance

- A. Determine CDE child Thyroid using I-131 air sample results as follows:

$$\text{DE-Thyroid(Rem)} = \text{I-131 Conc.}(\mu\text{Ci/cc}) \times \text{time breathed(hr)} \times 2.6 \times 10^6 \text{ (Rem/hr/}\mu\text{Ci/cc)}$$

- B. If CDE child Thyroid is greater than 5 Rem, then consider relocation of that facility, or issuance of KI in accordance with EAP-19.

#### 5.0 ATTACHMENTS

NONE

ENTERGY NUCLEAR OPERATIONS, INC.  
JAMES A. FITZPATRICK NUCLEAR POWER PLANT  
EMERGENCY PLAN IMPLEMENTING PROCEDURE

EMERGENCY USE OF POTASSIUM IODIDE (KI)  
EAP-19  
REVISION 23

APPROVED BY:

[Signature]  
RESPONSIBLE PROCEDURE OWNER

DATE:

9/24/03

EFFECTIVE DATE:

September 30, 2003

FIRST ISSUE ☐

FULL REVISION ☐

LIMITED REVISION ☒

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PERIODIC REVIEW DUE DATE:

MAY 2008

## REVISION SUMMARY SHEET

## REV. NO.

- 23
  - Revised sections 4.2.1, 4.2.2, 4.2.3, and 4.2.4 to change adult thyroid to child thyroid.
  - Revised Attachment 3 for child thyroid values.
- 22
  - Complete rewrite to implement the use of KI as a protective action during a general emergency.
  - Added attachments 5 and 6
  - Updated procedure references
  - Updated reference in 2.1 with current Rad Protection procedures and current name of mini scaler.
  - Updated attachment 2 with additional personnel allergic to potassium iodide.
  - Changed threshold level for KI use form for 25 rem to 5 rem CDE thyroid.
  - Updated Attachment 3 for 5 Rem CDE thyroid.
- 21
  - The company name on the coversheet has been changed due to a recent sale of.
  - In Section 1.0, the reference to New York Power Authority employees has been changed to James A. Fitzpatrick employees due to the sale.
  - References to NYPA in Sections 4.1.2 and 4.2.3 have been changed to JAF.
  - In Section 4.2.4 the references to "The Authority's" were changed to "the site's".
  - Updated attachment 2 - added/omitted personnel with an allergy to KI.

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## 1.0 PURPOSE

The purpose of this procedure is to provide instructions for the use of thyroid blocking Potassium Iodide (KI).

## 2.0 REFERENCES

### 2.1 Performance References

- 2.1.1 EAP-1.1, OFFSITE NOTIFICATIONS
- 2.1.2 EAP-4, DOSE ASSESSMENT CALCULATIONS
- 2.1.3 EAP-5.3, ONSITE/OFFSITE DOWNWIND SURVEYS AND ENVIRONMENTAL MONITORING
- 2.1.4 EAP-6, IN-PLANT EMERGENCY SURVEY/ENTRY
- 2.1.5 RP-INST-02.09, MINI-SCALER MS-2 and MS-3
- 2.1.6 RP-RESP-04.02, PORTABLE AIR SAMPLERS
- 2.1.7 AM-03.04, RADIOIODINE CARTRIDGE ANALYSIS USING GAMMA SPECTROSCOPY

### 2.2 Developmental References

- 2.2.1 National Council on Radiation Protection and Measurements Report No. 55. PROTECTION OF THE THYROID GLAND IN THE EVENT OF RELEASES OF RADIOIODINE.
- 2.2.2 Manufacturer's (Wallace Laboratories) Recommendations on Use of Thyro-Block Tablets.
- 2.2.3 EPA-400-R-92-001, MANUAL OF PROTECTIVE ACTION GUIDES AND PROTECTIVE ACTIONS FOR NUCLEAR INCIDENTS
- 2.2.4 New York State Nuclear Emergency Preparedness Subcommittee Technical Issues Task Force, IMPLEMENTATION OF THE USE OF KI AS A PROTECTIVE ACTION FOR THE PUBLIC.

### 3.0 INITIATING EVENTS

- 3.1 Abnormal radiological conditions are indicated in the plant or environs, or:
- 3.2 A General Emergency has been declared.

### 4.0 PROCEDURE

NOTE: The Emergency Director is the only individual who can authorize the use of KI for personnel in the JAF Owner Controlled Area and other JAF Emergency Workers who may be located outside the Owner Controlled Area

- 4.1 The TSC and EOF Radiological Support Coordinators shall maintain an awareness of onsite/in-plant and offsite radiological conditions, respectively.

- 4.2 If abnormal radiological conditions exist, then the appropriate Radiological Support Coordinator shall:

- 4.2.1 Determine the projected child thyroid dose to personnel in the affected area(s) using Attachment 3 as a guide.

- 4.2.2 If the projected child thyroid dose exceeds 5 Rem CDE child thyroid to any personnel, then obtain Emergency Director authorization to issue KI to those personnel for use on a voluntary basis.

