DISTRIBUTION AND ADMINISTRATION OF POTASSIUM IODIDE IN THE EVENT OF A NUCLEAR INCIDENT

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

DISTRIBUTION AND ADMINISTRATION OF POTASSIUM IODIDE IN THE EVENT OF A NUCLEAR INCIDENT

Committee to Assess the Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident

Board on Radiation Effects Research

Division on Earth and Life Studies

NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

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During the course of the committee's deliberations, several people provided information to the committee. Their contributions invigorated committee deliberations and enhanced the quality of this report. The committee expresses its appreciation to the Centers for Disease Control and Prevention for sponsoring the study and, in particular, to Dr. James Smith.

The committee and the staff of the Board on Radiation Research Effects (BRER) are grateful for the information provided by invited speakers who generously contributed their time and participated in the committee's information-gathering meetings: James Smith, Ed Hildebrand, Craig Conklin, Brian Mattiello, Ron Fraass, Ed Tupin, Brad Leissa, Patricia Milligan, Nicki Pesik, Ruth Hagstrom, Jan Carney, John Harrald, Jan Wolff, Andre Bouvillé, Stephen Floyd, Ralph Andersen, and David Reid. The committee and the BRER staff appreciate the information, feedback, and background materials provided by Alan Morris and Michael Sinclair. We also appreciate the effort of LaTeya C. Foxx, Banneker-Anderson summer intern, for contacting all the states and collecting data on past, current, and future state plans to distribute potassium iodide to the public and nuclear workers. The committee is indebted to the input from each

state's authority for taking the time to summarize plans for distribution of potassium iodide.

The committee was extremely fortunate in the staffing of this study. We wish to thank our study director, Dr. Isaf Al-Nabulsi, for her expertise, dedication, and hard work; for keeping the committee focused and assisting in the writing and preparation of our report; and for her enormous effort in producing a clearly written, well-organized report that reflects the thought of the committee. Dr. Al-Nabulsi was well assisted in the administration of the committee's work by Laura E. Waters and Doris E. Taylor.

REVIEWERS

This report has been reviewed in draft form by persons chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purposes of this review are to provide candid and critical comments that will assist the institution in making the published report as sound as possible and to ensure that the report meets institutional standards of objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following for their participation in the review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release. The review of this report was overseen by Richard B. Setlow, Brookhaven National Laboratory (Senior Biophysicist). Appointed by the National Research Council, he was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the author committee and the National Research Council.

CONTENTS

EXECUTIVE SUMMARY

This report responds to the congressional mandate of Public Law 107-188, Section 127. To satisfy the requirement of this law, the Centers for Disease Control and Prevention (CDC) asked the National Research Council to assess strategies for the distribution and administration of potassium iodide (KI) in the event of a nuclear incident, taking into account projected benefits and harms and the populations that should be included in such a program, and to recommend studies that will improve the base of knowledge on which to make related public-health decisions. The Research Council's Board on Radiation Effects Research assembled a committee of experts representing an array of relevant disciplines to address the issues related to the distribution of KI. The committee was asked to consider the issues and make recommendations on the basis of scientific knowledge and principles.

The task set before the committee is described in the following scope of work. On the basis of its assessment, the committee was to make recommendations to the President of the United States and Congress within 9 months after the start of the study regarding

(a) the projected benefits and harms of a KI distribution program as part of a nuclear incident preparedness program;
(b) the most effective and safe way to distribute and administer KI on a mass scale to prevent radiation effects;
(c) the populations that should be included in the KI distribution program;
(d) the appropriate roles for local, state and federal agencies related to KI distribution in such a preparedness program; and
(e) any additional issues that need to be researched, resolved, or addressed.

To understand the context of the statement of task presented above, the committee believed that it was important to provide background information on the effects of radioactive iodine and KI on the thyroid gland and to explore various options for using KI to protect the thyroid. In this report, we describe the benefits of and risks posed by KI administration to different population groups and focus particularly on protecting children, the most vulnerable group (tasks a and c); identify alternatives for KI distribution that have been chosen to be best in different parts of the United States and in other countries and recommend a procedure for a local area to evaluate different distribution plans on the basis of site-specific characteristics (task b) and current roles played by local, state, and federal agencies regarding KI distribution (task d); make some recommendations regarding the level at which decisions should be made (state and local level), programs should be funded (federal level), and supplemental stockpiles should be maintained and adequate KI supply (in suitable dosages) ensured (federal level); and identify additional issues that need to be researched or addressed (task e).

Radioactive iodines (radioiodines, such as ^{131}I) are produced during the operation of nuclear power plants (NPPs) and during the detonation of nuclear weapons. Radioiodine is one of the contaminants that could be released into the environment in the event of a nuclear incident that involves a disruption of the integrity of the fuel assembly and containment structures of a NPP, because of an

accident or terrorist activity. Exposure to ^{131}I (and other radioisotopes of iodine) by inhalation of contaminated air or ingestion of contaminated food or milk can lead to radiation injury to the thyroid, including increased risk of thyroid cancer and other thyroid diseases, because the thyroid gland concentrates and stores iodine from the blood. For example, the 1986 nuclear accident in Chornobyl exposed many people to ^{131}I, and reports of radiation epidemiology studies indicate that that exposure caused excess cases of thyroid cancer years later in the exposed susceptible population. The Chornobyl experience is discussed in this report because it shows the consequences of exposure in a qualitative sense, even though it is not as relevant for determining quantitatively the risk of such an event in the United States in light of substantial safety and other facility design features in US reactors. Nevertheless, nuclear power plants in the United States contain a source of radioactive iodine that in the event of a very severe incident might impose risks of exposure, which could lead to thyroid cancers. Given that KI is effective in protecting against potential thyroid cancer, KI distribution plans should be considered.

The detonation of a nuclear weapon would lead to release of radioiodine, but radioiodine would not be a primary concern compared to the principal thermal and blast effects and the large amount of radiation and non-iodine radioactive materials that would be released.

Radiation incidents may be unintentional, as in NPP accidents, or intentional, as in terrorist attacks that damage NPPs or explode "dirty bombs" or nuclear weapons. In the event of an accidental or intentional release of radioactive iodine into the environment, radiation doses[1] to the thyroid from radioiodine can be limited by

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[1] To eliminate confusion over the use of the word dose which is often used to describe both the radiation absorbed dose, expressed in Gray, and the medically administered dose, often expressed in grams or milligrams—the committee has chosen to use the term dose when indicating the radiation absorbed dose and the term dosage when referring to the amount of a drug administered. To eliminate confusion due to the various ways that radiation doses are expressed in the literature, the committee decided to limit its usage to the SI unit for radiation absorbed dose, the Gray (Gy) when possible. For informational purposes SI units are followed in brackets by their equivalent in terms of the older English units. For units presented in the literature in terms of dose equivalent and effective dose equivalent, Sievert (Sv) and rem, the committee converted these doses to the absorbed dose units of Gray and rad when possible. To eliminate confusion over the use of the term “dose” and “exposure” for the radiation absorbed dose to the thyroid gland, the committee chose to use only the term thyroid dose.

appropriate administration of stable iodine such as KI. The nonradioactive iodine in KI is readily taken up by the thyroid gland, thereby competing with and effectively blocking thyroid uptake of radioactive iodine. KI tablets are readily available, are inexpensive, and have a long shelf-life if the tablets are stored in a package designed to prevent exposure to light and moisture. Although the iodate chemical form is used in some European countries and is also stable, it has traditionally not been used as a blocking agent in the United States and is not as readily available. KI tablets are the only form of iodine approved by the US Food and Drug Administration (FDA) for use as a blocking agent. To be most effective, KI must be taken within a few hours before or after exposure to radioiodine. KI does not protect other organs or tissues from external exposure to radiation or from internal exposure to other radioactive isotopes, such as strontium, cesium, and cobalt. It is assumed throughout this report that the need for administration of KI is necessary only once to protect the thyroid gland against inhalation of radioiodine from a passing plume (cloud) and that further protection from radioiodine will be accomplished by evacuation and control of contaminated milk and other foods.

Epidemiological studies have shown that fetuses, infants, children, and pregnant and lactating women are most in need of protection from radioiodine exposure. Children are most likely to benefit from KI prophylaxis. Radioiodine can cross the placenta and enter the fetal thyroid. Lactating women can concentrate radioiodine in their milk and transfer it to their nursing infants. Infants and children are more vulnerable to the potentially harmful effects of radioiodine than are adults because their thyroids concentrate iodine more actively on an organ-weight basis and because their thyroids are biologically more radiosensitive.[2]

For its report, the committee concentrated on three main subjects for assessing the five issues posed in the statement of task: benefits of and risks posed by potassium iodide distribution,

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[2] The thyroids of fetuses, infants, and children are more susceptible to the effects of ionizing radiation in part because the glands are growing rapidly (especially during the third trimester of gestation and during the first 5 years of life) and have more cell division and higher metabolic activity.

implementation issues related to potassium iodide distribution and stockpile programs, and additional research needed.

Benefits of and Risks Posed by Potassium Iodide Distribution

On the basis of its assessment, the committee reached the following conclusions and offers a number of recommendations.

Conclusions

1. Exposure of susceptible populations to radioiodine from a radiation incident increases the risk of thyroid cancer and other thyroid disorders.
2. Potassium iodide is an important agent for protection against thyroid-related health effects of exposure to radioiodine, if taken shortly before or after exposure.
3. In planning for responses to nuclear incidents in the United States, the likelihood and possible magnitude and extent of a release in the United States cannot be extrapolated from the Chornobyl accident, because of substantial safety and other facility-design features in US reactors.

Recommendations

1. KI should be available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident. KI should be available to infants, children, and pregnant and lactating women. There is little benefit in providing KI to adults over 40 years old. To be most effective, KI must be taken within a few hours before or after exposure to inhaled or ingested radioiodine.
2. KI distribution should be included in the planning for comprehensive radiological incident response programs for nuclear power plants. KI distribution programs should consider pre-distribution, local stockpiling outside the

emergency planning zone (EPZ), and national stockpiles and distribution capacity.

3. The FDA should re-evaluate current dosing recommendations and consider extending the shelf-life of KI tablets stockpiled or distributed for use in response to a radiological incident involving radioiodine.

Implementation Issues Related to Potassium Iodide Distribution and Stockpile Programs

On the basis of its assessment, the committee reached the following conclusion and offers a number of recommendations regarding potassium iodide distribution programs.

Conclusion

A strategy is needed whereby local planning agencies could develop geographic boundaries for a KI distribution plan based on site-specific considerations because conditions and states vary so much that no single best solution exists.

Recommendations

1. A better understanding of the strengths and weaknesses, short-term and long-term successes and failures, and resource requirements of different KI distribution plans implemented in the United States and abroad would be extremely helpful for designing and implementing effective future KI distribution programs.
2. State and local authorities should make the decision regarding implementation and structure of a KI distribution program. The choice of program should be based on how well specific plans would perform on decision objectives, given features of the local region. The decision regarding the geographical area to be covered in a KI distribution program should be based on

risk estimates derived from calculations of site-specific averted thyroid doses for the most vulnerable populations.

3. KI distribution and administration plans developed at the state and local level should receive federal resources for implementation and maintenance.
4. The federal government should maintain stockpiles and a distribution system as a supplement to states' programs to ensure availability of KI to affected populations in the event of a major radiological incident involving radioiodine.
5. The federal government should ensure an adequate supply of KI tablets in suitable dosages for use by the target populations of infants, children, adults under 40 years old, and pregnant and lactating women of all ages.

Additional Research Needed

On the basis of its assessment of the current state of information regarding KI distribution programs, the committee reached the following conclusion and offers a number of recommendations for further studies that will improve the base of knowledge on which to make related public-health decisions.

Conclusion

Although questions remain regarding long-term health risks from radioiodine, particularly among potentially high-risk subgroups, there is now sufficient medical and scientific literature to estimate dose-related thyroid cancer risks following exposure to radioactive iodine.

Recommendations

1. KI distribution plans should include a carefully developed and tested public-education program with continuing evaluation to ensure effectiveness and continued access to KI by the appropriate populations.

2. A national program should be developed for follow-up of all individuals to whom KI was administered following a radiological incident, to assess short- and long-term health effects of KI administration.
3. Research is needed in a number of areas, as discussed in chapter 8, to provide better information to inform policy-makers and health-care providers about the risks posed by radioiodine exposure and methods to minimize long-term health effects. An evaluation of the strengths and weaknesses, successes and failures (short-term and long-term), and resource requirements of the different KI distribution plans implemented in the US and abroad should be conducted by a federal agency to aid states and local regions in designing and implementing effective KI distribution programs.

1

INTRODUCTION

Radioactive iodines (radioiodines, such as ^{131}I) are produced during the operation of nuclear power plants (NPPs) and during the detonation of nuclear weapons. In the event of a radiation incident involving a disruption of the integrity of the fuel assembly and the containment structures of a nuclear power plant or a detonated nuclear device, radioiodine is one of the contaminants that could be released into the environment. The major historical environmental releases of radioiodine were from the Hanford nuclear processing plant in the 1940s; from the Mayak processing plant in Russia in the 1940s and early 1950s; from the atmospheric nuclear-weapons tests conducted in the 1950s and 1960s; and from the nuclear reactor accidents at Windscale, UK, in 1957, and the Chornobyl Power Plant in Ukraine (in the former Soviet Union) in 1986. The Chornobyl accident caused the most serious consequences: it exposed many people to thyroid radiation from radioactive iodine and consequently induced thyroid cancer in a large number of children.

Because iodine concentrates in the thyroid gland (it is essential for the synthesis of thyroid hormones), exposure to radioiodine by inhalation of contaminated air or ingestion of contaminated food or milk can lead to radiation injury to the thyroid, including increased risk of thyroid cancer and other thyroid disorders.

Radiation to the thyroid from radioiodine can be limited by taking nonradioactive iodine (stable iodine) such as potassium iodide (KI).[1] Fetuses, infants, children, and pregnant and lactating women are most in need of protection from radioiodine exposure and most likely to benefit from KI. To be most effective, KI must be taken within a few hours before or after exposure to radioiodine. KI does not protect other organs or tissues from external exposure to radiation or from internal exposure to other radioactive isotopes, such as strontium, cesium, or cobalt.

To ensure that KI will be available in the event of an incident at a nuclear power plant that causes release of radioiodine, the US Nuclear Regulatory Commission has supplied participating states with KI sufficient for two dosages for every person who lives or works within 10 miles of a nuclear power plant. In addition, the US Department of Health and Human Services has purchased KI tablets for the national pharmaceutical stockpile. Some local agencies have developed their own plans for stockpiling and distributing KI (see Chapter 6 and Appendix C for details).

To establish a coordinated program based on the latest scientific advice, Public Law 107-188, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Section 127 (see Appendix A), requested that the president—in consultation with representatives of appropriate federal, state, and local agencies—establish guidelines for the stockpiling of KI tablets and for their distribution and use in the event of a nuclear incident. Before establishing the guidelines, the president was requested to enter into an agreement with the National Academy of Sciences to conduct a study to recommend the most effective and safest way to distribute

[1] Potassium iodide is a chemical compound that contains iodine that can be used to protect the thyroid from possible radiation injury by blocking subsequent accumulation of radioiodine, thereby reducing the radiation to the thyroid that could result from the inhalation or ingestion of radioiodine.

and administer KI tablets on a mass scale in the event of a nuclear incident, taking into account projected benefits and harms and the populations that should be included in such a program.

In response to the congressional mandate, the Centers for Disease Control and Prevention (CDC) asked the National Research Council's Board on Radiation Effects Research to convene a Committee to Assess the Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident, taking into account projected benefit and harms and the populations that should be included in such a program, and to recommend studies that will improve the base of knowledge on which to make related public-health decisions. The committee was asked to consider the issues and make recommendations on the basis of scientific knowledge and principles. The study began on March 27, 2003.

The task set before the committee is described in the following scope of work:

The Board on Radiation Effects Research proposed to put together a slate of individuals to assess the distribution of the potassium iodide (KI) issue. On the basis of this assessment, the committee will make recommendations to the President and Congress within 9 months after the start of the study regarding:

(a) the projected benefits and harms of a KI distribution program as part of a nuclear incident preparedness program;
(b) the most effective and safe way to distribute and administer KI on a mass scale to prevent radiation effects;
(c) the populations that should be included in the program;
(d) the appropriate roles for local, state and federal agencies in such a preparedness program;
(e) any additional issues that need to be researched, resolved, or addressed.

The committee made several important distinctions early in its deliberations. First, it was determined that in the United States, the inhalation pathway (breathing in contaminated air) is the primary

initial concern after a radiological incident. Radiation exposure can also result from ingestion of contaminated milk or other foods, but in the United States this is unlikely because of the wide-spread regulations and procedures in place for food testing and interdiction in the event of a radiological incident, particularly one involving radioiodine. In circumstances where food interdiction is not feasible, KI does provide protection to the thyroid from radioiodine ingestion. Second, the committee noted that the term "distribution", in the context of KI, includes predistribution, local stockpiling outside of the emergency planning zone (EPZ), and national capacities to rapidly mobilize and deliver large inventories of KI as needed in the event of a radiological incident. Finally, the committee recognized the tremendous variability in the geographical, demographic, and political characteristics of areas where nuclear power plants are located. This variability makes comparisons with specific international experiences difficult and emphasizes the need for flexibility and a high degree of independence for state and local agencies to decide the most effective and efficient means to protect the public in the event of a radiological incident involving radioiodine. Within the context of this independence, however, the committee concluded that for many geopolitical regions, a KI predistribution program may provide the best assurance of timely KI availability to appropriate populations in the event of a radiological incident involving radioiodine.

To understand the context of the statement of task presented above, the committee believed that it was important to provide background information on the effects of radioactive iodine and KI on the thyroid gland, explore various options for using KI to protect the thyroid, explain how nuclear fallout that contains radioactive iodine can endanger the thyroid gland and how KI can protect it (such as sources and types of radiation affecting the thyroid after a nuclear incident), discuss current and pending federal policies on KI, and consider how European and US governments stockpile and distribute KI. The committee was not charged to do any quantitative analysis; it is beyond the committee's scope. However, the committee has proposed a method in Chapter 7 and Appendix D that could be used for site-specific planning. For each nuclear power plant, there is specific information on population size, ages, and location,

geographical and meteorological conditions, evacuation routes, and resources available. This information can be used for quantitative analysis to aid planning in a specific region.

This report constitutes the results of the committee's assessment and its recommendations. It is organized into eight chapters. Chapter 2 discusses thyroid physiology, Chapter 3 discusses potential exposure to radioactive iodine, Chapter 4 discusses previous radiation incidents and their potential health effects, Chapter 5 discusses protective measures, Chapter 6 discusses existing distribution plans for distribution of KI, Chapter 7 provides a scheme for evaluating KI distribution programs and options for KI distribution, and Chapter 8 contains the concluding remarks and recommendations for KI administration and distribution.

To fulfill its charge, the committee met five times in 2003: on May 29-30 in Washington, DC; on June 23-24 in Washington, DC; on July 25-26 in Irvine, CA; on August 21-22 in Washington, DC; and on September 29-30 in Woods Hole, MA. Three of the meetings included public information-gathering sessions, and the committee also received and considered other public comments and communications. The committee interacted with various federal agency representatives and other interested parties, and it benefited from the information provided by states' authorities about the past, current, and future state plans to distribute KI. The committee appreciated and was impressed by the efforts of various speakers and other interested parties to work with us during the project; it has been important to the committee's efforts.

Consistent with the policies of the National Academies, the committee conducted fact-finding activities involving outside parties in public information-gathering meetings and met in closed session only to develop committee procedures, review documents, and consider findings and recommendations. The information-gathering meetings were structured to solicit information from technical experts and the study sponsor on topics related to the study. All the information gathered at the open meetings is part of the National Research Council's public-access file and is available on request.

2

THYROID PHYSIOLOGY

This chapter provides background information on thyroid function, physiological need for and sources of iodine, benefits and harms of radioiodine, and benefits of and risks posed by potassium iodide administration.

Overview of Thyroid Function

The iodine-rich thyroid hormones thyroxine (T4) and triiodothyronine (T3) are necessary for growth and development and they stimulate all aspects of cell metabolism, including protein synthesis and oxygen consumption. The synthesis of T4 and T3 takes place through a complex series of enzymatic steps on the interface between the thyroid follicular cell and the large protein thyroglobulin. Thyroid peroxidase is the major enzyme responsible for the oxidation (organification) of the iodine actively transported from the blood into the thyroid by the sodium-iodide symporter (NIS), the addition of the

oxidized iodine to the amino acid tyrosine to generate mono- and diiodotyrosine (MIT and DIT, respectively), and the coupling of a MIT and a DIT to generate T3, and two DITs to generate T4. T4 and T3 are then secreted into the peripheral circulation where they are tightly bound to plasma proteins, primarily the thyroid-hormone binding globulin (TBG), an inter alpha globulin. Very small fractions of the circulating hormones are not bound to TBG, and these free or unbound hormones are available to enter all peripheral cells. It is generally recognized that T3, not T4, is the bioactive hormone and that the major source of T3 is not the thyroid but, in the peripheral tissues, the removal of an iodine from the outer or phenolic ring of T4 by a selenoenzyme, 5'-deiodinase. T3 binds to T3 nuclear receptors in the cells of the peripheral tissues and stimulates a wide variety of genomic events that result in enhanced protein synthesis and increased metabolism.

Central nervous system control of thyroid function resides in the anterior hypothalamus, which synthesizes and secretes a tripeptide, thyrotropin-releasing hormone (TRH), into the hypothalamic-pituitary portal circulation. TRH binds to the TRH receptor on the beta cells of the anterior pituitary to stimulate and release into the peripheral circulation the glycoprotein, thyroid-stimulating hormone (thyrotropin or TSH), which consists of an alpha (α) subunit and a beta (β) subunit. The β subunit binds to the TSH receptor on the basal cell surface of the thyroid cell, stimulates the synthesis of the iodine-rich thyroid hormones, T4 and T3, and releases them into the peripheral circulation.

It is evident that to maintain normal thyroid function (euthyroidism), the synthesis of the thyroid hormones and their release from the thyroid must be under tight control. That is accomplished by the classical negative-feedback system so typical of endocrine systems. Thus, a small rise in the circulating free thyroid hormones results in a decrease in the release of TSH from the anterior pituitary and, less so, TRH from the hypothalamus, thereby decreasing T4 and T3 synthesis and their release from the thyroid and maintaining euthyroidism. In contrast, a small decrease in circulating T4 and T3 concentrations enhances the release of TSH from the anterior pituitary and, less so, TRH from the anterior hypothalamus

and results in stimulation of the thyroid to maintain serum T4 and T3 concentrations in the normal, euthyroid range. Changes in circulating T4 and T3 concentrations will result in far greater changes in the serum TSH concentration; this emphasizes the sensitivity of TSH secretion in maintaining euthyroidism. Overt hyperthyroidism is associated with increases in the serum free T4 and T3 concentrations and suppression of the serum TSH concentration. In contrast, overt hypothyroidism will result in decreases in the serum free T4 and T3 concentrations and an increase in the serum TSH concentration. Abnormalities in thyroid function may be mild and are usually diagnosed on the basis of low or high serum TSH and normal circulating free T4 and T3 concentrations; again, this emphasizes the use of serum TSH in diagnosing thyroid dysfunction.

Physiologic Need for Iodine and Sources of Iodine

It has been recognized for more than 50 years that iodine is an essential component of the thyroid hormones, T4 and T3, and that severe iodine deficiency (less than 50 μg iodine intakes daily) is the major cause of mental retardation and endemic goiter and cretinism worldwide. Major efforts have been made over the last decade to eradicate iodine deficiency, and remarkable success has been achieved. However, much work remains, and careful continued monitoring of populations is necessary to confirm that proper iodine intake continues. The major and most efficient method to provide iodine to a population is the dietary use of iodized salt, but production and stability pose problems in many areas of the world. Other methods include the ingestion of iodized oil (lasts for about a year after a single dosage), iodination of the central water system (which is also antimicrobial), use of iodinated water to irrigate crops, and addition of iodine to animal feed. In the United States and other countries, dairy products, especially milk, are important sources of iodine because of the use of iodophors in the dairy industry. Fish is also an important dietary source of iodine.

Daily average iodine intake in the United States decreased from about 300 μg in 1971-1974 to about 150 μg in 1988-1994

(Hollowell et al., 1998). Preliminary data from the current National Health and Nutrition Examination Survey (NHANES IV) suggests that daily iodine intake remains about 150 µg. This amount of iodine is appropriate for normal adult thyroid function, except for pregnant and lactating nursing women in whom 220 µg and 290 µg iodine daily, respectively, is recommended.

The thyroid responds to dietary iodine deficiency by enlarging and more actively transporting iodine from the blood, thereby concentrating sufficient iodine to maintain normal function. In contrast, when iodine ingestion is excessive, the thyroid decreases the transport of iodine from the blood into the thyroid. The mechanism responsible for the adaptation of the thyroid to excess iodine is described below.

It has been recognized since the 1940s that excess iodine exposure causes a transient decrease in thyroid-hormone synthesis for about 48 hours—called the acute Wolff-Chaikoff (W-C) effect (Wolff et al., 1944)—and that normal thyroid-hormone synthesis resumes shortly thereafter despite continued ingestion of excess iodine (adaptation to or escape from the acute W-C effect) (Wolff et al., 1949). The transient inhibition of hormone synthesis is most likely due to the generation of an iodinated lipid or an iodolactone that inhibits thyroid peroxidase activity and the oxidation of iodine, iodination of tyrosines, and the coupling of the iodinated tyrosines MIT and DIT to generate T4 and T3 (Pisarev and Gartner, 2000). The escape from the acute W-C effect was postulated to be due to a decrease in the active transport of iodine from the blood to the thyroid that decreased intrathyroidal iodine and allowed normal thyroid hormone synthesis to resume (Braverman and Ingbar, 1963).

The cloning of the NIS in 1996 by Dai et al. (1996) provided a unique opportunity to restudy the W-C effect in the rat. In 1999, Eng et al. (1999) reported that during the first 24 - 48 hours of excess iodine ingestion, there was a marked reduction in thyroid NIS mRNA and NIS protein that persisted during continued ingestion of iodinated water. Thus, escape from the acute W-C effect is due at least partially to the decrease in NIS and the iodine trap and later decrease in intrathyroidal iodine. Excess iodine ingestion by healthy subjects may slightly decrease the secretion of T4 and T3 from the thyroid

with a small compensatory rise in the serum TSH to maintain the serum T4 and T3 concentrations well within the normal range. Thus, many studies have reported that pharmacologic quantities of iodine given to healthy volunteers (without underlying thyroid disease) will induce small decreases in serum T4 and a compensatory small rise in serum TSH; both remain well within the normal range. Those findings indicate that healthy subjects can ingest excessive quantities of iodine for a long period of time, i.e. escape from the acute W-C effect, and maintain the euthyroid state.

Radioactive Iodine

Medical Uses

Radioactive iodine plays an important role in the diagnosis and treatment of various thyroid disorders. The two iodine isotopes used for those purposes are ^{123}I, primarily a gamma-emitter with a short physical half-life of 13 hours, and ^{131}I, a beta- and gamma-emitter with a longer physical half-life of 8 days. Since greater cellular damage or cell death is produced by the higher energy beta emissions of ^{131}I than by the gamma emissions of either isotope, ^{123}I is now the preferred choice for diagnostic studies of the thyroid. Its short half-life and its mainly gamma emission reduce potential radiation effects on the thyroid.

The ability of the thyroid to concentrate iodine permits the use of radioiodine to quantify the iodine-concentration activity of the thyroid because the isotope equilibrates with blood iodine and reflects the uptake of stable (nonradioactive) iodine into the thyroid. Thyroid radioiodine uptake is elevated in patients with hyperthyroidism, is usually low in hypothyroid patients, and varies inversely with iodine intake. Thus, the radioiodine uptake will be higher than normal in subjects with low iodine intake and lower in subjects with high iodine intake. The former probably occurred in Chornobyl because of dietary iodine deficiency, and the latter would occur in Japan, where iodine intake is high. The ability of the thyroid to concentrate radioiodine also permits visualization of the thyroid with appropriate

imaging instruments to determine its location, configuration, and the functional status of thyroid nodules if they are present.

Radioiodine concentrated by the thyroid in large amounts can cause cell death primarily because of ^{131}I's beta radiation. Large doses of ^{131}I are, therefore, given to treat patients with hyperthyroidism; those who have large nodular goiters that are causing local compressive symptoms on the trachea and esophagus, and those who cannot tolerate thyroid surgery; and to ablate functioning residual normal or malignant thyroid tissue after definitive surgery for thyroid cancer. The very large doses used to treat thyroid cancer occasionally lead to radiation-induced salivary gland inflammation and loss of taste because iodine is also concentrated by the salivary glands.

Harmful Effects

A large amount of ^{131}I delivered to the thyroid almost always leads to hypothyroidism because of permanent radiation-induced destruction of thyroid cells. Therefore, with a smaller population of vulnerable thyroid cells remaining, these large radiation doses from ^{131}I are much less likely to cause thyroid cancer. In contrast, a surprising number of children exposed to a relatively low radiation dose from ^{131}I and possibly other shorter-lived isotopes of iodine after the 1986 Chornobyl accident developed thyroid cancer within a few years. There are several potential reasons for the differences between the medical use of radioactive iodine and exposure to radiation fallout in causing thyroid cancer.

- As noted above, large amounts of ^{131}I can result in thyroid-cell death. In contrast, low-dose exposure damages but does not kill thyroid cells and can induce nuclear damage and mutations, which can result in thyroid cancer.
- Radioiodine released to the atmosphere may likely include a number of shorter-lived isotopes of iodine in addition to ^{131}I, which are also potentially carcinogenic.

- Because their thyroid-cells divide more frequently than in adults, children are at far greater risk of nuclear mutations and thyroid cancer when exposed to low level radiation to the thyroid.
- As noted earlier, the presumed low dietary iodine intake in the Chornobyl area probably resulted in an increased uptake of radioactive iodines.

How KI Works

Under normal circumstances, excess iodine decreases NIS on the thyroid-cell surface, thereby inhibiting the further entrance of iodine into the thyroid. Excess iodide administration at the appropriate time decreases the thyroid radioactive iodine uptake (RAIU) by decreasing NIS and by increasing the amount of nonradioactive iodine available for binding to thyroid cells. In the event of release of radioiodine from a nuclear incident, a marked decrease in thyroid RAIU could be achieved by the timely administration of stable iodine that would be extremely useful in reducing internal radiation to the thyroid caused by exposure to iodine radioisotopes from inhalation or by consumption of radioiodine-contaminated foods, especially milk, other dairy products, and leafy vegetables.

In healthy volunteers, thyroid uptake of radioactive iodine has been reported to be essentially blocked for at least 24 hours by administration of 30-200 mg of stable iodine, administered in the form of KI, just before and minutes after exposure. If KI is given one to three hours after exposure to radioactive iodine, further thyroid radioiodine uptake (that is, beyond what is already in the thyroid) is blocked for at least 24 hours. The inhibitory effect on the thyroid RAIU of a single dosage of 130 mg of iodine as KI lasts for about 48 hours. Even if KI is given 8 hours after exposure to radioiodine, the normal uptake of 28% of the radioiodine would be reduced by about 40% to an uptake of about 16% (see Table 2.1). However, it should be noted that if KI is given first 2 to 3 days after ^{131}I exposure, there is some concern that the retention of the ^{131}I would be slightly

prolonged, theoretically enhancing the radiation effect of the retained ^{131}I. Because of normal prolonged retention of radioiodine by the thyroid (half-life 80-120 days) further slowing of thyroid discharge by subsequent KI is likely to be small. If ^{131}I continues to be detected in the air at concentration capable of producing a thyroid dose of 5 Gy (500 rad) or more, then KI should be given.

Table 2.1 Percent Thyroid Protection from ^{131}I after a Single 130 mg Dosage of KI

Time of KI with Respect to ^{131}I Exposure (hours)	**Protection Afforded KI Ingestion (% of control)**
-96	Very little
-48	~80
-1	~100
0	98
2	80
3	60
8	40
24	16

[a] Data at 0 and 3 hours from experimental observations (Blum and Eisenbud, 1967, Sternthal et al., 1980, Ramsden et al., 1967); other data derived from models of iodine metabolism (Zanzonico and Becker, 2000).

Why KI is Used

KI is readily available, inexpensive, and stable, and it has a long shelf-life if tablets are stored in a blister package to prevent exposure to light and moisture. Although iodate is used in some European countries and is also stable, it has traditionally not been used as a blocking agent in the United States and is not as readily

available as is KI. KI tablets are the only form of iodine approved by the Food and Drug Administration (FDA) for use as a blocking agent.

Other antithyroid drugs have been proposed to block the entrance of iodine into the thyroid, including thiocyanate and perchlorate. The former is too toxic, and the latter may not be acceptable due to concerns over the unproven adverse thyroid effects of the trace amounts of perchlorate that are in groundwater in at least 14 states (Engell and Lamm, 2003).

Current Recommended Use of KI in the Event of a Nuclear Incident

According to the WHO *Guidelines for Stable Iodine Prophylaxis Following Nuclear Accidents*, the uptake of radioiodine by the thyroid is effectively blocked by administration of 100 mg of stable iodine, corresponding to 130 mg of KI or 170 mg of potassium iodate, KIO_3, in adults and adolescents. For children, the administered dosage of KI must be reduced. Table 2.2 summarizes single dosage of stable iodine for different age groups recommended by WHO in 1999.

According to the IAEA *International Basic Safety Standards*, the generic optimized intervention level for iodine blockade is 100 mGy (10 rad) of avertable committed absorbed dose to the thyroid due to radioiodine. Iodine prophylaxis is recommended when this postulated dose is exceeded.

The lifetime thyroid cancer risk to exposed children, the most vulnerable population, is estimated by WHO at 1% per Gy (1% per 100 rad) and the risk of severe side effects from a single administration of stable iodine at 10^{-7} (WHO, 1999). WHO recommends an age-specific intervention level for this group of 10 mGy (1 rad) of avertable dose to the thyroid (one-tenth of the IAEA generic optimized intervention level). WHO considers that justified because, even with the lower intervention level—some 2 to 5 extra thyroid cancer cases per 1,000,000 children exposed per year are expected, which is still several times higher than the generally encountered background incidence (WHO, 1999).

Table 2.2 Recommended Single Dosage of Stable Iodine to Block Radioiodine Uptake According to Age Group

Age group	Mass of Iodine mg	Mass of KI mg	Mass of KIO_3 mg	Fraction of KI 130-mg Tablet
Adults and adolescents (over 12 years old)	100	130	170	1
Children (3-12 years old)	50	65	85	½
Infants (1 month to 3 years old)	25	32	42	¼
Neonates (birth to 1 month old)	12.5	16	21	⅛

Source: WHO, 1999.

Table 2.3 summarizes the reference levels for the implementation of iodine blockade recommended for different age groups by WHO in 1999. WHO recommends different intervention levels for different age groups and pregnant and lactating women. The intervention level for neonates, infants, children, and adolescents up to 18 years old and for pregnant and lactating women is, because of the higher radiation risks in this group, only one-tenth of that for adults up to 40 years old. But because the risk of thyroid cancer is very small in adults over 40, WHO recommended iodine blockade only in the case of very high exposure—more than 5 Gy (500 rad),

which may cause thyroid effects other than cancer (such as hypothyroidism).

Table 2.3 WHO Reference Levels for the Implementation of Iodine Blockade for Different Age Groups

Population	**Exposure Pathway To Be Considered**	**Reference Level**
Neonates, infants, children, adolescents up to 18 years old and pregnant and lactating women	Inhalation (and ingestion[b])	10 mGy[c] avertable dose to thyroid
Adults up to 40 years old	Inhalation	100 mGy[c] avertable dose to thyroid
Adults over 40 years old	Inhalation	5 Gy[d] projected dose to thyroid

[a]These levels do not take into account the practicalities involved in planning to respond to an accident involving many radionuclides in unknown quantities in real time. For this reason, a generic intervention level of 100 mGy (10 rad) has been specified in the *International Basic Safety Standards*; but it does not obviate consideration of the IAEA practicality of planning to implement iodine prophylaxis for specific age groups.
[b]Ingestion of milk by infants where alternative supplies of milk cannot be made available.
[c]Adherence to these values would ensure that doses for all age groups would be well below the threshold for deterministic effects.
[d]Intervention undertaken to ensure prevention of deterministic effects in the thyroid. 5 Gy (500 rad) is recommended lower limit for deterministic effects given in *International Basic Safety Standards*.
Source : WHO, 1999.

On the basis of WHO, 1999 and FDA, 2001a guidelines, we recommend that dosage of stable iodine according to age groups be as follows (Table 2.4):

Table 2.4 Predicted Thyroid Exposures to Radioactive Iodines and Recommended Dosages of KI for Different Risk Groups

Group	Predicted Thyroid Exposure (mGy)[a]	KI Dosage (mg)	No. of 130 mg KI Tablets (100 mg I)	No. of 65 mg KI Tablets (50 mg I)	No. of 32 mg KI Tablets (25 mg I)
Adolescents and Adults 12 - 40 Years Old	≥50	130	1	2	4
Pregnant and Lactating Women					
Children 3 - 11 Years Old		65	½	1	2
Infants 1 Month to 3 Years Old		32	¼	½	1
Neonates Birth to 1 Month Old		16	⅛	¼	½

[a]50 mGy is equivalent to 5 rad.

The single intervention level of 50 mGy (5 rad) for all exposed people under the age of 40 years was chosen based upon the FDA guidelines for pregnant women, infants, and children (FDA, 2001a). The KI dosage levels are based on recommendations accepted by many other bodies, including the WHO, and when taken appropriately, are levels known to block almost all the thyroid uptake of radioiodine. We also recommend that this threshold for intervention be kept under review as further information on the consequences of exposure to radiation from fallout from Chornobyl and from other radiation incidents becomes available.

Since infants and children are most vulnerable to the thyroid cancer producing effect of radioactive iodine, appropriate scored KI tablets should be made available. A 32 mg scored KI tablet would be preferable to the currently available 130 mg and 65 mg tablets to more efficaciously and conveniently deliver the recommended KI dosage to the very young. The highest KI dosage could still be easily achieved by the ingestion of multiple tablets.

The lactating woman presents a unique situation since the breast removes iodine from the blood which is then transported into breast milk. Approximately ¼ of iodine ingested by the mother is secreted into breast milk. An excess of stable iodine can partially decrease the transport of radioiodine into the breast. Thus, the mother must minimize her potential thyroid exposure to radioiodine by taking the recommended adult dosage of KI and ensure that the nursing infant be given KI as recommended for infants. Both mother and infant must take KI for both to be protected from thyroid radioiodine exposure.

Adverse Effects of KI

Few nonthyroidal side effects were observed after KI administration to a large population, including children, in Poland after the Chornobyl accident (Nauman and Wolff, 1993). Indeed, it would be difficult to attribute some reported effects, such as skin rashes and gastrointestinal symptoms, to a single administration of KI inasmuch as such mild events are common, especially in infants and children. Most of the potential nonthyroidal side effects reported although often unverified, are listed in Table 2.5. It should be understood that most of these are very rare.

Extremely rare disorders reported to be aggravated by excess iodine ingestion include dermatitis herpetiformis Duhring, ioderma tuberosum, hypocomplementemia vasculitis, and myotonia congenita.

Table 2.5 Potential Nonthyroid Side Effects of KI

Gastrointestinal
Nausea, vomiting, diarrhea, and stomach pain
Allergy-related
Angioedema (generalized swelling)
Arthralgia (joint pains)
Eosinophilia (abnormal white blood cells)
Lymphadenopathy (enlarged lymph nodes)
Urticaria (itching)
Skin Rashes

People with underlying thyroid disease—such as autoimmune thyroiditis or nontoxic nodular goiter, both of which are more prevalent in the elderly and may occur in approximately 25 percent of older individuals, especially women—are at risk for iodine-induced thyroid dysfunction. People who develop iodine-induced hypothyroidism do not escape from the acute W-C effect described earlier under physiologic need for iodine and sources of iodine. Underlying thyroid disorders and other clinical situations that would predispose to iodine-induced thyroid dysfunction are listed in Tables 2.6 and 2.7 (Roti et al., 1997).

People over 40 years old appear to be more resistant to the thyroid-cancer causing effects of ^{131}I exposure as well as to the underlying thyroid disorders that predispose to iodine-induced thyroid dysfunction occur later in life. Therefore, people over 40 probably should not take KI tablets after a nuclear incident as they are at virtually no risk of developing thyroid cancer from the radiation, and are more likely than younger people to develop side effects from the KI.

In contrast with iodine-induced hypothyroidism, excess iodine ingestion may induce hyperthyroidism or Iod Basedow disease, especially in regions of iodine deficiency, including many countries in Western Europe.

Table 2.6 Risk Groups for Iodine-Induced Hypothyroidism

No underlying thyroid disease

Fetus and neonate, mostly preterm
: Secondary to transplacental passage of iodine or exposure of neonate to topical or parenteral iodine-rich substances

Infant
: Occasionally reported in infants drinking iodine-rich water (China)

Adult
: In Japanese subjects with high iodine intake where Hashimoto's thyroiditis has been excluded

Elderly
: Reported in elderly subjects with and without possible defective organification and autoimmune thyroiditis

Chronic nonthyroidal illness
: Cystic fibrosis
: Chronic lung disease (including Hashimoto's thyroiditis)
: Chronic dialysis treatment
: Thalassemia major
: Anorexia nervosa

Underlying thyroid disease

Hashimoto's thyroiditis
Euthyroid patients previously treated for Graves disease with ^{131}I, thyroidectomy, or antithyroid drugs
Subclinical hypothyroidism, especially in the elderly
After transient postpartum thyroiditis
After subacute painful thyroiditis
After hemithyroidectomy for benign nodules

Euthyroid patients with a previous episode of amiodarone-induced destructive thyrotoxicosis

Euthyroid patients with a previous episode of interferon-alpha-induced thyroid disorders

Patients receiving lithium therapy

Table 2.7 Risk Groups for Iodine-Induced Hyperthyroidism

Underlying thyroid disease

- Iodine supplementation for endemic iodine-deficiency goiter
- Iodine administration to patients with euthyroid Graves disease, especially those in remission after antithyroid drug therapy
- Nontoxic nodular goiter
- Autonomous nodules
- Nontoxic diffuse goiter

No underlying thyroid disease

- Iodine administration to patients with no recognized underlying thyroid disease, especially in areas of mild to moderate iodine deficiency

Iodine may also be useful in some clinical situations other than a need to prevent iodine deficiency (Table 2.8).

