Group C

FOIA/PA NO: 2015-0276

RECORDS BEING RELEASED IN THEIR ENTIRETY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

MEMORANDUM TO: Those on the Attached List

FROM: Richard H. Wessman, Director
Incident Response Operations

SUBJECT: FINAL GUIDANCE ON USE OF POTASSIUM IODIDE BY NRC EMPLOYEES

This memorandum provides final guidance for use of potassium iodide by NRC employees. We request that each regional office begin using the attached "read-and-sign" training immediately by providing it to all resident inspectors and all potential site-team members. The responses should be treated as sensitive information. Also attached is a summary of comments provided by many of the NRC offices, along with IRO's disposition.

By copy of this memorandum, we are requesting that the Office of Nuclear Material Safety and Safeguards revise the policy statement in Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," as follows:

> It is the policy of the U.S. Nuclear Regulatory Commission to maintain occupational radiation doses to NRC employees below the limits established in this directive and as low as reasonably achievable (ALARA). Where an approved radiation safety program exists at a site, NRC shall rely on the program to protect NRC employees assigned to the site (i.e., resident inspectors) or visiting the site. This applies to normal operations and emergency response activities. NRC employees shall comply with the requirements established by the local radiation safety program and obtain protective equipment from the program, including potassium iodide (KI) offered for voluntary use during emergency response activities. NRC shall provide dosimeters to employees in accordance with the provisions of this directive. NRC shall also provide protective equipment (including KI for voluntary use) to employees dispatched from NRC offices in response to an emergency.

Attachments: 1. Read and Sign Training
2. Comment Summary

CONTACT: Kevin M. Ramsey, IRO
415-7887

Attachment 1

Addressees for Memorandum Dated:

SUBJECT: FINAL GUIDANCE ON USE OF POTASSIUM IODIDE BY NRC EMPLOYEES

Karen D. Cyr, General Counsel O-15D21
Hubert T. Bell, Inspector General T-5D28
Paul E. Bird, Director, Office of Human Resources T-3A2
Martin J. Virgilio, Director, Office of Nuclear Material Safety and Safeguards T-8A23
Samuel J. Collins, Director, Office of Nuclear Reactor Regulation O-5E7
Ashok C. Thadani, Director, Office of Research T-10F12
Paul H. Lohaus, Director, Office of State and Tribal Programs O-3C10
Hubert J. Miller, Regional Administrator, Region I ..... Region I
Luis A. Reyes, Regional Administrator, Region II ..... Region II
James E. Dyer, Regional Administrator, Region III ..... Region III
Ellis W. Merschoff, Regional Administrator, Region IV ..... Region IV

ANNUAL READ AND SIGN TRAINING
USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why would I be offered KI?

As a resident inspector, regional inspector or site team member, you may be offered potassium iodide (KI) while responding to an emergency. It will be offered only when exposure to radioactive iodine is possible. The purpose of KI is to saturate your thyroid gland with stable iodine to prevent absorption of radioactive iodine you may inhale or ingest. In children and young adults (18 - 40 years old), the primary concern is the prevention of thyroid cancer. In adults over 40 years old, the primary concern is the prevention of hypothyroidism (deficient activity in the thyroid gland). It takes a very large radiation dose to impact thyroid function ($\geq$ 500 cGy[1]) so older adults may not be offered KI unless very large exposures are possible.

The U.S. Food and Drug Administration (FDA) recommends that pregnant women should be given KI to protect themselves and their fetuses, however repeated dosing should be avoided because excess iodine could block fetal thyroid function. Nursing mothers should take KI for their own protection, but not their infants who should get their KI directly. As with fetuses, repeated dosing of newborn infants (0 - 1 month) should be avoided.

When is KI use recommended?

FDA is responsible for guidance on the use of KI. The attached guidance was recently issued by FDA based on lessons learned from the 1986 Chernobyl reactor accident. The guidance is summarized in the following table:

Threshold Radiation Exposures and Recommended Daily Doses of KI[2]				
	Predicted Thyroid Radiation Exposure (cGy)	KI dose (mg)	Number of 130 mg tablets	Number of 65 mg tablets
Adults over 40 yrs	$\geq$ 500	130	1	2
Adults 18-40 yrs	$\geq$ 10			
Pregnant or lactating women[3]	$\geq$ 5			

Why isn't thyroid cancer the primary concern for older adults?

According to experts at the FDA Center for Drug Evaluation and Research, the thyroid gland in children is more sensitive to radioactive iodine. The marked increase in thyroid cancer after the

[1] 1 cGy = 1 rad

[2] FDA Procedural Guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," December 2001. It is available at www.fda.gov/cder/guidance/4825fnl.pdf.

[3] Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," specifies that the dose to a declared pregnant woman must not exceed 0.5 rem during the entire pregnancy. A committed dose equivalent (CDE) of 5 rem to the thyroid is equal to a committed effective dose equivalent (CEDE) of 0.15 rem, which is well below the dose limit for declared pregnant women.

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Chernobyl accident occurred in children less than 4 years of age at the time of the accident. Adults are relatively insensitive to the cancer risks of low doses of radioactive iodine. Also, on a population basis, the risk of adverse reactions to KI increases with age. Therefore, KI is not recommended for older adults unless the potential radiation dose is so high (500 cGy or more) that it could damage the thyroid gland, which would result in a lifelong requirement for thyroid hormone replacement.

Who will provide the KI?

If you are at a licensed facility when an emergency occurs, the licensee will provide any protective equipment required, including KI. If you are in the region when an emergency occurs, the region will provide the KI. Each regional office maintains a supply of KI for site teams dispatched during an emergency. KI is typically provided as tablets and instructions will be included similar to other medications. We do not plan to stock KI at Headquarters. The Site Team typically includes regional staff only. If Headquarters staff are requested, they will obtain their KI from the region leading the Site Team.

Who decides whether KI should be used?

The NRC Site Team Leader, in consultation with the Site Team Protective Measures Coordinator, will decide if KI should be provided to site team members before they arrive at the site. Radiation protection officials at the site will decide when KI should be used and NRC staff at the site should follow their directions as appropriate. In determining whether to provide KI to site team members, managers will assess the total projected exposure to the individuals consistent with maintaining exposures as low as reasonably achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI. In the absence of a Site Team Leader decision to use KI, site team member requests for KI during an emergency will be considered on a case-by-case basis.

How effective is KI?

The effectiveness of KI in blocking the uptake of radioactive iodine by the thyroid is well established. The protective effect of KI lasts for 24 hours. For optimal protection against inhaled, radioactive iodine, KI should be used before or immediately coincident with exposure to a radioactive cloud. though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. If a release is protracted, even a delayed use may help reduce the radiation dose to the thyroid. KI should be taken daily until the risk of significant exposure to radioactive iodine no longer exists. Once radioactive iodine is concentrated in your thyroid, KI is not effective at removing it.

ANNUAL READ AND SIGN TRAINING
USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Are there any side effects?

Adverse reactions are uncommon, but they are possible. The risks of stable iodine include sialadenitis (an inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions and minor rashes. Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects, but they require chronic high doses of stable iodine also.

The use of KI is voluntary and you have the right to decline it. You should decline the KI if any of the following statements apply to you. You are encouraged to consult with your personal physician or the NRC Health Center (301-415-8400) if you have questions about your personal situation

1. Your thyroid gland has been removed.
2. You are sensitive to iodine, or allergic to iodine.
3. You have dermatitis herpetiformis, or hypocomplementemic vasculitis.[4]
4. You have multinodular goiter.
5. You have Grave's disease.
6. You have autoimmune thyroiditis.
7. You are undergoing lithium therapy.
8. You are using potassium-sparing diuretics or Angiotensin Converting Enzyme inhibitors.
9. You have experienced an adverse reaction after a medical diagnostic procedure.
10. You have experienced an adverse reaction after eating seafood or shellfish.
11. You have experienced an adverse reaction after eating iodized salt.
12. You have experienced an adverse reaction after applying topical iodine to a cut or injury. Topical iodine preparations include tincture of iodine, povidone-iodine, betadine, and iodophore solutions.

If I decline, how will that information be used?

The information will be used to plan appropriate exposure control measures. The dose limits for emergency workers in Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," apply whether you take KI or not. Taking KI is one way to minimize your dose, but there are other methods available. NRC managers will need to consider your decision when deciding where you should go and how long you should stay there. If you are a Site Team member, you could be assigned to a position less likely to be exposed to an airborne release. If you are a Resident Inspector, you could become respirator qualified at your site.

[4] Extremely rare conditions associated with an increased risk of iodine hypersensitivity.

ANNUAL READ AND SIGN TRAINING
USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Signature:

I have read the preceding information and the attached FDA guidance, and I understand the benefits and risks of taking potassium iodide (KI). I also understand that I may decline to use KI. If KI was offered to me while responding to an emergency, I would probably respond as follows.

[ ] I would accept it and take it as directed.

[ ] I would decline it.

Please note that if you decline to use KI, we will assume that you have a healthy thyroid and retention of radioactive iodine is possible. If that assumption is incorrect, you may provide additional information below if you wish (not required):

_____

_____

_____ _____

Print Name Signature/Date

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Additional copies are available from:

Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573
(Internet) http://www.fda.gov/cder/guidance/index.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2001
Procedural

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Guidance
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. INTRODUCTION

The objective of this document is to provide guidance to other Federal agencies, including the Environmental Protection Agency (EPA) and the Nuclear Regulatory Commission (NRC), and to state and local governments regarding the safe and effective use of potassium iodide (KI) as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment. The adoption and implementation of these recommendations are at the discretion of the state and local governments responsible for developing regional emergency-response plans related to radiation emergencies.

This guidance updates the Food and Drug Administration (FDA) 1982 recommendations for the use of KI to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. The recommendations in this guidance address KI dosage and the projected radiation exposure at which the drug should be used.

These recommendations were prepared by the Potassium Iodide Working Group, comprising scientists from the FDA's Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH) in collaboration with experts in the field from the National Institutes of Health (NIH). Although they differ in two respects (as discussed in Section IV.B), these revised recommendations are in general accordance with those of the World Health Organization (WHO), as expressed in its *Guidelines for Iodine Prophylaxis Following Nuclear Accidents: Update 1999* (WHO 1999).

II. BACKGROUND

Under 44 CFR 351, the Federal Emergency Management Agency (FEMA) has established roles and responsibilities for Federal agencies in assisting state and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (HHS), are to carry out these roles and responsibilities as members of the Federal Radiological Preparedness Coordinating Committee

(FRPCC). Under 44 CFR 351.23(f), HHS is directed to provide guidance to state and local governments on the use of radioprotective substances and the prophylactic use of drugs (e.g., KI) to reduce the radiation dose to specific organs. This guidance includes information about dosage and projected radiation exposures at which such drugs should be used.

The FDA has provided guidance previously on the use of KI as a thyroid blocking agent. In the *Federal Register* of December 15, 1978, 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 the *Federal Register* of June 29, 1982, FDA announced final recommendations on the administration of KI to the general public in a radiation emergency. Those recommendations were formulated after reviewing studies relating radiation dose to thyroid disease risk that relied on estimates of ***external*** thyroid irradiation after the nuclear detonations at Hiroshima and Nagasaki and analogous studies among children who received therapeutic radiation to the head and neck. Those recommendations concluded that at a projected dose to the thyroid gland of 25 cGy or greater from ingested or inhaled radioiodines, the risks of short-term use of small quantities of KI were outweighed by the benefits of suppressing radioiodine-induced thyroid cancer.[1] The amount of KI recommended at that time was 130 mg per day for adults and children above 1 year of age and 65 mg per day for children below 1 year of age. The guidance that follows revises our 1982 recommendations on the use of KI for thyroid cancer prophylaxis based on a comprehensive review of the data relating radioioidine exposure to thyroid cancer risk accumulated in the aftermath of the 1986 Chernobyl reactor accident.