NOTE: For those personnel known to be allergic to KI as listed on Attachment 2, consider use of alternate personnel prior to issuing KI.

- 4.2.3 Issue one (1) 130 mg KI tablet and a copy of Attachment 6, 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 TSC, OSC, EOF, Training Building, Security, and in Field Team Survey Kits.

- 4.2.4 Continue to issue one (1) 130 mg KI tablet and a copy of Attachment 6 once per day, if appropriate, as long as the personnel are expected to receive > 5 Rem CDE child thyroid.

4.3 If a General Emergency is declared, then all personnel in the owner controlled area are authorized for voluntary use of KI by the Emergency Director via a site announcement.

4.3.1 The TSC Radiological Support Coordinator shall ensure that KI is made available to all personnel in the JAF Owner Controlled Area. This shall include Security personnel, National Guard, personnel in the Training Building, and other personnel who may be in outlying areas at the JAF site. KI tablets are available in the TSC, OSC, EOF, Training Building, Security, and in Field Team Survey Kits.

4.3.2 Consider distribution of KI during the Accountability process, if practical.

4.3.3 The EOF Radiological Support Coordinator shall ensure that KI is made available to all JAF emergency personnel offsite within the 10-mile EPZ. This shall include downwind survey field teams and may include EOF/JNC personnel as applicable. KI tablets are available in the TSC, OSC, EOF, Training Building, Security, and in Field Team Survey Kits.

4.3.4 Continue to issue one (1) 130 mg KI tablet and a copy of Attachment 6 once per day as necessary to personnel for the duration of the General Emergency.

4.3.5 After the initial issuance of KI, consideration may be given to discontinue ongoing issuance of KI if a release is no longer occurring or is unlikely.



5.0 ATTACHMENTS

1. PATIENT PACKAGE INSERT FOR "THYRO-BLOCK" POTASSIUM IODIDE
2. MEMO RE: POTASSIUM IODIDE ALLERGY
3. STAY TIME VS I-131 CONCENTRATIONS RESULTING IN 5 REM CDE CHILD THYROID
4. IMPLEMENTATION OF THE USE OF POTASSIUM IODIDE (KI) AS A PROTECTIVE ACTION FOR THE PUBLIC
5. USE OF POTASSIUM IODIDE DURING RADIOLOGICAL EMERGENCIES: QUESTIONS & ANSWERS
6. DOH: USE OF POTASSIUM IODIDE DURING RADIOLOGICAL EMERGENCIES - INFORMATION FOR THE PUBLIC

PATIENT PACKAGE INSERT FOR THYRO-BLOCK POTASSIUM IODIDE**IOSAT™  
Tablets**

(Potassium Iodide Tablets, U.S.P.)  
(Pronounced pee-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. 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 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).

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

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.

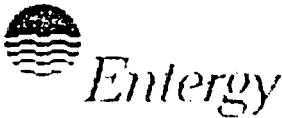
**HOW SUPPLIED**

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, N.Y. 10016  
www.anbex.com

## ATTACHMENT 2

Page 1 of 1

MEMO RE: POTASSIUM IODIDE ALLERGYInteroffice  
CorrespondenceMay 7, 2003  
JSECOHN-05-023

MEMORANDUM TO NICHOLAS AVRAKOTOS  
FROM DEBRA J. CALTABIANO, RN  
SUBJECT: POTASSIUM IODIDE ALLERGY

The following is an updated listing of individuals allergic to Potassium Iodide.

1. Alschimer, Dominick
2. Barnes, Robert F.
3. DeSarro, Anthony J.
4. Feyn, Helen C.
5. Gould, Eric C.
6. Korfien, Janet
7. Moskalych, Thomas R.
8. Proctor, Wesley
9. Ratigan, James D.
10. Reynolds, Peter M.
11. Roman, Paul W.
12. Spicer, Michael P.
13. Stark, Anne L.
14. Stell, Pamela D.
15. Troia, Paul S.
16. Warchol, Michael J.

*Debra J. Caltabiano, RN*  
DEBRA J. CALTABIANO, RN, OHN  
OCCUPATIONAL HEALTH NURSE

DJC:ats

Cc J. Rogers  
J. Haley  
D. Caltabiano  
C. Izyk

## ATTACHMENT 3

Page 1 of 1

STAY TIME VS I-131 CONCENTRATION RESULTING IN 5 REM CDE CHILD  
THYROID

Given: DCF for I-131 =  $2.6E6$  rem/hr/ $\mu$ Ci/cc (a factor of 2 applied for child thyroid)

DCF is in terms of committed dose equivalent (CDE) from EPA-400-R-92-100

In developing DCF, the adult lung class that resulted in the most restrictive value was selected.

The DCF is for dose due to inhalation only.

No credit is taken for radioactive decay.