Table 2.8 Medical Uses of Stable Iodine

- Treatment and prevention of iodine deficiency goiter
- Thyroid storm
- Preoperative preparation of toxic goiter
- Post ^{131}I therapy of Graves disease
- As sole therapy of Graves disease (when sensitive to antithyroid drugs)

3

POTENTIAL EXPOSURE TO RADIOACTIVE IODINE

This chapter lists sources of radioiodine that potentially can affect public health and safety. It presents information on the routes by which radioiodine could reach members of the public after a nuclear incident and general guidelines for protection against radioiodine exposure. It evaluates the safeguards built into US nuclear power plant designs to demonstrate the multiple barriers that must be breached before radioiodine is released to the environment and to contrast these plants with the Chornobyl type of nuclear power plants. Radioiodine used in medical diagnosis and therapy has limited potential for use in weapons of mass destruction (dirty bombs), and nuclear-powered submarines represent a potential for affecting public health and safety only when they are involved in accidents in port.

Sources of Radioactive Iodine

Radioactive iodine[1] is a byproduct of the fission of uranium atoms. Two processes that lead to the creation of radioiodine are the fission of uranium as fuel in nuclear reactors and its use as an explosive material in atomic bombs. Under normal circumstances, minimal radioiodine is released to the environment from operating nuclear reactors, whether such reactors are operated for power production, for production of radioisotopes for use in medical diagnosis or treatment, or in materials testing or teaching. In the case of nuclear power plants (NPPs), the uranium fuel is contained in sealed metal tubes (fuel rods), the fuel rods are placed inside an eight inch thick steel reactor vessel, the reactor vessel is contained inside a thick (several feet), reinforced-concrete reactor building. In addition, all aspects of the reactor operation are carefully monitored with sensitive instruments, and highly effective filtration systems are used to remove radioiodine from air or water released from the reactor facility. For the smaller, teaching-type, reactors, many of these same safety features are used. The quantities of radioactive iodine normally found at locations related to medical use are small enough to be unlikely to be used in radioactive dispersal devices (so-called dirty bombs).

Before radioactive iodine from the nuclear fuel of a NPP can reach the environment, extensive damage must occur to the fuel elements in the reactor core with additional damage to the containment structure enclosing the reactor. Radioactive iodine (^{131}I) has a short half-life (8 days) and is of concern only with respect to the fuel in an operating NPP or with fuel from a reactor core that has recently been shut down. Spent nuclear fuel stored at NPPs is free of significant radioiodine within weeks after shutdown of the reactor and cessation of the fissioning process that produces the radioiodine. Spent nuclear fuel that is stored outside a nuclear-reactor building is old fuel that has been kept so long that it contains minimal quantities of short lived radioiodines. Spent nuclear fuel in transportation does

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[1] Typically, when radioiodine from fission products is discussed, ^{131}I is the radionuclide of concern.

not present a potential for release of radioiodine. NPPs in the United States are designed and built to withstand severe accidents and to prevent the escape of radionuclides that could threaten public health. Severe damage to the reactor core coupled with extreme damage to the reactor facility is required for radioiodine to be released to the environment. US NPP design features ensure that in the worst-case situations there will be a delay, usually days, before radionuclides can escape to the environment in amounts that would be of a public-health significance. Additional steps are taken in reactor design to ensure that such unexpected events as earthquakes and tornadoes do not lead to damage of nuclear fuel or release of radionuclides to the environment. These rigid design features coupled with heightened security measures make radioiodine releases from terrorist activities highly unlikely.

Nuclear Power Plant Radioiodine Inventory

The approximate inventory of ^{131}I and other iodine radioisotopes in the core of a NPP depends on the size of the reactor core (megawatt-electrical (MWe)) and on how long the reactor has been in operation. The table in Appendix B can be used to estimate the approximate inventory (actual inventory will depend on how long the reactor has been in operation) of the predominant radionuclides of public-health concern that are present in a reactor core. By multiplying the "Ci/MWe" value indicated in the appendix by the operational power level of the plant, one can obtain an approximation of the total activity (in curies) of each radionuclide. For example, in the case of Three Mile Island, a 740 MWe reactor, the ^{131}I inventory at the time of the accident was equal to about 740 MWe × 85,000 Ci/MWe or 63 megacuries (MCi). Less than one-millionth of the inventory of radioiodine in the Three Mile Island core was postulated to have escaped to the environment, that is, about 15 Ci (Kemeny et al., 1979). In the United States, nuclear power plants are designed to isolate the reactor building in the event of an accident. In the case of Three Mile Island, initial isolation of the reactor building was not totally successful. As accident-generated water began to flood the lower levels of the reactor building, sump pumps began pumping this

water into a holdup tank outside the reactor building, in the Auxiliary Building. The tank was already three-fourth full at the time of the accident and quickly overflowed, discharging radioactive materials into the Auxiliary Building. If radioiodine did escape to the environment after the Three Mile Island accident, the most likely pathway would have been discharge from the Auxiliary Building. However, the determination of radioiodine in environmental samples immediately after the accident was uncertain because the overwhelming activity of radioactive noble gases in collected samples that led to erroneous interpretations of radioiodine. Later analysis of samples showed that what was first thought to be radioiodine was xenon-133 and xenon-135. Of 57 samples collected in the first 3 days of the accident, 40 were analyzed later using gamma spectroscopy and shown to be free of detectable radioiodine (USNRC, 1979).

Other Radionuclides in Nuclear Fuel

Radioiodine is but one of many radionuclides presents in nuclear fuel or released when an atomic bomb detonates. Some of the radionuclides that are important from a public radiation dose standpoint are given in Appendix B. A review of this list indicates that radioactive fission products are typically either gasses (such as the radioactive noble gasses of xenon and krypton), particulates (such as strontium) or volatile (can be readily evaporated) materials, such as radioiodine. Radioactive noble gasses are, in general, not considered a threat to public health because they do not stay in the body if breathed in and they do not concentrate in the environment. While particulate radionuclides are of concern from a public health standpoint, they have a very low probability of being released to the environment as a result of an accident at a NPP. Under normal operating conditions, or even accident conditions, they do not escape nuclear reactor facilities in quantities to be of concern from a public health standpoint because they do not mix readily with air and because they are easily removed from a reactor facility's water and air by filters. Furthermore, the rigid NPP design features discussed above are designed to prevent particulate radionuclides from reaching the environment, even under accident conditions. Radioiodine is of

particular concern because of the ease with which it can convert to a vapor state and because radioiodine taken into the body will concentrate in the thyroid gland if the thyroid is not saturated with nonradioactive iodine before the radioiodine reaches it. Under normal operating conditions, radioiodine is easily removed from a NPP's air and water with highly effective filtration systems. A review of the nuclear accidents at Three Mile Island and Chornobyl, see Chapter 4, illustrates how the design of reactors in the United States specifically addresses the nature of radioactive fission products and makes releases to the environment unlikely. In contrast, poor design of the Chornobyl reactor facility led to the release of a considerable portion of its entire fission-product inventory, including radioiodine.

Nuclear Weapons Radioiodine

Radioactive iodine is produced in the detonation of a nuclear weapon just as it is produced in a NPP. However, in addition to radioiodine, many other fission products are produced when a nuclear weapon detonates. For those far enough away to survive the blast from such a weapon, protection from the radionuclides in fallout from the ensuing plume, including radioiodine, would be required. Such actions are outlined in National Council on Radiation Protection and Measurements (NCRP, 2001) and include:

- Evacuation when possible and safe to do so.
- Remaining inside and the minimizing opening of doors and windows.
- Turning off fans, air conditioners, and forced-air heating units that bring fresh air in from the outside.
- Avoiding consumption of fruits, vegetables, and milk from the area until shown to be free of contamination.

Routes of Exposure

Radioiodine can exist in particulate form, such as cesium iodide (Cs ^{131}I) or sodium iodide (Na ^{131}I), as a radioiodine vapor, or

as a solution with the radioiodine dissolved in water. In the environment, the different physical and chemical states of radioiodine provide several pathways for it to reach humans.

Exposure from inhalation. Radioiodine in the gaseous state can be inhaled into the lungs where it can dissolve and enter the blood. The blood then circulates through the body, including the thyroid gland. Under the condition of normal nutritional iodine supply, a normally functioning thyroid gland will take up and store between 15-30% of the iodine to which it is exposed, whether it is radioiodine or the chemically identical nonradioactive iodine (the thyroid does not recognize any difference between radioactive and nonradioactive iodine). Studies have shown that about 55% of radioiodine breathed in is absorbed into the blood in the lungs and transported throughout the body (Costa et al., 1982). However, the inhalation-exposure route was not the major contributor to the thyroid doses of the populations exposed to radioiodine released in the Chornobyl accident; rather, as previously discussed, it was estimated that most of the radioiodine taken into the thyroid entered the body in contaminated food or drink.

Evacuation and sheltering are the preferred methods of protecting populations from direct exposure to radioactive materials (including radioiodine) in a nuclear emergency. When plumes (radioactive clouds) are passing, considerable protection is provided by staying indoors and shutting off air-handling systems that bring outside air into buildings. Additional protection can be gained by moving to areas of buildings that provide the most shielding from radiation coming from radionuclides in outside air (for example, moving inward and downward within the building). Evacuation before or as soon as possible after plume passage is the preferred way of getting people out of harm's way and ensuring that they are not exposed to released radionuclides.

Radioiodine in food and water. The ability of radioiodine to exist in a particulate form or as a solution in water makes it possible for it to contaminate drinking water, soil, and plants used as food. Radioiodine on pasture grasses or on feed for cattle or goats can contaminate their milk. After Chornobyl, most of the dose to people's

thyroids was due to consumption of contaminated water and food, including milk. During a nuclear incident, specific guidance would be given on foods and drinks that should not to be consumed by humans because of the presence of radioiodine or other radionuclides. It is unlikely that contaminated foods would be a major source of exposure to radioiodine in the United States.

Reactor Design

The accident at Chornobyl provided considerable information on reactor design, the types and quantities of radionuclides that can escape the nuclear fuel (source term), environmental pathways and potential risks of released radionuclides to public health and safety. That accident was precipitated by an explosion and a fire in the graphite-moderated core. The fire carried large quantities of fission products, including radioiodine and noble gases, into the environment.

Reactor designs in the United States are different from the Chornobyl design in that:

- The choice of moderators (material used to slow down neutrons) is different for US NPPs. In the United States, water is used, whereas the Chornobyl type reactors use graphite (graphite is combustible, water is not).
- US NPP designs prevent sudden, difficult to control increases in power level (sudden increases in the fissioning process).
- US NPPs employ multiple layers of ("defense-in-depth") barriers to ensure that nuclear fuel and fission products cannot escape from the core. In the United States LWRs have pressure vessels with walls that are about 187 mm (7.4 in) thick (NUREG-1250) (USNRC, 1987). The Chornobyl Reactor had no such reactor containment vessel.
- US NPPs are designed on the basis of "full containment" or the complete enclosure of all reactor and primary support systems for the reactor in the event of a design basis accident (DBA) (NUREG-1250) (USNRC, 1987). In the United States,

full primary containment is achieved by a thick steel reactor vessel and heavily reinforced concrete reactor building that surrounds all primary reactor systems. The containment can contain the peak pressure reached in DBAs or has sufficient pressure-suppression capacity to contain the worst-case peak pressure.

- In the case of the accident at Three Mile Island, ignition of accumulated hydrogen gas in the reactor containment building caused a pressure pike of 28 psi but, did not lead to a breach of the containment building or any apparent increase in the escape of radioactivity to the environment (USNRC, 1988). On the other hand, the thin metal of the Chornobyl reactor's building was easily breached by the explosion and fire that accompanied that accident. The breaching of the reactor building allowed the fire that consumed much of the reactor core to spew radionuclides, including radioiodine, directly to the atmosphere.
- In NPP licensing, the US Nuclear Regulatory Commission subscribes to the "defense-in depth" (multiple layers) safety strategy, which includes: accident prevention, redundant safety systems, containment, accident management, siting, and emergency planning. US NPPs have considerable redundancy in their design to prevent consequential releases of radioactive material to the environment. Thus, fission products in the reactor core of US NPPs have to pass through several distinct fission-product barriers, including the fuel matrix, the fuel cladding, the reactor vessel and coolant system and the reactor building before reaching the environment.

Design Basis Accidents

A design basis accident (DBA) is a hypothetical accident that is assumed to include substantial meltdown and then release of appreciable quantities of fission products. It is used in the design of nuclear power facilities in the United States and in emergency planning.

When a NPP is proposed, NRC regulations require the site and reactor-design combination must be such that the consequences of DBAs at the site boundary are below the plume-exposure dose limits of 250 mSv (25 rem) total effective dose equivalent (TEDE) to the whole body and 3 Gy (300 rad) thyroid dose. The design basis loss-of-coolant accident (DBA-LOCA) has been typically the most severe DBA because it usually results in the largest calculated offsite doses. The DBA-LOCA is not a realistic accident scenario because of the engineering assumptions made to cause the damage used in the dose modeling. These assumptions result in release magnitudes that are much more severe than would be expected in a real incident. A realistic assessment of the release after a LOCA is much smaller than that from the DBA-LOCA used for siting purposes. DBA-LOCA assessments initially conducted by the NRC in evaluating the size requirement of the plume emergency planning zone concluded that plume exposures of 250 mGy (25 rad) thyroid dose would not be exceeded beyond 16 km (10 miles). Even under the more restrictive protective-action recommendations for thyroid protection recently published by the FDA considered in this report (50 mGy (5 rad) thyroid dose), over 70% of the DBAs modeled would not require any consideration of emergency responses due to inhalation radioiodine from a plume beyond 16 km (10 miles).

Severe Accidents

Severe accidents are accidents that 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. Severe accidents cover the spectrum of releases involving life-threatening, environmental releases of large fractions of the available radioactive materials in a reactor (tens of millions of curies). The lower range of the spectrum involves accidents in which a core "melt-through" of the containment would occur. The upper range includes catastrophic containment failure. Emergency response plans for severe accidents have as their highest priority the reduction of early severe health effects. Evacuation of the area impacted by the resulting plume from the power plant would

significantly reduce early injuries and deaths from even the most severe atmospheric releases (USNRC, 2002). For a severe accident to occur, multiple safety systems would have to fail and extreme reactor and atmospheric conditions would have to exist, circumstances which are extremely unlikely.

Source Terms

The fission-products that could be released from reactor fuel to the containment are known as the source term. The source term 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 in evaluating the radiological consequences of DBAs and severe accidents. Some fission products tend to form more often than others during the fission process. In 1962, the Atomic Energy Commission adopted the analysis 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 to consist of 100% of the noble gases, 50% of the halogens (particularly radioiodine), and 1% of other fission products; half the released halogens were assumed to be deposited on reactor building surfaces. It was thought, at that time, that a major radioiodine release was possible, and that radioiodine was considered to pose a major risk because it was subject to inhalation and not just external exposure. The simplistic critical-organ dose model used at that time supported that conclusion. The 1% of fission product particulates was dropped from the source term because without massive failure of the containment structure, release of particulates was seen as negligible in comparison with iodine and noble gases. That source term was offered for conservatism and calculational convenience.

Meteorology

The release of radioactive material into the atmosphere creates the greatest potential for offsite consequences. Meteorology is

important because it determines where the offsite release (the plume) goes, and the concentration of the radionuclides to which the downwind public is exposed.

Meteorological information includes wind speed, direction, persistence and variability, and vertical dispersion. Those factors describe the stability of the atmosphere and indicate how fast, far and wide radionuclides would be transported in air. Under very stable atmospheric conditions, there is little dispersion of the plume and the radionuclide concentration is much greater than under very unstable atmospheric conditions that would disperse the plume and lower radionuclide concentrations in it. Stable conditions (unfavorable meteorology) are usually chosen for performing DBA calculations, rather than the prevailing meteorological conditions.

Under normal meteorological conditions, the plume from a site moves away from the release point much as smoke moves away from a chimney. Only those in the direct path of the plume would be in immediate danger. Just as smoke dissipates as it moves away from a source, so does a radioactive plume. This dissipation quickly decreases the concentration of radioactive materials within the plume. If the quantities of radionuclides in the plume have public-health significance for people in the path of the plume, such protective actions as sheltering (remaining indoors) and evacuation would be considered. Weather conditions that might prevent immediate evacuation, such as blizzards or torrential rainfalls, would remove radioactivity from the plume close to the point of release and actually help to protect people who are downwind.

Reactor-Accident Exposure Pathways

In a reactor accident, there are three principal ways for radioactive materials to deliver radiation doses to people: external exposure to radiation emitted by radionuclides in the passing plume or from radionuclides deposited on surfaces, including the ground, internal exposure from inhalation of airborne radioactive material, and internal exposure from the ingestion of radioactively contaminated food or water. Absorption of radioactive material through the skin, either by direct absorption or absorption from contaminated wounds is

possible for some radionuclides but this method of exposure is of much less concern.

During the plume phase of a reactor-accident release, the thyroid might be exposed externally to gamma radiation from radionuclides in the plume or it might be exposed internally if radioiodine is present and inhaled. The thyroid can also be exposed internally through the intake of radioiodine by the consumption of contaminated milk, water or foods, such as leafy vegetables. Consideration of the ingestion of milk is particularly of concern because radioiodine deposited on pasture grass is reconcentrated in the milk of grazing animals (particularly cows, goats, sheep and reindeer). It takes a day or two for the radioiodine to appear in milk. To reduce exposure via the ingestion pathway, including thyroid exposure, officials would recommend that dairy animals be fed uncontaminated stored feed or recommend the interdiction of local milk supplies and contaminated foods (USNRC, 2002).

Other Types of Incidents

Facilities that use radioactive iodine in research, medical diagnosis, and medical treatment and vehicles that transport the material could also be sources of exposure as a result of an incident. However, such facilities or vehicles would not involve the quantities of radioiodine present in an operating NPP. The objectives of emergency response to incidents that involve these types of facilities are the same as the objectives of response to NPP incidents: to ensure public safety and to minimize the effects of radiation exposure.

The principles of evaluating the consequences of and developing response plans for incidents associated with other types of nuclear plants (other than NPPs) are the same as with NPPs. An analysis (Hotspot 2.01, 2002) that simulated release of large quantities of ^{131}I from a large-structure fire showed that the evacuation zone for a 50 mGy (5 rad) dose to the thyroid was within the normal area of evacuation for a fire of the size that would be needed to release all the radioactive iodine typically in such a facility. A radiological dispersion device (dirty bomb) scenario associated with a transportation incident also indicated that the evacuation zone for a 50

mGy (5 rad) dose to the thyroid was in the normal area of evacuation (DOT, 2000). In general, the large-fire scenario results in more dispersion of the radioactive iodine than a dirty bomb containing approximately the same amount. Therefore, existing emergency-response actions of local first responders to these incidents constitute a sound basis of an emergency response.

Medical Applications

Radioactive iodine has been used in medicine since 1946 when the first thyroid cancer treatment was conducted with ^{131}I, dubbed an "atomic cocktail". ^{131}I continues to be a favored treatment for overactive thyroid glands and thyroid cancer. Typically, the procedures are performed with a few thousandths of a curie (several millicuries) to a few tenths of a curie (several hundred millicuries) of ^{131}I (see Chapter 2 for a more detailed description of the medical aspects of radioiodine use). As was seen after the Three Mile Island accident, if several curies of radioiodine were released to the environment, as was postulated, radioiodine was barely detectable in the environmental samples collected later. Thus, it is unlikely that the radioiodine used by a hospital for patient treatment, if used in a dirty bomb, would pose any significant public health threat. The National Council on Radiation Protection and Measurements (NCRP) has estimated that the harm from such a device would be primarily psychosocial (NCRP, 2001).

Naval Nuclear Propulsion Plants

Naval nuclear propulsion plants are smaller than commercial NPPs, operate at low power or are shut down in or near port, and are operated by highly trained crews. Less than 1% of the radioactivity contained in a typical commercial NPP could be released from a naval reactor, and this limits the possible dose to the general public and the size of the area of potential concern. In addition, naval nuclear propulsion plants are ruggedly designed to withstand battle shock conditions, sit in an unlimited source of water that can be used for

emergency cooling, and can be moved away from a nearby population if necessary.

In our discussions with the Naval Nuclear Reactor Program and our knowledge of the program, we know that ^{131}I exposure is possible for the crew and base personnel near the vessel. Base personnel are not considered the public in this situation just like employees at a reactor are not considered the public. However, significant thyroid doses at significant distances for the public located off the naval base are not likely if one takes into account all protective actions. The primary protective action would be to evacuate near the base if necessary; ^{131}I will not be the only radionuclide released. Due to this smaller release, dilution of the plume prior to reaching the base boundary, and relatively small area required for protective actions, evacuation of the public would be completed before a 50 mGy (5 rad) thyroid dose would be received. All of this is in addition to the physical restrictions on the release previously mentioned: these reactors are very small compared to commercial reactors, operate at low power, and built to withstand battle damage.

Because of those design and operational features, the occurrence of a reactor accident on a Navy submarine is highly unlikely, and the radiological impacts of any credible event would be localized and not severe. The public would not be required to take any immediate protective action, and the thyroid dose of radiation received by any member of the public would be less than the threshold dose established by FDA and EPA for administering KI. Stockpiling or distributing KI to the public surrounding naval bases due to operation of naval nuclear-powered warships is not necessary.

4

HEALTH CONSEQUENCES OF RADIATION EXPOSURE

This chapter discusses briefly how radiation can lead to deleterious effects, such as cancer, and then reviews the evidence on the health effects seen in various populations exposed to external radiation (for example, from atomic bombs) or to internal radiation from isotopes of iodine. Among the nuclear power plant accidents discussed, particular attention is paid to the 1986 Chornobyl accident because of the high levels of fallout to which a large population was exposed. One of the most important conclusions is that evidence on both external and internal radiation shows that very young children are the most sensitive to the carcinogenic effects of radiation to the thyroid; the risk decreases with increasing age, and there is no appreciable risk to adults, particularly those over 40 years old. Young children are therefore the group requiring particular attention for prophylaxis.

Understanding the consequences to human health of exposure to radioisotopes of iodine depends largely on experience with its use

in investigation and treatment of thyroid disease and on studies of populations exposed to fallout from various nuclear incidents. Radiation effects can result from external radiation (from a source of radiation outside the body, such as x rays) and from internal radiation (from a source of radiation in the body, such as radioisotopes absorbed from food or drink or absorbed from the air). The effects of internal radiation from iodine radioisotopes on the thyroid depend on the gland's ability to concentrate and store the isotopes, which lead to a much higher radiation dose to the thyroid than to other tissues. Some other tissues (such as salivary glands, breast, and stomach) concentrate radioiodine but do not store it, so their dose, although more than that to most tissues, is much less than that to the thyroid.

Radiation from any source—including ingested or inhaled isotopes, medical or dental investigations with x rays, and direct radiation from an atomic bomb—can damage DNA and thus pose a risk of tumors and, in high doses, cell death. The main expected consequences of exposure of the thyroid to radiation are an increase in the incidence of thyroid tumors and an increase in the occurrence of loss of thyroid function (hypothyroidism, myxedema). Tumors occur because DNA damage can lead, in a small minority of cells, to activation of genes that stimulate cell growth, to loss of function of genes that suppress cell growth, or to various other changes that give cells and their progeny the ability to multiply more rapidly than normal. Radiation can damage DNA directly or through the formation of free radicals. The damage can be double strand breaks, with resultant loss of a portion of a chromosome (deletions), or rearrangement, in which a piece of a chromosome is reinserted inappropriately. Misrepair of radiation-induced damage, including single strand breaks, can also lead to point mutation, in which a base is replaced by an inappropriate one. Many mutagenic chemicals lead to point mutations, but radiation causes mostly deletions and rearrangements (Sankaranarayanan, 1991). Much attention has recent been focused on genetic instability, a phenomenon observed in vitro in which radiation, of both high- and low-energy-transfer types, leads not only to mutations in irradiated cells but also to a persistent increase in mutation rate in the non-irradiated daughter cells (Little et al., 1997). Surprisingly, it has been shown that such instability is

shared by the descendants of non-irradiated cells adjacent to those irradiated, the so called bystander effect (Lorimore and Wright, 2003). Those observations are of considerable potential importance in the understanding of human carcinogenesis. The observations so far on thyroid carcinoma induced by radiation show that the main mutation observed has been rearrangement of the RET oncogene, the type of mutation expected as a result of radiation-induced double strand breaks (Williams, 2002). These can be explained as direct radiation effects without the need to postulate the involvement of genomic instability. The chance of tumor development rises with increasing radiation dose up to a level that is high enough to kill all or most thyroid cells. Very high doses do not cause tumors, because cells that are fatally damaged cannot proliferate to produce tumors. However, such extensive damage can lead to hypothyroidism. In addition to tumors and cell death, a third possible thyroid-related consequence of radiation is autoimmune disease of the thyroid: the body's own lymphocytes become sensitized to thyroid cells and can destroy them and in a small proportion of cases lead to hypothyroidism. More rarely, the antibodies produced by the lymphocytes can react with the hormone-receptor switch that turns up thyroid function and thus lead to thyrotoxicosis (Graves disease, or hyperthyroidism). The mechanism through which radiation causes autoimmune disease has been postulated to be due to a differential effect of radiation on different types of lymphocytes.

The health effects of use of iodine isotopes in investigation and treatment of adults with thyroid disease have been well studied; no significant consequences have been found in association with the small radiation doses used in investigation. Several large studies of the higher doses used in treatment for thyroid hyperfunction have shown no increase in thyroid cancer but have shown a high incidence of hypothyroidism due to destruction of thyroid cells—easily treatable with hormone replacement (Holm et al., 1991).

Population exposure to radioisotopes in fallout began in 1945 with the atomic bombs in Japan, although these detonations were more relevant to direct external radiation from neutrons and gamma rays. Between 1951 and 1962, the aboveground testing of nuclear weapons in Nevada led to the release of large amounts of ^{131}I, the

main radioisotope used in therapy (half-life, 8 days). The amounts released and the exposure of the US population have been carefully documented, and a full report is available (NCI, 1997). One particular US test carried out in the Pacific Ocean led to a significant exposure of the population of the Marshall Islands. Aboveground tests were also carried out by the USSR and in smaller numbers by the UK and France, mostly in the Southern Hemisphere, and other countries have tested a small number of nuclear weapons.

Releases of radioiodine from the Hanford facility in Washington state led to population exposure through fallout, and this too is well documented, as is the release of iodine isotopes from an accident at the Windscale nuclear plant in the UK in 1957 (Crick and Linsley, 1984, Cate et al., 1990, Robkin, 1992, Ramsdell et al., 1996). Releases similar to those from Hanford took place around the Mayak plant in the USSR. A very small release followed the accident at the Three Mile Island plant in 1979. By far the largest release of radiation from a nuclear reactor took place in 1986 after an accident at the Chornobyl nuclear power plant. The estimated amounts of ^{131}I released during those incidents are shown in Table 4.1. The observed health consequences of events that are the most relevant to this report will be dealt with in turn, with particular attention to Chornobyl because of the size of the release and the studies that have been carried out in the 17 years since the accident.

Table 4.1 Environmental Releases of ^{131}I[a]

Site	Location	Year	Amount of Ci	^{131}I release Bq	Scale of Release Compared with Windscale Accident
Hanford Facility[b,d]	Washington State	1945-1947	7×10^{5}	2.6×10^{16}	35
Hanford "green run"[e]	Washington State	1949	1.1×10^{4}	4×10^{14}	0.5
Windscale NPP[c,f]	UK	1957	2×10^{4}	7.4×10^{14}	1
Aboveground tests[b,g]	Nevada	1951-1962	1.5×10^{8}	5.6×10^{18}	7,500
Three Mile Island NPP	Pennsylvania	1979	15	5.6×10^{11}	0.00075
Chornobyl NPP[h]	Ukraine (former USSR)	1986	4.6×10^{7}	1.7×10^{18}	2,300

[a]Not comprehensive.
[b]Release over a long period.
[c]The first significant nuclear power plant accident.
[d]Ramsdell, et al., 1996.
[e]Robkin, 1992.
[f]Crick and Linsley, 1982.
[g]NCI, 1997.
[h]UNSCEAR, 2000.

Radiation from Atomic Bombs

Hiroshima and Nagasaki

The detonation of an atomic bomb releases a huge blast and thermal wave, large amounts of neutrons and gamma rays, and a variety of isotopes, including isotopes of iodine. The health effects in a populated area are dominated by the blast and thermal waves and the direct radiation. The external radiation from neutrons and gamma rays, unlike internal radiation from isotopes of iodine, does not irradiate the thyroid gland to a greater extent than the other tissues of the body, and KI will not prevent thyroid damage from external radiation. Studies of the survivors of the atomic bombs in Hiroshima

and Nagasaki have shown increases (by a factor of about 2-3) in cancers of many different tissues in survivors who were close to the point of detonation (hypocenter) (Thompson et al., 1994). The approximately 2 fold increase in thyroid cancer incidence was similar to that in many other cancer types—such as cancer of the colon, breast, ovary or bladder—and this suggests that it was due to direct whole-body external radiation and that exposure to iodine isotopes made no observable contribution to the occurrence of thyroid cancer in the population studied.

Atomic-Bomb Tests

Atomic-bomb testing has been carried out in unpopulated areas to avoid significant exposure of population to direct radiation from neutrons and gamma rays. However, fallout may occur at a considerable distance, and exposure may be cumulative if many tests are carried out at the same site. One test of a large nuclear device led to the release of large amounts of iodine isotopes, and an unpredicted weather change led to exposure of the population of some of the Marshall Islands to large amounts of radioisotopes of iodine.

Marshall Islands

On March 1, 1954, on Bikini Atoll in the northern Marshall Islands, a 15-megaton thermonuclear device was detonated on a tower in an atmospheric nuclear test code-named BRAVO. The yield was 3 times greater than anticipated, about 15 megatons, and an unexpected wind-shear condition resulted in heavy fallout outside the test area. About 4-6 hours after the explosion, the radioactive cloud deposited particulate, ash-like material on 65 inhabitants of Rongelap and 18 Rongelapese on Sifo Island on the nearby Ailinginae Atoll. In addition, 23 fishermen on the Japanese fishing boat Fukuryu (Lucky Dragon) Maru were heavily contaminated (cloud deposits were 4-6 hours after the explosion and 160 Km eastward). Twenty-eight American servicemen on Rongerik were also exposed. After 22 hours, the cloud reached Utirik, where 167 people were contaminated.

Most of the people from Rongelap developed acute radiation sickness. Between 1954 and 1985, thyroid nodules developed in about 33% of the Rongelap population, including 63% of the children who were less than 10 years old at the time of exposure. And 10% of the Utirik population also developed thyroid nodules.

Those populations have been carefully and closely followed by several teams of investigators. A major problem has been uncertainty about the exact radiation exposure. The major data from which thyroid exposure was derived came from analysis of a single pooled-urine ^{131}I assay obtained 17 days after exposure. Early calculations of accumulated whole-body dose of gamma rays were about 1.9 Gy (190 rad) on Rongelap, 1.10 Gy (110 rad) on Ailinginae, and 0.11 Gy (11 rad) on Utirik (Adams et al., 1987). Recalculated doses from the internal radionuclide burden would be derived later from estimated thyroid content of five radioiodine isotopes and two tellurium radionuclides, all with shorter half-lives than ^{131}I. Most of the thyroid absorbed dose was from short-lived isotopes. Only a minor portion of the thyroid dose could be attributed to inhalation and to a negligible amount of beta-particle irradiation from skin deposits; thus, the internal thyroid dose was due almost entirely to ingested radionuclides.

Significant early radiation effects were seen, including leukopenia to about 50% of the comparison level when first examined 3 days after exposure. Thrombocytopenia was maximal at 30% by 4 weeks, and neutropenia was evident by 5-6 weeks.

During the first decade after exposure, the general health of this population appeared to be no different from that of the nonexposed Marshallese control group. Late radiation effects were noted when 9 years after the accident a 12-year-old Rongelap girl was found to have a thyroid nodule. Within the next 3 years, 15 of the 22 Rongelap people who had been under 10 years old at the time of exposure had developed thyroid lesions; and 15 years after the accident, the first thyroid nodule appeared in the exposed people on Utirik.

The first thyroid abnormality to appear in the thyroid glands themselves in the exposed Marshallese, however, was radiation-induced thyroid atrophy which resulted in profound growth failure in

two boys; the etiology was not recognized until after thyroid nodules began to appear. Later surveys with thyroid stimulating hormone (TSH) measurements and stimulation tests, in addition to routine measurements of thyroid hormone, showed 12 cases of subacute thyroid hypofunction that could not be attributed to thyroid surgery.

The first thyroid cancer was diagnosed 11 years after exposure in a Rongelap woman who was 30 years old at the time of the detonation. An excess of thyroid cancer was also seen in exposed Rongelap and Utirik people, and all were papillary carcinomas.

Thyroid nodules and thyroid cancer are major causes of late morbidity. Mild hypothyroidism in a large number of people might have occurred through radiation effect resulting in increased TSH secretion. Thyroid-hormone therapy was instituted generally in the Rongelap exposed population in 1965 to decrease the risk of thyroid tumorogenesis.

The short-lived isotopes of iodine and tellurium contribute 80-90% of the absorbed thyroid dose in the Marshall Islands data. Follow-up data can therefore provide no information about the risk posed by radiation associated with ^{131}I, which has a longer half-life of 8 days.

Study of this population raised the issue of multiple exposures. There were 66 announced nuclear tests in the Marshall Islands between 1946 and 1958, and many of these tests took place in Eniwetok Atoll, which is 200 miles west of Bikini. The BRAVO test was the largest of the 66.

Several studies have explored the affected populations to examine the relation between exposure to fallout from nuclear-weapon tests and the occurrence of subsequent thyroid abnormalities. It has proved particularly difficult to examine that relationship because of the need to determine the individual thyroid radiation dose of each person. Attempts to use distance from the explosion site as a proxy for radiation dose has produced conflicting results (Hamilton et al., 1987, Takahashi et al., 2001). Additional available data suggest that fallout from the tests spread over a wider area than originally thought. The Marshall Islands Nationwide Thyroid Disease Study found a high prevalence of thyroid nodules in the entire population of the Marshall Islands that appears to correlate with increasing age

(Takahashi at al., 2001). A further difficulty in follow-up became apparent when thyroid ultrasound diagnostic procedures were added to palpation for case-finding; it greatly increased the sensitivity of nodule detection (Takahashi et al., 2001) and doubled the estimated prevalence of nodules.

Nevada Tests

Over 90 aboveground tests were carried out at the Nevada Test Site between 1951 and 1962; after this period, aboveground tests ceased, and the underground tests that followed released negligible amounts of radioactive iodine into the atmosphere. The exposure of the US population has been estimated by taking into account age, residence, and dietary variation (NCI, 1997). Epidemiologic studies investigating the health consequences have been carried out, relating both incidence and mortality from thyroid cancer to dose estimates from the NCI study. Data from the Surveillance, Epidemiology, and End Results (SEER) tumor registries was used, these derived largely from some of the less exposed areas of the United States. An association was found between dose and thyroid cancer in children under 1 year old at exposure (Gilbert et al., 1998).

The theoretical calculations of Charles Land (NRC, 1999) suggest that the number of lifetime excess cases of thyroid cancer in the United States resulting from exposure to fallout from the aboveground tests can be estimated at 49,000 (range of 11,300-212,000). The estimate assumes that significant risk was restricted to those under 20 years old at exposure and that the excess risk persisted unchanged throughout life. The figure of 49,000 represents just over 12% of the number of cases of thyroid cancer expected in the absence of radiation exposure. The number of assumptions in the calculations and the lack of reliable data from the most exposed areas suggest that although it can be accepted that there has been an increase in thyroid cancer incidence due to exposure to fallout from the aboveground tests, it is not now possible to rely on these figures to provide a basis for estimating risk from radioiodine exposure generally.

Other Tests

No detailed studies of the consequences of population exposure to the fallout from the Russian or Chinese testing programs are available, but a possible link between exposure from the Novaya Zemblya tests and the incidence of thyroid cancer in Scandanavia has been suggested (Lund et al., 1999).

Nuclear Power Plant Accidents

The Windscale Accident

The Windscale reactor in the United Kingdom was of the air-cooled type with a graphite core and lacked secondary containment. In reactors of this type, the structure of the graphite is gradually distorted by the energy released during normal use, and the energy stored in the structural change (Wigner energy) must be periodically released. That is achieved by controlled heating; but in one particular operation in early October 1957, the process was carried out too rapidly. Excessive energy was released, and some of both the graphite core and the metallic uranium fuel overheated. It was not at first detected, because the heat sensors were in the areas of the expected greatest heat during normal operation, not of the heat that occurred during the release of the Wigner energy. The overheating led to a fire in the graphite core that proved extremely difficult to extinguish; the reactor was eventually flooded with water the day after the fire had been detected. The release of isotopes took place through the plant stack; the filter removed particulate material and the main radioactivity released was about 20,000 Ci of ^{131}I.

Detection of the release led to a ban on the distribution of milk originating in an area of about 200 square miles. This ban was continued for over a month in the most affected areas. The avoidance of contaminated milk, the main route through which radioisotopes of iodine in fallout reach the human thyroid, greatly reduced the risk to the population. The collective thyroid dose to the UK population was estimated to be 2.5×10^4 person-Sv, and one estimate suggested that

this could lead to 260 excess thyroid cancers, of which 13 would be fatal. It is not surprising that no significant increase in thyroid cancer has been observed in the exposed population, the excess cases were predicted to occur at a rate of about 6.5 per year, and the expected natural incidence in the UK was over 600 per year (Crick and Linsley, 1982).

Three Mile Island Accident

On March 28, 1979, a nuclear accident occurred at the Three Mile Island Nuclear Power Station Unit 2, in south-central Pennsylvania. The accident began when the plant experienced a total loss of feed water and a simultaneous tripping (shutting down) of the main turbine (USNRC, 1979, Nuclear Information Bulletin, 1990). Emergency feed water pumps started, as designed, and the reactor continued to operate at full power. Unbeknownst to the operators, valves had been closed so that the emergency feed water pumps could not discharge water from the auxiliary pumping system. When the reactor core cooling system temperature and pressure began to increase the reactor scrammed (control rods were suddenly inserted into the reactor core). Simultaneously, a pilot-operated relief valve (PORV) opened to relieve pressure as the reactor's cooling water rapidly began to heat up. Once the pressure decreased to desired levels, the PORV stayed in the open position. That led to the loss of cooling water in the reactor vessel. Operators failed to recognize that the PORV had stayed open. That and other human errors caused the reactor core to be deprived of necessary cooling water, and an estimated 50% of the reactor core melted down (Langer et al., 1989).

As a result of the meltdown, an estimated 52% of the reactor core inventory of radiocesium and 40% of the radioiodine were released from the core into the reactor building, (FDA, 1979) but no detectable amount of the radiocesium and only a minute proportion (0.00002%) of the radioiodine escaped to the environment. Considerable environmental monitoring followed the accident, and the maximum concentrations of ^{131}I found in milk were 41 pCi/L (1.52 Bq/L) in goat's milk and 36 pCi/L (1.33 Bq/L) in cow's milk (Weidner et al., 1980)—0.003 of the concentrations at which the FDA

would recommend removal of cows from contaminated pastures (FDA, 1978). Cesium-137 in milk after the accident was comparable with that expected in milk from residual fallout from previous nuclear weapons testing.

Within three days after the start of the accident, nearly 250,000 bottles of KI solution were obtained and rushed to the area (tablets were not available). It was decided that there were no indications for its use, and none was distributed to the general public (Kemeny et al., 1979, Scranton WW II, 1980). Megacurie ($>10^{15}$ Bq) quantities of radionuclides were released to the environment as a result of the accident (Kemeny et al., 1979), gamma-ray spectroscopy of collected samples indicated that radioactive noble gases were the only radionuclides detectable. It is estimated that 15 Ci (5.6×10^{11} Bq) of ^{131}I was released. The highest radiation dose recorded offsite was 830 μGy (83 mrad) by thermoluminescent dosimeter reading (FDA, 1979), and the highest estimated dose to one person was 370 μGy (37 mrad) (FDA, 1979), less than half the annual dose from natural background radiation. In a 20-year follow-up study of mortality data on residents living within a 5-mile radius of Three Mile Island, researchers at the University of Pittsburgh's Graduate School of Public Health found no significant increase overall in deaths from cancer (Talbott et al., 2000).

Chornobyl

Most of our understanding of the consequences of exposure of a population to radioiodine in fallout comes from studies of the population in Belarus, northern Ukraine, and part of the Russian Federation exposed after the Chornobyl accident, in which large quantities of radioiodine were released and a large population was exposed.[1] The incident, which occurred on April 26, 1986, resulted from a combination of an inappropriate experiment and human error

[1] No adequate distribution of stable iodide in the exposed areas was carried out. Some stable iodide was distributed, but it was taken by only a minority of the population and often so long after the start of exposure that it would have had little effect on uptake (UNSCEAR 2000).

and led to the release of about 8 x 10^{18} Bq of radioisotopes (UNSCEAR, 2000). The experiment involved a test at NPP unit 4 at Chornobyl to determine how long turbines would spin and supply power after a loss of main electrical power supply. When the control rods were inserted to reduce the reactor's power level, there was an initial drop to considerably below the desired power level. To compensate, the operators removed some control rods. That led to a sudden surge in the power level that the operators tried to compensate for by inserting control rods. The result was an erratic distribution of power throughout the reactor core. Damaged water lines in the bottom portion of the reactor, coupled with fuel damage, allowed escaping water to interact with hot fuel and flash to steam. That resulted in an explosion equivalent to that of 30-40 tons of TNT that destroyed the reactor building, which lacked secondary containment. Fires erupted, including fire in the graphite moderator in the reactor core. The result was that about 4% of the nuclear material in the core, particularly the volatile isotopes, was released to the environment.

