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

OFFICE OF THE
SECRETARY

November 26, 2002

COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0089

TITLE: REVISED DRAFT NUREG-1633 AND PUBLIC INFORMATION BROCHURE ON POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC

The Commission (with Chairman Meserve and Commissioners Diaz, McGaffigan, and Merrifield agreeing) disapproved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of November 26, 2002. Commissioner Dicus approved the paper with changes.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR

VOTING SUMMARY - SECY-02-0089

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MESERVE		X			X	11/14/02
COMR. DICUS	X				X	9/20/02
COMR. DIAZ		X			X	10/28/02
COMR. McGAFFIGAN		X			X	11/12/02
COMR. MERRIFIELD		X			X	10/29/02

COMMENT RESOLUTION

In their vote sheets, Chairman Meserve and Commissioners Diaz, McGaffigan, and Merrifield disapproved the subject paper. Commissioner Dicus approved the paper with changes. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on November 26, 2002.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN MESERVE

SUBJECT: **SECY-02-0089 - REVISED DRAFT NUREG-1633 AND PUBLIC INFORMATION BROCHURE ON POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC**

Approved _____ Disapproved X Abstain _____

Not Participating _____

COMMENTS:

SIGNATURE

Nov. 14, 2002

DATE

Entered on "STARS" Yes ✓ No ____

COMMENTS OF CHAIRMAN MERSERVE ON SECY-02-0089

I concur with the conclusion of a majority of the Commission that we can best protect our limited staff resources by not expending more effort on the revision of NUREG-1633 or a brochure on potassium iodide (KI). As my colleagues have noted, there are a variety of on-going events that would likely make these efforts stale by the time the work is completed.

In light of the changing circumstances, however, I believe that the staff should make special efforts to ensure that our website fully reflects activities at the NRC and our sister agencies. As Commissioner McGaffigan has noted, much of the current interest in KI has arisen as a result of concerns about terrorist incidents. The website should provide information on the role of KI in responding to such events at nuclear power plants, as well as information as to the limits of KI effectiveness (e.g., for events involving most radiological dispersal devices). In short, there is a continuing need for accurate information about KI, which can best be served by the updating and revision of our website.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-02-0089 - REVISED DRAFT NUREG-1633 AND PUBLIC INFORMATION BROCHURE ON POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC**

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

Subject to incorporation of attached edits. See attached.

Greta Joy Dicus
SIGNATURE

September 20, 2002
DATE

Entered on "STARS" Yes X No ____

COMMISSIONER DICUS' COMMENTS ON SECY-02-0089:

I approve, subject to the attached revisions, the publication of both NUREG-1633, "Consideration of the Use of Potassium Iodide During Severe Nuclear Reactor Accidents" and the Public Information Brochure for public comment. I believe that these documents provide a well-balanced discussion on the uses of potassium iodide (KI) as a supplemental protective action within the plume exposure pathway of an emergency planning zone during a severe reactor accident.

I have also recommended a considerable number of changes throughout NUREG-1633 (as shown in the attached redline/strikeout version). Although many of the changes are editorial in nature (i.e., spelling errors or adding references to the bibliographic list), many are technical to correct for errors in SI or English unit conversions, use of the term "deterministic" rather than "non-stochastic" when discussing risk, including appropriate references where necessary (including correct websites), and providing the latest up-to-date information on the use of KI in France (e.g., see p. 32 for a discussion of France's current KI program). For the French update, I have included a copy of the August 2002 *Health Physics Society* Journal article by B. Le Guen, et. al., that I referenced in this section for both my fellow Commissioners and the staff's information.

Minor edits to the Public Information Brochure on KI are also attached.

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gjd
9-20-02

GTD
ATTACH TO VOTE ON SECY-02-0089 (KI)

Operational Topic

FRENCH APPROACH FOR THE DISTRIBUTION OF IODINE TABLETS IN THE VICINITY OF NUCLEAR POWER PLANTS

B. Le Guen,* P. Y. Hémidy,† and Y. Garcier‡

Abstract—**In the event of an accident, isotopes of iodine including ^{131}I can be released into the atmosphere. In 1997, as a safety measure, the French government decided to begin the distribution of stable iodine tablets in advance, directly to those living in the vicinity of the nuclear power plants, to avoid having to do so in an emergency. The tablets were previously stored by Electricite de France (EDF), which held them at the disposal of the government authorities. This year, as the existing tablets pass their use—by date, EDF has begun redistributing stable iodine within a ten-kilometer radius around its nineteen nuclear sites. We review the effectiveness of this countermeasure as well as the nature and incidence of possible side effects while measuring the duration of its action under the conditions in which it was administered. A bibliographic study of the kinetics of iodine in the human body has enabled the indications and the means of use to be determined. The effectiveness of the preventive effect and the onset of thyroid dysfunction depends on both external and individual factors: uptake of iodine from food, functional condition of the thyroid, and age. In an individual with a healthy thyroid, taking 100 mg of stable iodine immediately before exposure to radioactive iodine reduces the dose to the thyroid by at least 95%. In cases of prolonged exposure, the reduction is smaller. Therefore, if exposure lasts for a number of days, consideration needs to be given to taking stable iodine again, to maintain maximum protection. In addition to the bibliographic study, this presentation covers the impact of making iodine available and the action taken to educate the public; the attitudes of populations concerned; and the reaction of the health professionals.**

Health Phys. 83(2):293–300; 2002

Key words: iodine; exposure, population; health effects; accidents, nuclear

INTRODUCTION

When radioactive iodine is accidentally released into the atmosphere, stable iodine tablets can be taken by the public to limit the fixing of radioactive iodine in the thyroid and reduce the extent to which it is irradiated in situ or even prevent this from happening at all (Crocker 1984; Malarbet et al. 1998; Riggs 1952; Saxena et al. 1962). Of all the organs in the body, the thyroid gland is among the most sensitive to radioactivity (Ramsden et al. 1967), particularly in young people under 18 y. After the Chernobyl accident in 1986, a considerable increase in the number of thyroid cancers in children and adolescents was observed in Belarus, Ukraine, and Russia (Jacob et al. 1999). The predominant reason for this increase was exposure to radioactive iodine, including ^{131}I, and failure to protect the thyroid at the time of release. + No preventative shelter.

Since 1986, the WHO (1990) (Vulsma et al. 1989), the ICRP (1991) and the IAEA (1996) have published recommendations for administering stable iodine in the event of a radiological accident. In 1997, the Prime Minister of France issued a directive stating that stable iodine (KI) tablets were to be distributed to those living in the vicinity of nuclear power plants; this was intended as a preventive measure, eliminating the need for emergency action. The tablets were stored by Electricité de France (EDF) and made available to the government.

The tablets distributed in 1997 will soon be out-of-date and the government has charged EDF with coordinating and running a new distribution campaign within a radius of 10 km around each of its 19 plants currently in operation (Fig. 1). This document gives a brief reminder of the characteristics of iodine prophylaxis following nuclear accidents and describes the impact of the two information and stable iodine distribution campaigns, public attitudes and behavior and the reactions of health professionals.

Reminder of iodine metabolism

Iodine is a trace element and is essential for synthesis of the thyroid hormones (T3 and T4). It is mainly provided by foodstuffs and it is generally agreed that an iodine intake of between 100 and 150 $\mu g\ d^{-1}$ covers the requirements of an adult (Pennington 1990) (Table 1). The thyroid contains a store of between 10 and 15 mg of

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0017-9078/02/0

Fig. 1. Location of EDF nuclear power plants in France.

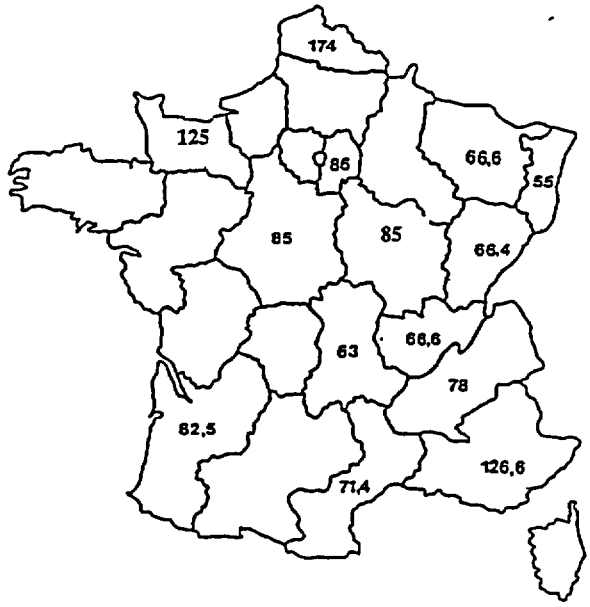

Fig. 2. Comparison of the iodine content in urine in France in $\mu g\ d^{-1}$ (Mornex et al. 1987; Le Guen et al. 2000).

Table 1. Average daily iodine requirements (in μg).

Type of person	Required daily intake (μg)
Infant	25–45
Child	50–100
Woman	100–120
Pregnant woman	125–200
Man	150

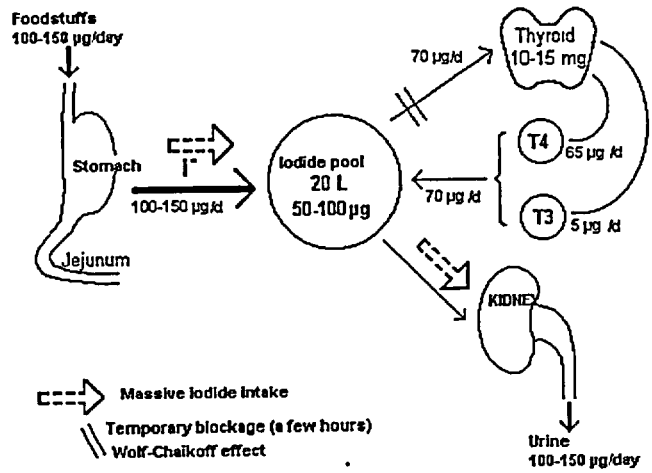

Fig. 3. Correlation between iodine prophylaxis and thyroid protection.

iodine to compensate for insufficient intake (Cavalieri 1997).

In France, the national average dietary iodine intake varies between 85 and 100 $\mu g\ d^{-1}$ (Fig. 2) (Mornex 1987; Le Guen et al. 2000) with regional values ranging from 55 to 174 $\mu g\ d^{-1}$. This results from variations in eating habits between one area and another and one individual and another.

Iodine is absorbed in the digestive tract (stomach and small intestine) in its reduced form, namely iodide (I^-). Once in the bloodstream, it rapidly diffuses into the extracellular area constituting the extracellular iodide pool and follows two major paths (Fig. 3), namely:

- it is captured by the thyroid gland and used to make thyroid hormones; and
- it is excreted in urine (Gaffney et al. 1962).

Iodide capture by thyroid cells (thyreocytes) is an active process. It adapts to the concentration of iodide in plasma and thus to iodine intake from foodstuffs. The process is regulated by an ante-hypophyseal hormone known as thyreo-stimulating hormone (TSH). Thyroglobulin (Tg) constitutes a hormone stock corresponding to requirements for 30 to 60 d. They are released into the bloodstream by thyroglobulin proteolysis, assisted by TSH. Enzyme breakdown of the thyroglobulin releases 10 μg of T3 and 100 μg of T4 (containing 65 μg of iodine) daily, which passes into the plasma. After acting on the target tissues, the iodine is released and passes back into the extracellular area. It can either be recaptured by the thyroid gland (recycling) and used for hormone synthesis or eliminated, to a large extent, by the

kidneys. A diagram of iodine metabolism can be found in Fig. 3 (Le Guen et al. 2000).

These reminders help to understand the way in which radioactive iodine is fixed to the thyroid gland (Rubery 1990). This fixation of radioactive iodine could result in cancer, particularly in children and young adults. When a stable iodine tablet is taken prior to the inhalation or ingestion of radioactive iodine, the thyroid becomes saturated with iodine and is effectively protected against the absorption of radioactive iodine (Stanbury 1990; Nauman and Wolff 1993). The radioactive iodine is eliminated naturally. To echo the slogan used during the 2000 campaign for the distribution of iodine tablets to the public, "prevention is the best form of protection."

Distribution of iodine tablets

Potassium iodide tablets were granted medication status on 24 January 1997 by the French Agency for the Safety of Foodstuffs and Health Products (AFSSAPS), the French equivalent of the American FDA. Like all medicines, they require a marketing permit. This was revised in October 1999, at the manufacturer's request after new information had been obtained on the stability of the product. Indeed, accelerated aging tests (artificial variations in ambient temperature, hygrometry, etc.) and tests in real time had shown the period during which the product was stable to be longer. Consequently, it was decided that iodine tablets should be renewed every 5 y instead of 3.

A single pharmaceutical company, the Central Military Pharmacy, manufactured 350,000 boxes of ten tablets, each containing 130 mg of potassium iodide, i.e., 99.38 mg of iodine.

The boxes were distributed in the conventional manner for the pharmaceutical industry:

- they were supplied to the regional representatives of various wholesalers and distributors; and
- they were then sent to the various pharmacies over a period of several days.

Every person living within a 10 km radius of an EDF power plant received an explanatory letter signed by the Préfet (i.e., the governor of the county) and a coupon to be exchanged for the iodine tablets at the pharmacy. It should be emphasized that schools, local industry, and public buildings (town halls, etc.) were also given adequate supplies of tablets.

Since pharmacists have an important role to play in public health, it was agreed that the public should obtain the iodine tablets from the pharmacy, like any other medication, except that it would be free of charge in exchange for the coupon received by post.

The agreement signed by EDF and representatives of the profession specified that when the tablets were handed over, advice was to be given on how they should be taken (directions for use, side effects, cases when they should not be taken, storage, etc.) and answers were to be given to any questions the public might ask. To help them do so, pharmacists were invited to attend many information meetings, and they were given a whole wad of documents.

QUESTIONS RAISED DURING INFORMATION MEETINGS

Directions for use and administration mode

Stable iodine tablets should only be used in cases-of-exceptional exposure and only when the order is given by the competent health authorities, namely the government representative in the area concerned (the Préfet).

In France, the maximum value allowed is a dose of 100 mSv to the thyroid. This value is within the range of levels recommended in ICRP Publication 63 (ICRP 1991) and is in line with the intervention levels for emergency action recommended in the IAEA *Safety Series* 115 (IAEA 1996). For those most at risk, i.e., under eighteen years of age, discussions are currently underway to determine whether the threshold can be reduced to between 10 and 100 mSv (WHO/CEC 1990).

Treatment consists of a single tablet containing 130 mg of potassium iodide, taken in the following ways:

1. Adults [men, women, and pregnant women (Evans et al. 1967)] and children over 12 y: 1 tablet dissolved in a glass of water, milk, or fruit juice;
2. Children aged 3 to 12 y: half a tablet dissolved in a glass of water, milk, or fruit juice;
3. Infants from birth to 3 y: a quarter of a tablet dissolved in a glass of water, milk, or fruit juice.

To assess the length of time during which the thyroid is blocked by the stable iodine, Table 2 shows the relationship that exists between the time the stable iodine tablet is taken and the degree of protection of the thyroid (Kovari 1994; Wolff 1969).

The optimum moment to give KI is 1 h before exposure to the radioactive iodine.

Zanzoniko and Becker (2000) have shown that 48 h after the administration of KI, there is still a 75% rate of protection against fresh exposure to ^{131}I. After 72 h, the rate of protection falls to 32%.

