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

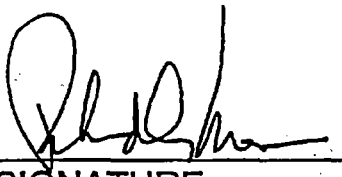
FROM: CHAIRMAN MESERVE

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

Mar. 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

ATTACH TO GTD 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 chat teeing.

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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(*Manuscript received* 7 *May* 2001; *revised manuscript received* 15 *November* 2001, *accepted* 6 *March* 2002)

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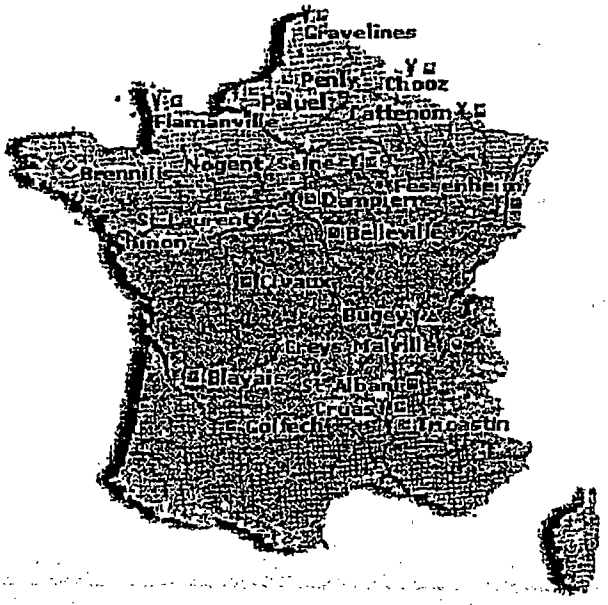

Fig. 1. Location of EDF nuclear power plants in France.

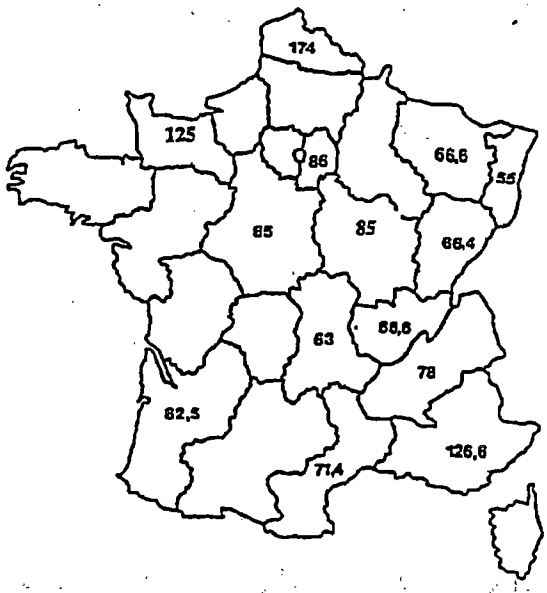

Fig. 2. Comparison of the iodine content in urine in France in μg d^{-1} (Mornex et al. 1987; Le Guen et al. 2000).

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

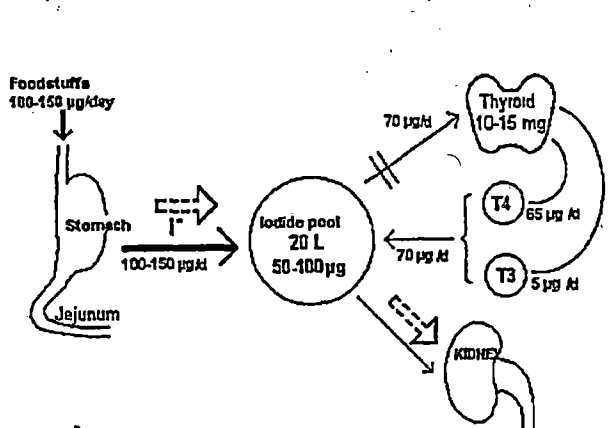

Fig. 3. Correlation between iodine prophylaxis and thyroid protection.

iodine to compensate for insufficient intake (Cavalieri 1997).

In France, the national average dietary iodine intake varies between 85 and 100 μg d^{-1} (Fig. 2) (Mornex 1987; Le Guen et al. 2000) with regional values ranging from 55 to 174 μg 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[a]	1 tsp	½ tsp

[a] 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 isand 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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EXECUTIVE SUMMARY

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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ACKNOWLEDGMENTS

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.

Additionally, special thanks to Brian Shanks, Point Lepreau Generating Station, New Brunswick, Canada for his insight and advice.

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.

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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.

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..."

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.

[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 Societyhttp://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; ~~"~~(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 ~~s~~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):

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~~"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 ~~4~~four years after the accident, a sharp increase in the incidence of thyroid
cancer among children and adolescents in Belarus and Ukraine (areas covered by the radioactive plume) was observed. In some regions, for the first ~~4~~four 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." (~~66FR543~~66 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~~ 66FR5430). 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

~~Belguim~~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: ~~(0-100 to~~10 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).

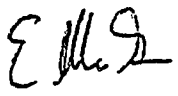
This is not to say that the current draft NUREG isn't a distinct improvement over previous versions. But it has been overtaken by events, and would, as Commissioner Diaz points out, likely continue to be overtaken by events. Most of our national experience in KI distribution has been accumulated over 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 ____

ATTACHMENT 1

REFERENCES SUPPLIED TO STATES

December 20, 2001

Kirksey E. Whatley, Director
Office of Radiation Control
Alabama Department of Public Health
The RSA Tower, Suite 700
P.O. Box 303017-3017
Montgomery, AL 36130-3017

Dear Mr. Whatley:

As you know, the Nuclear Regulatory Commission (NRC) has amended its emergency planning regulations to require that States consider including the prophylactic use of potassium iodide (KI) as a protective measure for the general public in the plume exposure pathway Emergency Planning Zone (EPZ) (66 FR5427, January 19, 2001). The use of KI would serve as a supplement to sheltering and evacuation. Subject to available funding, the NRC will provide an initial supply of KI for States that choose to incorporate KI for the general public in their emergency plans. The term "States" includes local governments that have been designated by the State to request such funding.

The NRC, in coordination with the Federal Emergency Management Agency (FEMA) and the Food and Drug Administration (FDA), is developing the means to provide KI to States. Within approximately 30 days, the NRC should be able to supply KI to States upon written request.

If Alabama concludes that incorporating KI for use by the general public is appropriate, you may request the NRC to provide KI by writing to Kathy Halvey Gibson, Chief, Emergency Preparedness and Health Physics Section, U.S. NRC, Washington, D.C. 20555. Your letter must provide the following information: the nuclear power plant (NPP) site(s); the population in the NPPs' 10-mile EPZ for which you are responsible; the contact person authorized to receive the KI; and the "Ship to" address for KI delivery. Upon receipt of this information, the NRC will validate the data and make arrangements for NRC's contractor to ship KI directly to your designated contact/address. The NRC will supply two KI tablets for each person in the 10-mile EPZ(s). You may also fax your request to (301) 415-2968.

We request that one request for KI be submitted for each State or Native American government. If decisions about emergency planning and the use of KI are the responsibility of local, rather than State authorities, we request that the State consolidate the local requests and forward the consolidated request covering all NPPs within the State to the NRC.

The following information is enclosed to this letter for your consideration and use: FDA guidance on use of KI (Enclosure 1); FEMA guidelines for KI program implementation (Enclosure 2); NRC Statements of Consideration published in support of the final KI rule (Enclosure 3); and NRC Disclaimer (Enclosure 4). A revision to the KI Federal policy will be issued shortly and will be provided to you when it is available. States are encouraged to begin their process for considering the use of KI as early as possible, recognizing that the NRC's resources for this purpose will be limited. NRC will provide KI to requesting States on a first come, first serve basis.

If you have questions or require assistance in this matter, please contact either Kathy Halvey Gibson, NRC, 301-415-1086 or Vanessa Quinn, FEMA, 202-646-3664.

Thank you for your consideration of this important issue.

Sincerely,

/RA/
Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

Attachment 2:
FEMA Guidelines For Potassium Iodide Program Implementation
For the Use of Potassium Iodide by the General Public

CONTENTS:

FEMA GUIDANCE ON THE USE OF POTASSIUM IODIDE BY THE GENERAL PUBLIC FOR COMMERCIAL NUCLEAR POWER PLANT ACCIDENTS

The Federal Emergency Management Agency (FEMA) believes that potassium iodide (KI) can be an effective supplement to sheltering and evacuation in the unlikely event of a release of radioactive iodine as a result of a commercial nuclear power plant accident.

The decision to include KI in the range of public protective actions rests with the States. FEMA is available to assist States with the decision making process and has developed a decision matrix to aid in that process. There are two basic methods of distribution: (1) pre-distribution to the public and (2) stockpiles in facilities such as reception or mass care centers. Based on the distribution method adopted by a State, the capability to implement the decision will be evaluated by FEMA as part of its "Reasonable Assurance Finding" recommendation to the NRC.

The evaluation of a State's capability to distribute KI to the general public can be achieved through the Annual Letter of Certification, when KI is pre-distributed, and/or a combination of Staff Assistance Visits and biennial exercise demonstrations, when KI is in a fixed facility.

If a State chooses to include KI in its range of public protective actions, we recommend that the State immediately prepare a procedure as to how it would disseminate the KI, if needed. The State must complete and submit revised plans and procedures, public information materials, and prescripted emergency instructions to the public by the end of the calendar year in which the State submits an application for the receipt of KI. Because States are not required to have their emergency plans revised prior to receipt of KI tablets, the tablets should be stored in convenient locations for ad hoc distribution, should that become necessary.

The capability to distribute KI tablets to the general public will be demonstrated by all

Offsite Response Organizations (ORO) during the first exercise following the submission of plans and procedures (but no sooner than 90 days); and, thereafter, OROs will demonstrate their capability as specified in the frequency of demonstration table for the evaluation areas.

OROs will address any issues regarding the distribution of KI to the general public in their Annual Letter of Certification, including the number of KI tablets issued or reissued during the previous year. Specific plan review requirements are attached.

PLAN REVIEW REQUIREMENTS
REGARDING THE USE OF POTASSIUM IODIDE
BY THE GENERAL PUBLIC

The plans and procedures submitted by the States need to:

- Address legal authority
  - Identify the person with the legal authority to made the decision to recommend the ingestion of potassium iodide (KI) by the general public
- Assign responsibility for implementing the KI decision
- Specify decision criterion (projected dose, actual release data)
- Identify eligibility criteria for issuance
- Describe the distribution method (pre-distribution to resident population only, distribution at an Offsite Response Organization [ORO] facility, or distribution to a special segment of the population only)
- Specify procedure to determine the quantity of pills needed
- Specify procedure to ensure that the supply of KI is sufficient for the Emergency Planning Zone population, including the estimated transient/seasonal population, that may be advised to take KI
- Identify ORO procedures to request, store, monitor and safeguard, dispense (to include, if applicable, tracking who received the drug, when, in what quantity and maintenance of waivers from liability), and dispose of KI stocks
  - Provisions should include the availability of adequate quantities, storage, and means of the distribution of radioprotective drugs (NUREG 0654/FEMA-REP-1, Rev.1 Planning Standards E, J, and N)
  - Available supplies of KI are within the expiration date indicated on KI bottles or blister packs or there is appropriate documentation extending the shelf life
- Describe the method to alert and notify the general public of the decision to recommend that they ingest KI
  - ___Review Alert and Notification system
  - Review and approve pre-scripted Emergency Alert System message and/or news advisories
  - Review and approve public education materials to include brochures, calendars, newspaper inserts, telephone book inserts

Checklist for items covered in the instructions:

____ Groups and location of people advised to take KI

____ Reason for taking KI
____ Dosage and time period within which KI should be taken
____ Information on where KI can be obtained or how it will be distributed
____ Possible side effects (Check with your doctor before taking KI)
____ Other (Specify)_____

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Rules and Regulations

Federal Register
Vol. 66, No. 13
Friday, January 19, 2001

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150–AG11

Consideration of Potassium Iodide in Emergency Plans

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its emergency planning regulations governing the domestic licensing of production and utilization facilities. The final rule requires that consideration be given to including potassium iodide (KI) as a protective measure for the general public that would supplement sheltering and evacuation. KI would help prevent thyroid cancers in the unlikely event of a major release of radioactivity from a nuclear power plant. The final rule responds to petitions for rulemaking (PRM 50–63 and PRM 50–63A) submitted by Mr. Peter G. Crane concerning the use of KI in emergency plans.