The largest component released was Xenon-133, an inert gas, which did not form part of fallout. Iodine isotopes formed the second largest component and included ^{131}I, the most important, with a half-life of 8 days (about 1.8 x 10^{18} Bq); ^{133}I, with a very short half-life and therefore important only in the immediate vicinity of the reactor; and Tellurium-132, which decays to ^{132}I, another isotope with a short half-life. The iodine released to the environment amounted to about 50% of that present in the reactor, compared with the 0.00002% released after the Three Mile Island accident. The amount of activity of the iodine isotopes released was much greater than that of other isotopes that contributed to fallout, such as two cesium isotopes. Because of their short half-lives (up to 8 days with one minor exception), the iodine isotopes disappear rapidly from the environment and do not pose a long-term threat. The two cesium isotopes (^{134}Cs and ^{137}Cs), although present in much lower activity, have longer half-lives (2.1 and 30 years, respectively), are not concentrated or retained in any specific tissue and therefore pose a different problem.

The plume from Chornobyl reached as high as 6 miles and led to the dispersal of radioactive material over portions of Ukraine,

Belarus, and Russia. The reactor accident was first detected in Western Europe when it triggered alarms at nuclear power stations in Finland and Sweden. The initial wind direction blew the radioactive cloud to the Northwest, so the earliest and the heaviest fallout affected the population along this route. Weather changes led to a more varied distribution, and some radioactivity from Chornobyl could be detected throughout the Northern Hemisphere. By far the largest exposure to fallout, mainly iodine isotopes, occurred in the southern regions of Belarus (Gomel province) and immediately around the reactor in northern Ukraine and the neighboring provinces. The population of Pripyat, the town closest to the reactor, was evacuated about 2 days later, and the population of all the villages within 30 km of the site was evacuated later than that; return is still forbidden because of the ground contamination, mostly with cesium. In all, about 30,000 Km^2 was contaminated to more than 185 kBq/m^2, and this led to the evacuation of some 116,000 people. In the years after the accident, an additional 210,000 people were resettled into less-contaminated areas, and the initial 30 km radius exclusion zone (2,800 km^2) was modified and extended to a 37-km-radius exclusion zone (4,300 km^2).

Retrospective dose-reconstruction studies (Vargo et al., 2000) indicated that in the city of Pripyat, 40-60% of children up to 3 years old, 20% of children 4-7 years old, and less than 4% of adults had thyroid doses of 2 Gy (200 rad) or higher.

Estimates of thyroid doses for residents of various locations in Belarus were made for three age groups (0-6 years, 7-17 years, and adults) (Gavrilin et al., 1999). There were over 250,000 thyroid doses; the arithmetic means were 0.08-4.7 Gy (8-470 rad) in the 0- to 6-year group, 0.029-2.1 Gy (2.9-210 rad) in the 7- to 17-year group, and 0.018-1.6 Gy (1.8-160 rad) in adults. In Kiev, where the radioiodine contamination was lower, the estimated individual thyroid doses for five age groups were assessed; these range from 104 mGy (10.4 rad) for those born in 1983-1986 to 14 mGy (1.4 rad) for those born before 1971. The collective thyroid doses were estimated as 83×10^3 person-Gy for those born before 1971 and 38×10^3 person-Gy for younger people.

In the west of Poland, bordering Belarus, it has been estimated (Pietrzak-Flis, et al., 2003) that in the absence of countermeasures, the

highest thyroid doses from inhalation and ingestion of ^{131}I would have been 178 mGy (17.8 rad) in 5-year-olds, 120 mGy (12 rad) in 10-year-olds, and 45 mGy(4.5 rad) in adults. The countermeasures, including administration of stable iodine to children and teenagers, reduced those doses by about 30%.

About 150 of the personnel involved at the reactor in the immediate aftermath of the accident were exposed to large amounts of whole-body radiation from fuel elements; 32 of them have died from acute radiation sickness (UNSCEAR, 2000). The stress of known or suspected radiation exposure, lack of information, concern for children, and the forced evacuation also had considerable health consequences. Apart from those related to stress, the first indication of health problems in the population exposed to fallout came 4 years after the accident with reports from hospitals in Minsk, the capital of Belarus, and Kiev, the capital of Ukraine, of an increase in the numbers of children with thyroid carcinomas. Reports of the increase and its validation were published in 1992 (Kazakov et al., 1992, Baverstock et al., 1992). The increase continued. Thyroid carcinoma in children is extremely rare, affecting perhaps one in a million children. The reported incidence varies somewhat among countries; it is usually 0.5–3 per million per year; but some registries report up to six per million per year. The incidence in Belarus as a whole after the Chornobyl accident rose to about 30 per million per year, and in the Gomel region it rose to about 90 per million per year in the years after the initial reports. By the year 2000, about 2,000 cases of thyroid cancer attributed to exposure to fallout from Chornobyl had been reported in Belarus, northern Ukraine, and the adjacent parts of the Russian Federation that also received high levels of fallout. Details of the distribution of fallout and numbers of cases and a discussion of risk in relation to dose received can be found in a United Nations Scientific Committee on Effects of Atomic Radiation report (UNSCEAR, 2000), and a recent review discusses the pathology, molecular biology, and age-related sensitivity (Williams, 2002). Cases are still occurring, and the full consequences will not be known for decades.

One observation that is central to the understanding of the consequences of exposure to iodine isotopes in Chornobyl fallout

concerns age-related sensitivity of the thyroid to carcinogenesis. Early studies showed that the age of incidence of thyroid carcinoma in exposed children was changing: the peak age of exposed children diagnosed with thyroid carcinoma in 1992 was about 7 years, but the peak age of children diagnosed in 1994 was about 9 years. It soon became apparent that the difference was due to a rapid decrease in the risk of developing thyroid cancer with age at the time of exposure to radioiodine; children who were youngest at exposure were carrying an increased risk that continued as they aged (Williams, 1996). Children who were newborn at the time of Chornobyl are now 17 years old, and the exposed population continues to show an increased risk of developing new cases of thyroid cancer.

Calculations suggest that the relative risk in children 0-1 year old at exposure to the Chornobyl fallout is 40 or more times that of children 10 years old or older at exposure (Cardis et al., 1999), but this ratio may change with study over a longer period. It appears that the risk in those exposed as adults is extremely small. The thyroid gland of the fetus begins to concentrate iodine at about the 3-month stage of pregnancy; those who were in utero at the time of the accident show an increase in thyroid cancer, but much less than those who were newborn. Those who were born more than 6 months after the accident show no increase in thyroid cancer; because of the short half-life of the iodine isotopes they would not have had appreciable exposure.

Three factors contribute to the high sensitivity of very young children to the risk of thyroid cancer after exposure to iodine isotopes: a high intake of isotopes mainly through milk, the high uptake of radioiodine by the infant thyroid, and increased biologic sensitivity. The intake of milk is important as an exposure pathway because in the absence of precautions it is the main route through which radioiodine reaches individuals. Grazing animals collect fallout from a considerable area of ground, and iodine, including radioactive iodine, is concentrated in milk. Other foods, such as green vegetables, may also be contaminated. If a nursing mother consumes contaminated food, in particular milk from cows or goats exposed to fallout, she will pass the radioactivity on to her child through breast-feeding. The relatively high breathing rate of children will increase the amount of

radioiodine absorbed through inhalation, although this is only a small proportion of the total. The radiation dose to the infant thyroid is therefore higher than that to older children or adults because infants take in relatively more iodine radioisotopes, have a smaller thyroid gland, and have a higher uptake by the thyroid, leading to a thyroid dose estimated to be up to 5 times that of adults (IAEA, 1991). Infants are also more sensitive to the risk of carcinogenesis, probably because of the way the thyroid develops—growing rapidly during the early years of life but hardly at all during adult life. Although thyroid cancer has been the main thyroid consequence of exposure to fallout from Chornobyl, benign thyroid tumors also appear to be increasing in frequency; this is similar to the findings after exposure to x rays (Shore et al., 1993).

The long-term incidence of hypothyroidism in those exposed to fallout from Chornobyl is not known. One study reported higher levels of thyroid-stimulating hormone in children from the more heavily exposed areas than in those from the less exposed areas (Yamashita et al., 2002); this suggests that some degree of thyroid damage occurred. An alternative explanation could be iodine deficiency, but the main exposed areas do not appear to have more iodine deficiency than the rest. Juvenile hypothyroidism was found in about 0.1% of a large population of children exposed to fallout from Chornobyl; the evidence that it was exposure-related depended on correlation with the body burden of ^{137}Cs (Goldsmith et al., 1999). Radiation may also lead to an increase in circulating antibodies to the thyroid; this has been demonstrated to occur after treatment of thyrotoxicosis with high doses of radioactive iodine. The same study also examined circulating thyroid antibodies in more and less exposed areas and found no correlation. A separate study compared circulating thyroid antibodies in villages with different levels of fallout exposure and concluded that there was a relationship between radiation exposure and the development of autoimmune disease of the thyroid (Yamashita et al., 2002). The clinical significance of those observations is uncertain but is likely to be small.

No adequate studies have been published of possible effects of exposure to fallout from Chornobyl on the incidence of diseases of the breast, salivary glands, or stomach, which concentrate radioiodine to

some degree but do not store it. It is the combination of concentration and storage that leads to a thyroid dose around 1,000 times higher than the average body dose after administration of radioactive iodine. Tissues that can concentrate but not store iodine would receive doses much lower than the thyroid. As yet unconfirmed reports suggest that there has been no great increase in tumors of those tissues.

Further studies are needed to clarify this issue and to determine whether particular susceptibility groups, such as lactating mothers, are at higher risk of breast cancer than the general population.

Another subject that needs more study is the possibility that exposure to fallout can lead to inherited DNA damage. In theory, that is less likely to occur after exposure to isotopes that concentrate little or not at all in the gonads than after whole-body exposure to external radiation, but sensitive tests have shown minisatellite instability in nonexposed children born to parents who were exposed to Chornobyl fallout (Dubrova et al., 2002). The instability involves the insertion or deletion of one or two base pairs in simple repeat sequences in DNA that have no known function. The likelihood that that instability will be translated into identifiable health effects is not clear, but the observation is important, and long-term studies are needed. It should be noted that no similar effects were found in studies of those exposed to external radiation from the atomic bombs (Kodaira et al., 1995).

An accurate estimate of the overall effect of the Chornobyl accident on the incidence of thyroid disease can be made only when all those alive at the time have died. However, the number of cases of thyroid tumors that have occurred so far in those exposed as children or adolescents to fallout from the Chornobyl accident in Belarus, northern Ukraine, and the adjacent parts of Russia can be used to predict the total consequences of the accident. Because no previous accident is comparable with Chornobyl, such estimates are necessarily imprecise.

The type of thyroid cancer that has occurred usually carries a good prognosis. The deaths so far due to thyroid cancer in the exposed children in Belarus are still in single figures, but this is a slowly growing tumor, and death can occur decades after diagnosis.

The number of benign thyroid tumors is more difficult to assess; they are less closely monitored than malignant tumors, and studies after exposure to external radiation suggest that benign tumors have a longer latent period than malignant tumors. Although benign tumors do not directly cause death, they require investigation and operation to exclude cancer or the possibility of progression to cancer. While accurate predictions are not possible, it can be speculated that the deaths from Chornobyl related thyroid cancer will probably be in the hundreds, the number of cases of thyroid cancer in the thousands, and the number of people requiring thyroid operations in the tens of thousands.

Relevance of Fallout Exposure to Stable Iodine Prophylaxis

One of the most important findings in the studies of the largest exposure to have occurred is the greatly increased sensitivity of the youngest children to thyroid carcinogenesis after exposure to radioactive iodine in fallout. Thyroid cancer has also been shown to occur after external radiation from x-rays used in treatment of nonthyroid diseases, and both here and in atomic-bomb follow-up studies it has also been shown that young children are more likely than older children to develop carcinoma (Ron et al., 1995). For external radiation such as x-rays not involving isotopes, uptake and concentration of iodine are irrelevant.

The risk of thyroid carcinogenesis in adults from radiation exposure is absent or extremely low (Ron et al., 1995), although some studies have suggested that high-dose external radiation in a patient with an existing thyroid tumor may lead to development of a more serious lesion (Getaz and Shimoaka, 1979). Studies carried out on adult patients given small doses of radioiodine for investigation of thyroid problems or larger doses for treatment of thyroid hyperfunction have shown no subsequent increase in thyroid cancer later.

A pooled analysis of seven studies of thyroid cancer after exposure to external radiation, found an excess relative risk per Gy of 7.7 for children under 15, with little risk apparent after the age of 20

(Ron et al., 1995). The youngest children were the most susceptible, with an excess relative risk (ERR) of 9.0 for those 0-4 years old at exposure, 5.2 for those 5-9 years old, and 2.4 for those 10-14 years old.[2] A study of A-bomb survivors (included in the pooled analysis) found no significant excess of thyroid cancers in those over 20 at exposure (Thompson et al., 1994). The increased risk in younger children after exposure to external radiation shows that a biologic mechanism is involved, probably related to the kinetics of growth of the gland (Williams, 1999). The risk is magnified after exposure to radioiodine isotopes in fallout by the greater intake of iodine (especially from milk) and the greater uptake by the thyroid. The relevance when one is considering KI prophylaxis is that the youngest children are the most vulnerable group and must be given the highest priority for KI administration in any situation where exposure to radioiodine cannot be avoided. It is also especially important to avoid ingestion of contaminated milk and other foodstuffs in this group. Because iodine, including radioactive iodine, is concentrated in breast milk, lactating mothers must take every precaution to reduce exposure (see Chapter 2). The great drop in sensitivity to thyroid carcinogenesis with increasing age suggests that iodine prophylaxis in adults is of little value.

Although the qualitative results after Chornobyl are valuable, the quantitative results cannot be transposed to the United States situation without many caveats.

First, the risk of an accident involving a large release of radioactive iodine is greatly influenced by the reactor design. The type of reactor in the four units at Chornobyl contained a number of design flaws particularly the lack of secondary containment (Vargo et al., 2000), as described in Chapters 3 and 4.

Second, even if an event in the United States did involve large-scale releases, it could not be concealed from the population in the way it was after the Chornobyl accident. After Chornobyl, the population at risk was not informed of the nature of the accident, or of the precautions that should be taken, until long after the precautions would have been effective. Milk with a high radioiodine content

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[2] Data from Elaine Ron.

continued to be used, as did contaminated food; the population was not told to take shelter; stable iodine was not immediately distributed or used; and even limited evacuation was not started until about 36 hours after the accident. If contaminated milk and food had been avoided, most of the resulting thyroid cancers would almost certainly have not occurred. If KI had been effectively distributed within the appropriate time, the numbers of resulting thyroid cancers would have been even more greatly reduced.

Third, the concentration of stable iodine intake in the diet is probably relevant. In experimental studies, fewer tumors develop when radioiodine is administered to animals that have a high iodine intake than in animals that have a low-iodine diet. The population around Chornobyl had a low iodine intake; in the United States, dietary stable iodine is 3-5 times higher than in much of the area around Chornobyl. The greater dietary iodine is associated with a smaller thyroid gland and also with a lower uptake of radioiodine than in areas that have iodine deficiency. The population around Chornobyl would therefore be predicted to take up more radioiodine into their thyroids than a US population exposed to similar levels of contamination.

The evidence derived from studies of the effects of internal irradiation of the thyroid for medical reasons, of external radiation from the atomic bombs, and of internal radiation from iodine isotopes after Chornobyl shows that the group most susceptible to the development of thyroid cancer is young children and that the risk falls rapidly with increasing age at exposure. The studies also suggest that there was no appreciable risk of thyroid cancer in those who were adults at the time of exposure to radiation from radioiodine, although reliable information on the risk to those who were adults at the time of exposure to fallout from Chornobyl is not available, and future work in this area is needed. Studies from external radiation show no significant risk above the age of 20 years (Thompson et al., 1994), although there might be a very small risk between the ages of 20 and 30 years. A number of countries and the World Health Organization have adopted a precautionary approach, stating that 40 years is the age above which there is no risk that thyroid cancer will occur as a result of radiation to the thyroid and that therefore there is no

requirement for this group to take stable iodine to prevent the development of cancer after exposure to radioiodine.

It is logical to use the risk to the most vulnerable group, young children, as the basis for deciding whether to use stable iodide to avert the risk of thyroid cancer after exposure to radioiodine.

Evidence on the quantitative risk of thyroid cancer after thyroid exposure to external and internal radiation is available. For external radiation, the lifetime risk estimates are derived from observations over much of the lifetime of those who were children at the time of the atomic bomb, or were irradiated for medical reasons as children in the 1930s and later. The lifetime risk posed by exposure to iodine isotopes from Chornobyl fallout is based on the experience of less than 17 years since the accident and on dose estimates that are less certain than those for external radiation. Experimental studies suggest that external radiation is 1-3 times as effective as radiation from ^{131}I in inducing thyroid tumors (Lee et al., 1982). We therefore use the data from external radiation to estimate the relationship between thyroid radiation dose from iodine isotopes and risk of thyroid cancer, knowing that the actual risk is likely to be lower than the predicted risk. At very low doses of radiation, it is not certain that the direct relationship between thyroid-cancer induction and dose continues. Some predictions suggest that radiation is proportionally less effective in inducing tumors at very low doses. We have assumed that the straight-line relationship continues and that radiation from ^{131}I is equally effective as external radiation in inducing thyroid cancer.

The best available data are based on a pooled analysis of seven studies of the development of thyroid cancer after exposure to radiation (Ron et al., 1995). Data derived from the study show that for children under 5 years old at exposure the excess relative risk (ERR) per gray was 9.0; that is, those exposed to 1 Gy (100 rad) of radiation before the age of 5 years would develop up to 9 times as many extra cases of thyroid cancer during their lifetime as they would have developed without such exposure. The ERR per Gy for children 5-9 years old at exposure was 5.2, and for children 10-14 years old at exposure 1.7.[3] On the basis of the lifetime risk of developing thyroid

[3] Data from Elaine Ron.

cancer in the United States and the lifetime risk of dying from thyroid cancer (SEER Cancer Statistics Review 1975-2000, National Cancer Institute) and a linear relationship between dose and risk, the chance of developing thyroid cancer in those exposed to different doses of radiation as children can be calculated. Evidence on the risk to the unborn from maternal exposure to radioiodine after Chornobyl suggests that it is considerably less than the risk to very young children. We believe that the risk to the most vulnerable group (children under 5 years old) should be the basis for determining precautionary measures.

The predicted radiation dose to the thyroid for each of the age groups can be calculated for a variety of accident scenarios. We will base the risk on the so-called design-base accident (DBA), which is the most severe accident that has more than an extremely remote chance of occurring. It is assumed, for example, that there is a complete failure of secondary containment with a large-scale rupture of fuel rods and loss of various control mechanisms. The dose used to estimate the risk is the averted dose, that is, the dose derived from inhalation. The potential dose from ingestion will be avoided through measures that take contaminated milk and other foodstuffs out of the food chain immediately after a major accident occurs. The averted dose would in practice be reduced or abolished by evacuation or sheltering. We have assumed that neither sheltering nor evacuation take place and that no stable iodine is taken, again, to avoid underestimating the risk.

With those assumptions, the estimates that already exist for emissions in the event of a DBA and the estimated dose to the population exposed because of these emissions can be used to calculate the risk of thyroid carcinoma in the most vulnerable group. The results can be presented as idealized contours; in practice, the plume from any accident is likely to be concentrated in one direction, so risk in that direction will extend beyond the idealized contour, and risk in other directions will be much lower. The plan for each NPP will differ, depending on the design and capacity of the reactor and on the prevailing weather patterns. The information given here can be used to determine the risk contours for each NPP; taken together with other local variables such as population density and distribution, these

provide the basis for determining the extent and method of distribution of KI.

In summary, a review of experience with thyroid cancer in populations exposed to the consequences of nuclear events shows that:

- Exposure to external radiation or internal radiation from radioactive iodine is linked to a dose-dependent increase in thyroid-cancer incidence.
- Young children are by far the most sensitive to the carcinogenic effect of radiation on the thyroid, especially after exposure to radioactive iodine in fallout.
- The risk of thyroid carcinoma in adults exposed to radioactive iodine in fallout is very low, and can be assumed to be absent for adults over 40 years old although at very high doses there is a risk of hypothyroidism.
- The probability of a large release of radioactive iodine from the type of reactor used in the United States is much lower than the chance of a large release in countries that use reactors of the type used at Chornobyl. Therefore, the risk of thyroid carcinoma in the US population in the event of a nuclear accident is likely to be considerably less than the risk after Chornobyl both because of the level of dietary iodine and because of the use of precautionary measures.

5

PROTECTIVE MEASURES

This chapter describes accident classifications and the sequences of events for responding to an incident at a commercial nuclear power reactor. The roles of local, state, and federal agencies are detailed; they are influenced by the severity of the incident. Detailed plans are in place in the communities near commercial nuclear power reactors that address incidents that proceed from a notification of unusual event all the way through a general emergency. Sheltering, evacuation, food interdiction, and so on are reviewed, in addition to postincident response measures. For cases when administration of KI is required, details are provided regarding its appropriate preparation. The chapter also discusses concerns about the various pharmaceutical issues surrounding KI, such as ease of use, dosage forms for children and infants, stability of KI, and non-FDA-approved formulations.

In the United States, public health and safety are state responsibilities. However, states generally have delegated some

authority to respond to incidents to local public officials and local responders. Local responders are generally the first to arrive at the scene of an accident or incident and have the best knowledge of local conditions that might affect response decisions. If the situation overwhelms the response capability of local responders, state and then federal resources may be called on to assist. In general, incidents that overwhelm local resources affect large geographic areas or large populations.

States have developed response plans to guide them through the decision-making process in connection with an incident to mitigate the consequences of large events. The emergency-preparedness plans include predetermined actions related to credible scenarios that enable quick responses to ensure public safety with limited initial information. Emergency-response plans take into consideration such items as general types of incidents, general traffic conditions, location of different types of fixed facilities, predominant weather for different times of year, population densities, available state and local resources, prearranged contracts for services with private industries, and other relevant observations. Planning allows for quick decision-making in the face of sparse information to ensure public health and safety.

Emergency preparedness for NPP incidents is a cooperative effort involving the NPP facility, local government, county government, state government, and the federal government. Since the emergency-preparedness plans must be capable of initially addressing several possible incidents, they must be based on simple and consistent assessment methodologies, and the agencies involved must be capable of implementing their assigned actions. To ensure that plans developed on the local, county, and state level will protect public health and safety, the US Nuclear Regulatory Commission and the Federal Emergency Management Agency (FEMA) evaluate emergency preparedness at and around NPPs. Evaluation takes place regularly to ensure that adequate protective measures will be taken in the event of a NPP incident.

Accident Classifications

The US Nuclear Regulatory Commission has developed four action levels to address how agencies should respond to NPPs incidents that could lead to serious consequences. The actions taken by state and local agencies in response to a notification of an incident are graduated from a notification to be aware of a situation to full emergency response actions. This graduated response ensures that emergency response preparations can be taken in advance of a severe accident if a minor situation worsens. The four accident classifications are: Notification of Unusual Event, Alert, Site Area Emergency, and General Emergency, and are described below.

Notification of Unusual Event

This classification is used to describe events that indicate a potential degradation of safety at a NPP. Offsite response or monitoring is not expected unless further degradation of safety systems occurs. Its purpose is to assure that the first steps in response preparations have been carried out and to bring state and local response organizations to a state of readiness. During this classification authorities provide fire or security assistance as requested and standby for additional information.

Alert

Events are in process or have occurred that indicate an actual or potential substantial degradation of safety at a plant. Any release of radioactive material is expected to be limited to small fractions of the EPA Protective Action Guideline (PAG) Exposure Levels. It assures that emergency personnel are readily available to respond if the situation becomes more serious or to perform confirmatory radiation monitoring if required and provide state and local authorities current status information. In addition to the assistance requested for an unusual event, authorities augment emergency response resources, provide confirmatory offsite radiation monitoring or ingestion

pathway dose projections as appropriate, and standby for additional information.

Site Area Emergency

During this emergency classification events are in process or have occurred that involve actual or likely major failure of plant functions needed for protection of the public. Radioactive material releases are not expected to exceed EPA Protective Action Guideline Exposure Levels except near the site boundary. It assures that state and local authorities have manned emergency operation centers, dispatched monitoring teams, activated personnel required for evacuation, placed reception centers on standby, and are capable of providing the public with updates of the situation. In addition to the activities taken at an Alert, authorities activate public notification systems as appropriate, provide the public with periodic updates on emergency status, dispatch emergency response personnel to near-site duty stations, provide offsite monitoring results to the licensee and other government agencies to jointly assess findings, consider placing milk producing animals within the EPZ on stored feed, and standby for additional information.

General Emergency

This is the most serious emergency classification. Events are in process or have occurred that involve actual or imminent substantial reactor core degradation with a potential loss of containment integrity resulting in a need for protection of the public. Radioactive material releases are expected to exceed EPA Protective Action Guideline exposure levels. It assures that state and local authorities initiate predetermined protective actions, continuously assess information from a nuclear power plant and offsite measurements, and are capable of providing the public with updates of the situation. In addition to the activities taken at a Site Area Emergency, authorities activate the emergency alert systems to immediately notify the public of the emergency status, implement Protective Action Recommendations, continuously assess information

from the licensee and offsite monitoring with regard to changes to protective actions already initiated for the public, mobilize evacuation resources, activate reception centers, and maintain general emergency status until closeout or reduction of emergency class.

Emergency Workers

Radiological Emergency Response Plans (RERP) must address not only public health and safety, but also the health and safety of offsite emergency workers, those who are not employees or contractors directly associated with the NPP. The federal government cannot specify the protective policies that must be in place for this population, but the certification process for facilities requires that an acceptable plan be in place.

Emergency workers who might be exposed to radiation while performing assigned duties include law-enforcement officers, firefighters, emergency medical personnel, and other responders performing activities in areas with increased radiation fields. While the overall objective is to minimize individuals' radiation exposure to the maximum extent possible, protective actions for the public and dose limits for emergency workers are based on different assumptions. Protective actions for the public compare the risks to people posed by radiation exposure with the risks associated with specific protective actions to minimize the total risk. Emergency workers, however, are allowed to receive a certain level of radiation exposure to protect the public and property. The planning assumption for emergency workers compares the risk posed by radiation exposure with the overall benefits to society associated with specific activities (USEPA, 1992).

Existing emergency preparedness plans for NPP incidents address the use of KI by emergency workers. Emergency workers are authorized to receive radiation exposure exceeding the dose limits for the general public during an incident to protect the public and property, and they accept the risk associated with it. Because there may be a need for extended activity by emergency workers in a radiation field that could result in exposure to various radionuclides in various concentrations, minimizing exposure to even a single

radionuclide is beneficial. Therefore, existing plans already provide guidance on the administration of KI to emergency workers to reduce their risk associated with radioactive iodine. On the other hand, guidance for the administration of KI to the general public is still under development in many states (see Chapter 6). Traditionally, KI for emergency workers has been distributed in packages that provide a daily dosage for a 2-week period. This continued dosage of KI would not be appropriate for the general public. As will be described later in this chapter, protective action for the public minimizes the total risk from all sources. The general public should be given KI only if this action is expected to result in a minimization of the total risk.

Strategies for the General Public

Radiological Emergency Response Plans for NPP incidents are designed to simplify the decision-making process for local responsible authorities, to avoid radiation exposure and perform lifesaving activities. The plans must be specific enough to provide a sound basis on which to respond to incidents without unnecessarily depleting available resources. They must be general enough to be applicable to a variety of situations so that only workable and useful actions are considered during an emergency. Accordingly, emergency-response plans address the consequences of an incident, both in nature and in degree, but not its cause. That allows the development of specific actions that can be taken by response organizations during the decision-making process for an unknown future event, based on what is known at each site about the potential consequences, local conditions, and release characteristics of the spectrum of accidents.

Phases of Emergency Response

Response plans are bound by the timing of response actions to incident consequences and play a significant role when resources are

deployed. In general, all nuclear power plant incidents follow a common sequence of events characterized as the early, intermediate, and late phases. The *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents, Report No. 400-R-92-001, U.S. Environmental Protection Agency, 1992* published by the US Environmental Protection Agency, describes each phase as follows:

> "*The early phase* (also referred to as the emergency phase or plume phase) is the period at the beginning of a nuclear incident when immediate decisions for effective use of protective actions are required and must therefore usually be based primarily on the status of the nuclear facility and the prognosis for worsening conditions. This phase may last from hours to days."
> "*The intermediate phase* (also referred to as the ingestion phase) is the period beginning after the source and releases have been brought under control and reliable environmental measurements are available for use as decisions on additional protective actions. This phase may overlap the early and late phase and may last from weeks to many months."
> "*The late phase* (also referred to as the recovery phase) is the period beginning when recovery action designed to reduce radiation levels in the environment to acceptable levels for unrestricted use is commenced, and ending when all recovery actions have been completed. This phase may extend from months to years." (USEPA, 1992).

In the United States, the Nuclear Regulatory Commission and FEMA use NUREG 0654, *Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Plants,* to evaluate state and local emergency response plans.

Early Phase Planning

NUREG 0654 contains the guidance used by the federal government to evaluate emergency-response plans developed by state and local governments. The predominant route of exposure that a planning agency must consider in developing a radiological emergency response plan for the early phase is from the emitted plume, i.e. plume-exposure pathway. NUREG 0654 states:

> "Plume exposure pathway—The principal exposure sources from this pathway are: 1) whole body external exposure to gamma radiation from the plume and from deposited material; and 2) inhalation exposure from the passing radioactive plume. The duration of the release leading to potential exposure could range from one-hour to days." (USNRC, 1980).

Limits on the available resources dictate that the size of the planning area, i.e. emergency planning zone (EPZ), needs to be considered. The EPZ is determined by the actions needed for emergency response, the source term for the radiation, the time required to respond, and the consequences of a credible event. The *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents Report No. 400-R-92-001, U.S. Environmental Protection Agency, 1992* discusses guidance on the relationship between the acceptable level of radiation to which the general public can be exposed and recommended actions to be taken. The Nuclear Regulatory Commission has determined the size of an early phase or plume phase EPZ (USNRC, 1980). NUREG 0654 states:

> "The size (about 10 miles radius) of the plume exposure EPZ was based primarily on the following considerations:

a) projected doses from the traditional design basis accident would not exceed Protective Action Guide levels outside the zone;
b) projected doses from most core melt sequences would not exceed Protective Action Guide levels outside the zone;
c) for the worst core melt sequences, immediate life threatening doses would generally not occur outside the zone;
d) detailed planning within 10 miles would provide a substantial base for expansion of response efforts in the event that this proved necessary."

"…the plume exposure EPZ is of sufficient size for actions within this zone to provide for substantial reduction in early severe health effects (injuries or deaths) in the event of a worst-case core melt accident."

The EPZ is established to provide a basis for planning. This includes details on how to advise the population on protective actions, routes for evacuation, and where to evacuate outside the EPZ (reception centers). A specific incident might call for protective actions to be restricted to a small part of the EPZ or require that they be implemented beyond the EPZ as well.

Decision-making during the early phase is difficult. Information about environmental conditions resulting from an incident is generally not available, because there is an inevitable delay in the initiation of a release of radioactive material and plume arrival at a point of interest. The need to make early decisions to protect the public requires that decision-making criteria be identified well in advance. This simplifies the decision making process to ensure that timely measures are taken to protect the public. Accordingly, during the early phase, protective action decisions are based on the status of the NPP and on the prognosis for a worsening of conditions (USEPA, 1992).

Because plant conditions are the basis for decision-making, it is likely that evacuation (or sheltering) will begin before a significant radiologic release requiring an offsite response starts. If there is a release, it may not contain radioactive iodine. If evacuation is completed prior to exposure to radioactive iodine or if radioactive iodine is not a component of the plume, there is no need to administer KI.

The presence of radioactive iodine in a plume is usually indicated on plant monitors. With this information and using dose modeling techniques, decision-makers can estimate the radiation dose to the thyroid and take steps to initiate administration of KI in accordance with FDA recommendations about dosages. The public will be advised to take KI through the Emergency Alert System when the projected radiation dose to the thyroid is greater than predetermined PAG. This PAG should be set at a projected radiation dose to the thyroid of 50 mSv (5 rem) for the most vulnerable populations: infants, children, adults under age 40 and pregnant or lactating women of any age. KI should be given only when an exposure or potential exposure to radioactive iodine is suspected. Once a protective action eliminates exposure to radioactive iodine, KI does not provide any benefit. Continued dosing with KI only increases the total risk of rare side effects or adverse effects and therefore dosing should be stopped as soon as exposure is terminated.

Table 5.1 provides a combination of the existing Protective Action Guides (PAG) recommended for evacuation or sheltering for the early phase provided in the *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents Report No. 400-R-92-001, U.S. Environmental Protection Agency, 1992* combined with the new FDA guidance for administration of KI to the public published in 2001.

Table 5.1 Protective Action Guides for Early Phase of a Nuclear Incident

Protective Action	Protective Action Guide (projected dose)		Comments
Evacuation (or sheltering[a])	1-5 rem Total Effective Dose Equivalent (TEDE)		Evacuation (or, for some situations, sheltering[a]) should normally be initiated at 1 rem. Further Guidance is provided in EPA 400.
Administration of stable iodine	Adults over 40 yrs	>500 rem[b]	Requires approval by a medical official as determined by individual state law.
	Adults over 18 through 40 years	>10 rem[b]	
	Birth through 18 yrs Pregnant or lactating women	>5 rem[b]	

[a]Sheltering may be the preferred protective action when it will provide protection equal to or greater than evacuation, based on consideration of factors such as source term characteristics, temporal or other site-specific conditions (See USEPA, 1992).

[b]Committed Dose Equivalent (CDE) to the thyroid from radioiodine (USEPA, 1992, FDA, 2001a).

Intermediate Phase Planning

The predominant exposure to radiation during the intermediate phase changes from plume exposure to internal exposure, i.e. via the ingestion exposure pathway. Though the principal radiation exposure changes, emergency actions will continue to monitor external exposure to radiation.

> "Ingestion exposure pathway—The principal exposure from this pathway would be from ingestion of contaminated water or food such as milk, fresh vegetables or aquatic foodstuffs. The duration of potential exposure could range in length from hours to months. For the ingestion exposure pathway, the planning effort involves the identification of major exposure pathways from contaminated food and water and the associated control and interdiction points and methods. The ingestion pathway exposures in general would represent a longer term problem, although some early protective actions to minimize subsequent contamination of milk or other supplies should be initiated e.g. remove cows from pasture and put them on stored feed." (USNRC, 1980).

Limits on the available resources require that the size of this EPZ must be considered as well. The size of the ingestion EPZ is determined by the same basic factors used to determine the plume phase EPZ—namely, the actions needed for emergency response, the source term for the radiation, the time required to respond, and the consequences of credible events. The primary focus is on preventing ingestion of radioactive material. The *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents Report No. 400-R-92-001, U.S. Environmental Protection Agency, 1992* and *Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies, U.S.*

Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 1998 (FDA, 1998) provide guidance on the relationship between the acceptable level of radiation exposures of the general public and recommended actions that should be taken by public officials and emergency responders. The planning effort for this phase ensures that effective actions can be taken to protect the public from the ingestion of radioactive material in the event of an accident. The Nuclear Regulatory Commission (USNRC, 1980) determined the appropriate size of an intermediate phase EPZ as follows:

> "The size of the ingestion exposure EPZ (about 50 miles in radius, which also includes the 10-mile radius plume exposure EPZ) was selected because:
>
> a) the downwind range within which contamination will generally not exceed the Protective Action Guides is limited to about 50 miles from a power plant because of wind shifts during the release and travel periods;
> b) there may be conversion of atmospheric iodines (i.e. iodine suspended in the atmosphere for long time periods) to chemical forms which do not readily enter the ingestion pathway;
> c) much of any particulate material in the radioactive plume would have been deposited on the ground within about 50 miles from the facility; and
> d) the likelihood of exceeding ingestion pathway protective action guide levels at 50 miles is comparable to the likelihood of exceeding plume exposure pathway protective action guide levels at 10 miles".

It must be remembered that like the plume phase EPZ, the ingestion phase EPZ is established to provide a planning basis. A

specific incident might call for protective actions to be restricted to a small part of the ingestion phase EPZ or require that they be implemented beyond the ingestion phase EPZ as well.

Decision-making during the intermediate phase is not as difficult as that during the early phase. Environmental information is generally available because the release is terminated and plume deposition has occurred, allowing evaluation by emergency-response teams. Protective actions during the intermediate phase include not only protection against the ingestion of radioactive material but also protection against external exposure due to ionizing radiation from plume deposition. Protective actions are taken to ensure that (USEPA, 1992) (see Table 5.2):

1) Dose in the first year does not exceed 20 mSv (2 rem);
2) Dose in any single year after the first will not exceed 5 mSv (0.5 rem);
3) The cumulative dose over 50 years (including the first and second years) will not exceed 50 mSv (5 rem).

Relocation of some people may take place during this phase to limit the general public's long-term exposure to radiation as additional contaminated areas are identified. As areas are verified as not being contaminated, people who have been relocated may be allowed to return to them.

Exposure to radioactive iodine is possible through the ingestion pathway, so it is important that plans address this situation. Monitoring of the environment and food products controls this route of exposure. Removing contaminated products from the market and isolating contaminated products until the radioactive iodine decays to safe levels are the most effective way to eliminate radiation exposure and damage to the thyroid. That also eliminates the need for the use of KI by the general public as a protective action.

Table 5.2 Protective Action Guides for Exposure to Deposited Radioactivity During the Intermediate Phase of a Nuclear Incident

Protective Action	Protective Action Guide (projected dose)[a]	Comments
Relocate the general population[b]	>20 mSv (2 rem)	Beta dose to skin may be up to 50 times higher.
Apply simple dose reduction techniques[c]	<20 mSv (2 rem)	These protective actions should be taken to reduce doses to low as practicable levels.

[a]The projected sum of effective dose equivalent from external gamma radiation and committed effective dose equivalent from inhalation of resuspended materials, from exposure or intake during the first year. Projected dose refers to the dose that would be received in the absence of shielding from structures or the application of dose reduction techniques. See USEPA, 1992.

[b]Persons previously evacuated from areas outside the relocation zone defined by the Protective Action Guideline (PAG) may return to occupy their residences. Cases involving relocation of persons at high risk from such action (e.g., patients under intensive care) should be evacuated individually.

[c]Simple dose reduction techniques include scrubbing and/or flushing hard surfaces, soaking or plowing soil, minor removal of soil from spots where radioactive materials have been concentrated, and spending more time than usual indoors or in other low exposure rate areas (USEPA, 1992).

Late Phase Planning

The federal government does not provide specific guidance for protective actions during the late phase. Response to this phase depends on the specific incident. Planning requirements are general and address issues with re-entry and recovery methods used to determine relaxation of previous protective actions, periodic

estimation of total population exposure, recovery organization, and communication.

KI Pharmaceutical Issues

KI Dosage forms

The current FDA-approved KI products for radioprotective use include

IOSAT®—130-mg tablet (Anbex).
THYROSAFE®—65-mg tablet (R. R. Registrations).
THYROBLOCK®—130-mg tablet (Wallace Labs; distributed by MedPointe, Inc.).

Source: *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book") www.fda.gov/cder/ob/default.htm

FDA appropriately regulates KI for radioprotective use as an over-the-counter drug (that is, no prescription is required). Although the FDA Web site indicates that "only the KI products approved by FDA may be legally marketed in the United States", other Web sites advertise numerous products for radioprotective use. Some advertise products as being FDA-approved and suggest in their general wording that the use of KI will be useful against NPP incidents and "dirty bombs" (for example, see *NukePills.com*). Only on closer examination of the site does the wording reveal that KI is to be used to protect the thyroid, not the rest of the body, in the event of radioactive iodine exposure.

The FDA Web site www.fda.gov/cder/drugprepare/kiprep.htm provides detailed information on home preparation for emergency administration of KI tablets to infants and small children. There are detailed instructions for the 65-mg and 130-mg tablets with dosing guidelines. Suggested "drink" vehicles include water, low-fat milk (white or chocolate), orange juice, such flat sodas as colas, raspberry syrup, and infant formula. Initially, the tablet is to be crushed and ground to a fine powder with a metal spoon. A volume of water is then added to solubilize the KI, and then an equal volume of the "drink" above. It is suggested that the resulting mixture should be

refrigerated and can be stored for up to a week, after which it should be discarded. The instructions on the Web site clearly caution people numerous times regarding the differences between 65-mg and 130-mg tablets. The instructions are carefully detailed but may be impractical in an emergency situation. Therefore, there is a need for development of practical dosage forms (for example, 32-mg tablets or liquid formulations) for infants and children, the most vulnerable population; such a tablet size could also be convenient for adults.

At the time of the writing of this report, advertisements of KI products on various Internet sites sometimes implied that the products were FDA-tested and approved, had a 5-year shelf-life, and were available in various types of packaging. Radioprotective products described on such Web sites that are FDA-approved include

Iosat®.
ThyroSafe®.
ThyroBlock®.

Several other products are advertised as radioprotective, but they are not FDA approved at the time of writing this report.

A product not approved by FDA for use as a radioprotective should not be used for that purpose. Although some of the nonapproved products appear to be marketed as "dietary supplements", this designation is not appropriate, inasmuch as the use of KI to prevent damage to the thyroid due to radioiodine exposure designates KI as a drug.

Additionally, although other legal products containing KI are available as nutritional sources of iodine, these typically contain only very small quantities and at the dosage used for nutritional replacement would not be expected to provide any significant thyroid protection.

Potassium iodate (KIO_3) is available as a radioprotective for the thyroid in some European countries, but FDA does not approve it for use in the United States. KI is generally preferred to KIO_3, which is believed to be a stronger gastrointestinal irritant.