Blum and Eisenbud (1967) have examined protection by KI 48 and 72 h after its administration by administering another dose of radioactive iodine. A 25-mg dose of potassium iodide did not block uptake after 48 h. Doses of 50 mg and 100 mg blocked 66% and

Table 2. Time tablet is taken/effectiveness of iodine prophylaxis for an intake of 1 MBq.

Time in hours between administration of potassium iodide and inhalation of radioactive iodine	Dose to thyroid in mSv/MBq	Degree of protection to thyroid (%)
−96 h	375	5
−72 h	267	32
−48 h	97	75
−24 h	25	93
0 h	12	97
+2 h	81	80
+8 h	235	40
+16 h	329	17
+24 h	367	7

78% of the thyroid dose, respectively. After 72 h, a 100-mg dose of KI blocked only about 25% of the thyroid dose. Sternthal et al. have shown that an averted dose of more than 90% can be maintained, after an initial administration of 100 mg of iodide (130 mg of KI), by taking repeat doses of 15 mg of iodide (about 20 mg of KI) for several successive days. The results show that 10 mg is not enough to effectively protect the gland in the event of prolonged exposure to radioactive iodine and increasing the doses to 50 or even 100 mg a day would not appear to increase the degree of protection to any significant extent (Sternthal et al. 1980).

Because of the significant decrease in the degree of thyroid protection with time after taking the first stable iodine tablet, and in the event of exposure to radioactive iodine lasting several days, a second iodine tablet could be taken should the persons involved fail to be evacuated, although this would be less effective.

But taking a second tablet increases the risk of an iodine overdose. Therefore, to make the treatment easier to tolerate and more especially to reduce the risk of undesirable effects, the authors (Koutras and Livadas 1966; Ron et al. 1995; Verger et al. 2001) have published another therapeutic diagram: for adults, one stable iodine tablet the first day and a quarter of a tablet in the days that follow.

Side effects

For the population as a whole, the side effects are very rare, being estimated at less than 0.3% (0.35% for children and 0.2% for adults):

- They are not specific and cause a certain amount of discomfort (nausea, vomiting, diarrhea, metallic taste in the mouth) (NCRP 1977; WHO/CEC 1990);
- In some cases, hyperthyroidism is possible (Braverman 1990; Stanbury et al. 1998). Those most at risk are patients with thyroid pathologies. The most common is development of hyperthyroidism in patients over 60 y with goiter. This complication can be serious when the patient also has heart disease. A few rare cases of hyperthyroidism have been observed (Dunn et al. 1998; Schober and Hunt 1976);
- If a mother is breastfeeding, care must be taken to ensure that an infant who has received a dose of stable iodine is not exposed to an overdose of iodine (Castaing et al. 1979; Sternthal et al. 1980). Overdose, and therefore the increased risk of undesirable side effects, is due to the fact that the stable iodine taken by the mother is concentrated in breast milk and the iodine given to the infant (Thompson et al. 1994). As a precaution, it may be wise to halt breastfeeding for 36 h after ingestion of a dose of stable iodine;
- Proven cases of oversensitivity to iodine are extremely rare, at around 10^{-7}. The allergic reactions that can be observed after using medication containing iodine [antiseptic (povidone iodine), contrast media] are mainly due to the immunity producing power of the excipients and not the iodine itself (Conn et al. 1996).

The effectiveness of prophylaxis using stable iodine and its generally harmless nature were proved in Poland, where 18 million doses were distributed after the Chernobyl accident. No significant side effects were observed, particularly in children, infants, or pregnant women. Only three instances of allergy involving bronchial spasms required treatment (Nauman and Wolff 1993).

When should stable iodine not be taken?

Although the risk of side effects after taking stable iodine is very low, special attention should be paid to a few rare, well documented cases in which the patients are aware of the risks (NCRP 1977; WHO/CEC 1990):

- Proven hypersensitivity to iodine;
- Severe goiter with bending or narrowing of the trachea;
- Dermatitis herpetiformis;
- Pemphigus vulgaris; and
- Congenital myotony.

Persons with this type of pathology should be informed that alternative treatment is available, provided expert medical advice is sought:

- Sodium or potassium perchlorate, which competes with iodine; and
- Synthetic antithyroids such as carbimazole and propylthiouracil that block thyroid hormonogenesis by inhibiting iodine organification.

Generally speaking, the extent to which the advantages of prophylaxis after age 60 y outweigh the disadvantages is doubtful in the minds of certain authors since

the risk of cancer due to radioactivity is almost null, but also because there is a risk of thyrotoxicosis by iodine in patients with thyroid pathologies.

In 1999, when the proposed revision of the 1996 guidelines was published, the WHO suggested that there be no prophylaxis beyond age 40 y (WHO 1999).

In January 2001, the FDA (FDA 2001) took a stance on the WHO document by recommending the administration of stable iodine for a dose risk of

- 50 mSv to the thyroid for children from birth to 18 y and for pregnant or breastfeeding women;
- 100 mSv for persons aged between 18 and 40 y; and
- 5 Gy for those over 40 y.

For the latter, protection is provided against hypothyroidism and not cancer.

The IAEA was asked for its opinion when the document was being drafted but did not wish to be associated with its publication in view of the fact that the member states had not been formally consulted and because the text contained some unresolved issues.

Therefore, an IAEA/WHO Technical Committee meeting was held in Vienna in September 2001, to assess and review the international safety standards for intervention in emergency exposure situations involving radioactive iodine. As regards the intervention level for the administration of stable iodine in a nuclear accident, the meeting recommended to the secretariats that the requirements be amended to reflect the following position:

- The administration of stable iodine (iodine prophylaxis) to the public is an early, effective measure for protection of the thyroid to prevent deterministic and minimize stochastic effects at any age. However, it is primarily intended for the protection of children, including the unborn;
- The Generic Intervention Level (GIL) of 100 mGy provides an operational basis for rapid decision and efficient application in the event of a nuclear emergency;
- However, as there are strong indications that the risk induced by radioiodine is age-dependent, the administration of stable iodine may be recommended at significantly lower levels of avertable dose to make allowance for the higher sensitivity of children and the unborn; and
- It is intended that this framework be used as a starting point for planning and that it be optimized to take into account specific practical, operational, social and economic considerations. It must also make allowance for the introduction of other protective actions such as sheltering and food control as measures to reduce the uptake of radioiodine.

In addition, the meeting recommended to the secretariats that the safety guide should introduce the idea that some countries may find it useful to adopt intervention levels for children and pregnant women that are lower than the proposed 100 mGy (GIL) and that an explicit reference to the WHO publication that proposes a value of 10 mGy be made as an example of an intervention level that could be appropriate for children. Furthermore, the meeting also recommended that the safety guide include a footnote to the effect that the WHO publication only recommends single dose administration for newborn infants. In any case, the meeting recommended to the secretariats that the levels be re-examined with a view to their being lowered (IAEA/WHO 2001).

Alternative iodine-based treatments

In emergency situations, several options are available to persons who have lost their iodine tablets or were unable to procure them (Table 3.). These alternative solutions have their advantages: no prescriptions are required; they can be found in all pharmacies; the doses can be adjusted (1 drop of Lugol = 1.25 mg of iodine), which is particularly useful for children; they remain relatively stable over time and they are easy to prepare in the event of an emergency. But they also have their disadvantages: the drops have to be counted, they smell and taste unpleasant, and the directions for use are known only to health professionals. Alcohol containing iodine and iodine tincture are not recommended for infants because of their alcohol content, and yet prophylactic measures are directed mainly at this section of the population.

Table 3. Possible alternative to potassium iodide tablets in emergency situations.

Form	Daily doses		
	Adult (including pregnant women)	Children (18 mo to 12 y)	Infants (under 18 mo)
LUGOL (strong iodine-iodide solution)	80 drops = 100 mg of iodine	40 drops	20 drops
Iodine tincture (solution of iodine in alcohol available from pharmacies)	80 drops	40 drops	20 drops
Alcohol containing 1% iodine	2 tsp*	1 tsp	½ tsp

*tsp: 1 teaspoon = 5 mL.

ASSESSMENT OF 1997 AND 2000 IODINE TABLET DISTRIBUTION CAMPAIGNS

Information

Before distribution began, information meetings organized jointly by EDF and the government were held for elected representatives, health professionals (physicians, pharmacists, etc.), and the public. The information was broadcast simultaneously in the press and on the radio. The involvement of elected representatives should be emphasized since it enabled them to be perceived by the public as responsible players, which is essential if the close links between EDF, elected representatives, and the public are to be strengthened.

The 1997 meetings were very well attended, with an average of 400 people per meeting, representing around 15,000 people in the whole of France. Conversely, when the meetings were held again in 2000, average attendance was around 50. It must be said that only three years later, the population involved had changed very little.

Distribution

Various distribution protocols were tested in 1997:

- Coupon sent to inhabitants;
- Home delivery by firemen and/or civil defense representatives, with a coupon being left if occupants were absent; and
- Postal delivery.

From the outset, it is interesting to note that home delivery made it possible to cover over 90% of the population involved, as opposed to 60–70% for withdrawal from pharmacies, depending on region.

The 2000 campaign involved all EDF nuclear power plants with the exception of Creys-Malville, which is currently being decommissioned. The preliminary results of the iodine tablet distribution campaign are lower, with a national average of around 43%, despite the considerable effort made by EDF as regards logistics and funding. It was decided to consider this preliminary result as unsatisfactory. Since most of the individuals concerned by distribution (> 77%) live within a 5 to 10 km radius of the nuclear power plants, a special effort was made in this area by ensuring that schools and other buildings open to children and/or the public were supplied with iodine tablets.

Some power plants have already started taking action to improve on the result:

- Two areas have begun a new campaign to inform the public. In one case, a letter signed by the Préfet was sent to every household thanking those who had been to collect their iodine tablets and inviting those who had not to do so; in the other case, a statement from the Prefecture (county hall) was published in the local press. Both methods led to a 15% increase in the distribution rate; and
- Two plants took advantage of a civil defense drill to remind the population involved of the existence of stable iodine tablets. The results are satisfactory, with around 70% of the population covered. Drills would appear to be an effective way of reminding the population that the tablets exist since those involved take part and are therefore more receptive to the information they are given.

Several hypotheses can be put forward to explain the downturn in local interest:

- The population in "nuclear" areas has become used to the risk over the years and may even have renewed confidence in the operator;
- Those living near nuclear power plants are mainly those who work or have worked in them;
- The novelty aspect of the first distribution campaign has worn off;
- The fact that no accidents with consequences for the population have arisen in power plants may account for the lack of interest in the iodine tablet distribution campaign;
- It was perhaps unwise to launch the "iodine tablet" campaign at the start of the summer, just before people went on holiday;
- A lack of motivation on the part of health professionals (pharmacists, physicians etc.); and
- All players have to be involved if the campaign is to be successful and it is hard to work up enthusiasm again a mere three years later.

CONCLUSION

In addition to the information meetings, iodine tablet distribution provides an opportunity for the operator to communicate with those living in the vicinity of the plant. Making the tablets available in pharmacies means that personal behavior has a role to play (people are used to the risk, they are disinterested, etc.), and, therefore, only part of the population is covered. The excellent results obtained in the vicinity of Fessenheim Nuclear Power Plant in 1997, when tablets were delivered to each household, could encourage the government to consider extending this type of distribution during the next campaign in 2005, making allowance for disparities in population density in the vicinity of the various nuclear power plants. But this would require a special authorization from the health minister. The French government is currently of the opinion that to prepare for a significant incident, stocks of iodine tablets should be available throughout the country, in addition to

those held in the vicinity of power plants. Moreover, the Minister for Health will almost certainly be requesting nuclear operators to distribute greater quantities of tablets around their plants so that more people living in the vicinity can be protected. France will therefore have a system by which the entire population could be provided with tablets if necessary.

Acknowledgments—The authors thank Chantal Amaru for her attentive reading of this publication.

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ABSTRACT

The use of potassium iodide as a supplemental protective action within the plume exposure pathway emergency planning zone (EPZ) during severe reactor accidents is presented. A brief history of severe reactor accident source terms as well as the Three Mile Island Unit-2 accident is presented. Thyroid and whole body dosimetry, their associated risk assessment, and their relationship to accident and its consequences are discussed. State, international, and European practices and the World Health Organization's recommendations for protective actions are reviewed.

CONTENTS

~~ATTACHMENTS~~APPENDICES

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ABBREVIATIONS

AEC	Atomic Energy Agency
BMR	basal metabolic rate
CEC	Commission of the European Communities
CEDE	committed effective dose equivalent
CF	containment failure
DBA	design-basis accident
DBA-LOCA	design-basis loss-of-coolant accident
DEPZ	detailed emergency planning zone
EAL	emergency action level
EP	emergency preparedness
EPA	Environmental Protection Agency
EPZ	emergency planning zone
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
GIL	Generic Intervention Level
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
KI	potassium iodide
LPZ	low population zone
LWR	light-water reactor
NPP	nuclear power plant
NRC	Nuclear Regulatory Commission
PAG	protective action guideline
RCS	reactor coolant system
REPAC	Radiological Preparedness Advisory Committee
RI	radioactive iodine
SHO	State health officer
State	State, Tribal, or in some cases, local governments
TEDE	total effective dose equivalent
TID	technical information document
TMI-2	Three Mile Island Unit 2

TSH	thyroid-stimulating hormone
VB	vessel breach
WHO	World Health Organization

PREFACE

This document presents information to assist State officials in determining whether the prophylactic use of KI for their population is appropriate in the unlikely event that a severe reactor accident occurs within their state. The Commission finds that the use of KI is a reasonable, prudent, and an inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission also finds that KI could help reduce the risk of thyroid cancers in the unlikely event of a major release of radioactive iodine. Therefore, the Commission has amended its emergency planning regulations to include consideration of KI as a protective measure for the general public that would supplement evacuation and sheltering.

In order to assist emergency management officials to make fully-informed decisions about the use of KI, the staff has presented information on offsite consequences of reactor accidents, source terms, exposure pathways, the role of emergency preparedness, and appropriate protective action measures, including the benefits and risks of using KI. This document contains final guidance from the Food and Drug Administration on the use of KI as a thyroid blocking agent. A discussion of the World Health Organization recommendations ~~is~~and the International Atomic Energy Agency guidance are also included. In addition, information on stockpiling KI for the general public, logistics, amounts of KI, and public information needs from the experience of State and foreign governments that have made KI available to the public is included.

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In response to petitions for rulemaking, the Commission directed the NRC staff in June 1998 to proceed with rulemaking to require that in developing the range of protective actions, consideration should be given to evacuation and sheltering, and, as a supplement to these, the prophylactic use of KI, as appropriate. In a final rule (10 CFR 50.47(b)(10)), published in the *Federal Register* on January 19, 2001, the Nuclear Regulatory Commission amended its emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule requires that consideration to be given to including potassium iodide (KI) as a protective measure for the general public that would supplement sheltering and evacuation. KI ~~could help prevent~~, when used correctly, reduces the risk of thyroid cancers in the unlikely event of a major release of radioactive iodine from a nuclear power plant. The Commission found that KI is a reasonable, prudent, and an inexpensive supplement to evacuation and sheltering for specific local conditions.