III. DATA SOURCES

A. Reliance on Data from Chernobyl

In epidemiological studies investigating the relationship between thyroidal radioiodine exposure and risk of thyroid cancer, the estimation of thyroid radiation doses is a critical and complex aspect of the analyses. Estimates of exposure, both for individuals and across populations, have been reached in different studies by the variable combination of (1) direct thyroid measurements in a segment of the exposed population; (2) measurements of ^{131}I (iodine isotope) concentrations in the milk consumed by different groups (e.g., communities) and of the quantity of milk consumed; (3) inference from ground deposition of long-lived radioisotopes released coincidentally and presumably in fixed ratios with radioiodines; and (4) reconstruction of the nature and extent of the actual radiation release.

All estimates of individual and population exposure contain some degree of uncertainty. The uncertainty is least for estimates of individual exposure based on direct thyroid measurements.

[1] For the radiation emitted by ^{131}I (electrons and photons), the radiation-weighting factor is equal to one, so that the absorbed dose to the thyroid gland expressed in centigrays (cGy) is numerically equal to the thyroid equivalent dose expressed in rem (1 cGy = 1 rem).

Uncertainty increases with reliance on milk consumption estimates; is still greater with estimates derived from ground deposition of long-lived radioisotopes, and is highest for estimates that rely heavily on release reconstruction.

Direct measurements of thyroid radioactivity are unavailable from the Hanford, Nevada Test Site, and Marshall Islands exposures. Indeed, the estimates of thyroid radiation doses related to these releases rely heavily on release reconstructions and, in the former two cases, on recall of the extent of milk consumption 40 to 50 years after the fact. In the Marshall Islands cohort, urinary radioiodine excretion data were obtained and used in calculating exposure estimates.

Because of the great uncertainty in the dose estimates from the Hanford and Nevada Test Site exposures and due to the small numbers of thyroid cancers occurring in the populations potentially exposed, the epidemiological studies of the excess thyroid cancer risk related to these radioiodine releases are, at best, inconclusive. As explained below, the dosimetric data derived in the studies of individual and population exposures following the Chernobyl accident, although not perfect, are unquestionably superior to data from previous releases. In addition, the results of the earlier studies are inadequate to refute cogent case control study evidence from Chernobyl of a cause-effect relationship between thyroid radioiodine deposition and thyroid cancer risk.[2]

The Chernobyl reactor accident of April 1986 provides the best-documented example of a massive radionuclide release in which large numbers of people across a broad geographical area were exposed acutely to radioiodines released into the atmosphere. Therefore, the recommendations contained in this guidance are derived from our review of the Chernobyl data as they pertain to the large number of thyroid cancers that occurred. These are the most comprehensive and reliable data available describing the relationship between thyroid radiation dose and risk for thyroid cancer following an environmental release of ^{131}I. In contrast, the exposures resulting from radiation releases at the Hanford Site in Washington State in the mid-1940s and in association with the nuclear detonations at the Nevada Test Site in the 1950s were extended over years, rather than days to weeks, contributing to the difficulty in estimating radioactive dose in those potentially exposed (Davis et al., 1999; Gilbert et al., 1998). The exposure of Marshall Islanders to fallout from the nuclear detonation on Bikini in 1954 involved relatively few people, and although the high rate of subsequent thyroid nodules and cancers in the exposed population was likely caused in large part by radioiodines, the Marshall Islands data provide little insight into the dose-response relationship between radioactive iodine exposure and thyroid cancer risk (Robbins and Adams 1989).

Beginning within a week after the Chernobyl accident, direct measurements of thyroid exposure were made in hundreds of thousands of individuals, across three republics of the former Soviet Union (Robbins and Schneider 2000, Gavrilin et al., 1999, Likhtarev et al., 1993, Zvonova and Balonov 1993). These thyroid measurements were used to derive, in a direct manner, the thyroid doses received by the individuals from whom the measurements were taken. The thyroid measurements were also used as a guide to estimate the thyroid doses received by other people, taking into account differences in age, milk consumption rates, and ground deposition densities, among other things. The thyroid doses derived from thyroid measurements have a large degree

[2] We have included in this guidance an extensive bibliography of the sources used in developing these revised recommendations.

of uncertainty, especially in Belarus, where most of the measurements were made by inexperienced people with detectors that were not ideally suited to the task at hand (Gavrilin et al., 1999 and UNSCEAR 2000). However, as indicated above, the uncertainties attached to thyroid dose estimates derived from thyroid measurements are, as a rule, lower than those obtained without recourse to those measurements.

It is also notable that the thyroid radiation exposures after Chernobyl were virtually all ***internal***, from radioiodines. Despite some degree of uncertainty in the doses received, it is reasonable to conclude that the contribution of external radiation was negligible for most individuals. This distinguishes the Chernobyl exposures from those of the Marshall Islanders. Thus, the increase in thyroid cancer seen after Chernobyl is attributable to ingested or inhaled radioiodines. A comparable burden of excess thyroid cancers could conceivably accrue should U.S. populations be similarly exposed in the event of a nuclear accident. This potential hazard highlights the value of averting such risk by using KI as an adjunct to evacuation, sheltering, and control of contaminated foodstuffs.

B. Thyroid Cancers in the Aftermath of Chernobyl

The Chernobyl reactor accident resulted in massive releases of ^{131}I and other radioiodines. Beginning approximately 4 years after the accident, a sharp increase in the incidence of thyroid cancer among children and adolescents in Belarus and Ukraine (areas covered by the radioactive plume) was observed. In some regions, for the first 4 years of this striking increase, observed cases of thyroid cancer among children aged 0 through 4 years at the time of the accident exceeded expected number of cases by 30- to 60-fold. During the ensuing years, in the most heavily affected areas, incidence is as much as 100-fold compared to pre-Chernobyl rates (Robbins and Schneider 2000; Gavrilin et al., 1999; Likhtarev et al., 1993; Zvonova and Balonov 1993). The majority of cases occurred in children who apparently received less than 30 cGy to the thyroid (Astakhova et al., 1998). A few cases occurred in children exposed to estimated doses of < 1 cGy; however, the uncertainty of these estimates confounded by medical radiation exposures leaves doubt as to the causal role of these doses of radioiodine (Souchkevitch and Tsyb 1996).

The evidence, though indirect, that the increased incidence of thyroid cancer observed among persons exposed during childhood in the most heavily contaminated regions in Belarus, Ukraine, and the Russian Federation is related to exposure to iodine isotopes is, nevertheless, very strong (IARC 2001). We have concluded that the best dose-response information from Chernobyl shows a marked increase in risk of thyroid cancer in children with exposures of 5 cGy or greater (Astakhova et. al., 1998; Ivanov et al., 1999; Kazakov et al., 1992). Among children born more than nine months after the accident in areas traversed by the radioactive plume, the incidence of thyroid cancer has not exceeded preaccident rates, consistent with the short half-life of ^{131}I.

The use of KI in Poland after the Chernobyl accident provides us with useful information regarding its safety and tolerability in the general population. Approximately 10.5 million children under age 16 and 7 million adults received at least one dose of KI. Of note, among newborns receiving single doses of 15 mg KI, 0.37 percent (12 of 3214) showed transient increases in TSH (thyroid stimulating hormone) and decreases in FT4 (free thyroxine). The side

effects among adults and children were generally mild and not clinically significant. Side effects included gastrointestinal distress, which was reported more frequently in children (up to 2 percent, felt to be due to bad taste of SSKI solution) and rash (~1 percent in children and adults). Two allergic reactions were observed in adults with known iodine sensitivity (Nauman and Wolff 1993).

Thus, the studies following the Chernobyl accident support the etiologic role of relatively small doses of radioiodine in the dramatic increase in thyroid cancer among exposed children. Furthermore, it appears that the increased risk occurs with a relatively short latency. Finally, the Polish experience supports the use of KI as a safe and effective means by which to protect against thyroid cancer caused by internal thyroid irradiation from inhalation of contaminated air or ingestion of contaminated food and drink when exposure cannot be prevented by evacuation, sheltering, or food and milk control.

IV. CONCLUSIONS AND RECOMMENDATIONS

A. Use of KI in Radiation Emergencies: Rationale, Effectiveness, Safety

For the reasons discussed above, the Chernobyl data provide the most reliable information available to date on the relationship between internal thyroid radioactive dose and cancer risk. They suggest that the risk of thyroid cancer is inversely related to age, and that, especially in young children, it may accrue at very low levels of radioiodine exposure. We have relied on the Chernobyl data to formulate our specific recommendations below.

The effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well established (Il'in LA, et al., 1972) 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 include sialadenitis (an inflammation of the salivary gland, of which no cases were reported in Poland among users after the Chernobyl accident), gastrointestinal disturbances, allergic reactions and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity.

Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people and in iodine deficient areas but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects more common in iodine sufficient areas, but they require chronic high doses of stable iodine (Rubery 1990). In light of the preceding, individuals with multinodular goiter, Graves' disease, and autoimmune thyroiditis should be treated with caution, especially if dosing extends beyond a few days. The vast majority of such individuals will be adults.

The transient hypothyroidism observed in 0.37 percent (12 of 3214) of neonates treated with KI in Poland after Chernobyl has been without reported sequelae to date. There is no question that the benefits of KI treatment to reduce the risk of thyroid cancer outweigh the risks of such treatment in neonates. Nevertheless, in light of the potential consequences of even transient hypothyroidism for intellectual development, we recommend that neonates (within the first month of life) treated with KI be monitored for this effect by measurement of TSH (and FT4, if indicated) and that thyroid hormone therapy be instituted in cases in which hypothyroidism develops (Bongers-Schokking 2000; Fisher 2000; Calaciura 1995).

B. KI Use in Radiation Emergencies: Treatment Recommendations

After careful review of the data from Chernobyl relating estimated thyroid radiation dose and cancer risk in exposed children, FDA is revising its recommendation for administration of KI based on age, predicted thyroid exposure, and pregnancy and lactation status (see Table).

Threshold Thyroid Radioactive Exposures and Recommended Doses of KI for Different Risk Groups

	Predicted Thyroid exposure(cGy)	KI dose (mg)	# of 130 mg tablets	# of 65 mg tablets
Adults over 40 yrs	≥500	130	1	2
Adults over 18 through 40 yrs	≥10			
Pregnant or lactating women				
Adoles. over 12 through 18 yrs*	≥ 5	65	1/2	1
Children over 3 through 12 yrs		32	1/4	1/2
Over 1 month through 3 years		16	1/8	1/4
Birth through 1 month				

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

The protective effect of KI lasts approximately 24 hours. For optimal prophylaxis, KI should therefore be dosed daily, until a risk of significant exposure to radioiodines by either inhalation or ingestion no longer exists. Individuals intolerant of KI at protective doses, and neonates, pregnant and lactating women (in whom repeat administration of KI raises particular safety issues, see below) should be given priority with regard to other protective measures (i.e., sheltering, evacuation, and control of the food supply).