<u>Stay Time (minutes)</u>	<u>I-131 Concentration <math>\mu</math>Ci/cm<sup>3</sup></u>
96	1.20E-6
84	1.37E-6
72	1.60E-6
60	1.92E-6
48	2.40E-6
36	3.21E-6
24	4.81E-6
12	9.62E-6
9	1.28E-5
6	1.92E-5
3	3.85E-5

ATTACHMENT 4 - IMPLEMENTATION OF USE OF KI

New York State

Nuclear Emergency Preparedness Subcommittee

Technical Issues Task Force

# **Implementation of the Use of Potassium Iodide (KI) as a Protective Action for the Public**

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

The following individuals and organizations participated in the development of this position paper, and agree to its purpose and contents. All participants agree to implement the guidance contained herein, to the extent possible.

Constellation Energy Group (Nine Mile Point)James D. Jones

Name

James D. Jones  
Signature4/8/2003

Date

Entergy Nuclear Northeast (J.A. FitzPatrick and Indian Point Energy Center)Michael Slobodien

Name

Michael Slobodien  
Signature31 March 2003

Date

Rochester Gas and Electric (R.E. Ginna Station)Timothy Laursen

Name

T. Laursen  
Signature4/2/03

Date

New York State Emergency Management OfficeAndrew Feeney

Name

Andrew Feeney  
Signature4/16/03

Date

New York State Health DepartmentAdela Salame-Alfie, Ph.D.

Name

Adela Salame-Alfie  
Signature4/18/03

Date

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

## EXECUTIVE SUMMARY

Utility and State members of the Potassium Iodide (KI) Task Force (KI Task Force) developed this position paper to detail the decision process by which several recommendations regarding KI distribution will be made. The Task Force agreed that upon declaration of a General Emergency by the utility, a recommendation to evacuate and take KI would be made simultaneously. It was also agreed that a single trigger level would be used (projected dose of 5-rem child thyroid). This paper discusses several approaches to determine doses/iodine concentrations and whether one approach was selected over the others due to effectiveness, timeliness, ease of implementation, etc.

The following five specific recommendations were agreed upon by the KI Task Force:

1. ***"Upon declaration of a General Emergency, members of the public that are directed to evacuate shall also be directed to take KI. Captive populations within the evacuated area shall also be directed to take KI".***
2. ***"Members of the public and captive populations who are directed to take KI shall be directed to take one 130-mg tablet per person if they are over one year of age. Persons less than one year of age are directed to take 65 mg (1/2 of a 130-mg tablet)".***
3. ***"As part of a pre-distribution effort, each member of the public should be offered a quantity of KI tablets equivalent to the following: Maximum ETE (in days-rounded up) x 1 KI tablet/day"***
4. ***"Only members of the public who have been directed to evacuate shall be directed to take KI. Emergency workers and captive populations in the evacuated area should also be directed to take KI".***
5. ***"If the indications detailed in section 4.1 are present, emergency workers will be directed to take KI (one 130 mg tablet every 24 hours) at the same time as the general public".***

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

The group recognizes that a strong public information campaign and clear messages during the emergency is key to a successful KI implementation program. Some implementation guidance is provided at the end of the document.

## 1. Purpose

The purpose of this paper is to document a technical assessment of issues associated with the distribution of Potassium Iodide (KI) to the general public, emergency workers and captive populations, and to provide implementation guidance for:

- Usage
  - General Public
  - Emergency Workers
  - Captive Populations
- Dosage and frequency
- Pre-distribution criteria

## 2. Regulatory Requirements and Guidance

### 2.1 Applicable regulations

The NRC amended emergency planning regulations to require that States consider including the prophylactic use of KI as a protective measure for the general public in the plume exposure pathway Emergency Planning Zone in 66 FR 5427 on 19 Jan 2001. (Ref. 1)

FEMA provided notice that the FRPCC revised its 1985 Federal policy regarding KI use in 67 FR 1355 on 10 Jan 2002. (Ref. 2)

### 2.2 Current guidance

The FDA issued guidance on the use of KI in radiation emergencies in December 2001 (Ref. 3). This document concludes "Short-term administration of KI at thyroid blocking doses is safe..." (Ref. 3 IV.A.) and indicates KI dosage is dependent on age and "Predicted Thyroid Exposure" (Ref. 3 IV.B.). This document states that "The recommendation should be interpreted with flexibility as necessary to allow optimally effective and safe dosing..." Additionally, "...the overall benefits of KI far exceed the risks of overdosing..." (Ref. 3 IV.B.).



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ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

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## 2.3 New York State Position

In 2002, New York State, in its consideration of the subject CFR, chose to incorporate KI as an adjunct to the current range of protection actions for the public. The New York State Revised KI Policy was issued in April 2002.

## 2.4 Upcoming Guidance

This Position Paper will be revised as necessary to accommodate any new Federal guidance.

## 3. Assumptions

- For optimal protection against inhaled radioiodine, KI should be administered before or immediately coincident with passage of the radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. (Ref. 3. V.).
- The recommended daily dose protects the user from radioiodine uptake for approximately 24 hours.
- KI should be taken until the person is no longer exposed to radioiodine.
- Radioiodine would only be present in the environment in sufficient quantities to exceed 5 rem child thyroid dose ( $CDE_T$ ), which is the minimum dose at which KI is recommended, if a General Emergency had been declared at the facility from which the source term originates. This assumption is based on the fact that radioiodine can only be present in quantities capable of producing 5 rem child  $CDE_T$  in the presence of significant core damage and loss of primary containment, which are criteria that constitute a General Emergency (GE).
- There will only be one trigger level to recommend KI: 5 rem to the child thyroid ( $CDE_T$ ). This trigger level applies to the general public, emergency workers and captive populations.