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The use of KI is intended to supplement, not replace, other protective measures, such as evacuation and sheltering, which the Commission continues to view as the most effective measures in the event of a radiological emergency. The Commission recognizes the supplemental value of KI and the prerogative of the State to decide on the appropriateness of the use of KI by its citizens. The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's initial supply of KI strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' role in such matters. In addition, the Commission notes that issues surrounding the prophylactic use of KI following such accidents do not lend themselves to across-the-board solutions. Therefore, the Commission has chosen to leave this decision to State and local emergency response planners, who may find that KI should be a supplementary protective measure, rather than to mandate its use. To assist the State and local officials, the Commission directed the staff to develop this guidance document to help State and local planners in reaching an informed decision concerning use of KI as an appropriate protective supplement.

Following the Chernobyl accident, excess thyroid cancer has been detected among children in Belarus, the Ukraine, and Russia. Most of the affected children lived more than 16 km (10 miles) from the reactor and ingestion of contaminated foodstuffs contributed the majority of their thyroid doses. This experience indicates the importance of early action to prevent ingestion of contaminated foodstuffs by the general public, especially children. Conversely, Poland has not detected excess cancers resulting from the intake of radioiodines. In Poland, a 40-45% reduction in thyroid burden due to thyroid blocking by KI and milk restrictions demonstrates the value of implementing a range of protective measures. The Polish experience supports the use of KI as a safe and effective prophylaxis for the thyroid gland across a large population.

This guidance document presents information and discusses the various factors that need to be weighed in State and local decisions on the use of KI. The basis for emergency planning, reactor accidents and associated consequences, and an overview of severe reactor accident source terms are briefly discussed. Thyroid and whole body doses, their associated risk assessments, and their relationship to severe reactor accident source terms are also discussed. A discussion of how the practical issues in KI stockpiling, distribution, and use are handled in the States which already

use KI as a supplement and in the several nations which use KI as a supplement. In addition, this document contains the final guidance from the Food and Drug Administration which should be helpful to state decision makers, as well as references to other international documents, such as those of the World Health Organization (WHO) and the International Atomic Energy Agency (IAEA) to assist the States in their decision-making process.

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This document is dedicated to the memory of our esteemed colleague, Charlie Willis.

To assist in the development of this guidance document, the Commission accepted the staff's proposal to form a KI Core Group. The Core Group comprised representatives from the three States that already have KI as a supplemental protective action (Alabama, Tennessee, and Arizona), as well as, the State of Connecticut, National Emergency Management Association (NEMA), Conference of Radiation Control Program Directors (CRCPD) Emergency Response Committee, Food and Drug Administration (FDA), Environmental Protection Agency (EPA), Federal Emergency Management Agency (FEMA) and the NRC. The KI Core Group helped the staff review public comments on the first draft of the revised NUREG and was instrumental in the development of this document.

The following NRC staff is thanked for their assistance: Robert Bores, RGN-I; Kathy Halvey Gibson, NRR; Glenn Tracy, NRR; Ted Quay, NRR; Falk Kantor, NRR (retired); Steve LaVie, NRR; Roland Lickus, RGN-III, Stephen McGuire, IRO; and Marjorie Rothschild, OGC.

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CHAPTER 1
BASIS FOR EMERGENCY PLANNING

1.1 Introduction

The Nuclear Regulatory Commission (NRC) and Federal Emergency Management Agency (FEMA) are the two Federal agencies that evaluate emergency preparedness at and around nuclear power plants (NPP). The NRC will not issue an operating license for a nuclear power reactor unless it has determined that 'there is reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency'. The NRC bases its finding on a review of the FEMA findings and determinations about the adequacy of State emergency plans and whether there is reasonable assurance that the state plans can be implemented, and on the NRC assessment about the adequacy of the licensee's onsite emergency plans and whether there is reasonable assurance that the licensee plan can be implemented.

In NPP licensing, the ~~U.S. Nuclear Regulatory Commission (NRC)~~ subscribes to the "defense-in-depth" safety strategy. The elements of that strategy are: accident prevention, redundant safety systems, containment, accident management, siting, and emergency planning. After the accident at Three Mile Island Unit 2 (TMI-2), both onsite and offsite emergency response capabilities were expanded with improved emergency plans, equipment, and facilities. Emergency response personnel from industry, State and local organizations, and Federal agencies receive training and are evaluated by periodic drills and exercises.

Each NPP in the United States has two emergency planning zones (EPZs): the plume EPZ and the ingestion pathway EPZ. The plume EPZ is that area requiring immediate action to reduce risk to the public and it is approximately 16 kilometers (10 miles) in a radius. The zone is sufficiently large that protective actions within it provide for substantial reduction in early health effects (injuries or deaths) in the event of a worst-case core-melt accident. The ingestion EPZ is the area in which actions must be taken to protect the public from the consumption of foods contaminated[1] with radioactive materials and for which there is considerable time for action to reduce risk. The ingestion EPZ is approximately 80 kilometers (50 miles) in a radius, which also includes the 16 kilometer (10 mile) radius plume EPZ.

One of the emergency planning elements that the NRC and FEMA evaluate is the adequacy of public protective actions. In general, evacuation, sheltering, and access control are the principal protective actions considered for the early phase of an accident. Evacuation before the start of a release is the preferred protective action for projected severe accidents with *prompt* evacuation clearly the most effective. To ensure that evacuations are prompt, protective actions are recommended as soon as core damage is projected, which for most reactor accidents is well before a major release begins.

Although there have been no evacuations in the United States from NPP emergencies since the TMI-2 accident in 1979, the likelihood of public evacuation is considerably higher without an

[1]Contaminated does not mean unfit for consumption, rather it refers in this specific instance to those agricultural products, milk, and water that may contain some amount of radioactive material directly resulting from the accident/event.

associated release of radioactive material, than one accompanied by a significant release. This is because the current practice, as described in references published by the NRC and Environmental Protection Agency (EPA), recommends protective actions (i.e., evacuation, when possible) when core damage is deemed probable. The intent is to move people away from potential harm well in advance of any possible radionuclide release. Because the potential exists that health effects may result when significant core damage occurs, evacuation is the principal effective action used to protect the general public. In the unlikely event of a reactor accident resulting in the release of significant quantities of radioactive iodine, those communities within the 10-mile EPZ could benefit from having KI available.

1.2 Accident Classification and Source Term History

In NUREG-0396, the NRC considered the complete spectrum of accidents postulated for various purposes, and from these analyses, design basis accidents (DBA) were identified and severe accidents were chosen as the accidents considered in emergency planning and, therefore, in this discussion.

1.2.1 Design-Basis Accidents

A DBA is an accident hypothesized for purposes of site analysis or postulated from considerations of possible accidental events that would result in potential hazards not exceeded by those from any accident considered credible. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

When a NPP is proposed, the site/reactor design combination must be such that the consequences of design basis accidents (DBA) are below the plume exposure guidelines of 10 CFR -100.11.a.1, 0.25- Sv (25 rem) to the whole body and 3 Sv (300 rem) to the thyroid. The design basis loss-of-coolant accident (DBA-LOCA) has been typically the most severe design basis-accident because it usually results in the largest calculated offsite doses of any accident in this class. The DBA-LOCA is not a realistic accident scenario because the release magnitudes are much more severe than would be realistically expected. A best-estimate assessment of the release following a loss-of-coolant-accident (LOCA) would be significantly smaller than the DBA-LOCA used for siting purposes. The DBA-LOCA accident has been analyzed for most licensed power plants. This analysis concluded that the higher plume exposures of 0.25 Sv (25 rem) (thyroid) and 0.05 Sv (5 rem) (whole body) would not be exceeded beyond 10 miles for any site analyzed. Even under the most restrictive protective action guideline (PAG) plume exposure values of 0.05 Sv (5 rem) to the thyroid and 0.01 Sv (1 rem) whole body, over 70 percent of the accidents would not require any consideration of emergency responses beyond 16 km (10 miles). It should be noted that even for the DBA-LOCA, the lower range of the plume PAGs would likely not be exceeded outside the low population zone (LPZ) for average meteorological conditions.

1.2.2 Severe Accidents

Accidents that are considered to be so low in probability as not to require specific additional provisions in the design of a reactor facility are known as severe accidents accompanied by core melt. Such accidents would involve sequences of successive failures more severe than those postulated for the purpose of establishing the design basis for protective systems and engineered safety features. The consequences of severe accidents are those leading to a gross fuel clad failure or partial melt with independent failures of the containment boundary and total core melt and consequent degradation of the containment boundary.

Severe accidents cover a full spectrum of releases involving doses on the order of PAGs within 16 km (10 miles) to those accidents that release significant fractions of the available radioactive materials in the reactor (tens of millions of curies) to the atmosphere, thus having the potential for life-threatening doses. The lower range of the spectrum comprises accidents in which a core "melt-through" of the containment would occur. The upper range of the core-melt accidents is categorized by those in which the containment catastrophically fails and releases large quantities of radioactive materials directly to the atmosphere because of over pressurization or a steam explosion. These accidents have the potential to release very large quantities (hundreds of millions of curies) of radioactive materials. There is a full spectrum of releases between the lower and upper range with all of these releases involving some combination of atmospheric potential for causing serious injuries and deaths. Therefore, emergency response for these conditions must have as its first priority the reduction of early severe health effects. Studies have been performed indicating that if emergency actions such as evacuation were taken within about 4.8 to 8 km (3 to 5 miles) of a power plant, there would be significant prevention of early injuries and deaths from even the most "severe" atmospheric releases. It is important to stress that these accidents are only *postulated* events. These consequences are based on assuming multiple safety systems fail and the existence of extreme reactor and atmospheric conditions.

1.3 Reactor Accidents and Source Terms

The fission product release from the reactor fuel to the containment is known as the source term and it is characterized by the composition and magnitude of the radioactive material, the chemical and physical properties of the material, and the timing of the release from the reactor core. The source term is used to evaluate the radiological consequences of DBAs. Certain fission products tend to form more often than others during the fission process. In 1962, the Atomic Energy Commission (AEC) adopted the analysis contained in Technical Information Document TID-14844 as the licensing model source term. This "hypothesized source term" was postulated to appear instantaneously in the containment atmosphere and consist of 100 percent of the noble gases, 50 percent of the halogens, and 1 percent of the other fission products; half of the released halogens were assumed to be deposited on reactor building surfaces. The report also contained specific provisions for performing the dose calculations. The 1% fission product particulates were dropped from the source term, because without massive failure of the containment structure, releases of particulates were seen as negligible in comparison to iodine and noble gases.

This source term was not presented as a realistic source term. Rather, this source term offered conservatism and calculational convenience. It was thought that a major iodine release was possible and the iodine was considered a major risk because it was considered an inhalation risk rather than only an external exposure problem. The simplistic critical organ dose model used at that time supported that conclusion.

1.3.1 The Accident at Three Mile Island

In the United States, the worst commercial nuclear power plant accident occurred at the Three Mile Island Unit 2 (TMI-2) reactor. The two nuclear power reactors at TMI are light water-cooled and moderated.

The accident was caused by a series of errors in operation and maintenance. As a consequence of these errors, the reactor core was not continuously covered with water, so a major fraction of the core melted and released much of its fission product inventory into the containment building. The initial release was through pipes (that should have been blocked), which allowed the containment to be bypassed. This release consisted almost entirely of noble gases and it was eventually limited by operator action.

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The TMI accident did not cause deaths, injuries or over-exposures to radiation. The maximum dose to a member of the public was about 0.85 mSv (85 mrem), the equivalent of the dose the average person receives from ~~natural~~naturally-occurring radioactive sources every 3 months. The TMI accident had a major impact on the US nuclear power program, including a major increase in regulatory requirements. TMI also showed the need for improved emergency preparedness, both on-site as well as off-site. Additionally, this accident also cast serious doubt on the emphasis that had been placed on the importance of the radioiodines in a U.S. nuclear accident. At TMI-2, a major core melt occurred, millions of curies of noble gases were released to the environment but the iodine release was limited to approximately 15 curies. As a result of the radionuclides released from Three Mile Island, an alternate source term was developed which reevaluated the behavior of radioactive iodines as well as other particulates. This alternate source term, however, did not address the wide spectrum of possible events that make up the planning basis of emergency preparedness and is not to be used for emergency planning applications. In Regulatory Guide 1.183, the NRC determined that the "...alternate source term (AST) is insufficient *by itself* as a basis for requesting relief from the emergency preparedness requirements..."

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1.3.2 The Chernobyl Reactor Design vs. the Light-Water Reactor Design

The accident at Chernobyl provided more information on reactor accidents and source terms. This accident, which involved an explosion and a fire in the graphite-moderated core, rapidly carried fission products including noble gases and large quantities of iodines, into the environment. There are many important lessons that were learned from the Chernobyl accident: the function of containment, operating within the safety envelope, human performance in safety, emergency planning, early public notifications, the importance of administration of KI to large population groups at risk of exposure to significant quantities of radioiodine and the importance

of evacuation, sheltering and embargoing of food stuffs. The Chernobyl experience validated the value and effectiveness of the emergency planning process.

The reactor designs in the U.S. are different from the Chernobyl design:

- the choice of moderators is different, in the U.S., water is used, whereas the Chernobyl type reactors (RBMK-1000) use graphite;
- because of the core characteristics, the RMBK is less stable and more difficult to control, unlike U.S. designs, and power excursions present a greater risk;
- a graphite moderator, unlike water, is flammable;
- "defense-in-depth" barriers provided to ensure that nuclear fuel and fission products cannot escape from the core. Both the RMBK-1000 and U.S. LWRs use uranium oxide (UO_2) fuel pellets surrounded by zirconium cladding, however, the RMBK-1000 ~~reactors~~ use more than 1600 individual pressure tubes to contain the fuel elements and the light-water coolant that flows past these elements. The pressure tube walls are about 4 mm (0.16 in) thick, whereas, the U.S. LWRs use a pressure vessel with walls that are about 187 mm (7.5 in) thick, (NUREG-1250);
- ~~full~~"full containment" concept (NUREG-1250).

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"Full containment" is the complete enclosure of all reactor and primary support systems for the reactor so that any DBA is fully contained inside (NUREG-1250). In the U.S., full primary containment is achieved by a strong, thick steel and concrete vessel around all primary reactor systems. This containment either is large enough to contain the peak pressure reached in DBA or has sufficient pressure-suppression capacity to contain the worst-case peak pressure. The RBMK-1000 reactor was surrounded by thick biological shield walls, situated inside of the reactor cavity. The reactor vault was made of reinforced concrete; however, it was designed to withstand only a single pressure tube rupture. The rupture of more than one pressure tube is beyond the design basis of the RBMK-1000 reactor type, and such an event would exceed the stated relief capacity of the reactor vault and over pressurize it (NUREG-1250).

These important design differences, as well as other factors, contributed to the iodine releases which were approximately 5 million times greater than in the TMI-2 accident.

1.4 Meteorology

The atmospheric release of radioactive material is the most significant release mode for off-site consequences. Therefore, meteorology is important because it determines: (1) where the offsite release (also known as the plume) goes, and (2) the concentration of the radionuclides to which the public is exposed at some point downwind. Meteorological information includes wind speed, wind direction, wind persistence, wind variability, and vertical dispersion. These factors describe the stability of the atmosphere or how fast and far radionuclides are transported in air. Atmospheric stability is very important in determining how the radioactive effluents will be

dispersed. Atmospheric stability is described by Pasquill-Gifford stability classes. This model breaks down stability into six classes, ranging from very unstable (A) to very stable (F). Under very stable atmospheric conditions, there is not much dispersion of the plume and the radionuclide concentration in the air, or plume, is much greater than under very unstable atmospheric conditions. Stable conditions (unfavorable meteorology[2]) are usually chosen when performing DBA calculations. Most often, the prevailing meteorological conditions are not the conditions under which the DBA analysis are performed. In other words, the more unfavorable conditions chosen for the DBA analysis are not typically the predominant meteorological conditions.