Note that adults over 40 need take KI only in the case of a projected large internal radiation dose to the thyroid (>500 cGy) to prevent hypothyroidism.

These recommendations are meant to provide states and local authorities as well as other agencies with the best current guidance on safe and effective use of KI to reduce thyroidal radioiodine exposure and thus the risk of thyroid cancer. FDA recognizes that, in the event of an emergency, some or all of the specific dosing recommendations may be very difficult to carry

out given their complexity and the logistics of implementation of a program of KI distribution. The recommendations should therefore be interpreted with flexibility as necessary to allow optimally effective and safe dosing given the exigencies of any particular emergency situation. In this context, we offer the following critical general guidance: ***across populations at risk for radioiodine exposure, the overall benefits of KI far exceed the risks of overdosing, especially in children, though we continue to emphasize particular attention to dose in infants.***

These FDA recommendations differ from those put forward in the World Health Organization (WHO) 1999 guidelines for iodine prophylaxis in two ways. WHO recommends a 130-mg dose of KI for adults and adolescents (over 12 years). For the sake of logistical simplicity in the dispensing and administration of KI to children, FDA recommends a 65-mg dose as standard for all school-age children while allowing for the adult dose (130 mg, 2 X 65 mg tablets) in adolescents approaching adult size. The other difference lies in the threshold for predicted exposure of those up to 18 years of age and of pregnant or lactating women that should trigger KI prophylaxis. WHO recommends a threshold of 1 cGy for these two groups. As stated earlier, FDA has concluded from the Chernobyl data that the most reliable evidence supports a significant increase in the risk of childhood thyroid cancer at exposures of 5 cGy or greater.

The downward KI dose adjustment by age group, based on body size considerations, adheres to the principle of minimum effective dose. The recommended standard dose of KI for all school-age children is the same (65 mg). However, adolescents approaching adult size (i.e., >70 kg) should receive the full adult dose (130 mg) for maximal block of thyroid radioiodine uptake. Neonates ideally should receive the lowest dose (16 mg) of KI. Repeat dosing of KI should be avoided in the neonate to minimize the risk of hypothyroidism during that critical phase of brain development (Bongers-Schokking 2000; Calaciura et al., 1995). KI from tablets (either whole or fractions) or as fresh saturated KI solution may be diluted in milk, formula, or water and the appropriate volume administered to babies. As stated above, we recommend that neonates (within the first month of life) treated with KI be monitored for the potential development of hypothyroidism by measurement of TSH (and FT4, if indicated) and that thyroid hormone therapy be instituted in cases in which hypothyroidism develops (Bongers-Schokking 2000; Fisher 2000; Calaciura et al., 1995).

Pregnant women should be given KI for their own protection and for that of the fetus, as iodine (whether stable or radioactive) readily crosses the placenta. However, because of the risk of blocking fetal thyroid function with excess stable iodine, repeat dosing with KI of pregnant women should be avoided. Lactating females should be administered KI for their own protection, as for other young adults, and potentially to reduce the radioiodine content of the breast milk, but not as a means to deliver KI to infants, who should get their KI directly. As for direct administration of KI, stable iodine as a component of breast milk may also pose a risk of hypothyroidism in nursing neonates. Therefore, repeat dosing with KI should be avoided in the lactating mother, except during continuing severe contamination. If repeat dosing of the mother is necessary, the nursing neonate should be monitored as recommended above.

V. ADDITIONAL CONSIDERATIONS IN PROPHYLAXIS AGAINST THYROID RADIOIODINE EXPOSURE

Certain principles should guide emergency planning and implementation of KI prophylaxis in the event of a radiation emergency. After the Chernobyl accident, across the affected populations, thyroid radiation exposures occurred largely due to consumption of contaminated fresh cow's milk (this contamination was the result of milk cows grazing on fields affected by radioactive fallout) and to a much lesser extent by consumption of contaminated vegetables. In this or similar accidents, for those residing in the immediate area of the accident or otherwise directly exposed to the radioactive plume, inhalation of radioiodines may be a significant contributor to individual and population exposures. As a practical matter, it may not be possible to assess the risk of thyroid exposure from inhaled radioiodines at the time of the emergency. The risk depends on factors such as the magnitude and rate of the radioiodine release, wind direction and other atmospheric conditions, and thus may affect people both near to and far from the accident site.

For optimal protection against inhaled radioiodines, 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. Furthermore, if the release of radioiodines into the atmosphere is protracted, then, of course, even delayed administration may reap benefits by reducing, if incompletely, the total radiation dose to the thyroid.

Prevention of thyroid uptake of ingested radioiodines, once the plume has passed and radiation protection measures (including KI) are in place, is best accomplished by food control measures and not by repeated administration of KI. Because of radioactive decay, grain products and canned milk or vegetables from sources affected by radioactive fallout, if stored for weeks to months after production, pose no radiation risk. Thus, late KI prophylaxis at the time of consumption is not required.

As time is of the essence in optimal prophylaxis with KI, timely administration to the public is a critical consideration in planning the emergency response to a radiation accident and requires a ready supply of KI. State and local governments choosing to incorporate KI into their emergency response plans may consider the option of predistribution of KI to those individuals who do not have a medical condition precluding its use.

VI. SUMMARY

FDA maintains 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 obviate the risk of thyroid cancer in the event of a radiation emergency. Based upon review of the literature, we have proposed lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than we recommended in 1982. As in our 1982 notice in the *Federal Register*, FDA continues to recommend that radiation emergency response plans include provisions, in the event of a radiation emergency, for informing the public about the magnitude of the radiation hazard, about the manner of use of KI and its potential benefits and

risks, and for medical contact, reporting, and assistance systems. FDA also emphasizes that emergency response plans and any systems for ensuring availability of KI to the public should recognize the critical importance of KI administration in advance of exposure to radioiodine. As in the past, FDA continues to work in an ongoing fashion with manufacturers of KI to ensure that high-quality, safe, and effective KI products are available for purchase by consumers as well as by state and local governments wishing to establish stores for emergency distribution.

KI provides protection only for the thyroid from radioiodines. It has no impact on the uptake by the body of other radioactive materials and provides no protection against external irradiation of any kind. FDA emphasizes that the use of KI should be as an adjunct to evacuation (itself not always feasible), sheltering, and control of foodstuffs.

ACKNOWLEDGEMENTS

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SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Contact: Kevin Ramsey, IRO
415-7887

Region I:

Comment 1: Under side effects - Add: *You are concurrently using potassium-containing medications or potassium-sparing diuretics.* This could result in hyperkalemia and cardiac arrhythmia or cardiac arrest - Physicians' Desk Reference (45th Edition).

Response: The comment was forwarded to Dr. Regier at the NRC Health Unit. Dr. Regier responded that it made "medical sense" to take precautions in using potassium iodide (KI) when on potassium-sparing diuretics or Angiotensin Converting Enzyme inhibitors. The language provided by Dr. Regier was incorporated into the guidance.

Comment 2: Under who decides - Add at the end of the paragraph - *In determining whether to recommend the use of KI, the Protective Measures Coordinator will assess the total projected exposure to the individuals consistent with maintaining exposures As Low As Is Reasonably Achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI.*

Response: Comment incorporated.

Comment 3: Threshold Table - To simplify the table for NRC responders, only the top three categories of individuals need be presented (Adults over 40 yrs, Adults 18 - 40 yrs, and Pregnant or lactating women) need be included, along with the U.S. Food and Drug Administration (FDA) recommended projected (predicted) thyroid exposures at which KI should be prescribed (500 rem, 10 rem and 5 rem, respectively). For pregnant or lactating women, a footnote should be added to remind the responder that the recommended NRC guidance for exposure to the fetus is <500 mrem total effective dose equivalent (TEDE) for the entire gestation with the exposures uniformly distributed over entire the nine months.

Response: The table was changed and a footnote was added comparing the thyroid exposure threshold to the dose limit for a declared pregnant woman.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Region II:

Comment 1: What is the frequency (annually - every five years?) for the Read and Sign Document? As you know Region II has "annually" implemented the "Region II KI Allergy Survey" - because each year the number increases for Region II response members who experience side effects from KI or they develop reasons for not being able to take KI. Since implementing the Region II KI Allergy Survey about 7 years ago, we have learned from REACTS that there is a prescription alternative to KI. Does the Agency want to further investigate the use of this alternative for those who are in critical response positions - yet cannot take KI?

Response: We believe annual confirmation will adequately capture changes in individual medical situations. The title of the document was changed to Annual Read and Sign Training. We do not intend to pursue a prescription alternative because NRC is not in a position to recommend or dispense prescription drugs.

Comment 2: Since Region II has KI at each Resident Inspector Office - can a region continue to provide KI at the sites? Region II has had KI at each site for about 10 years and each resident office seems to know exactly where the KI is (in their offices), the guidance for taking KI, and the expiration date.

Response: If the officials responsible for the local radiation safety program have no objection, the region may continue to provide KI to resident inspectors. Resident inspectors should work within the local radiation safety program regarding KI and other protective equipment.

Comment 3: Is the proposed guidance only for KI? Since the KI guidance mentions "licensee and NRC protective equipment" -- do we need further clarifications about the definition of "protective equipment" (respiratory qualifications of site personnel and site team members, NRC respiratory equipment, dosimetry calibrations frequency, dosimetry types, etc). Additional guidance is "definitely needed" for protective equipment; however, do we include the protective equipment guidance in the KI guidance —- or eliminate the protective equipment wording from this guidance and provide separate protective equipment guidance?

Response: The policy statement in Management Directive (MD) 10.131 is intended to a broad statement covering any protective equipment needed by NRC employees. However, the Read and Sign Training document is limited to the KI issue. Implementing guidance for other protective equipment will need to be issued separately.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Region III:

Comment 1: Under Why KI is Offered - The words "very large exposures" should be quantified in the last sentence, so that the trainee may make a more informed decision on whether to be willing to ingest KI.

Response: The last sentence already specifies that very large doses are ≥ 500 cGy. No change.

Comment 2: Under Why Cancer Isn't a Concern - In the last sentence, the clause "dose is so high that it could damage the thyroid gland" should be quantified, so that the trainee could make a more informed decision on whether to be willing to ingest KI.

Response: A quantity was added to the second paragraph.

Comment 3: Under Side Effects - A number of questions and comments were received after staff review of the effects of taking KI on the body. To assist staff in evaluating whether they will accept administration of KI, we should consider providing the opportunity for staff to consult with a physician, for example during the annual NRC physical. Some of the reasons for not taking the pills are not clear - auto immune diseases - some people may have a disorder but not sure if this means they should not take the pills in an emergency.

Response: A statement was added encouraging employees to consult with their personal physician.

Comment 4: Under How Information Will Be Used - Resident Inspectors are relatively more likely to be NRC's "first responders" from their office or residences. Per the current (1996) revisions of their incident response procedures, their duty stations are the Control Room and Technical Support Center. The draft guidance should, therefore, be revised to indicate potential response activities a resident inspector could be requested to perform where KI issuance would **not** be a possible concern, including the potential scenario that a resident may be requested to go to a site from his/her residence during off-hours during an ongoing or potential radioiodine release.

Response: The guidance was revised to clarify this issue, however a lengthy discussion of how management may assign their staff is not appropriate in this guidance.