EFFECTIVE DATES: April 19, 2001.

FOR FURTHER INFORMATION CONTACT: Michael T. Jamgochian, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Telephone: (301) 415–3224. Internet: MTJ1@nrc.gov.

SUPPLEMENTARY INFORMATION: Section 50.47 of the Commission's regulations establishes requirements for emergency plans for nuclear power reactors to provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. Section 50.47(b) contains 16 planning standards, and in particular, § 50.47(b)(10) requires that emergency plans include "a range of protective actions" for the plume exposure pathway emergency planning zone (EPZ) for emergency workers and the public. This provision does not identify specific protective actions that must be included in these emergency plans.

The Petitioner's Requested Amendment to the NRC Regulations

On November 27, 1995 (60 FR 58256), the NRC published a document announcing the receipt of a petition for rulemaking (PRM 50–63) filed by Mr. Peter G. Crane on his own behalf and requested public comment on the suggested action. In the original petition (PRM 50–63), submitted on September 9, 1995, the petitioner requested that 10 CFR part 50 be amended to include language taken from FEMA's Federal Radiological Emergency Response Plan of September 1994. The petitioner requested that the NRC amend its regulations concerning emergency planning to include a requirement that emergency planning protective actions include the prophylactic use of potassium iodide (KI), which the petitioner stated prevents thyroid cancer after nuclear accidents.

The petitioner proposed that section 50.47(b)(10) be amended to read as follows:

(10) A range of protective actions *including sheltering, evacuation and prophylactic use of iodine* have been developed for the plume exposure pathway EPZ [emergency planning zone] for emergency workers and the public. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

In the September 9, 1995, petition (PRM 50–63), the petitioner stated that he believes that if his proposed rule change is adopted, the plan will become an accurate description of emergency preparedness for radiological emergencies; the recommendation of the Kemeny Commission to stockpile KI will at last be implemented; and the United States will be in compliance with the International Basic Safety Standards.

On November 11, 1997, the petitioner submitted a revision to his original petition (PRM 50–63A). In the revised petition, the petitioner requested that 10 CFR 50.47(b) be amended to read: (10) "A range of protective actions have been developed for the plume exposure EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidelines, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed."

The petitioner also provided a marked-up version of the NRC staff's proposed Federal Radiological Preparedness Coordinating Committee (FRPCC) **Federal Register** document concerning a revision to the Federal policy relating to the use of KI by the general public. The NRC published a document announcing the receipt of the amended petition on December 17, 1997, (62 FR 66038) and requested public comment on the amended petition.

As part of the petitioner's comments on the proposed rule, the petitioner also stated that his original petition was incorporated by reference and resubmitted because the amended petition was based in part upon the June 30, 1997, Commission decision to fund State supplies for those States that request it.

The petitioner also requested in PRM 50–63 that the NRC, either on its own or jointly with other agencies, issue a policy statement declaring that KI stockpiling is a sensible and prudent measure necessary to assure that the drug will be available in the event of a major accident. The petitioner believes that this statement would clarify that KI can be used in conjunction with evacuation and sheltering to maximize protection to the public.

Commission Action Concerning the Petitions

By staff requirements memorandum (SRM) dated June 26, 1998, to SECY 98–061, "Staff Options for Resolving a Petition for Rulemaking (PRM 50–63 and 50–63A) Relating to Re-evaluation of the Policy Regarding the use of Potassium Iodide (KI) by the General Public after a Severe Accident at a Nuclear Power Plant," the Commission decided to grant the revised petition for rulemaking (PRM 50–63A). The Commission also directed that the

preamble for the proposed rule include a statement to the effect that State and local decision makers, provided with proper information, may find that the use of KI as a protective supplement is reasonable and prudent for specific local conditions.

By SRM dated April 22, 1999, to SECY 98–264, "Proposed Amendments to 10 CFR 50.47; Granting of Petitions for Rulemaking (PRM 50–63 and 50–63A) Relating to a Re-evaluation of Policy on the Use of Potassium Iodide (KI) After a Severe Accident at a Nuclear Power Plant," the Commission voted to approve publication in the **Federal Register** of a [7590–01–P] proposed rule that would grant in part both the original petition (PRM 50–63) and the revised petition for rulemaking (PRM 50–63A). The proposed rule was published for public comment on June 14, 1999 (64 FR 31737). That notice provides greater detail concerning the basis for the petition and the NRC's rationale for the proposed rule language put forth for comment.

Other Activities Related to the Rulemaking on KI

In its decision on June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States at their request. On June 26, 1998, in a decision on this rulemaking petition, the Commission again noted that the Federal government (most likely the NRC) is prepared to fund the purchase of a stockpile of KI for the States, upon request.[1] However, in its April 22, 1999, SRM, the Commission decided: (1) Not to fund State stockpiles of KI; (2) to direct the NRC staff to work with FEMA to establish and maintain regional KI stockpiles; and (3) to support NRC funding of the purchase and resupply of the regional KI stockpiles to the extent that this cannot be covered by FEMA under its initiatives. The Commission determined that notwithstanding the June 30, 1997, and June 26, 1998, intention that "most likely the NRC" would fund the purchase of State stockpiles of KI, NRC was not prepared to fund State stockpiles of KI absent Congressional funding specifically for this purpose.

The Federal Radiological Preparedness Coordinating Committee (FRPCC) is responsible to coordinate all Federal responsibilities for assisting state and local governments in emergency planning and preparedness for peacetime radiological emergencies. Federal agencies which participate in the FRPCC include (among others): the Federal Emergency Management Agency (FEMA), NRC, the Environmental Protection Agency (EPA), and the Department of Health and Human Services (HHS). The 1985 Federal Policy recommends the stockpiling or distribution of KI during emergencies for emergency workers and institutionalized persons, but does not recommend requiring pre-distribution or stockpiling for the general public. In parallel with petitioning the NRC for rulemaking, Mr. Crane requested that the FRPCC policy be reconsidered. In early 1996, the FRPCC convened a subcommittee on Potassium Iodide. The subcommittee recommended the following to the FRPCC regarding the Federal KI policy: (1) Without changing the Federal policy that it is the State's prerogative to make its own decisions on whether to use KI, the Federal Government (NRC through FEMA), should fund the purchase of a stockpile for a State that, hereafter, decides to incorporate KI as a protective measure for the general public; (2) the language in the 1985 policy should be softened to be more flexible and balanced, as for instance, rewording it to state "it [potassium iodide for use by the general public] is not required, but may be selected as a protective measure at the option of the State or, in some cases, local governments;" and (3) local jurisdictions that wish to use KI should consult with the State to determine if the arrangements are appropriate. If local governments have the authority or secure the approval to incorporate KI as a protective measure for the general public, they would need to include such a measure in their emergency plans.

On June 16, 1997, the NRC staff forwarded to the Commission a staff version of the FRPCC-proposed Policy Regarding Use of Potassium Iodide After a Severe Accident at a Nuclear Power Plant. In its SRM of June 30, 1997, the Commission endorsed the Federal offer to fund the purchase of KI for States. On June 26, 1998, the Commission directed that the FRPCC proposed Policy be modified to include a statement to the effect that State and local decision makers, provided with proper information, may find the use of KI as a protective supplement is reasonable and prudent for specific local conditions. As noted above, the Commission also reiterated its endorsement of the Federal offer to fund KI stockpiles for States. Subsequently, on April 22, 1999, the Commission directed the staff to amend the draft FRN on the Federal KI Policy to conform to the Commission decision on the petitions for rulemaking, and the decision not to fund State KI stockpiles.

On April 29, 1999, the Director of FEMA, Mr. James Lee Witt, forwarded a letter to the Commission commenting on the issue of funding of stockpiles of KI for States. The letter objected to the Commission's "unilateral" decision on funding, and also noted "FEMA has always opposed the notion that Federal regional stockpiles of KI would be effective [and believes that] regional stockpiles would complicate, not strengthen radiological emergency preparedness." FEMA believes that if a State opts to use KI as a supplemental protective measure, the NRC should provide the funds for such a purchase.

The NRC responded to Mr. Witt's letter on June 15, 1999. This letter noted the Commission's decision not to fund state stockpiles of KI as well as the reasons underlying that decision. The letter also referred to the Commission's direction to "the NRC staff to work with FEMA staff to establish and maintain regional KI stockpiles to be used in the event that local stockpiles prove to be insufficient, or when a state without a stockpile elects to use KI on an ad hoc basis in the case of a nuclear emergency." The letter expressed confidence that the staffs, working together would successfully resolve the KI supply issue. The status of the stockpile and funding issues are discussed later in this notice. NRC is working closely with the other Federal agencies to determine appropriate changes to the 1985 policy. A decision regarding policy changes will be reached after the conclusion of this rulemaking.

In accordance with a Memorandum of Understanding between NRC and FEMA, NRC sent draft versions of this **Federal Register** notice to FEMA for its review and comment. FEMA responded by letter dated January 12, 2000. That letter reiterated their previous comments opposing regional stockpiles and instead favoring NRC funding of State stockpiles. The letter also noted that the development of regional stockpiles of KI had not progressed.

As discussed in the public comment evaluation, the Commission, as part of its decision to grant in full the amended rulemaking petition, has withdrawn its support for the funding of regional KI stockpiles and has reinstated its offer to provide for NRC funding of State or, in some cases, local stockpiles. The Commission agrees to fund a State's

[1] This was in contrast to previous Commission statements, such as those made when the Commission amended its emergency planning regulations (45 FR 55402) on November 3, 1980, wherein the Commission stated that any direct funding of State or local governments solely for emergency preparedness purposes by the Federal government would come through the Federal Emergency Management Agency (FEMA).

stockpile of KI, subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). NRC intends to work closely with FEMA and the other Federal agencies in FRPCC to finalize the draft Federal Policy to replace the 1985 Federal Policy. A decision regarding changes to the draft policy will be reached after the conclusion of this rulemaking. The substance of the specific comments attached to the FEMA letter is addressed by the issues in the public comment evaluation.

On September 30, 1998, the Commission also directed the staff to withdraw its guidance document, NUREG–1633 and substantially revise it, in a number of respects, including an improved discussion on how the practical problems in KI stockpiling, distribution and use are handled by States and other nations who use KI as a supplement. To accomplish this task, the NRC formed a KI Core Group, consisting of representatives from those States that have KI as a supplemental protective action, the Conference of Radiation Control Program Directors, the National Emergency Management Association, the U.S. Food and Drug Administration (FDA), EPA and FEMA. The revised draft guidance document, NUREG–1633, "Assessment of the Use of KI as a Supplemental Protective Action During Severe Reactor Accidents", Rev. 2 is expected to be issued for comment following receipt of the FDA's draft revised position on exposure action levels and proper dosage of KI which was issued for public comment on January 4, 2001 (66 FR 801).

In addition, the NRC plans to develop a public information brochure concerning the use of KI by the general public following completion of the final NUREG.

Public Comment Evaluation

On November 27, 1995 (60 FR 58256), the NRC announced the receipt of the original petition for rulemaking (PRM 50–63), and requested public comment on the suggested rule amendment. A total of 65 comment letters were received.[2] Letters in favor of granting the petition came from 5 environmental groups, 22 members of the public (including 1 from the petitioner), and the American Thyroid Association. Letters opposed to the petition came from 20 utilities, 9 State governmental agencies, 2 utility interest organizations, a letter signed by 12 health physicists, 2 State university medical centers and 1 member of the public.