In typical emergency preparedness full-scale exercises, worst-case meteorology is used to ensure that fission products from the postulated accident are transported from the reactor offsite to ensure that the necessary offsite participants can participate. The consistent use of this conservative meteorology in drills and exercises over the decades has led a great many people, emergency planners, State and local officials, NPP staff, as well as the general public, to believe that a release from an NPP will always result in a large spread of radioactive contamination and large doses to the population.

1.5 Dose and Health Effects

To understand the consequences of reactor accidents, it is important to understand the health effects of radiation and the concept of dose. Dose is the amount of energy delivered to a specified volume such as an organ or tissue or to the whole body. Dose delivered to an individual organ or tissue is not the same as the dose delivered to the entire body. The NRC has defined total effective dose equivalent (TEDE) to be "the sum of the deep-dose equivalent (DDE) (for external exposures) and the committed effective dose equivalent (CEDE) (for internal exposures)." In other words this dose includes not only the dose from radionuclides inside the body but also the external radiation dose. ~~A component of the TEDE is the dose to individual organs, known as the committed effective dose equivalent (CEDE).~~ An example of ~~this~~the CEDE would be the dose received by the thyroid gland from the ingestion or inhalation of radioiodine.

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In an effort to relate the significance of individual organ doses to the TEDE, the International Commission on Radiological Protection (ICRP) developed a set of "tissue weighting factors." For example, a thyroid dose is said to be only 3 percent as effective as the deep-dose equivalent of the same magnitude (e.~~For example~~g., 1 Sv (100 rem) to the thyroid is equivalent in risk as 0.03 Sv (3 rem) to the whole body). Other organs such as the lung, are even more sensitive to the effects of radiation, and yet the dose to the lung is less biologically significant (by a factor of 8) than a dose to the whole body. Therefore, control of the deep-dose equivalent is the primary consideration in protecting people from radiation-related injuries.

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[2] Stable meteorological conditions are considered the most unfavorable conditions in emergency planning because there is very little atmospheric dispersion or mixing of the plume, and the plume tends to stay concentrated and travel greater distances than in unstable meteorological conditions.

The possible adverse health effects from exposure to radiation are categorized as either "stochastic" or ~~"non-stochastic"~~deterministic." Stochastic effects are those effects for which the probability of the effect occurring, rather than its severity, is assumed to be directly related to dose~~, while non-stochastic. Deterministic~~ effects are ~~those for which the magnitude of the effect directly relates to dose~~health effects, the severity of which varies with doses, and for which a threshold is believed to exist (e.g., radiation-induced cataracts).

There is debate over whether radiation-induced stochastic effects require a minimum dose (the threshold hypothesis) or whether small doses produce a proportionately small risk of injury (linear hypothesis). ~~Non-stochastic~~Deterministic effects typically require doses in excess of 0.5 Sv (50 rem) (IAEA No. 109) and include effects ranging from reddening of the skin to dermatitis to necrosis of the skin. Some other effects are sterility ([either temporary or permanent, doses typically greater than 2 Sv (200 rem)], and radiation sickness, (ranging from mild nausea to death in a short period of time). An acute dose of about 4 Gy (400 rad)[3] to the whole body[3] can cause death in about 50 percent of exposed individuals within about 60 days (Hall 1988). Large doses to the thyroid also cause ~~non-stochastic~~deterministic effects, such as destruction of the thyroid gland from doses in the range of 200 Gy (20,000 rad). These effects require relatively large doses, and emergency response programs are designed to move people away from the source of radiation before ~~they receive such large doses~~any intake could occur.

The principal stochastic effects are cancer and genetic damage. Radiation-related cancer is the primary (and perhaps the only) concern for relatively lower doses. The survivors of the atomic bombs at Hiroshima and Nagaskai who had high doses, have experienced a higher incidence of cancer than the individuals who received lower doses (as have several groups of radiation therapy patients). Increased cancer rates are not detected among the Hiroshima and Nagasaki survivors where the doses are below about 0.1 Sv (10 rem). At these low levels, cancer incidences are inferred. According to the American Cancer Society, approximately 24 percent of all deaths in the United States result from cancer, and the estimated number of cancers attributable (by calculation) to low-level radiation [e.g., less than 0.1 Gy (10 rad)] is ~~only a very~~an extremely small fraction (< 0.5%) of the total number that occur. Further complicating the issue is that the cancers that result from radiation have no special features by which they can be distinguished from those produced by other causes. Thus the probability that cancer will result from a small dose of radiation has to be estimated by extrapolation from the increased rates of cancer that have been observed after much larger doses, based on assumptions and models about the dose-response at low doses.

It is estimated that if 100,000 persons of all ages received a whole-body dose of 0.1 Gy (10 rad) of gamma radiation in a single brief exposure, about 500 extra cancer deaths might be expected to occur during their remaining lifetimes in addition to the nearly 24,000 cancer deaths that would occur naturally. Because the extra cancer deaths would be indistinguishable from those that occurred naturally, even to obtain a measure of how many extra deaths occurred is a difficult statistical estimation problem (~~BEIR-V~~NRC/BEIR 1990).

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[3] Higher doses are usually expressed in Gray (rad) rather than Sievert (rem) to indicate that no quality factors are used.

1.6 Reactor Accident Exposure Pathways

In a reactor accident, there are three principal ways for radioactive materials to deliver doses to people: (1) external exposure to the passing plume and direct radiation from sources deposited on surfaces such as the ground; (2) internal exposure from inhalation of airborne radioactive material; and (3) internal exposure from the ingestion of radioactively contaminated food or water. Absorption of radioactive material through the skin or the injection through wounds, particularly, for tritium, are also possible, but of much less concern. For emergency preparedness purposes, the immediate concern is the inhalation pathway; this takes place in what is commonly called the "plume phase" immediately after the accident. The plume phase is the release of radioactive materials to the environment during the reactor accident. The radioactive materials escape into the environment and travel in an atmospheric plume or cloud. During the plume phase of a reactor accident release, the thyroid may be exposed in one of two ways: (1) ~~externally~~ externally from the passing plume gamma radiation associated with gamma-emitting isotopes; or (2) externally and internally, if inhalation is also a pathway (if radioiodines are present and inhaled). It is in the plume phase and in the plume EPZ that the potential for large doses to the whole body and to the thyroid exist in postulated worst-case severe accidents in the U.S.

The thyroid can also be exposed internally from the intake of radioiodines by the consumption of contaminated milk or leafy vegetables, commonly known as the ingestion pathway. The milk pathway is particularly important because radioiodines deposited on pasture grass are effectively transferred to the milk of grazing animals (particularly, cows, goats, and reindeer). It takes a day or two before the radioiodines first appear in milk. To reduce any internal exposure from the ingestion pathway, including thyroid exposure, officials should recommend that dairy animals be given stored feed and/or recommend the interdiction of local milk supplies and leafy vegetables within 80 km (50 miles) (FDA 1982). ~~T~~In the event of a radioactive material release, this distance can be altered when actual plume pathways are established.

In the more likely accident scenarios, primarily noble gases are released to the environment. Noble gases primarily irradiate the whole body externally. The thyroid, as well as other organs would receive a dose from this external radiation. In much less likely scenarios particulates, including radioiodines, may accompany the noble gases resulting in thyroid doses that could be numerically much higher than the doses resulting from external exposure (DDE) particularly if ingestion of these radioiodines occurs. Those exposed are at risk of adverse health effects including thyroid disease and cancer. A person who receives a very high thyroid dose of approximately 200 Gy (20,000 rad) might experience serious thyroid damage (ablation) and ~~possibly~~would also probably receive a lethal whole body dose.

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CHAPTER 2
BASIS FOR IODINE PROPHYLAXIS

2.1 Physiology of the Thyroid Gland

To understand the basis for the use of KI, also known in this report as iodine prophylaxis, it is important to understand how the thyroid works and the importance of iodine to the thyroid gland. This chapter discusses the potential for adverse reactions to stable iodide, the risks for thyroid cancer, and the evaluation of specific modifying factors relating to internal thyroid dose.

The thyroid gland is the largest gland in the neck (Surks 1999). It is situated in the front of the neck attached to the lower part of the voice box (or larynx) and the upper part of the windpipe (or trachea). The thyroid gland has the shape of a butterfly: the two wings being the right and left lobes which wrap around the trachea. Each lobe is about 4 cm (1.5 in) long and 1 to 2 cm (0.65 to 0.78 in) wide (Surks 1999). The sole function of the thyroid gland is to produce thyroid hormones. These hormones affect nearly all tissues of the body by increasing metabolism or cellular activity. Thyroid hormones contain iodine and iodine is important in the function of the thyroid gland. In addition to being the important component of thyroid hormones, iodine is important in producing them.

The function of the thyroid gland is to take iodine found in the foods we eat and the water we drink, and convert it into thyroid hormones, thyroxine (T4) and triiodothyronine (T3). Thyroid cells are the only cells in the body that can absorb iodine. These cells combine iodine and an amino acid to make T3 and T4, which are then released into the blood stream where they control metabolism. Every cell in the body depends upon thyroid hormones for regulation of their metabolism. The average adult body contains between 20 and 50 mg of iodine and more than 60 percent of this is concentrated in the thyroid gland.

As early as 1824, it was recognized that: (1) iodine is an essential element for humans; and (2) the lack of stable iodine in the diet leads to a condition called colloid goiter (Brucer 1990).

Subsequently, when stable iodine was added to most table salt (about half of a teaspoonful of salt provides the minimum daily requirement of up to 150 μg of iodine), colloid goiter essentially disappeared from the U.S. In recent decades, stable iodine has also become an important additive to bread and fast foods. It is estimated that the average American takes in over 200 micrograms of stable iodine daily (~~Thyroid Society~~http://the-thyroid-society.org). The primary significance of dietary iodide levels is that for a common exposure to radioiodide (inhalation or ingestion), individuals with a lower dietary intake of stable iodide will have a higher thyroid uptake of radioiodide, resulting in a proportionately higher thyroid exposure. Daily intake levels of stable iodide may also influence adverse reactions to stable iodide when administered in doses that greatly exceed dietary levels. However, daily dietary intake of iodine is not a factor in the consideration of the use of iodine prophylaxis.

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2.2 Thyroid Pathologies

The thyroid gland is prone to several distinct problems, some of which are extremely common. These problems can be broken down into: (1) those concerning the production of hormone (too much or too little); (2) those due to increased growth of the thyroid; (3) the formation of nodules or lumps within the thyroid which might signify the presence of thyroid cancer; and (4) those that are cancerous (American Cancer Society (ACS)).

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2.2.1 Hormonal Imbalance

The thyroid gland is not critical to life, but the hormones it produces are necessary for normal growth and development, heat production, and the well-being of the individual. The most prominent effect of the thyroid hormones is their regulatory control of respiratory exchange and basal metabolic rate (BMR). The thyroid gland serves as the body's metabolic thermostat by controlling the rate of oxidative metabolism of individual cells, which collectively produce heat and maintain body temperature.

Under conditions of hyperthyroidism (increased production or administration of the thyroid hormone), there is increased oxygen consumption, heat production, food metabolism, cardiac output, and plasma volume. This clinical state is also referred to as thyrotoxicosis.

Hypothyroidism is marked by a depression of thyroid hormone production that leads to a progressive slowing down of all bodily activities. Symptoms of hypothyroidism include intolerance to cold, dry skin, and sometimes thickening of the skin, hoarse voice, constipation, slow speech, weight gain, fatigue, and emotional changes often confused with depression. In adults, thyroid hormones also participate in the organization of cells. When thyroid function is reduced or eliminated, certain cellular functions become disorganized.

During childhood and puberty, thyroid hormones have a significant effect on the rate of body growth and development. A reduced hormone level during this time causes marked reduction in skeletal maturation and prevents full-body growth to adult dimensions. Thyroid deficiency during human fetal life and the postnatal period produces a significant depression in development and growth, including the central nervous system with a negative impact on intellectual development.

2.2.2 Thyroid Enlargement

A thyroid goiter is a substantial enlargement of the thyroid gland. The thyroid can become very large so that it can easily be seen as a mass in the neck. There are a number of factors that may cause the thyroid to become enlarged. A diet deficient in iodine can cause a goiter, but this is rarely the cause in the United States because iodine is readily available in the diets of Americans. Typically, in America a goiter is caused by an increase in thyroid-stimulating hormone (TSH) in response to a defect in normal hormone synthesis within the thyroid gland. Most small to

moderate-sized goiters can be treated by prescribing thyroid hormone in the form of a pill. By supplying thyroid hormone in this manner, the pituitary will make less TSH which should result in stabilization in size of the gland. This technique often will not cause the size of the goiter to decrease but will usually keep it from growing any larger.

2.2.3 Thyroid Nodules

Single or multiple nodules of sufficient size may cause obvious enlargement of the thyroid and may be seen as bumps on the neck. Usually a nodular thyroid is without symptoms but with continued growth, there may be a visible enlargement in the neck and compression of the trachea which results in a sensation of choking or coughing and hoarseness. The incidence of nodules is 10 to 20 times as great in women as in men, and since it develops and progressively increases in size during life, it is most frequently found in females 50 to 70 years of age. It is very common for nodules to remain undetected during a person's life, and only be detected upon autopsy.

2.2.4 Thyroid Cancer

The thyroid gland, like other body tissues, can develop cancer. The incidence of thyroid cancer is relatively rare; about 18,000 cases are diagnosed per year. Of these, about 13,500 will occur in women and 4,500 in men (ACS 2002).

In "normal" populations the incidence of clinically diagnosed thyroid cancers ranges from less than 0.5 per 100,000 persons (USA and Central Europe) to 8 per 100,000 in Chinese people. Thyroid cancers are often hidden or "occulted" and remain so during the lifetime of the patient. Often they are not discovered until the patient's death from other causes. The "occulted" thyroid cancers occur in the normal populations with a thousand times higher incidence, which ranges from 5,600 per 100,000 in Columbia to 35,000 per 100,000 in Finland. In the younger age group (0-15 years), the incidence of occult cancers in Finland is lower, 2,400 per 100,000. (Fransilla & ~~Harach,~~and Harach ~~et al~~1986).~~)~~

Thyroid cancers are generally classified on the basis of cell origin, such as: (1) papillary~~,~~; (2) ~~follicular,~~ follicular; (3) medullary~~,~~; and (4) anaplastic carcinomas. Radiation is generally considered a causative agent for the induction of papillary and follicular carcinomas.

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2.3 Radiation Induced Thyroid Diseases

Radioiodine uptakes from inhalation or ingestion, or both could result in acute, chronic, and delayed thyroid effects. For very high doses, acute effects include thyroiditis induced within two to three weeks after exposure. Following a latency period of years to decades, chronic and delayed thyroid effects may involve the gradual insufficiency of thyroid hormone production (hypothyroidism) or the appearance of thyroid nodules and cancer.