KI Shelf-Life

Distributed or stockpiled KI has a manufacturer-determined and FDA-acknowledged expiration date, so there is a need to replenish supplies periodically. Current FDA-approved formulations generally range in shelf-life from 2 to 3 years. It is well known that KI is extremely stable and should have a much longer shelf-life if stored under optimal conditions (for example, foil-wrapped for protection from air, moisture, heat, and light).

In March 2003, FDA (2003a) issued "draft guidance" for KI tablets shelf-life extension to provide guidance to state and local governments. It is a draft and is not officially available for implementation. There are two kinds of shelf-life extension: ordinary shelf-life extension with the manufacturer responsible for testing and DOD-sponsored shelf-life extension with FDA responsible for testing of stockpiled product.

Assay content and dissolution are the two specifications of concern in shelf-life consideration. None of the components of the KI tablets would be expected to significantly degrade or react with appropriate storage containers, but some KI tablets have failed to dissolute according to US Pharmacopeia (USP) specifications (75% within 15 min). However, the 75% dissolution was claimed to be achieved in a slightly longer period; this suggests that even if the USP requirement of 75% in 15 min were not reached, the product would be expected to be useful and provide appropriate protection. That is, the product should be considered as "usable".

The March 2003 FDA draft document indicates that because KI is considered to be "very stable" when protected from moist air (KI is deliquescent and can release iodine and form iodate), additional testing "is probably unnecessary as long as the market package remains intact and continues to be stored under controlled conditions as described in the labeling." A recommended protocol for shelf-life extension is also described with guidelines for accelerated stability testing with increased temperature and humidity) to achieve a 5-7-yr shelf-life designation. Recommendations for choosing a suitable laboratory for testing and the identification of batches qualified for extension and notification of expired batches are also discussed.

6

EXISTING DISTRIBUTION PLANS FOR POTASSIUM IODIDE

Various governments have decided to distribute KI to protect populations against exposures to radioactive iodine in connection with nuclear facilities; others have decided not to distribute it. This chapter reviews US and international experiences in deciding to distribute KI and implementing those decisions. It emphasizes factors important to consider when contemplating whether and how to distribute KI. First, the international experience is discussed, beginning with international guidelines and recommendations for countermeasures. The development of countermeasures to mitigate radioiodine exposures in the event of a release by various countries is then outlined, followed by details on how various countries have made KI available. The US experience is then discussed, starting with recommendations made by public-health institutions regarding KI distribution and the roles and guidance of the involved federal

agencies. Before the September 11, 2001, attacks, few states were prepared to distribute KI to the general population. After the attacks and the offering of KI by the Nuclear Regulatory Commission, several states began KI distribution programs. The decisions of states regarding whether to distribute are discussed with the experiences of the states that decided to distribute KI. The chapter then discusses the elements of state distribution programs, highlighting options and limitations to consider in planning such programs. Finally, some obstacles to and limitations of distribution efforts are summarized with observations regarding improvements to overcome them.

International Experience with Potassium Iodide and Other Countermeasures in Nuclear Emergency

Guidelines and Database

The International Atomic Energy Agency (IAEA) and the World Health Organization (WHO) have published general recommendations for countermeasures in the case of a nuclear emergency: *the International Basic Safety Standards for Protection Against Ionising Radiation and for the Safety of Radiation Sources* (IAEA, 1996) and the *Guidelines for Stable Iodine Prophylaxis Following Nuclear Accidents* (WHO 1989, Update 1999). However, radiological emergency preparedness and rules for countermeasures differ from country to country. The Nuclear Energy Agency (NEA) of the Organisation for Economic Co-operation and Development (OECD) initiated a questionnaire-based evaluation of short-term countermeasures in March 2001. The results of this evaluation have recently been published under the title *Short-term Countermeasures in the Case of Nuclear or Radiological Emergency* (NEA/OECD, 2003)[1]. The NEA distributed questionnaires to its 22 European and 6 non-European member countries. It received 15 completed questionnaires—from Australia, Canada, the Czech Republic, Finland, Germany, Hungary, Ireland, Japan, Luxembourg, the

[1] The report is available at the OECD/NEA publication services (email: neapub@nea.fr).

Netherlands, Norway, Sweden, Switzerland, the United Kingdom, and the United States. Results of the NEA/OECD evaluation, which included general approaches for short-term countermeasures and more specific information on evacuation, sheltering, and iodine blockade will be the primary basis for the discussion of the international experience in KI distribution in this chapter. This is supplemented with data from other reports from Germany, France, and other countries.

General Approach to Countermeasures

All countries responding to the NEA/OECD questionnaire consider evacuation, sheltering, and administration of stable iodine the preferred short-term countermeasures in areas close to an emergency site. The planning zone for evacuation is generally an area some 10 km (6.2 miles) in radius around the NPP, whereas the planning zones for sheltering and stable iodine are generally larger—a radius of 10-20 km (6.2-12.4 miles). This indicates that sheltering and use of stable iodine administration may be implemented together.

The decision to implement the different countermeasures is based on non-uniform criteria, such as the safety status at NPP, results of radiation monitoring on site and in the vicinity, the meteorological situation, the actual release of radioactivity, and, most important, the dose expected or the dose likely to be averted by the protective measures.

Interestingly, the timing of countermeasures is handled differently in different countries: some countries do not expect to implement them consecutively, but other countries plan to implement them first for the nearby areas and for specific populations (such as pregnant women and schoolchildren) and then address the remaining populations and areas further out.

In developing emergency-plan guidelines and procedures, the responsible organizations have considered various factors. Table 6.1 shows that the most important factor in all countries is the time necessary to implement countermeasures, followed by public-health risk, the shielding qualities of average houses, and the public trauma induced by emergency measures.

Table 6.1 Considerations for Emergency Plan Guidelines

Factors	Countries														
	Australia	Canada	Czech Republic	Finland	Germany	Hungary	Ireland	Japan	Luxemburg	Netherlands	Norway	Sweden	Switzerland	United Kingdom	United States
Public health risk	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Time necessary for the implementation	X	X	X	X[b]	X	X	X	X	X	X	X	X	X	X	X
Shielding qualities of average houses	X	X	X		X	X		X	X	X	X	X	X	X	X
Availability of basement and shelters			X		X			X	X	X	X		X		
Transportation availability			X		X			X	X	X	X	X	X	X	
Public trauma		X	X			X	X	X	X	X	X	X	X	X	X
Night or day			X		X			X	X	X	X		X		
Nuclear power plant near a border			X		X	X			X		X	X	X		
Costs		X	X			X		X	X		X	-	-	X	X
Countermeasure applied to entire population		X	X		X	X	X	X	X	X[c]	X	X	X		
Other:					X[a]					X[d]		-	-		

[a]Only for evacuation.
[b]Stable iodine and sheltering could be only for children. In the case of evacuation, if there is not enough time or transport facilities, pregnant women and children first.
[c]Weather conditions.
[d]Weather conditions and number of people involved.
Source: NEA/OECD, 2003.

For most European countries, the IAEA *International Basic Safety Standards* is the basis for radiation-emergency planning. Recently, the WHO *Guidelines for Stable Iodine Prophylaxis Following Nuclear Accidents*, which were updated in 1999, were implemented by many countries.

In Germany, a country with a federal constitution comparable with that of the United States, general guidelines are laid down in the *Basic Recommendations for Disaster Preparedness in Areas Surrounding Nuclear Facilities* (The German Minister for the

Environment, Nature Conservation and Nuclear Safety 1999). These guidelines were approved by the Conference of Ministers of the Interior of the Federal States, and the responsible organizations of the states (county district magistrates or district authorities) developed procedures for the implementation of short-term countermeasures.

Evacuation

According to the IAEA *International Basic Safety Standards* a generic optimized intervention level of 50 mGy (5 rad) of avertable effective dose in a period of no more than 1 week is recommended for temporary evacuation, that is, evacuation is indicated when the action averts a dose greater than this level. The national intervention levels for evacuation differ considerably, with intervention levels for most countries falling within a wide range of anticipated effective dose: 30-500 mGy (3-50 rad), typically with an integration time of 7 days.

Timely evacuation offers the highest degree of protection against external and internal exposure. If evacuation cannot be finished in the pre-release phase, sheltering may be more effective. Evacuation, compared with sheltering or iodine blockage, however, can have more severe psychological, social, and economic consequences.

Sheltering

According to the IAEA *International Basic Safety Standards,* for sheltering the generic optimized intervention level is 10 mGy (1 rad) of avertable effective dose[2] in a period of no more than 2 days.

Staying indoors is a relatively simple way to reduce external or internal radiation exposure in the event of an emergency. Protection against external radiation depends strongly on the shielding capabilities of the building and the building material used. People should use cellars or protection rooms of solid construction.

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[2] The committee discussed and decided to use the term "avertable dose" for its recommendation (averted dose addresses the same issue). This decision follows the recommendations of the International Committee on Radiological Protection given e.g. in publication No. 60.

Windows and outer doors have to be closed, and ventilation systems must be shut down. For a sheltering period of 24 h or longer, food, water, and medical care should be provided. Long-term sheltering may cause social, medical, and hygiene problems.

The variation in intervention levels used for sheltering is smaller than that in other countermeasures (evacuation and iodine blockage). Generally, the recommendations of the IAEA *International Basic Safety Standards* are followed. For almost all countries, sheltering is implemented as the initial countermeasure because it is easy to organise and the compliance of the population is expected to be relatively high. During sheltering, people are easy to find if it is decided to use iodine blockage. In fact, sheltering is usually combined with the administration of KI. In some countries, the recommendation that children stay indoors is used as a "lighter" countermeasure.

Iodine Blockade

Iodine blockade will rarely be used as a stand-alone protective action. It normally is combined with sheltering or evacuation. All countries recommend the additional use of stable iodine when inhalation of radioiodine is the major exposure pathway. In the case of ingestion of contaminated food (such as milk and leafy vegetables), however, restricting the production and consumption of foodstuffs will be more effective (WHO, 1999).

Dose criteria used to initiate iodine blockade in the 14 countries that completed the NEA questionnaire are summarized in Table 6.2.

In nearly all countries, KI is the preferred chemical form for administration of stable iodine, but three countries use potassium iodate (KIO_3). The dosages, administration mode, and duration of iodine blockade used by different countries are shown in Table 6.3.

Table 6.2 Criteria for Stable Iodine Intervention

Country	Intervention level	Dose type at intervention level	Dose integration time	Operational intervention criteria
Australia	100 mGy	Averted[a] dose		Under review at present
Canada	100 mSv[b]	Thyroid organ dose (averted dose)		[c]
Czech Republic	5–50 mSv 50–500 mSv	Effective dose Organ dose (averted)		0.1 mSv/h[d]
Finland	10 mGy (for children under 18) 100 mGy (for adults)	Averted dose to the thyroid		10 µSv/h (for children under 18) 100µSv/h (for adults)
Germany	50 mSv (for children up to 18 and pregnant women) 250 mSv (for adults up to age of 45)	Thyroid organ dose (anticipated)	Radioactive iodine inhaled over a period of 7 days including dose equivalent commitment	Criteria are given for - released activity of iodine at the source and - time integrated air concentration (see Annex A)
Hungary	100 mGy	Thyroid organ dose (averted)		0.1 mSv/h; 4 h plume transition[e]
Ireland	100 mSv	Anticipated averted thyroid dose		Thyroid dose from radioiodines
Japan				Where a high thyroid dose is anticipated, stable iodine prophylaxis taken according to judgement of experts.
Luxembourg	30–250 mSv (children)	Anticipated organ dose		
Netherlands	250 mSv (for children < 17 and pregnant women) 1000 mSv (for adults)	Projected thyroid dose		
Norway	100 mGy	Averted dose		
Sweden	10–100 mGy (for children)	Averted dose to the thyroid		
Switzerland	30–300 mSv	Organ dose (anticipated dose)	Inhalation dose integrated over time of plume passage	Source term estimation
United Kingdom	30–300 mSv	Committed thyroid dose, averted by countermeasure		Varies with site/operator
United States	5 Gy (for adults over 40 yrs) 100 mGy (for adults 18-40 yrs) 50 mGy (for pregnant/lactating women and those under 18 yrs)	Committed dose equivalent to thyroid		

[a] The averted (or avertable) dose is the dose to be prevented by the particular protective action (i.e., the difference between the dose to be expected without stable iodine blockade and that to be expected with it).
[b] Health Canada's Federal Recommendation. The province of Quebec has other intervention levels: 50 mSv. (0– 20years), 100 mSv (20–40 years).
[c] To be developed.
[d] The default value of several ten mSv/h will be used, depending on real course and conditions of radionuclides release; for calculation the averted dose of 100 mSv from inhalation was used as basis assumption, and various accident sequences for WWER-213 reactor were calculated to assess the possible consequences for country specific conditions.
[e] To be included into the National Nuclear Emergency Plan being revised, not yet accepted.
Source: NEA/OECD, 2003. The table shows that different countries use different dose units.

Table 6.3 Dosages of Stable Iodine Recommended for Radioiodine Prophylaxis

Country	Population[a]	Dosage (mg)		Frequency	Duration
		Mass of KI	Mass of iodine		
Australia	Infants Children Adults Pregnant women Emergency Workers		25–50 50 100 100 100	Single dosage Single dosage Single dosage Single dosage 1 per day	10 days
Canada	Neonates Infants Children Adults		12.5[b] 25[b] 50[b] 100[b]	[c]	[c]
Czech Republic	Infants Children Adults Pregnant women Others	32 65 130 130 130		24 h 16 mg 24 h 3.5 mg 24 h 65 mg 24 h	48 h 48 h 48 h max. 2x
Finland	Neonates Infants Children Adults Pregnant women	16 32.5 65 130 130		[d]	24 h
Germany	Neonates Infants Children Adults Pregnant women	12.5 25 50 100 50		Normally single dosage. In exceptional cases taking an additional tablet may be recommended	The intake for neonates should be confined to one day.
Hungary	Infants[e] Children[e] Adults[f] Pregnant women[e]	65		Twice daily	10 days
Ireland	Neonates Infants Children Adults Pregnant women		12.5 (1/4 tablet) 25 (1/2 tablet) 50 (1 tablet) 100 (2 tablets) 100 (2 tablets)		One day
Japan	Infants Children Adults Pregnant women	50 100 100 100		50 mg/day 100 mg/day 100 mg/day 100 mg/day	Max. 10 days; Less than 1 g (total)
Luxemburg	Neonates Infants Children Adults Pregnant women		12.5 25 50 100 100	1	Only 1 dosage 2 days 2 days 2 days Only 1 dosage
Netherlands	0-4 year 5-16 year > 16 year Pregnant women	KIO_3	25 50 100 100	Normally single dosage. In exceptional cases taking an additional tablet may be recommended	Only during the passage of the plume. Normally, 'clean' food can be supplied
Norway	Neonates Infants Children Adults Pregnant women	16 32.5 65 130 130		[d]	24 h

Country	Population[a]	Dosage (mg)		Frequency	Duration
		Mass of KI	Mass of iodine		
Sweden	0-1 month Infants < 3yrs Children < 12 yrs Adults < 40 yrs Pregnant women	16 32.5 65 130 130		Normally single dosage. In the case of prolonged release, an additional dosage may be recommended	
Switzerland	Neonates Infants Children Adults Pregnant women	16.2 32.5 65 130 130		Single dosage Single dosage Per day Per day Per day	Only one time Only one time [g] [a] Max. 2 days
United Kingdom	Neonates Infants Children Adults (including pregnant and lactating women)		12.5 25 50 100	Single administration only, preferred	Single administration provides protection for 24 hours
United States[h,i]	Birth through 1 mo 1 mo through 3 yrs Children 3-12 yrs Adults 12-18 yrs Adults over 18 yrs Pregnant/lactating women	16 32 65 130			Until risk of significant exposure to radioiodine by either inhalation or ingestion no longer exists

[a] Neonates: birth–1 month old
Infants: 1 month–3 years old
Children: 3–12 years old
Adults: include adolescents aged 13–16 years old
[b] Federal recommendation follows the 1989 WHO Guidelines. Varies by province.
[c] Varies by province. In New Brunswick, the frequency is 1 dosage per 24 hr (except for newborns, where a single dosage is advised), until instructed to stop. At the federal level, a protracted dosage is generally not advised
[d] If needed, authorities give an order for another dosage after 24 h
[e] ½ or ¼ may be administered depending on age or in case of iodine sensitivity
[f] Adults under 40 years old
[g] The duration depends on the actual situation
[h] In the United States, the plume phase exposure lasts 24 hours or less due to evacuation being the primary protective action. KI is provided to address plume exposure and one dose should be taken to address the first 24 hour period during which time evacuation is occurring.
[i] It is assumed throughout this report that the need for administration of KI is necessary only once and to protect the thyroid gland against inhalation of radioiodine from a passing plume (cloud) and that further protection from radioiodine will be accomplished by evacuation and control of contaminated milk and other foods.
Source: NEA/OECD, 2003.

For practical use of iodine the pharmacological shelf life of predistributed tablets is of interest. Table 6.4 summarizes how the shelf life for stable iodine tablets is taken into account by different countries.

Table 6.4 Assumed Stable Iodine Tablets Shelf-Life

Country	**Assumed Shelf-Life for Stable Iodine Tablets in years**	
	KI	**KIO_3**
Australia	5[a]	
Canada	5	
Czech Republic	5	
Finland	5	
Germany	10–15	
Hungary	5	
Ireland		5
Japan		
Luxemburg	10	
Netherlands		Check every 5 years
Norway	5	
Sweden	5	
Switzerland	8	
United Kingdom		3

[a]After 5 years, the tablets are tested; depending on result, shelf-life might be extended.
Source: NEA/OECD, 2003.

Information about possible side effects of iodine tablets is presented in leaflets that are distributed by most of the countries to households in EPZs before an emergency. In Luxembourg, people who may suffer severe side effects from a large dosage of stable iodine or who have thyroid disease are invited to consult their doctors in advance. In Germany, two types of leaflets are distributed: one to households and the other to family doctors. The German information about possible side effects and countermeasures for family doctors reads as follows:

> Persons with a known hypersensitivity to iodine (very rare disorders, such as genuine iodine allergy, dermatitis herpetiformis Duhring, iododerma

tuberosum, hypocomplementaemic vasculitis, myotonia congenita) must not take iodine tablets. In rare cases, iodine tablets may also lead to skin rashes, edema, sore throat, watering eyes, nasal catarrh, swelling of the salivary glands and elevated temperature.

In very rare cases, signs of hypersensitivity to iodine (genuine iodine allergy), e.g. iodic rhinorrhea or iodic rash, may be observed. However, the possibility of intolerance to iodine should not be overrated. Absorption of iodine by the body can be inhibited by gastric irrigation with starch solution (30 g to 1 litre until blue colour disappears) or with a 1-3% solution of sodium thiosulphate. Administration of Glauber's salt and forced diuresis are recommended to speed up excretion. Any shock and any water and electrolyte disorders are to be treated according to guidelines well known by physicians.

In cases of a previous history of thyroid disorders, even if its course has been so far asymptomatic (especially in case of nodular goiter with functional autonomy) hyperthyroidism may be triggered within weeks or months after administration of iodine.

If stable iodine is contraindicated because of the reasons mentioned, the most suitable medication apart from iodine is perchlorate, which competitively inhibits the uptake of iodine. The following dosage is recommended for adults:

Sodium perchlorate (as Irenat®): on first day 60 drops, thereafter 15 drops every 6 hours for seven days (15 drops = 345 mg).

Contra-indications such as hypersensitive reactions (agranulocytosis) and serious liver damage must be watched for.

In Germany, it is recommended that people over 45 years old not take iodine tablets because, owing to the still prevailing general iodine deficiency in Germany, early forms of thyroid overactivity (so-called functional autonomy or hot nodules) are relatively common in this age group (up to 50% of the population). The risk posed by taking iodine tablets—possible induction of hyperthyroidism—outweighs the risk posed by exposure to radioactive iodine, which is negligible in this age group.

The distribution logistics and availability of stable iodine have not been evaluated in depth by the NEA/OECD questionnaire. However, interesting details about this issue have been collected by NEA/OECD and reported as follows:

> With the exception of **Austria, Canada,** and the **United Kingdom,** stable iodine tablets are commercially available at pharmacies. In **Luxembourg**, tablets are only available for children not older than four years.
>
> In **Australia**, the tablets will be distributed in an emergency situation only. The tablets are not commercially available, e.g. at pharmacies, but are stockpiled by the police and local and national authorities. In case of an emergency, they will be distributed to the residences of the population and to pre-designated locations.
>
> In **Canada**, the provinces are responsible for the decision to distribute stable iodine. There are various policies, some provinces decided to predistribute the iodine tablets to residences, other provinces make them available at pre-designated locations. Within a radius of about 8 km around Gentilly 2 nuclear power plant, for example, iodine tablets will be predistributed to some 12,500 persons (inhabitants and workers). In New Brunswick, 3500 people living within 20 km radius around Pt. Lepreau NPP received stable iodine tablets. Pills are also

provided in quantity to police departments, public health offices, schools and local facilities. Additional supplies are stockpiled at the generating station and at the offsite emergency centre in Lepreau, New Brunswick. In Canada, iodine tablets are not commercially available at pharmacies.

The **Czech Republic** has the most widespread predistribution of stable iodine tablets to residences, businesses, pharmacies, schools and other locations. Around the nuclear power plant Dukovany, about 110,000 people living in the emergency planning zone have already received the tablets. Around the Temelin nuclear power plant, about 40,000 people living in the emergency planning zone received the tablets. People may also buy stable iodine tablets in designated pharmacies.

In **Finland**, tablets are predistributed to residences surrounding (5 km) nuclear power plants. The tablets are also predistributed to companies near the nuclear power plant. Stable iodine tablets are predistributed to about 1,150 people living around Loviisa NPP (50 permanent inhabitants and about 400 holiday homes with a maximum of 1,100 inhabitants) and 1,370 people surrounding Olkiluoto NPP (70 permanent inhabitants and about 450 holiday homes with a maximum of 1,300 inhabitants). In case of an emergency, tablets will also be distributed by emergency services at pre-designated locations and at public shelters.

In other parts of **Finland**, iodine tablets are also made widely available, e.g. in schools and nurseries. In addition, tablets are commercially available at pharmacies.

In **Germany,** stable iodine tablets are currently stockpiled in schools, public shelters, pharmacies and at local authorities. In case of an emergency they will be distributed at pre-designated locations or, with the help of emergency services, directly to the residences of the population.

In **Hungary**, tablets are stored at pharmacies and will be distributed at pre-designated locations during an emergency.

Tablets will be distributed to every household in **Ireland**.

In **Japan**, the tablets are stockpiled by local authorities and distributed at public shelters during an emergency.

In **Luxembourg**, stable iodine tablets will be commercially available in pharmacies for children of up to five years only. For other population groups, the tablets are stockpiled at schools and other pre-designated locations (e.g. local and national authorities).

In **The Netherlands**, stable iodine tablets are stockpiled in a central depository. They are also available around Borssele in Health Service Centres.

In **Norway**, stable iodine will be distributed by the emergency services at designated locations. The distribution system is being revised. In Northern Norway, tablets will be available for all relevant groups and distributed through local authorities (from schools, hospitals etc). For the rest of the country, national authorities keep a central storage (few tablets). Around the research reactors, the operator has supplied some tablets (stored at the plant and by the police).

In **Sweden**, iodine tablets are predistributed to all households within the inner emergency zone around the

four NPPs. This procedure is repeated every 5 years. There is also central storage of tablets for additional distribution. Larger workplaces, schools and hospitals have also received tablets.

In **Switzerland**, iodine tablets are predistributed about 4 km (zone 1) around the nuclear power plants. Depending on the location of the NPP, between 3,000 and 30,000 tablets are predistributed to residences of the population, to places of business, local authorities and pharmacies. Up to a distance of 20 km (zone 2) around nuclear power plants, tablets need not be distributed if the population can get them within the first two hours of an emergency. In this case, the public in general must go and fetch their tablets at specially designated locations. The solution chosen depends on the decision taken by the local authority. Currently, discussions are underway to change the legal basis to allow for a predistribution in zone 2 as well. In addition, a national central stockpile is available from which tablets can quickly be transported by helicopters to any location in Switzerland. Stable iodine tablets are also available commercially from pharmacies.

In general, there is no predistribution of potassium iodate tablets in the **United Kingdom**. However, the local health authority together with the operator, the police and the local government makes the decision for a predistribution in certain areas. Around Sellafield and Hinkley Point, the population density is low and residences are widespread around the sites. The local authorities therefore decided to predistribute tablets in an area of 1–3 km around the sites. Apart from that, tablets are stockpiled in schools, places of business, public shelter, and local authorities. Potassium iodate tablets are not accessible by the general public, e.g. cannot be purchased at pharmacies. They will only be distributed as part of the agreed upon emergency response

arrangements after decision of the relevant Directors of Public Health.

In the **United States,** the distribution of KI for the general public is the responsibility of State and local officials. Because the Federal policy addressing the use of KI by the general public was only recently changed, there is not much experience with the logistics associated with the distribution and storage of KI on a large scale. However, each State that desires to stockpile KI for the population living in the vicinity of a nuclear power plant will have to develop a distribution plan that will be reviewed by the Federal government. In the **United States**, KI is available over the counter. But, most pharmacies do not keep it in stock and thus it is not readily available to the general public in large quantities.

Recently, the German government started to implement the recommendations of the Radiological Protection Commission (SSK, 1997) to predistribute KI tablets to households within a radius of up to 5 km around a NPP. In the zone between 5–10 km, it is being recommended that stocks of iodine tablets at several locations in the communities (town halls, schools, hospitals, workplaces, and so on) should be made available or predistribution should be considered. For people living at a distance of 10–25 km, stocks of iodine tablets in communities or in suitable establishments are being recommended; predistribution to households is considered only for exceptional cases. Generally, in the zone with a radius of 25 km around a NPP, it recommended that stocks of iodine tablets should be made available for all persons up to 45 years old. For areas outside a radius of 25 km around a NPP in the entire territory of the Federal Republic of Germany, central stocks (at several places, if appropriate) of iodine tablets should be made available for children and adolescents up to 18 years old and for pregnant women. Blister packs with 20 tablets provided by the federal government will contain 65 mg of KI per tablet and will be exempted from usual regulations concerning shelf-

life; 130-mg KI tablets are also commercially available at pharmacies without prescription.

In *France,* the Central Military Pharmacy has manufactured 350,000 packages of 10 tablets, each containing 130 mg of KI. These were distributed in a conventional manner to pharmacies all over the country. Every person living within 10 km of a NPP received an informational letter signed by the governor of the county and a coupon to be exchanged for the tablets at a pharmacy. Schools, local industry, and public buildings were also supplied with tablets. In comparison, two other distribution protocols have been tested in *France*: home delivery by firemen or civil defense representatives and postal delivery. The French experience revealed that home delivery allowed successful distribution to over 90% of the population involved, compared to 60-70% for pickup from pharmacies (Le Guen et al., 2002).

In the UK, experience 2 years after the predistribution of iodine tablets to households, almost 60% of the tablets were still available for the target population. The authors of the English study (Astbury et al., 1999) recommended arrangements be made for redistribution of tablets earlier than the shelf-life of stable iodine would indicate.

The Polish Experience

Two days following the explosion of the Chornobyl No. 4 Reactor (April 27 and 28, 1986) considerable activity of ^{131}I in air was measured by Polish authorities. So, the government decided to implement countermeasures on April 29, taking into consideration that although some thyroid uptake had already occurred, stable Iodine would be still useful to protect the gland against continuing contamination resulting from the accident (Nauman and Wolff 1993). On April 29, 1986, the Minister of Health gave orders to prepare KI-solution in the centralized pharmacy for distribution to the 11 provinces most affected. This was to be made available to all hospitals, public health centers, school, kindergartens etc. The following KI-dosage protocol was used: 15 mg for newborns, 50 mg for children 5 years or under and 70 mg for all others. Because the

cancer risk for adults was believed to be low and some side-effects in persons with nodular goiter were anticipated, iodine prophylaxis was not recommended for adults; pregnant and lactating women, however, were included in the program. Distribution of KI-solution was accompanied by additional protective measures: fresh-milk with radioactivity above 1,000 Bq/l was banned for consumption by children and pregnant and lactating women, all children below age of 4 were provided with powdered milk, and children and pregnant or lactating women were advised to minimize their ingestion of fresh leafy vegetables until May 16. A total of 10.5 million dosages of KI-solution were given to children and 7 million dosages to adults. So, from the fourth day to the seventh day after the beginning of the release of radioactivity from the Chornobyl nuclear power plant, KI-solution was distributed to more than 90% of the children younger than 16 and about a quarter of the adults.

Three years later, questionnaires were sent to 52,000 people and 35,000 responded (response rate of 62%). Children up to the age of 16 accounted for 37% of the group. Measurements of thyroid radioactivity and reconstruction of thyroid doses revealed that the projected mean maximum burden would have exceeded 50 mGy (5 rad) in children below the age of 1 year in 12 provinces with a range of 53 to 88 mGy (5.3 to 8.8 rad) with minimal burdens ranging between 3 and 15 mGy (0.3 to 1.5 rad). The average total reduction in thyroid burden in three fourths of the children (age 1 to 4) in the 11 provinces treated between April 29 and May 2 was 62%, whereas the remaining fourth of the children received an average of 40% reduction. No thyroid cancers have been found in the study population; comparison of total and nodular goiter prevalence before and after the accident showed no significant difference.

In addition, the survey probed quite intensively for possible adverse reactions to Iodide. No permanent effects on thyroid function could be detected by TSH-measurements in children of the study group. Only 0.4% of newborns who received KI-prophylaxis on the second day of life showed transient increases of serum TSH levels accompanied by decreases of free T4. Among extrathyroidal side-effects after KI-prophylaxis, vomiting and skin-rashes in 2.4% and 1.1% of the children and 0.9% and 1.2% of the adults, respectively,

were the only side-reactions considered to be statistically significant. Nauman and Wolff concluded that the present program involved the largest population ever studied after a single pharmacological (high) dosage of KI. The administration proved to be effective and safe since no increase of the incidence of thyroid cancer was registered after Chornobyl in Poland and adverse reactions to KI were very rare.

US Experience in the Distribution of Potassium Iodide

Until recently, there has been limited experience in the United States in distributing KI to the general population. A few states with commercial nuclear facilities distributed KI, and one state experimented with different methods of distribution. After the Chornobyl experience and the increased concern over a possible terrorist attack that would lead to radioiodine exposure, several states and the federal government reassessed their policies and initiated KI distribution programs to cover emergencies at NPPs. Guiding some of the policies are recommendations from public-health institutions regarding the KI distribution and protective dosages. All state distribution plans are subject to federal review.

This section describes guidance from various federal agencies and public-health institutions in KI distribution, the application of this guidance in the US. It also outlines experience of the states in planning and implementing KI distribution programs. The discussion of states' experience is based on responses to a request for information sent by the committee to each of the 50 states, presentations heard by the committee, reports and other data retrieved from the Internet, and a few publications in scientific journals.

Recommendations from Public-Health Institutions

Since 1984, the American Thyroid Association (ATA) has recommended the stockpiling of KI, and it currently recommends the predistribution of KI to households within a 50 mile radius of a NPP and stockpiling of KI at distribution centers 50-200 miles from

nuclear plants (see the American Thyroid Association Web site http://www.thyroid.org/professionals/publications/statements/ki/02_04_09_ki_endrse.html; the site was accessed on September 23, 2003). The American Academy of Pediatrics (AAP, 2003) notes the high risk of thyroid cancer from fetal and childhood exposure to radioiodine and its effective prevention with KI near the time of exposure. AAP therefore recommends the development of strategies that permit the rapid administration of KI to large numbers of children potentially at risk. It also recommends that communities near a NPP have access to KI as an adjunct to evacuation and sheltering and that schools and child-care centers within a 10-mile radius of a reactor have immediate access to KI. AAP notes that it is prudent for parents living within a 10-mile radius of a reactor to keep KI in their homes. Noting that KI distribution to all US families remains controversial, the AAP nonetheless asks that universal access to KI be considered. Because rapid and complete evacuation of a region depends on population density, APP suggests distribution of KI within a 50-mile radius of a NPP in densely populated regions and within a 10-mile radius in less densely populated region. AAP recommends preparatory training exercises and recommends that FDA facilitate the development of a pediatric preparation of KI. With regard to the dosage administered, ATA and AAP defer to FDA's 2001 guidelines for KI administration (Table 6.5). One caveat is that, contrary to FDA (2001a), the AAP recommends that women exposed to radioiodine cease breastfeeding unless there are no alternatives. The FDA advice suggests breastfeeding can continue if the mother has received KI.

Table 6.5 FDA (2001a) Guidance for KI Administration: Threshold Thyroid Radioactive Exposures and Recommended Dosages of KI for Different Risk Groups[1,2]

Patient	Predicted thyroid exposure (cGy)	KI dosage (mg)	No. of 130 mg tablets	No. of 65 mg tablets
Adults: > 40 years old	> 500	130	1	2
Adults: 18–40 years old	≥ 10	130	1	2
Pregnant or lactating women	≥ 5	130	1	2
Adolescents[3]: 12–17 years old	≥ 5	65	½	1
Children: 4–11 years old	≥ 5	65	½	1
Infants and children: 1 month–3 years old[4]	≥ 5	32	¼	½
Neonates: Birth–1 month old	≥ 5	16	⅛	¼

[1]Footnote 2 to this table was given in the FDA (2001a) guidance. The remaining table footnotes were provided in the AAP (2003) presentation of FDA guidance. AAP presented the predicted thyroid dose in units of Gy and rad (1 cGy is equivalent to 1 rad).

[2]KI is useful only in a severe emergency situation when there is a risk of exposure to radioiodine. KI is given once only to pregnant women and neonates unless other protective measures (evacuation, sheltering, and control of the food supply) are unavailable. Repeat dosing should be on the advice of public health authorities.

[3]Adolescents weighing more than 70 kg should receive the adult dosage (130 mg).

[4]KI from tablets or as a freshly saturated solution may be diluted in water and mixed with milk, formula, juice, soda, or syrup. Raspberry syrup disguises the taste of KI the best. KI mixed with low-fat chocolate milk, orange juice, or flat soda (for example, cola) has an acceptable taste. Low-fat white milk and water did not hide the salty taste of KI.

Federal Agencies

The FDA (2001a) guidance modifies earlier recommendations (FDA, 1982) on KI intervention with respect to KI dosages and the radiation levels that trigger prophylaxis. The update came after a federal interagency working group examined the data on radioiodine and post-Chornobyl thyroid cancer. The working group found that thyroid-cancer risk may accrue in children and adolescents from "very low doses of radiation exposure" and that KI administration in Poland after the Chornobyl accident was safe and effective. The main changes from the earlier guidance were the establishment of lower radiation levels that should prompt KI administration and the recommendation of relatively low minimum effective dosages of KI for the very young. FDA has also issued the guidance *Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Children* when using 65- and 130-mg tablets (FDA, 2003b; 2003c).

The earlier FDA guidance (FDA, 1982), recommended dosages of 130 mg/day for those over 1 year old, and 65 mg/ day for those under 1 year old. FDA (2001a) now recommends effective dosages of 32 mg/day for very young children (1 month–3 years old) and 16 mg/day for neonates (less than 1 month old) (Table 6.5). It indicates that the lowering of effective dosages was based on bodyweight considerations. The 2001 guidance emphasizes the importance of avoiding overdosing of the fetus and very young child. Of special concern is transient hypothyroidism, which can lead to intellectual developmental deficits. Although deficits have not been reported in neonates treated with KI in Poland after Chornobyl, transient hypothyroidism was reported, and the potential for deficits remains a concern. FDA therefore advises that neonates and pregnant and lactating women be given priority with regard to other countermeasures to reduce radioiodine exposure and thereby obviate repeat dosing with KI. FDA further recommends that those under 1 month old treated with KI be monitored for hypothyroidism and hormone therapy be instituted in the event it develops.

Because the graded dosing recommended by FDA (2001a) may be logistically difficult, FDA has issued further guidance and fact

sheets (FDA, 2001b, 2002, 2003d) indicating that the benefits of KI far exceed the risks posed by overdosing. According to FDA (2002), "the overall benefits of taking up to 130 mg instead of the lower dosages recommended for certain age groups far exceed the small risks of overdosing. However, where feasible, adherence to FDA guidance should be attempted when dosing infants." In discussing overdosaging, FDA (2001b) had provided the caveat that "particular attention should be paid to dosage and duration of treatment in infants and in pregnant women." The FDA (2001a) recommendation for monitoring neonates for hypothyroidism is not repeated in these materials. Indeed, the most recent informational release (FDA, 2003d) does not mention adhering to dosage levels for neonates but stresses "the risks posed by KI are far outweighed by the benefits with regard to prevention of thyroid cancer in susceptible individuals."

In 2001, FDA (2001a) reduced the radiation dose levels that would trigger intervention by about a factor of 5 from the earlier (1982) guidance for neonates, children, and pregnant and lactating women and increased the level for adults over 40 years old. The 1982 FDA guidance recommended thyroid blocking for anyone likely to receive a dose of at least 250 m Gy (25 rad for radioiodine). The 2001 update recommends KI intervention for those under 18 years old and pregnant and lactating women receiving 50 mGy (5 rad) or more and recommends no prophylaxis for those over 40 years old unless they receive 5000 mGy (500 rad) or more.

With regard to KI dosage administration, the 2001 FDA guidance (2001a) differs from the WHO guidance (1999) (see above section on iodine blockade) in two ways. First, FDA recommends a dosage of 65-mg for children 12-18 years old, the same as for younger schoolchildren, so all school-age children would receive the same dosage. WHO recommends 130 mg for children 12-18 years old. FDA indicates, though, that two 65-mg tablets should be given to children approaching adult size. Thus, the guidelines are fairly similar with respect to administered dosage. Second, with regard to the level of radioiodine exposure that would trigger KI intervention, the guidelines differ substantially. WHO (1999) recommends KI intervention for children and pregnant and lactating women exposed to 10 mGy (1 rad) in contrast with the FDA recommendation of 50

mGy (5 rad). That is because FDA found the most reliable human evidence of an effect in the Chornobyl data at child exposures of 50 mGy (5 rad) or more (FDA, 2001a), presumably owing to the absence of population data on doses less than 50 mGy (5 rad) (Leissa, 2003). WHO performed a modeling exercise to estimate risk. Given the WHO (1999) lifetime cancer risk of 1% per Gy for exposed children cited earlier in this chapter, the risk to children at the FDA intervention threshold would be 0.05%, or 5 cancers per 10,000 exposed.

The updated FDA guidance states that KI is optimally effective when taken in advance or coincidentally with the passage of the radioactive cloud but has a substantial protective effect even if taken 3–4 hours after exposure. The guidelines call for continued dosing until the risk no longer exists. The guidelines (FDA, 2001a) go on to say that because timing is of the essence, state and local governments that choose to incorporate KI into their emergency-response plans may consider the option of predistribution of KI to people who do not have a medical condition that would contraindicate its use.

In 2003, FDA issued draft guidance to advise stockpilers on how to extend the shelf-life of KI maintained in controlled conditions (FDA, 2003a).

The Federal Emergency Management Agency (FEMA), now housed in the Department of Homeland Security, is responsible for assessing the adequacy of offsite emergency planning for nuclear-reactor accidents. In January 2002, FEMA issued its revised federal policy regarding the use of KI. The guidance was issued for use by state and local agencies involved in emergency planning and preparedness for accidents at NPPs (FEMA, 2002). The policy states the federal position that KI should be stockpiled and distributed to emergency workers and institutionalized persons, and that its use should be considered for the general public within the 10-mile EPZ. It notes that the decision on whether to use KI for the general public is left to the discretion of the states and in some cases local governments. FEMA questions the need for distribution of KI beyond a 10-mile radius of a facility, and further finds that an interim 20-mile

standard is not needed, and finds the need for a large distribution to respond to a terrorist event questionable.

The Nuclear Regulatory Commission is ultimately responsible for the safety of commercial nuclear facilities in the United States, and it regulates the facilities and the development of on-site emergency plans. For emergency-planning purposes, the commission defines two planning zones around NPPs. The first covers the area roughly up to 10 miles from the facility, called the plume exposure emergency planning zone (EPZ). The second, larger planning zone, the ingestion pathway zone, is larger than the first zone—roughly up to 50 miles from the facility (see Chapter 5 for a more complete description of emergency planning procedures). The commission relies on FEMA determinations that adequate protective measures will be taken offsite in the event of an emergency. On April 19, 2001, the commission amended 10 CFR 50.47(b)(10) to state that a range of protective actions has been developed for the plume (10-mile) EPZ for a commercial NPP, including the consideration of prophylactic KI use as a supplement to evacuation and sheltering. In January 2001, the commission offered states affected by the 10-mile radius criterion an initial supply of KI amounting to two free tablets per resident living within 10 miles of a NPP (Federal Register, 66(13):5427, 2001). On December 20, 2001, the commission sent letters discussing its program to the 31 states that have NPPs (see Table 6.6), to the two states that did not have NPPs but had NPPs within 10 miles of their borders (Delaware and West Virginia), and to one tribe (Prairie Island Indian Community in Minnesota). The commission did not commit to replenishing states' supplies.