On December 17, 1997 (62 FR 66038), the Commission published a request for public comment on the amended petition (PRM 50–63A) in the **Federal Register**. In response to several requests, the comment period was extended until February 17, 1998, by a **Federal Register** notice published on January 21, 1998 (63 FR 3052). A total of 86 comment letters were received. The letters in favor of granting the petition came from 8 public interest groups, 48 members of the public (including 3 from the petitioner), 3 physicians, 2 U.S. Senators, one State Representative, FEMA, the American Thyroid Association, a KI manufacturer, and the US Pharmacopeia Convention. Fourteen utilities, 3 State government agencies, 1 utility interest association, and 2 members of the public opposed the petition for rulemaking. A detailed analysis of the issues raised by the public comments with the response to those issues was published in the June 14, 1999, proposed rule **Federal Register** notice.

On June 14, 1999 (64 FR 31737), the Commission published a proposed rule in the **Federal Register**, based on the revised petition for rulemaking (PRM 50–63A) and requested public comment by September 14, 1999. A total of 77 comment letters were received.[3] The letters in favor of the proposed rulemaking and the revised petition for rulemaking originated from a United States Senator; a member of the U.S. House of Representatives; 3 State agencies; 4 public interest groups; 10 members of the public (including two from the petitioner); and one letter with 529 signatures. Letters that opposed the proposed rulemaking came from 14 utilities; 13 State or local government agencies; 1 utility interest association; one letter from the Conference of Radiation Control Program Directors Standards committee representing 5 committee members; a letter from the National Emergency Management Association representing emergency management directors in 50 states; a law firm representing 15 utilities; and a former Assistant Secretary of Nuclear Energy at DOE. The FEMA letter of April 29, 1999, was submitted before the rule was published and discussed KI stockpiles. Another 24 letters requested the Commission to grant the original petition (PRM 50–63) by *requiring* the use of KI rather than the *consideration* of KI in emergency planning. These letters originated from members of the public as well as public interest groups. As part of the petitioner's comment letter dated August 17, 1999, on the proposed rule the petitioner stated that, in light of the Commission's decision not to fund state stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted. He also requested the Commission to grant the petition as originally submitted.

The following discussion addresses the significant comments and issues raised in the three public comment periods for the original and amended petitions for rulemaking and the proposed rule.

Issue A: Should KI Be Considered as a Supplemental Protective Action to Evacuation and Sheltering

Several commenters on the proposed rule state that the rulemaking would not add significant public health and safety benefit beyond the current emergency plans, because evacuation and sheltering are the best means to protect the public in the event of a radiological emergency. According to these commenters, evacuation and sheltering are more effective at dose reduction because they reduce dose to all organs, not just to the thyroid.

Other comments express the view that the Chernobyl experience (including use of KI in Poland) shows that (1) thyroid cancer is a major result of reactor accidents, (2) the exposure can continue for days and thus the institution of KI blocking at any time is beneficial, (3) deployment of KI is safe, and (4) shelf life is extremely long. These commenters note that EPA Manual [Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, EPA–400–R–92–001 (May 1992)] quotes the FDA as stating that potassium iodide "will have substantial benefit even if it is taken 3 or 4 hours after acute exposure." Thus, these commenters believe that the advantage of having a supply of KI on hand outweighs moderate cost and that KI should be a supplemental protective action. Further, these commenters note that just because there may be other radionuclides to which people are exposed is not a reason to deny them the availability of KI.

Commenters who favor the use of KI as a supplemental protective action conclude that evacuation and sheltering alone may not be sufficient safety actions in the event that evacuation is not feasible. They state that natural

[2] Two letters that were received in response to the notice did not address the issues in the petition and are not discussed further.

[3] Three of the letters (those from FEMA, the senator and the congressional representative) were not submitted during the comment period in response to the notice, but are being treated as comment letters for purposes of this discussion.

disasters could occur that would make evacuation difficult and time consuming at best, as for instance, earthquakes, hurricanes, blizzards, and ice storms. According to these commenters, a point against strong reliance upon evacuation is the evacuation routes themselves. As an example, a commenter cites the area around the Seabrook Nuclear Plant, noting that during the summer tourist season especially, it can be predicted that evacuees will be forced to wait in traffic for great lengths of time. This commenter believes that if KI were predistributed, instances of cancer, hypothyroidism and other thyroid disorders might be avoided.

Response. 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 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, it is evacuation or sheltering *with* KI versus evacuation or sheltering *without* KI. The use of KI is intended to supplement, not to replace, other protective measures. This amendment represents no change in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. Depending on the circumstances, KI may offer additional protection for one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. 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 but the use of KI can be a reasonable and prudent supplement. Therefore, it seems reasonable, while continuing to recognize the role of the State and local governments in matters of emergency planning, to require explicitly that emergency planners consider the use of KI.

Issue B: Is There a Need for New Regulation

Commenters in favor of the proposed rule note that a host of countries—France, Germany, Belarus, Russia, Switzerland, Austria, the Czech Republic, Japan, Great Britain, Sweden, Slovakia, and others—protect themselves with stockpiles of KI. These commenters point to soaring rates of thyroid cancer appearing in children in the Soviet Union who were exposed to the Chernobyl nuclear accident and who received too little potassium iodide, and too late. Thus, these commenters support the view that there is new information that suggests the need for consideration by State and local governments. In addition, many of these commenters would go further than the proposed rule language and require the use of KI, not just its consideration.

In contrast to the above, letters from some state and local governments, and from utilities, say that the State and local governments have already considered the use of KI. They believe that the petitioner has not provided any compelling reasons why additional Federal requirements are needed or how they would benefit the health and safety of the public. These State and local government commenters reject the view that the States have not had access to sufficient technical information regarding potassium iodide, and that without accurate and current information on KI—including the Chernobyl experience and the consensus of international experts—States cannot make an informed judgment. They conclude that this assertion is without merit, as there has been no shortage of information related to the use of potassium iodide available to State radiological emergency planners, and oppose the implication that State and local governments, absent Federal actions, are incapable of making informed decisions regarding the protection of their citizens during a radiological emergency. One commenter stated that by issuing this rule, the Commission is ignoring the views of States where KI has been stockpiled or pre-distributed, and where experience shows the system is ineffective.

The commenters opposing the proposed rule on this basis also note that reliance on the Chernobyl experience discounts the vast technical, political, and socio-economic differences between the United States and Eastern European countries at the time of the Chernobyl accident. The efficacy of any protective measure will depend on a large number of factors, including but not limited to: the type of reactor involved; accident sequences and timing; source term; timeliness of notification; the manner in which protective action decisions are made and transmitted to the public; the mobility of the public; and the receptiveness of the general public to official instructions. These commenters believe that the above factors have already been considered by State and local governments in the development of existing emergency response plans.

Response. The Commission did not intend to imply that States are not capable of making informed decisions regarding the protection of their citizens during a radiological emergency. In fact, the final rule calls on offsite authorities to make their own decision on this matter. Additionally, the Commission recognizes that most State and local governments have already considered the use of KI in the event of an emergency as part of their planning. Nevertheless, the Commission believes it appropriate to provide information that may be of aid to offsite authorities in their consideration of this matter. Offsite authorities may, of course, use this information as they see fit.

Several States have welcomed the NRC's efforts in developing information relating to the benefits and risks associated with using KI as a supplemental protective measure for the general public. This information is intended to supplement and update information already available on this subject, including experience from State and foreign governments that have made KI available to the public. As noted earlier, this information will be in a revised NUREG–1633, which is scheduled for publication for comment after the FDA issues its draft guidance and in an information brochure.

The Commission finds that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. Through its decision to require that the use of KI be "considered" (rather than being required), the Commission is acknowledging that the efficacy of any protective measure will depend upon a number of factors, including those noted by the commenter, that can vary not only between countries but in individual States. Thus, the Commission concluded that decisions on the use of KI need to be resolved on a State-by-State basis. As part of this consideration, State and local governments can weigh all relevant factors.

Issue C: The Importance of Information in the Decisionmaking Process Concerning the Public Use of KI

In the proposed rule, the Commission noted that NUREG–1633 was being revised to provide information about experience in the United States and abroad with distribution of KI, and that an information brochure was also being prepared. According to some commenters, distribution of information on the benefits and risks associated with

the use of KI should not be limited to people living within nuclear power plant emergency planning zones. Further, commenters note that a comprehensive public information program outlining the potential range of benefits and risks of using KI and how to employ it most effectively in the event of a radiological emergency would be necessary to allow personal decisionmaking. Making the information and the KI itself available directly to members of the public provides them with the ability to decide for themselves how best to take advantage of the benefits associated with the use of KI as supplementary protection. One vehicle currently used for disseminating regular preparedness information which could be used to provide information on KI is the public information brochures and calendars already required to be distributed annually within each emergency planning zone. In this commenter's view, making information and KI available provides the greatest level of protection for the greatest number of people.

Some State government organizations were concerned that making provisions for KI might give the public a false sense of security that they are fully protected, and that the public might not evacuate. Thus, these organizations believe that there is a need for public information concerning the supplemental role that the use of KI could play.

Several of the commenters stated that it is desirable that the NRC would work with other appropriate Federal agencies to develop and promulgate clear and necessary guidance on the subject, similar to the guidance on sheltering and evacuation. These commenters also believe that the final decision should lie at the discretion of the State and local governments. A few commenters expressed the view that the rule puts the burden of assessment on States who have fewer technical resources than the NRC, the EPA or the FDA.

One commenter thought that the decisionmaking about stockpiling KI must include rigorous assessments to ensure sufficient quantities of KI will be available for distribution to members of the public, in both the plume exposure pathway and the ingestion exposure pathway.

Response. The Commission recognizes that once a State decides to include KI as a protective measure for the general public, it would be up to the State to decide how and when to conduct an educational program on the benefits and risks associated with using KI and to supply KI for appropriate distribution to the general public. Additionally, the Commission agrees that more detailed guidance on the use of KI would be useful in assisting States to assess the merits of stockpiling KI for the general public, including logistics, amounts and public information needs. The Commission has formed a KI "Core Group" consisting of representatives of State, local, and Federal agencies whose responsibility is to develop clear guidance relating to the use of KI. This guidance (NUREG–1633, Rev. 2) should be published for comment after FDA issues its draft guidance, which was issued for public comment on January 4, 2001 (66 FR 801). The NRC is continuing to work with other Federal agencies through the FRPCC to coordinate government policies concerning radiation protection and emergency planning. Further, a public information brochure to be published later will assist States and individuals in making an informed decision on KI.

Issue D: Making KI Available to the General Public

A range of comments were submitted concerning ways by which KI could be made available to the general public in the event of a radiological emergency. Many commenters simply asked NRC to "make KI available" without further detail. In the proposed rule, the NRC discussed Federal stockpiles of KI as part of Federal response to terrorist acts. One commenter indicated that expanding this supply may be the best approach. Another commenter stated that the public is not interested in stockpiles, but instead wants information to make their own decisions. Of those comments related to specific methods of availability, these can be generally grouped into individual availability, State stockpiles in the vicinity of nuclear power plants, or regional stockpiles.

Individual Availability

One State submitted, as part of its comments, a report that discussed a plan they have developed that would allow citizens to gain access to KI in advance of an accident. The plan calls for the State to secure agreements with KI manufacturers to sell the medication directly to individuals or retail outlets, and to urge local pharmacies to stock KI as an over-the-counter drug. Information concerning KI availability and use would be included in the annual emergency information mailings prepared by nuclear power plant staffs and distributed to every property owner within the emergency planning zones. The State concluded that this method would allow individuals to make their own decisions about the use of KI. This State noted that one can envision this activity being conducted in conjunction with existing programs designed to remind and encourage family members to periodically check home first aid kits, smoke detectors, spare batteries for flashlights and radios, and other items that they might employ for their comfort and protection in the event of any emergency. In addition, one commenter noted that KI is now available via the Internet from at least two vendors at an affordable price. (See also comments above in issue C about decisionmaking.)