Radiation-induced thyroid cancers are essentially confined to papillary and follicular. Nearly 80 percent of all thyroid carcinomas (and about 90 percent of radiation induced thyroid carcinomas) are papillary tumors (ACS 2002). Papillary lesions are frequently very small. Tumor growth tends to be partially dependent on TSH and is less aggressive in individual under the age of 40. The 10-year survival rate with various forms of therapy is about 90 percent.

Follicular thyroid cancers (about 10% of the radiation induced thyroid cancers) tend to metastasize early by way of the blood stream to lung and bones. The tumors are TSH responsive and tend to pick up and metabolize iodide and to form the thyroid hormone. They are not a common type of thyroid cancer. This type of cancer has a lower survival rate than papillary carcinomas, typically a 10-year survival rate of 50 percent (ACS 2002).

Acute radiation thyroiditis generally occurs within 2 to 3 weeks after an internal exposure to radioiodine and is characterized by inflammation and necrosis of thyroid tissue (Maxon et al., 1977). The symptoms are generally mild but in some instances may be made worse by the rapid release of stored thyroid hormones (thyroid storm) (Shafer, and Nuttal 1971). In most instances, this syndrome abates within several weeks of onset.

Hypothyroidism is a metabolic state in which the thyroid produces an insufficient quantity of the thyroid hormone for normal physiologic function. For radiation-induced hypothyroidism, it must be assumed that a substantial number of cells are either killed or rendered nonfunctional, because of the large reserve capacity of the normal thyroid. Thyroid doses of 600 Gy (60,000 rad) could be expected to result in a 100 percent probability of hypothyroidism. The latency period between exposure and symptoms of hypothyroidism ranges from less than 1-year to several decades and increases with decreasing doses.

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CHAPTER 3
POTASSIUM IODIDE AS A THYROID BLOCKING AGENT

3.1 What is KI?

KI is potassium iodide. It is a salt, similar to table salt and, in fact, KI is the ingredient that is routinely added to table salt to make it ~~"iodized"~~ "iodized." KI will be taken up by the thyroid gland and, if taken in large enough quantities, will effectively saturate the thyroid gland. This saturation of the thyroid gland can prevent the uptake of radioactive iodine that may be released in the unlikely event of a severe nuclear reactor accident.

After an oral administration, iodide is rapidly absorbed into the bloodstream from the stomach where it is progressively removed either by the thyroid or by the kidneys. This exponential clearance of iodide from the blood stream in normal subjects has been shown to have a half-period value of about five to six hours (Myant 1949). (In the cases of very high or very low dietary iodide intakes, there is a corresponding reduction and elevation in thyroid uptake rates that result in longer and shorter half-period values, respectively.) Given the rapid uptake of iodide (radioactive or stable), there is declining benefit of KI administration following exposure to radioiodine. For KI to serve as an efficient blocking agent, it must be administered in sufficient quantities before, concurrently with, or shortly after, radioiodine exposure.

KI offers additional protection for one radiation-sensitive organ, the thyroid, under conditions of inhalation or ingestion of radioactive iodine. It does not protect against external irradiation of the thyroid, as might happen if one is immersed in a cloud of noble gases.

3.2 FDA Guidance

The FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of KI. In December 2001, the FDA published its final guidance "Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies" (Attachment ~~1~~2). The FDA revised its 1982 recommendation based on a comprehensive review of the data relating radioiodine exposure to thyroid cancer risk accumulated in the aftermath of the 1986 Chernobyl reactor accident (FDA 2001). The objective of this document is to provide guidance to other Federal agencies, and to state and local governments regarding the safe and effective use of potassium iodide as an adjunct to other public health protective measures in the event that radioactive iodine is released to the environment.

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~~The FDA revised its 1982 recommendation based on a comprehensive review of the data relating radioiodine exposure to thyroid cancer risk accumulated in the aftermath of the 1986 Chernobyl reactor accident (FDA 2001).~~

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These recommendations, as provided by the FDA, 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. The FDA states

that the administration of KI is a safe and effective means to reduce the risk of thyroid cancer in the event of exposure to radioactive iodine. However, ~~the "FDA recognizes~~FDA also stated that~~;~~ ~~i~~(FDA 2001):

> *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. These 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."~~ ~~*(FDA 2001)*~~

3.3 World Health Organization Guidance

In 1989, the World Health Organization (WHO) Regional Office for Europe issued "Guidelines for ~~i~~Iodine ~~p~~Prophylaxis ~~f~~Following ~~n~~Nuclear ~~a~~Accidents" at the request of two member States. Workshops were held to discuss the various issues of iodine prophylaxis. In 1991, there were indications of a significant increase in thyroid cancers in the population of children in the areas surrounding the Chernobyl Nuclear Power Plant. The ~~World Health Organization (WHO)~~ convened a technical group to advise it on the need to revise its guidelines on guidelines on iodine prophylaxis.

~~T~~In 1999, the result of this reevaluation was published by WHO ~~in 1999~~as "Guidelines for ~~i~~Stable Iodine ~~p~~Prophylaxis ~~f~~Following ~~n~~Nuclear ~~accidents".~~Accidents." These guidelines evaluated the apparent heightened sensitivity of children and adolescents to radioactive iodine uptake. ~~As a result of the increased thyroid cancers in the children in the areas surrounding the Chernobyl reactor, the WHO recommended KI prophylaxis at lower intervention levels, to as low as 10 mSv (1 rem) for the population at risk (young children).~~

The WHO states that "the sensitivity of the child's thyroid to the carcinogenic effects of radiation represents a significant public health risk in the event of exposure to radioactive iodine. With effective planning and the use of stable iodine prophylaxis, in association with other preventive measures, this risk is to a large degree ~~avoidable."~~avoidable" (WHO 1999). As a result of the increased thyroid cancers in the children in the areas surrounding the Chernobyl reactor, the WHO recommended KI prophylaxis at lower intervention levels, to as low as 10 mSv (1 rem) for the population at risk (young children).

3.4 International Atomic Energy Agency Guidance

The use of iodine prophylaxis has long been a recommendation of the International Atomic Energy Agency (IAEA). As a result of the publication of the WHO guidance, in 1999, the IAEA met to review the guidance in Safety Series 109 and 115. ~~As a result of meetings~~In September

~~17 to 19, 2001, in Vienna, Austria~~, the IAEA recommended that the requirements be amended to reflect the following (IAEA 2001):

Indented all

~~"The~~ The administration of stable iodine (iodine prophylaxis) to the public is an early effective measure for the protection of the thyroid to prevent deterministic and to minimize stochastic effects at any age. However, it is primarily intended for the protection of children, including the unborn.

The current GIL (generic intervention level) of 100 mGy provides an operational basis for rapid decision and an efficient application in case of a nuclear emergency.

However, as there are strong indications of an age-dependency of the risk induced by RI (radioactive iodine), to recognize the higher RI sensitivity of children and the unborn, the administration of stable iodine may be recommended at significantly lower levels of avertable dose.

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This framework is intended to be used as a starting point for planning and to be optimized to take into account specific practical, operational, social and economic considerations and it must also consider the introduction of other PA (protective actions) such as sheltering and food control as measures to reduce the uptake of RI." ~~(IAEA 2001)~~

In addition, the meeting recognized that young children are at greatest risk from thyroid disease as a result of exposure to radioactive iodine, and stable iodine prophylaxis can eliminate acute effects while significantly reducing cancer risks. The conclusion of the meeting recommended to the secretariats that the safety guides introduce the concept that some countries may find it useful to adopt intervention levels for children and pregnant women that are lower than the proposed 100 mGy (10 rad) GIL and that an explicit reference to the WHO publication that proposes a value of 10 mGy (1 rad) be made as an example of an intervention level that may be appropriate for children.

3.5 Chernobyl Experience

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. The recommendations made by the FDA are based on their review of the Chernobyl data as they pertain to the large number of thyroid cancers that occurred.

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 I-131 (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. The 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.

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 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 (FDA 2001). 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. In some areas, direct thyroid measurements as well as survey data indicate that the dose from ingestion, with the largest contribution to the thyroid dose from consumption of fresh cows' milk, was responsible for most of the thyroid dose (UNSCEAR 2000). It is reasonable to conclude, that 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 (ingestion or inhalation of large quantities of radioactive iodine) in the event of a nuclear accident.

The Chernobyl reactor accident resulted in massive releases of I-131 and other radioiodines. Beginning approximately 4four 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 4four years of this 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. The majority of cases occurred in children who apparently received less than 30 cGy (30 rad) to the thyroid (Astakhova et al.,

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1998). A few cases occurred in children exposed to estimated doses of < 1 cGy (1 rad); 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).– 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). 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 I-131.

The UNSCEAR 2000 report is consistent with and fully supportive of the WHO report and the FDA final guidance [UNSCEAR 2000]. ~~They a~~All identify a strong relationship between the increases of thyroid cancers and releases from the Chernobyl accident. UNSCEAR 2000 also ~~suggests~~stated that, ~~"other~~

> *. . . other factors that might influence radiation risks have been identified. Many of the regions around Chernobyl are iodine-deficient and iodide dietary supplementation had been terminated before the accident. Although large amounts of stable iodine were distributed to the population living near the plant as prophylaxis shortly after the accident, the distribution was incomplete and is thought not to have been effective. Genetic susceptibility to radiation-associated thyroid cancer also has been suggested as a potential modifier of risk. Finally, other potential environmental contaminants need to be investigated.*~~"~~

3.6 Poland and the Chernobyl Accident

The use of KI in Poland after the Chernobyl accident provides useful information regarding its safety and tolerability in the general population.

Polish authorities detected increased levels of airborne radioactive contamination on the night of April 27, 1986. Although there was no official notification of the accident by the USSR, it was assumed, on the basis of Tass News Agency reports, that the increases were attributable to the accident at Chernobyl. On April 28, Poland formed a governmental commission to recommend protective actions. Among these actions, the commission recommended intervention levels for taking protective actions on the morning of April 29 (Wolff 1995).

On April 29, 1986, Poland's Minister of Health gave orders to prepare and distribute KI to the 11 provinces most affected. KI was to be made available through hospitals, public health centers, schools, and kindergartens. The country used its mass media to announce the protective action and to appeal for volunteers to assist in the nationwide distribution (Wolff 1995).

The commission then instituted the following additional protective measures (Wolff 1995):

- Feeding of cows on pastures or with fresh fodder was banned countrywide until May 15, 1986.
- Fresh milk with radioactivity above 1,000 Bq/L was banned for consumption by children and pregnant or lactating women.

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- All children under the age of 4four were given powdered milk through numerous distribution —centers.

- Children and pregnant or lactating women were advised to eat a minimum of fresh leafy vegetables (until May 16, 1986).

The distribution of KI was initiated on April 29 and was completed by May 2. This included the distribution of KI to more than 90 percent of the children under the age of 16 and about a quarter of the adults. A total of 10.5 million doses of KI were given to children and 7 million doses were given to adults. Multiple doses, although not recommended, were taken in a number of cases. In addition, about 6 percent of the prophylaxis resulted from self-administered tincture of iodine before the KI program was initiated (Wolff 1995). Because of diminishing air contamination, the KI prophylaxis was not repeated. In the second phase of the response, powdered milk was made available to all children less than 4four years of age.

In the past, the quantitative aspects of adverse reactions to iodide have been hampered by the small size of the study groups, the selection bias, anecdotal reports, the use of very large amounts of KI or limited follow-up. The accident at the Chernobyl reactor and the administration of KI to large numbers of the population in Poland provided an opportunity to assess use of KI across the population. A field study was conducted in Poland, after the administration of KI;: (1) to gather more information on the side effects of KI; (2) to determine, the degree of protection achieved during the acute phase;; (3) the effect of KI on newborns exposed in utero;; (4) to evaluate the effect of a single dose of KI of subjects with a previous history of thyroid disease; and (5) to determine the incidence of side effects to KI.

It was reported that a total of about 18 million doses of KI were administered in Poland after the Chernobyl accident. Of these doses, about 11 million were administered to children and the remaining to adults. A group of 52,092 persons were selected from the population that had received KI and questioned about their experiences with KI. A total of 34,491 completed the study. ~~There were,~~ comprising 12,641 children ~~in the study~~ and 20,578 adults. Thyroid doses and the effect of the KI prophylaxis were calculated. The field study estimated that dose reduction due to KI blocking was about 40% on the fourth day ~~4~~ after the accident. If prompt warning had been given by the Russian authorities, the 24- or 48-hour gain in time might have provided as much as 53 % and 67% respectively. The study found the side effects from a single dose of KI included headache, stomachache, diarrhea, vomiting, shortness of breath, skin rashes; (about 1% prevalence); and assorted other reactions. Of the 18 million doses administered, only 36,000 medically significant adverse reactions to KI were reported. Intrathyroidal side effects in newborns were examined in newborns administered KI within the first 20 days of life. Of the studied infants, 0.37% exhibited acute thyroid related reactions (increases in TSH and decreases in FT4 (free thyroxine)) (WHO 1999).

In adults with known iodine sensitivity, only two allergic reactions were observed (Nauman and Wolff 1993). In adult patients with confirmed thyroid diseases, it was reported that there was no exacerbation of their thyroid disease as a result of a single dose of KI (WHO 1999).

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While it was estimated that approximately a 40-45 percent reduction in thyroid burden was achieved by thyroid blocking and milk restrictions, (OECD ~~Stockholm Workshop~~1994), due to the relatively low iodine concentrations in Poland, it is not likely that epidemiological studies could detect excess cancers resulting from intake of radioiodine (WHO 1995).

The Polish experience supports the use of KI as safe and effective when administered to large populations.

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CHAPTER 4
EMERGENCY PREPAREDNESS AND THE ROLE OF KI

4.1 Emergency Preparedness and Nuclear Power Plants

The purpose of radiological emergency preparedness is to protect people from the effects of radiation exposure after an accident at a nuclear power plant. The radiological emergency preparedness system is designed to base protective measures on plant conditions, so that people closest to the plant can be evacuated before significant releases of radioactive materials occur (10 CFR 50.47 and Appendix E, and draft NUREG-0654, Supp. 3). To allow early protective measures, the licensee is required to notify State and local officials, within about 15 minutes and the NRC within 1 hour when an emergency is declared and to recommend evacuation to those officials if conditions reach a point at which core damage appears probable.

To permit protective measures to be taken effectively, two emergency planning zones (EPZ) are established around each commercial NPP. The zone within 16 km (10 miles) of the plant is considered the plume EPZ and the region within 80 km (50 miles) from the plant is considered the ingestion EPZ. Current analyses indicate that, in the unlikely event of a severe accident, direct exposure to the plume will dominate doses near the plant, and people who had not evacuated would be exposed to radiation from the airborne radioactive material, material deposited on the ground or other surfaces, and materials taken into the body by inhalation. Within the plume EPZ, some very-low-probability events may produce doses, which if delivered in a short period of time, may be high enough to produce ~~non-stochastic effects~~deterministic effects in people who had not yet evacuated. Farther from the plant, the dominant doses would come from radioactive materials taken into the body, primarily by the consumption of contaminated foodstuffs if their consumption were not limited. Logically, the planned protective measures differ in the two zones. There is flexibility, and protective measures will be adapted to the circumstances at the time of the accident.

The U.S. emergency response plans intend for areas close to the plant to be evacuated before any radioactive material associated with a nuclear reactor emergency is released. This approach is chosen for the following reasons:

- A gross release of fission products could produce significant radiation doses several miles downwind; for example, even if the release were delayed 4 hours and limited to noble gases, there could be significant doses more than 4 miles downwind if meteorological conditions were stable at the time.