Comment 5: Under Who Provides the KI - The change in the policy statement implies that KI will no longer be provided directly to the Resident Inspectors by the NRC, but rather the Resident's will rely on the licensee's radiation safety program for the potential use and distribution of KI. This rationale seems reasonable as KI can be considered a form of protective equipment which is most commonly issued by the licensees. If the agency elects to rely on licensees

to provide protective equipment such as KI, the agency needs to ensure that licensees are formally informed that NRC employees (especially NRC Residents) may rely on the licensee (and its procedures) to obtain KI in emergency situations just as they would any other piece of "protective equipment."

Response: We expect Regional Emergency Response Coordinators to discuss this issue during their regular meetings with licensees. In addition, Kathy Gibson in NRR has indicated that she will discuss this issue with Alan Nelson at the Nuclear Energy Institute (NEI). He leads an industry working group on emergency preparedness. This is one mechanism used routinely by the Office of Nuclear Reactor Regulation (NRR) to communicate with industry.

Comment 6: Under Who Decides to Use KI - Consider revising the draft guidance to address situations in which a resident inspector, or a Regional Office-based inspector on official travel, may be requested during off-hours to travel to a site during an ongoing or potential radioiodine release. In such cases, it seems appropriate for these inspectors to have a supply of KI available before they commute to the site. The Protective Measures Coordinator, or a qualified designee, could then advise these inspectors on whether they should ingest KI before they go to the site.

Response: This is another implementation issue that will need to be addressed separately. We don't believe it is necessary for regional inspectors to carry KI at all times, but that is an option managers may want to consider.

Comment 7: Under Who Decides to Use KI - Consider clarifying the draft guidance to better reflect current NRC incident response pre-planning and the allowed options for locating an Emergency Operations Facility (EOF) and a Joint Public Information Center (JPIC). For example, current pre-planning indicates that a relatively large number of Site Team responders' primary destination is an EOF, which may be within the site's plume exposure pathway Emergency Planning Zone (EPZ) but offsite (beyond the Owner Controlled Area). Other licensees' EOFs and/or JPICs may be located near to, but beyond the plume pathway EPZ; however, relevant Site Team personnel's most direct route to either facility may involve traversing a portion of the plume pathway EPZ. Thus, the concern on whether KI should be used is relevant to any Site Team member whose destination could involve entry into the plume exposure pathway EPZ.

Response: This is another implementation issue that will need to be addressed separately. This level of detail isn't appropriate in the Read and Sign Training.

Comment 8: The Regions' Emergency Response Coordinators (ERCs) and/or Protective Measures Coordinators should have prompt access to lists of personnel who would decline ingesting KI based on the "read and sign" training, so that this information can readily be factored into decisions on selecting personnel to travel into a plume exposure pathway EPZ during an event involving an ongoing or potential radioiodine release.

Response: We agree. We will recommend that each region factor the information obtained from the "read and sign" training directly into the roster of potential site team members, or otherwise make it readily available.

Comment 9: There should be provisions for periodic review and updating of the lists of personnel who initially agree or decline to ingest KI based on the "read and sign" training. Who will be the responsible individual for maintaining the "database" of employee responses to the question? It seems reasonable that the Regional ERC or Headquarters Operations Center would be the reasonable choice. A proper tool (and its maintenance) for maintaining this "database" is required (i.e., a computer database rather than a file folder of paper responses).

Response: Regional management will task an individual to coordinate this effort. We believe the Regional ERC is a logical choice. We don't intend to provide a predesigned database, however, we are available to help design a database if needed.

Comment 10: How often should this training document be read and re-certified/re-signed? Health conditions of NRC employees can change and thus situations may arise when declining KI may be the more appropriate choice. Suggestion: Include the training/signature process during the annual physical for employees and/or during the regional training week for those employees who do not have the annual physical. Or, as a minimum, the "read and sign" training on the use of KI, including completion of the related employee signature page, should be done biennially, which is the minimum frequency of some other types of incident response training.

Response: As noted above, we believe the "read and sign" training should be completed annually by each potential Site Team member.

Comment 11: What is the basis for requesting that the staff member document the basis for declination if they choose to decline? We suggest this be deleted.

Response: The intent of asking why the employee would decline KI was to identify individuals who couldn't retain radioactive iodine in their thyroid (i.e., their thyroid was ablated or surgically removed). However, based on concerns raised by commenters, we have revised the document to indicate that we will assume an employee declining KI has a healthy thyroid unless they choose to inform us otherwise.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Region IV:

Comment 1: The decision to administer KI should be a management decision. Region IV recommends that the decision to administer KI be made by the Site Team Leader/Director of Site Operations. This decision would be made upon the recommendation of the Protective Measures Coordinator. Looking at an analogous approach, licensee's consider this to be a protective action decision which is a senior management function.

Response: Comment incorporated.

Comment 2: The guidance contains new FDA criteria for supplying KI according to age groups and for pregnant or lactating females. This new criteria affects how KI would be administered to NRC response personnel and needs to be incorporated into the NRCs emergency response procedures. For example, the current response procedure for the Protective Measures Coordinator is silent on use of KI. In Region IV, we have been using the guidance in Response Technical Manual (RTM) Section J. Region IV recommends that the Response Procedure for Protective Measures Coordinator be revised to include the new guidance.

Response: We agree. We will pursue changes to related procedures to reflect the new guidance.

Comment 3: The read and sign guidance should include information on the effectiveness of KI relative to the timing of administration and the exposure similar to that contained in RTM Section J.

Response: Comment incorporated.

Comment 4: The read-and-sign guidance contains details about administration of KI to children and adolescents which are categories of recipients that would not be included on any NRC response team. Consideration should be given to tailoring the guidance to NRC response personnel.

Response: The table has been revised.

Comment 5: The read and sign guidance should contain a footnote with the conversion factor 1cGy=1Rad.

Response: Comment incorporated.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Office of the General Counsel (OGC):

Comment 1: The proposed NRC policy statement requires NRC employees to comply with the local radiation safety program at a site. This appears to be inconsistent with guidance that accepting KI is voluntary.

Response: We recognize the concern, but if the local radiation safety program establishes an entry requirement for an area that an inspector can't satisfy, the inspector will comply with the program and stay out of the area until the matter is resolved. Please note that we do not expect licensees to require the use of KI.

Office of the Inspector General (OIG):

Comment 1: What happens if an NRC employee refuses to take the KI? Will the employee still be required to be present at the accident site?

Response: Possibly. The dose limits for emergency workers in Management Directive 10.131 (see Part VI of the Handbook) will apply whether the employee takes KI or not. Taking KI is one way to minimize an employee's radiation dose, but there are other methods available also (see Comment 2 from Region I). We expect regional managers to work with employees to address any concerns they may have before they are placed on the roster of Site Team candidates.

Comment 2: What is the purpose in obtaining the employee's reason for refusing the KI? Will these responses be kept in a system of records retrievable under the Freedom of Information Act (FOIA)?

Response: With regard to the reason for refusing KI, see the response to Comment 11 from Region III. With regard to FOIA requests, we intend that these responses will be treated as sensitive information that would not be released to the public.

Comment 3: Page 2, paragraph 2 should state that the "licensee will provide KI."

Response: Comment incorporated.

Office of Human Resources (HR):

No comments.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Office of Nuclear Materials Safety and Safeguards (NMSS):

Comment 1: The attached "read and sign training" includes the question "Who will provide the KI?" The response addresses NRC personnel on site or in the Regional offices, however, it does not address NRC personnel dispatched directly from Headquarters to a site. The training form should be revised to address whether Headquarters will have KI available, and if so who keeps and administers it (e.g., Incident Response Operations or the Office of Administration).

Response: The guidance was revised to state that we do not plan to stock KI at Headquarters. Although Headquarters staff are often part of investigation teams, we would not expect Headquarters staff to be part of a Site Team dispatched during an emergency. If any Headquarters staff are called, they will obtain KI from the Region leading the Site Team.

Comment 2: The training form states that the NRC Protective Measures Coordinator (in consultation with other managers) decides whether KI should be used. This should be clarified to specify that it is the NRC Site Team Protective Measures Coordinator.

Response: Comment incorporated.

Comment 3: It is not clear when or how the read-and-sign training is provided to NRC employees (including Headquarters employees) that might respond to an emergency. Who gets the training? Will it be signed during periodic training or at the time an employee needs to respond to an emergency? Who provides the read and sign training and maintains the record?

Response: We intend that each Region will provide the training to all staff currently on the roster of Site Team candidates, or assigned to a site. This training should be completed before any new staff are placed on the roster or assigned to a site. We don't plan to provide the training to Headquarters staff unless they identified by the Region as potential Site Team members.

Comment 4: Management Directive 10.131 should be reviewed and possibly revised to ensure that the new policy statement is adequately reflected in the remainder of the directive. Also, new procedures may need to be developed if Headquarters is to maintain a KI supply.

Response: We have reviewed MD 10.131 and do not believe other changes are needed. There are no plans to stock KI at Headquarters.

Comment 5: The proposed revision to MD 10.131 contains statements that may result in confusion, either for the NRC employee, the licensee, or both:

> "NRC employees shall comply with the requirements established by the local radiation safety program and obtain protective equipment from the program, including potassium iodide (KI) offered for use during emergency response activities. . . . NRC shall also provide protective equipment (including KI when appropriate) to employees dispatched from NRC offices."

If NRC employees are expected to rely on the local radiation safety program, and if this is the expectation of the licensee whose site the NRC employees are visiting, it may be difficult for the employees to convince the local authority (i.e., licensee) that the NRC has already provided them with the appropriate dosage of KI. The attached "Read-and-Sign Training" indicates that the use of KI is optional, but this is not made clear in the MD. It may be necessary to develop a mechanism to provide assurance to NRC employees that a licensee will have a clear understanding of NRC policy. Note, however, that this may be a moot point if (and only if) the licensee's program is entirely voluntary.

Response: See the response to Comment 5 from Region III. We cannot guarantee that there will be no confusion or misunderstandings, however we plan to work with licensees to ensure they understand our policy.

Office of Nuclear Reactor Regulation (NRR):

Comment 1: On the Use of KI During an Emergency Question and Answer (Q&A), it presently states that "It (KI) will be offered only when exposure to radioactive iodine is possible." The Environmental Protection Agency (EPA) recommendations for use of KI for emergency workers is 25 rem to the thyroid. That is actually quite a lot of radioactive iodine. Some nuclear power plants have limits set at 15 rem and some are still at 25 rem. We suggest that the Q&A statement be revised to read "KI will be offered in accordance with the licensee's requirements for administration of KI to plant emergency workers."

Response: The guidance refers to the fact that KI blocks iodine only and won't be offered when responding to events involving other nuclides. In addition, the response to the question on who decides whether KI should be used (fourth question) already states that radiation protection officials at the site will decide for NRC staff at the site. We believe the guidance adequately addresses this issue without adding this statement. No change.

Comment 2: Under the Side Effects Q&A, rather than say that side effects are "rare," we would substitute "uncommon."

Response: Comment incorporated.

Comment 3: Under the signature block, it may be inappropriate to require that an individual state the reason(s) for declining KI tablets. These reasons may include sensitive medical information. We suggest that the statement of a reason be optional.

Response: The guidance was revised. See the response to Comment 11 from Region III.

Office of Nuclear Regulatory Research (RES):

No comments.

Office of State and Tribal Programs (STP):

No comments.