State Stockpiles

A number of commenters believe that KI should be stockpiled in schools, fire houses or reception centers near nuclear power plants. These commenters state that this is the advice of the experts, for instance the World Health Organization and Dr. Jean Temeck, from FDA. These commenters believe that the young are the most vulnerable; and, in the words of Dr. Temeck, "in an emergency you want to get it to the children as quickly as possible and the teacher is right there on the spot. * * * You do not need to be medically trained to give KI. A permission slip to administer KI can be sent out by the school at the beginning of each year." Further, it makes sense to these commenters that this time-critical medicine be available nearby, such as in a local school, hospital, or fire-station. Thus, these commenters believe that State stockpiles are appropriate because regional stockpiles will not adequately protect the public since KI must be taken prior to exposure, or very shortly thereafter (within about six hours), to be an effective blocking agent.

Regional Stockpiles

A number of commenters, including emergency preparedness and response officials and FEMA, are concerned about the regional stockpiling and distribution process and its potential for reducing the effectiveness of measures which will provide much greater protection to the public. In their view, the complex logistics of storage and distribution of regional stockpiles far outweigh the usefulness of such a stockpile and that regional stockpiles of potassium iodide would complicate, not strengthen radiological emergency preparedness. These commenters believe regional stockpiling has disadvantages as compared to State stockpiling. The administration of KI is time-critical and regional stockpiling means critical time will be spent transporting the drug from a regional stockpile to the area where it is needed. For these reasons, they believe that

regional stockpiles should supplement, not substitute for State stockpiles.

Response. If a State decides to use KI as a supplemental protective measure, the Commission agrees that the State should focus on the early administration of KI to children. A decision to make KI available to the general public will require some planning by the State for its own supplies of KI and methods of distribution. Such planning (for implementation of protective actions) is a normal part of a State's emergency planning activities. As noted earlier, the NRC plans to issue a guidance document (NUREG–1633) to assist the States. The Commission recognizes the logistical challenges associated with the distribution of KI to the general public. For this reason, the staff intends to include a discussion of experience with KI distribution in the United States and abroad in the guidance document NUREG–1633.

There are different approaches that a State can use in incorporating KI as a supplemental protective measure for the general public. One approach is that mentioned by a commenter to distribute information about the over-the-counter availability of KI. Making KI available over the counter would provide members of the public with the opportunity to decide for themselves if they wanted to store and use KI. In fact, some KI manufacturers have indicated that they would make KI available to any person who requests it, at a fee. This approach would minimize the need for State stockpiles or predistribution and would put KI in the hands of the public before an accident occurs, rather than attempting to distribute the KI from stockpiles after an emergency is declared.

The concerns about the effectiveness of regional stockpiles for rapid deployment of KI to the public are also acknowledged. FEMA has stated that in its view, regional stockpiles will not enhance local radiological emergency preparedness because of complex logistics. The Commission agrees. As part of its decision on this final rule, the Commission has decided to provide funding for a supply of KI for States that request such funding through FEMA and to discontinue support of regional stockpiles. The Commission believes that in light of logistic difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue E: Requiring versus Considering Use of KI

Several commenters thought that the proposed rule should be modified to require the use of KI, not just the consideration by State and local officials. These commenters believe, for instance, that the tragic comedy of errors surrounding attempts to distribute KI in the wake of the Three Mile Island partial core melt accident only serves to highlight the need for predistribution. The health of our children is too important to leave their protection to the consideration of states. These commenters ask that if the U.S. system is adequate, why do other industrialized nations believe that sheltering and evacuation alone are insufficient? Some of these commenters want all commercial reactor licensees to distribute KI to all individuals within the EPZ and to make KI available to anyone within a 50-mile radius of the reactor upon request. These commenters believe that the prophylactic use of KI for the general public should be a *mandatory* emergency planning requirement and should not be merely an optional consideration, because, if given the choice, many States may not adequately protect their citizens. Another reason cited for wanting NRC to require KI is that "without a federal mandate for stockpiling KI, the nuclear industry will simply shift its fight against the policy to the State and local levels."

Response. 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.

The use of KI is intended to supplement, not to replace, other protective measures. This rule change thus represents no alteration in the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. 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. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. 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. Additionally, 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.

Issue F: Funding

Some commenters, including FEMA, state that the recent decision of the Commissioners *not* to fund the purchase of KI is an unfortunate reversal to the goal of providing supplementary protection for the general public. Thus, citing the Chernobyl accident, they urge the Commission to reconsider its position in light of the proven usefulness of KI in preventing childhood thyroid cancer. One State commenter was concerned that after two years of efforts made toward implementing this supplementary protection, the Commission's recent actions undermine that State's effort. While understanding the Commission's financial concerns leading to this decision, this commenter proposed that the Commission could approach Congress for a supplemental appropriation.

Another commenter stated that the Commission's withdrawal of the offer to pay for State KI stockpiles sends a message that KI preparedness is not important, and that States who were considering plans to establish stockpiles have dropped such plans. Further, some commenters believe that the NRC reversal of position regarding funding of KI for States that elect to stockpile it adversely affects the implementation of the policy proposed by the Federal Radiological Preparedness Coordinating Committee (FRPCC). [That draft policy currently provides that if a State chooses to add KI as a supplement to its evacuation and sheltering protective

actions, the State will inform FEMA, which will forward the request to the NRC for payment.] Another commenter noted that the Kemeny Commission supported stockpiling KI, and that the Commission should fulfill an earlier NRC commitment to do so.

Several States expressed the view that the requirement that use of KI be considered is an unfunded State mandate and is contrary to an Executive Order of 8/5/99.

A number of commenters stated that they thought the utilities should pay for supplies of KI in the vicinity of the power plants. Some utilities expressed concern that the rulemaking might result in requests to the utilities from State and local organizations for such funding.

Response. The Commission decision not to fund State stockpiles has been reversed as the result of public comment on this rulemaking. Promulgation of this final rule underscores the Commission's views on the importance of emergency preparedness, including consideration of the use of KI. The Commission has decided to fund State and, in some cases, local stockpiles of KI, subject to certain restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000). The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant. The Commission's offer to fund the purchase of a supply of KI for a State choosing to use KI prophylaxis as a supplemental protective measure retains the FRPCC's proposal that the State remain responsible for all other funding connected with the incorporation of KI, such as preparing guidelines for its stockpiling, maintenance, distribution and use, and for all other ancillary costs.

The Commission agrees that, in the past, licensees may have found it in their own self interest to assist State and local governments by providing resources for emergency planning needs. The Commission expects that those States who decide to use KI for the general public will make suitable arrangements to fund costs other than the initial purchase of a supply of KI. After funding the initial purchases of KI, the Commission may consider extending the program to fund stockpile replenishment, but has made no commitments in this regard. As with other aspects of offsite emergency planning, the NRC will not require licensees to fund State activities, but the States can, of course, act in cooperation and coordination with licensees.

As to the issues whether the rule constitutes an "unfunded State mandate" or is contrary to an Executive Order of August 5, 1999, the Nuclear Regulatory Commission, as an independent regulatory agency, is not subject to the requirements of Title II of the Unfunded Mandates Reform Act of 1995 or Executive Order 13132, "Federalism," August 5, 1999.

Issue G: Whether This Rulemaking Is a Backfit

A commenter representing nuclear utilities raised a concern that if licensees would be required to expend significant resources in considering the use of KI in emergency plans, then the proposed rule is clearly a backfit and a backfitting analysis should be performed. Thus, the commenter requested that the NRC either limit the specific actions which would be required to be taken by licensees to demonstrate that the adequate consideration required by the proposed rule has been implemented, or the required backfitting analysis should be conducted and a suitably revised proposed rule should be published for comment.

Response. This notice contains a "Backfit Analysis" section, which notes that the Commission concludes that the rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to States or local governments, the entities with the responsibility to determine the appropriateness of the use of KI for their citizens, calling upon the governments to consider KI as one of the elements of their offsite emergency planning. The final rule imposes no binding requirement for State or local governments to alter emergency plans and procedures.

Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions is already set forth in the existing § 50.47(b)(10). Once again, the rule does not impose new requirements on nuclear power plant licensees who are the intended beneficiaries of the Backfit Rule provisions. Therefore, no backfit is involved.

Issue H: State Liabilities in Providing KI for the General Public

State and local government organizations raised concerns about legal implications should a member of the general public be given KI at their directive or recommendation and the individual has an extreme allergic reaction. Commenters note that the **Federal Register** notice does not address legal issues for States who decide to adopt KI and for States who do not decide to adopt or administer KI to the public. Further, if the NRC decides to require stockpiling of KI for the general public, the commenters ask whether NRC has considered what liability may arise from any adverse health effects. Another concern was about who would assume liability if the KI was used prior to a Governor ordering its use.

Response. These comments focus principally on concerns that State and local governments involved in distribution and administration of KI may be liable in tort if an individual receiving the KI has a significant adverse medical reaction to the KI. As stated in the proposed rule FR notice, the question of whether a State or locality might be liable for involvement with administration of KI to the general public can only be answered by reference to the laws and precedents of particular States. The NRC presumes that this would be part of the "consideration" that States and localities will undertake as a result of promulgation of this rule. To the extent that commenters are raising the potential for Federal government liability for the promulgation of this proposed rule, the proposed rule FRN notes NRC views that whether the Commission may be subject to tort liability through the implementation of a KI program depends upon a number of factors. However, it would appear that a Commission decision to require State and local emergency planning officials to consider stockpiling KI for public distribution should be subject to the "discretionary function" exception to the Federal Tort Claims Act. 28 USC 2671, *et seq.*, which protects the Federal Government from liability. The Commission's offer to fund State stockpiles would similarly be subject to the "discretionary function" exception. The Commission has directed the staff to ensure that NRC funding for KI is accompanied by appropriate disclaimers to ensure that the NRC and any of its employees are not to be held responsible for any activity connected with transporting, storing, distributing, administering, using, or determining proper doses of KI for adults and children.

Issue I: FDA Input on KI

A few commenters thought that the dosage and intervention levels should be lowered from the values in the existing FDA guidance. For instance, they conclude that NRC should require using KI prophylaxis at one rem projected dose exposure not at the

current 25 rem. It was noted that Poland uses a 5 rem intervention level. The concern of these commenters is that continued use of the old guidance subjects children to greater risk than necessary.

Response. The FDA is the Federal agency responsible for decisions about appropriate thresholds and dosages for use of KI. Existing FDA guidance related to the use of KI on dosage intervention levels is contained in a June 29, 1982 notice (47 FR 28158). As stated therein, "FDA concludes in the final recommendations that risks from the short-term use of relatively low doses of potassium iodide for thyroid blocking in a radiation emergency are outweighed by the risks of radioiodine-induced thyroid nodules or cancer at a projected dose to the thyroid gland of 25 rem." That notice also provides recommended dosages for adults and children. New FDA guidance was published in the **Federal Register** for public comment on January 4, 2001 (66 FR 801). The Commission will incorporate it into its guidance documents.

Issue J: Original Petition Versus Revised Petition

A few commenters state that in the proposed rule, the Commission claims to have granted the alternative submitted in the amended petition, but did not actually do so. In their view, the amended petition contained the combination of three elements— the requirement to consider KI stockpiling, the unequivocal recommendation that States establish stockpiles, and the offer of Federally-funded State stockpiles. Since the promise of funding removed a major impediment to States adopting a pro-KI policy, the commenters believe that the petitioner felt that amending his petition to require only "consideration" of the use of KI would likely result in State decisions favorable to using KI. In their view, the amended PRM was premised on the now-withdrawn NRC offer of Federally-funded State stockpiles of KI, and therefore it would be entirely appropriate for the petitioner to rescind his amendment to PRM 50–63 and to insist that the NRC adopt what was requested in his original petition.