- If the containment fails or is bypassed, there is relatively little time for taking protective measures; that is, even with low (1 m/sec or 0.037 mi/hr) wind speed, the cloud could be 8 km (5 miles) downwind in about 2¼ hours.

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- The responsible State and local officials are expected to take some time before ordering evacuation or other protective actions.

- It is best to remove the population from the source of the radiation exposure.

- These events are so rare that the potential benefits of evacuation outweigh the social cost of the evacuation.

To achieve the objective of action before exposure, emergency action levels (EALs) that trigger recommendation of protective measures are based on such plant conditions as the loss of barriers to fission product release. For example, a General Emergency (GE) is triggered by conditions such as: (1) prolonged loss of all offsite power; or (2) loss of two fission product barriers and potential loss of the third. EALs are discussed in Section B of the "Response Technical Manual" (NUREG/BR-0150). Reaching an EAL means the margin of safety may have been reduced and protective measures are warranted, not that there actually has been or will be damage to the reactor core or a large release of fission products from the fuel. When a GE condition has been reached, the licensee will recommend public protective actions to offsite officials. The offsite officials are responsible for making public protective measures decisions, including the use of KI if appropriate, and implementing them.

In addition to not knowing whether there will be a serious release of fission products, there is great uncertainty about the composition of the possible release. Since the actual releases from an accident cannot be known before they occur, it has been necessary to base emergency actions on hypothesized source terms. The use of these source terms has supported the implementation of responsible protective measures. To date, however, the protective measures recommended have been measures, such as evacuation, that would be effective against all nuclides because there was no way of knowing the actual magnitude or nuclide composition until after the release had occurred.

4.2 Consideration of the Use of KI

"Because the Commission believes that current emergency planning and protective measures-evacuation and sheltering-are adequate and protective of public health and safety, the Commission will not require use of KI by the general public. Rather, the Commission recognizes the supplemental value of KI and the prerogative of the State to decide on the appropriateness of the use of KI by its citizens. The Commission believes the final rule together with the Commission's decision to provide funding for the purchase of a State's supply of KI strikes a proper balance between encouraging (but not requiring) the offsite authorities to take advantage of the benefits of KI and acknowledging the offsite authorities' role in such matters." (~~66FR543266~~ FR 5432).

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A State's "consideration" should involve at least an internal review of the Federal Register Notice and brief deliberation on the State's position on the use of KI by the general public.

Some issues that may need to be evaluated by the State and local authorities in deciding whether to institute a program for the use of potassium iodide by the general public include (FEMA 2002):

(1) whether ~~potassium iodide~~KI should be distributed to the general population before an accident occurs or as soon as possible after an accident occurs;
(2) whether the risks of exposure to radioactivity will be lower if the evacuation of the general population is initiated with or without the use of ~~potassium iodide~~KI or if the general population is sheltered and the administration of ~~potassium iodide~~KI initiated;
(3) how ~~potassium iodide~~KI will be distributed during an emergency;
(4) if ~~potassium iodide~~KI is predistributed, what assumptions should be made about its actual availability and use in the event of an incident;
(5) what medical assistance will be available for the individuals who may have some adverse reaction to ~~potassium iodide~~KI;
(6) how medical authorities will advise the population to take ~~potassium iodide~~KI and under what circumstances this advice will be given, i.e., methods for public education, information and instruction; and
(7) how the authorities will provide ~~potassium iodide~~KI to transient populations. ~~(Federal Policy)~~

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In NRC's experience, States periodically review their emergency plans and preparedness, typically on an exercise frequency basis, to ensure that plans are up-to-date and account for local changed circumstances. For those States that conduct such periodic reviews, it is expected that the States would undertake their consideration of the use of KI during the first periodic review conducted by the State of offsite emergency plans and preparedness following the effective date of the rule amendment and issuance of this guidance document. For those States that do not routinely conduct periodic reviews, it is expected that the States would undertake their consideration of the use of KI on the same frequency as periodic emergency preparedness exercises following the effective date of the rule and issuance of this document. The rule does not require States to provide written notice of their consideration. It is expected that the States would inform FEMA and the NRC of the results of their consideration. The consideration process is not subject to continuing oversight or recurring evaluation by the NRC or by any other Federal Agency.

If States have previously considered the use of KI, it is expected that they will reconsider based on new information. Reliance on earlier evaluations would not be consistent with the rule requirement.

4.3 Funding of KI

The Commission has determined that for a State that has decided to stockpile KI, NRC initial funding for purchases of KI for use by that State during a radiological emergency would make a direct contribution to fulfilling NRC's regulatory mission.

The funding available for KI is not intended to fund any ancillary costs, including costs associated with storing stockpiles or distributing KI in the event of an emergency.

On December 20, 2001, the NRC sent letters to the 33 States and 1 Tribal Government with populations within the 10 mile EPZ of nuclear reactors. This letter discussed the NRC program to initially provide KI to those States requesting it and included a copy of the NRC Statements of Consideration in support of the final rule, the NRC disclaimer, the FDA guidelines on KI use, and the FEMA guidelines on incorporating KI into emergency plans. These documents are included in Attachments 1 and 2. Additionally, the revised Federal Policy on the Use of KI was also provided to the states. In response to these letters, a number of states (12 as of 5/1/02) have requested KI tablets.

4.4 The Role of Evacuation and Sheltering in Emergency Preparedness

Early evacuation is the most effective protective action for NPP accidents. Plant operators are expected to recommend prompt evacuation to offsite authorities without waiting for a release of radioactive materials. They base their recommendations on current and expected plant conditions.

In some cases, sheltering may be the appropriate protective measure. If travel conditions present an extreme hazard, public officials may initially decide to shelter (rather than evacuate) the nearby population until conditions improve. Sheltering may also be the appropriate initial action for people requiring assistance with transportation. In addition, sheltering may be the appropriate protective action for controlled releases of radioactive material from the containment if there is assurance that the release will be of short duration and if the area near the plant cannot be evacuated before the plume arrives.

After performing the initial early evacuation near the plant, licensee and offsite officials could modify the protective action recommendations, as appropriate, on the basis of: (1) dose projections indicating that the EPA PAG doses may be exceeded in areas beyond those that have been evacuated; and (2) field monitoring results that have located areas with high levels of contamination. On the basis of this information, plant and offsite officials may expand the evacuations to encompass other areas in the plume EPZ .

4.5 The Role of KI in Emergency Preparedness

The Commission has found that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The use of KI for public protection is a special kind of protective measure in that it offers very specialized protection. ~~KI can provide protection against~~ for internal doses to the thyroid from radioiodines. Depending on the specific

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circumstances around an NPP and the type of accident, a State may find the availability of KI to be an added benefit.

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The Commission recognizes evacuation to be the most effective protective measure to be taken in the event of a radiological emergency because it protects the whole body (including the thyroid and other organs) from all radionuclides and all exposure pathways. However, the Commission recognizes that there may be situations when evacuation is not feasible or is delayed. In-place sheltering is an effective protective action in such a situation. However, it is important to note that the issue is not evacuation or sheltering versus KI. Rather, is it evacuation or sheltering with KI versus evacuation or sheltering without KI. The use of KI is intended to supplement, not replace, other protective measures. (~~66FR54306~~66 FR 5430). One of the challenges of adding KI as a supplement to the range of public protective actions is to ensure that evacuation is not delayed.

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The Food and Drug Administration (FDA) has approved the use of KI as a radioprotective drug for use during radiological emergencies (see Appendix 2). KI, when taken in a timely manner, can significantly reduce thyroid exposure from an intake of radioiodines and is, therefore, an effective prophylactic. KI is readily available and does not require a prescription for purchase. The FDA has determined that KI is safe and effective for short-term use if administered in proper dosage with proper medical advice to those patients who are not also taking certain medications, have an allergy to iodine or do not have certain medical conditions. The FDA guidance concludes that the studies following the Chernobyl accident supports the causative role of relatively low doses of radioiodines in the increase in cancers found among children who were between the ages of 0 to 14 years of age at the time of the accident. The FDA further concludes that the Polish experience of widespread distribution of KI supports the use of KI as a safe and effective means by which to reduce the risk of thyroid cancer caused by inhalation of radioactive iodine or ingestion of foodstuffs contaminated with radioactive iodine when exposure cannot be prevented by evacuation, sheltering, or food and milk control. The use of KI will reduce the radiation exposure to the thyroid gland *only* from inhalation or ingestion of radioiodines. KI will not protect the thyroid gland from external exposures to radiation, nor will it protect the thyroid gland from exposure to any other inhaled or ingested radionuclides. For optimum benefit, KI should be administered just prior to, concurrent with, or within 3 to 4 hours after the release. The FDA concluded that 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.

Previously, KI was considered primarily for ~~administration to~~ NPP plant workers and emergency workers. Thyroid blocking for emergency workers was recommended because: (1) these individuals have more emergency response responsibility that may not permit them to evacuate; (2) the number of individuals involved at any site is relatively small and requires a limited supply of KI that can be readily distributed; (3) the storage, distribution, and administration of KI can be readily controlled; (4) the known sensitivity to iodide of this limited number of individuals

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can be reviewed; and (5) these individuals can be readily monitored for adverse side effects by medical personnel. In certain situations, KI may also be appropriate for institutionalized individuals for similar reasons.

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CHAPTER 5
U.S. EXPERIENCE WITH KI AS A SUPPLEMENTAL PUBLIC PROTECTIVE ACTION

The information in this chapter is reflected as submitted by the respective States. These States have implemented a KI program. Each State submitted a description of its KI program as well as discussion reflecting the State's experiences with the public and the distribution of KI, as well as any lessons learned.

5.1. Tennessee

In the early 1980s, the State of Tennessee considered, and decided to implement a program, to distribute stable potassium iodide (KI) to be used as a supplement to the emergency response plans already in place in the event of a nuclear reactor accident.

The first distribution took place from November 16 through December 11, 1981. Staff of the Tennessee Department of Health distributed KI to the 5,591 households within 8 km (5 miles) of the Sequoyah nuclear power plant. Staff members visited each household until they either had made contact with the residents or made four visits. During all visits where there was no one at home, information was left informing the residents about the program, future visits, and the opportunity to obtain KI by visiting their local health department office. When residents were home, the program was explained, questions were answered, and the residents were given the option to accept and keep the KI (one bottle for each member of the family) in their homes. A supply of KI was also distributed to the two schools located within 8 km (5 miles) of the plant. When the program ended, 66 percent of the households had accepted the KI.

In the years following this active distribution, KI was made available to residents if they wished to pick it up at their local health department. This was intended to cover new residents to the area. Another major campaign was not attempted until 1983 when the first doses of KI expired. The door-to-door campaign was not repeated this time. Instead, a direct mailing and a media campaign was used to inform residents that they could come to their local health department, weekdays between 8 a.m. and 4 p.m., to pick up a new bottle of KI for each member of the household. During this second distribution, 32 percent of the eligible households came to the health department offices. Nurses distributed the KI, and went over the safety information provided as an insert with the tablets and questions were answered. Special attention was paid to explaining the proper way to crush the tablets if they were to be administered to infants. Logs were also kept at the health department listing who picked up the KI, and how many bottles they received. No demographic information was recorded. The decision was made not to collect the old tablets but instead residents were instructed to dispose of the old KI in the sanitary water system. During the 1983 campaign and in all subsequent campaigns, no attempt has been made to estimate the cost of the program to the state, but other than the cost of the drug, which has been covered by the licensee; it is believed to be minimal.

KI was distributed in the same manner in 1988 and 1992. In 1993 distribution was extended to include the 0 to 5 mile area around Watts Bar in anticipation of that plant coming on line. The only difference in the 1993 distribution was that in some offices, clerks were allowed to distribute the KI after they had received training. Distribution was repeated around both plants in 1996. By this time, the response to the distribution of KI around Sequoyah had dropped to such a small percentage of the population that the decision was made to discontinue the extensive media campaign. One local press release was sent out only in the Sequoyah area. Notification of the public that the KI was available to be picked up, was made through the information calendar that is distributed to all residents within 16 km (10 miles) of either plant each year. Fewer than 15 percent of the population responded to this offer within 8 km (5 miles) of the two plants. One county had no one come by to get the drug.

In addition to the distribution, Tennessee maintains an inventory of KI for distribution during an incident. The quantity of KI is based on 100 percent of the population within 8 km (5 miles) plus 20 percent of the population out to 16 km (10 miles). The population of the two sites within 8 km (5 miles) and within 16 km (10 miles), respectively, is 22,656 and 78,221 around Sequoyah and 5,772 and 18,362, respectively, around Watts Bar. The supply of KI is maintained in county and regional health department offices around both power plants. Because the plants are so close to each other, a separate supply is not maintained for each plant. Only 200 extra cases of tablets were purchased for the addition of the Watts Bar plant. The nurses stationed at the emergency reception centers will take this supply with them when the centers are activated. If an additional supply is needed, Tennessee can request more KI from Alabama, which maintains a supply for the Browns Ferry power plant close to the Tennessee border.

5.2 Alabama

The current Alabama Radiological Emergency Plan (REP) follows the recommendations of the FDA's final report on KI of April 1982. Around 1988, the decision was made to have KI available through public health nurses at reception centers in potentially affected counties. KI will only be made available to evacuees from sectors in which they may have been exposed to a release of radioactive iodine before or during evacuation. KI will only be made available when ordered by the State health officer (SHO).

Because of time considerations, climate, and other reasons, the State of Alabama decided against distributing KI to the general public, but established a mechanism for possible distribution to: (1) emergency workers who may be required to enter the evacuation area; (2) certain institutionalized individuals; and (3) selected general public evacuees who may have been exposed to radioiodines during evacuation. The drug would be issued after the recipient signed an informed consent statement.

The climate in Alabama is such that the roadways are seldom impassable due to weather conditions, nor is serious traffic congestion anticipated near either of the nuclear power plants in Alabama. Provisions would be made for distributing KI to evacuees when they arrive at the reception centers if exposure to radioiodine received before or during the evacuation

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corresponded to a child's thyroid dose in excess of 0.1 Gy (10 rad). The drug would be ordered for arriving evacuees according to evacuation sectors. The evacuees would be issued "informed consent" forms and upon signature, evacuees would be given a 3-day supply of KI tablets for each member of the family.

The Alabama Department of Public Health decided not to have advanced individual home storage of KI for the following reasons:

- KI was packed only in bottles containing 14 tablets. Therefore, each member of the family would not have an individual supply.
- Potassium iodide has a 3-year expiration date and must be replaced.
- Administration of KI is not appropriate if radioactive iodines are not being released. Some persons may take the KI and assume that they are "safe" when, in fact, they should be evacuated.
- It is possible that many families would misplace or lose their KI before they needed it.
- There was no way to have advanced distribution of the medication to such groups as transients and other visitors.

In the area surrounding Browns Ferry Nuclear Plant, in north Alabama, the Tennessee Valley Authority provides KI for emergency workers near the plant and all of the population within the 8-km (5-mile) EPZ and for 20 percent of the population beyond the 8-km (5- mile) but still within the 16-km (10-mile) EPZ. At Browns Ferry, there are 561 people within the 3.2-km (2-mile) EPZ, 2,749 people in the 3.2 km to 8 km (2 mile to 5 mile) EPZ, and 38,347 people in the 8 km to 16 km (5 mile to 10 mile) EPZ for a total of 41,657 people within the 16-km (10-mile) EPZ. The evacuation times are 2 hours for the 3.2-km (2-mile) EPZ, 2 to 6 hours for the 3.2-km to 8-km (2-mile to 5-mile) EPZ, and 4 to 6 hours for the 8-km to 16-km (5-mile to 10-mile) EPZ.