NRC Health Unit (Dr. Regier):

Comment 1: The document looks okay and in agreement with the FDA. The one spot that might be clarified is no. 3 — dermatitis herpetiformis and hypocomplementemia under the section "Are there any side-effects?" You might add these are exceptionally rare diseases and are associated with an increased incidence of thyroid disease.

Response: The information is provided in a footnote.

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why would I be offered KI?

As a resident inspector, regional inspector or site team member, you may be offered potassium iodide (KI) while responding to an emergency. It will be offered only when exposure to radioactive iodine is possible. The purpose of KI is to saturate your thyroid gland with stable iodine to prevent absorption of radioactive iodine you may inhale or ingest.

When is KI use recommended?

FDA is responsible for guidance on the use of KI. The attached guidance was recently issued by FDA based on lessons learned from the 1986 Chernobyl reactor accident. The guidance is summarized in the following table:

Predicted Thyroid Radiation Exposures at which KI Prophylaxis is Recommended and Recommended Daily Doses of KI[1]

	Predicted Thyroid Radiation Exposure (cGy)	KI dose (mg)	Number of 130 mg tablets	Number of 65 mg tablets
Adults over 40 yrs	≥ 500	130	1	2
Adults 18-40 yrs	≥ 10			
Pregnant or lactating women[2]	≥ 5			

In children and young adults (18 - 40 years old), the primary concern is the prevention of thyroid cancer. In adults over 40 years old, the primary concern is the prevention of hypothyroidism (deficient activity in the thyroid gland). It takes a very large radiation dose to impact thyroid function (≥ 500 cGy[3]).

The U.S. Food and Drug Administration (FDA) recommends that pregnant women should be given KI to protect themselves and their fetuses, however repeated dosing should be avoided because excess iodine could block fetal thyroid function. Nursing mothers should take KI for their own protection, but not their infants who should get their KI directly. As with fetuses, repeated dosing of newborn infants (0 - 1 month) should be avoided.

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[1] FDA Procedural Guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," December 2001. It is available at www.fda.gov/cder/guidance/4825fnl.pdf.

[2] Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," specifies that the dose to a declared pregnant woman must not exceed 0.5 rem during the entire pregnancy. A committed dose equivalent (CDE) of 5 rem to the thyroid is equal to a committed effective dose equivalent (CEDE) of 0.15 rem, which is well below the dose limit for declared pregnant women.

[3] 1 cGy = 1 rad

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why isn't thyroid cancer the primary concern for older adults?

According to experts at the FDA Center for Drug Evaluation and Research, the thyroid gland in children is more sensitive to radioactive iodine. The marked increase in thyroid cancer after the Chernobyl accident occurred in children less than 4 years of age at the time of the accident. Adults are relatively insensitive to the cancer risks of low doses of radioactive iodine. Also, on a population basis, the risk of adverse reactions to KI increases with age. Therefore, KI is not recommended for older adults unless the potential radiation dose is so high (500 cGy or more) that it could damage the thyroid gland, which would result in a lifelong requirement for thyroid hormone replacement.

Who will provide the KI?

NRC will provide KI to each resident inspector office. In addition, each regional office maintains a supply of KI for site teams dispatched during an emergency. KI is typically provided as tablets and instructions will be included similar to other medications. We do not plan to stock KI at Headquarters. The Site Team typically includes regional staff only. If Headquarters staff are requested, they will obtain their KI from the region leading the Site Team.

Who at NRC determines when KI is recommended?

The NRC Regional Administrator, in consultation with the Headquarters Executive Team, will determine when to recommend KI to resident inspectors and site team members. In determining whether to recommend KI, managers will utilize the best available information from licensees and other response organizations to assess the total projected exposure to the individuals consistent with maintaining exposures as low as reasonably achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI. In the absence of a recommendation to use KI, employee requests for KI during an emergency will be considered on a case-by-case basis.

How effective is KI?

The effectiveness of KI in blocking the uptake of radioactive iodine by the thyroid is well established. The protective effect of KI lasts for 24 hours. For optimal protection against inhaled, radioactive iodine, KI should be used before or immediately coincident with exposure to a radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. If a release is protracted, even a delayed use may help reduce the radiation dose to the thyroid. KI should be taken daily until the risk of significant exposure to radioactive iodine no longer exists. Once radioactive iodine is concentrated in your thyroid, KI is not effective at removing it.

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Are there any side effects?

Adverse reactions are uncommon, but they are possible. The risks of stable iodine include sialadenitis (an inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions and minor rashes. Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects, but they require chronic high doses of stable iodine also.

The use of KI is voluntary and you have the right to decline it. You are encouraged to consult with your personal physician or the NRC Health Center (301-415-8400) if you have questions about your personal situation.

You should decline the KI if any of the following statements apply to you.

1. Your thyroid gland has been removed.
2. You are sensitive to iodine, or allergic to iodine [for example, you have experienced an adverse reaction after eating seafood, shellfish, or iodized salt; after applying topical iodine (e.g., tincture of iodine, povidone-iodine, betadine, and iodophore solutions) to a cut or injury; or after a medical diagnostic procedure involving the use of iodinated contrast material that you were told was likely a reaction to iodine].
3. You have dermatitis herpetiformis, or hypocomplementemic vasculitis.[4]

You should use caution in taking KI if you have any of the following conditions, especially if dosing extends beyond a few days:

1. You have multinodular goiter.
2. You have Grave's disease.
3. You have autoimmune thyroiditis.

[4] Extremely rare conditions associated with an increased risk of iodine hypersensitivity.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 3, 2002

MEMORANDUM TO: Those on the Attached List

FROM: Roy P. Zimmerman, Director
Office of Nuclear Security and Incident Response

SUBJECT: FINAL GUIDANCE ON USE OF POTASSIUM IODIDE BY NRC EMPLOYEES

This memorandum provides final guidance for use of potassium iodide by NRC employees. We request that each regional office begin using the attached guidance by providing it to all resident inspectors and all staff on the Site Team roster on an annual basis. Each office should obtain written confirmation from each individual that the guidance was received. The written confirmation records should be maintained in each region. Also attached is a summary of comments provided by many of the NRC offices, along with our disposition.

By copy of this memorandum, we are requesting that the Office of Nuclear Material Safety and Safeguards revise the policy statement in Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," as follows:

> It is the policy of the U.S. Nuclear Regulatory Commission to maintain occupational radiation doses to NRC employees below the limits established in this directive and as low as reasonably achievable (ALARA). Where an approved radiation safety program exists at a site, NRC shall rely on the program to protect NRC employees assigned to the site (i.e., resident inspectors) or visiting the site. This applies to normal operations and emergency response activities. NRC employees shall comply with the requirements established by the local radiation safety program. NRC shall provide dosimeters to employees in accordance with the provisions of this directive. NRC shall also provide potassium iodide (KI) and other protective equipment (as appropriate) to employees involved in emergency response activities.

Attachments: 1. KI Guidance
2. Comment Summary

CONTACT: Kevin M. Ramsey, NSIR/DIRO
301-415-7887

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why would I be offered KI?

As a resident inspector, regional inspector or site team member, you may be offered potassium iodide (KI) while responding to an emergency. It will be offered only when exposure to radioactive iodine is possible. The purpose of KI is to saturate your thyroid gland with stable iodine to prevent absorption of radioactive iodine you may inhale or ingest.

When is KI use recommended?

FDA is responsible for guidance on the use of KI. The attached guidance was recently issued by FDA based on lessons learned from the 1986 Chernobyl reactor accident. The guidance is summarized in the following table:

Predicted Thyroid Radiation Exposures at which KI Prophylaxis is Recommended and Recommended Daily Doses of KI[1]

	Predicted Thyroid Radiation Exposure (cGy)	KI dose (mg)	Number of 130 mg tablets	Number of 65 mg tablets
Adults over 40 yrs	≥ 500	130	1	2
Adults 18-40 yrs	≥ 10			
Pregnant or lactating women[2]	≥ 5			

In children and young adults (18 - 40 years old), the primary concern is the prevention of thyroid cancer. In adults over 40 years old, the primary concern is the prevention of hypothyroidism (deficient activity in the thyroid gland). It takes a very large radiation dose to impact thyroid function (≥ 500 cGy[3]).

The U.S. Food and Drug Administration (FDA) recommends that pregnant women should be given KI to protect themselves and their fetuses, however repeated dosing should be avoided because excess iodine could block fetal thyroid function. Nursing mothers should take KI for their own protection, but not their infants who should get their KI directly. As with fetuses, repeated dosing of newborn infants (0 - 1 month) should be avoided.

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[1] FDA Procedural Guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," December 2001. It is available at www.fda.gov/cder/guidance/4825fnl.pdf.

[2] Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," specifies that the dose to a declared pregnant woman must not exceed 0.5 rem during the entire pregnancy. A committed dose equivalent (CDE) of 5 rem to the thyroid is equal to a committed effective dose equivalent (CEDE) of 0.15 rem, which is well below the dose limit for declared pregnant women.

[3] 1 cGy = 1 rad

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why isn't thyroid cancer the primary concern for older adults?

According to experts at the FDA Center for Drug Evaluation and Research, the thyroid gland in children is more sensitive to radioactive iodine. The marked increase in thyroid cancer after the Chernobyl accident occurred in children less than 4 years of age at the time of the accident. Adults are relatively insensitive to the cancer risks of low doses of radioactive iodine. Also, on a population basis, the risk of adverse reactions to KI increases with age. Therefore, KI is not recommended for older adults unless the potential radiation dose is so high (500 cGy or more) that it could damage the thyroid gland, which would result in a lifelong requirement for thyroid hormone replacement.

Who will provide the KI?

NRC will provide KI to each resident inspector office. In addition, each regional office maintains a supply of KI for site teams dispatched during an emergency. KI is typically provided as tablets and instructions will be included similar to other medications. We do not plan to stock KI at Headquarters. The Site Team typically includes regional staff only. If Headquarters staff are requested, they will obtain their KI from the region leading the Site Team.

Who at NRC determines when KI is recommended?

The NRC Regional Administrator, in consultation with the Headquarters Executive Team, will determine when to recommend KI to resident inspectors and site team members. In determining whether to recommend KI, managers will utilize the best available information from licensees and other response organizations to assess the total projected exposure to the individuals consistent with maintaining exposures as low as reasonably achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI. In the absence of a recommendation to use KI, employee requests for KI during an emergency will be considered on a case-by-case basis.

How effective is KI?

The effectiveness of KI in blocking the uptake of radioactive iodine by the thyroid is well established. The protective effect of KI lasts for 24 hours. For optimal protection against inhaled, radioactive iodine, KI should be used before or immediately coincident with exposure to a radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. If a release is protracted, even a delayed use may help reduce the radiation dose to the thyroid. KI should be taken daily until the risk of significant exposure to radioactive iodine no longer exists. Once radioactive iodine is concentrated in your thyroid, KI is not effective at removing it.

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Are there any side effects?

Adverse reactions are uncommon, but they are possible. The risks of stable iodine include sialadenitis (an inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions and minor rashes. Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects, but they require chronic high doses of stable iodine also.

The use of KI is voluntary and you have the right to decline it. You are encouraged to consult with your personal physician or the NRC Health Center (301-415-8400) if you have questions about your personal situation.

You should decline the KI if any of the following statements apply to you.