Response. The Commission agrees with this comment. Since the Commission has decided to reinstate its offer to fund a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans, the Commission believes that it is granting the amended petition (PRM–50–63A) in all respects.

Issue K: Meaning of "Consideration"

Several commenters stated that the proposed rule is vague in that it did not define "consideration." They believe that the rule should clarify that the KI "consideration" within the context of radiological emergency planning and preparedness needs to be performed only once by the responsible State agency, which would provide written notice of the consideration to the Commission. Thereafter, no further "consideration" should be required unless the State determines there is reason to reconsider its position and that the "consideration" process is not subject to continuing oversight or recurring evaluation by the NRC, or any other federal agency.

Another commenter questioned whether a State that considered the issue in the early 1980s, and rejected the use of KI, could now claim that the Commission's current proposal has already been fulfilled. Reliance upon the earlier consideration would violate the intent of the petitioner's proposal.

Another commenter questioned whether the following scenario would be considered acceptable and in compliance with the rule: a State considered the use of KI, but found the licensee unwilling to pay for it, so the State decided that although use of KI might be a good idea, it couldn't afford it.

Response. The Commission would expect that a State's "consideration" would involve at least an internal review of this notice and brief deliberation on the State's position on the use of KI by the general public. 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, the Commission would expect the States to 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 this rule amendment and issuance of revised NUREG–1633 guidance. For those States that do not routinely conduct periodic reviews, the Commission would expect the States to undertake their "consideration" of the use of KI on the same frequency as periodic emergency preparedness exercises following the effective date of this rule amendment and issuance of guidance. The rule does not require States to provide written notice of their "consideration." The Commission expects that States will inform FEMA and the NRC of the results of their consideration.

Additionally, the Commission agrees that the "consideration" process is not subject to continuing oversight or recurring evaluation by the NRC or any other Federal agency.

By issuing this rule, the Commission is stating its conclusion that consideration of the use of KI that might have been performed many years ago, needs to be reexamined in light of new information. Thus reliance upon such earlier evaluations would not be consistent with the rule requirement.

Issue L: Federal Distribution of KI

One commenter noted that the Commission's proposed rule would seem to support the same techniques used for forced KI distribution that were dictated by governments in Eastern Europe during the Chernobyl accident. The commenter urged the Commission to consider whether this posture would be endorsed by any government, be it Federal, State, or local. This commenter believes the NRC staff ignores the testimony of those States where KI is stockpiled or pre-distributed for the public and where experience shows the system is ineffective. Additionally, a commenter thought that the proposed rule is predicated on the false assumption that even if States decide not to stockpile KI for the general public, they will have access to Federal reserves of the drug. By the Commission's own admission, such reserves have yet to be established nor has the funding mechanism to support such reserves been identified. The proposal suggests that states "consider" the availability of resources that do not exist.

Likewise, a commenter stated that the proposed rule implies that even when a State decides as a matter of public policy against distribution of KI for the general population, the Federal government will develop plans to override that decision. The purpose of such plans is unclear in the context of the proposed rule. Once a State has given due consideration to the use of KI stockpiling as a supplemental protective action and determined it to be unwarranted, the commenter seeks the basis on which the Commission proposes to develop a contingency plan.

Response. The Commission has never endorsed "forced KI distribution." Under this final rule the use of KI continues to be a State option. Moreover, revised NUREG–1633 will discuss the benefits and risks associated with using KI and the U.S. and foreign experience with public distribution. While the Commission has always

recognized that distribution at the time of an accident will present difficulties if there has been no advance planning, the Commission believes that the States will take the distribution matters into account when they consider the use of KI for the general public under this rule.

The Commission has decided to withdraw its decision to provide funding for regional Federal KI stockpiles. However, it should be noted that Commission efforts in this regard were not intended to "override" a State decision not to use KI during an emergency; rather, they were intended to make KI available in the event that a particular State changed its views and decided to use KI in an actual emergency, and had nowhere else to go for KI. The Commission believes that in light of logistical difficulties, it is doubtful that regional stockpiles of KI could be effectively employed in the unlikely event of a radiological emergency at a commercial nuclear power plant.

Issue M: Importance of Emergency Planning

A few commenters feel that safe siting and Design-Engineered features alone do not optimize protection of the public-health and safety and that the Commission should not rely upon probabilistic risk assessments to obviate the need for stockpiling and predistribution of KI. Another commenter is concerned that the premature aging of reactor components, the economics of utility restructuring, and the long-term storage of high-level waste at reactor sites all contribute to the need for KI stockpiling.

Response: The Commission agrees with the importance of emergency planning to complement site and design features and stated so in the August 19, 1980, **Federal Register** Notice (45 FR 55402) which codified the NRC's emergency planning regulations following the Three Mile Island accident: "The Commission's final rules are based on the significance of adequate emergency planning and preparedness to ensure adequate protection of the public health and safety. It is clear * * * that onsite and offsite emergency preparedness as well as proper siting and engineered design features are needed to protect the health and safety of the public. As the Commission reacted to the accident at Three Mile Island, it became clear that the protection provided by siting and engineered design features must be bolstered by the ability to take protective measures during the course of an accident."

The Commission did not rely upon probabilistic risk assessments in developing this final regulation on consideration of the use of KI.

The Commission interprets the third comment to relate to factors that the commenter believes could increase the likelihood of an accident and which, in the commenter's view, heighten the importance of emergency planning. The Commission's regulations recognize the importance of emergency planning by requiring development of a range of protective actions, which include sheltering and evacuation and, by this rulemaking, consideration of the use of KI for the general public.

Issue N: Cost of KI and Shelf-Life

One commenter feels that the NRC has exaggerated the estimated cost of KI, ignoring comments that point to the availability of inexpensive and long-lasting KI. This commenter thinks that market forces are likely to bring down the cost of KI and that savings in the NRC budget could be effected without diminishing the safety of America's children.

The U.S. Pharmacopeia wrote in its comment letter that the long-term viability of the drug was tested and it was found that 11 years after manufacture and eight years after the expiration date, the tablets were assayed at 99.1% of the labeled content of KI. The petitioner expressed the view that since the U.S. is currently engaged in a $15 million study of radiation-caused thyroid disease in the Ukraine, it was hard to understand why the government was not willing to spend a fraction of that amount to prevent radiation caused thyroid disease at home.

Response. Cost estimates used in past documents were based upon information available at those times. NRC presently estimates the cost of KI to be about 18 to 20 cents per tablet if purchased in bulk, with a shelf life of 7 to 10 years. As a result, the Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for the general public for specific local conditions.

As noted earlier, the Commission has decided to offer to provide funding for a supply of KI for State or, in some cases, local governments that choose to incorporate KI prophylaxis in their emergency plans.

Issue O: Safety of KI

Commenters believe that there is new information available from Poland and Belarus regarding use of KI following a radioactive release. They state that there were no reported serious adverse reactions. Specifically, 18 million individuals received prophylactic KI with overall toxicity of 2.5% (mostly nausea) but with only a fraction of 1% having serious side-effects.[4] Commenters state that this experience has been recognized by other countries who are stockpiling KI for use by the general public. This data has led some commenters to say that just because there are other lethal radionuclides to which people may be exposed, why deny them the availability of KI, which can counteract the deadly effects of radioactive iodine. Every drug has contraindications and the potential for allergic reactions. In an emergency as dire as a reactor accident where people risk illness and death, a possible adverse reaction to KI seems relatively minimal, and people absolutely should have the choice of making an informed decision and assuming possible risk.

Response. The Commission did consider the experience with mass distribution of KI during the Chernobyl radiological emergency (although the record on that distribution is not complete). That experience is still being investigated and evaluated by public health authorities worldwide. When the appropriate health agencies have established the applicability of the Polish experience to the United States, the findings will be followed in NRC guidance. The NRC acknowledges that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission guidance on emergency planning has long taken KI into consideration (see NUREG–0654/FEMA–REP–1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," Rev. 1, p. 63, items e and f). The FDA has approved KI as an over-the-counter medication and has found it effective and safe as discussed in the response to issue I.

Commission Decision on the Petitions for Rulemaking

Based on the foregoing, and as noted herein, the action by the Commission to approve this final rule grants in part and denies in part the original petition (PRM 50–63) and grants in all respects the amended petition (PRM 50–63A). The rule change, which requires "consideration" of the use of KI, is responsive to the amended petition. Further, including in this **Federal Register** notice for the final rule, a

[4] Comment letter from the Massachusetts Coalition To Stockpile KI dated September 10, 1999.

statement that "KI is a reasonable, prudent, inexpensive supplement to evacuation and sheltering for specific local conditions," is also responsive to both petitions. This statement does not use the petitioner's exact language but is responsive to the petitioner's request. The Commission's final position on funding of State stockpiles grants that part of the original and amended petition to include a statement of such support in the Statement of Considerations for the rule. However, the final rulemaking would deny that part of the original petition requesting that the Commission amend 10 CFR 50.47(b)(10) to *require* that the range of protective actions developed for the plume exposure pathway EPZ include sheltering, evacuation, and the prophylactic use of iodine.

The Commission has found that "[I]n developing the range of actions for severe accidents at nuclear power plants, evacuation and sheltering provide adequate protection for the general public." (Proposed Rule, 64 FR at 31745). 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 such decisions to State and local emergency response planners to determine whether their emergency plans should include the use of KI as a supplementary protective measure for the general public. The Commission's decision is implemented through this final rule that changes 10 CFR 50.47(b)(10). This final rule completes NRC action on PRM 50–63 and PRM 50–63A.

Rationale for the Commission Decision

The Commission has considered the KI policy question on numerous occasions since 1984. The history of the Commission deliberations shows that reaching consensus on this policy question has been an elusive goal. An important reason for this historical lack of consensus is that this policy question is not a clear-cut one. Individual Commissioners, past and present, have differed in their views with respect to the relative importance to be given to factors bearing on the KI issue. These honest differences have led to divided Commission views on how to resolve the policy question. The Commission agrees that its historical difficulty in reaching consensus on the KI policy question underscores the reality that this policy question is not a simple one, is not one that is easily resolved and, as a result, has been the subject of protracted deliberation.

After considering all public comments received, the information available in the literature, 20 years of experience gained in evaluating licensee emergency preparedness plans, and the arguments presented by the petitioner, the Commission has decided to amend 10 CFR 50.47(b)(10), by adding a sentence similar to the one suggested in the revised petition. Specifically the following sentence is inserted in § 50.47(b)(10), after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate."

The Commission finds that KI is a reasonable, prudent and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG–0654/FEMA–REP–1, Rev. 1, p. 63, items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency, and though the record on that distribution is not complete, the indications thus far are that mass distribution is effective in preventing thyroid cancer and causes few threatening side effects. Moreover, many nations in Europe and elsewhere—nations as different in their circumstances, politics, and regulatory structures as France, Canada, and Japan—have stockpiled KI and planned for its use. So have some U.S. States. The World Health Organization and the International Atomic Energy Agency recommend its use. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it is reasonable to take a further small step and, continuing to recognize the important role of the States and local governments in matters of offsite emergency planning, explicitly require that planners consider the use of KI.

The amendment should not be taken to imply that the NRC believes that the present generation of nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has significantly improved since the current emergency planning requirements were put in place after the Three Mile Island-2 accident in 1979.

The use of KI is intended to supplement, not to replace, other protective measures. This amendment does not change the NRC's view that the primary and most desirable protective action in a radiological emergency is evacuation of the population before any exposure to radiation occurs. 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. Depending on the circumstances, KI may offer additional protection to one radiation-sensitive organ, the thyroid, if used in conjunction with evacuation and sheltering. 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. In appropriate circumstances, KI can provide additional protection. 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 such decisions to State and local emergency response planners, who may find that KI should be a supplementary protective measure.