Table 6.6 Commercial Nuclear Power Plants in United States[a]

State	Plants
Alabama	Brown's Ferry, Joseph Farley (Dotham)
Arizona	Palo Verde (near Wintersburg)
Arkansas	Arkansas Nuclear (Pope County)
California	Diablo Canyon (San Luis Obispo Co.), San Onofre (San Clemente)
Connecticut	Millstone (Waterford)
Florida	Crystal River (Citrus County), St Lucie (Ft. Pierce), Turkey Point (Miami)
Georgia	Edwin Hatch (Baxley), Vogtle (near Augusta)
Illinois	Braidwood (Will Co.), Byron (Ogle Co.), Clinton (Clinton), Dresden (Grundy Co.), LaSalle County, Quad Cities (Davenport, Rock Is., Moline, E. Moline)
Iowa	Duane Arnold (Palo)
Kansas	Wolf Creek (Coffee County)
Louisiana	River Bend (W. Feliciana), Waterford (Taft)
Maryland	Calvert Cliffs
Massachusetts	Pilgrim (Plymouth)
Michigan	Donald C. Cook (Berrion Co.), Enrico Fermi (Detroit), Palisades (South Haven)
Minnesota	Monticello, Prairie Island (Red Wing)
Mississippi	Grand Gulf (Vicksburg)
Missouri	Callaway
Nebraska	Cooper Station (Brownsville), Fort Calhoun (Omaha)
New Hampshire	Seabrook (Portsmouth)
New Jersey	Hope Creek (Lower Alloways Creek), Oyster Creek (Forked River), Salem
New York	Fitzpatrick (Oswego), Indian Point (Buchanan), Nine Mile Point (Oswego) Robert E. Ginna (Rochester)
North Carolina	Brunswick, McGuire (near Charlotte), Shearon-Harris (Raleigh)
Ohio	Davis-Besse (Oak Harbor), Perry (near Cleveland)
Pennsylvania	Beaver Valley (Shippingport), Limerick (near Philidelphia), Peach Bottom, Susquehanna (Luzerne Co.), Three Mile Island (near Harrisburg)
South Carolina	Catawba, Oconee (Greenville), H.B. Robinson (Hartsville), Virgil C. Summer (Jenkinsville)
Tennessee	Sequoyah (Chattanooga), Watts Bar (Chattanooga/Knoxsville)
Texas	Comanche Peak (Somervell Co.), South Texas Project
Vermont	Vermont Yankee (Vernon)
Virginia	North Anna (Louisa Co.), Surry (near Williamsburg)
Washington	Columbia (Benton Co.)
Wisconsin	Kewaunee (Carlton), Point Beach (near Two Rivers)

[a]Source: Energy Information Agency, Nuclear Regulatory Commission, *Nuclear Power Plants Operating in the United States,* 2001 and request for information responses.

FEMA is available to assist states that decide to predistribute or stockpile KI as a method of preparedness for an accident at a NPP. If a state incorporates KI administration to the general public, FEMA evaluates a state's ability to disseminate KI as embodied in documented plans and procedures, public-information materials, and emergency instructions that must be submitted to FEMA within a year of receipt of KI from the Nuclear Regulatory Commission (Conklin, 2002). The capability to distribute KI tablets to the general public is to be demonstrated by state and local governments that incorporate KI administration to the general public in their plan during the first required exercise "emergency drill" after the submission of plans and procedures. Issues regarding distribution of KI to the general public if incorporated into the plan are to be addressed in the annual letter of certification for the radiological emergency response plan (RERP). The letter is to discuss the number of KI tablets issued or reissued during the previous year.

KI distributed to the states was taken from the Strategic National Stockpile (formerly called the National Pharmaceutical Stockpile), a stockpile of pharmaceuticals and other medical supplies maintained by the Centers for Disease Control and Prevention for rapid deployment in the event of a public-health emergency.

US Postal Service Distribution of KI

After the September 11 terrorist attack and the anthrax mailings, the US Postal Service (USPS) formed the Mail Security Task Force consisting of representatives of postal unions and management associations and of USPS management. A USPS decision to offer KI to all its 750,000 employees (USPS, 2002a, 2003b; APWU, 2002) grew out of meetings of the task force. One consideration in the decision was the Nuclear Regulatory Commission's offering of KI to the states with populations in the vicinity of commercial NPPs. The offering came on the heels of the anthrax mailings and generated much fear and anxiety among postal workers (Reid, 2003). USPS decided to fund a KI distribution program for all its employees and purchased 1.6 million tablets at a cost of 18.3 cents per tablet, or about 37 cents per employee.

The basic USPS KI distribution program (APWU, 2002) involves the distribution and storing of KI tablets at all postal facilities. A safety talk is given to inform employees about the program, to provide information needed "to make an educated decision about whether to take the tablets in the event of a radiation emergency", and to distribute informed-consent forms ("Potassium Iodide Distribution Employee Acceptance Form"). A signature on the form is required to receive KI in a facility distribution conducted in response to a nuclear emergency. The form confirms that the signatory understands that the taking of KI is voluntary and that KI is for his or her own use; it lists the side effects, and contraindicating medical conditions. It also confirms that the tablets are to be held at their work location and distributed when the appropriate notifications have been received in a nuclear emergency.

Purchase of KI by Individual Members of the Public

In late 1978, 3 months before the Three Mile Island accident, FDA announced its conclusion that KI is an effective and safe prophylactic for radioiodine exposures resulting from nuclear emergencies. It also encouraged manufacturers to submit new drug applications for oral forms of KI. These would be used to approve over-the-counter formulations of KI. Since that notice, FDA has approved four KI drugs, two of which are currently marketed and available through the Internet at relatively low cost: one as 130-mg tablets (IOSTAT by Anbex), and the second as 65-mg tablets (ThyroSafe by Recip AB) (FDA, 2003a, 2003d; The Medical Letter, 2002). An oral solution (KI oral solution by Roxane) and an oral tablet product (ThyroBlock by Wallace Laboratories) were approved by FDA but are no longer marketed. FDA and some states (such as Maine and Maryland) make information known to the public on how to purchase FDA-approved KI through their Web sites (see Appendix E). Non-FDA-approved KI is also available through the Internet. The committee did not have information on the extent of KI purchases over the Internet.

Dosaging directions available from the manufacturer on the Internet for the 130-mg tablet formulation follow the 1982 FDA

guidance, and dosaging for the 65-mg formulation follows the 2001 guidance of graded dosing for children of different body size. The 65-mg formulation has cross scoring to enable quartering. One quarter of a 65-mg tablet is the recommended dosage for those under 1 month old.

States

As the responsible party for protecting the public in the event of a nuclear incident, a state must decide whether to obtain KI for distribution, the means of distribution, and other policies regarding KI distribution. Until recently, Alabama, Arizona, and Tennessee were the only states that stockpiled and predistributed KI in the event of an emergency. Maine had had a program that was discontinued with the decommissioning and dismantling of the Maine Yankee power plant. After the September 11, 2001, attack and the Nuclear Regulatory Commission's provision of KI to requesting states, several states began KI distribution programs.

Appendix C summarizes material made available to the committee regarding the distribution programs in different states and information on states that had decided not to distribute KI.

States Without KI Distribution Programs

Several states do not distribute KI, because commercial nuclear plants are believed to be too distant to cause concern or do not perceive KI as an effective supplement to evacuation or sheltering for their jurisdiction (see Table 6.7). In the highly unlikely event of exposure to radioiodine, they would rely on the Strategic National Stockpile (formerly called the National Pharmaceutical Stockpile). Some states that have nuclear facilities within their borders decided not to request KI from the Nuclear Regulatory Commission. The committee heard from some of those states about their plans to protect the public in the event of a radioiodine release.

Table 6.7 States Without KI Distribution Programs for the General Population

No NPPs within or near borders		
Alaska	Kentucky	Oklahoma
Colorado	Maine	Oregon
District of Columbia	Montana	Rhode Island
Hawaii	Nevada	South Dakota
Idaho	New Mexico	Utah
Indiana	North Dakota	Wyoming
NPPs within borders		
Arkansas[a]	Louisiana	Nebraska
Georgia	Michigan	Texas
Iowa	Minnesota	Washington
Kansas	Missouri	Wisconsin

[a]In process of changing policy to distribute to general population.

Several states (such as Texas, Michigan, Kansas) note that prompt evacuation is the only sure means of comprehensive protection from radioiodine and other radionuclide exposures. A resolution recently adopted by the Texas Radiation Advisory Board on the use of KI in NPP emergencies (Texas Department of Health, 2002-2003) articulates issues discussed by other states that have chosen not to distribute KI to the general population:

- Providing KI to the general public is a complex enterprise that involves the timing of administration, the logistics of stockpiling and distribution, and potential adverse reactions.
- KI protects only against radioiodine
- KI provides only partial protection at best. The public is therefore given an unwarranted sense of protection by KI.
- Prompt evacuation gives sure and effective protection.

The practicality with safe and effective distribution of KI on a mass scale, and uncertainty with regard to the benefits were emphasized by Michigan. Georgia noted that the federal program for KI distribution does not cover the substantial administrative costs associated with distribution.

Several states that chose not to distribute KI to the general population have made provisions for protecting of special populations that would be difficult to evacuate. For example, Louisiana, Michigan, and Missouri have plans to distribute KI to institutionalized people or those who would shelter in place. Michigan has made special provisions for providing KI to the homebound public. Some states stockpile KI at facilities that would shelter in place; others rely on postincident distribution to special populations. Rather than develop plans to distribute KI, Nebraska has made provisions for early evacuation of nonambulatory persons.

Several states (Georgia, Missouri, and Nebraska) indicate that KI is available for emergency workers, some through local emergency-operations centers. Some require signature on forms that indicate receipt and briefing on exposure issues; others require that forms be completed when emergency workers ingest KI. Various states reported that during an emergency, the consumption of KI by emergency workers would be voluntary. Some states routinely provide training that include instruction on distribution of KI to special populations and emergency workers and assess the effectiveness of the distribution plan in such training.

Few statistics were available to the committee with regard to total amounts of KI required for emergency workers and special populations. Missouri has distributed 4,000 packets (14 tablets, 130-mg per tablet), and Michigan maintains a stockpile of 3,200 bottles (14 tablets, 130-mg per tablet) distributed among eight local entities for such purposes.

Arkansas provides KI only to emergency workers but is changing its policy. It is considering stockpiling KI at the evacuation centers and making it available to the general population for pickup at local pharmacies, county health units, and other locations on “county KI days”.

Idaho has a test reactor and an associated Fixed Nuclear Facility Emergency Plan but notes that there are no residents within 10 miles of the facility. Emergency workers would use KI; the state is still considering the best means of supplying KI to them. New Mexico also noted that although it had no commercial facilities, it did have some small experimental reactors, but none that operates continuously and none capable of releasing substantial radiation in any conceivable scenario. The state noted the availability of KI through the Strategic National Stockpile in the event of a nuclear incident.

Some states that do not have commercial nuclear plants (Alaska, Colorado, Maine, and Wyoming) noted the possibility of dirty bombs used by terrorists but stated that radioiodine risk from such bombs is extremely unlikely, implying that stockpiling of KI was unnecessary for protection of their residents.

States With KI Distribution Programs

Table 6.8 lists the states with KI distribution programs. Three basic approaches have been adopted thus far for distributing KI to the general public: stockpiling KI for postincident distribution; predistributing KI to the general population via the mail; and a combination of the two. Stockpiling involves collecting and retaining KI at one or more fixed locations from which it is dispensed directly to the potentially affected population in an emergency, or moved to evacuation centers for distribution. Predistribution involves providing KI to the potentially affected population as part of the preparation to respond to an incident. KI can be predistributed to individuals and groups via the mail, voluntary pick-up or door-to-door; making KI available on a voluntary basis to those interested in obtaining it; or a combination of both. All states with predistribution programs, on which the committee had detailed information, also had postincident distribution programs, many of them extensive. KI is supplemental to the primary policy of evacuation in the event of a nuclear emergency, and several states noted the importance of establishing KI programs that did not interfere with evacuation.

Table 6.8 States with KI Distribution Programs for General Population

Stockpile KI for postincident distribution:		
Alabama	Florida	Mississippi
Arizona		
Predistribution (includes stockpiling for postincident distribution):		
California	New Hampshire	South Carolina
Connecticut	New Jersey[a]	Tennessee
Delaware[a]	New York	Vermont
Illinois	North Carolina	Virginia
Maryland	Ohio	West Virginia[a]
Massachusetts	Pennsylvania[a]	

[a]State border within 10 miles of nuclear facility (Delaware, Salem/Hope facility in New Jersey; West Virginia, Shippingport facility in Pennsylvania).

Four states have decided to stockpile KI for postincident distribution (Table 6.9). Each plans full coverage of the population within the 10-mile radius of the NPP. Florida notes that the flexibility of its plan enables coverage of populations beyond the 10-mile radius. All four states plan to distribute KI to the evacuated population at the reception centers. The Alabama plan includes administration of KI under the supervision of physicians and registered nurses; Arizona will provide information sheets to recipients, and public-health nurses and educators will be available to answer questions. Two states with postincident distribution plans, Arizona and Mississippi, have relatively small populations living in the 10-mile EPZ. Mississippi notes that the estimated evacuation time for the entire EPZ is 2.5 h. Effectiveness of postdistribution is evaluated in drills required by

federal oversight procedures, but data on such drills were not available to the committee.

Table 6.9 Tablets for States with Only Postincident-Distribution Programs

State	**Where Stockpiled**	**No. of 130-mg KI Tablets Available**
Alabama	County health departments in vicinity of plants	270,410 on hand; does not cover all people within 10-mile radius of facilities
Arizona	Data not available	7000 for general public, 2800 for emergency workers, 800 for schools
Florida	Near power plants	780,000 for general population
	9 facilities named in FDEM	28,000 for emergency workers, special populations
Mississippi	Data not available	For a population of 10,000

To provide some background on issues that arise with predistribution, the experiences of Connecticut, Tennessee, and Maryland are presented in more detail below. Connecticut predistributed tablets by mass mailing, Tennessee distributed initially by door-to-door delivery and then by a voluntary pickup program, and Maryland by pickup. The various other state predistribution programs are described in Appendix C.

Connecticut

Connecticut completed its application to the Nuclear Regulatory Commission for KI tablets on February 6, 2002, and on March 15 received 450,000 130-mg tablets packaged in individual

foil strips of 14 tablets each. Numerous groups participated in the development of the state distribution plan, including the state's Department of Public Heath, Department of Environmental Protection, Department of Consumer Protection, Department of Education, Office of Policy and Management, Office of Emergency Management, Nuclear Energy Advisory Council, chief elected officials, local health departments, school officials, the state pharmacists association, state legislators, and NPP representatives.

Distribution was conducted in phases. Targets of the distribution included the general population, host communities where KI would be stockpiled, and special populations, such as schools, day-care facilities, nursing homes, businesses, hospitals, prisons, and colleges (see Table 6.10). As a major means of making KI available and accessible in an emergency, the state decided to predistribute by mass mailing in the initial phase. The mailing was also seen as another avenue to inform the public and encourage emergency preparedness. The mass mailing to 68,000 households occurred on October 16 and 17, 2002. The first phase also included predistribution to towns to cover nonresident workers, seasonal and part-time residents, and large households. During the first phase, the state engaged in a mass-media campaign of education that involved newspaper ads and a press conference. Postings were placed on the Department of Public Health's Web site. The physician and pharmacist communities were also involved in this phase, and local emergency-management training was given.

Table 6.10 Distribution of KI Tablets in Connecticut

Route	**No. Tablets**
Mass mailing	268,800
Town surplus	50,000 (5,000 distributed)
Schools	29,000
Colleges	10,000
Hospital	7,800
Prisons	11,116
Nursing homes	12,816
Large businesses	24,358
Local emergency workers	27,300
Military facilities	6,600
Day care facilities	5,600
Host communities	183,176

The second phase targeted schools—public, private, parochial, and charter schools—with outreach to school superintendents and principals and training of school officials. Kits were developed with parental-consent forms, establishment of school procedures, and development of other information material. The third phase targeted identified special-needs populations noted above. Also during phase 3, the state developed procedures for distributing KI to stockpiles in the host communities. An additional 235,000 tablets were purchased by the state for distribution to host communities.

A series of public-information materials were developed to provide basic information about use and side effects, to warn of allergy, and to reinforce the idea that KI protects only the thyroid and that it is to be taken only at the direction of state officials. The information was disseminated in a variety of educational materials: letters to physicians and residents, newspaper ads, press releases and a press conference, a cable television program, and the *Millstone Emergency Planning Guidebook*. The Nuclear Regulatory

Commission issued the tablets with the label "IOSTAT™"—not "potassium iodide" or "KI"—that required additional packaging so that the identity of the tablet was easily recognizable. The state developed a fact sheet, a small envelop to hold and label the medication, and a letter to residents and packaged the mailing in consultation with the US Postal Service. The state decided to provide emergency dosage-administration instructions based on the 1982 FDA dosage guidance: one tablet, or 130 mg, for everyone 1 year old and older and 1/2 tablet, or 65 mg, for children less than 1 year old.

In discussing FDA (2001a), the state (Connecticut DPH, 2003) indicated that "FDA recently provided additional guidance on what is the smallest amount of KI you can take and still protect the thyroid. The smaller amounts may reduce the risk of side effects such as a minor upset stomach or rash. It may not be practical to administer very small dosages during an emergency. If you want to use smaller dosages, the FDA recommends taking the following minimum amount of KI . . ." In answer to the question "Are there any other concerns regarding taking KI", the fact sheet does not mention FDA's recommendations regarding neonates or repeat exposures of young infants and nursing and pregnant women. Connecticut developed its advice after making inquiries of FDA. The state was informed that the FDA (2001a) guidance gave minimum effective dosages and that the higher FDA dosages (1982) were safe.

The Connecticut fact sheet (Connecticut DPH, 2003) suggested that parents check with their pediatricians for appropriate KI dosages for their children. There do not appear to be any specific precautions given regarding exposure to young infants in the materials distributed by Connecticut.

The cost of the distribution was upwards of $172,000, or roughly $0.50 per tablet distributed, in addition to staff time. The supply will expire in March 2007. The state is planning to conduct public-education campaigns annually. It has heard various criticisms regarding its distribution program, for example, objection to mass mailing medication, the delay in distribution (KI was received in March and mailed in October), the idea that one tablet will not be enough in some circumstances, and the idea that coverage of only the towns in the EPZ will not be sufficient in some emergencies.

Tennessee

Tennessee began its program to distribute KI to populations near nuclear facilities in 1981 with a pilot project to assess door-to-door predistribution of KI to households within 5-mile radius of the Sequoyah NPP near Chattanooga operated by the Tennessee Valley Authority (TVA) (Fowinke et al., 1983). The decision to predistribute KI was made after emergency drills that simulated distribution after an emergency had been declared; distribution was found to be too slow to protect the public effectively. Because the pilot door-to-door distribution was expensive, it was replaced with a system of community stockpiles that would be moved to mass shelters for administration to the evacuating population. In addition, since the early 1980s, the Tennessee Department of Health has publicized KI and made it available to those who wished to pick it up and store it at home. That continues, although only about 5% of the population near the facility takes advantage of the offering.

The pilot door-to-door distribution of KI is well described in Fowinkle et al. (1982). It took place from November 16 to December 11, 1981. Thirty-eight employees of county health departments, after a 1-day training session, attempted to distribute KI to the 5,591 households within 5 miles of the power plant. The households were identified from addresses on TVA meter-reader sheets. Those distributing were local health professionals with experience in communicating with the public. They were prepared to answer general questions about the response plan for a nuclear accident. Some 3,022 households accepted the KI at the door. A letter left if residents were not at home indicated that they could pickup KI at two local health centers at specific times on three designated Saturdays; an additional 682 residents availed themselves of this opportunity. A few more residents arranged to pickup KI later. In total, 66% of the targeted households received KI. KI was packaged in a dark clear glass vial wrapped in the manufacturer's package insert. To discourage indiscriminate use, this was placed in a childproof brown plastic vial. The glass vial contained 14 130-mg tablets. Before the distribution, a letter from the commissioner of public health was mailed to the targeted households. News media also attended the training sessions given to those distributing KI. In the expectation

that people would consult their physicians regarding the distribution, a program to inform local physicians through the local medical society was conducted before the distribution. As a partial indication of cost, it took 166 person-days to visit the 5,591 households.

Because of the costliness of the pilot program, a program of stockpiling, supplemented with voluntary pickup, was established in 1983, and it remains in place. The program has been described by Hagstrom (2003). KI is stored at central community stockpiles that are to be distributed to mass shelters in the event of an emergency. At the shelters, it would be administered to the evacuated public by public-health nurses. The Tennessee Department of Health decided not to make KI available to schools or day-care centers, because the facilities would not have health-care professionals available at the time of an emergency to oversee the administration of KI. The plan is to relocate schoolchildren by bus to schools outside the 10-mile radius around a nuclear facility immediately on declaration of an on-site emergency at the power plant.

The amount of KI in the stockpile is sufficient to cover all those living within 2-mile radius of the power plant and 20% of the population living within 2–10 miles. KI is packaged in blister packs of 14 130-mg tablets. Dosages recommended in the 2001 FDA guidelines are to be administered. As part of the communication strategy for the stockpiling program, calendars are mailed yearly to all living within 10-mile radius of the power plant. The calendars contain instructions for parents of schoolchildren, information on evacuation routes and sectors and on a location of shelters, and other information related to NPP emergencies.

Anyone living within 10 miles of a nuclear facility can pickup KI from the few health-department offices near the power plants. The Tennessee Department of Health states that it continues to publish availability of KI for home storage. In the early 1990s about 20% of those affected picked up KI. That proportion has declined, and now only about 5% of those affected pickup KI for their household. Besides information made available in packaging, through calendars, and in publicizing KI availability for pickup, it is planned to have the mass media play a role in advising the public on dosing and possible side effects during an emergency.

Maryland

Information on Maryland's program comes in response to the committee's request for information and presentations by Sharon (2003) and Rogers (2003). In response to the committee's request for information, Maryland emphasized evacuation as the principal means of protecting the public in a NPP emergency. KI is relied on as a supplemental measure when evacuation is infeasible because of weather conditions or an extremely rapid accident.

The state requested KI from the Nuclear Regulatory Commission in January 2002 and began distributing it in the following spring. Maryland opted for a multipronged distribution strategy—predistribution enabling people to pickup dosages at clinics, providing for stockpiles at reception centers in the event of a disaster, and preplacing KI at schools and other facilities, such as senior centers and scout camps. Five counties fall within the 10-mile EPZ, with a total affected population of 85,000. In planning the distribution, the mixed results of past distribution efforts were acknowledged with an understanding that full coverage was unlikely. Distribution of KI is limited to those living and working within 10 miles of the nuclear facility.

To plan the distribution, an ad hoc KI working group was established; it was made up of local health officers, emergency-management directors, and staff in the involved state health, environment, and emergency-management departments. The group considered various distribution options, such as predistribution door to door, voluntary pickup, and mail and post-distribution through reception centers at the time of event. The group decided on voluntary distribution through pickup at scheduled clinics. In addition, a decision was made to place KI at schools and scout camps and other facilities for distribution to students, staff, and others at the facility at the time of the event and also to make KI continually available through local health departments. The decision to take KI would be reached through consensus of local governments and the state health, environment, and emergency-management departments. The public would be notified and instructed through the Emergency Alert System and the mass media.

One of the most effective predistribution programs with respect to reaching residents that came to the committee's attention was that of Calvert County, Maryland. This county, the fastest-growing county in Maryland, has a population of 75,000, with 35,000 residents within the 10-mile vicinity of the NPP. The county relied heavily on the public schools and other facilities for distribution, using school mails to disseminate information to families, health-department mails to inform designated facilities for KI placement, and the local print and television media to alert residents. From April to June, 2002, KI was placed in 97 schools and other facilities for distribution to the public. Five Saturday clinics were held at two high schools to inform and distribute to families that had been identified through the elementary-school network, and two additional clinics were held at the high school and four at the health department for the general public. The public was also encouraged to visit the county health department. Home visits were made to the homebound. KI reached about 24,400 of 35,000 residents living within 10 miles of the Calvert Cliffs NPP: 2,421 households covering some 11,450 people reached by the school framework and about 12,955 people reached via other facilities (a large LNG plant, 65 small workplaces, senior facilities and nursing homes, and day-care centers). Those reached by the school framework received two tablets per person, and those reached through other facilities received one tablet per person. The cost of the Calvert County predistribution program was fairly low, totaling $13,126 for county health-department staff and printing and mailing. That corresponds to $0.55 per person reached.

In response to the committee's request for information, limitations in the plan were noted. The major limitations have to do with resources, which were characterized as "sorely limited". That affects the evaluation and monitoring of the distribution program, the degree of public education and outreach, the general management of the distribution and related programs, and access to people who may not be aware of the program but might wish to obtain KI. It was noted that federal resources, if made available, would best be applied to fund staff to support the plan, assist in distribution, carry out public education and outreach, and evaluate the program. It was felt that additional federal guidance was unnecessary and that local

jurisdictions and states were the best equipped to plan and execute KI distribution because of their familiarity with the affected communities.

Elements of State Distribution Programs

The differing experiences and implementation plans of Connecticut, Maryland, Tennessee and other states (see Appendix C) highlight options and limitations to consider in planning distribution programs, as discussed below.

Predistribution with Postincident Stockpiling. All states on which the committee had detailed information about predistribution programs also had extensive plans for stockpiling and postincident distribution.

Target Population. All states target predistribution efforts to those living in the 10-mile EPZ. The Nuclear Regulatory Commission decision to offer KI dosages to the general public in the 10-mile EPZ no doubt was a dominant factor in producing this uniformity. Some states are evaluating populations beyond the 10-mile radius. States with predistribution programs currently distribute or offer KI to the entire population; age has not been a factor in predistribution of KI, despite the fact that children and pregnant women with fetuses in the second and third trimester of pregnancy are at most risk. States' stockpiling programs also target the general and special populations in the 10-mile EPZ. Some states attempt complete coverage of the entire population that may be present in the EPZ during an emergency, others a specified fraction of those residing in the EPZ (such as Tennessee), while others decided to use the residual KI not distributed in predistribution programs for stockpiling and distribution in the event of an emergency.

Advice on Dosages. The complexity of the public health message that must be given to mitigate overdosages and ensure adequate dosages appears to have contributed to the oversimplified dosages information given by some state programs. Different dosages

messages and advice are used by the states. Some states (such as California, Massachusetts, and South Carolina) recommend dosages at the recent FDA (2001a) guidance levels for minimum effective dosage (see Table 6.11). Others (such as Ohio and New York) found that a scheme of graded dosages would be difficult to implement during a radiologic emergency. Some noted that adherence to the FDA minimum effective-dosage guidance should be followed where feasible, but compliance would be more likely if the simple instruction for two dosages (Dosage Message 2 in table 6.11) were given. Vermont recommended the administration of one tablet to children above 3 years old in such settings as schools, and ½ tablet to those under 3.

Several states appear to be unaware of the important precautions regarding overdosing neonates given in the FDA 2001 guidance (see section above Recommendations from Public Health Institutions in the U.S.). This may result from the interpretative guidance and fact sheets issued by the FDA (2001b, 2002, 2003c); they all emphasize the benefits of KI compared to the risks of overdosage, and none discuss TSH monitoring of neonates after KI dosage, as recommended in FDA (2001a). An example of the confusion in the FDA guidance on dosing is provided above in discussion of Connecticut's distribution program.

Table 6.11 Dosages recommended by States

Dosage Message 1 1 tablet = 130 mg	
Adults 18 years and older	1 tablet
Pregnant or nursing women	1 tablet
Adolescents 12-18 years old	½-1 tablet
Children 3-12 years old	½ tablet
Children 1 month-3 years old	¼ tablet
Infants—birth-1 month old	⅛ tablet

Dosage Message 2 1 tablet = 130 mg	
Children over 1 year old and adults	1 tablet
Children under 1 year old	½ tablet

Number of Tablets to Predistribute. Some states provided two dosages per person, others (such as New York) provided one dosage. One state provided two tablets per individual residing in households identified and reached via schools and one tablet per individual in households reached by other facilities. In this case, a greater proportion of children compared to adults would be expected to have multiple tablets available to them. States stockpile and reserve for post-accident distribution the tablets not predistributed. Inefficient predistribution programs (ones who do not manage to predistribute most of the KI they plan to) following this strategy could be expected to have an adequate supply for a single day of post-distribution. Connecticut, with its efficacious predistribution program, purchased additional KI tablets to ensure adequate supply for stockpile and postdistribution.

Method of Predistribution. The efficacy of the voluntary-pickup predistribution program appears to depend heavily on the methods used, the intensity of community and stakeholder involvement in planning and distributing KI, public-education materials and messages, and mass-media involvement (Table 6.12). The general methods used have included door-to-door distribution (as was done in 1981 in Tennessee), mass mailing of tablets and information on use (Connecticut), request by mail after mass mailing (California), formal application for KI via a mailed application (some involving an informed-consent form), and pickup at identified locations in the community on particular "KI days." Some states routinely provide residents information on the predistribution and make KI available to persons moving into the EPZ after the initial distribution.

States' programs of voluntary pickup by residents at specified locations generally resulted in distribution to no more than 5% of residents. In addition to the door-to-door distributions of Tennessee in the early 1980s, other means appear to have been effective. KI reached 2/3 of the effective population in a program involving mass mailing accompanied by publication and public education effort, and a well-orchestrated distribution through schools and local facilities (Calvert County, Maryland).

Table 6.12 Coverage of Some Predistribution Programs

State	Predistribution Method	Coverage Statistics
California	Mass mailing of brochures including postcard to request KI; mass-media campaign	KI distributed to 31.7% residents ordering
Connecticut 450,000 tablets[a]	Mass mailing of tablets	High
Illinois 360,000 tablets	KI made available for residents to pickup at distribution stations	6% of eligible population requested KI
Maryland Other counties	Predistributed to local residents through clinics; continuing distribution through local health-department offices	State estimates that 25% of eligible population obtained KI
Calvert County	Voluntary pickup; distributed to general population through schools, workplaces, other facilities	70%
New Hampshire 350,000 tabletes[a]	Requires submitting application available at town halls, and health-department offices, over Internet	3.5%
New Jersey 722,000 tablets[a]	KI made available at designated locations via "public education and distribution" sessions	About 10%
New York 1.2 million tablets	Distribution varied by county; provided locations for pickup, pickup via mail	15% of population in EPZ
North Carolina 750,000 tablets[a]	Voluntary pickup	35% of public picked up tablets
Ohio	Mass mailing of information letter with coupon for KI pick-up; mass-media campaign	40% of amount received was distributed
Pennsylvania for 640,000 people	Voluntary pickup	About 34%
Tennessee	Voluntary pickup	<5%
Vermont	Application required for distribution	<5%

[a]Tablets requested.

Predistribution to Schools and Workplaces. States have varied in their approach to predistribution and requirements of consent forms for postincident administration of KI at day-care facilities, schools, and workplaces. Some leave it to school districts and workplaces to design programs for distribution. Others have standardized education materials, methods for distribution, and consent materials.

Education and Communication Strategies. Distribution programs with extensive public education and use of mass media appeared to be much more effective than those without. Structuring, implementing, and sustaining a public-awareness campaign appear to be necessary elements of a predistribution program.

Provisions for Special Populations Difficult to Evacuate. One state has plans for early evacuation of nonambulatory residents. Several states have plans to administer KI and to shelter in place at prisons, hospitals, and nursing homes. One state routinely identifies the homebound and has plans for distributing KI to them. Morbidity and mortality associated with evacuating segments of special populations were important considerations in state decisions on strategies for their protection.

Packaging and Labeling of KI Tablets. Because the tablets are issued by the Nuclear Regulatory Commission in blister packages of 14 tablets each, repackaging for distribution is necessary. Information with the packages can include the identity of the drug, the dosage, and precautionary messages. The Commission makes tablets available to the states in amounts of 130 mg, which may in an emergency make it more difficult to achieve accurate dosage of small children. An FDA-approved 65-mg KI tablet with cross scoring is available. This enables the tablet to be quartered. One-quarter tablet is the dosage required for a young infant.

It has been a challenge to provide with sufficient clarity the rather complex notion that the very young are very sensitive to the radioiodine exposure, that it is essential that they receive a sufficient dosage, and that it is important not to overdosage, because of risks to

normal growth and development. The additional message for full disclosure is that although taking KI will reduce the risk of thyroid disease, it will not protect against the radiation effects of other radioactive materials released with the radioactive iodine. States would clearly benefit from research to ensure that such messages are given in a manner that would lead to the desired outcome.

Number of Tablets to Stockpile for Postdistribution. Some states merely stockpiled tablets that were not retrieved by the public in the predistribution. Other states set aside a specified number per person, and at least one purchased for post distribution tablets beyond those given by the Nuclear Regulatory Commission.

Means and Circumstances of Advising the Public to Take KI. All states on which such information was available refer to the triggering dosage levels given in the FDA guidance. Some that have predistributed KI will advise the public to take KI at the same time that emergency workers in the EPZ are given word to ingest the tablets. If KI is to be provided at evacuation or reception centers, several states have information sheets for advising the public of adverse reactions and dosages. Some states will administer KI under the supervision of physicians and registered nurses. Others will have other public-health professionals available to answer questions.

Distribution Postincident from Stockpiles to Reception Centers and Shelter in Place Locations. Issues to be considered include the number and placement of stockpiles with respect to where they will be needed in a nuclear incident.

Restocking and Resupply. Few states have in place plans for resupply when official or actual shelf-life expires. The Nuclear Regulatory Commission has made no commitment to resupply states. If needed in the days after a major incident, resupply is dependent on the Strategic National Stockpile.

Conclusions

In the United States and internationally, iodine blockade is supplemental to evacuation and sheltering in place, and this is appropriate. Because KI is most effective when taken within a few hours of exposure to radioiodine, predistribution programs are used extensively. Some states do not have distribution programs and rely on evacuation for protection. The committee did not review the relevant information to conclude whether, in the event of a serious incident, rapid and complete evacuation could be accomplished for sites without rapid access to KI, but it notes the need for such an evaluation.

Local, rapid access to KI is accomplished through stockpiling and predistribution. Predistribution to residences alone is not sufficient to protect the public, and local stockpiling appears to be a part of all local KI distribution programs. Because of low coverage and inadequate education, some predistribution programs offer little more protection than a stockpiling program, although these ineffective programs do provide a "right to have" KI even though few decide to obtain it. Several states had predistribution programs that reached less than 10% of the affected population. Voluntary pickup programs reach more than 50% of the general population only if there is active community involvement. Door-to-door delivery appears more effective, but can be costly. With mass mailing, greater coverage can be obtained, especially when it does not involve completion of request forms. It may be, though, that fewer recipients of mass mailings will be able to retrieve stored KI in an emergency. The fraction of residents recalling where they have stored KI, say, 2-3 years after obtaining it and how this might be related to the method of distribution and public-information campaigns have not been adequately studied. Even with the most efficacious predistribution programs, well-developed programs for local stockpiling and postdistribution are required to ensure protection.

The Nuclear Regulatory Commission offered KI coverage for those working and living within the 10-mile EPZ, and all local distribution programs in the United States are designed for this coverage. Geographic features and weather conditions vary

substantially among NPPs and alternative coverage areas might be preferable. These could be based on analyses to evaluate the populations that may be at significant risk from radiation exposures under different release scenarios and on the related contours to circumscribe the area associated with that risk. It would also aid in consideration of whether more-detailed planning of KI distribution to populations beyond the 10-mile EPZ is warranted. Furthermore, such analyses would provide the states and communities a framework for considering alternative intervention and significant risk levels. FDA recommends intervention with KI administration at 50 mGy (5 rad) exposure to children; at this level, FDA determined that radiation-induced cancers were not observed to be increased in the Chornobyl population. Using the WHO dose-response analysis, 50 mGy (5 rad) corresponds to a risk of five thyroid cancers per 10,000 children exposed. Some states may wish to afford a different level of risk protection to potentially exposed populations.

FDA's messages regarding advice on dosages are not uniform. The current guidelines, interpretive guidance, and approved labeling of KI differ, and considerably different messages have been developed by states to provide advice and procedures for KI administration. Precautions regarding overexposure of neonates and follow-up monitoring of the very young for hypothyroidism once KI is administered are not given by some states. Different messages are also given for populations that may be sensitive to iodine. A consistent set of advice from FDA regarding adequacy of messages to protect the public from the risks of overexposure but to encourage adequate dosage is needed. The difficulty of providing complicated messages to effect optimal behavior under emergency conditions is recognized. In this regard, research would benefit the states in the development of effective education and mass-media strategies and benefit FDA and the states in developing packaging and labeling messages.

Several states' distribution efforts were hampered by the limited support given for distribution programs by the Nuclear Regulatory Commission. Many states noted that they did not have sufficient funds for resupply and stockpile, which the commission has

not committed to support. For some states, decisions on whether to use KI and how to use it also appear to depend on federal funding.

7

PROCESS FOR EVALUATION OF OPTIONS FOR DISTRIBUTION OF POTASSIUM IODIDE

This chapter first discusses the responsibilities for distribution of KI at different government levels and then presents an example with sample plans and multiple objectives for evaluating plans. (A decision-analysis method that could be used by local authorities to quantify the performance of plans on multiple objective is presented in detail in Appendix D.) The chapter concludes with a discussion of implementation issues.

The previous six chapters of this report have presented evidence to address the following key questions:

- Is there a risk of a nuclear accident releasing radioactive iodine and causing ingestion/inhalation by vulnerable people?

Depending on local conditions surrounding nuclear power plants, there will be some very rare scenarios in which vulnerable members of the general public could inhale radioactive iodine. We assume that

food and milk sources will be controlled, so ingestion of radioactive iodine will be very unlikely.

- Is KI effective in preventing the risk of thyroid cancer after a nuclear incident?

Yes, taking stable iodine (in the form of KI) within a few hours before or after exposure to radioactive iodine through inhalation or ingestion of fallout will protect the thyroid from thyroid cancer caused by such exposure in vulnerable populations. See Chapter 2 for thyroid physiology and Chapter 4 on stable iodine prophylaxis.

- Who should take KI when an accident occurs?

The most vulnerable people are the young. It is most important for KI to be taken by children, infants and pregnant and lactating women (to protect fetuses and breast-feeding infants). See Chapter 2.

- What is the radiation exposure intervention level at which KI or other protective measures should be taken?

We recommend that KI prophylaxis be ordered if there is likely to be an avertable cumulative radioiodine dose of 50 mGy (5 rad) to children's thyroids. See Chapters 2 and 5 for discussion of different agencies' recommendations on radiation dose thresholds beyond which protective actions should be taken. We also recommend that this threshold for intervention be kept under review as further information on the consequences of exposure to radiation from fallout from Chornobyl and from other radiation incidents becomes available. See Chapter 6 for radiation dose levels used in other countries.

- Is KI safe?

Yes, in general. Relatively small numbers of people should not take KI, including those with some pre-existing thyroid conditions, iodine allergies, and some other rare medical conditions. Thyroid conditions tend to occur after the age of 40 years. See Chapter 2. It is important to avoid overdosage of the fetus and the very young child, by following the 2001a FDA guidelines. When KI is given to infants

under one month of age, FDA guidance for monitoring for hypothyroidism should be followed. See Chapter 6.

- Does the terrorist threat add significantly to the risk beyond that with an accident?

The terrorism threat does not appear to add significantly to the risk, because of existing safety mechanisms and procedures. See Chapters 3 and 5.

In summary, KI is effective and generally safe. Nuclear power plants in the United States contain a source of radioactive iodine that, in the event of a very rare severe incident, might impose risks of exposure to radioactive iodine via inhalation and ingestion in the vulnerable population, which could lead to thyroid cancers. Given that KI is effective in protecting against thyroid cancer, KI distribution plans should be considered.

A general process for evaluating the advantages and disadvantages of different types of KI distribution plans, given the specific features of a local region, is presented in this chapter. It allows us to address the following questions:

- Should KI be predistributed to individuals or households around NPPs? If so, within which geographical area should it be predistributed (that is, a 10-mile or a 20-mile radius or some other area)? If not, what are the other options, and on what grounds should decisions be made?

For each nuclear power plant, there is specific information on population size, ages, and location, geographical and meteorological conditions, evacuation routes, and resources available. This information can be used for quantitative analysis to aid planning in a specific region. Since the committee was not charged to carry out quantitative analysis of health risks and emergency plans at specific plants, such detailed analysis is beyond the committee's scope. The general method presented here and in Appendix D could be used for such site-specific quantitative planning.

Responsibilities for Distribution of KI at Different Government Levels

In general, emergency preparedness requires coordination between federal agencies and state and local authorities, both during responses to an incident and in making preparedness plans. Decisions and planning actions regarding KI made at different government levels need to be coordinated.

In planning related to KI, it is important to keep in mind that its timely use reduces only the radiation exposure to the thyroid gland. That is important because it does not protect the rest of the body from radioactivity. Accordingly, KI is a *supplementary measure* to the primary options of evacuation and sheltering.

Federal Level

At the federal level, information and resources have been and could be provided for KI distribution in the event of a nuclear incident. Various agencies (including the FDA, the Nuclear Regulatory Commission, FEMA, and the Environmental Protection Agency) have issued guidelines regarding KI, as discussed in Chapter 6.

Potassium Iodide Distribution Before Incident

As described in Chapter 6, the Nuclear Regulatory Commission made a one-time offer to provide a supply of KI tablets to states to be made available to populations near NPPs. States accepting KI were required to develop and submit a plan within a year after receiving the KI for how it would be distributed (to people or stockpiles) in advance of an incident. The Nuclear Regulatory Commission provided only the KI, not resources for funding its distribution or for related communication or education campaigns. When the KI that was supplied reaches its expiration date, states might request resupply from the Federal Government, although no

offer to resupply KI has been made. The KI provided by the Nuclear Regulatory Commission did not come from the Strategic National Stockpile (formerly called the National Pharmaceutical Stockpile), maintained by the Centers for Disease Control and Prevention (CDC).

Potassium Iodide Availability at Time of Incident

A federal-level option is to use the potassium iodide which is included in the formulary of the CDC Strategic National Stockpile (SNS) for rapid deployment of KI to the affected part of the country in the event of an incident. The Department of Homeland Security is responsible for deploying the SNS. Day-to-day pre-emergency management of the SNS is overseen by Department of Health and Human Services, which deploys CDC to carry out the task. See the CDC Web site www.bt.cdc.gov. Two general approaches are available:

- *Stockpiling KI in Vendor-Managed Inventory.* The vendor-managed inventory for the SNS has KI in it. Vendors are responsible for managing and restocking these inventories. This allows shipments of packages with just KI or any other incident-specific items that are needed within a day, or perhaps sooner. A modification of current procedures might be possible to ensure even quicker delivery of KI, in the very unlikely event that it would be needed.