## 4. Implementation Analysis

This section presents five recommendations as well as the rationale, benefits and risks associated with each. Recommendations are presented for when to issue a KI recommendation, dosage, and criteria for pre-distribution. These analyses apply to members of the public, emergency workers and captive populations.

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

## 4.1 Task Force Recommendation # 1

*"Upon declaration of a General Emergency, members of the public that are directed to evacuate shall also be directed to take KI. Captive populations within the evacuated area shall also be directed to take KI".*

Analysis:

Three methods were investigated to arrive to this recommendation:

- Use of a dose value,
- Use of deterministic methods, and
- Use of emergency classification.

Each analysis is described separately.

**Using Dose Value**

This analysis examines a method that utilizes projected dose to the thyroid as an indication of recommendation of KI use by the public (specifically, Committed Dose Equivalent to the child thyroid ( $CDE_T$ )). In accordance with FDA Guidance (Ref. 3), child  $CDE_T > 5$  rem is the indication at which KI use should be recommended.

To date, none of the New York State nuclear power facilities utilize real-time iodine monitoring. Hence, releases of radioiodine to the environment during an emergency are inferred from either grab samples or back calculated from field data. Both of these methods require several steps that need, at a minimum:

- Allocation and briefing of personnel, or
- Assembling equipment and procedures to enter the field to collect and analyze samples, reporting the results to an emergency facility, and performing calculations to determine child  $CDE_T$ .

These steps are routinely performed during emergency drills, and our experience indicates that it may take anywhere from 30-90 minutes to calculate the child  $CDE_T$  once a decision has been made to obtain a sample.

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**ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)**

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Normally, the calculation of the child  $CDE_T$  takes place after the completion of protective action recommendations (PARs) based on "plant conditions". The PARs for a General Emergency (GE) are to evacuate people within two-miles around and five miles downwind of the site, and shelter (for heightened awareness) all other ERPAs. Additionally, the emergency facilities that implement this analysis must be activated within 60 minutes of a declaration of an emergency.

Given the above:

- Child  $CDE_T$  would likely be calculated and provided to the County and the State within 105-165 minutes after the declaration of the GE.
- If the County decides that the use of KI is appropriate, this instruction could be provided to the public in 150-210 minutes after the declaration of the GE.

**Use of Deterministic Methods**

In this case, methods that determine child  $CDE_T$  utilizing parameters such as containment high range monitor status, gross core damage estimate, and/or reactor pressure vessel and containment integrity were considered. Unfortunately, the data needed to make even rough estimations of these parameters would typically be assessed after the GE-related recommendations. Hence, the time-delay risks of such a method still apply.

**Benefits of this method**

Administration of KI would occur only in the presence of radioiodine in quantities that meet or exceed the "Predicted thyroid exposure guidance" in Reference 3.

**Risks of this method**

- Administration of KI would occur after the release of radioiodine, decreasing the effectiveness of the prophylaxis.
- Administration of KI would likely occur after other protective actions (that is evacuation) have already been recommended to the public. It is unknown if the public would comply with instructions to bring KI with them.
- If two separate protective actions are issued to the public (for example, an order to evacuate not accompanied by a recommendation to take KI), compliance with the respective recommendations is unknown. It is possible that the public will not differentiate between the protective actions and, when told to evacuate, may take KI as well. The risk is that the public sees these as two separate protective actions, potentially providing confusion and non-compliance.

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)**Use of Emergency Classification**

This analysis examines a method that would use the emergency classification level as the indication for KI use. Specifically, the indication for KI use is a declaration of a General Emergency (GE).

- The General Emergency classification is currently used to determine evacuation PARs.
- If the KI use was always implemented concurrently with the "plant condition" protective actions, the public would receive the recommendation to take KI at the same time they received the order to evacuate; that is, within an hour of the declaration of the General Emergency.
- The declaration of a General Emergency presumes that "Events are in process or have occurred which involve actual or imminent substantial core degradation or melting with potential for loss of containment integrity. Releases can be reasonably expected to exceed EPA Protective Action Guideline exposure levels offsite for more than the immediate site area." (Ref. 8).
- The EPA Protective Action Guideline is to evacuate populations whose actual or projected exposure level equals or exceeds 5 rem Committed Dose Equivalent to the (adult) thyroid (Ref. 9).
- New York State nuclear power plant licensees calculate  $CDE_T$  to the child thyroid, and provide this number to the counties and state for comparison against the PAG's (Ref. 10).
- Hence, when the licensee recommends evacuation due to a General Emergency declaration, a child  $CDE_T \geq 5$  rem either exists or is anticipated to exist at the site boundary or beyond. Though there are exceptions to this (such as GE's declared due to security issues or electrical problems) all GE's have the potential to exceed the 5-rem child  $CDE_T$  level. Calculations performed by New York State on a variety of plant conditions postulated to exist during a GE provide confirmation of this (Ref. 7).
- Given the above, it can be reasonably assumed that the radiological conditions present within the context of a General Emergency will result in meeting or exceeding the child  $CDE_T \geq 5$  rem, which is also the thyroid exposure at which the FDA recommends the use of prophylactic KI.