The NRC recognizes that any decision to use KI as a supplemental protective measure for the general public presents issues of how best to position and distribute the medicine, to ensure: (1) That optimal distribution takes place in an emergency, with first priority given to protecting children; (2) that persons with known allergies to iodine not take it; and (3) that members of the public understand that KI is not a substitute for measures that protect the whole body. To date, these issues have been addressed in different ways in the numerous countries that currently use KI as a protective measure for their citizens. The NRC is working with States and other Federal agencies to develop guidance on these and other issues relating to the use of KI. The NRC believes that these implementation issues can be solved, given the level of expertise in the relevant Federal and State agencies, and the experience of numerous nations that have built KI into their emergency plans.

Commission Decision on Funding of State Stockpiles or Supplies of KI

The **Federal Register** notice for the proposed rule (64 FR 31737) stated the Commission's then-held position only to support funding of regional stockpiles or other supplies of KI as opposed to funding of State stockpiling of KI. As described above, in its deliberations on this final rule, the Commission has withdrawn its support for funding of regional KI stockpiles and has reinstated its offer to provide NRC funding of State or, in some cases, local stockpiles,

subject to various restrictions and limitations (see Staff Requirements Memorandum for the Affirmation Session on December 22, 2000).

In doing this, the Commission has responded to comments from FEMA and other commenters. The Commission is supporting the 1996 FRPCC's Ad Hoc Subcommittee on Potassium Iodide recommendation that the Federal government (NRC through FEMA) should fund the purchase of State, or in some cases local, KI stockpiles. The Commission recognizes that this policy contradicts the Commission's historical policy that funding for State and local emergency planning is the responsibility of those governments often working with licensees. The Commission is making this exception to the long-standing policy on the basis of the FRPCC's recommendation and recent petitions received. The Commission has determined that for a State that has decided to stockpile KI, NRC funding for purchase of KI for use by that State during a radiological emergency would directly contribute to fulfilling NRC's regulatory mission. The Commission also recognizes that any State choosing to incorporate KI prophylaxis as a supplemental protective action in its emergency planning will face costs, other than the cost of the purchase of KI. Consistent with the long-standing policy, these ancillary costs will remain the responsibility of the State government. Depending on how the State incorporates KI prophylaxis in its emergency plans, the ancillary costs could significantly exceed the cost of the purchase of the KI supply.

Metric Policy

On October 7, 1992, the Commission published its final Policy Statement on Metrication. According to that policy, after January 7, 1993, all new regulations and major amendments to existing regulations were to be presented in dual units. The amendment to the regulations contains no units.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending its emergency planning regulations to require that consideration be given to including potassium iodide as a protective measure for the general public that would supplement sheltering and evacuation in the event of a severe reactor accident. This action does not constitute the establishment of a consensus standard that contains generally applicable requirements to which the provisions of the Act apply.

Environmental Assessment and Finding of No Significant Impact for Completing Action on the Petitions for Rulemaking Relating to the Use of Potassium Iodide (KI) for the General Public

I. Introduction

On September 9, 1995, a petition for rulemaking (PRM 50–63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY–97–245, dated October 23, 1997, the NRC staff provided three options for the Commission's consideration in order to resolve PRM 50–63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition PRM 50–63A, that requested two things:

1. A statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure, and

2. A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

On June 26, 1998, the Commission disagreed with the NRC staff's recommendation in SECY–98–061 dated March 31, 1998, "Staff Options for Resolving a Petition for Rulemaking (PRM 50–63 and 50–63A) Relating to a Re-evaluation of the Policy Regarding the use of Potassium Iodide (KI) by the General Public after a Severe Accident at a Nuclear Power Plant," to deny the revised petition for rulemaking (PRM 50–63A) and directed the NRC staff to grant the petition by revising 10 CFR 50.47 (b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY–97–124 (June 16, 1997), "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant," the NRC staff identified three options, one of which contained three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents.

On April 22, 1999, the Commission voted to approve publication in the **Federal Register** of a proposed rule that would grant the revised petition for rulemaking (PRM 50–63A). The proposed rule was published on June 14, 1999 (64 FR 31737). In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this final rulemaking, is denying in part the original petition for rulemaking (PRM 50–63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State by explicitly requiring that planners *consider* (PRM 50–63A) the use of KI for the general public. The Commission is granting in all respects the amended petition, including reinstating its support for funding State stockpiles of KI.

II. Need for Action

In SECY–97–245, the NRC staff proposed options for resolving the original petition for rulemaking. In an SRM on SECY–98–061, the Commission directed the NRC staff to proceed with the rulemaking. In so doing, the Commission found that KI is a reasonable, prudent, and inexpensive supplement to evacuation and sheltering for specific local conditions. The Commission's guidance on emergency planning has long taken KI into consideration (NUREG–0654/FEMA–REP–1, Rev. 1, p. 63 items e and f). However, since the last revision of that guidance, there has been experience with the mass distribution of KI during an international radiological emergency. Although the record on that distribution is not complete, the indications thus far are that mass distribution is effective in

preventing thyroid cancer and causes few threatening side effects. Therefore, in order to achieve greater assurance that KI will receive due attention by planners, it seems reasonable, while continuing to recognize the important role of the States in matters of offsite emergency planning, to explicitly require that planners consider the use of KI. The rule is needed to ensure that the States are aware of and take into consideration the costs, risks, and benefits of KI in their decision making process in order to optimize emergency planning for the public health and safety.

III. Environmental Impact of the Final Action

The environmental impacts of the final action and its alternative (deny the petitions in their entirety and take no action) are considered negligible by the NRC staff, given that the final action would only add the sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate." The NRC staff is not aware of any environmental impacts as a result of this final action.

IV. Alternative to the Final Action

The alternative to the final action at this time is to deny the petitions and take no action with respect to the use of KI by the public. Should this no-action alternative be pursued, the NRC staff is not aware of any resulting environmental impact.

V. Agencies and Persons Consulted

Cognizant personnel from the States, FEMA, and FDA were consulted, as was the petitioner, as part of this rulemaking activity.

VI. Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that the amendment is not a major Federal action significantly affecting the quality of human environment and; therefore, an environmental impact statement is not required. This amendment will require that consideration be given to evacuation, sheltering, and as a supplement to these, the prophylactic use of KI. This action will not have a significant impact upon the environment.

Paperwork Reduction Act Statement

This final rule does not contain a new or amended information collection requirement subject to the Paperwork Reduction Act of 1995 (44 U.S.C 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB) approval numbers 3150–0009 and 3150–0011.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis of the Final Rulemaking Completing Action on Petitions for Rulemaking (PRM 50–63) and (PRM 50–63A) Relating to the Use of Potassium Iodide (KI)

On September 9, 1995, a petition for rulemaking (PRM 50–63) was filed with the NRC by Mr. Peter Crane. The petitioner requested that the NRC amend its emergency planning regulations to require that emergency plans specify a range of protective actions to include sheltering, evacuation, and the prophylactic use of KI.

In SECY–97–245, dated October 23, 1997, the NRC staff provided three options for the Commission's consideration to resolve PRM 50–63.

On November 5, 1997, the Commission was briefed by the NRC staff, the Federal Emergency Management Agency (FEMA), and the petitioner regarding the options available for resolving the petition for rulemaking. During the meeting, the Commission invited the petitioner to submit a modification to his petition in order to address views he discussed during the meeting.

On November 11, 1997, the petitioner submitted a revision to his petition (PRM 50–63A), which requested two things:

A statement clearly recommending stockpiling of KI as a "reasonable and prudent" measure; and

A proposed rule change to 10 CFR 50.47(b)(10) which would be accomplished by inserting the following sentence after the first sentence: "In developing this range of actions, consideration has been given to evacuation, sheltering, and the prophylactic use of potassium iodide (KI), as appropriate."

In the petitioner's comment letter on the proposed rule, he stated that in light of the Commission decision not to fund State stockpiles of KI, the Commission should consider his original petition (PRM 50–63) to be incorporated by reference and resubmitted in his comment letter. He also requested the Commission to grant the petition as originally submitted. The Commission, by undertaking this rulemaking, is granting the amended petition and is granting in part and denying in part the original petition. The Commission is denying that portion of the original petition for rulemaking (PRM 50–63), which would *require* the use of KI for the general public. In so doing, the Commission has decided to continue to recognize the important role of the State in matters of emergency planning by explicitly requiring that planners *consider* (PRM 50–63A) the use of KI for the general public.

In SECY–97–245, the NRC staff proposed options for resolving the original petition for rulemaking. By SRM dated June 26, 1998, on SECY–97–245, "Staff Options for Resolving a Petition for Rulemaking (PRM 50–63) Relating to a Re-evaluation of the Policy Regarding use of Potassium Iodide (KI) after a Severe Accident at a Nuclear Power Plant," the Commission directed the NRC staff to revise 10 CFR 50.47(b)(10). This final rule responds to this directive.

Alternatives were essentially considered in previous documents. In SECY–97–124 dated June 16, 1997, "Proposed Federal Policy Regarding Use of Potassium Iodide after a Severe Accident at a Nuclear Power Plant," the NRC staff identified three options, one of which contained three sub-options, concerning a proposed change in the Federal policy regarding the use of potassium iodide (KI) as a protective measure for the general public during severe reactor accidents. Given that the Commission considered the options and directed the NRC staff to grant the amended petition, the only alternatives considered here are the Commission-approved option and the baseline, no-action alternative.

The final rule does not "require" any action of licensees. States are to "consider" the use of KI along with evacuation and sheltering as protective actions. It is estimated that no more than 30 States will need to make this consideration. The rule does not impose any substantive requirements on States to actually stockpile or plan for the use of KI. Therefore, States would not accrue the costs associated with such actions. However, the Commission recognizes that consideration of using KI as a supplemental protective measure may result in some State expenditures. The NRC staff estimates that the labor needed by the States could range from a staff-week, to half of a staff-year. The latter would be the case if a State decided to hold hearings on the issue.

If one assumes an average hourly salary of $70 (this estimate includes benefits, prorated secretarial and managerial assistance, but not overhead), the range of estimates would be from $2800 to $63,000 per State. Using a base of 30 States, the range of impacts for the States to make the KI consideration is from $84,000 to $1.9 million.

The Commission notes that when it amended its emergency planning regulations on November 3, 1980, the regulatory standards for emergency planning were a restatement of basic joint NRC-FEMA guidance to licensees and to State and local governments incorporated in NUREG–0654; FEMA–REP–1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants for Interim Use and Comment." This guidance was cited in the regulation and addresses the use of radioprotective drugs by the general public, including quantities, storage, and means of distribution and State and local plans for decision making with respect to their use. The Commission removed the citations of the guidance from the regulation in 1987, but the guidance has continued in use for planning purposes by States and licensees and by the Federal agencies for evaluating emergency plans. As a result, it is believed that all of the 30 affected States have at some point considered the use of KI. A few of the 30 affected States have made the decision to stockpile KI. Thus, in practical terms, the projected costs will occur only in those States that have not previously elected to stockpile KI and choose stockpiling in light of the Chernobyl accident, recent international practice, and the NRC requirement to consider the use of KI.

It is difficult to estimate the benefit of a State's consideration to use KI for the general public. However, we believe the benefit of such an action by the States is summed up by the petitioner who stated that the decision to use KI for the general public should turn on whether, given the consequences of being without KI in a major accident, the drug is a prudent measure; not on whether it will necessarily pay for itself over time. As the petitioner further noted, "KI represents a kind of catastrophic-coverage insurance policy offering protection for events which, while they occur only rarely, can have such enormous consequences that it is sensible to take special precautions, especially where, as here, the cost of such additional precautions is relatively low."

Nonetheless, the Commission notes that this rule will introduce another element in the context of emergency planning requirements for which licensees are ultimately responsible. Licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. While this ultimate responsibility could have practical implications, with some associated burdens, the extent is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Additionally, the rule does not articulate any implementation date or inspection criteria.