1. Your thyroid gland has been removed.
2. You are sensitive to iodine, or allergic to iodine [for example, you have experienced an adverse reaction after eating seafood, shellfish, or iodized salt; after applying topical iodine (e.g., tincture of iodine, povidone-iodine, betadine, and iodophore solutions) to a cut or injury; or after a medical diagnostic procedure involving the use of iodinated contrast material that you were told was likely a reaction to iodine].
3. You have dermatitis herpetiformis, or hypocomplementemic vasculitis.[4]

You should use caution in taking KI if you have any of the following conditions, especially if dosing extends beyond a few days:

1. You have multinodular goiter.
2. You have Grave's disease.
3. You have autoimmune thyroiditis.

[4] Extremely rare conditions associated with an increased risk of iodine hypersensitivity.

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Additional copies are available from:

Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573
(Internet) http://www.fda.gov/cder/guidance/index.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 2001
Procedural

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

MEMORANDUM TO: Those on the Attached List

FROM: Richard H. Wessman, Director
Incident Response Operations

SUBJECT: FINAL GUIDANCE ON USE OF POTASSIUM IODIDE BY NRC EMPLOYEES

This memorandum provides final guidance for use of potassium iodide by NRC employees. We request that each regional office begin using the attached "read-and-sign" training immediately by providing it to all resident inspectors and all potential site-team members. The responses should be treated as sensitive information. Also attached is a summary of comments provided by many of the NRC offices, along with IRO's disposition.

By copy of this memorandum, we are requesting that the Office of Nuclear Material Safety and Safeguards revise the policy statement in Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," as follows:

> It is the policy of the U.S. Nuclear Regulatory Commission to maintain occupational radiation doses to NRC employees below the limits established in this directive and as low as reasonably achievable (ALARA). Where an approved radiation safety program exists at a site, NRC shall rely on the program to protect NRC employees assigned to the site (i.e., resident inspectors) or visiting the site. This applies to normal operations and emergency response activities. NRC employees shall comply with the requirements established by the local radiation safety program and obtain protective equipment from the program, including potassium iodide (KI) offered for voluntary use during emergency response activities. NRC shall provide dosimeters to employees in accordance with the provisions of this directive. NRC shall also provide protective equipment (including KI for voluntary use) to employees dispatched from NRC offices in response to an emergency.

Attachments: 1. Read and Sign Training
2. Comment Summary

CONTACT: Kevin M. Ramsey, IRO
415-7887

Attachment 1

Addressees for Memorandum Dated:

SUBJECT: FINAL GUIDANCE ON USE OF POTASSIUM IODIDE BY NRC EMPLOYEES

Karen D. Cyr, General Counsel O-15D21
Hubert T. Bell, Inspector General T-5D28
Paul E. Bird, Director, Office of Human Resources T-3A2
Martin J. Virgilio, Director, Office of Nuclear Material Safety and Safeguards T-8A23
Samuel J. Collins, Director, Office of Nuclear Reactor Regulation O-5E7
Ashok C. Thadani, Director, Office of Research T-10F12
Paul H. Lohaus, Director, Office of State and Tribal Programs O-3C10
Hubert J. Miller, Regional Administrator, Region I ..... Region I
Luis A. Reyes, Regional Administrator, Region II ..... Region II
James E. Dyer, Regional Administrator, Region III ..... Region III
Ellis W. Merschoff, Regional Administrator, Region IV ..... Region IV

ANNUAL READ AND SIGN TRAINING
USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why would I be offered KI?

As a resident inspector, regional inspector or site team member, you may be offered potassium iodide (KI) while responding to an emergency. It will be offered only when exposure to radioactive iodine is possible. The purpose of KI is to saturate your thyroid gland with stable iodine to prevent absorption of radioactive iodine you may inhale or ingest. In children and young adults (18 - 40 years old), the primary concern is the prevention of thyroid cancer. In adults over 40 years old, the primary concern is the prevention of hypothyroidism (deficient activity in the thyroid gland). It takes a very large radiation dose to impact thyroid function ($\geq$ 500 cGy[1]) so older adults may not be offered KI unless very large exposures are possible.

The U.S. Food and Drug Administration (FDA) recommends that pregnant women should be given KI to protect themselves and their fetuses, however repeated dosing should be avoided because excess iodine could block fetal thyroid function. Nursing mothers should take KI for their own protection, but not their infants who should get their KI directly. As with fetuses, repeated dosing of newborn infants (0 - 1 month) should be avoided.

When is KI use recommended?

FDA is responsible for guidance on the use of KI. The attached guidance was recently issued by FDA based on lessons learned from the 1986 Chernobyl reactor accident. The guidance is summarized in the following table:

Threshold Radiation Exposures and Recommended Daily Doses of KI[2]				
	Predicted Thyroid Radiation Exposure (cGy)	KI dose (mg)	Number of 130 mg tablets	Number of 65 mg tablets
Adults over 40 yrs	$\geq$ 500	130	1	2
Adults 18-40 yrs	$\geq$ 10			
Pregnant or lactating women[3]	$\geq$ 5			

Why isn't thyroid cancer the primary concern for older adults?

According to experts at the FDA Center for Drug Evaluation and Research, the thyroid gland in children is more sensitive to radioactive iodine. The marked increase in thyroid cancer after the

[1] 1 cGy = 1 rad

[2] FDA Procedural Guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," December 2001 It is available at www.fda.gov/cder/guidance/4825fnl.pdf.

[3] Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," specifies that the dose to a declared pregnant woman must not exceed 0.5 rem during the entire pregnancy. A committed dose equivalent (CDE) of 5 rem to the thyroid is equal to a committed effective dose equivalent (CEDE) of 0.15 rem, which is well below the dose limit for declared pregnant women.

ANNUAL READ AND SIGN TRAINING
USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Chernobyl accident occurred in children less than 4 years of age at the time of the accident. Adults are relatively insensitive to the cancer risks of low doses of radioactive iodine. Also, on a population basis, the risk of adverse reactions to KI increases with age. Therefore, KI is not recommended for older adults unless the potential radiation dose is so high (500 cGy or more) that it could damage the thyroid gland, which would result in a lifelong requirement for thyroid hormone replacement.

Who will provide the KI?

If you are at a licensed facility when an emergency occurs, the licensee will provide any protective equipment required, including KI. If you are in the region when an emergency occurs, the region will provide the KI. Each regional office maintains a supply of KI for site teams dispatched during an emergency. KI is typically provided as tablets and instructions will be included similar to other medications. We do not plan to stock KI at Headquarters. The Site Team typically includes regional staff only. If Headquarters staff are requested, they will obtain their KI from the region leading the Site Team.

Who decides whether KI should be used?

The NRC Site Team Leader, in consultation with the Site Team Protective Measures Coordinator, will decide if KI should be provided to site team members before they arrive at the site. Radiation protection officials at the site will decide when KI should be used and NRC staff at the site should follow their directions as appropriate. In determining whether to provide KI to site team members, managers will assess the total projected exposure to the individuals consistent with maintaining exposures as low as reasonably achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI. In the absence of a Site Team Leader decision to use KI, site team member requests for KI during an emergency will be considered on a case-by-case basis.

How effective is KI?

The effectiveness of KI in blocking the uptake of radioactive iodine by the thyroid is well established. The protective effect of KI lasts for 24 hours. For optimal protection against inhaled, radioactive iodine, KI should be used before or immediately coincident with exposure to a radioactive cloud. though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. If a release is protracted, even a delayed use may help reduce the radiation dose to the thyroid. KI should be taken daily until the risk of significant exposure to radioactive iodine no longer exists. Once radioactive iodine is concentrated in your thyroid, KI is not effective at removing it.

Are there any side effects?

Adverse reactions are uncommon, but they are possible. The risks of stable iodine include sialadenitis (an inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions and minor rashes. Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects, but they require chronic high doses of stable iodine also.

The use of KI is voluntary and you have the right to decline it. You should decline the KI if any of the following statements apply to you. You are encouraged to consult with your personal physician or the NRC Health Center (301-415-8400) if you have questions about your personal situation

1. Your thyroid gland has been removed.
2. You are sensitive to iodine, or allergic to iodine.
3. You have dermatitis herpetiformis, or hypocomplementemic vasculitis.[4]
4. You have multinodular goiter.
5. You have Grave's disease.
6. You have autoimmune thyroiditis.
7. You are undergoing lithium therapy.
8. You are using potassium-sparing diuretics or Angiotensin Converting Enzyme inhibitors.
9. You have experienced an adverse reaction after a medical diagnostic procedure.
10. You have experienced an adverse reaction after eating seafood or shellfish.
11. You have experienced an adverse reaction after eating iodized salt.
12. You have experienced an adverse reaction after applying topical iodine to a cut or injury. Topical iodine preparations include tincture of iodine, povidone-iodine, betadine, and iodophore solutions.

If I decline, how will that information be used?

The information will be used to plan appropriate exposure control measures. The dose limits for emergency workers in Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," apply whether you take KI or not. Taking KI is one way to minimize your dose, but there are other methods available. NRC managers will need to consider your decision when deciding where you should go and how long you should stay there. If you are a Site Team member, you could be assigned to a position less likely to be exposed to an airborne release. If you are a Resident Inspector, you could become respirator qualified at your site.

[4] Extremely rare conditions associated with an increased risk of iodine hypersensitivity.

ANNUAL READ AND SIGN TRAINING
USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Signature:

I have read the preceding information and the attached FDA guidance, and I understand the benefits and risks of taking potassium iodide (KI). I also understand that I may decline to use KI. If KI was offered to me while responding to an emergency, I would probably respond as follows.

[ ] I would accept it and take it as directed.

[ ] I would decline it.

Please note that if you decline to use KI, we will assume that you have a healthy thyroid and retention of radioactive iodine is possible. If that assumption is incorrect, you may provide additional information below if you wish (not required):

_____

_____

_____ _____

Print Name Signature/Date

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Contact: Kevin Ramsey, IRO
415-7887

Region I:

Comment 1: Under side effects - Add: *You are concurrently using potassium-containing medications or potassium-sparing diuretics.* This could result in hyperkalemia and cardiac arrhythmia or cardiac arrest - Physicians' Desk Reference (45th Edition).

Response: The comment was forwarded to Dr. Regier at the NRC Health Unit. Dr. Regier responded that it made "medical sense" to take precautions in using potassium iodide (KI) when on potassium-sparing diuretics or Angiotensin Converting Enzyme inhibitors. The language provided by Dr. Regier was incorporated into the guidance.

Comment 2: Under who decides - Add at the end of the paragraph - *In determining whether to recommend the use of KI, the Protective Measures Coordinator will assess the total projected exposure to the individuals consistent with maintaining exposures As Low As Is Reasonably Achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI.*

Response: Comment incorporated.

Comment 3: Threshold Table - To simplify the table for NRC responders, only the top three categories of individuals need be presented (Adults over 40 yrs, Adults 18 - 40 yrs, and Pregnant or lactating women) need be included, along with the U.S. Food and Drug Administration (FDA) recommended projected (predicted) thyroid exposures at which KI should be prescribed (500 rem, 10 rem and 5 rem, respectively). For pregnant or lactating women, a footnote should be added to remind the responder that the recommended NRC guidance for exposure to the fetus is <500 mrem total effective dose equivalent (TEDE) for the entire gestation with the exposures uniformly distributed over entire the nine months.