Around Farley Nuclear Plant in southeast Alabama, there is only enough KI for emergency workers. Alabama Power Company provides KI for emergency workers near the plant.

Public health nurses are able to get to the reception centers within a time of 15 to 45 minutes. If ordered by the State health officer, they would make KI available to evacuees from designated sectors described in the appropriate health order. The evacuees would be given the KI drug leaflet to read. They would also have an opportunity to ask questions and decide whether to take KI or not. If they decide to take KI, they must sign a release form before KI will be issued to them. Counseling on KI benefits and risks should not be an added burden to the public health nurses at the KI distribution point.

Since Alabama has chosen to store KI at selected local health departments until such time as it might be needed at pre-determined distribution centers, there are no identifiable costs associated

with public education, staffing/training, management, follow-up, maintenance, and distribution. Any costs involved with these areas of interest would be covered as part of the standard REP training. The drug is stored under the control of the nursing director in the effected local health departments.

5.3. Arizona

Most of the postulated accidents at Palo Verde Nuclear Generating Station do not release radioactive iodine. The decision to provide KI to emergency workers would be initiated by a projected dose to an adult thyroid exceeding 0.25 Sv (25 rem) to an emergency worker. The State has a supply of KI for emergency workers. The present emergency plan requires that dose assessments be made to determine the unprotected worker's potential exposure.

Evacuation is the preferred protective action. In the event a member of the public could not evacuate in time to avoid inhaling of radioactive iodine, the State has enough KI available to give to the public on an *ad hoc* basis. For a limited number of individuals, this can be done within 3 to 6 hours of exposure.

5.4. New Hampshire

The New Hampshire KI Policy Study Group implemented the following:

- Supplement the annual emergency public information materials that are distributed every year to all households in the New Hampshire portion of the Vermont Yankee and Seabrook Station EPZs. The supplemental information explains what KI is; what its benefits are; what its limitations are; potential medical side effects; how it should be used in the event of a radiological emergency; when it should be used; how it can be obtained; how it should be stored.

- The supplemental material encourages anyone considering acquiring KI for themselves and their families to consult their personal physician about potential individual benefits and detriments of KI.

- The State of New Hampshire obtained an agreement with manufacturers of KI to make it available for over-the-counter purchase by members of the public. The State encouraged retail pharmaceutical outlets in New Hampshire to maintain supplies of KI for purchase by members of the public.

The State of New Hampshire continues to monitor the evolving Federal policies and guidance on KI, and the KI policies adopted by its neighboring States, and will make appropriate adjustments to the New Hampshire policy as needed.

CHAPTER 6
INTERNATIONAL EXPERIENCE WITH KI AS A SUPPLEMENTAL PUBLIC PROTECTIVE ACTION

6.1 Canada

6.1.1 New Brunswick

New Brunswick has a long standing practice of distributing KI to residents of the Lepreau Area surrounding the Pt. Lepreau nuclear power station. Approximately 3,000 residents live in a 20 km (12.5-mile) zone surrounding the nuclear plant. All area residents are currently listed in a demographic database that is updated annually. KI is distributed to residents as part of the door-to-door survey conducted every summer to update the database. This mechanism ensures that new residents have the chance to obtain KI within one year of moving to the area, and it also gives health officials the chance to replace expired stocks of KI tablets. Compliance with the survey is excellent. Residents who receive KI are also given cards explaining its usage. Additionally, stockpiles of KI are provided to police departments, public health offices, schools and local tourist facilities.

New Brunswick officials see KI as a supplement to evacuation, and do not rely on sheltering. KI use is currently recommended at radiation doses to the thyroid of 0.1 Sv (10 rem).

6.1.2 Ontario

The Province of Ontario has a policy that requires nuclear power plants to procure and stock adequate quantities of KI for their Primary Zone population. The Primary Zone is the 10-km (6.25 mile) zone around the nuclear power stations. Local governments determine how this is best done. Currently, all affected local governments are relying on stockpiles that are maintained at evacuation reception centers. KI has also been distributed to schools (parental permission slips are kept on file), hospitals, day care centers, prisons, essential services facilities, and nursing homes. KI has not been pre-distributed to individuals in the Primary Zone.

Ontario Hydro is the licensee for nuclear power plants in the province. The 10-km (6.25-mile) EPZ surrounding the Pickering plant contains between approximately 220,000 residents of the Toronto metropolitan area, and that surrounding the Darlington plant includes 170,000 residents. The third plant is in a less urbanized area, with approximately 20,000 residents in the EPZ. The EPZ for the Fermi-2 plant in Michigan also crosses into Ontario, potentially affecting up to 10,000 people.

Distribution is called for at projected radiation doses to the thyroid of between the lower bound of 100 mSv (10 rem) up to the upper level of 1 Sv (100 rem) .

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The approved dosage of KI for thyroid blocking is:

Adults/children over 12	1 tablet (130mg)
Children 3-12 years	1/2 tablet (65mg)
Children under 3	1/4 tablet (32 mg)
Neonates to 1 month	1/8 tablet (16 mg) (one dose only)

6.2 Sweden

In 1982, the Swedish Parliament decided that stable iodine tablets should be distributed to all households within the 12-km to 15-km (7 to 10 miles) area around the four Swedish NPP sites. Approximately 45,000 households have received 10 tablets containing 65 mg KI. The distribution is repeated every 5 years through a mailing organized by the regional authorities. The mailing contains information on basic facts about radiation, the related risks, and what to do in case of a nuclear accident.

In addition to the already distributed tablets, there are two central storage sites, one in Malmo, close to the Barseback NPP and one in Stockholm. These two storage sites contain tablets to be used if needed as a complement to the already distributed tablets in the vicinity of an accident. KI held in stockpiles, under controls of temperature and humidity, have been demonstrated to hold their potency for at least 14 years. After that period of time, they are replaced with new pills.

6.3 Czech Republic

In the event of a severe reactor accident, the basic protective actions in the Czech Repbulic are as follows:

- Evacuation: averted effective dose 100 mSv (10 rem)
- Sheltering: averted effective dose 10 mSv (1 rem)
- Iodine tablets: averted effective dose 100 mSv (10 rem)

If there is an accident condition, then KI is implemented immediately, for the region within 5 to 7 km (~~3~~ 4.3 to 4.2 miles) of the nuclear power plant without waiting on the monitoring results. In other parts of the EPZ, the iodine prophylaxis is implemented depending on consequences of the accident.

The licensee is responsible to pay for the KI tablets and the public information associated with KI, as well as other emergency planning costs.

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The KI tablets were pre-distributed through pharmacies to magistrates, mayors, and from them, to the public in all emergency planning zones as far as 20 km (12 miles) from the sites of the nuclear power plants.

~~6.4 France~~

~~The government issued update guidance on November 14, 2001 for KI distribution. The Prefects (local governments) are to complete~~

6.4 France

In France, in the event of a severe reactor accident, the maximum value allow is a dose of 100 mSv (10 rem) to the thyroid. In 1997, the French government decided to begin the distribution of KI ~~tablets~~in advance, directly to all households within the 10 km (6 mile) radius around each of ~~the~~France's 19 nuclear power stations. ~~The tablets are to be distributed in an efficient manner that allows for protections of children, teenagers and young adults in the vicinity of nuclear installations. Options for distribution include door-to-door as well as free distribution from the local pharmacies. The new program has not yet been implemented. Previous programs, which included stockpiles at schools, hospitals, day nurseries and other~~On November 14, 2001, the government issued updated guidance on KI distribution which directed the Electricite de France (EDF) to coordinate and establish a distribution campaign in the country. Every person living within a 10 km (6 mi) radius of a NPP received an explanatory letter by the Préfet (governor or chancellor of the county) and a coupon to be exchanged for the iodine tablets at a pharmacy [Le Guen, et. al., 2002]. The agreement signed by the EDF and representatives of the profession specified that when the KI was issued, advice should be given as to how it should be taken (directions for use, side effects, cases where it should not be taken, storage, etc.) and answers were to be provided to any questions the public might have. In addition, schools, local industry, and public buildings ~~that had been implemented were deemed to be ineffective in distributing KI to the public in the communities surrounding nuclear power plants.~~(town halls, etc.) were also given adequate supplies of KI tablets [Le Guen et. al., 2002].

Before distribution began, information meetings organized jointly by the EDF and the government were held for elected representatives, health professionals (such as physicians and pharmacists), and the public [Le Guen et. al., 2002]. When the first meetings were held in 1997, attendance was fairly well attended, with about 400 people per meeting, representing around 15,000 people in the whole of France. However, when the meetings were held again in 2000, the average attendance dropped to 50, even though the population had changed very little [Le Guen et. al., 2002]. Although home delivery made it possible to cover over 90% of the population involved, as opposed to 60-70% for withdrawal from pharmacies, depending on the region, the 2000 campaign results appeared even lower, with a national average of 43%, despite considerable effort made by EDF with regard to logistics and funding. Consequently, both the Préfet and several NPPs initiated a new campaign in 2000 to use both the civil defense drills and thank you letters to remind the affected population of the existence of the KI tablets. Both methods led to an increase in the distribution rate, and the results were satisfactory, with about 70% of the population covered [Le Guen et. al., 2002]

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6.6 Slovak Republic

Potassium iodide tablets have been distributed directly to households (through the Municipal Offices), to schools, health facilities and hospitals, military bases, police forces, fire protection units by the Civilian Protection Departments of the County offices. The tablets are distributed in a 30 km (18 mile) radius around the Bohunice plant and in a 20 km (12 mile) radius around the Mochovce plant.

The nuclear power plants train the local authorities on emergency preparedness matters, including the use of KI. A public information leaflet is provided to citizens within the emergency planning zones of the nuclear reactors. This leaflet details emergency planning measures and also includes a section on KI, including use, contraindications, and side effects.

Tablets have been distributed without regard to age. Two tablets per person were distributed and a reserve or stockpile is available for the transient population.

Citizens are notified by the authorities to take KI through radio and television broadcasts.

6.7 Hungary

Potassium iodide tablets are only available for persons under 40 years of age. The population in the communities surrounding the nuclear power station are listed by name and age, so that they KI only goes to those most at risk. They are distributed only during an emergency and are available from pharmacies, medical centers, mayors' offices, and in some communities, established election voting facilities.

The criteria for KI distribution is based on avertable thyroid dose of 100 m~~Gy~~Sv (10 rem), assuming a 4-hour release. The tablets are distributed within 30 km (18 miles) of the nuclear power station.

The decision not to pre-distribute was made to insure, that when KI was needed, it would be available and at the appropriate dosages for the various age groups.

6.8 Belgium

~~Belgium~~Belgium distributes KI to its citizens using a "4 zone" method of distribution. The Federal Agency for Nuclear Control, under the guidance of the Ministry of Interior, has the responsibility for KI distribution.

Evacuation Zone: ~~(0-10~~0 to10 km (0 to 6.2 mi)

- Predistribution to households via coupons to be redeemed at pharmacies

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- Stocks of tablets available in schools, hospitals, leisure centers, business areas
- Reserve stocks in pharmacies
- Public information brochure on KI use and availability

Sheltering Zone ~~(10-20~~, 10 to 20 km ~~(~~6.2 to 12 ~~mi)~~

- Stocks of tablets available in schools, hospitals, leisure centers, business areas
- Reserve stocks in pharmacies
- Public information brochure on KI use and availability

Zone of ~~20-30~~20 to 30 km ~~(~~12 to 18 ~~mi)~~

- Provincial stocks of KI tablets
- Arrangements for distribution to pharmacies, schools, nurseries
- Public information campaign

Whole-territory

- Central stockpiles of KI tablets
- Strategic reserve of base products which contain iodine in pharmacies
- Public information campaign

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CHAPTER 7
DISTRIBUTION OF KI

7.1 KI Distribution

Once a State has decided to incorporate KI into its emergency plans, there are decisions regarding the method of distribution of the tablets to the public that need to be addressed. At least three States have added KI as a supplemental protective action for the general public. Their experiences in implementing KI as a supplemental protective action for the general public were presented in Chapter 5. Chapter 6 detailed some international experiences with KI prophylaxis distribution. The results of these lessons learned from both the domestic as well as the international experiences are summarized in terms of "objectives to be accomplished" and "elements to be considered" in sections 7.2 and 7.3.

When the decision is made to provide KI to the public, a method of availability or distribution must be selected. Specifically, the availability or distribution system must provide for the recipient to take KI just prior to, concurrent with the release or within 3 to 4 hours of exposure to the radioactive iodine. This Chapter discussed several methods of distribution. An example of an effective program would have the following attributes:

- the distribution system must be capable of assuring that the exposed population understands the proper use of KI, receives the proper dose of KI, and maintains a record of the administration of KI
- ~~in this section several methods of distribution will be discussed~~ sentence moved to
- a combination of these methods may fit the local situation at a specific site
- this is not an exhaustive list of methods, but rather provides a starting point to assist emergency planning officials in the development of a KI program appropriate for their specific location

7.2 Pre-Accident Distribution

The State takes action to obtain KI and distribute the tablets to individuals prior to an accident.

KI is available to citizens through one or more of the following distribution methods:

- door to door distribution by State or local officials
- distributed at county health department, government agencies, utility offices
- mailed to households within the EPZ
- distributed at pharmacies/drugstores
- distributed at convenience or grocery stores

Several important objectives are accomplished with pre-distribution of KI:

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- avoids the time delay in administration of KI
- it may reduce congestion at the reception or KI distribution centers.
- provides an opportunity for personal discussion about the use of KI and may also provide for other needed contacts with the public
- the appropriate dosage instructions can be tailored for each household

Some elements that need to be considered with pre-distribution include:

- this distribution may require additional staff time and resources
- if the tablets are distributed door-to-door, follow-up is needed to insure that the household received the KI and understood the instructions for its use
- transient populations, such as visitors or workers in the 16 km (10 mile) EPZ, need to be considered for potential KI prophylaxis
- public education must make people aware that evacuation must not be impeded because of KI, i.e. if tablets are lost or not with the individuals, they must not spend time to look for the tablets or attempt to go back into the EPZ to get their tablets
- availability of the KI may result in it being used when radioiodine has not been released

7.3 Post-accident distribution of KI

Once the States takes action to obtain KI ~~is~~and stockpiled ~~by the States and is made~~it, it can be available during the accident response by one of the following methods:

- available at evacuation centers
- available at pre-designated centers
- available at designated points ~~on~~along the evacuation ~~routes~~ route(s)

Stockpiling of KI allows States to accomplish several objectives:

- States maintain positive control for the storage of KI assuring drug product integrity
- evacuees can be questioned to determine their need for KI and KI could be distributed only as needed
- medical staff could be available at the reception center or designated KI center to respond to questions regarding the usage of KI
- records of usage can be made at these centers as well as records of consent
- since the distribution takes place under supervised conditions, dosage error should be minimized
- the distribution can be made to all personnel in the affected sectors, including transient populations

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Some elements that need to be considered with post-accident distribution include:

- ~~there may be~~the potential for increased traffic to the reception or evacuation center~~-~~ as residents attempt to get KI tablets
- ~~some~~ persons outside of the areas of concern may ask for KI and may slow down or disrupt the distribution of KI to the affected population
- may need to increase number of staff members at the reception centers to process individuals through KI distribution lines
- reception centers may not be adequately sized to process the number of persons who might want to obtain KI
- medical staff may need to be available at each KI distribution point to dispense appropriate dosages~~of~~
- ~~KI~~Explanation and ~~discuss~~discussion of the use ~~of~~ KI, including potential side-effects and contraindications

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CHAPTER 8
CONCLUSION

The overall objective of emergency planning and preparedness is to provide dose savings for a spectrum of accidents that could potentially produce offsite doses in excess of Protective Action Guidelines (PAGs). The Commission recognizes that in developing the range of public protective actions for severe accidents at commercial nuclear power plants, evacuation and in-place sheltering provide adequate protection for the general public. Additionally, the use of KI is a reasonable, prudent and inexpensive supplement to a State's public protective actions for specific local conditions. The Commission has determined that funding for purchases of an initial supply of KI for use by States who choose to incorporate KI for the general public in their emergency plans would make a direct contribution to fulfilling the NRC's regulatory mission.