As stated above, this analysis focuses on the rule being codified as the result of petitions for rulemaking and on the Commission direction to grant the amended petition in all respects and to grant in part the original petition.

This constitutes the regulatory analysis for this action.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities. This final rule would affect only States and indirectly licensees of nuclear power plants. These States and licensees do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act, 5 U.S.C. 601, or the size standards adopted by the NRC (10 CFR 2.810).

Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" that was approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), Part 50 is classified as compatibility Category "NRC." The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations.

Plain Language

The President's Memorandum dated June 1, 1998, entitled "Plain Language in Government Writing," directed that the government's writing be in plain language. This memorandum was published June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in the final revisions to improve the organization and readability of the existing language of the paragraphs being revised. These types of changes are not discussed further in this notice.

Backfit Analysis

The definition of backfit, as set forth in 10 CFR 50.109(a)(1), is clearly directed at obligations imposed upon licensees (and applicants) and their facilities and procedures. Section 50.109(a)(1) defines a backfit as:

> * * * the modification of or addition to *systems, structures, components, or design of* a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility, any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position * * *

Section 50.109 is replete with references to "facilities" and "licensees," which in their totality make clear that the rule is intended to apply to actions taken with respect to nuclear power plant licensees and the facilities they operate. *See* § 50.109(a)(7), "If there are two or more ways to achieve compliance with a license or the rules or orders of the Commission, or with written *licensee* commitments * * * then ordinarily the applicant or *licensee* is free to choose the way that best suits its purposes [emphasis added]." This focus on licensees and their facilities is further confirmed by the Statement of Considerations accompanying the backfit rule (53 FR 20603; June 6, 1988), where the Commission stated that backfitting "means measures which are intended to improve the safety of nuclear power reactors * * *." (53 FR at 20604). The nine factors to be considered under 10 CFR 50.109(c) further make clear that the rule is aimed at requirements applicable to licensees and facilities. These include: "(2) General description of the activity that would be required by the *licensee* or *applicant* in order to complete the backfit; * * * (5) Installation and continuing costs associated with the backfit, including the cost of *facility* downtime or the cost of construction delay; [and] (6) The potential safety impact of changes in plant or operational complexity. * * * [emphasis added]."

The final rule imposes no new requirements on licensees, nor does it alter procedures at nuclear facilities. Rather, it is directed to State or local governments, the entities with the important role to determine the appropriateness of the use of KI for their citizens, calling on these governments to

"consider" KI as one of the elements of their offsite emergency planning. However, the rule imposes no binding requirement to alter plans and procedures on State or local governments. Furthermore, the basic standard that emergency planning must include consideration of a range of protective actions is already set forth in the existing wording of § 50.47(b)(10). On this basis, the final rule does not impose new substantive requirements on *anyone*. After consideration of these factors, no backfit is involved and no backfit analysis as defined in § 50.109 is required.

Commission precedent also makes clear that the amendment does not constitute a backfit. The Commission's position was stated explicitly in 1987, when the last major change took place in emergency planning regulations (52 FR 42078; November 3, 1987). The Commission's final rule involving the "Evaluation of the Adequacy of Off-Site Emergency Planning for Nuclear Power Plants at the Operating License Review Stage Where State and Local Governments Decline to Participate in Off-Site Emergency Planning" stated that the emergency planning rule change in question "does not impose any new requirements on production or utilization facilities; it only provides an alternative method to meet the Commission's emergency planning regulations. The amendment therefore is not a backfit under 10 CFR 50.109 and a backfit analysis is not required" (52 FR 42084). Likewise, when the Commission altered its emergency planning requirements in 1987 to change the timing for full participation emergency exercises (a change that, as a practical matter, could be expected to result in licensees' modifying emergency preparedness-related procedures to accommodate exercise frequency changes), it stated: "The final rule does not modify or add to systems, structures, components or design of a facility; the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct, or operate a facility. Accordingly, no backfit analysis pursuant to 10 CFR 50.109 is required for this final rule" (52 FR 16828; May 6, 1987). The final emergency planning rule change is of a similar nature and similarly does not involve a backfit.

It has been argued by at least one commenter on the petition for rulemaking that, although licensees are not directly burdened by the final rule, they would be indirectly burdened because they would feel called upon to explain the new policy to their customers. By this logic, almost any Commission action that led an NRC licensee to issue a press release could be considered a backfit. Such a position is unsound law and policy. Here, the burden of public information on licensees or applicants, if any, appears *de minimis*. It plainly does not rise to the level of the type of concrete burden contemplated by the Commission when it enacted the backfit rule. It might also be argued that, if a State or local government were to decide to stockpile and use KI for the general public, it would undertake interactions with the affected licensee to coordinate offsite emergency planning. Although this could result in some voluntary action by the licensee to coordinate its planning, the final rule itself does not impose any requirement or burden on the licensee. Accordingly, the Commission concludes that the final rule would not impose any backfits as defined in 10 CFR 50.109.

Nonetheless, the Commission notes that this rule will introduce another element in the context of the emergency planning requirements that licensees are ultimately responsible for, whereby licensees have the obligation to confirm that offsite authorities have considered the use of KI as a supplemental protective action for the general public. That ultimate responsibility could have practical implications, with some associated burdens, the extent of which is considered minimal when viewed in the overall licensee burden of complying with all of the existing emergency planning requirements.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act for 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendment to 10 CFR part 50.

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for 10 CFR part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended 1244, 1246, (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. Law 95–601, sec. 10, 92 Stat. 2951, as amended by Pub. Law 102–486, sec. 2902, 106 Stat. 3123, (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. Law 91–190, 83 Stat. 853 (42 U.S.C. 4332). Section 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. Law 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. Law 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 50.47, paragraph (b)(10) is revised to read as follows:

§ 50.47 Emergency plans.

* * * * *

(b) * * *

(10) A range of protective actions has been developed for the plume exposure pathway EPZ for emergency workers and the public. In developing this range of actions, consideration has been given to evacuation, sheltering, and, as a supplement to these, the prophylactic use of potassium iodide (KI), as appropriate. Guidelines for the choice of protective actions during an emergency, consistent with Federal guidance, are developed and in place, and protective actions for the ingestion exposure pathway EPZ appropriate to the locale have been developed.

* * * * *

Dated at Rockville, Maryland, this 9th day of January, 2001.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

[FR Doc. 01–1156 Filed 1–18–01; 8:45 am]

BILLING CODE 7590–01–P

sewage disposal hours of operation are 5:00am–8:00pm seven days per week, from May through September.

Ocean Pines Marina is an 86-slip marina located near the Route 90 bridge in Ocean Pines on the St. Martins River. The marina has one fixed pumpout located at the end of pier A. The marina's sewage disposal hours of operation are 8:00am–6:00pm Monday through Friday, 7:00am–7:00pm Saturday and 7:00am–6:00pm Sunday, from May through October.

Sunset Marina is a 204-slip marina located at the Ocean City Inlet in West Ocean City on Isle of Wight Bay. The marina has one fixed pumpout with two remote stands, each at the end of successive piers, one portable unit with potty wand attachment for emptying portable toilets, and one dump station on the bulkhead. The marina's sewage disposal hours of operation are 9:00am–5:00pm seven days per week, from May through September.

Townes of Nantucket II is a 92-slip marina located at Nantucket Point near the Delaware state line in Ocean City on Assawoman Bay. The marina has one fixed pumpout and one dump station for portable toilets, both located at the "A" bulkhead. The marina's sewage disposal hours of operation are 24 hours a day, seven days per week, from April through October.

Marinas participating in the Maryland Pumpout Program are required by law (Natural Resources Article § 8–707) to have an approved method of sewage disposal as determined by MDE and local (county or municipal) health inspectors. Four of the six marinas participated in the Maryland Pumpout Program, and therefore are in compliance with state and Federal laws. Information about the removal of pumpout waste from the other two marinas was obtained through marina surveys. Of the six marinas described above, five discharge to the Ocean City Wastewater Treatment Plant; the remaining marina discharges to the Ocean Pines Wastewater Treatment Plant.

The MDNR maintains records of all documented and registered boats in the state. In order to estimate the number of transient boaters, several methods were employed. First a marina survey was conducted where marina owners were asked to estimate the percentage of transient boaters that utilize their facility and the northern Coastal Bays. Second, information collected from a 1999 aerial survey of the northern Coastal Bays, conducted by the MDNR Fisheries Department, was used to determine types and sizes of boats using the waters on a peak day in-season. Finally, a land survey was conducted where MDNR employees surveyed Coastal Bay vessel usage on a typical day during the season. All of these methods were employed to come up with a best estimate for transient usage. It was estimated, using the above techniques, that Ocean City/northern Coastal Bays have approximately 10,000 wet slips. It was also assumed that the transient boat population mirrored the resident population as far as relative percent of the size and numbers of boats. Based on this information the vessel population of the northern Coastal Bays based on length is 2,800 vessels less than 16 feet, 6,600 vessels between 16 and 26 feet, 600 vessels between 26 and 40 feet, and 100 vessels over 40 feet. Based on the number and size of boats, and using various methods to estimate the number of holding tanks and portable toilets, it was determined that the northern Coastal Bays need three pumpouts and five dump stations. There are currently eight operating pumpouts and one proposed pumpout in the northern Coastal Bays along with two dump stations and three pumpouts equipped to empty portable toilets making a total of five portable toilet waste facilities. There is also one proposed pumpout that would accept portable toilets by the start of the next boating season in early 2002.

Finding

The EPA hereby makes a final affirmative determination that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for Herring Bay, Anne Arundel County, Maryland, and the northern Coastal Bays (Ocean City Inlet, Ocean City commercial fish harbor (Swordfish Basin), Isle of Wight Bay and Assawoman Bay), Worcester County, Maryland. This final determination will result in a Maryland state prohibition of any sewage discharges, whether treated or not, from vessels into Herring Bay and the northern Coastal Bays.

Donald S. Welsh,

Regional Administrator, Region III.

[FR Doc. 02–627 Filed 1–9–02; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

DATE & TIME: Tuesday, January 15, 2002 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE & TIME: Thursday, January 17, 2002 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.

Revised Draft Advisory Opinion 2001–17: DNC Services Corporation/ Democratic National Committee by counsel, Neil Reiff.

Draft Advisory Opinion 2001–18: BellSouth Corporation by counsel, Jan Witold Baran.

Draft Advisory Opinion 2001–19: Oakland Democratic Campaign Committee by Gary Kohut, Chair.

Administrative matters.

PERSON TO CONTACT FOR INFORMATION: Mr. Ron Harris, Press Officer, Telephone: (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 02–776 Filed 1–8–02; 2:32 am]

BILLING CODE 6715–01–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Federal Policy on Use of Potassium Iodide (KI)

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice of revised Federal policy.

SUMMARY: The Federal Radiological Preparedness Coordinating Committee (FRPCC) has revised the 1985 Federal policy regarding the use of potassium iodide (KI) as a thyroidal blocking agent by emergency workers, institutionalized persons and the general public in the vicinity of nuclear power plants. This policy is for use by State [1] and local

[1] Consistent with FEMA initiative 4.0–4.4, Include Native American Tribal Nations in the REP

Continued

agencies responsible for radiological emergency planning and preparedness in the unlikely event of a major radiological emergency at a commercial nuclear power plant.

The Federal position is that KI should be stockpiled and distributed to emergency workers and institutionalized persons for radiological emergencies at a nuclear power plant and its use should be considered for the general public within the 10-mile emergency planning zone (EPZ) of a nuclear power plant. However, the decision on whether to use KI for the general public is left to the discretion of States and, in some cases, local governments.

EFFECTIVE DATE: The modifications to this policy are effective January 10, 2002.

FOR FURTHER INFORMATION CONTACT: Russell Salter, Chair, Federal Radiological Preparedness Coordinating Committee; (202) 646–3030; *russ.salter@fema.gov*.