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ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

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Benefits of this method

- The recommendation to take KI could be issued earlier than the other indication methods, concurrently with evacuation, and would likely occur prior to the presence of radioiodine in the environment, providing maximum loading dose of stable iodine to the thyroid.
- Compliance in taking KI is more likely since all protective actions are being implemented at once. Also, people would be more likely to have access to pre-distributed KI.

Risks to this method

- KI could be ingested without significant radioiodine ever being present in the environment. For example, the accident may not result in a release of radioiodine to the environment. Hence the public incurs the risk of taking KI without benefit.

Risk Analysis

- The risk of taking KI is minor (Ref. 3. IV.B.).
- A GE condition carries a risk of radioiodine release to the public.
- KI should be taken as soon as possible once the risk of radioiodine exposure is present.
- Using projected child CDE<sub>T</sub> could significantly delay KI administration.
- Providing the public with a recommendation to take KI concurrent with an order for evacuation or sheltering provides the earliest and most effective thyroid protection with the greatest likelihood of compliance.

## 4.2 Task Force Recommendation # 2

***"Members of the public and captive populations who are directed to take KI shall be directed to take one 130-mg tablet per person if they are over one year of age. Persons less than one year of age are directed to take 65 mg (1/2 of a 130-mg tablet)".***

Analysis

The FDA guidance (Ref. 3) contains a number of age dependent doses. 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.

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups			
	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	130	1	2
Adults over 18 through 40 yrs			
Pregnant or lactating women			
Adolescents. over 12 through 18 yrs*	65	1/2	1
Children over 3 through 12 yrs			
Over 1 month through 3 years	32	1/4	1/2
Birth through 1 month	16	1/8	1/4

\*Adolescents approaching adult size ( $\geq 70$  kg) should receive the full adult dose (130 mg).

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. However, where feasible, adherence to FDA guidance should be attempted when dosing infants. Excess iodine intake can lead to transient iodine-induced hypothyroidism. Individuals who are intolerant of KI at protective doses, as well as neonates, pregnant, and lactating women, should be given priority with regard to other protective measures (i.e., sheltering, evacuation, and control of the food supply) (Ref. 11).

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ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

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This analysis recognizes:

- Potential confusion relating these doses to the public.
- Practical issues associated with delivering doses based on fractions of a tablet. This would require sectioning small KI tablets in order to achieve a desired delivered dose.
- Likely lack of compliance regarding dose given the above issues.

Benefits to this method

- Instructions for a two dosages (example: "take one tablet for each person in the household over one year of age and a half tablet for infants under one year of age") are easily related in public information material.
- Simple instructions are more likely to be complied with.

Risks to this method

This recommendation would provide a dose to children significantly in excess of the FDA requirements. In accordance with Reference 3, neonates who receive KI should be medically monitored for adverse affects. This action should be incorporated into the State plan.

Risk Analysis

- The risk associated with excessive KI is less than the risk of exposure to radioiodine (Ref. 3).
- The public is more likely to comply with simple dose instructions.
- The FDA has indicated that the use of a single 130-mg dose for all members of the public is safe, regardless of age.

**4.3 Task Force Recommendation # 3**

**"As part of a pre-distribution effort, each member of the public should be offered a quantity of KI tablets equivalent to the following:**

**Maximum ETE (in days-rounded up) x 1 KI tablet/day"**

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)Analysis

- The public should be provided with sufficient KI to assure that thyroid prophylaxis is available to accommodate an expected duration of exposure to radioiodine
- Given that evacuation of the public is the preferred method of preventing exposure, in an incident that could result in the release of radioiodine, the public could be expected to be exposed for a period of time equal to the greatest Evacuation Time Estimate (ETE) for the facility in question.

It is possible that impediments to evacuation may prevent the egress of portions of the population that would otherwise be evacuated (examples are road impediments such as heavy snowfall or transportation resource shortfalls), however, those conditions are accommodated in each nuclear facility's ETE.

- Given the above, pre-distribution efforts should provide sufficient KI in accordance with the following:

Maximum ETE (in days-rounded up) x 1 KI tablet/day = # KI tablet(s) per person that should be pre-distributed

Example: At Nine Mile Point, the maximum amount of time it would take to evacuate any member of the public is 20 hours, as indicated in that facility's ETE (Ref. 4). Rounded up, that is equivalent to 1 day. Plugging this into the above formula:

$$1 \text{ day} \times 1 \text{ KI tablet/day} = 1 \text{ tablet}$$

In this example, one tablet per person should be offered in a pre-distribution method.