- *Stockpiling KI in 12-Hour Push Packages.* KI could be added to all SNS push packages, which are prepackaged with a set of supplies useful for a variety of disaster incidents. The push packages will reach the incident area first, by air to the nearest safe airport or ground transport within 12 h of the incident. KI is relatively small, so many dosages could be stored in a relatively small space.

After the September 11th World Trade Center disaster, a push package reached its New York City destination in 7 hours, and 60 loads of vendor-managed inventory packages began to arrive within 12 hours. Federal-level stockpiling provides the possibility of restocking of local stockpiles in the days after an incident if fallout exposure persists. This might also provide protection in an extremely unlikely incident away from a NPP facility or in the event of a somewhat more likely but still rare spread of a radioactive iodine plume far from a NPP if the general public is not evacuated.

State and Local Levels

State and local authorities have different specific responsibilities and authority in different locales. Two general approaches for distributing KI are stockpiling in local areas near NPPs but outside the EPZ and predistribution to people within the EPZ. As discussed in Chapter 6, some authorities have determined that KI is not needed for the public, because prompt evacuation is feasible for the entire nearby population except emergency workers, plant workers, and non-mobile special populations. Others combine evacuation plans with KI predistribution. A key decision, if KI distribution is deemed needed, is what type of distribution (stockpiling or predistribution) to use in each area surrounding each plant. Chapter 6 contains details of what decisions different states and other countries have made on predistribution areas and delivery. The next section discusses local distribution options in more detail.

Local Area Potassium Iodide Distribution Options

For optimal benefit, KI should be administered to the potentially affected populace just before, concurrently with, or within a few hours after exposure to radioiodine. (Note that we are focusing on the threat posed by *inhalation, not ingestion.* We assume that sufficient controls and procedures are in place to eliminate dangers

posed by *ingestion*. See Chapters 2 and 5.) In light of the stringent timeline, there are two primary options around fixed nuclear facilities: predistribution and stockpiling.

Predistribution

Predistribution involves providing KI to all or segments of the potentially affected population as part of the preparation for responding to an incident. The principal modes are: direct distribution to individuals or groups, making KI available on a voluntary basis to those interested in obtaining it, and a combination of the two. The main advantage of predistribution is the potential immediate availability of KI to the affected population at the time of an incident and in a time span when it can do the most good. However, predistribution raises a number of questions:

- How will distribution occur? Some states have mailed KI to households. Others have used public officials to distribute KI door to door. Still others have instituted voluntary programs that publicize the availability of KI at such locations as county health offices, government agencies, and local pharmacies. Table 6.12 in Chapter 6 shows states' experiences with distribution methods and success in reaching target populations. Voluntary programs have rarely exceeded 50% participation by the potentially affected population.
- Where will it be distributed? For example, some plans predistribute to all households in the 10-mile radius EPZ around a plant. The size and location of the geographic area should be determined based on the projected averted radioiodine dose (and subsequent morbidity or mortality), see Chapter 4. The aim should be to have KI available for the vulnerable population that the state predicted would be exposed to 50 mGy (5 rad) or higher committed dose equivalent to the thyroid during an incident after other protective actions had been implemented.

- How will those receiving KI be instructed in its purpose, proper storage, and use, including instruction that evacuation should not be impeded by attempts to locate the tablets?
- What assurance is there that people will be able to find the KI when it is needed?
- What resources are needed for a predistribution program?

Stockpiling

Stockpiling involves collecting and retaining KI at fixed locations, usually outside the designated EPZ, from which it is dispensed to the potentially affected population before, concurrently with, or immediately after actual or expected release of radioactive iodine into the atmosphere. Its advantages are increased certainty of the availability of KI to the affected population (those individuals who were not in the EPZ, individuals evacuated from the EPZ or individuals impacted beyond the EPZ), better control of its administration, and better recordkeeping. However, as a method of distribution to the general public, stockpiling does not work well in the relatively rare instances in which evacuation would be impractical, undesirable, or delayed. Associated issues include the location of the stockpiles and the resource requirements for a postincident distribution program, particularly in light of the short period during which KI is to be administered.

Sample Plan Options

There are tremendous regional differences in geography, population density, meteorological conditions and other characteristics related to NPPs. Thus, it is preferable for each local area to develop specific plan options and evaluate them on the basis of how well they meet their objectives in light of the area's characteristics (such as population size, ability to evacuate the entire affected population, and risk of radioactive iodine exposure). Table 7.1 contains four sample options for KI distribution plans. The list is not comprehensive; see Chapter 6 for the large variety of actual plans.

Local areas would need to augment the plans with specifics about reaching special populations and communication and education plans. Specific details that would need to be included in a plan are discussed at the end of this chapter, under implementation issues.

Table 7.1 Four Sample KI Distribution Plans[a]

MM:	Predistribute KI tablets inserted in mass mailing to households in KI planning zone (KIPZ); additional stockpiles at reception centers
VP:	Predistribute to individuals in KIPZ via Voluntary Pickup; additional stockpiles at evacuation reception centers outside KIPZ
RC:	Stockpile at evacuation reception centers outside KIPZ
ND:	No distribution of KI

[a]It is assumed that emergency workers are covered under pre-existing plans for the plant site; that each plan will stockpile for special populations (may include schools, day-care centers, prisons, nursing homes, hospitals, and major employers) that are difficult to move; and that there will be resupply from the federal Strategic National Stockpile.

Objectives to Consider in Evaluating Plans

The overall goal of a KI plan is assumed to be this:

> To ensure the availability of KI to the vulnerable population soon enough to be effective in incidents with a potential or actual release of radioactive iodine into the atmosphere.

Local areas should establish their own objectives to be used in evaluating their plans. Keeney (1992) provides guidelines for constructing objectives for evaluating decision

options. Objectives should specify the preferred direction for improved performance (for example, to minimize panic and anxiety). In some situations, it may be useful to characterize the objectives of different stakeholder groups (Winn and Keller, 1999, 2001). For example, Keeney, Renn, and von Winterfeldt (1987) constructed an objectives hierarchy for the former West Germany's energy supply by combining objectives of multiple stakeholders with divergent views.

Table 7.2 contains typical objectives that may be used by state or local officials in evaluating plans. The presence or importance of each objective may vary from one region to another because of specific features of the local situation. For example, it may be important to make sure that special nonmobile populations have access to KI, but an objective of covering special populations may not be included if this population will be dealt with by a separate stand-alone plan. For a specific region, it may be that evacuation could be complete within 24 h in all scenarios, so ensuring multiple-day supplies of KI in homes would not be a planning objective. Also, objectives might explicitly include minimizing mortality and morbidity due to radioiodine exposures to thyroids.

Table 7.2 Objectives for Evaluating Plans

A. Minimize Radioactive Iodine Risk to Thyroid
a.1. Maximize KI availability (measured by coverage of KI now, and after any planned distribution)
a.1.1. For children and pregnant women residents (including at home and not at home)
a.1.2. For other residents (including at home and not at home)
a.1.3. For mobile population
a.2. Optimize ability to take KI on time
a.2.1. Number of people who know where KI is
a.2.2. Optimal time if no evacuation (not too early; KI accessible at time of incident)
a.2.3. Optimal time if evacuation (not too early; KI accessible at time of incident)
a.2.4. Storage to ensure stability
a.3. Minimize harm from inappropriate KI administration
a.3.1. Correct dosage given (and taken) for age
a.3.2. First dosage not taken too late (avoid possible increase in thyroid risk)
a.3.3. Adverse side effects (non-thyroid cancer) minimized (in healthy people, thyroid patients, and those with iodine allergies)
B. Minimize Harm from Other Aspects of Incident
b.1. KI procedures don't impede evacuation
b.2. Avert mortality and morbidity from radiation or accidents (beyond thyroid risks)
b.3. Minimize panic and anxiety due to KI procedures
b.4. Avoid excessive resources use in KI procedures
b.5. Simplify KI procedures before and during incident
b.6. Educate public to respond to nuclear incident

Once a set of alternative plan options is developed, their performance can be evaluated, and advantages and disadvantages of the plans can be identified. For example, residents may all be told to store predistributed KI tablets in a specific safe place. The advantage would be that they could help each other to remember where the tablets are stored. The disadvantage is that in the disaster people might panic and "borrow" (steal) from each other because they would know where the tablets would be.

The performance of a KI distribution-plan option may be evaluated according to the objectives by using descriptive text or a 0-10 scale, where 10 is best and 0 is worst. Appendix D contains a sample set of scales to evaluate performance on the objectives in Table 7.2.

If an option appears dominant on all objectives, it should be seriously considered for implementation by decision-makers. However, it is likely that no plan option will be dominant on all objectives. The relative importance of objectives may need to be examined in more depth by assigning importance weights. By convention, weights are normalized to sum to 100%.

The overall value of a plan can be computed by multiplying the weight of an objective by the rating of the plan's performance on the objective, and then summing the products over all objectives. The plan with the highest overall value would be the one recommended. The evaluation template in Table 7.3 shows the format for such an evaluation. This multiple-objective evaluation approach has been used widely, for example, in evaluating Los Angeles Unified Schools desegregation plans (Edwards, 1979, 1980) and Mexico City airport siting (Keeney and Raiffa, 1976), and the merger of two professional societies in operations research and management science (Keller and Kirkwood, 1999).

Table 7.3 Plan Evaluation Template

		Description of How Well each Plan Meets Each Objective (Rate from 0 to 10 = best)			
	Importance Weights (Sum = 100%)	MM: Predistribute in Mass Mailing in KIPZ	VP: Predistribute via Voluntary Pickup in KIPZ	RC: Stockpile at Evacuation Reception Centers outside KIPZ	ND: No Distribution of KI
Minimize Radiation Health Risks to Public					
A. Minimize Radioactive Iodine Risk to Thyroid					
a.1. Maximize KI Availability					
a.1.1. For children and pregnant women residents					
a.1.2. For other residents					
a.1.3. For mobile population					
a.2. Optimize Ability to Take KI on Time					
a.2.1. Number of people who know where KI is					
a.2.2. Optimal time if no evacuation					
a.2.3. Optimal time if evacuation					
a.2.4. Storage to ensure stability					
a.3. Minimize Harm from Inappropriate KI Administration					
a.3.1. Correct dosage given (and taken) for age					
a.3.2. First dosage not taken too late					
a.3.3. Adverse side effects (nonthyroid cancer) minimized					
B. Minimize Harm from Other Aspects of Incident					
b.1. KI procedures don't impede evacuation					
b.2. Avert mortality and morbidity from radiation or accidents					
b.3. Minimize panic and anxiety due to KI procedures					
b.4. Avoid excessive resources use in KI procedures					
b.5. Simplify KI procedures before and during incident					
b.6. Educate public to respond to nuclear incident					
OVERALL VALUE (SUMPRODUCT OF WEIGHTS TIMES RATINGS)					

Note that a plan may combine a number of mechanisms for ensuring redundancy in the KI distribution, such as mass mailing plus voluntary pick-up. Such a plan could be evaluated with this evaluation template, as could plan variants that considered different sizes of geographical areas for direct predistribution of KI.

When considering different geographical areas for predistribution of KI, plume dispersion models could be used to examine how far and how fast the radioactive iodine fallout might spread, as discussed in Chapter 4. When considering predistribution of KI compared with stockpiling at reception centers, as the distance from a plant increases, decisive factors will likely be 1) decreasing likelihood of potential exposures given increasing amount of time available to evacuate prior to plume passage and 2) increasing resources needed to predistribute KI to a larger region.

Appendix D contains an illustration of the process of evaluation that a local region could go through. The four generic distribution plans presented above in Table 7.1 are evaluated against the objectives above for a hypothetical plant site. The purpose of this exercise is to demonstrate a process, not to identify the best generic one-size-fits-all approach. It also demonstrates that different regions might choose different plan types, depending on regional characteristics and weights of objectives.

Implementation Issues

A number of specific details should be considered in developing a KI distribution plan**.**

Who Advises the Population To Take KI, and Under What Circumstances?

Disaster management officials in each state or locale will need to predetermine who will advise the public to take KI and the expected radioactive iodine dose at which vulnerable persons will be ordered to take KI if they will be remaining in an area where exposure

may occur or has occurred. The officials will also tell the public when to stop taking KI.

See Chapter 2 for discussion of the scientific evidence supporting radioactive-dose thresholds. Table 2.4 contains our recommendation to administer KI to the vulnerable population when the predicted avertable dose to the thyroid in that group due to radioiodines reaches the threshold of 50 mGy (5 rad). Table 6.2 in Chapter 6 contains different thresholds used in different countries.

What Number of KI Dosages Should Be Issued and Stockpiled for Each Type of Person (Children, Pregnant and Lactating Women, Teenagers, and Young Adults)?

See Chapter 6 for the number of tablets issued or stockpiled for different groups of people at different locations. Table 2.4 contains guidelines on the amount of KI tablets (or parts of tablets) of different sizes to take for different ages. See also Chapters 2 and 5 for related discussion on the need for simplicity in dosing instructions and confusion about old and new FDA guidelines.

Education and Communication Plans

The plan should include structuring, implementing, and sustaining a public-awareness and education campaign to support a predistribution program (if there is one) and to inform people about the use of KI and radiation risks.

For more information on communication considerations, see *Improving Risk Communication* (NRC, 1989), in particular Chapter 6, "Problems of Risk Communication", and Chapter 7, "Recommendations for Risk Communication":

> "Risk communication requires its own specialized expertise and deliberate planning and evaluation. Senior managers need to devote attention and time to managing risk communication efforts per se. It is a mistake to simply consider risk communication to be an add-on activity for

> either scientific or public affairs staff; both elements should be involved. There are clear dangers if risk messages are formulated ad hoc by public relations personnel in isolation from available technical expertise; neither can they be prepared by risk analysts as a casual extension of their analytic duties [NRC, 1989, p. 148].
>
> Both the management of the process of formulating risk messages and the content of the messages should be systematically oriented to the intended audience…the best procedures for formulating risk messages have been those that elicited recipients' perceptions and needs" [NRC, 1989, p. 148].

Of special concern is the effect that communication in a KI predistribution program might have on the public's psychological reactions. It might be that predistribution of KI will raise fears of nuclear incidents, even though it is intended to decrease risks. Conversely, it is possible that KI might be erroneously seen as a "magic bullet" against all radiation risks, making all other risk-reduction steps wrongly perceived as unnecessary.

See Appendix E for examples of materials used in communicating with the public about KI and for informed-consent forms and response forms used for brief two-way communication. The message to be conveyed to the public, to public-health workers, and to others will need to cover many details. For example, in the event of a nuclear incident, people should take a specific amount of KI (for children, tablets can be broken into fourths or halves). Increased amount of KI should not be taken in the mistaken assumption that if a small amount is good for protecting your child or yourself, larger will be better; and taking KI will reduce your risk of thyroid disease but will not protect you from the radiation effects of other radioactive materials released with the radioactive iodine.

Plans for Special Populations

When people are in schools or other institutions (such as day-care centers, prisons, and hospitals), extra procedures may need to be planned. Institutions with the most vulnerable populations (children and pregnant and lactating women) should consider having stockpiles of KI onsite with distribution permission slips from parents of children. Professionals who provide services to children might develop specialized programs for distributing KI and information, such as pediatricians and infant services. Methods may need to be developed for tracking which institutionalized persons have taken KI. For example, if schoolchildren are given KI at school and then sent home, they might be given a sticker on their shirt or a mark on their hand so that their parents or emergency workers do not give them a second dosage. This would also give workers a quick way to make sure that everyone who should be given KI is covered. Populations that are hard to move, such as those in jails or hospitals, may need KI on site for multiple days of sheltering, especially if they include vulnerable people.

Restocking and Resupplying

Plans for restocking should be made in case the official or practical shelf-life of KI expires. It would be appropriate for the Federal Government to provide the required resources to support restocking. Plans should also include sources for resupplying—from the Strategic National Stockpile or other sources—in the days after a major disaster.

Legal and Liability Issues

Legal constraints and liability concerns may vary from state to state and should be considered in plans. Communication materials may be designed to limit liability. For example, Vermont had informed consent forms that public-health nurses instructed people to sign if they accepted predistributed KI tablets. Written parental

consent for schools to administer KI to children, in the event of an emergency, and if advised to do so by the appropriate public health authority, would appear advisable.

Resources and Opportunity Costs

Plans should determine the resources needed for KI distribution and consider the opportunity costs of forgoing other emergency or health activities when resources are devoted to KI distribution. The benefit of KI administration should be weighed against the costs.

Evaluation and Tracking System

Plans should include setting up an evaluation and tracking system to evaluate the effectiveness of predistribution programs before and after an incident. For example, the percentage of people who know where their predistributed tablets were could be tracked after 1 year, 3 years, and 5 years. The mobility of the population in the vicinity of a plant could be examined to determine how often new tablets should be predistributed.

National Registry

A national registry should be developed to be activated in the event of an incident for tracking radioactive iodine exposures (including airborne release concentrations, contamination levels in food and drink and measured thyroid radioiodine levels in individuals) and the extent of use of KI as a preventive measure (including date and time taken and dosage vs. time of release or exposure to radioiodine) and for evaluating long-term health outcomes. This would allow accumulation of greater knowledge that would be helpful in later planning.

8

CONCLUSIONS AND RECOMMENDATIONS

From the data presented in this report, it is apparent that exposure of susceptible populations to radioiodine from a radiation incident poses an increased risk of thyroid cancer and other thyroid conditions. It is also clear that KI is a useful agent for protection against thyroid-related health effects of exposure to radioiodine. However, evidence is sparse or absent on a number of important issues related to KI distribution and radioiodine exposure. Most important, there is a need for more-effective KI distribution and predistribution strategies and methods that ensure timely availability of KI to appropriate populations in the event of a radiological incident involving radioiodine. Further studies of the influence of perceived risk on public reaction to various KI distribution programs could inform decisions about whether and how most effectively to provide KI to appropriate populations. In addition, a number of issues related to disease risk posed by radioiodine exposure after a radiological incident need further study. Subjects of particular need include the

effect of dietary iodine in modifying the carcinogenic risk posed by radioiodine; the type, frequency, and clinical course of thyroid tumors in those exposed to radioiodine as children; the risk of thyroid carcinogenesis in adults exposed to radioiodine in fallout; the risk and mechanisms of autoimmune disease and hypothyroidism after radioiodine exposure; and the risk of tumor development at other sites after radioiodine exposure.

On the basis of information presented in this report, the committee concentrated on three main subjects for assessing the five issues posed in the statement of task: risks and benefits of potassium iodide distribution; implementation issues related to potassium iodide distribution and stockpile programs; and additional research needed. A summary of the background and rationale is provided for each recommendation, and the text is organized to present the link between the various elements of the committee's charge and the findings and recommendations.

Benefits of and Risks Posed by Potassium Iodide Distribution

On the basis of its assessment, the committee reached the following conclusions and offers a number of recommendations.

Conclusions

Conclusion 1: Exposure of susceptible populations to radioiodine from a radiation incident increases the risk of thyroid cancer and other thyroid disorders.

Radioactive iodines (radioiodines, such as ^{131}I) are produced during the operation of nuclear power plants (NPPs) and during the detonation of nuclear weapons. Radioiodine is one of the contaminants that could be released into the environment in the event of a radiation incident that involves a disruption of the integrity of the fuel assembly and containment structures of a nuclear power plant (NPP), because of an accident or terrorist activity. Because iodine concentrates in the thyroid gland (it is essential for the synthesis of

thyroid hormones) and because the thyroid cannot distinguish between radioactive iodine and nonradioactive iodine, exposure to radioiodine by inhalation of contaminated air or ingestion of contaminated milk or other food can lead to radiation injury to the thyroid, including increased risk of thyroid cancer and other thyroid diseases. The risk of thyroid cancer resulting from exposure to radioiodine is strongly age-related; fetuses, infants, and children are at highest risk. Fetuses are at risk through their pregnant mother's exposure and breast-feeding infants are at risk through breast-feeding milk from their exposed mothers, or through inhalation or ingestion from another source. Reports of radiation-epidemiology studies indicate that those exposures to radioiodine caused excess cases of thyroid cancer years later in the sensitive groups within the exposed population. See Chapters 2, 3, and 4 for details.

Conclusion 2: Potassium Iodide (KI) is an important agent for protection against thyroid-related health effects of exposure to radioiodine, if taken shortly before or after exposure.

Radiation doses to the thyroid from radioiodine can be limited by taking nonradioactive (stable) iodine in such a form as KI. KI has been widely used as a safe means to block uptake of radioiodine in diagnostic or therapeutic nuclear medicine or in the event of a radiological incident. KI is highly effective in blocking uptake of radioiodine if taken shortly before or shortly after exposure, and side effects after short-term use have been minimal. KI is inexpensive to manufacture and is stable for long periods if properly packaged and stored. Fetuses, infants, children, and pregnant women (to protect the fetus because iodine readily crosses the placenta), and nursing mothers (to protect breast-feeding infants because iodine is concentrated in breast milk) are most in need of protection from radioiodine exposure and most likely to benefit from KI. For the general population, there is little benefit in providing KI to adults over 40 years old. KI does not protect other organs or tissues from external exposure to radiation or from internal exposure to other radioactive isotopes, such as strontium, cesium, and cobalt. See Chapters 2 and 5 for details.

Conclusion 3: In planning for responses to nuclear incidents in the United States, the likelihood and possible magnitude and extent of a release in the United States cannot be extrapolated from the Chornobyl accident, because of substantial safety and other facility-design features in US reactors.

The accident at Chornobyl was precipitated by an explosion and a fire in the graphite-moderated core. The persistent fire resulted in the release of large quantities of fission products, including radioiodine and noble gases, into the environment. That series of events would not occur in US reactors, because of fundamental differences in reactor design. Reactor designs in the United States are different from the Chornobyl design in several ways. The choice of moderators (material used to slow down neutrons) is different in US nuclear power plants (NPPs). In the United States, water is used; Chornobyl-type reactors use graphite (graphite is combustible, and water is not). US NPP designs prevent sudden, difficult-to-control increases in power level (sudden increases in the fissioning process). US NPPs use multiple layers of barriers to ensure that nuclear fuel and fission products cannot escape from the core. In the United States, NPPs have a pressure vessel with thick walls; the Chornobyl reactor had no such containment vessel. US NPPs are designed on the basis of full containment, the complete enclosure of all reactor and primary support systems for the reactor in the event of a design-basis accident. In NPP licensing, the US Nuclear Regulatory Commission subscribes to the "defense-in-depth" (multiple-layer) safety strategy, which includes accident prevention, redundant safety systems, containment, accident management, siting, and emergency planning. See Chapters 3 and 5 for details.

Recommendations

Recommendation 1: Potassium iodide (KI) should be available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident. KI should be available to infants, children, and pregnant and lactating women. There is little benefit in

providing KI to adults over 40 years old. To be most effective, KI must be taken within a few hours before or after exposure to inhaled or ingested radioiodine.

Radioactive iodines (radioiodines, such as ^{131}I) are fission products present in nuclear power plants (NPPs) and released from detonated nuclear weapons. In the event of nuclear accidents or as a result of nuclear terrorism, radioiodine could be released to the environment. Because iodine concentrates in the thyroid gland, exposure to radioiodine by inhalation of contaminated air or ingestion of contaminated milk and other foods can lead to radiation injury to the thyroid, including increased risk of thyroid cancer and other thyroid diseases. Thyroid radiation exposure from radioiodine can be limited by taking stable iodine. KI is a chemical compound that contains iodine and can be used to protect the thyroid gland from possible radiation injury by reducing the amount of radioiodine concentrated by the thyroid after inhalation of radioiodine. KI is also effective for protection against the harmful thyroid effects of radioiodine ingested in contaminated milk and other foods, but food testing and interdiction programs in place throughout the United States are more effective preventive strategies for ingestion pathways.

The risk of thyroid cancer from exposure to radioactive iodine is strongly age-related. Fetuses, infants, and children are at highest risk. Pregnant and lactating women should take KI to protect their unborn or breast-feeding children. Among older adults, there is little risk of thyroid cancer and a higher risk of complications from KI; therefore, for the general public, there is little benefit in providing KI for adults over 40 years old. To be most effective, KI must be taken within a few hours before or after exposure to inhaled or ingested radioiodine.

The existing Food and Drug Administration (FDA) guidance in the United States addresses seven risk groups with three different thresholds of thyroid radiation exposure for the administration of KI. Developing a distribution program that addresses every risk group will be too complicated to administer. Thus, to provide a conservative and simple protective action during a nuclear incident, a single directive for the entire public should be adopted at an

intervention level that is protective for the most susceptible population groups: 50 mGy (5 rad) of predicted thyroid exposure for infants, children, adults under 40 years old, and pregnant and lactating women.

Recommendation 2: KI distribution should be included in the planning for comprehensive radiological incident response programs for nuclear power plants. KI distribution programs should consider predistribution, local stockpiling outside the emergency planning zone (EPZ), and national stockpiles and distribution capacity.

Emergency preparedness for potential radiological incidents involves extensive planning and development of a comprehensive response program capable of responding to various credible scenarios. Such response programs require involvement and cooperation of local, state, and federal agencies and organizations, with periodic review and evaluation of programs' effectiveness. Currently, for example, the US Nuclear Regulatory Commission and the Federal Emergency Management Agency (FEMA) require and regularly evaluate emergency preparedness at and around NPPs. Availability of KI for administration in the event of a radiological incident involving radioiodine is an important component of such preparedness programs. See Chapters 5 and 7 for details.

Recommendation 3: FDA should re-evaluate current dosing recommendations and consider extending the shelf-life for KI tablets stockpiled or distributed for use in response to a radiological incident involving radioiodine.

Current FDA-approved KI formulations generally range in shelf-life from 2 to 3 years. It is known that KI is relatively stable and should have a much greater shelf-life when stored under optimal conditions. It would be desirable to have a longer shelf-life for KI that is to be stockpiled or used in a KI distribution program to limit the need for frequent replacement of outdated product. Given the known stability of KI when properly packaged and stored, the current

shelf-life determinations appear to be unreasonable for a product that would be used only in an emergency situation.

Implementation Issues Related to Potassium Iodide Distribution and Stockpile Programs

On the basis of its assessment, the committee reached the following conclusion and offers a number of recommendations regarding potassium iodide distribution programs.

Conclusion

A strategy is needed whereby local planning agencies could develop geographic boundaries for a KI distribution plan based on site-specific considerations because conditions and states vary so much that no single best solution exists.

KI distribution planning in the United States has focused on the Nuclear Regulatory Commission's early-phase Emergency Planning Zone (EPZ) of a 10-mile radius. However, the EPZ provides only a basis for planning. A specific incident might call for protective actions to be restricted to a small part of the EPZ or require that they be implemented beyond the EPZ as well. See Chapters 5 and 7 for details.

Recommendations

Recommendation 1: A better understanding of the strengths and weaknesses, short-term and long-term successes and failures, and resource requirements of different KI distribution plans implemented in the United States and abroad would be extremely helpful for designing and implementing effective future KI distribution programs.

KI distribution plans have been implemented for decades. However, their long-term success in terms of community awareness

(both of the plan and of the location of distributed KI tablets), continuing availability of KI to all appropriate populations, and impact on perceptions of risk have not been well studied. A more thorough assessment of these programs' successes and limitations is necessary.

Recommendation 2: State and local authorities should make the decision regarding implementation and structure of a KI distribution program. The choice of program should be based on how well specific plans would perform on decision objectives, given features of the local region. The decision regarding the geographical area to be covered in a KI distribution program should be based on risk estimates derived from calculations of site-specific averted thyroid doses for the most vulnerable populations.

In the United States, public health and safety are state responsibilities. However, states generally have delegated some authority for incident response to local public officials and local responders. Local responders are generally the first to arrive at the scene of an accident or incident and have the best knowledge of local conditions that might affect response decisions. Similarly, state and local authorities are in the best position to assess site-specific characteristics that will influence the selection, development, and implementation of the public-health protection strategies that will be most effective in meeting their objectives, including the availability of KI for appropriate populations. A major objective might be to "minimize radioactive iodine risk to thyroid" with subobjectives of maximizing KI availability, especially for the most vulnerable population; optimizing ability to take KI on time; and minimizing harm from inappropriate KI administration. Another major objective might be to "minimize harm from other aspects of incident" with subobjectives of ensuring that KI procedures do not impede evacuation, averting mortality and morbidity from radiation or accidents (beyond thyroid risks), and avoiding excessive resource use in KI procedures. Specific localities may have added objectives, such as minimizing legal liability.

For fixed facilities, NPPs, it is possible to calculate anticipated radiation exposures after an incident, and there is now a sufficient medical and scientific literature to estimate dose-related thyroid-cancer risks after exposure to radioiodine. The established dose-modeling methods approved for each site make it possible to construct site-specific thyroid dose estimates based on local conditions. The radiological dose to the thyroid can then be used to determine site-specific risk estimates, taking into account demographics and distance from the radioactive iodine source for use in incident-response planning to protect the vulnerable population in geographic areas determined to be at significant risk for radioiodine exposure.

The existing FDA guidance in the United States addresses seven risk groups with three different thresholds of thyroid radiation exposure at which the administration of KI would be advised. Developing a distribution program that addresses every risk group will be too complicated to administer. Thus, to provide a conservative and simple protective action during a nuclear incident, site-specific risk estimates should be based on recommending KI administration for the entire vulnerable population if the highest-at-risk members of that population reached the recommended threshold (for example, advising administration of KI to all infants, children, pregnant and lactating women and adults under age 40 when the predicted thyroid dose without KI prophylaxis in children under 4 years of age reaches 50 mGy (5 rad)). The committee recommends that the scientific information that is becoming available from epidemiology studies of the Chornobyl populations and from other radiation incidents be carefully monitored to determine if the FDA recommendation on threshold dose needs to be reconsidered.

The choice of the best plan will depend on the site-specific features and the decision objectives. For example, predistribution of KI to households (with secondary postdistribution at reception centers) might be the preferred option in a local area with a large population and limited evacuation routes, whereas stockpiling KI at reception centers might be preferred if evacuation of the population could occur within a few hours.

Recommendation 3: KI distribution and administration plans developed at the state and local level should receive federal resources for implementation and maintenance.

Notwithstanding the need for state and local authorities to make the decision regarding the most appropriate public-health protection strategies for a comprehensive incident-response program, implementation and maintenance of such programs requires substantial resources. The potential scope of such incidents may extend beyond local or state jurisdictions, and costs may vary widely depending on local conditions and population demographics. In addition, the cost of resupplying depleted reserves and outdated stocks is significant. For all those reasons, it would be appropriate for the federal government to provide resources for these programs.

Recommendation 4: The federal government should maintain stockpiles and a distribution system as a supplement to states' programs to assure availability of KI to affected populations in the event of a major radiological incident involving radioiodine.

Radiological incidents have the potential for widespread contamination and population exposure. Like any large-scale disaster, such an incident may quickly outstrip the response capability of local and state authorities and resources. The federal government already has in place a number of mechanisms to provide assistance in the event of a natural disaster, accident, or other incident through such organizations as the Centers for Disease Control and Prevention and FEMA. It is appropriate that KI remains in the vendor managed inventory provisions available to local and state authorities in the event of a radiological incident involving radioiodine. In addition, KI could also potentially be included in the US government's push package program.

Recommendation 5: The federal government should ensure an adequate supply of KI tablets in suitable dosages for use by the target populations of infants, children, adults under 40 years old, and pregnant and lactating women of all ages.

Several organizations, including the World Health Organization, have developed recommendations for KI dosage according to age group for protection against thyroid cancer in the event of a radiological incident involving radioiodine. Available FDA-approved tablet formulations of KI include 65-mg and 130-mg scored tablets. The recommended dosage for neonates is 16 mg, which requires administration of one-fourth or one-eighth of a tablet. FDA provides detailed instructions on how to achieve and administer that dosage, but this is a formidable task, particularly in an emergency situation. Therefore, there is a need for development of practical dosage forms (for example, 32-mg scored tablets, so that a half-tablet could be administered to a neonate) that are readily available.

In addition, FDA maintains two guidance documents that provide different KI dosage recommendations. FDA should review its guidance documents and develop a single guidance strategy for administration of KI in the event of a radiological incident involving radioiodine, with particular attention to dosage for infants and children.

Additional Research Needed

On the basis of its assessment of the current state of information regarding KI distribution programs, the committee reached the following conclusion and offers a number of recommendations for further studies that will improve the base of knowledge on which to make related public-health decisions.

Conclusion

Although questions remain regarding long-term health risks from radioiodine, particularly among potentially high-risk subgroups, there is now sufficient medical and scientific literature to estimate dose-related thyroid cancer risks following exposure to radioactive iodine.

KI distribution planning in the United States has focused on the Nuclear Regulatory Commission's early-phase Emergency Planning Zone (EPZ) of a 10-mile radius. However, the EPZ provides only a basis for planning. A specific incident might call for protective actions to be restricted to a small part of the EPZ or require that they be implemented beyond the EPZ as well. See Chapters 4 and 5 for details.

Recommendations

Recommendation 1: KI distribution plans should include a carefully developed and tested public education program with continuing evaluation to ensure effectiveness and continued access to KI by the appropriate population.

Implementation of a KI distribution plan is only the first step in providing protection against thyroid cancer from radioiodine exposure. The plan should include structuring, implementing, and sustaining a public-awareness and public-education campaign to support any distribution programs and to inform people about radiation risks and the use of KI. In addition to a public-education program, health-care professionals, the mass media, and other groups may need tailored communication processes. There is a continuing need for resupply of KI stocks (including stocks that become outdated) and for assurance of access by appropriate populations. In addition, the overall effectiveness of the distribution program should be periodically assessed.

Recommendation 2: A national program should be developed for follow-up of all individuals to whom KI was administered following a radiological incident, to assess short- and long-term health effects of KI administration.

There is little information on the long-term health effects of KI administered for public protection from radiological incidents. Such information would be important for planning of incident

preparedness programs. To be effective, such a program would need to be national in scope and in the form of a registry to follow affected people for many years.

Recommendation 3: Research is needed in a number of areas to provide better information to inform policy-makers and health-care providers about the risks posed by radioiodine exposure and methods to minimize long-term health effects. An evaluation of the strengths and weaknesses, successes and failures (short-term and long-term), and resource requirements of the different KI distribution plans implemented in the US and abroad should be conducted by a federal agency to aid states and local regions in designing and implementing effective KI distribution programs.

Research is needed to develop more effective KI distribution programs that address the critical issues of KI availability to appropriate at-risk populations, predistribution approaches to improve long-term public awareness of the location of KI tablets, and effective risk-communication strategies to maximize information transfer and minimize public anxiety. Research is also required to improve understanding the effect of dietary iodine in modifying the carcinogenic risk posed by radioiodine; of the type, frequency, and clinical course of thyroid tumors that develop in those exposed to radioiodine as children; of the risk of thyroid carcinogenesis in adults exposed to radioiodine in fallout; of the risk and mechanisms of autoimmune disease and hypothyroidism after radioiodine exposure; and of the risk of tumor development at other sites after radioiodine exposure.

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APPENDIX A

PUBLIC LAW 107-188, PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002, CONFERENCE COMMITTEE (05/21/02)

SEC. 127. POTASSIUM IODIDE.

(a) IN GENERAL.-Through the national stockpile under section 121, the President, subject to subsections (b) and (c), shall make available to State and local governments potassium iodide tablets for stockpiling and for distribution as appropriate to public facilities, such as schools and hospitals, in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant.

(b) STATE AND LOCAL PLANS.-

(1) IN GENERAL.-Subsection (a) applies with respect to a State or local government, subject to paragraph (2), if the government involved meets the following conditions:

(A) Such government submits to the President a plan for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident.

(B) The plan is accompanied by certifications by such government that the government has not already received sufficient quantities of potassium iodide tablets from the Federal Government.

(2) LOCAL GOVERNMENTS.-Subsection (a) applies with respect to a local government only if, in addition to the conditions described in paragraph (1), the following conditions are met:

(A) The State in which the locality involved is located-

(i) does not have a plan described in paragraph (1)(A); or

(ii) has a plan described in such paragraph, but the plan does not address populations at a distance greater than 10 miles from the nuclear power plant involved.

(B) The local government has petitioned the State to modify the State plan to address such populations, not exceeding 20 miles from such plant, and 60 days have elapsed without the State modifying the State plan to address populations at the full distance sought by the local government through the petition.

(C) The local government has submitted its local plan under paragraph (1)(A) to the State, and the State has approved the plan and certified that the plan is not inconsistent with the State emergency plan.

(c) GUIDELINES.-Not later than one year after the date of the enactment of this Act, the President, in consultation

with individuals representing appropriate Federal, State, and local agencies, shall establish guidelines for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident. Such tablets may not be made available under subsection (a) until such guidelines have been established.

(d) INFORMATION.-The President shall carry out activities to inform State and local governments of the program under this section.

(e) REPORTS.-

(1) PRESIDENT.-Not later than six months after the date on which the guidelines under subsection (c) are issued, the President shall submit to the Congress a report-

(A) on whether potassium iodide tablets have been made available under subsection (a) or other Federal, State, or local programs, and the extent to which State and local governments have established stockpiles of such tablets; and

(B) the measures taken by the President to implement this section.

(2) NATIONAL ACADEMY OF SCIENCES.-

(A) IN GENERAL.-The President shall request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale. If the Academy declines to conduct the study, the President shall enter into an agreement

with another appropriate public or nonprofit private entity to conduct the study.
(B) REPORT.-The President shall ensure that, not later than six months after the date of the enactment of this Act, the study required in subparagraph (A) is completed and a report describing the findings made in the study is submitted to the Congress.

(f) APPLICABILITY.-Subsections (a) and (d) cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants.

APPENDIX B

FISSION PRODUCT INVENTORIES

Fission Product Inventories (Ci/MWe)[a]

Fission Product	Half-life	Inventory (Ci/MWe)
Kr-85	10.7 yrs560	560
Kr-85m	4.5 hours	24,000
Kr-87	1.3 hours	47,000
Kr-88	2.8 hours	68,000
Sr-89	50.5 days	94,000
Sr-90	29.1 years	3,700
Sr-91	9.5 hours	110,000
Y-91	58.5 days	120,000
Mo-99	2.7 days	160,000
Ru-103	56.1 min	110,000
Ru-106	2.2 hours	25,000
Te-129m	33.6 days	5,300
Te-131m	1.4 days	13,000
Te-132	3.3 days	120,000
Sb-127	3.8 days	6,100
Sb-129	4.4 hours	33,000
I-131	8.0 days	85,000
I-132	2.3 hours	120,000
I-133	20.8 hours	170,000
I-134	52.6 min	190,000
I-135	6.6 hours	150,000
Xe-131m	11.9 days	1,000
Xe-133	5.2 days	170,000
Xe-133m	2.2 days	6,000
Xe-135	9.1 hours	34,000
Xe-138	14.1 min	170,000
Cs-134	2.1 years	7,500
Cs-136	13.2 days	3,000
Cs-137	30.2 years	4,700
Ba-140	12.8 days	160,000
La-140	1.7 days	160,000
Ce-144	284.6 days	85,000
Np-239	2.4 days	1.64×10^6

[a]Adapted from NUREG-1228 (USNRC, 1988) and Wash-1400 (USNRC, 1975).

APPENDIX C

POTASSIUM IODIDE DISTRIBUTION IN THE STATES

The Table C.1 indicates whether a particular state distributes KI.

Table C.1 Status of KI Distribution in the 50 States and District of Columbia

State	Not within 10 miles vicinity of NPP; do not distribute KI	NPP within 10 miles vicinity; KI not pre- or post-distributed	KI Distributed postincident	KI distributed pre- and postincident	State	Not within 10 miles vicinity of NPP	NPP within 10 miles vicinity; KI not pre- or post-distributed	KI Distributed postincident	KI distributed pre- and post-incident
Alabama			√		Montana	√			
Alaska	√				Nebraska		√		
Arizona			√		Nevada	√			
Arkansas		√			New Hampshire				√
California				√	New Jersey				√
Colorado	√				New Mexico	√			
Connecticut				√	New York				√
Delaware				√	North Carolina				√
District of Columbia	√				North Dakota	√			
Florida			√		Ohio				√
Georgia		√			Oklahoma	√			
Hawaii	√				Oregon	√			
Idaho	√				Pennsylvania				√
Illinois				√	Rhode Island	√			
Indiana	√				South Carolina				√
Iowa		√			South Dakota	√			
Kansas		√			Tennessee				√
Kentucky	√				Texas		√		
Louisiana		√			Utah	√			
Maine	√				Vermont				√
Maryland				√	Virginia				√
Massachusetts				√	Washington		√		
Michigan		√			West Virginia				√
Minnesota		√			Wisconsin		√		
Mississippi			√		Wyoming	√			
Missouri		√							

Information used in developing this appendix was culled from responses to a request for information sent to states by the committee; information posted on the Internet by state, federal, and public-health institutions; and a few published articles.

States that do not have commercial NPPs within their borders or within 10 miles of their borders do not distribute KI. Maine discontinued its distribution program after the decommissioning of the Maine Yankee power plant (Maine Bureau of Health, 2003).

Several states with commercial NPPs have thus far decided not to distribute KI. These are listed in Table C.2 with information regarding KI distribution provided by the state to the committee or otherwise available. In addition, an entry is given for Idaho, a state with a test rather than a commercial NPP; it cannot envision an accident of a magnitude that would require distribution of KI to those in the sparsely populated area near the facility.

Chapter 6 discusses the four states with only postincident distribution programs.

The discussion below provides some information on the several states with predistribution programs except Connecticut, Maryland, and Tennessee, which are discussed in detail in Chapter 6.