Response: The table was changed and a footnote was added comparing the thyroid exposure threshold to the dose limit for a declared pregnant woman.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Region II:

Comment 1: What is the frequency (annually - every five years?) for the Read and Sign Document? As you know Region II has "annually" implemented the "Region II KI Allergy Survey" - because each year the number increases for Region II response members who experience side effects from KI or they develop reasons for not being able to take KI. Since implementing the Region II KI Allergy Survey about 7 years ago, we have learned from REACTS that there is a prescription alternative to KI. Does the Agency want to further investigate the use of this alternative for those who are in critical response positions - yet cannot take KI?

Response: We believe annual confirmation will adequately capture changes in individual medical situations. The title of the document was changed to Annual Read and Sign Training. We do not intend to pursue a prescription alternative because NRC is not in a position to recommend or dispense prescription drugs.

Comment 2: Since Region II has KI at each Resident Inspector Office - can a region continue to provide KI at the sites? Region II has had KI at each site for about 10 years and each resident office seems to know exactly where the KI is (in their offices), the guidance for taking KI, and the expiration date.

Response: If the officials responsible for the local radiation safety program have no objection, the region may continue to provide KI to resident inspectors. Resident inspectors should work within the local radiation safety program regarding KI and other protective equipment.

Comment 3: Is the proposed guidance only for KI? Since the KI guidance mentions "licensee and NRC protective equipment" -- do we need further clarifications about the definition of "protective equipment" (respiratory qualifications of site personnel and site team members, NRC respiratory equipment, dosimetry calibrations frequency, dosimetry types, etc). Additional guidance is "definitely needed" for protective equipment; however, do we include the protective equipment guidance in the KI guidance —- or eliminate the protective equipment wording from this guidance and provide separate protective equipment guidance?

Response: The policy statement in Management Directive (MD) 10.131 is intended to a broad statement covering any protective equipment needed by NRC employees. However, the Read and Sign Training document is limited to the KI issue. Implementing guidance for other protective equipment will need to be issued separately.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Region III:

Comment 1: Under Why KI is Offered - The words "very large exposures" should be quantified in the last sentence, so that the trainee may make a more informed decision on whether to be willing to ingest KI.

Response: The last sentence already specifies that very large doses are ≥ 500 cGy. No change.

Comment 2: Under Why Cancer Isn't a Concern - In the last sentence, the clause "dose is so high that it could damage the thyroid gland" should be quantified, so that the trainee could make a more informed decision on whether to be willing to ingest KI.

Response: A quantity was added to the second paragraph.

Comment 3: Under Side Effects - A number of questions and comments were received after staff review of the effects of taking KI on the body. To assist staff in evaluating whether they will accept administration of KI, we should consider providing the opportunity for staff to consult with a physician, for example during the annual NRC physical. Some of the reasons for not taking the pills are not clear - auto immune diseases - some people may have a disorder but not sure if this means they should not take the pills in an emergency.

Response: A statement was added encouraging employees to consult with their personal physician.

Comment 4: Under How Information Will Be Used - Resident Inspectors are relatively more likely to be NRC's "first responders" from their office or residences. Per the current (1996) revisions of their incident response procedures, their duty stations are the Control Room and Technical Support Center. The draft guidance should, therefore, be revised to indicate potential response activities a resident inspector could be requested to perform where KI issuance would **not** be a possible concern, including the potential scenario that a resident may be requested to go to a site from his/her residence during off-hours during an ongoing or potential radioiodine release.

Response: The guidance was revised to clarify this issue, however a lengthy discussion of how management may assign their staff is not appropriate in this guidance.

Comment 5: Under Who Provides the KI - The change in the policy statement implies that KI will no longer be provided directly to the Resident Inspectors by the NRC, but rather the Resident's will rely on the licensee's radiation safety program for the potential use and distribution of KI. This rationale seems reasonable as KI can be considered a form of protective equipment which is most commonly issued by the licensees. If the agency elects to rely on licensees

to provide protective equipment such as KI, the agency needs to ensure that licensees are formally informed that NRC employees (especially NRC Residents) may rely on the licensee (and its procedures) to obtain KI in emergency situations just as they would any other piece of "protective equipment."

Response: We expect Regional Emergency Response Coordinators to discuss this issue during their regular meetings with licensees. In addition, Kathy Gibson in NRR has indicated that she will discuss this issue with Alan Nelson at the Nuclear Energy Institute (NEI). He leads an industry working group on emergency preparedness. This is one mechanism used routinely by the Office of Nuclear Reactor Regulation (NRR) to communicate with industry.

Comment 6: Under Who Decides to Use KI - Consider revising the draft guidance to address situations in which a resident inspector, or a Regional Office-based inspector on official travel, may be requested during off-hours to travel to a site during an ongoing or potential radioiodine release. In such cases, it seems appropriate for these inspectors to have a supply of KI available before they commute to the site. The Protective Measures Coordinator, or a qualified designee, could then advise these inspectors on whether they should ingest KI before they go to the site.

Response: This is another implementation issue that will need to be addressed separately. We don't believe it is necessary for regional inspectors to carry KI at all times, but that is an option managers may want to consider.

Comment 7: Under Who Decides to Use KI - Consider clarifying the draft guidance to better reflect current NRC incident response pre-planning and the allowed options for locating an Emergency Operations Facility (EOF) and a Joint Public Information Center (JPIC). For example, current pre-planning indicates that a relatively large number of Site Team responders' primary destination is an EOF, which may be within the site's plume exposure pathway Emergency Planning Zone (EPZ) but offsite (beyond the Owner Controlled Area). Other licensees' EOFs and/or JPICs may be located near to, but beyond the plume pathway EPZ; however, relevant Site Team personnel's most direct route to either facility may involve traversing a portion of the plume pathway EPZ. Thus, the concern on whether KI should be used is relevant to any Site Team member whose destination could involve entry into the plume exposure pathway EPZ.

Response: This is another implementation issue that will need to be addressed separately. This level of detail isn't appropriate in the Read and Sign Training.

Comment 8: The Regions' Emergency Response Coordinators (ERCs) and/or Protective Measures Coordinators should have prompt access to lists of personnel who would decline ingesting KI based on the "read and sign" training, so that this information can readily be factored into decisions on selecting personnel to travel into a plume exposure pathway EPZ during an event involving an ongoing or potential radioiodine release.

Response: We agree. We will recommend that each region factor the information obtained from the "read and sign" training directly into the roster of potential site team members, or otherwise make it readily available.

Comment 9: There should be provisions for periodic review and updating of the lists of personnel who initially agree or decline to ingest KI based on the "read and sign" training. Who will be the responsible individual for maintaining the "database" of employee responses to the question? It seems reasonable that the Regional ERC or Headquarters Operations Center would be the reasonable choice. A proper tool (and its maintenance) for maintaining this "database" is required (i.e., a computer database rather than a file folder of paper responses).

Response: Regional management will task an individual to coordinate this effort. We believe the Regional ERC is a logical choice. We don't intend to provide a predesigned database, however, we are available to help design a database if needed.

Comment 10: How often should this training document be read and re-certified/re-signed? Health conditions of NRC employees can change and thus situations may arise when declining KI may be the more appropriate choice. Suggestion: Include the training/signature process during the annual physical for employees and/or during the regional training week for those employees who do not have the annual physical. Or, as a minimum, the "read and sign" training on the use of KI, including completion of the related employee signature page, should be done biennially, which is the minimum frequency of some other types of incident response training.

Response: As noted above, we believe the "read and sign" training should be completed annually by each potential Site Team member.

Comment 11: What is the basis for requesting that the staff member document the basis for declination if they choose to decline? We suggest this be deleted.

Response: The intent of asking why the employee would decline KI was to identify individuals who couldn't retain radioactive iodine in their thyroid (i.e., their thyroid was ablated or surgically removed). However, based on concerns raised by commenters, we have revised the document to indicate that we will assume an employee declining KI has a healthy thyroid unless they choose to inform us otherwise.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Region IV:

Comment 1: The decision to administer KI should be a management decision. Region IV recommends that the decision to administer KI be made by the Site Team Leader/Director of Site Operations. This decision would be made upon the recommendation of the Protective Measures Coordinator. Looking at an analogous approach, licensee's consider this to be a protective action decision which is a senior management function.

Response: Comment incorporated.

Comment 2: The guidance contains new FDA criteria for supplying KI according to age groups and for pregnant or lactating females. This new criteria affects how KI would be administered to NRC response personnel and needs to be incorporated into the NRCs emergency response procedures. For example, the current response procedure for the Protective Measures Coordinator is silent on use of KI. In Region IV, we have been using the guidance in Response Technical Manual (RTM) Section J. Region IV recommends that the Response Procedure for Protective Measures Coordinator be revised to include the new guidance.

Response: We agree. We will pursue changes to related procedures to reflect the new guidance.

Comment 3: The read and sign guidance should include information on the effectiveness of KI relative to the timing of administration and the exposure similar to that contained in RTM Section J.

Response: Comment incorporated.

Comment 4: The read-and-sign guidance contains details about administration of KI to children and adolescents which are categories of recipients that would not be included on any NRC response team. Consideration should be given to tailoring the guidance to NRC response personnel.

Response: The table has been revised.

Comment 5: The read and sign guidance should contain a footnote with the conversion factor 1cGy=1Rad.

Response: Comment incorporated.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Office of the General Counsel (OGC):

Comment 1: The proposed NRC policy statement requires NRC employees to comply with the local radiation safety program at a site. This appears to be inconsistent with guidance that accepting KI is voluntary.

Response: We recognize the concern, but if the local radiation safety program establishes an entry requirement for an area that an inspector can't satisfy, the inspector will comply with the program and stay out of the area until the matter is resolved. Please note that we do not expect licensees to require the use of KI.

Office of the Inspector General (OIG):

Comment 1: What happens if an NRC employee refuses to take the KI? Will the employee still be required to be present at the accident site?

Response: Possibly. The dose limits for emergency workers in Management Directive 10.131 (see Part VI of the Handbook) will apply whether the employee takes KI or not. Taking KI is one way to minimize an employee's radiation dose, but there are other methods available also (see Comment 2 from Region I). We expect regional managers to work with employees to address any concerns they may have before they are placed on the roster of Site Team candidates.

Comment 2: What is the purpose in obtaining the employee's reason for refusing the KI? Will these responses be kept in a system of records retrievable under the Freedom of Information Act (FOIA)?

Response: With regard to the reason for refusing KI, see the response to Comment 11 from Region III. With regard to FOIA requests, we intend that these responses will be treated as sensitive information that would not be released to the public.

Comment 3: Page 2, paragraph 2 should state that the "licensee will provide KI."

Response: Comment incorporated.

Office of Human Resources (HR):

No comments.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Office of Nuclear Materials Safety and Safeguards (NMSS):

Comment 1: The attached "read and sign training" includes the question "Who will provide the KI?" The response addresses NRC personnel on site or in the Regional offices, however, it does not address NRC personnel dispatched directly from Headquarters to a site. The training form should be revised to address whether Headquarters will have KI available, and if so who keeps and administers it (e.g., Incident Response Operations or the Office of Administration).

Response: The guidance was revised to state that we do not plan to stock KI at Headquarters. Although Headquarters staff are often part of investigation teams, we would not expect Headquarters staff to be part of a Site Team dispatched during an emergency. If any Headquarters staff are called, they will obtain KI from the Region leading the Site Team.