#### 4.4 Task Force Recommendation # 4

***"Only members of the public who have been directed to evacuate shall be directed to take KI. Emergency workers and captive populations in the evacuated area should also be directed to take KI".***

Analysis

- The recommendation to take KI should be given to any persons likely to be exposed to radioiodine in quantities that may exceed the "Predicted thyroid exposure guidance" presented in Reference 3.



ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

- This analysis suggests that persons who are ordered to evacuate due to plant conditions or due to subsequently determined projected dose may exceed the predicted thyroid dose, and should take KI.
- For the population who has been told to shelter for the purposes of bringing them to a heightened state of awareness, the risk of radioiodine exposure is low. The reasons for this are:
  - Due to the distance from the reactor, this population is at significantly less risk from radiation exposure from all sources, versus person closer to the reactor.
  - Sheltering is used for projected doses of  $< 1$  rem TEDE or  $< 5$  rem  $CDE_T$ . Hence this population is not at risk of significant exposures to radioiodine.
  - Populations who took, or were recommended to take KI coincident with the order to shelter are at risk of depleting their pre-distributed KI supply, making it unavailable in the event of radioiodine exposure.
  - If it has been determined that an impediment to evacuation exists (lack of transportation resources or road impediment) then the county or state may decide to shelter for the purpose of reducing dose. In this case, KI should be recommended when the projected child  $CDE_T$  exceeds 5 rem.

The conclusion is that the recommendation to take KI should only apply to those persons ordered to evacuate. The above argument assumes that sheltering is being done to bring the public to a heightened state of awareness and not as a means of dose reduction. The above does not apply to sheltering being done in place of evacuation.

## 4.5 Task Force Recommendation # 5

***"If the indications detailed in section 4.1 are present, emergency workers will be directed to take KI (one 130 mg tablet every 24 hours) at the same time as the general public".***

Analysis

- Though currently the trigger levels for emergency worker KI use vary within New York State, all methods use trigger levels greater than the 5 rem child  $CDE_T$  that is associated with the general public.
- The KI Task Force has agreed that there will be one trigger level to recommend KI, and that trigger level will be 5 rem child  $CDE_T$ .

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

- Most emergency workers are members of the public, and many will encounter the evacuating public, who will have been told to take their KI. Additionally, emergency workers have access to the same public information that would be instructing the public to take KI. These emergency workers:
  - May not differentiate themselves from the public in the presence of instructions regarding KI.
  - May not comply with directions that differ from those being broadcast to the public.
- Using the same arguments as in section 4.1, if current methods are continued, emergency workers would receive a recommendation to take KI while in the field. This method:
  - Is likely to result in a recommendation to take KI after exposure to radioiodine has already occurred.
  - Has potential delays due to the communications lag present when contacting several hundred emergency workers in the field.
- Directing emergency workers to take KI in the absence of radioiodine has the same risks and benefits detailed in section 4.1.

## 5. Implementation Considerations

This section provides suggestions for implementing the recommendations contained above.

### 5.1 Licensee actions

The Part 1 Notification Fact Sheet item 7.B. should be modified to read, "Evacuate and implement the KI plan for the following ERPA's". This action should be completed by 5 May 2003.

### 5.2 County and State actions

- Emergency plans should be modified to include:
  - The addition of KI as a protective action for the public
  - The above protective action may be implemented for the evacuating public upon declaration of a General Emergency
  - If the public is sheltered in place, KI may be recommended if any population may be subject to a dose  $> 5$  rem child CDE<sub>T</sub>

ATTACHMENT 4. IMPLEMENTATION OF USE OF KI (continued)

- The recommended dose will be one tablet (130 mg) per person every 24 hours for persons over one year of age; ½ tablet (65 mg) per person every 24 hours for persons under one year of age.
- Emergency workers will be instructed to take KI upon declaration of a General Emergency (that is, concurrent with the recommendation to the evacuating population)
- Public information plans should be modified to include:
  - KI purpose, dose, distribution methods (pre- and post-event) and precautions (consistent with NYS and FDA guidance) in public education materials
  - Incorporation of KI protective action details into EAS follow-up messages

ATTACHMENT 4 IMPLEMENTATION OF USE OF KI (continued)

## 6. References

- (Ref. 1) 66 FR 5427 (19 Jan 2001).
- (Ref. 2) 67 FR 1355 on (10 Jan 2002).
- (Ref. 3) Guidance: Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies: U.S.F.D.A, Dec 2001.
- (Ref. 4) Evacuation Travel Time Estimates, James A. FitzPatrick/Nine Mile Point Emergency Planning Zone, July 1993 (Harborfest Weekend Scenario, Adverse Weather).
- (Ref. 5) EPA 400-R-92-001, Manual or Protective Action Guides and Protective Actions for Nuclear Incidents, U.S.E.P.A, May 1992.
- (Ref. 6) Evacuation Travel Time Estimates, James A. FitzPatrick/Nine Mile Point Emergency Planning Zone, July 1993.
- (Ref. 7) (NYSDOH RASCAL calculation).
- (Ref. 8) NUREG-0654 FEMA REP 1: Appendix 1.
- (Ref. 9) EPA 400-R-92-001, Manual or Protective Action Guides and Protective Actions for Nuclear Incidents, U.S.E.P.A, May 1992, Table 2-2 footnote b.
- (Ref. 10) Implementation of the new EPA Protective Action Guides in Existing Emergency Programs for Nuclear Power Plants in New York State, March 1994.
- (Ref. 11) Guidance for Industry: KI in Radiation Emergencies – Questions and Answers, Revision 1, USFDA, December 2002.