Table C.2 States with Nuclear Facilities that Do Not Distribute KI to General Population

State	Comments	References
Arkansas	KI made available only to emergency workers. Policy of no provision of KI to general population under revision. State considering making KI available to special populations and general public.	Response to Request for Information
Georgia	KI made available only to emergency workers through local emergency operations centers. No plans to distribute to general or special populations.	Response to Request for Information
Idaho	Idaho has test reactor; no residents within 10 miles. State currently determining best means of storing and distributing KI to emergency workers.	Response to Request for Information
Iowa	Limited information available to committee. KI not requested from the Nuclear Regulatory Commission. Iowa Department of Public Defense (2003) notes in fact sheet that states may decide to provide the public with KI, but provides no information on availability. Iowa Bureau of Radiological Health prepared information notice on KI for people seeking information in wake of mass-media attention on distribution of KI to postal workers (Iowa Department of Public Health 2003).	Iowa Department of Public Defense (2003)
Louisiana	During event, KI will be authorized for emergency workers and institutionalized people unable to evacuate quickly.	Response to Request for Information; Loiusiana Department of Health and Hospitals (2003)
Kansas	KI distributed to emergency workers only. State has evacuation-only policy for all but emergency workers.	Response to Request for Information
Michigan	KI distributed to emergency workers, homebound public, and institutionalized persons. State concludes that occurrence of a radioiodine exposure significant enough to warrant KI use is questionable. Policy change awaits any new federal guidance or national recommendations concerning use of KI by general public	Response to Request for information; Michigan DEQ (2003)

State	Comments	References
Minnesota	Limited information available to committee. KI not requested from the Nuclear Regulatory Commission. KI available to emergency workers.	MDEM (2001)
Missouri	Missouri decided not to distribute KI to general public. It stockpiles for emergency workers at county emergency operations centers and at such facilities as nursing homes and prisons that would shelter in place. MSEMA (1997) discusses evacuation as means of protecting general public in event of an incident.	Response to Request for Information
Nebraska	State has evacuation-only policy, with early evacuation plans for institutionalized and nonambulatory persons. KI distributed to emergency workers for voluntary self-administration.	Response to Request for Information
Texas	Distribution of KI to special-needs populations. Special populations identified and listed in annually updated process. State found evacuation of general population to reception centers outside emergency planning zone to be sufficient protection. State provides Centers for Disease Control and Prevention KI fact sheet on Web site (TDH, 2003).	Response to Request for Information
Wisconsin	No KI stockpiled for general public or special populations for any emergency planning zone for the three relevant NPPs. Some KI stockpiled for emergency workers. State Web site provides two Federal Emergency Management Agency (1993a, 1993b) fact sheets on nuclear emergencies. Neither mentions KI.	Response to Request for Information

California instituted a three-pronged program of predistribution, public education, and stockpiling and emergency distribution. Predistribution involved a mass-mailing of information on the availability of KI, which included a postcard order form to return to the state to obtain KI for the household or business. KI was then returned, two tablets per person, for the number of people indicated on the order form as residing or working at the household or business (California Office of Emergency Services, 2002). Businesses and residents received a "Potassium Iodide Fact Sheet" with an information sheet regarding dosage, how to address side effects, dosages for children and infants (FDA 2001a guidance), and where to purchase additional KI. Materials were available in Spanish and English. The education program involved releases to newspapers, television, and radio; placing information in telephone directories serving the area; and establishing a public-information telephone line. Non-English media serving the area were also used in the public-education program. As of July 29, 2003, mailers had been sent to 154,000 addresses, and orders were received from 26,000 addresses; 275,000 dosages have been distributed.

City and country governments have the responsibility of maintaining KI for emergency workers in the emergency planning zone (EPZ). California provided KI on request to state agencies and public schools within the EPZ. The schools were given guidance on how to develop their own distribution plan for the inventory. The state coordinated with military institutions to ensure that KI was offered to military personnel and their families within the EPZ.

Stockpiled KI would be distributed to evacuation reception centers in an incident. When the emergency classification level is at the "Alert" stage, the state Office of Emergency Services plans to deliver KI to the evacuation centers if the situation appears to worsen or on request of a county operational area.

All costs of the California KI distribution program are covered by the owners of the state's two commercial NPPs with other costs of emergency planning, training, and exercises. The state noted that with more federal funding the state would be better placed to maintain the stockpile when shelf-life is reached and to offset costs of the public-information line and the Web site.

Delaware requested KI from the Nuclear Regulatory Commission in March 2002 to distribute to permanent and transient populations within 10 miles of the Salem/Hope Creek Generating Stations in New Jersey (Delaware Emergency Management Agency, 2002). The predistribution occurred from August to October 2002 (Delaware Emergency Management Agency, 2002, Delaware Health and Social Services, 2002a,b). The predistribution consisted of providing KI at specified locations on specific days to residents showing proof of residence, such as a driver's license or utility bill; child-care center operators; and those employed in the area who provided verification of employment on business letterhead from their employer (Delaware Health and Social Services, 2002b). Two tablets per person affected were provided. The KI that remains after the predistribution will be available at emergency registration facilities as a supplement to evacuation during an emergency (Delaware Health and Social Services, 2002a). A fact sheet (Delaware Health and Social Services, 2002c) provides information on KI, when it is to be taken, contraindications (dermatitis herpetiformis and hypocomplementemic vasculitis are named), side effects, how it should be stored, and recommended dosages. Precautions regarding high-risk groups over 40 years old and overdosing of neonates are not provided in the fact sheet. The recommended dosage was that given in the Food and Drug Administration (FDA, 2001a) guidelines.

Illinois. Before the Nuclear Regulatory Commission offering of KI, the state made KI available for designated emergency workers and immobile populations. After the offering, the state acquired 360,000 tablets to cover 180,000 people within the EPZ for six sites. The state indicated in its response to the committee's request for information that the cost of the initial acquisition of KI was $78,000 and that it acquired an additional 750,000 dosages at a cost of $150,000. The inventory is in storage as part of the state's emergency preparedness stockpile. Recipients of KI were required to sign a disclaimer indicating they would read and follow the instructions for proper use of the drug and would consume it only when advised by state or local authorities. Distribution was to persons "claiming to live or work within 10-miles of the nuclear plants, not by household". Some 12,000 tablets were dispensed in the predistribution; the state

noted that this was about 6% of the eligible population requesting the drug.

The state attempted to recruit local public-health agencies as outlets for KI distribution, but most declined because of liability concerns. Individual businesses in or near the EPZs requested KI for employees, but schools, day-care centers, and other facilities have not, citing liability issues. Jails, nursing homes, and hospitals are given KI because they are considered to be housing immobile populations.

The state considered the KI distribution program as an element of bioterrorism preparedness and highlighted it in a "Security Update" (Illinois Homeland Security, 2002a): "New federal bioterrorism legislation passed by Congress last week directs the United States Department of Health and Human Services (HHS) to provide potassium iodide (KI) for stockpiling and distribution within a 20-mile radius of nuclear power plants in those states that elect to do so. The current Nuclear Regulatory Commission initiative on KI distribution within 10 miles of each plant site would affect about 180,000 residents, but expansion to 20 miles would boost that population base in Illinois to more than one million. The new legislation and its implications for Illinois are being reviewed."

The state advises that the dosages provided in the FDA 2001a guidelines be given and further that "these guidelines are important to follow, particularly for children and infants whose thyroid glands are more active than adult thyroids and thus more sensitive to iodine levels" (Illinois Emergency Management Agency, 2002). The state also advises that "in instances where KI is given to a newborn, the infant should be monitored by a physician for symptoms of transient hypothyroidism following administration of the drug." The state further cautions under the header "KI Is Not Safe For Everyone!" that those with known iodine allergies including those who are must avoid some sea foods and other foods with high natural iodine content. It also cautions that "those suffering certain thyroid disorders or taking thyroid medications, as well as pregnant women, nursing mothers, and individuals taken certain heart medications or antipsychotic drugs should consult their physicians before deciding to use KI." "As with any medication, you should consult your physician to determine if KI is safe for you." The state sought clarification regarding dosage

guidelines from FDA (Illinois Homeland Security, 2002b), indicating that two other states, Washington and New York, were also doing so. Illinois noted that "the FDA issued age-related guidelines for KI use last year warning that children should be limited to lower dosages not commercially available. With regards to the state's liability if dosage guidelines could not be reasonably addressed, the FDA advised compliance with its guidance was voluntary."

Noting that predistribution is the only practical means of ensuring that KI is available on a timely basis to those affected, the state emphasized that there was no effective means of ensuring that those who need it will actually possess it or use it appropriately. "Only through controlled application of KI is the effectiveness of the drug assured. At least some portion of the affected population will misconstrue the effectiveness of the drug and assume it provides a level of total exposure protection that could only be achieved by prompt evacuation, while others who consume the drug inappropriately will suffer adverse reactions." The state also noted that the cost of the drug was inexpensive but that developing and maintaining a distribution system was time- and labor-intensive. It also said that "a key impediment to widespread availability of the drug through state-sponsored outlets is liability. The Nuclear Regulatory Commission's 2001 offer of a free stockpile to any state that wanted to distribute KI contained an explicit disclaimer of any liability for the drug's use or misuse. Any endorsement or promotion of KI use by the federal government should absolve state or local jurisdictions of liability."

New Hampshire. Originally, New Hampshire's Radiological Emergency Response Plan provided for issuing KI to emergency workers and institutionalized persons but not the general public. After the Nuclear Regulatory Commission's offer, New Hampshire acquired 350,000 tablets for distribution in a voluntary program covering the public living, working, or attending school within the 10-mile EPZ. Schools and workplaces can obtain KI for their students and workers and are expected to develop their own plans to manage distribution in the event of an emergency. Interested members of the public can order KI by submitting an application that is available at town halls, at district offices of the Department of Health and Human

Services, and on the Internet. As of June 23, 2003, only 12,410 pills (3.5% of the total) had been distributed to the public within the 10-mile EPZ. The remainder of the allotment will be used for any needed emergency distribution.

The state notes that ingestion of KI as a supplementary protection is advisable if it will not interfere with evacuation. The planned approach to informing the public in an emergency is to advise the public in the evacuation area to take KI when an announcement advises emergency workers to take KI.

Massachusetts. The state requested 660,000 tablets from the Nuclear Regulatory Commission and engaged in a predistribution program of one tablet per person for each employee or resident within the 10-mile EPZ of the three nuclear facilities—two in Massachusetts and one in Vermont. Completion of a KI request form from the Massachusetts Department of Public Health was required (MDPH) (form available at www.state.ma.us/dph/rcp/rcpkifrm.htm). An employer could obtain KI for all employees at a facility. A notice was sent to employers within the EPZ outlining how to obtain KI for their employees and advising them about Web sites and phone numbers for employees to use to obtain information (MDHP, 2002a).

With regard to dosage, MDPH (2002b) posted a letter to interested parties on its Web site. The letter noted that the only formulation available was a 130-mg pill and gave the FDA 2001 advice on "lowest effective dosage". MDPH noted that "until the 65 mg table is available, MDPH supports the administration of the 130 mg tablet for children in settings such as schools or child care centers in the event of emergencies. This is in agreement with FDA statements. The dosage is safe and well within the recommended therapeutic rage of KI for other indications. The blocking effect of iodide on the thyroid lasts only a few days (daily dosing is needed as long as the child is exposed to the radioiodine) and any suppressive effect of KI on thyroid function has been shown to be minimal, even in young children. The logistics of providing KI to persons too young to take pills are more complicated. KI pills can be crushed and dissolved . . ." There are no notes of precaution or about follow-up for dosages given to neonates; rather "the FDA has noted that absolute precision in dosing is generally not critical to safety or

efficacy . . .” the overall benefits of KI far exceed the risks of overdosing, especially in young children.”

New Jersey acquired 722,000 KI pills from the Nuclear Regulatory Commission in April 2002 for pre- and post- incident distribution and stockpiling. The plan is to distribute KI to people living, working, or visiting in areas within a 10-mile vicinity of the state’s four NPPs (New Jersey Department of Health and Senior Services [NJDHSS], 2002a, 2002b). The policy for KI distribution was developed by NJDHSS in collaboration with the state’s Department of Environmental Protection and the NJ State Police Office of Emergency Management. The intervention level identified by New Jersey is a projected 50 mGy (5 rad) to the child thyroid.

In the predistribution anyone living or working within the 10 mile EPZ is offered KI, to be acquired by pickup from the local health department. KI is offered this way on a continuing basis. KI public-education and distribution sessions were held in the evenings on weekday and during the day on Saturday. Identification—such as a driver’s license, paycheck stub, or phone bill—was required as proof that the individual picking up KI resided or worked in the EPZ. As of July 14, 2003, 75,000 dosages of KI had been distributed. Post-distribution would occur at designated evacuation reception centers (NJDHSS, 2002c, 2002d).

New York. New York uses a multitiered distribution program of predistribution (voluntary pickup), stockpiling for the general and special populations, and postaccident distribution. Some 1.2 million tablets were received from the Nuclear Regulatory Commission for distribution. One KI tablet per person was offered for distribution, with the other tablet reserved for stockpiling and postaccident distribution. The distribution program covered people residing or working within the 10-mile EPZ. About 15% of people within the EPZ were covered by the distribution. The state noted that it was expensive to develop the plan. It found that the issuance of the FEMA guidance after Nuclear Regulatory Commission issuance of KI created a public perception problem and that the mass media were not helpful in educating the public. The state developed fact sheets to assist counties with public education—two for the general public and one for physicians. A *KI Guidance Document* was developed to assist

counties in planning. Most recently, the state's Nuclear Emergency Preparedness Subcommittee (NEPS) issued recommendations on implementation, including triggering levels (50 mGy (5 rad) to the child thyroid), dosage (one tablet to those over a year old and a half-tablet to those under a year old), the amount to be predistributed (expected time of evacuation in days-rounded up-time tablet/day), and when specified members of the public will be directed to take KI (those evacuated or in evacuated areas) (NY NEPS, 2003).

North Carolina. North Carolina requested 750,000 tablets from the Nuclear Regulatory Commission to cover the EPZ for four NPPs (June 28, 2002 letter from Leah Devlin and Linda C. Sewall to Kathy Gibson of NRC). The full distribution program has yet to be completed, but KI has been distributed through local health departments in a pickup program. In voluntary pickup (two tablets per person), roughly 35% of the population was covered by the predistribution, which occurred in October and November 2002 (NC Division of Public Health, 2003).

Ohio. The Ohio program (Ohio Department of Health, 2003) involves voluntary distribution to residents in the 10-mile EPZ and stockpiling the remainder (not picked up by residents or set aside for transients) at care and receiving centers for those evacuating. That is, excess stocks of KI are to be kept at monitoring and decontamination centers for evacuees but on a priority basis to those contaminated by the plume (Ohio Department of Health, 2002). Two KI tablets were placed in a plastic bag containing the FDA-approval label and the manufacturer's insert. The public was informed through a mass media campaign. Information about KI was also mailed to each resident in the EPZ. With the information came a coupon for obtaining KI. About 40% of the amount received from the Nuclear Regulatory Commission was distributed to the public by voluntary pickup. Because of the requirements involved in repackaging the 14-tablet packages provided by the Commission, and other logistics surrounding making KI available, $117,000 (more than the $75,000 provided by the federal government) was spent by the state and local health departments.

Ohio recommends that dosages be administered at levels in the FDA-approved manufacturer's guidance to minimize confusion

between differing FDA guidance regarding dosage. That is, Ohio recommends that children over a year old and adults receive one 130-mg table and children under a year old receive a half-tablet. The Ohio Department of Health (2002) notes that the lower dosage recommended by FDA in alternative guidance is the "minimum effective dosage".

Pennsylvania. Little information was available to the committee on Pennsylvania's distribution of KI. Before KI was made available to the states by the Nuclear Regulatory Commission, a KI working group consisting of state government and other experts concluded that the state should expand its KI distribution program beyond its policy of providing KI to emergency workers and special difficult-to-evacuate groups (Pennsylvania Department of Environmental Protection, 2001). Pennsylvania recently acquired KI from the Commission and offered free tablets to all residents living within the 10-mile EPZ of the states five nuclear facilities (Pennsylvania Department of Health, 2003). Of the more than 640,000 people covered by this offering, 34% picked up KI. KI was also offered to businesses and schools.

South Carolina. In October 2002, South Carolina requested 800,000 dosages of KI for predistribution (letter from Commissioner of Health Services C. Earl Hunter and Deputy Commissioner Lisa F. Waddell to Kathy Helvay Gibson of the Nuclear Regulatory Commission). The state is distributing KI to residents living within 10 miles of NPPs, as indicated in press releases available on the Internet (SC Department of Health and Environmental Control [DEH], 2003a and 2003b). Sites for distribution to the public included school locations. Dosage information, provided in a fact sheet (SC DEH, 2002), is the same as that given in the most recent FDA guidance.

Vermont has just initiated a KI distribution program. The goal of the program is to make available to every citizen within the 10-mile EPZ of the Yankee Nuclear Power Reactor an opportunity to receive KI before a radiological event. That involves six towns: Brattleboro, Dummerston, Guilford, Halifax, Marlboro, and Vernon. The state acknowledges its responsibility to maintain adequate stockpiles of KI near the EPZ for use in the event of a radiological

emergency by persons who either do not have their own KI or cannot access their own KI. The State has three methods of distribution:

- People who live or work within the EPZ will be offered the opportunity to obtain their own personal dosage of KI, one dosage per person. That will be accomplished through outreach and education efforts by the Department of Health in concert with locally stationed public-health nurses.
- Within and just outside the EPZ, offsite response organizations (OROs) will store sufficient quantities of KI. In the event of a radiological emergency, the OROs will be used for mass distribution of KI. OROs will be in local fire departments, police barracks, and other central, easily secured structures.
- Special population segments will have their own specific distribution systems in or near their own settings. Such populations as those served in hospitals, nursing homes, schools, and child- and adult-care facilities will be provided KI in this manner.

The formal request for KI was made by the state's health commission on January 31, 2002. Predistribution was begun on April 15. People wanting predistribution have to complete applications, which are available at a variety of locations (libraries, town clerks, health department offices, various other government offices, and on the Internet). Parents must submit informed-consent forms for children. People with contraindications require medical releases. After 6 months fewer than 5% of residents had requested dosages, 3,000-4,000 dosages had been distributed to public schools, and there had been partial distribution to child-care facilities, hospitals, nursing homes, and private schools. The state indicated that it was using multiple channels of communication to convey information about its program to the public, including the broadcast media, the Internet, and community groups. A mass mailing is being contemplated for the second year, and other means of distribution are being considered.

The state calculated that 92,756 tablets were needed—two tablets for each resident, transient, and school-age child in the EPZ.

KI ingestion will be advised when the estimated radioiodine dose approaches the FDA recommended intervention level. The health-services coordinator may recommend that KI be administered when specific exposure is not known.

Virginia received 660,000 dosages of KI from the Nuclear Regulatory Commission to cover the estimated 330,000 people who live, work, or visit within 10 miles of the two NPPs in the state (Virginia Department of Health, 2002a,b). One dosage of KI was available for pickup during September and October 2002; the remainder was stored for postincident distribution. Proof of residence was required for pickup. Some health department offices, community centers, schools, and fire departments were designated as pick-up locations on specific dates. In the event of an incident, the state health commissioner would issue a recommendation regarding who should take KI. The FDA 2001a guidelines were provided for recommended dosage levels with the caution that "taking a higher dosage than recommended or taking KI more often than recommended can result in allergic reactions and other side effects" (Virginia Department of Health, 2002b). Pregnant women would be advised to take KI for their own protection and to protect their fetuses, although it was recommended that repeat dosing be avoided because of the risk of blocking fetal thyroid function. Dosing was also recommended to protect lactating women. However, it was noted that "stable iodine in breast milk may also pose a risk of hypothyroidism in nursing neonates", and that repeat dosing should be avoided unless there was continuing severe contamination, in which case it was recommended that nursing neonates be monitored for hypothyroidism. The advisory noted FDA's recommendation that neonates receiving KI be monitored for hypothyroidism and that thyroid-hormone therapy be instituted if it is found to occur. Administration to those over 40 years old was recommended against unless a large internal radiation dose was expected. The precautions regarding neonatal exposure were repeated in a fact sheet, but not the general precaution regarding those over 40 years old (Virginia Department of Health, 2002c).

West Virginia. As of July 11, 2003, a plan for KI distribution for West Virginia had not been fully developed. The state is developing a working group in the West Virginia Department of Health and Human Resources. The plan would cover residents in Hancock County who reside within 10 mile of the EPZ in Shippingport, Pennsylvania.

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APPENDIX D

ILLUSTRATION OF PROCESS FOR EVALUATING KI DISTRIBUTION PLANS

Template for Evaluation of KI Plans

This appendix shows a process that a local region could use to evaluate the four sample distribution plans against the objectives for a hypothetical plant site. The aim is to demonstrate a process, not to identify a best distribution approach.

Example Sites

Three hypothetical stylized examples of local regions surrounding nuclear power plants are given here (Tables D.1-3). Each local region will be called the **KI P**lanning **Z**one (**KIPZ**). This term is used in place of the commonly used **E**mergency **P**lanning **Z**one term, because existing plans set specific distances for the radius of such zones (for example, the 10-mile **EPZ**), and this process is meant to be generic for whatever plans are considered, with possibly different geographic areas. The regions will be characterized by features that affect performance of a KI plan on the objectives.

Urban: The KIPZ has a large, highly concentrated, permanent population that is increased by 25% during the week from the influx of large numbers of workers and families from the surrounding area. The transportation network, which also contains major interstate highways, is barely able to handle this daily ebb and flow. The area contains three major hospitals (one associated with a university), a

jail, and a school system with a total enrollment of 100,000. The KIPZ itself is contained within one political jurisdiction, but it borders several other jurisdictions, including a neighboring state. The most severe weather threats come from potential hurricanes in the fall and ice storms in the winter.

Suburban: This KIPZ contains two rapidly developing counties that are on the outer fringes of a major metropolitan area. It is populated primarily by a mixture of young families, drawn by the comparatively open spaces and lower housing prices, and retirees. Many of the working-age adults are employed outside the KIPZ. The school systems of the counties are expanding to accommodate the growing number of children, but the school facilities are widely dispersed, and there is extensive daily busing of students. Day care for preschool children is a booming business. The largest employer in the KIPZ is a Department of Defense facility with 6,000 military and civilian employees. The second-largest is the NPP itself. Each county has a hospital and a penal facility. The KIPZ also contains a large assisted-living and nursing-home facility with 200 residents. There are two interstate-quality roads in the KIPZ that parallel each other; the remainders are primarily rural two-lane roads. The most important severe weather is occasional major snowstorms.

Rural: This KIPZ is contained in one county that is overwhelmingly agricultural, and is predominantly covered by dairy farms. The thinly-distributed population numbers about 15,000 and is generally middle-aged, with a smaller number of children per household than the national average. The schools are small, and there is extensive busing of the students. The road system is basically two-lane and farm roads, but it is estimated that the entire KIPZ can be evacuated in less than 3 hours under normal conditions. The NPP is the largest employer in the county. The most important natural hazards come from deep winter snows and a river that occasionally floods during the spring thaw, making several of the main roads impassable.

Table D.1 Urban Site Example

Minimize Radiation Health Risks to Public			Relevant Characteristics of Urban Site Example
A. Minimize Radioactive Iodine Risk to Thyroid			
	a.1. Maximize KI Availability		
		a.1.1. Max. Availability for Children and Pregnant Women Residents	100,000 -student school system
		a.1.2. Max. Availability for Other Residents	Large resident population
		a.1.3. Max. Availability for Mobile Population	Population increases by 25% from mobile workers
	a.2. Optimize Ability to Take KI on Time		
		a.2.1. Max. Number of People who Know Where Pill is	Possible new residents won't be covered by earlier predistribution
		a.2.2. KI Taken at Optimal Time if No Evacuation	Possible hurricane or ice storms might impede evacuation
		a.2.3. KI Taken at Optimal Time if Evacuation	Delays possible if evacuation impeded by traffic or weather
		a.2.4. Ensure KI is Stored to ensure Stability	KI might be stored in cars/wallets
	a.3. Minimize Harm from Inappropriate KI Administration		
		a.3.1. Correct KI Dosage Given (and Taken) for Age	Large population of children
		a.3.2. First KI Dosage Not Taken Too Late	Weather or traffic might impede evacuation to KI stockpile site
		a.3.3. Adverse KI Side Effects (nonthyroid cancer) Minimized	Some pre-existing thyroid cases in large population of older adults or mobile workers
B. Minimize Harm from Other Aspects of Incident			
	b.1. KI Procedures Don't Impede Evacuation		Transport network barely able to handle routine peak loads
	b.2. Avert Mortality and Morbidity from Radiation or Accidents		Transport network barely able to handle routine peak loads
	b.3. Minimize Panic/Anxiety due to KI Procedures		Large crowds possible
	b.4. KI Procedures' Resource Use Not Excessive		Large population to cover for KI/predistribution and communication costs
	b.5. Simple KI Procedures before and during Incident		Multiple nearby jurisdictions
	b.6. Educate Public to Respond to Nuclear Incident		Emergency planning zone in one political jurisdiction

*Assume all plans will stockpile KI at schools, hospitals, and jails in KI Planning Zone (KIPZ)

Table D.2 Suburban Site Example

Minimize Radiation Health Risks to Public			Relevant Characteristics of Suburban Site Example
A. Minimize Radioactive Iodine Risk to Thyroid			
	a.1. Maximize KI Availability		
		a.1.1. Max. Availability for Children and Pregnant Women Residents	Young families, expanding schools and day care, extensive busing
		a.1.2. Max. Availability for Other Residents	Many working-age residents employed outside EPZ
		a.1.3. Max. Availability for Mobile Population	Rapidly developing population, near major metro. area
	a.2. Optimize Ability to Take KI on Time		
		a.2.1. Max. Number of People who Know Where Pill is	Possible new residents won't be covered by earlier predistribution
		a.2.2. KI Taken at Optimal Time if No Evacuation	Occasional major snowstorms might impede evacuation
		a.2.3. KI Taken at Optimal Time if Evacuation	Occasional major snowstorms might impede evacuation
		a.2.4. Ensure KI is Stored to ensure Stability	KI might be stored in cars or wallets
	a.3. Minimize Harm from Inappropriate KI Administration		
		a.3.1. Correct KI Dosage Given (and Taken) for Age	Large population of children
		a.3.2. First KI Dosage Not Taken Too Late	Weather or traffic might impede evacuation to KI stockpile site
		a.3.3. Adverse KI Side Effects (nonthyroid cancer) Minimized	Some pre-existing thyroid cases in older or retired residents
B. Minimize Harm from Other Aspects of Incident			
	b.1. KI Procedures Don't Impede Evacuation		Transport network might not be able to handle peak loads
	b.2. Avert Mortality and Morbidity from Radiation or Accidents		Buses available for children, two interstates + rural two-lane roads
	b.3. Minimize Panic/Anxiety due to KI Procedures		Many day-care facilities, power plant second largest employer
	b.4. KI Procedures' Resource Use Not Excessive		Moderate-size population to cover for KI predistribution and communication costs
	b.5. Simple KI Procedures before and during Incident		Two counties
	b.6. Educate Public to Respond to Nuclear Incident		Emergency planning zone in two counties

*Assume all plans will stockpile KI at schools, hospitals, and jails in KI Planning Zone (KIPZ)

Table D.3 Rural Site Example

Minimize Radiation Health Risks to Public			Relevant Characteristics of Rural Site Example
A. Minimize Radioactive Iodine Risk to Thyroid			
	a.1. Maximize KI Availability		
		a.1.1. Max. Availability for Children and Pregnant Women Residents	Small schools, extensive busing, few children
		a.1.2. Max. Availability for Other Residents	Very small resident population of 15,000 in agricultural area
		a.1.3. Max. Availability for Mobile Population	Power plant largest employer in county
	a.2. Optimize Ability to Take KI on Time		
		a.2.1. Max. Number of People who Know Where Pill is	Few residents
		a.2.2. KI Taken at Optimal Time if No Evacuation	Unlikely winter snows or spring river flooding could block main roads
		a.2.3. KI Taken at Optimal time if Evacuation	Unlikely winter snows or spring river flooding could block main roads
		a.2.4. Ensure KI is Stored to ensure Stability	KI might be stored in leaky barns
	a.3. Minimize Harm from Inappropriate KI Administration		
		a.3.1. Correct KI Dosage Given (and Taken) for Age/Body size	Small population of children
		a.3.2. KI Taken at Optimal Time	Weather or traffic might impede evacuation to KI stockpile site
		a.3.3. Adverse KI Side Effects Minimized	Small Chance of pre-existing thyroid cases in middle-aged residents
B. Minimize Harm from Other Aspects of Incident			
	b.1. KI Procedures Don't Impede Evacuation		Entire KIPZ can normally evacuate in < 3 hours
	b.2. Avert Mortality and Morbidity from Radiation or Accidents		Two-lane and farm roads
	b.3. Minimize Panic/Anxiety due to KI Procedures		School buses available for children; Power plant largest employer
	b.4. KI Procedures' Resource Use Not Excessive		Small population to cover for KI predistribution and communication costs
	b.5. Simple KI Procedures before and during Incident		One county jurisdiction
	b.6. Educate Public to Respond Appropriately to Nuclear Plant Incident		Emergency planning zone in one county

Rating Scale and Weights on Objectives

Once a region has determined how local area characteristics may affect the general performance of plans on objectives (as in the above three examples of an urban, a suburban, and a rural area), different plans can be created and evaluated.

The performance of each KI distribution plan option may be evaluated on the objectives by using descriptive text or on a 0-10 scale, where 10 is best and 0 is minimally acceptable. See the Rating Scale Table D.4 with sample rating scales for the sample objectives. The end points of the rating scale need not be absolute ratings of the best and worst conceivable levels; they can be set to be the best and worst levels attainable with a reasonable set of plan options. For example, for the objective of maximizing the number of people who know where the nearest KI is, "10% of the people knowing" may be the lowest-level rating of 0 and "85% of the people knowing" may receive the highest-level rating of 10 if this is the range for the set of options being considered.

After rating how well each plan does on each objective, an option may appear that is dominant on all objectives, and that option should be seriously considered for implementation by decision-makers. However, it is likely that no plan option will be dominant on all objectives. The relative importance of the different objectives may then need to be examined in more depth. The importance of objectives can be placed in rank order or, more precisely, given importance weights. By convention, weights are normalized to sum to 100%. A theoretically correct way to assess and interpret the meaning of importance weights is to use the swing weight method (Clemen, 1996; von Winterfeldt and Edwards, 1986). The decision-maker should think of a benchmark worst option that scores at the bottom of the rating scale on every objective. The most important objective is the one that the decision-maker would prefer to "swing" to the top of the rating scale first. The question is; If it was possible to meet only one objective completely, and the other objectives would be at their worst level of attainment, which one objective would be chosen to be met? The next-most-important objective is the one that would be chosen second. Note that this approach depends on the

range between worst and best levels that has been set in the rating scale.

The overall value of an option can be computed by multiplying the weight of an objective by the rating of the plan's performance on the objective and then summing the products over all objectives. The plan with the highest overall value would be the one that this model recommends be chosen. Sample calculations using a hypothetical set of importance weights on the objectives and sample ratings are shown in Table D.5, for example 1.

Table D.4 Sample Rating Scales

	Selected Points on Rating Scale for Each Objective		
	0	5	10
Minimize Radiation Health Risks to Public			
A. Minimize Radioactive Iodine Risk to Thyroid			
a.1. Maximize KI Availability			
a.1.1. Max. Availability for Children and Pregnant Women Residents	1 dosage/person in stockpile	50% have extra dosage at home now	85% have extra dosage at home now
a.1.2. Max. Availability for Other Residents	0 dosages/person in stockpile	10% have extra dosage at home now	25% have extra dosage at home now
a.1.3. Max. Availability for Mobile Population	1 dosage/child in stockpile	1 dosage/person in stockpile	25% have extra dosage at mobile location now
a.2. Optimize Ability to Take KI on Time			
a.2.1. Max. Number of People who Know Where KI is	10% know	50% know	85% know
a.2.2. KI Taken at Optimal Time if No Evacuation	2% take timely KI who bought on own	20% take timely predistributed KI	50% take timely predistributed KI
a.2.3. KI is Taken at Optimal Time if Evacuation	2% take own + 30% take reception KI	20% take own + 50% take reception KI	50% take own+40% take reception KI
a.2.4. Ensure KI is Stored to ensure Stability	50% of KI stored poorly	20% of KI stored poorly	1% of KI stored poorly
a.3. Minimize Harm from Inappropriate KI Administration			
a.3.1. Correct KI Dosage Given (and Taken) for Age	90% take KI take wrong dosage	40% take KI take wrong dosage	10% take KI take wrong dosage
a.3.2. First KI Dosage Not Taken Too Late	90% take KI take too late	40% take KI too late	10% take KI too late
a.3.3. Adverse KI Side Effects (nonthyroid cancer) Minimized	5% side effects	2.5% side effects	0.1% side effects
B. Minimize Harm from Other Aspects of Incident			
b.1. KI Procedures Don't Impede Evacuation	evacuation slowed by 1 hour/person	Evacuation slowed by 30 min./person	evacuation slowed by 5 min./person
b.2. Avert Mortality and Morbidity from Radiation or Accidents	expect 25 serious (nonthyroid) cases	expect 15 serious cases	expect $\leq$ 2 serious cases
b.3. Minimize Panic/Anxiety due to KI Procedures	much panic or anxiety due to KI	little panic or anxiety due to KI	no extra panic or anxiety
b.4. KI Procedures' Resource Use Not Excessive	very costly in labor time and money	somewhat costly in labor time	very inexpensive
b.5. Simple KI Procedures Before and During Incident	Very complicated	some complications	very simple

Table D.5. Example 1

Template for Evaluating Plans on Objectives

Example 1. Original Weights	Importance Weights (Sum = 100%)	Description of How Well Each Plan Meets Each Objective (Rate from 0 to 10 = best) MM: Predistribute in Mass Mailing in KIPZ	VP: Predistribute via Voluntary Pickup in KIPZ	RC: Stockpile at Evacuation Reception Centers Outside KIPZ	ND: No Distribution of KI
Minimize Radiation Health Risks to Public					
A. Minimize Radioactive Iodine Risk to Thyroid					
a.1. Maximize KI Availability					
a.1.1. Max. Availability for Children and Pregnant Women Residents	**20%**	10	2	0	0
a.1.2. Max. Availability for Other Residents	**2%**	10	1	0	0
a.1.3. Max. Availability for Mobile Population	**4%**	0	10	0	0
a.2. Optimize Ability to Take KI on Time					
a.2.1. Max. Number of People who Know Where Pill is	**5%**	0	5	10	0
a.2.2. KI Taken at Optimal Time if No Evacuation	**5%**	10	3	0	0
a.2.3. KI is Taken at Optimal Time if Evacuation	**3%**	10	10	10	0
a.2.4. Ensure KI is Stored to ensure Stability	**3%**	0	0	10	0
a.3. Minimize Harm from Inappropriate KI Administration					
a.3.1. Correct KI Dosage Given (and Taken) for Age	**5%**	0	5	10	0
a.3.2. First KI Dosage Not Taken Too Late	**3%**	10	10	0	10
a.3.3. Adverse KI Side Effects (nonthyroid cancer) Minimized	**1%**	0	8	10	10
B. Minimize Harm from Other Aspects of Incident					
b.1. KI Procedures Don't Impede Evacuation	**10%**	0	5	10	10
b.2. Avert Mortality and Morbidity from Radiation or Accidents	**18%**	10	3	0	10
b.3. Minimize Panic/Anxiety due to KI Procedures	**2%**	10	5	10	5
b.4. KI Procedures' Resource Use Not Excessive	**1%**	0	5	7	10
b.5. Simple KI Procedures before and during Incident	**8%**	0	3	10	10
b.6. Educate Public to Respond to Nuclear Incident	**10%**	8	10	0	0
OVERALL VALUE (SUM OF PRODUCTS OF WEIGHTS TIMES RATINGS)	**100%**	6.1	4.6	3.8	4.2

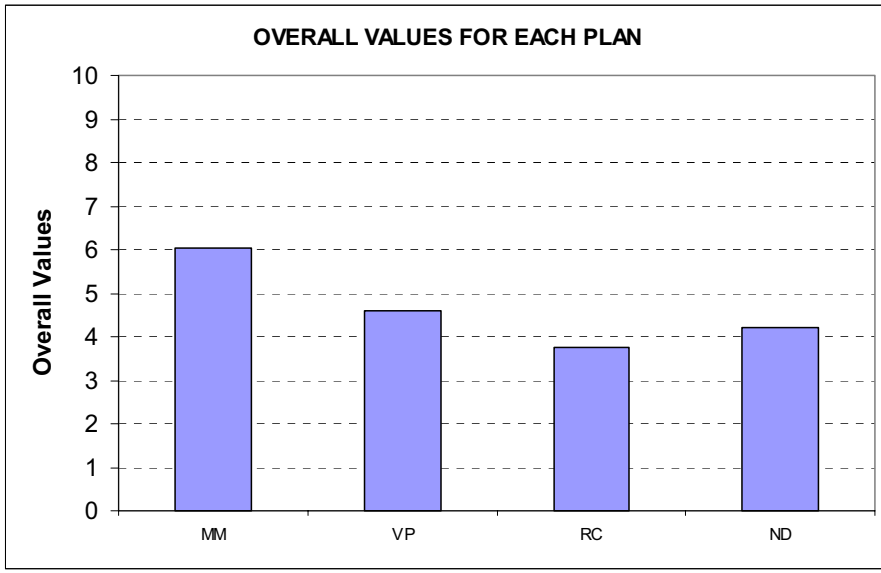

Figure D.1 Overall Values of Four Plan Options for Hypothetical Local Region

The mass-mailing plan scored highest, with an overall weighted value score of 6.1 out of 10 possible. A plan that was rated a 10 on each objective would earn an overall value score of 10. (Similarly, one that was rated 0 on each objective would earn an overall value of 0.) The weights and ratings in Figure D.1 are hypothetical and are not intended to apply to any one locale or set of plans. Local decision-makers should determine their own plans, weights and ratings on the basis of local conditions.

Note that if the weights on the objectives were different, the rank order of the options could change. For example, with new weights, and a particularly high weight of 24% out of 100% on simple procedures during and before an accident, the option of only stockpiling at reception centers scores highest, as seen in Table D.6 and Figure D.2 below.

Once preliminary analysis has been done, planners may be able to design a new plan that would combine the best features of multiple plans.

Table D.6. Example 2

Example 2. Revised Weights	Importance Weights (Sum = 100%)	Description of How Well Each Plan Meets Each Objective (Rate from 0 to 10 = best) MM: Predistribute in Mass Mailing in KIPZ	VP: Predistribute via Voluntary Pickup in KIPZ	RC: Stockpile at Evacuation Reception Centers Outside KIPZ	ND: No Distribution of KI
Minimize Radiation Health Risks to Public					
A. Minimize Radioactive Iodine Risk to Thyroid					
a.1. Maximize KI Availability					
a.1.1. Max. Availability for Children and Pregnant Women Residents	**9%**	10	2	0	0
a.1.2. Max. Availability for Other Residents	**5%**	10	1	0	0
a.1.3. Max. Availability for Mobile Population	**7%**	0	10	0	0
a.2. Optimize Ability to Take KI on Time					
a.2.1. Max. Number of People who Know Where Pill is	**6%**	0	5	10	0
a.2.2. KI Taken at Optimal time if No Evacuation	**3%**	10	3	0	0
a.2.3. KI is Taken at Optimal Time if Evacuation	**2%**	10	10	10	0
a.2.4. Ensure KI is Stored to ensure Stability	**6%**	0	0	10	0
a.3. Minimize Harm from Inappropriate KI Administration					
a.3.1. Correct KI Dosage Given (and Taken) for Age	**6%**	0	5	10	0
a.3.2. First KI Dosage Not Taken Too Late	**7%**	10	10	0	10
a.3.3. Adverse KI Side Effects (nonthyroid cancer) Minimized	**3%**	0	8	10	10
B. Minimize Harm from Other Aspects of Incident					
b.1. KI Procedures Don't Impede Evacuation	**2%**	0	5	10	10
b.2. Avert Mortality and Morbidity from Radiation or Accidents	**5%**	10	3	0	10
b.3. Minimize Panic/Anxiety due to KI Procedures	**11%**	10	5	10	5
b.4. KI Procedures' Resource Use Not Excessive	**1%**	0	5	7	10
b.5. Simple KI Procedures before and during Incident	**24%**	0	3	10	10
b.6. Educate Public to Respond to Nuclear Incident	**3%**	8	10	0	0
OVERALL VALUE (SUM of PRODUCT OF WEIGHTS TIMES RATINGS)	**100%**	4.4	4.6	6.1	4.8

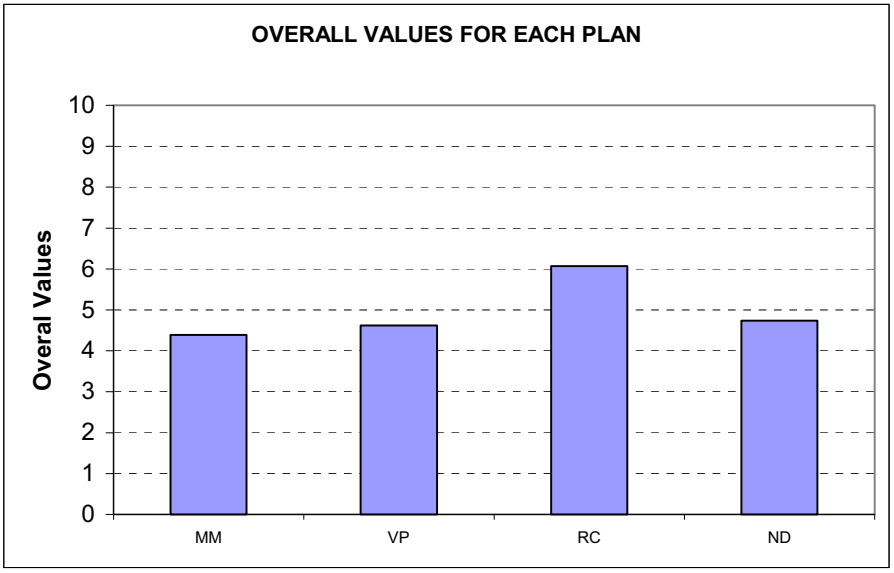

Figure D.2 Overall Values for Plans with Revised Set of Weights on Objectives

APPENDIX E
INFORMATION AND COMMUNICATION MESSAGES REGARDING POTASSIUM IODIDE OR RADIOACTIVE IODINE

A. It is important to tailor communication messages to the audience. The National Cancer Institute has materials for downwinders from nuclear test sites on its website: http://i131.nci.nih.gov/. This includes a way to calculate one's own risk from being exposed to radioactive iodine from fallout.