Comment 2: The training form states that the NRC Protective Measures Coordinator (in consultation with other managers) decides whether KI should be used. This should be clarified to specify that it is the NRC Site Team Protective Measures Coordinator.

Response: Comment incorporated.

Comment 3: It is not clear when or how the read-and-sign training is provided to NRC employees (including Headquarters employees) that might respond to an emergency. Who gets the training? Will it be signed during periodic training or at the time an employee needs to respond to an emergency? Who provides the read and sign training and maintains the record?

Response: We intend that each Region will provide the training to all staff currently on the roster of Site Team candidates, or assigned to a site. This training should be completed before any new staff are placed on the roster or assigned to a site. We don't plan to provide the training to Headquarters staff unless they identified by the Region as potential Site Team members.

Comment 4: Management Directive 10.131 should be reviewed and possibly revised to ensure that the new policy statement is adequately reflected in the remainder of the directive. Also, new procedures may need to be developed if Headquarters is to maintain a KI supply.

Response: We have reviewed MD 10.131 and do not believe other changes are needed. There are no plans to stock KI at Headquarters.

Comment 5: The proposed revision to MD 10.131 contains statements that may result in confusion, either for the NRC employee, the licensee, or both:

> "NRC employees shall comply with the requirements established by the local radiation safety program and obtain protective equipment from the program, including potassium iodide (KI) offered for use during emergency response activities. . . . NRC shall also provide protective equipment (including KI when appropriate) to employees dispatched from NRC offices."

If NRC employees are expected to rely on the local radiation safety program, and if this is the expectation of the licensee whose site the NRC employees are visiting, it may be difficult for the employees to convince the local authority (i.e., licensee) that the NRC has already provided them with the appropriate dosage of KI. The attached "Read-and-Sign Training" indicates that the use of KI is optional, but this is not made clear in the MD. It may be necessary to develop a mechanism to provide assurance to NRC employees that a licensee will have a clear understanding of NRC policy. Note, however, that this may be a moot point if (and only if) the licensee's program is entirely voluntary.

Response: See the response to Comment 5 from Region III. We cannot guarantee that there will be no confusion or misunderstandings, however we plan to work with licensees to ensure they understand our policy.

Office of Nuclear Reactor Regulation (NRR):

Comment 1: On the Use of KI During an Emergency Question and Answer (Q&A), it presently states that "It (KI) will be offered only when exposure to radioactive iodine is possible." The Environmental Protection Agency (EPA) recommendations for use of KI for emergency workers is 25 rem to the thyroid. That is actually quite a lot of radioactive iodine. Some nuclear power plants have limits set at 15 rem and some are still at 25 rem. We suggest that the Q&A statement be revised to read "KI will be offered in accordance with the licensee's requirements for administration of KI to plant emergency workers."

Response: The guidance refers to the fact that KI blocks iodine only and won't be offered when responding to events involving other nuclides. In addition, the response to the question on who decides whether KI should be used (fourth question) already states that radiation protection officials at the site will decide for NRC staff at the site. We believe the guidance adequately addresses this issue without adding this statement. No change.

SUMMARY OF COMMENTS ON DRAFT GUIDANCE FOR
USE OF POTASSIUM IODIDE BY NRC EMPLOYEES
ISSUED DECEMBER 14, 2001

Comment 2: Under the Side Effects Q&A, rather than say that side effects are "rare," we would substitute "uncommon."

Response: Comment incorporated.

Comment 3: Under the signature block, it may be inappropriate to require that an individual state the reason(s) for declining KI tablets. These reasons may include sensitive medical information. We suggest that the statement of a reason be optional.

Response: The guidance was revised. See the response to Comment 11 from Region III.

Office of Nuclear Regulatory Research (RES):

No comments.

Office of State and Tribal Programs (STP):

No comments.

NRC Health Unit (Dr. Regier):

Comment 1: The document looks okay and in agreement with the FDA. The one spot that might be clarified is no. 3 — dermatitis herpetiformis and hypocomplementemia under the section "Are there any side-effects?" You might add these are exceptionally rare diseases and are associated with an increased incidence of thyroid disease.

Response: The information is provided in a footnote.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 3, 2002

MEMORANDUM TO: Those on the Attached List

FROM: Roy P. Zimmerman, Director
Office of Nuclear Security and Incident Response

SUBJECT: FINAL GUIDANCE ON USE OF POTASSIUM IODIDE BY NRC EMPLOYEES

This memorandum provides final guidance for use of potassium iodide by NRC employees. We request that each regional office begin using the attached guidance by providing it to all resident inspectors and all staff on the Site Team roster on an annual basis. Each office should obtain written confirmation from each individual that the guidance was received. The written confirmation records should be maintained in each region. Also attached is a summary of comments provided by many of the NRC offices, along with our disposition.

By copy of this memorandum, we are requesting that the Office of Nuclear Material Safety and Safeguards revise the policy statement in Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," as follows:

> It is the policy of the U.S. Nuclear Regulatory Commission to maintain occupational radiation doses to NRC employees below the limits established in this directive and as low as reasonably achievable (ALARA). Where an approved radiation safety program exists at a site, NRC shall rely on the program to protect NRC employees assigned to the site (i.e., resident inspectors) or visiting the site. This applies to normal operations and emergency response activities. NRC employees shall comply with the requirements established by the local radiation safety program. NRC shall provide dosimeters to employees in accordance with the provisions of this directive. NRC shall also provide potassium iodide (KI) and other protective equipment (as appropriate) to employees involved in emergency response activities.

Attachments: 1. KI Guidance
2. Comment Summary

CONTACT: Kevin M. Ramsey, NSIR/DIRO
301-415-7887

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why would I be offered KI?

As a resident inspector, regional inspector or site team member, you may be offered potassium iodide (KI) while responding to an emergency. It will be offered only when exposure to radioactive iodine is possible. The purpose of KI is to saturate your thyroid gland with stable iodine to prevent absorption of radioactive iodine you may inhale or ingest.

When is KI use recommended?

FDA is responsible for guidance on the use of KI. The attached guidance was recently issued by FDA based on lessons learned from the 1986 Chernobyl reactor accident. The guidance is summarized in the following table:

Predicted Thyroid Radiation Exposures at which KI Prophylaxis is Recommended and Recommended Daily Doses of KI[1]

	Predicted Thyroid Radiation Exposure (cGy)	KI dose (mg)	Number of 130 mg tablets	Number of 65 mg tablets
Adults over 40 yrs	≥ 500	130	1	2
Adults 18-40 yrs	≥ 10			
Pregnant or lactating women[2]	≥ 5			

In children and young adults (18 - 40 years old), the primary concern is the prevention of thyroid cancer. In adults over 40 years old, the primary concern is the prevention of hypothyroidism (deficient activity in the thyroid gland). It takes a very large radiation dose to impact thyroid function (≥ 500 cGy[3]).

The U.S. Food and Drug Administration (FDA) recommends that pregnant women should be given KI to protect themselves and their fetuses, however repeated dosing should be avoided because excess iodine could block fetal thyroid function. Nursing mothers should take KI for their own protection, but not their infants who should get their KI directly. As with fetuses, repeated dosing of newborn infants (0 - 1 month) should be avoided.

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[1] FDA Procedural Guidance, "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies," December 2001. It is available at www.fda.gov/cder/guidance/4825fnl.pdf.

[2] Management Directive 10.131, "Protection of NRC Employees Against Ionizing Radiation," specifies that the dose to a declared pregnant woman must not exceed 0.5 rem during the entire pregnancy. A committed dose equivalent (CDE) of 5 rem to the thyroid is equal to a committed effective dose equivalent (CEDE) of 0.15 rem, which is well below the dose limit for declared pregnant women.

[3] 1 cGy = 1 rad

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Why isn't thyroid cancer the primary concern for older adults?

According to experts at the FDA Center for Drug Evaluation and Research, the thyroid gland in children is more sensitive to radioactive iodine. The marked increase in thyroid cancer after the Chernobyl accident occurred in children less than 4 years of age at the time of the accident. Adults are relatively insensitive to the cancer risks of low doses of radioactive iodine. Also, on a population basis, the risk of adverse reactions to KI increases with age. Therefore, KI is not recommended for older adults unless the potential radiation dose is so high (500 cGy or more) that it could damage the thyroid gland, which would result in a lifelong requirement for thyroid hormone replacement.

Who will provide the KI?

NRC will provide KI to each resident inspector office. In addition, each regional office maintains a supply of KI for site teams dispatched during an emergency. KI is typically provided as tablets and instructions will be included similar to other medications. We do not plan to stock KI at Headquarters. The Site Team typically includes regional staff only. If Headquarters staff are requested, they will obtain their KI from the region leading the Site Team.

Who at NRC determines when KI is recommended?

The NRC Regional Administrator, in consultation with the Headquarters Executive Team, will determine when to recommend KI to resident inspectors and site team members. In determining whether to recommend KI, managers will utilize the best available information from licensees and other response organizations to assess the total projected exposure to the individuals consistent with maintaining exposures as low as reasonably achievable and commensurate with the importance of the particular activity to the NRC mission. In doing this, overall exposure control such as available engineering controls, respiratory protection, stay times and evacuation of the area will be considered along with use of KI. In the absence of a recommendation to use KI, employee requests for KI during an emergency will be considered on a case-by-case basis.

How effective is KI?

The effectiveness of KI in blocking the uptake of radioactive iodine by the thyroid is well established. The protective effect of KI lasts for 24 hours. For optimal protection against inhaled, radioactive iodine, KI should be used before or immediately coincident with exposure to a radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. If a release is protracted, even a delayed use may help reduce the radiation dose to the thyroid. KI should be taken daily until the risk of significant exposure to radioactive iodine no longer exists. Once radioactive iodine is concentrated in your thyroid, KI is not effective at removing it.

NRC USE OF POTASSIUM IODIDE (KI) DURING AN EMERGENCY

Are there any side effects?

Adverse reactions are uncommon, but they are possible. The risks of stable iodine include sialadenitis (an inflammation of the salivary gland), gastrointestinal disturbances, allergic reactions and minor rashes. Thyroidal side effects of stable iodine include iodine-induced thyrotoxicosis, which is more common in older people but usually requires repeated doses of stable iodine. In addition, iodide goiter and hypothyroidism are potential side effects, but they require chronic high doses of stable iodine also.

The use of KI is voluntary and you have the right to decline it. You are encouraged to consult with your personal physician or the NRC Health Center (301-415-8400) if you have questions about your personal situation.

You should decline the KI if any of the following statements apply to you.

1. Your thyroid gland has been removed.
2. You are sensitive to iodine, or allergic to iodine [for example, you have experienced an adverse reaction after eating seafood, shellfish, or iodized salt; after applying topical iodine (e.g., tincture of iodine, povidone-iodine, betadine, and iodophore solutions) to a cut or injury; or after a medical diagnostic procedure involving the use of iodinated contrast material that you were told was likely a reaction to iodine].
3. You have dermatitis herpetiformis, or hypocomplementemic vasculitis.[4]

You should use caution in taking KI if you have any of the following conditions, especially if dosing extends beyond a few days:

1. You have multinodular goiter.
2. You have Grave's disease.
3. You have autoimmune thyroiditis.

[4] Extremely rare conditions associated with an increased risk of iodine hypersensitivity.

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Additional copies are available from:

Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573
(Internet) http://www.fda.gov/cder/guidance/index.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

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