ATTACHMENT 5 - USE OF KI DURING RADIOLOGICAL EMERGENCIES: Q&A**USE OF POTASSIUM IODIDE DURING RADIOLOGICAL EMERGENCIES: Q&A****1. Purpose**

In December 2001 the Food and Drug Administration (FDA) issued new recommendations for the administration of potassium iodide (KI) to the general public as a supplement to evacuation and sheltering during a radiological emergency. The State of New York in turn has revised its 1982 KI Policy to reflect this new guidance. This fact sheet presents general information on KI for members of the public.

**2. What is potassium iodide and what is it used for?**

Potassium iodide (KI) is a chemical compound that can be used to protect the thyroid gland from possible radiation injury caused by radioactive iodine (radioiodine). Some radiological emergencies may release large amounts of radioiodine to the environment. Since iodine concentrates in the thyroid gland, inhalation or ingestion of food contaminated with the radioiodine can lead to radiation injury to the thyroid, including increased risk of thyroid cancer and other thyroid diseases. Thyroid cancer is curable in most cases, but taking measures that reduce the chance of developing cancer are still preferable.

**3. How does potassium iodide work?**

Taking KI saturates the thyroid gland with stable (non-radioactive) iodine. This prevents or reduces the amount of radioiodine that can be taken up by the thyroid.

**4. What age group is at the highest risk from exposure to radioiodine?**

Children are the group with the highest risk. A significant late increase in the incidence of thyroid cancer among children in Belarus, Ukraine and Russia was observed as a result of exposure to radioiodine from the Chernobyl accident. The younger the children, the higher the observed risk. No similar increase was reported for adults.

## ATTACHMENT 5

USE OF KI DURING RADIOLOGICAL EMERGENCIES: Q&A (CONTINUED)

## 5. At what radiation dose is KI indicated?

On December 10, 2001, FDA issued new guidance that sets different radiation doses for different risk groups as follows:

Age Groups	Projected Radiation Dose to the Thyroid
0 - 18 years	5 rem
Pregnant and Lactating Women	5 rem
Over 18 - 40 years	10 rem
Over 40 years	500 rem

## 6. When should KI be taken?

To be most effective, KI should be taken before or shortly after exposure to radioiodine. Even if taken three to four hours after exposure, it still would reduce the uptake of radioiodine by the thyroid. However, its effectiveness would be reduced.

## 7. How will one know if the use of KI is indicated in an emergency?

The use of KI is only indicated in emergencies where the public is likely to be exposed to radioiodine. The State and County health departments monitor all radiation emergencies and will issue advisories informing the public whether KI should be taken. In those cases where KI is indicated, the health departments will also issue advisories on when the administration of KI is no longer needed.

## ATTACHMENT 5

USE OF KI DURING RADIOLOGICAL EMERGENCIES: Q&A (CONTINUED)**8. Is KI effective in all radiation emergencies?**

- KI is quite effective in reducing the radiation dose to the thyroid that could result from the intake of radioiodine;
- KI does not protect other organs or tissues;
- KI does not protect against radiation doses received from sources external to the body, such as the radiation dose from the radioactive plume or from exposure to radioactive materials deposited on the ground; and
- KI does not protect against radioactive materials, other than iodine, which are inhaled or ingested.

**9. What are other protective measures that can be taken in an emergency?**

The existing emergency response plans in New York State rely on evacuation and sheltering of potentially affected populations to prevent their exposure to the radioactive materials that could be released in an accident. Evacuation would continue to be the primary protective measure in such accidents along with sheltering individuals who cannot relocate (captive populations). KI, if used, would only supplement evacuation and sheltering. Also, ingestion of contaminated milk or other food products can lead to significant intake of radioiodine. The primary protective measure for the ingestion pathway is the control of the food supply to prevent ingestion of contaminated products.

**10. Does KI have side effects?**

A study of a sample of those who were administered KI in Poland, following the Chernobyl accident, provides information on side effects of KI. A rate of one in 270 of the newborns receiving 15 mg KI showed transient biochemical hypothyroidism. The effects observed in adults and children were generally of little clinical significance. Observed side effects included gastrointestinal distress in about 2% and rash in about 1%. In two cases, adults with known iodine sensitivity were hospitalized. FDA's position is that the overall benefits of KI far exceed the risks of KI overdosing, especially in children.