The site also contains communications materials specialized for Native Americans at:
http://cancer.gov/images/Documents/9967bda0-5059-4a3f-8d5e-ff5a70194221/NA_Flip_Chart_v_7_0.pdf

B. Web links for state information about potassium iodide

California- Governor's Office of Emergency Services
Potassium Iodide (KI) Fact Sheet
http://www.oes.ca.gov/oeshomep.nsf/all/Terror_KI/$file/KI_Page.pdf

Connecticut Department of Public Health
Potassium Iodide (KI) and Nuclear Emergency Readiness
http://www.dph.state.ct.us/BCH/eeoh/ki/ki_home.htm

Delaware Health and Social Services - Division of Public Health
Facts about "KI" Preparing for a Nuclear Emergency and

Potassium Iodide Request Form
http://www.state.de.us/dhss/dph/hsp/hspnews.htm

Florida Emergency Management
Radiological Emergency
http://www.dca.state.fl.us/fdem/bpr/Projects/CEMP%20Online/REP/Chapter10.htm

Illinois Department of Nuclear Safety
Important Information on the Use of Potassium Iodide (KI) Tablets
http://www.state.il.us/idns/html/emergencyinfo/kibrochure.asp

Maine Department of Human Services
Potassium Iodide - Answers to Your Questions
http://www.state.me.us/dhs/eng/rad/potassium_iodide.htm

Maryland Department of Health and Mental Hygiene
Potassium Iodide (KI)
http://www.dhmh.state.md.us/html/potiodide.htm
Massachusetts Department of Public Health
Massachusetts Radiation Control Program - Potassium Iodide(KI) Information
http://www.state.ma.us/dph/rcp/kitoc.htm

Michigan Department of Environmental Quality
The Potassium Iodide (KI) Issue
http://www.michigan.gov/deq/0,1607,7-135-3312_4120_4243-10401--,00.html

New Hampshire Department of Health and Human Services
Potassium Iodide Facts and Application
http://www.dhhs.state.nh.us/DHHS/BRH/LIBRARY/default.htm

New Jersey Department of Health and Senior Services
State Unveils Potassium Iodide Distribution Plan (*June 19, 2002*)
http://www.nj.gov/health/news/p20619a.htm

New York State Department of Health
Use of Potassium Iodide During Radiological Emergencies: Information for the Public
http://www.health.state.ny.us/nysdoh/ki/ki_high.htm

North Carolina Public Health
North Carolina's Potassium Iodide Program
http://www.dhhs.state.nc.us/dph/ki.htm

Ohio Department of Health
Distribution and Use of Potassium Iodide for the 10-Mile Emergency Planning Zone Population *(April 22, 2002)*
http://www.odh.state.oh.us/odhprograms/ENVRAD/KIPolicy.PDF

Pennsylvania Department of Health
Press Release (August 22, 2002)
Health Secretary Notes Success of PA's Potassium Iodide Distribution
http://webserver.health.state.pa.us/health/CWP/view.asp?A=190&QUESTION_ID=232081

South Carolina Department of Health and Environmental Control
Public Health Preparedness Topics – KI information
http://www.scdhec.net/co/media_relations/index.htm

Texas Department of Health
What People Need to Know About Potassium Iodide(KI)
http://www.r04.tdh.state.tx.us/ERT/radiaition/KI.htm

Vermont Department of Health
Vermont's Public Distribution Plan for Potassium Iodide (KI)
http://www.HealthyVermonters.info/hp/yankee/ki.shtml
Virginia Department of Health
Frequently Asked Questions on Potassium Iodide
http://www.vdh.state.va.us/HHControl/potassiumiodideQ&A.pdf
State Health Commissioner Announces Distribution Plans for Potassium Iodide Near Virginia Nuclear Power Plants (September 16, 2002)
http://www.vdh.state.va.us/hhcontrol/KIDistribution.PDF

Washington State Department of Health
Potassium Iodide (KI) Fact Sheet *(February 2003)*
http://www.doh.wa.gov/ehp/rp/air/Fact%20Sheet%2021.pdf

GLOSSARY

Absorbed dose: The energy imparted by ionizing radiation per unit mass of material irradiated. For purposes of radiation protection and assessing risks to human health, the quantity normally calculated is the average absorbed dose in an organ or tissue, equal to the total energy imparted to that organ or tissue divided by the total mass. The SI unit of absorbed dose is the joule per kilogram (J kg^{-1}), and its special name is the gray (Gy). In this report, absorbed dose is given in rads; 1 rad = 0.01 Gy.

Activation: The production of radionuclides by capture of radiation (for example, neutrons) in atomic nuclei.

Activity: The rate of transformation (or disintegration or decay) of radioactive material. The SI unit of activity is the reciprocal second (s^{-1}), and its special name is the Becquerel (Bq). In this report, activity is given in curies (Ci); 1 Ci = 3.7×10^{10} Bq.

Atom: The smallest particle of a chemical element that cannot be divided or broken up by chemical means. An atom consists of a central nucleus of protons and neutrons, and orbital electrons surrounding the nucleus.

Averted (or avertable) dose: The dose to be prevented by the particular protective action (i.e., the difference between the dose to be expected without stable iodine blockade and that to be expected with it).

Background radiation: Ionizing radiation that occurs naturally in the environment including: cosmic radiation; radiation emitted by naturally occurring radionuclides in air, water, soil, and rock; radiation emitted by naturally occurring radionuclides in tissues of humans and other organisms; and radiation emitted by human-made materials containing incidental amounts of naturally occurring radionuclides (such as building materials). Background radiation may also include radiation emitted by residual fallout from nuclear-weapons tests that has been dispersed throughout the world. The average annual effective dose due to natural background radiation in the United States is about 0.1 rem, excluding the dose due to indoor radon, and the average annual effective dose due to indoor radon is about 0.2 rem.

Becquerel (Bq): The special name for the SI unit of activity; 1 Bq = 1 disintegration per second.

Benign tumor: A general category of tumors that does not invade surrounding tissue. Benign tumors are characterized by slow growth through expansion. Such tumors are not malignant or cancerous.

Beta particle: An energetic electron emitted spontaneously from nuclei in decay of some radionuclides and produced by transmutation of a neutron into a proton; also called beta radiation and sometimes shortened to beta (for example, beta-emitting radionuclide). Beta particles are not highly penetrating, and the highest-energy beta radiation can be stopped by a few centimeters of plastic or aluminum.

Cancer: A malignant tumor of potentially unlimited growth that expands locally by invasion and systemically by **metastasis**.

Carcinogen: An agent capable of inducing cancer.

Carcinoma: A malignant tumor that occurs in epithelial tissues, which cover the body or body parts and serve to enclose and protect those parts, to produce secretions and excretions, and to function in absorption.

Cohort: A group of individuals having a common association or factor.

Committed dose equivalent (CDE): The dose equivalent to organs or tissues of reference that will be received from an intake of radioactive material by an individual during the 50-year period following intake.

Committed effective dose equivalent (CEDE): The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent (CDE) to each of these organs or tissues. This is a measure of the overall risk associated with internal deposition of radioactive material.

Containment: A gas-tight shell or other enclosure around a nuclear reactor to confine radioactive materials that otherwise might be released to the atmosphere in the event of an accident.

Core: The central portion of a nuclear reactor containing the fuel elements, moderator, neutron poisons and support structures.

Correlation: Most generally, the degree to which one phenomenon or variable is associated with or can be predicted from another. In statistics, usually refers to the degree to which a predictive relationship exists between variables. Correlation may be positive (both variables increase or decrease together) or negative or inverse (one variable increases when the other decreases).

Curie (Ci): The conventional unit of radioactivity, equal to 3.7×10^{10} Bq.

Deep dose equivalent (DDE): The dose equivalent at a tissue depth of 1 cm; applies to external exposure.

Design-basis accident: A postulated accident that a nuclear facility must be designed and built to withstand without loss to the systems, structures and components necessary to assure public health and safety.

Dirty bomb: Also known as a radiological weapon or radiological dispersion device, this is a conventional explosive such as dynamite packaged with radioactive material that scatters when the bomb goes off. A dirty bomb kills or injures through the initial blast of the conventional explosive and by airborne radiation and contamination—hence the term "dirty." Such bombs could be miniature devices or as big as a truck bomb.

Dose: A quantification of exposure to ionizing radiation, especially in humans. In this report, the term is used to denote average absorbed dose in an organ or tissue, **equivalent dose**, effective dose, or effective dose equivalent, and to denote dose received or committed dose. The particular meaning should be clear from the context in which the term is used. Units are rad, mrad, gray, or mgray.

Dosimeter: A portable instrument for measuring and registering the total accumulated exposure to ionizing radiation.

Effective dose: The sum over specified organs or tissues of the equivalent dose in each tissue modified by the tissue weighting factor, as defined in ICRP (1991). Supersedes effective dose equivalent.

Effective dose equivalent: The sum over specified organs or tissues of the average dose equivalent in each tissue modified by the tissue weighting factor, as defined in ICRP (1977). Now superseded by effective dose.

Element: A substance that cannot be separated by ordinary chemical methods. Elements are distinguished by the numbers of protons in the nuclei of their atoms.

Emergency planning zone: An area around a nuclear facility for which detailed planning and preparation are made in advance to ensure that appropriate protective measures can be applied in a timely and accurate manner.

Epidemiologic studies: Studies designed to examine associations—commonly, hypothesized causal relations. They are usually concerned with identifying or measuring the effects of risk factors or exposures. The common types of epidemiologic

studies are case-control studies, cohort studies, and cross-sectional studies.

Epidemiology: The study of the incidence, distribution, and causes of health conditions and events in populations.

Equivalent dose: A quantity obtained by multiplying the absorbed dose by a radiation-weighting factor to allow for the different effectiveness of the various types of ionizing radiations in causing late effect harm in tissue. The equivalent dose is theoretical and has replaced the earlier dose equivalent. The equivalent dose is often expressed in sievert (Sv). It is also sometimes expressed in rem (an older unit). One hundred rem equals 1 Sv.

Estimate: A measure of or statement about the value of a quantity that is known, believed, or suspected to incorporate some degree of error.

Evacuation: A protective measure in which individuals must leave their homes quickly, stay away for a limited period of time, to avoid or reduce radiation exposure.

Exposure: (A) A general term indicating human contact with ionizing radiation, radionuclides, or other hazardous agents. (B) For the purpose of measuring levels of ionizing photon radiation, the absolute value of the total charge of ions of one sign produced per unit mass of air when all electrons and positrons liberated or created by photons in air are completely stopped in air. Exposure is the quantity measured, for example, by a film badge. The SI unit of exposure is the coulomb per kilogram ($C\ kg^{-1}$). In conventional units used in this report, exposure is given in roentgens (R); $1\ R = 2.58 \times 10^{-4}\ C\ kg^{-1}$.

Exposure pathway: The physical course of a radionuclide or other hazardous agent from its source to an exposed person.

Exposure route: The means of intake of a radionuclide or other hazardous agent by a person (such as ingestion, inhalation, or absorption through the skin or an open wound).

External dose: The dose to organs or tissues of the body due to sources of ionizing radiation located outside the body, including sources deposited on the body surface.

Fission: The splitting of a nucleus into at least two other nuclei and the release of a relatively large amount of energy. Two or three neutrons are usually released during this type of transformation.

Gamma rays: Electromagnetic radiation emitted in de-excitation of atomic nuclei, frequently occurring as a result of decay of radionuclides; also called gamma rays and sometimes shortened to gamma (for example, gamma-emitting radionuclide). High-energy gamma radiation is highly penetrating and requires thick shielding, such as up to 1 m of concrete or a few tens of centimeters of steel.

Goiter: An enlargement of the thyroid gland.

Gray: The special name for the SI unit of absorbed dose; 1 Gy = 1 J kg^{-1} = 100 rad.

Half-life, physical: The average time it takes for one-half of any given number of unstable atoms to decay. Half-lives of isotopes range from small fractions of a second to more than a billion years. As an example, if on average 100 out of 200 radioactive atoms of a specified kind decay in 1 day (half-life=1 day), then of the remaining 100 atoms, 50 would be expected to decay during the second day. Similarly, 25 of the remaining 50 atoms would be expected to decay during the third day. This type of decay is called exponential.

Half-life, biological: The time required for half the quantity of a material taken into the body to be eliminated from the body by biological processes. For radionuclides, the biological half-time does not include elimination by radioactive decay.

Half-life, effective: The time required for the activity of a radioactive substance in the body to decrease to 1/2 its value due to the combined effects of biological elimination and radioactive decay. The effective half-life facilitates evaluating radiation dose from inhaled and ingested radionuclides and applies when the biological and physical half-lives are constant. For an effective half-life of 1 hour, 1/2 of the radioactivity would be expected to be eliminated during the first hour. Of the radioactivity that remained, 1/2 would be expected to be eliminated during the second hour. This

represents 1/4 of the initial radioactivity present. Thus, for each successive hour, the expected fractions of the initial radioactivity present that are eliminated would be 1/2, 1/4, 1/8 and so on. This type of decrease over time is called exponential.

Half-life, radioactive: See half-life, physical.

Hot spot: The region in a radiation/contamination area in which the level of radiation/contamination is noticeably greater than in neighboring regions in the area.

Hyperparathyroidism: Disorder that is characterized by the excessive production of parathyroid hormones.

Hyperthyroidism: Disorder that is characterized by the excessive production of thyroid hormones.

IAEA: The International Atomic Energy Agency, one of the specialized bodies of the United Nations charged with the responsibility of overseeing and setting standards and recommendations for the operation of nuclear activities and for radiation safety in the member states. It is headquartered in Vienna, Austria, and its members have played a major role in the accumulation and dissemination of the information derived from the Chornobyl accident as well as other accidents involving exposure to ionizing radiation.

Incidence: The rate of occurrence of new cases of a specific disease in a specific time period, calculated as the number of new cases during a specified period divided by the number of individuals at risk of the disease during that period.

Incident phase: This guidance distinguishes three phases of an incident (or accident). **Early phase**, the period at the beginning of a nuclear incident when immediate decisions for effective use of protective actions are required, and must be based primarily on predictions of radiological conditions in the environment. This phase may last from hours to days. For the purpose of dose projection, it is assumed to last for four days. **Intermediate phase**, the period beginning after the incident source and releases have been brought under control and reliable environmental measurements are available for use as a basis for decisions on additional protective actions and

extending until these protective actions are terminated. This phase may overlap the early and late phases and may last from weeks to many months. For the purpose of dose projection, it is assumed to last for one year. **Late phase**, also referred to as the recovery phase: the period beginning when recovery action designed to reduce radiation levels in the environment to permanently acceptable levels are commenced, and ending when all recovery actions have been completed. This period may extend from months to years.

Internal dose: The dose to organs or tissues of the body due to sources of ionizing radiation within the body.

International System of Units: A modern version of the meter-kilogram-second-ampere system of units, which is published and controlled by an international treaty organization (International Bureau of Weights and Measures), also referred to as SI units.

Iodine-131 (^{131}I): A radioactive isotope of iodine. Iodine is an element required in small amounts for healthy growth and development. It is mainly concentrated in the thyroid gland where it is needed to synthesize thyroid hormones. ^{131}I is used as a radioactive tracer in nuclear medicine and is found in fallout from nuclear testing. ^{131}I has been demonstrated to cause thyroid cancer in children after moderate and high doses following the Chornobyl accident. Whether very low radiation doses cause thyroid cancer is uncertain. Iodine-131 has a relatively short physical half-life (8 days).

Ionizing radiation: Any radiation capable of displacing electrons from atoms or molecules, thereby producing ions. Examples include alpha particles, beta particles, gamma rays or x rays, and cosmic rays. The minimum energy of ionizing radiation is a few electron volts (eV); 1 eV = 1.6×10^{-19} joules (J).

Irradiate: To expose to radiation.

Isotope: A form of a particular chemical element determined by the number of neutrons in the atomic nucleus. An element may have many stable or unstable (radioactive) isotopes.

KI: See potassium iodide.

Latent period: The earliest time after exposure to a carcinogenic agent when a cancer caused by that exposure can occur; also called latency period.

Leukemia: The term used to describe a group of malignant, commonly fatal blood diseases characterized by an uncontrolled increase in the number of white cells (generally their immature forms) in the circulating blood.

Mean: The arithmetic average of a set of values, given by the sum of the values divided by the number of values. The mean of a distribution of values is the weighted average of possible values, each value weighted by its probability of occurrence in the distribution.

Metastasis: The spread of cancer from one organ or part to another part not directly connected with it through transfer of malignant cells.

Model: A construct (generally mathematical) that attempts to describe the events that underlie some biological or physical phenomenon of interest, such as the occurrence of cancer following exposure to ionizing radiation.

Morbidity: A measure of a diseased condition or state; refers to illness, not death.

Mortality: A measure of the number of people who die from a specific disease or condition.

NAS: National Academy of Sciences. The National Academy of Sciences is a private, non-profit, self-perpetuating society of distinguished scholars engaged in scientific research. Upon the authority of the charter granted by the Congress in 1863, the NAS has a mandate that requires it to advise the federal government on scientific and technical matters.

NRC: National Research Council. The NRC is the principal operating agency of the National Academy of Sciences and the National Academy of Engineering to serve the federal government and other organizations.

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

Neutron: An elementary uncharged particle, of mass slightly greater than that of a proton that is a constituent of atomic nuclei.

Nuclear emergency: An emergency that has led, or could lead, to a radiological threat to public health and safety, property, or the environment.

Nuclear facility: A nuclear reactor, research reactor, or plant for the separation, processing, reprocessing, or fabrication of fissionable substances from irradiated fuel. It also includes all land, buildings and equipment that are connected or associated with these reactors or plants.

Nuclear incident: An event or series of events, either deliberate or accidental, leading to the release, or potential release, into the environment of radioactive materials in sufficient quantity to warrant consideration of protective actions.

Nuclear power plant: An electrical generating facility using a nuclear reactor as its heat source to provide steam to a turbine generator.

Organ dose: The energy absorbed in a specific organ divided by its mass. This quantity is expressed in gray (Gy) or its submultiples.

Plume: A cloud of airborne radioactive material that is transported from a nuclear or radiological source in the direction of the prevailing wind.

Potassium iodide (KI): Colorless or white crystals, having a faint odor of iodine; used as a "blocking agent" to prevent the human thyroid gland from absorbing radioactive iodine.

Prevalence: The number of cases of a specific disease existing in a particular population or area at a certain time. The value is different numerically from incidence.

Probability: The likelihood (chance) that a specified event will occur. Probability can range from 0, indicating that the event is certain not to occur, to 1, indicating that the event is certain to occur.

Protective measures: Measures taken to reduce radiation doses that could be incurred by the population or emergency workers during a nuclear emergency. Also referred to as a countermeasure or protective action.

Rad: The special name for the conventional unit of absorbed dose; 1 rad = 100 ergs g^{-1} = 0.01 Gy.

Radiation: Energy emitted in the form of waves or particles. See also ionizing radiation.

Radiation exposure: See exposure.

Radiation protection: The control of exposure to ionizing radiation by use of principles, standards, measurements, models, and such other means as restrictions on access to radiation areas or use of radioactive materials, restrictions on releases of radioactive effluents to the environment, and warning signs. Sometimes referred to as radiological protection.

Radioactive: Exhibiting radioactivity.

Radioactive decay: The spontaneous transformation of the nucleus of an atom to a state of lower energy.

Radioactivity: The property or characteristic of an unstable atomic nucleus to spontaneously transform with the emission of energy in the form of radiation.

Radiogenic: Causally linked to or possibly associated with exposure to ionizing radiation.

Radionuclide: A naturally occurring or artificially produced radioactive element or isotope.

Reactor coolant system: The cooling system used to remove energy from the reactor core and transfer that energy either directly or indirectly to the steam turbine.

Release: The controlled or accidental discharge of radioactive substances into the atmosphere or water that may occur during the operation of nuclear facility.

Rem: The special name for the conventional unit of equivalent dose; 1 rem = 100 ergs g^{-1} = 0.01 Sv = 10 mSv. For gamma and beta radiation and x rays, 1 rem = 1 rad = 0.01 Gy = 10 mGy.

Risk: The probability of an adverse event. In regard to adverse effects of ionizing radiation on humans, the term usually refers to the probability that a given radiation dose to a person will produce a health effect (such as cancer) or the frequency of health effects produced by given radiation doses to a specified population within a specified period. The risk of cancer due to a given radiation dose generally depends on the cancer type,

sex, age at exposure, and time since exposure (attained age), and it may depend on dose rate.

Risk, relative: The ratio of the risk in one population to that in another; for example, the ratio of the risk among individuals exposed to 2 Gy as contrasted with the background risk.

Roentgen: The special name for the conventional unit of exposure; 1 R = 2.58×10^{-4} coulomb per kilogram (C kg^{-1}).

Sheltering: A protective measure that consists of staying indoors, with closed doors and windows, to limit the inhalation of radioactive products that may present following a release of radiation, or to protect against direct gamma radiation from a radioactive cloud, or from radioactive material deposited on the ground.

Sievert: The special name for the SI unit of equivalent dose; 1 Sv = 1 J kg^{-1} = 100 rem.

SI units: See International System of Units.

Stable iodine: An isotope of iodine that does not undergo radioactive decay.

Thyroid blocking agent: A substance that prevents or reduces the uptake of radioactive iodine by the thyroid. See potassium iodide.

Thyroid burden: The total activity of a radionuclide in the thyroid.

Thyroid palpation: The procedure in which a physician characterizes the size, shape, and texture of the thyroid gland by manual examination of the neck.

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

Total effective dose equivalent (TEDE): The sum of the **deep dose equivalent** (DDE) for external exposures and the **committed effective dose equivalent** (CEDE) for internal exposures.

Uncertainty: The lack of sureness or confidence in results of measurements or predictions of quantities owing to stochastic variation or to a lack of knowledge founded on an incomplete characterization, understanding, or measurement of a system.

UNSCEAR: The United Nations Scientific Committee on the Effects of Atomic Radiation, one of the specialized bodies of the

United Nations charged with the responsibility of evaluating the effects of exposure to atomic (ionizing) radiation on behalf of the member nations.

Variability: The variation of a property or quantity among members of a population. Variability is often assumed to be random and can be represented by a probability distribution.

Whole body: For purposes of estimating radiation dose, especially from external exposure, the head, trunk (including male gonads), arms above the elbow, and legs above the knee.

W-C Effect (Wolff-Chaikoff Effect): Blocking of the organic binding of iodine and its incorporation into hormone caused by large doses of iodine; usually a transient effect, but in large doses in susceptible individuals it can be prolonged and cause iodine induced hypothyroidism.

X radiation: (A) Electromagnetic radiation emitted in de-excitation of bound atomic electrons, frequently occurring in decay of radionuclides, referred to as characteristic x rays, or (B) electromagnetic radiation produced in deceleration of energetic charged particles (such as beta radiation) in passing through matter, referred to as continuous x rays or bremsstrahlung; also called x rays.

Conversions between SI units and Traditional Units

Quantity	Previous unit	SI unit	Special name of SI unit	Conversion
Exposure	roentgen (R)	coulomb per kilogram (C kg^{-1})		1 R = 2.58×10^{-4} C kg^{-1}
Absorbed Dose	rad	joules per kilogram (J kg^{-1})	gray (Gy)	1 rad = 0.01 Gy
Equivalent Dose	rem	joules per kilogram (J kg^{-1})	sievert (Sv)	1 rem = 0.01 Sv
Activity	curie (Ci)	disintegrations per second (s^{-1})	becquerel (Bq)	1 Ci = 3.7×10^{10} Bq

LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
AEC	Atomic Energy Commission
ATA	American Thyroid Association
CDE	Committed Dose Equivalent
CEDE	Committed Effective Dose Equivalent
CRCPD	Conference of Radiation Control Program Directors, Inc.
DBA	Design Basis Accident
DHHS	U.S. Department of Health and Human Services
DHS	U.S. Department of Homeland Security
DIT	Diiodotyrosine
DOD	U.S. Department of Defense
DOE	U.S. Department of Energy
EPA	U.S. Environmental Protection Agency
EPZ	Emergency Planning Zone
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
IOM	Institute of Medicine
KI	Potassium Iodide
KIO3	Potassium Iodate
LET	Linear Energy Transfer
MIT	Monoiodotyrosine
NAS	National Academy of Sciences
NCI	National Cancer Institute
NCRP	National Council on Radiation Protection and Measurements
NEA	Nuclear Energy Agency
NEI	Nuclear Energy Institute
NEMA	National Emergency Management Association
NIH	National Institutes of Health

NIOSH	National Institute for Occupational Safety and Health
NIS	Sodium-Iodide Symporter
NPP	Nuclear Power Plant
NRC	U.S. Nuclear Regulatory Commission
OSTP	Office of Science and Technology Policy
PAG	Protective Action Guideline
PORV	Pilot Operated Relief Valve
RAIU	Radioactive Iodine Uptake
REF	Radiation Effectiveness Factor
REAC/TS	Radiation Emergency Assistance Center/Training Site
REP	Radiological Emergency Preparedness
SD	Standard Deviation
SI	Système International (International System)
TBG	Thyroid-Hormone Binding Globulin
T3	Thyroid Hormone Triiodothyronine
T4	Thyroid Hormone Thyroxine
TEDE	Total Effective Dose Equivalent
TNT	Trinitrotoluene
TSH	Thyroid-Stimulating Hormone
TRH	Thyrotropin-Releasing Hormone
W-C Effect	Wolff-Chaikoff Effect
WHO	World Health Organization

COMMITTEE BIOGRAPHIES

David J. Tollerud, MD, MPH (Chair), is professor of public health, medicine, and pharmacology/toxicology at the School of Public Health and Information Sciences, University of Louisville, and Chair of the Department of Environmental and Occupational Health Sciences. Dr. Tollerud received his MD from Mayo Medical School and his MPH from the Harvard School of Public Health. He has extensive clinical training, with specialty-board certifications in internal medicine, pulmonary and critical-care medicine, and occupational medicine. He has extensive experience in epidemiology and population studies, particularly those involving the use of immunological biomarkers, and in environmental and occupational health research focusing on prevention of injury and illness. In addition to his work in public health, he supervises clinical-trials data management and data-analysis activities for the multidisciplinary Institute for Cellular Therapeutics at the University of Louisville. Dr. Tollerud also has extensive experience in pulmonary medicine and respiratory disease, particularly asthma and occupational lung diseases, and in occupational hazards and indoor and outdoor air

pollution. He has a 10-year history of service to the Institute of Medicine (IOM), and was recognized for his contributions by his appointment as a National Academies fellow. He is a member of the IOM Board on Health Promotion and Disease Prevention, is the board liaison to the Committee on Poison Control, and is the former chair of the IOM Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides.

David V. Becker, MD, is professor of radiology and medicine at Weill-Cornell Medical College in the Department of Radiology in the Division of Nuclear Medicine at New York-Presbyterian Hospital in New York City. Dr. Becker's clinical and research interests are primarily in thyroid physiology, radiation effects on the thyroid, and the management of clinical thyroid disease, with a particular focus on the pathophysiology of thyroid disease in humans and animals with emphasis on iodine and thyroid hormone metabolism in a variety of clinical disorders. His major clinical activities are related to the use of radioiodine for the management of hyperthyroidism and thyroid cancer. Dr. Becker has been president of the American Thyroid Association, and is a fellow of the American College of Physicians, the American College of Endocrinology, and the New York Academy of Medicine. In recognition of his clinical activities in patient care, he has been cited in the last three editions of the *Best Doctors in the United States* in the areas of both nuclear medicine and thyroid disease. Since 1983, he has participated in the National Cancer Institute's I-131 Risk Assessment Study Group, which was mandated by Congress to determine the risk factors in radioiodine use. That group has evolved into the present Chornobyl Fallout Joint Study Group, which Dr. Becker chaired. He participates in a number of consultative and policy making committees. Dr. Becker was the founding member of the executive committee of a multicenter US Public Health Service study of 36,000 hyperthyroid patients, of whom 23,000 received radioiodine treatment. Initiated in 1960, that follow-up study represents the largest radioiodine-treated hyperthyroid population. After an internship in internal medicine, Dr. Becker was a fellow in the Biophysics Department of the Sloan-Kettering Institute from 1950 to 1952. Later, he entered the US Army, where he

established the Army's second clinical radioisotope laboratory at Brooke Army Hospital. At that time, he began the use of tracer technology for in-vivo studies of thyroid-hormone metabolism and aspects of iodide metabolism. After leaving the Army in 1954, he completed his residency at New York Hospital and established its nuclear medicine department.

Lewis E. Braverman, MD, is chief, Section of Endocrinology, Diabetes and Nutrition at Boston Medical Center and professor of medicine at Boston University School of Medicine. In addition, he is a senior physician at Brigham and Women's Hospital, a visiting professor of medicine at Harvard Medical School, and a visiting physician at St. Elizabeth's Hospital. Dr. Braverman has been affiliated with Tufts Medical School, the University of Massachusetts Medical School, and Beth Israel Hospital, in Boston. He was a visiting professor of medicine at Royal Perth Hospital, University of Perth, in Australia in 1983. In that year, he spent time as a professor of endocrinology at the University of Pisa Medical School in Italy. Dr. Braverman received his undergraduate degree from Harvard College and his MD from John Hopkins University School of Medicine. He completed his internship at Beth Israel Hospital and then spent two years as a captain in the US Army. He conducted his residency at Boston City Hospital on the Harvard Medical Services and finished his medical training as a research fellow in endocrinology at Harvard Medical School, the Thorndike Memorial Laboratory, and Boston City Hospital. He received an honorary MD from the University of Parma Medical School in Italy.

L. Robin Keller, PhD, is professor of operations and decision technologies at the graduate school of management of the University of California Irvine. She is an expert in decision analysis, risk analysis, creative problem-structuring and behavioral decision theory. She is a past president of the *Decision Analysis Society of INFORMS*. Dr. Keller has served as a program director and advisory-panel member for the Decision, Risk, and Management Science Program of the US National Science Foundation in Washington, DC. Her research interests focus on the development and use of techniques for

analyzing multiple-stakeholder, multiple-objective decisions. Dr. Keller received her PhD and MBA from the Anderson Graduate School of Management at the University of California, Los Angeles (UCLA) with specialization in management science. She has been on the University of California, Irvine (UCI) faculty since 1982 and has been a visiting professor at Duke and UCLA. She served as associate dean for research at UCI.

Karen S. Langley, MS, is director of the Radiological Health Department at the University of Utah. She received her MS in radiological health physics from San Diego State University. She is the radiation safety officer for the University of Utah, including the medical school, hospitals, and research and teaching facilities. She is a member of the Reactor Radiation Safety Committee and performs audits of operations and environmental and radiation safety monitoring. She also coordinates the oversight of radiation use applications in human research. She is an affiliate faculty member in the Department of Physics at Idaho State University. In the Health Physics Society, she is a member of the Board of Directors, president of the Medical Health Physics Section, and past chair of the Program and Symposia Committees. She is chair of the Radiation Control Board for the Utah Division of Radiation Control. She is also a member of Sigma Xi.

Timothy J. Maher, PhD, is professor of pharmacology and Sawyer Professor of Pharmaceutical Sciences at the Massachusetts College of Pharmacy and Health Sciences. He is also served as dean of research and graduate studies at the Massachusetts College of Pharmacy and Health Sciences. He is also the president and CEO of Longwood Pharmacology Research, Inc. Dr. Maher received his PhD in pharmacology at the Massachusetts College of Pharmacy and Health Sciences. His research interests include pharmacodynamics, pharmacokinetics, toxicological aspects of therapeutic agents, neuropharmacology, and nutritional pharmacology. He is also knowledgeable in drug-distribution functions, patient education, and monitoring and management of pharmaceutical care. He has served as an ad hoc expert for the Life Sciences Research Office under

contract for the Food and Drug Administration, and he is the author and co-author of several publications.

Kenneth L. Miller, MS, CHP, CMHP, is professor of radiology and director of the Division of Health Physics at the Milton S. Hershey Medical Center of the Pennsylvania State University in Hershey, Pennsylvania. He received his MS in radiological health at the University of Pittsburgh. He is comprehensively certified in health physics by the American Board of Health Physics and in medical health physics by the American Board of Medical Physics. In 1966, he began his career in health physics at the Pennsylvania State University. In 1971, he was appointed director of health physics and research associate at the Milton S. Hershey Medical Center of Penn State University. Since moving to the Hershey Medical Center, he has produced over 430 presentations, scientific exhibits, and publications (including 11 books). In 1995, he was elected to the National Council on Radiation Protection and Measurements (NCRP), and he was re-elected for another six-year term in 2001. He is a member of NCRP's Scientific Committee 46 on Operational Radiation Safety. He serves on numerous federal, state, and local advisory committees and is a member of various professional societies, including the Health Physics Society, the American Association of Physicists in Medicine, the American Association for the Advancement of Science, the Society for Magnetic Resonance Imaging, and the American Nuclear Society. He has been a delegate to the International Radiation Protection Association and has served on the Board of Directors and as parliamentarian of the Health Physics Society. He has served on the American Board of Health Physics and is a member of the Board of Directors of the American Board of Medical Physics. In 1982, he received the Elda E. Anderson Award from the Health Physics Society. From 1994 to 2000, he was editor-in-chief of *Health Physics*. Since 1998, he has been editor-in-chief of *Operational Radiation Safety.*

Christoph H-J Reiners, MD, is professor of medicine and director of the Clinic for Nuclear Medicine at the University of Würzburg. He received his doctorate in medicine at the Faculty of Medicine,

University of Würzburg. His research interests include diagnostics and therapy of thyroid diseases; studies of iodine metabolism; diagnosis, treatment, and follow-up of radiation-induced thyroid carcinoma; nuclear medicine diagnostics in oncology, neurology, gastroenterology, cardiology, and urology; quantitative determination of bone density; and application of statistical methods in diagnostic procedures. Starting in June 2003, he has served as a director of the German World Health Organization Radiological Emergency Medical Preparedness Assistance Network Center. Dr. Reiners has been a member of the Medical Working Party of the Commission of Radiation Protection (SSK) of the Federal Ministry of the Environment, Nature Conservation and Reactor Safety since 1989, and he was a chairman of SSK for three years. He has also been chairman of the working group for thyroid diseases of the German Society for Nuclear Medicine since 1995. He served as a member of the German delegation to the United Nations Scientific Committee on the Effects of Atomic Radiation in 2000. Since 1993, Dr. Reiners has run a Belorussian-German project aiming at treatment of thyroid cancer in children and adolescents who have been exposed to Chornobyl fallout. Since September 2003, Dr. Reiners has run a German liaison institute of the WHO radiological emergency medical preparedness assistance network (REMPAN), which is designated to become a WHO collaboration center in the REMPAN-Network.

John J. Russell, MS, is a radiobiologist and curator of the National Human Radiobiology Tissue Repository and associate director of the United States Transuranium and Uranium Registries (USTUR), College of Pharmacy, Washington State University. His research interests include genetic risk associated with internally deposited actinides; the histopathology and histochemistry of liver tumors induced by internal emitters or chemical carcinogens; the pharmacodynamics, histopathology, and histochemistry and therapy of metal poisons, tumor affinity of rare earths and actinides. Mr. Russell was among the first to demonstrate the microdistribution of plutonium in animal tissues using LR-115 film. He wrote several publications describing the genetic risks posed by internal emitters (such as plutonium and americium). His more recent work in

molecular biology has been an investigation to determine whether deletion, altered expression, or mutation of selected tumor-suppressor genes is associated with the various tumor types—hepatocarcinomas, cholangiocarcinomas, and osteogenic sarcomas—that have been found in some deceased USTUR registrants and, if so, whether the association depends on radiation dose or dose rate.

Robert H. Volland, MA, received a BA in International Affairs in 1962 and an MA in Public Administration in 1973 from the George Washington University. In 1976, he was named Executive Assistant to the Federal Disaster Assistant Administration. He became the first Federal Emergency Management Agency (FEMA) Director of Finance and Administration, a Senior Executive Service position with responsibility for budgeting, accounting, acquisition and administrative services. From 1979 to 1989, he served in a number of senior level positions in FEMA, including Director of Personnel, Assistant Chief of Staff for Administration, and Director, Office of Training. In 1989, he was assigned to the disaster relief program as Chief of the Individual Assistance Division. Mr. Volland served as acting associate director and later as acting deputy associate director. In his permanent assignment as Chief of Program Development and Coordination, Volland managed the development of the first National Mitigation Strategy and the convening of the first National Mitigation Conference. He also served as FEMA's representative to the federal interagency Subcommittee for Natural Disaster Reduction. In 1998, he became a senior volunteer consultant to the American Red Cross. He also helped develop and deliver training that "rolled out" the Red Cross's mitigation program at the Chapter level.

Edward L. Wilds, Jr., PhD, is director of the Bureau of Air Management's Division of Radiation at the Connecticut Department of Environmental Protection, which is responsible for ensuring public safety by establishing policies and practices for state control of the manufacture, use, and transportation of radioactive materials. Those duties include radiological emergency response, planning for the safe disposal of radioactive waste, monitoring the decommissioning of nuclear facilities, inspection of facilities that use ionizing radiation,

and managing the enforcement of Connecticut laws and regulations. He also represents Connecticut's interests in federal and state regulatory hearings. Dr. Wilds served for more than ten years as the radiation safety manager at the University of Connecticut, overseeing the radiation safety staff and operations. Before arriving at the University of Connecticut, he served as a physics instructor and radiation safety officer at the US Coast Guard Academy. Other Coast Guard assignments included assistant engineering officer, marine inspector, disaster control officer, and damage control assistant. He serves as chairman of the Conference of Radiation Control Program Directors E-37 Naval Nuclear Propulsion Committee; co-chair of the Council of State Governments Eastern Regional Conference's High-Level Radioactive Waste Transportation Task Force; and member of the Connecticut Nuclear Energy Advisory Council, the Three Rivers Community Technical College's Nuclear Advisory Committee, the State of Connecticut KI Working Group, and the US Department of Energy's Transportation External Coordination Working Group's Consolidated Grant and Tribal Issues Topic Groups. He is the Connecticut Department of Environmental Protection commissioner's representative on the Board of Directors for the Connecticut Hazardous Waste Management Service. He also has served on Connecticut's Low-Level Radioactive Waste Advisory Committee, the US Nuclear Regulatory Commission's National KI Core Working Group, the Low Level Waste Forum, and a working group for the Center for Strategic and International Studies report on the regulatory process for nuclear power reactors.

Sir E. Dillwyn Williams, MD, **FRCPath,** is an emeritus professor at Cambridge University in the United Kingdom and is involved in a small thyroid carcinogenesis research group. Previously, he served as the chair of histopathology at Cambridge and professor and chairman of pathology at the University of Wales. He was knighted in 1990 for his service to medicine. His early work combined experimental studies of thyroid growth and carcinogenesis with diagnostic thyroid pathology. He was the first to identify medullary carcinoma of the thyroid as being of C-cell origin, showing that it was the only type of thyroid cancer with a significant link to pheochromocytoma and to

Cushing syndrome and that it could be familial. He was alsothe first to describe tumor-associated diarrhea and gave the first description of its link to pheochromocytoma and multiple mucosal neuromas in what is now known as MEN IIB. He was the author of the World Health Organization (WHO) classification of thyroid and endocrine tumors and will be a contributor to the new edition. Throughout his career, he has been interested in the role of radiation in thyroid carcinogenesis and in the interaction of thyroid growth and radiation. That has led to involvement in the consequences of the Chornobyl accident; he chaired a joint European Community-World Health Organozation meeting when the first reports of an increase in thyroid carcinoma became available. And that in turn led to the recognition that there was an urgent need for an international investigation of the situation. He initiated the creation of an international group that created a Chornobyl tumor bank, which is now making nucleic acids available for approved research projects. He has chaired the Scientific Project Panel and the Pathology Panel of the tumor bank since its inception. His own studies of the Chornobyl-related tumors have included work on the confirmation of the diagnosis and on the relationship between tumor morphology and molecular biology. He has served as president of the European Thyroid Association, the Royal College of Pathologists, and the British Medical Association. Dr. Williams received his medical degree at Cambridge, and his interest in endocrinology and endocrine pathology began at the London Hospital and the Postgraduate Medical School in London in the 1960s. He was a US National Institutes of Health postdoctoral research fellow at Harvard University and Massachusetts General Hospital in Boston.

Lauren Zeise, PhD, is chief of reproductive and cancer hazard assessment in the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. She received her MS and PhD from Harvard University, where she also conducted postdoctoral research on risk-assessment methodology. Dr. Zeise serves on the US Environmental Protection Agency (EPA) Science Advisory Board and EPA FIFRA Science Advisory Panel and has served on various ad hoc advisory committees of the agency. Other

service includes membership on various committees of the Institute of Medicine (IOM), the National Research Council, the Consumer Product Safety Commission, the National Toxicology Program, and the Office of Technology Assessment. She now serves on the IOM Board on Health Promotion and Disease Prevention and the National Research Council Board on Environmental Studies and Toxicology. She is member, fellow, and councilor of the Society of Risk Analysis and is on the Editorial Board of the society's journal. The National Cancer Institute Smoking and Tobacco Smoke Monograph Health Effects of Environmental Tobacco Smoke was conceived and developed under her editorial direction. For the California EPA, she has overseen a variety of the state's cancer, reproductive, and ecological risk assessment of ecological risk guidance, establishment of baseline risks associated with gasoline use in California and guidance for evaluating risks to the fetus, children, and adolescents posed by environmental exposure. Her research has focused on cancer risk-assessment methodology and applications. She is coauthor and coeditor of the 1999 International Agency for Research on Cancer Monograph Quantitative Estimation and Prediction of Cancer Risk.