The use of KI in Poland, during the Chernobyl accident, supports the use of KI as safe and effective when administered to large populations. Both the FDA as well as the WHO endorse the use of KI as a thyroid prophylaxis during severe reactor accidents involving the release of radioactive iodines. The FDA and the WHO further conclude 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 (FDA 2001, WHO 1999).

The Commission recognizes evacuation to be the most effective protective measure to be taken in the event of a radiological emergency because it protects the whole body (including the thyroid and other organs) from all radionuclides and all exposure pathways. The use of KI for public protection is a special kind of protective measure in that it offers very specialized protection. KI can provide protection against internal doses to the thyroid from radioiodines, which will reduce the risk of thyroid cancer and prevent acute effects.

There are a number of practical considerations regarding KI stockpiling, distribution, and use. The issues surrounding the prophylactic use of KI following reactor accidents do not lend themselves to across-the-board solutions. The Commission's amendment to require explicitly that planners consider the use of KI, rather than require the use of KI, recognizes the important role of the States and local governments in matters of emergency planning and the use of medicinal protective measures by their citizens. Depending on the specific circumstances around a NPP and the type of accident, a State may find the inclusion of KI as a supplement to other protective actions to be an added benefit.

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~~ATTACHMENT~~APPENDIX 1

REFERENCES SUPPLIED TO STATES

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~~ATTACHMENT~~APPENDIX 2

FOOD AND DRUG ADMINISTRATION
FINAL GUIDELINES
ON POTASSIUM IODIDE USE

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~~ATTACHMENT~~APPENDIX 3

GLOSSARY OF TERMS

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GLOSSARY OF TERMS

Acute Radiation Thyroiditis: Inflammation and necrosis of thyroid tissue as a result of radiation doses greater than 200 Gy (20,000 rem) to the thyroid; symptoms are usually mild and abate in a few weeks, but can lead to a dangerous release of stored thyroid hormones (thyroid storm).

Deterministic Effects: Early deleterious radiation effects on living tissue (e.g., body, organ or tissue death, cataracts, tissue or organ damage), which generally occur only above a threshold dose and whose severity depends on the level of dose absorbed. They become evident within a short period of time from the irradiation (hours, days or weeks, depending on the dose received). Deterministic effects are expressed in grays (Gy).

Dose: A general term denoting a quantity of radiation. Depending upon its application it can be qualified as "absorbed dose, "equivalent dose", and "effective dose".

Absorbed dose: Quantity of energy imparted by radiation to a unit mass of matter such as tissue. Absorbed dose is measured in grays (Gy), where 1 Gy equals 1 joule of energy absorbed per kilogram of matter. One Gy produces a different intensity of biological effects on tissue depending on the type of radiation (alpha, beta, gamma, neutron). One common submultiple of the Gy, the milligray (mGy) is often used. One mGy is equal to 1/1000 of 1 Gy.

Effective dose : Weighted sum of the "equivalent doses" to various organs and tissues multiplied by weighting factors reflecting the differing sensitivities of organs and tissues to radiation. The weighting factor for each organ or tissue expresses the fractional contribution of the risk of death or serious genetic defect from irradiation of that organ or tissue to the total risk from uniform irradiation of the whole body. Effective dose is measured in ~~seiverts~~sieverts (Sv). Some submultiples of the Sv used are ~~milliseivert~~millisievert (mSv) and ~~microseivert~~microsievert (μSv). One mSv is equal to 1/1000 of 1 Sv and 1 μSv is equal to 1/1,000,000 of 1 Sv.

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Equivalent dose	Quantity obtained by multiplying the "absorbed dose" in an organ (e.g., thyroid) or tissue by a factor representing the different effectiveness of the various types of radiation in causing harm to the organ or tissue. This factor, whose value varies between 1 and 20 depending on the type of radiation, has been introduced in order to allow grouping or comparing biological effects due to different radiations. Equivalent dose is measured in ~~seiverts~~sieverts (Sv). One Sv produces the same biological effect, irrespective of the type of radiation.

Goiter: An enlargement of the thyroid gland.

Hyperthyroidism: A condition caused by excessive secretion of the thyroid gland.

Hypothyroidism: A condition caused by deficiency of the thyroid secretion resulting in lowered basal metabolism; may be radiogenic, estimated to be 100 percent for a dose of 600 Gy (60,000 rem) or more.

Neoplasm: Any new or abnormal growth, such as a tumor; neoplastic disease refers to any disease that forms tumors, whether malignant or benign.

Potassium Iodide: Colorless or white crystals, having a faint odor of iodine; used as an expectorant and as an amebicidal and bacteriocidal agent, as well as an additive to table salt and animal feed to eliminate iodine deficiency. Iodine is the active agent; iodines are also used as (inorganic) calcium iodide and as (organic) iodinated glycerol and other similar compounds.

Thyroiditis: Inflammation of the thyroid gland; may involve an enlarged thyroid and hypothyroidism and may require lifelong therapy with thyroid hormone.

Stochastic Effects: Late deleterious radiation effects (e.g., leukemia, tumors) whose severity is independent of dose and whose probability of occurring is assumed to be proportional to the dose received. It is also assumed that there is no threshold dose below which stochastic effects occur, therefore, at doses lower than those producing deterministic effects and may manifest themselves after a long time (years, decades) from the irradiation. Stochastic effects are expressed in ~~seiverts~~sieverts (Sv).

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Commissioner Dicus' Comments

PUBLIC INFORMATION ON POTASSIUM IODIDE (KI)

WHAT IS POTASSIUM IODIDE?
Potassium iodide is a salt, similar to table salt. Its chemical symbol is KI. It is routinely added to table salt to make it "iodized."

WHAT IS THE BENEFIT OF TAKING POTASSIUM IODIDE DURING A RADIOLOGICAL ACCIDENT?
If, during a radiological accident at a nuclear power plant, Radioactive iodine is released, the iodine seeks out the thyroid gland. Potassium iodide, if taken in time and at the right dosage, fills the thyroid with harmless iodine so there is no room for radioactive iodine in the thyroid. This could reduce the risk of thyroid cancers and other diseases that might otherwise be caused by exposure to radioactive iodine that could be dispersed in the unlikely event of a severe nuclear accident.

WHAT IS THE ROLE OF POTASSIUM IODIDE IN RADIOLOGICAL EMERGENCY PREPAREDNESS?
The purpose of radiological emergency preparedness is to protect people from the effects of radiation exposure in the unlikely event of a nuclear power plant incident. KI only protects one gland--the thyroid--from one substance--radioactive iodine. KI does not protect any other part of the body from radionuclides. Therefore, KI should only be considered in association with sheltering or evacuation, or a combination of sheltering and evacuation. Evacuation is the most effective protective measure in the event of a radiological emergency because it protects the whole body (including the thyroid gland and other organs) from all radionuclides. *The use of potassium iodide should not, in any way, delay or otherwise interfere with evacuation or sheltering.*

WILL POTASSIUM IODIDE PROTECT ME FROM OTHER RADIATION?

Potassium iodide only protects the thyroid gland from internal exposure to radioactive iodine. It will not protect any other organ or the whole body. The doses to the body at which evacuation is recommended are set at approximately 2 to 3 times the dose a person would receive from natural background exposure over the course of the year. Natural background radiation (depending upon where you live) can contribute between 0.36 to 0.60 rem per year. Evacuation is recommended if the whole body dose to the public from the power plant is projected to be 1.0 rem. Use of potassium iodide is recommended only if the dose to the thyroid is expected to be greater than or equal to 5 rem.

WHAT ARE THE RECOMMENDED DOSAGES OF POTASSIUM IODIDE?
The Food and Drug Administration (FDA) is the Federal agency responsible for recommendations as to the appropriate times to take KI and the dosages for different age groups. The FDA published revised guidelines in December 2001. The labeling on KI packaging may not yet reflect these new dosage guidelines. However, either dosage is safe and effective for thyroid protection. Neonates, nursing mothers, and pregnant women should only take one dose of potassium iodide, unless otherwise directed by their doctors.

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The FDA's recommended doses are:

- Neonates (birth to 1 month) 16 mg
- Children (1 month to 3 years) 32 mg
- Children/adolescents (3 years 18 years)* 65 mg
- Adults under 40 130 mg
- Adults over 40 (if doses greater than 500 rem) 130 mg

Adolescents approaching adult weight (70 kg) should take the adult dose

WHY DOES THE NUCLEAR REGULATORY COMMISSION (NRC) ONLY REQUIRE STATES TO CONSIDER THE USE OF POTASSIUM IODIDE FOR THE GENERAL PUBLIC?

The NRC will not require use of potassium iodide by the general public because the NRC believes that current emergency planning and protective measures--evacuation and sheltering--are adequate and protective of public health and safety. However, the NRC recognizes the supplemental value of potassium iodide and the right of the States to decide the appropriateness of the use of potassium iodide by its citizens under specific local. Upon request from a State with population within the 10 mile Emergency Planning Zone (EPZ) of a nuclear power plant, the NRC will supply two tablets of potassium iodide for each individual within the 10 mile EPZ.

DO TWO DOSES OF POTASSIUM IODIDE OFFER ENOUGH PROTECTION?

The tablets are to be used, if necessary, to supplement evacuation or sheltering. After individuals have evacuated the area, then they will no longer be exposed to significant quantities of radionuclides. Most (80% to 90%) of the thyroid dose received by children affected by the Chernobyl Nuclear Power Plant accident was because the children ate contaminated foods and drank contaminated milk over a period of many days. In the United States, we have measures in place to stop potentially contaminated foods and milk from reaching the consumer.

HOW WILL I GET THE KI FROM MY STATE?

The appropriate State officials will notify you whether KI will be stockpiled or distributed to you.

CAN INDIVIDUAL MEMBERS OF THE PUBLIC OBTAIN POTASSIUM IODIDE?

The FDA has approved potassium iodide as an over-the-counter medication. *As with any medication, individuals should check with their doctor or pharmacist before using it, to be sure it is safe for them and their family members.*

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NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DIAZ

SUBJECT: **SECY-02-0089 - REVISED DRAFT NUREG-1633 AND PUBLIC INFORMATION BROCHURE ON POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC**

Approved _____ Disapproved xx Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

SIGNATURE

Oct. 28, 02

DATE

Entered on "STARS" Yes xx No ____

Commissioner Diaz' Comments on SECY-02-0089

The staff proposed that we approve publication of a new version of NUREG-1633 and a brochure on KI. For the reasons that follow, I believe that the NUREG and brochure have been overtaken by events, and that no useful purpose would be served by expending any more time or resources on these two documents. On the contrary, doing so could revive criticism of the NRC for its lack of timeliness.

The draft NUREG now before us is the third version we have been asked to review since mid-1998. (The first version was withdrawn by the Commission and we disapproved the second one.) KI has been and continues to be a moving target, with significant new developments - actions by other agencies, by Congress, the states, etc. - occurring with some frequency. By the time the NUREG and brochure are put in final form, they would again be out of date and in need of revision.

Congress has asked the National Academies of Science to look at issues of KI distribution. The Food and Drug Administration has issued its guidance on the safety and effectiveness of KI. In addition, the NRC has provided its own guidance in its Federal Register notice on the new rule. In my opinion, the NUREG and the brochure at best can add little to what states and the public already know. At worst, they can confuse the public and the states. These projects have gone on too long, and cost too much, to be continued. In my opinion, it's time to pull the plug.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-02-0089 - REVISED DRAFT NUREG-1633 AND PUBLIC INFORMATION BROCHURE ON POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC**

w/comments

Approved _____ Disapproved X Abstain _____

Not Participating _____

COMMENTS:

See attached comments.

Edward McGaffigan Jr.
SIGNATURE

November 12, 2002
DATE

Entered on "STARS" Yes X No ____

Commissioner McGaffigan's Comments on SECY-02-0089

I concur with Commissioners Diaz and Merrifield that our limited resources would be better served by not expending any more time or resources on draft NUREG-1633 or a brochure on potassium iodide (KI).

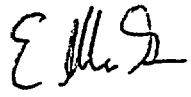
This is not to say that the current draft NUREG isn't a distinct improvement over previous versions. But it has been overtaken by events, and would, as Commissioner Diaz points out, likely continue to be overtaken by events. Most of our national experience in KI distribution has been accumulated over the past year. Seventeen States have requested initial supplies of KI from NRC. This does not yet include Tennessee, which previously made provisions for KI prophylaxis as a supplementary protective measure, and Illinois which has a KI program separate from NRC's funded from State resources.

Our web page's guidance has been adequate for the purpose of this effort. It includes the FDA guidance, the FEMA policy statement and the NRC Statements of Consideration, as well as practical details about how to apply for the initial KI supply.

Moreover, as Commissioner Diaz points out, Section 127 of Public Law 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, directs the President to request a National Academy of Sciences' study to determine the most effective and safe way to distribute potassium iodide tablets on a mass scale. This study will presumably go into far more detail about national and international experiences and the strengths and weaknesses of various approaches to KI distribution than the staff's brief discussion in Chapter 5 through 7 of the draft NUREG.

Finally, the terrorist events of September 11, 2001 are what has spurred this interest in KI prophylaxis among the States. The draft NUREG is silent on this subject. If we were going to go forward with the draft NUREG or a brochure, it would be important to point out for which terrorist incidents KI prophylaxis may be relevant, e.g., terrorist-induced events at operating nuclear power plants, and for which incidents it is not relevant, e.g., to deal with a radiological dispersal device, which will almost certainly not contain radio-iodines, or with a terrorist attack on a fuel cycle facility, where there are no radio-iodines present. There unfortunately is great confusion among the public and the media and even some in Congress on this point. The staff may want to add a brief discussion of this point to our web page on potassium iodide.

In short, I fully agree with Commissioners Diaz and Merrifield and believe that our limited staff resources would be better devoted to other more pressing tasks.



NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-02-0089 - REVISED DRAFT NUREG-1633 AND PUBLIC INFORMATION BROCHURE ON POTASSIUM IODIDE (KI) FOR THE GENERAL PUBLIC**

Approved _____ Disapproved __X__ Abstain _____

Not Participating _____

COMMENTS:

I agree with Commissioner Diaz that our resources would be better served by not expending any more time or resources on NUREG 1633 or the brochure on KI. We should direct our efforts toward our ongoing activities, including working with FEMA to supply KI stockpiles to the States that request it.

SIGNATURE

October 29, 2002
DATE

Entered on "STARS" Yes ✓ No ____