## ATTACHMENT 5

USE OF KI DURING RADIOLOGICAL EMERGENCIES: Q&A (CONTINUED)**11. Should any precautions be considered if KI is recommended for public use?**

- Because of possible side effects, individuals with known iodide sensitivity or who have conditions associated with increased risk of iodine hypersensitivity should avoid taking KI;
- Individuals should consult their physicians to determine if they have iodine sensitivity or conditions that may increase their risk of developing iodine hypersensitivity. Such information should be obtained prior to an emergency, since, to be effective, KI needs to be taken within a narrow time window from exposure.
- Because some newborns may develop transient hypothyroidism, newborns given KI should be monitored for hypothyroidism symptoms, and treated if such symptoms are observed. FDA recommends that neonates (newborn to one month), pregnant and lactating women, and those with known iodine sensitivity, should be given priority with regard to other protective measures.

**12. What dosage of KI should be administered?**

In December 2001, FDA issued a revised guidance document, which recommends the following lowest effective dosages for the different age groups:

Age Group	KI Dosage	# 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 to 1 month	16 mg	1/8



## ATTACHMENT 5

USE OF KI DURING RADIOLOGICAL EMERGENCIES: Q&A (CONTINUED)

At the time of this writing, the only currently available FDA-approved over-the-counter formulation is in the 130 mg tablets. 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. Due to the logistics involved in cutting multiple pills, the New York State Commissioner of Health supports the administration of the 130 mg tablet for children in settings such as schools or childcare centers in the event of emergencies. 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 and any suppressive effect of KI on thyroid function has been shown to be minimal, even in young children. For children or babies who cannot take pills, parents and caregivers can cut or crush the pill to make lower doses. For example, if a 130 mg pill were dissolved in 8 ounces of juice or other liquid, one ounce would contain 16 mg of KI.

13. How often should KI be taken?

Administered KI is effective for about 24 hours. The State or local health department will issue instructions regarding how long to continue taking KI. Once individuals are removed from the areas affected by the release, there is no need to continue taking KI.

14. Does KI come in liquid or pill form?

It could be in either form. For prophylactic use in nuclear power plant emergencies in the US it is marketed in a tablet form. After the 1986 Chernobyl accident, Poland used the liquid form to administer KI to its population. Currently, the FDA has only approved the 130 mg KI in tablet form. New York State has requested FDA to expedite approval of other dosages, as well as liquid form.

## ATTACHMENT 5

USE OF KI DURING RADIOLOGICAL EMERGENCIES: Q&A (CONTINUED)

## 15. Is there a shelf life for KI?

The shelf life approved by FDA for different manufacturers of the drug ranges from three to five years. However, if properly stored (protected from air, heat, light and moisture), KI can maintain its form for many years without significant degradation.

## 16. Does one need a prescription to obtain KI?

No. FDA approved the distribution of KI for prophylactic use as an over-the-counter drug.

## 17. Can KI be purchased at local pharmacies?

Despite FDA's approval to distribute it over-the-counter, the vast majority of pharmacies do not have it for sale over-the-counter. Individuals can purchase it over the Internet. New York State has requested a supply of KI for individuals who live within ten miles of a nuclear power plant in New York State (Monroe, Orange, Oswego, Putnam, Rockland, Wayne or Westchester Counties). Information regarding pre-distribution and availability will be provided with the annual emergency planning booklet or calendar distributed by either the power company or county government.

**For additional information contact:**

New York State Department of Health Hotline 1-800-458-1158 ext. 2-7550 or [berp@health.state.ny.us](mailto:berp@health.state.ny.us)

**Other source of information**

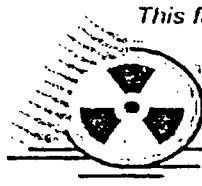
[www.fda.gov/cder/guidance/4825fnl.htm](http://www.fda.gov/cder/guidance/4825fnl.htm)

[www.who.int/environmental informaiton/Information resources/documents/Iodine/guide.pdf](http://www.who.int/environmental_informaiton/Information_resources/documents/Iodine/guide.pdf)

[www.health.state.ny.us/nysdoh/consumer/environ/homeenvi.htm](http://www.health.state.ny.us/nysdoh/consumer/environ/homeenvi.htm)

## ATTACHMENT 6

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

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babies who cannot take pills, parents and caregivers can cut or crush the pill to make lower doses. For example, if a 130 mg pill were dissolved in 8 ounces of juice or other liquid, one ounce would contain 16 mg of KI.

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 Infoline, 1-800-458-1158, extension 2-7550 or [BERP@health.state.ny.us](mailto:BERP@health.state.ny.us)

**Other sources of information:**

[www.fda.gov/cder/guidance/4825fnl.htm](http://www.fda.gov/cder/guidance/4825fnl.htm)

[www.who.int/environmental\\_information/Information\\_resources/documents/iodine/guide.pdf](http://www.who.int/environmental_information/Information_resources/documents/iodine/guide.pdf)

[www.health.state.ny.us/nysdoh/consumer/enviro/homeenvi.htm](http://www.health.state.ny.us/nysdoh/consumer/enviro/homeenvi.htm)

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