SUPPLEMENTARY INFORMATION:

Background

This revised Federal policy on the use of potassium iodide as a thyroidal blocking agent for the general public in the vicinity of nuclear power plant 10-mile emergency planning zones is part of a Federal interagency effort coordinated by FEMA for the FRPCC. FEMA chairs the FRPCC and assumes the responsibility for this publication. The FRPCC is an interagency organization, with membership from 17 Federal agencies, established to coordinate all Federal responsibilities for assisting State and local governments in emergency planning and preparedness for peacetime nuclear emergencies.

The issue is addressed in terms of two components of the population that might require or desire potassium iodide use: (a) Emergency workers and institutionalized individuals, and (b) general population. With respect to emergency workers and institutionalized individuals, the Nuclear Regulatory Commission (NRC) and FEMA have issued guidance to State and local authorities, as well as to licensees of operating commercial nuclear power plants, in NUREG–0654/FEMA–REP–1, Rev.1. The NUREG and FEMA guidance recommends the stockpiling and distribution of KI to emergency workers and to institutionalized individuals for thyroidal blocking during emergencies. The guidance provides information regarding protective actions to be taken in the event of an incident at a commercial nuclear power plant. NUREG 0654 and the 1985 FRPCC KI policy recommend thyroidal blocking for emergency workers and institutionalized individuals because they are thought to be more likely than other members of the public to be exposed to the radioiodine in an airborne radioactive release.

The decision for using KI as a protective measure for the general public is left to the discretion of States, or in some cases, local governments, since these entities are ultimately responsible for the protection of their citizens. The policy guidance in this **Federal Register** notice is intended for State and local governments that, within the limits of their authority, should consider these recommendations in the review of their emergency plans and in determining appropriate actions to protect the general public. In making a decision whether to stockpile KI, the States should be aware that the Federal government believes that the use of KI is a reasonable and prudent measure as a supplemental protective action for the public.

Revision of the policy to include members of the public reflects lessons learned from the Chernobyl Nuclear Power Plant accident of 1986, both about the consequences of an accident and about the safety and efficacy of KI. The Chernobyl accident demonstrated that thyroid cancer can indeed be a major result of a large reactor accident. Based on the experiences from Chernobyl, young children are at greatest risk of thyroid cancer from radioactive iodine exposure. Moreover, although the Food and Drug Administration (FDA) declared KI "safe and effective" as long ago as 1978, the drug had never been deployed on a large scale until Chernobyl. The experience of Polish health authorities during the accident has provided confirmation that large-scale deployment of KI is safe.[2] The Chernobyl experiences also led to wide-scale changes in international practice, specifically 1989 World Health Organization recommendations (updated in 1995 and 1999) and 1996 and 1997 International Atomic Energy Agency standards and guidance, which have led to the use of KI as a supplementary protective measure in much of Europe, as well as in Canada and Japan.

The NRC published changes to its emergency planning regulations at 66 FR 5441–5443, January 19, 2001. For States within the 10-mile planning zone of a nuclear power plant(s), the NRC believes that the use of KI is a reasonable and prudent measure as a supplement to sheltering and evacuation and in response to specific local conditions. The NRC requires consideration in the formulation of emergency plans as to whether to include the use of KI as a supplemental protective measure.

The FDA has evaluated the medical and radiological risks of administering KI for emergency conditions, has concluded that it is safe and effective, and has approved over-the-counter sale of the drug for this purpose. FDA has concluded that "* * * the effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well-established as are the doses necessary for blockage. As such, it is reasonable to conclude that KI will likewise be effective in reducing the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodines." Since the FDA has authorized the nonprescription sale of KI, it may be available to individuals who, based on their own personal analysis, choose to have the drug immediately available. The FDA guidance is the definitive Federal guidance on medical aspects of KI prophylaxis.

Considerations

In making a decision whether to stockpile KI, States should be aware that the Federal government believes that the use of KI is a reasonable and prudent measure as a supplemental protective action for the public.

While there may be logistical difficulties in providing KI to the general public, any distribution scheme should take care to ensure that KI distribution does not impede or delay orderly evacuation. There also may be a few medical side effects in pre-distributing the drug to potentially affected individuals or in distributing the drug to the general public in a radiological emergency. Although the post-Chernobyl data from Poland revealed few serious medical side effects associated with this drug, this possibility cannot be discounted, especially in certain groups of people. For example, people who are allergic to iodine should not take KI.

Other considerations to be evaluated by the State and local authorities in deciding whether to institute a program for the use of KI by the general public

Preparedness Process, references to State governments include Tribal governments.

[2] Nauman, J., and Wolff, J., Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks, American Journal of Medicine, Vol. 94, p. 524, May 1993.

include: (a) Whether KI should be distributed to the population before an accident occurs or as soon as possible after an accident occurs; (b) 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 KI—or if the general population is sheltered and the administration of KI initiated; (c) how KI will be distributed during the emergency; (d) if KI is pre-distributed, what assumptions should be made about its actual availability and use in the event of an incident; (e) what medical assistance will be available for the individuals who may have some adverse reaction to KI; (f) how medical authorities will advise the population to take KI and under what circumstances this advice will be given, i.e., methods for public education, information and instruction; and (g) how the authorities will provide KI to transient populations.

In addition, there are some site-specific considerations to evaluate. Any decision by State and local authorities to use KI following a specific emergency should be based on the site environment and conditions for the specific operating commercial nuclear power plant and would include detailed plans for distribution, administration and medical assistance.

Revised Policy

In most cases, evacuation and in-place sheltering are considered adequate and effective protective actions for the general public in the event of a radiological emergency at a commercial nuclear facility. However, the inclusion of KI as a supplemental protective measure is beneficial in certain circumstances. It should be noted that the timely use of KI effectively reduces the radiation exposure of only the thyroid gland. While this is an important contribution to the health and safety of the individual, it is not as effective as measures that protect the total body of the individual from radioactivity. Both in-place sheltering and precautionary evacuations can reduce the exposure to the thyroid and total body. The use of KI for thyroidal blocking is not an effective means by itself for protecting individuals from the radioactivity in an airborne release resulting from a nuclear power plant accident and, therefore, should only be considered in conjunction with sheltering or evacuation, or a combination thereof.

While the use of KI can clearly provide additional protection in certain circumstances, the assessment of the effectiveness of KI and other protective actions and their implementation indicates that the decision to use KI (or other protective actions) should be made by the States and, when appropriate, local authorities on a site-specific basis. Thus, the decision on use of KI by the general public during an actual emergency is the responsibility of these authorities.

In summary, the Federal position is that KI should be stockpiled and distributed to emergency workers and institutionalized persons for radiological emergencies at a nuclear power plant, and its use should be considered for the general public within the 10-mile EPZ of a nuclear power plant. However, the decision on whether to use KI for the general public is left to the discretion of States and, in some cases, local governments.

This revised policy should not be taken to imply that the present generation of U.S. nuclear power plants is any less safe than previously thought. On the contrary, present indications are that nuclear power plant safety has steadily improved.

References

The following references are intended to assist State and local authorities in decisions related to use of KI:

1. Nuclear Regulatory Commission, final rule, Consideration of Potassium Iodide in Emergency Plans, 66 FR 5427, January 19, 2001.

2. World Health Organization, Guidelines for Iodine Prophylaxis Following Nuclear Accidents, 1999. Http://www.who.int/environmental information/Information_resources/documents/Iodine/guide.pdf.

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

4. Food and Drug Administration (Health and Human Services), Potassium Iodide as a Thyroid-Blocking Agent in a Radiation Emergency, 43 FR 58798, December 15, 1978.

5. Food and Drug Administration, Notice, Guidance on Use of Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; Availability, 66 FR 64046, December 11, 2001.

6. Report of the President's Commission on the Accident at Three Mile Island, National Technical Information Service, Springfield, VA 22161.

7. Federal Emergency Management Agency, Federal Policy on Distribution of Potassium Iodide Around Nuclear Power Sites for Use as a Thyroidal Blocking Agent, 50 FR 30258, July 24, 1985.

8. Nauman, J., and Wolff, J., Iodide Prophylaxis in Poland After the Chernobyl Reactor Accident: Benefits and Risks, American Journal of Medicine, Vol. 94, p. 524, May 1993.

9. International Atomic Energy Agency, International Basic Safety Standards for Protection Against Ionizing Radiation and for Safety of Radiation Sources. Safety Series No. 115, 1996.

Dated: January 2, 2002.

Joe M. Allbaugh,

Director.

[FR Doc. 02–637 Filed 1–9–02; 8:45 am]

BILLING CODE 6718–02–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 4, 2002.

A. Federal Reserve Bank of Chicago (Phillip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. Marshall & Ilsley Corporation, Milwaukee, Wisconsin; to merge with Century Bancshares, Inc., Eden Prairie, Minnesota, and thereby indirectly acquire 100 percent of the voting shares of Century Bank, Eden Prairie, Minnesota.

ATTACHMENT 2

FOOD AND DRUG ADMINISTRATION
FINAL GUIDELINES
ON POTASSIUM IODIDE USE

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

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

December 2001
Procedural

Guidance

Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

Additional copies are available from:

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

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

December 2001
Procedural

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Guidance
Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies

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

I. INTRODUCTION

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

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

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

II. BACKGROUND

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

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

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

III. DATA SOURCES

A. Reliance on Data from Chernobyl

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

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

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

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

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

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

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

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

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

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

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

B. Thyroid Cancers in the Aftermath of Chernobyl

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

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

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

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

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

IV. CONCLUSIONS AND RECOMMENDATIONS

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

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

The effectiveness of KI as a specific blocker of thyroid radioiodine uptake is well established (Il'in LA, et al., 1972) as are the doses necessary for blocking uptake. As such, it is reasonable to conclude that KI will likewise be effective in reducing the risk of thyroid cancer in individuals or populations at risk for inhalation or ingestion of radioiodines.

Short-term administration of KI at thyroid blocking doses is safe and, in general, more so in children than adults. The risks of stable iodine administration include sialadenitis (an inflammation of the salivary gland, of which no cases were reported in Poland among users after the Chernobyl accident), gastrointestinal disturbances, allergic reactions and minor rashes. In addition, persons with known iodine sensitivity should avoid KI, as should individuals with dermatitis herpetiformis and hypocomplementemic vasculitis, extremely rare conditions associated with an increased risk of iodine hypersensitivity.

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

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

B. KI Use in Radiation Emergencies: Treatment Recommendations

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

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

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

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

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

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

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

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

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

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

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

V. ADDITIONAL CONSIDERATIONS IN PROPHYLAXIS AGAINST THYROID RADIOIODINE EXPOSURE

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

For optimal protection against inhaled radioiodines, KI should be administered before or immediately coincident with passage of the radioactive cloud, though KI may still have a substantial protective effect even if taken 3 or 4 hours after exposure. Furthermore, if the release of radioiodines into the atmosphere is protracted, then, of course, even delayed administration may reap benefits by reducing, if incompletely, the total radiation dose to the thyroid.

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

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

VI. SUMMARY

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

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

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

ACKNOWLEDGEMENTS

The KI Taskforce would like to extend special thanks to our members from the NIH: Jacob Robbins, M.D., and Jan Wolff, Ph.D., M.D., of the National Institute of Diabetes, Digestive, and Kidney Diseases and Andre Bouville, Ph.D., of the National Cancer Institute. In addition, we would like to thank Dr. David V. Becker of the Department of Radiology, Weill Medical College (WMC) of Cornell University and The New York Presbyterian Hospital-WMC Cornell Campus, for his valuable comments on the draft

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ATTACHMENT 3

GLOSSARY OF TERMS

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 (Sv). Some submultiples of the Sv used are milliseivert (mSv) and microseivert (μSv). One mSv is equal to 1/1000 of 1 Sv and 1 μSv is equal to 1/1,000,000 of 1 Sv.

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 (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 (Sv).